Health Care in the 21st Century:
Cost, Quality, and Access in the New Millennium

Leo Goodwin, Sr.

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Introduction: Health Care in the 21st Century: Cost, Quality, and Access in the New Millennium

Kathy L. Cerminara*

Everyone requires health care at some point during his or her lifetime, and the law increasingly regulates the cost, quality, and access to such health care. Through the 2001 Goodwin Seminar, Nova Southeastern University's Shepard Broad Law Center examined health care in the twenty-first century by adopting an interdisciplinary approach, focusing on concerns about cost, quality, and access as the linchpins of health care policy, and considering the future of health care in the United States and internationally. I am proud to have created and taught the seminar, memorialized in this special issue of the Nova Law Review.

The seminar's focus on health care policy was particularly timely during the Winter term of 2001 and continues to be timely as this issue appears. As the seminar proceeded, the news media reported debates about the use of human embryonic stem cells in medical research, an issue raising continuing moral, ethical, legal, and medical quandaries. Reports of numerous incidences of medical error had recently surfaced, leaving one to wonder and to continue wondering, about the basic level of problems that remain in the health care system, even as medical advances magnify the level of sophistication and expertise Americans expect in health care. As Americans hear of and expect to receive more and more technologically advanced medical treatment, policymakers struggle to facilitate appropriate access to

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such treatment, control costs, and assure quality of treatment. The decisions of those policymakers affect not only the United States but also the international medical community, for legal decisions governing health care policy in the United States can and do affect access to medicines and medical care in other countries.

In this issue of the *Nova Law Review*, the reader will find articles by four distinguished visiting professors, each addressing issues arising within his or her special sphere of expertise within the larger topic of health care policy. Ranging from a former secretary of the Department of Health and Human Services, to an epidemiologist with an international human rights organization, a former presidential advisor, and an expert in bioethics, these authors permit the reader to explore the full realm of policy issues confounding those attempting to improve health care.

For example, the Honorable Louis W. Sullivan, M.D. served as Secretary of Health and Human Services from March 10, 1989 through the end of President George H.W. Bush’s administration. Now president of Morehouse School of Medicine in Atlanta, Dr. Sullivan writes about health disparities in the United States, explaining that there exists severe and continuing disparities in the level of health care provided to and the health enjoyed by minorities as compared with Caucasians.

In 1993, hoping to resolve some of those health disparities as well as to equalize access to health care and coverage across the United States, President Bill Clinton proposed a comprehensive National Health Security Plan in an attempt to restructure the health care system. Goodwin Distinguished Visiting Professor, Christopher C. Jennings, served as Senior Health Policy


5. One example is the extent to which patent laws protect brand-name drugs. The availability of generic drugs greatly affects the prices manufacturers of brand-name drugs can charge for their products in both the United States and other countries. See generally S. Van McCrary & Cheryl J.C. Erwin, *Thinking Globally About Biotech Ethics: Is the Law Enough?*, 666 PRAC. L. INST./PAT. 983, 1008–09 (2001) (noting this struggle relating to availability of AIDS drugs in developing countries). Recent inroads on patent protections have encouraged generic drug makers in their economic battle against brand-name drug manufacturers. See, e.g., Glenn Singer, *Makers of Generics Get Boosts in Courts, Capitol, SUN-SENTINEL* (Ft. Lauderdale), Jan. 15, 2002, at D1.


7. See The President’s Health Security Plan (1993).
Advisor and Deputy Assistant to the President under President Clinton. As such, working out of the President's Domestic Policy Council and in conjunction with the National Economic Council, Mr. Jennings was charged with developing the Administration's health care policy and played a lead role in the drama surrounding the President's proposal and its subsequent failure in Congress. Here, Mr. Jennings, from the perspective of someone who has tried but whose efforts fell prey to the political process, discusses steps that must be taken and issues that must be addressed to improve the American health system.8

Many of the steps the United States may choose to take are governed, not only by economic and political considerations, but also by moral and ethical judgments. Medical research on human tissue, for example, holds great promise for bettering the health care system by leading to cures or treatments for a variety of diseases. Yet, the question arises as to how the law should regulate such research, especially in light of ethical and moral questions surrounding its use. R. Alta Charo is Professor of Law and Medical Ethics at the University of Wisconsin at Madison, where she is on the faculty of the Law School and the Medical School's Program in Medical Ethics. A former member of President Clinton's National Bioethics Advisory Commission, Professor Charo has considered the role that ethical and moral judgments play in health care policymaking. Her essay addresses legal issues arising from the use of human tissue and concludes that "[a] more robust form of national control over the market in human tissue... will probably depend upon resolution of political and legal views of the body."9

Finally, the United States should not forget that, given today's global economy, any decisions made with regard to health care policy inevitably will affect other nations in some way. United States regulation of the production of pharmaceuticals, for example, often impacts the drugs that are available and the prices at which they are available in other countries. Anne-Valerie Kaninda, M.D., a medical advisor and epidemiologist with Doctors Without Borders/Médecins Sans Frontières, writes of the interrelationship between pharmaceutical production, its regulation, intellectual property

rights, pricing, and the availability of certain drugs in developing countries.\textsuperscript{10} Dr. Kaninda’s appearance at Nova Southeastern University was important, not simply because of her distinguished career, but also because of the esteem with which others regard her employer. Doctors Without Borders/Médecins Sans Frontières received the Nobel Peace Prize in 1999 for its work in sending more than 2000 medical workers to provide care in nearly ninety countries.

In addition to the articles from these distinguished visiting professors, this issue of the \textit{Nova Law Review} contains student articles on medical-legal topics. Some of the students whose articles appear here—specifically, Daniel Cohen, Judith Goodman, Jesse Lieberman and Stacy Warman—were students in the Goodwin Seminar and benefited in their research and writing from interaction with the Goodwin professors. Another, Sandy Martin, has joined the \textit{Law Review} since the Goodwin Seminar but undoubtedly also has profited from the medical-legal knowledge \textit{Law Review} editors gained through the seminar. For all this, the NSU Law Center, and I in particular, owe a special debt of gratitude to the Leo Goodwin Foundation, Inc. for its generous support of the Goodwin Seminar and the Goodwin Chair in Law.

Finally, the reader should know that the seminar’s health care theme reflects the NSU Law Center’s commitment to its health law curriculum and programs. The NSU Law Center offers a health law concentration, providing law students the opportunity to specialize in either transactional or litigation-related health law studies. In July 2001, it also began offering an online master’s degree in health law for non-lawyers, the first such program to be offered by an ABA-accredited law school. Through the latter program, the NSU Law Center intends to both help improve the health care system and honor the American Bar Association’s suggestion that law schools educate non-lawyers about the law.\textsuperscript{11}

All of these efforts are linked. As the United States struggles with the form of its health care system, and as the choices it makes during that struggle affect patient care, health care professionals, lawyers and the public, all must become more conversant with health care policy issues. Legal decisions affecting health care cost, quality, and access in the new millennium will determine the sort of care patients receive, not just here in United States but also worldwide. This issue of the \textit{Nova Law Review}, the 2001 Goodwin

\textsuperscript{10} Anne-Valerie Kaninda, M.D., \textit{A Conversation with Dr. Anne-Valerie Kaninda}, 26 \textit{NOVA L. REV.} 451 (2002).

Seminar, and the NSU Law Center’s commitment to health law education will help prepare both health care lawyers and members of the health care industry to participate in decision making with regard to this important subject.
A Conversation with Christopher C. Jennings*

Christopher C. Jennings

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* Kathy Cerminara: Good afternoon everyone. Today we have with us Christopher
Jennings, one of our Goodwin Series speakers. Chris Jennings served as Senior Health Policy
Advisor and Deputy Assistant for Health Policy to President Bill Clinton. As Deputy Assis-
tant to the President for Health Policy, working out of the President’s Domestic Policy
Council and in conjunction with the National Economic Council, Jennings was in charge of
developing the Administration’s health care policy. In this capacity, beginning in 1994, he
coordinated the health policy work of numerous federal agencies, including the Office of
Management and Budget and the Departments of Health and Human Services, Treasury, and
Labor. As the President’s Senior Health Policy Advisor, Jennings advised the President on a
wide variety of issues, including Medicare, Medicaid, long term care, insurance coverage
expansions, and consumer protection. Recognizing his work, the National Journal in 1997
designated Mr. Jennings as one of Washington’s 100 most influential individuals in the
federal government.

Before his White House appointment, from 1993 to 1994, Jennings was the Senior
Legislative Health Reform Advisor to the Health Care Financing Administration (HCFA), and
during his tenure in this position he worked with first lady Hillary Rodham Clinton, preparing
her for testimony on Capitol Hill regarding health care reform. Prior to joining the Clinton
Administration, Mr. Jennings served as a committee staff member for Senators Glenn,
Belcher, and Pryor. Today he is going to talk about health care policy and about what we can
do, or maybe, what we should think about when we are reforming the health care system in
America.
I had an extraordinary experience as Health Care Advisor to the President in the Clinton White House and I want to talk to you a little bit about what we have done. More importantly, I have been asked to talk about how we can improve the health care system in this political world that we live in and how we can apply some of the lessons we learned to the future.

There is no question that the Clinton Administration experienced both the thrill of victory and the agony of defeat in our continuous struggle to reform and to improve the nation’s health system. Beyond the record, however, I believe there were many significant lessons learned that can and should be applied to future efforts to reform health care in the United States. The most important of these are the critical steps of effectively defining the problem, establishing the goals for reform, developing viable policy, and designing a workable strategy to pass and enact legislation.

II. DEFINING THE PROBLEM; ESTABLISHING GOALS FOR REFORM

Before embarking on any major reform, one has to effectively define the problem. Without first achieving broad agreement that there is a problem that virtually all understand and determine is worth addressing, it is impossible to proceed with meaningful reforms. Although it may seem that the problems of health care in this country are universally understood, many of the examples I will subsequently share will illustrate that defining the problem can actually be one of the most complicated parts of shaping health policy.

As important as defining the problem, though, is establishing objectives for change. Just as there are many differing opinions on the flaws (and strengths) of the health care system, there are just as many perspectives on what the goals of reforms should be. By providing examples of some of the
most prominent issues in health care today, I will try to illustrate how the broadly differing views people have about the problems and desired outcomes for reform severely complicate any effort to improve the nation’s health care system.

A. The Uninsured

The fact that more than forty million Americans lack health insurance is commonly believed to be the crux of the health care problem in this country. Improving access to health coverage is generally viewed as a primary goal of health care reform. But even this seemingly obvious conclusion has not achieved a consensus status.

Opponents of reform frequently argue that there really is not a problem of access; they suggest that anyone without a preexisting condition can purchase relatively affordable health insurance. They also argue that this issue is not, nor should be, a national domestic policy priority because the problem is overstated, as anyone can go into an emergency room and receive care, regardless of insurance status.

All the arguments and research to the contrary do not sway opponents of major change.

For instance, one can cite the fact that the percentage of uninsured adults who do not receive medical care is more than three times that of privately insured Americans. Or, one can point out that the uninsured are fifty to seventy percent more likely to need hospitalization for avoidable and expensive health conditions, like pneumonia and uncontrollable diabetes, than those who have private insurance. The fact that children without health insurance are nearly twice as likely to forego health care for conditions like asthma or recurrent ear infections, which can lead to serious problems throughout life, does not break through either.

3. *Id.*
4. *Id.*
B. Access to Coverage

Clearly, the insurance coverage issue reflects the difficult nature of identifying health care problems and corresponding goals. Even assuming a sufficient base of bipartisan support for the general notion of policies to expand insurance, (which parenthetically, I believe there generally is), there are so many other issues. Even when policymakers advocate for all Americans having health insurance, it becomes necessary to define what that means in order to develop policy and consensus around it. Does it mean that all Americans should have health insurance or should they have access to health insurance? Access to health insurance and actually having health insurance can be two very different concepts. Universal coverage requires a Federal mandate; universal access to coverage does not necessarily require one. However, the latter is generally less efficient and more costly per person covered.

In addition, there is no broad agreement about what type and level of coverage is minimally necessary to be defined as acceptable health insurance. Does it mean comprehensive, first-dollar coverage, catastrophic stop-loss coverage, or something in between? Similarly vexing is the definition of affordability. Does affordability mean insurance premiums should not be greater than a percentage of income, or does it mean an explicit dollar amount? What are the levels of government subsidies that are necessary, desirable and/or acceptable to make health care affordable for individuals and businesses? And, most importantly, how are they to be financed?

A similar challenge is how to define and assure quality of health care. This becomes frequently something more akin to the Supreme Court’s definition of pornography; you cannot define it, but you know it when you see it. And finally, how do you weigh the relative importance of each one of these essential issues? The following sampling of issues gives a sense of how complicated and controversial health care can be and why I believe it to be the most challenging domestic policy issue confronting the nation.

III. HEALTH CARE ISSUES THAT CHALLENGE THE NATION

A. Choice

A commonly identified health care policy problem is lack of choice. People constantly say that they want more choices in health care, but what does that mean? What should our goals be in this area? Do we want more choice of health plans? Assured choice of doctors? What about more choice
Jennings

of technology and new drugs? Do we need more choice of covered benefits? If choice increases costs, do we want choice in all cases? Choice often segments the healthy from the unhealthy, making it more difficult to affordably cover the most vulnerable populations. Is that an outcome we desire? In short, the concept of choice makes for great rhetoric, but not always great policy. Rarely is there a consensus around the definition or the desired outcome.

B. Health Care Costs

In identifying important problems in health care, it is impossible to ignore the issue of rising health care costs. Should we care about cost growth? Do we think that health care cost containment should be a significant part of health care reform?

As the largest purchaser of health care in this country, the employer community would certainly list cost containment as a major priority in principle. But they rarely pursue it aggressively on the federal legislative front. Regardless though, should this be a major priority of any federal government health initiative? If taxpayer dollars are used for subsidizing health care, should not health care be purchased in the most cost-effective manner? If so, what is the policy that should be implemented? Should we rely on price regulation or trust that market competition governed by certain rules will do the trick? Will those who say they support cost containment strongly advocate it in the end if it means confronting health care providers and insurers directly or limiting consumer choices or benefits?

C. Risk Selection and Insurance Reform

When discussing the problems of the health insurance market, there is more to think about than simply constraining costs. For example, can workable and politically viable reforms be structured to assure that insurers provide affordable health coverage to all Americans, and do not discriminate against people on the basis of preexisting conditions? In a voluntary market, would these types of reforms have potentially dire consequences?

For example, what would happen if insurers enrolled every individual with a preexisting condition at the same price as healthy populations? Inevitably, people would wait until they were sick to get insurance, causing insurance prices to skyrocket, as insurers could not afford to provide health care coverage if they were only insuring sick people. However, in the absence of insurance reforms, insurers tend to develop and effectively
implement strategies to avoid high-risk, high-cost enrollees. Because of these factors, the current health insurance system encounters all sorts of risk selection problems, pointing out the need for a balanced set of insurance reforms as a major health policy goal.

D. Quality

Every American and every policymaker stresses the importance of quality health care, but no one really knows how to measure, assure, or improve it. The whole debate around a Patients’ Bill of Rights illustrates this point. This debate has been driven by the population of Americans that has insurance, but is dissatisfied with the product and how it is delivered. The Patients’ Bill of Rights debate has clearly shown that the issue of quality cannot be ignored, particularly because the Americans who already have coverage may care more about this issue than covering the uninsured.

Long term care is also a concern. Presently, we do not provide any type of significant coverage for those people who are chronically ill of all ages, who want to stay in their home, in their communities, and want to be able to receive some sort of support for doing so. When we do provide care, it is generally Medicaid. We have tens of millions of Americans of all ages who are chronically ill and need to have assistance. Clearly, these are issues that need attention.

As a consequence, it is critically important to define and assure quality health care. How can this be done? Is it determined by the availability of certain health care services, the ability to appeal unsatisfactory health care decisions, or is there a way to actually measure medical outcomes that can work to hold plans and health care providers accountable? And lastly, should there be penalties for health care plans or providers who provide substandard care, and if so, what should they be, and how should they be

8. Study Says 100 Million Americans Chronically Ill, Nov. 12, 1996, at http://www.dien.net.com/cnnhealth.html. Study, done by researchers at the University of California in San Francisco, reveals that over 100 million people who are chronically ill in America today.
applied? Because the state of the art in the health care industry today is such that quality health care is frequently measured much more subjectively than objectively, it becomes an extremely challenging issue to address effectively and satisfactorily to all interested parties.

E. Technology

At the same time as the challenges of health care delivery are becoming ever more complex, the industry is in the midst of an extraordinary age of technology, with seemingly constant breakthroughs in pharmacological interventions, treatments, and diagnostic techniques. These represent great opportunities to improve the quality of life and to extend the life span. Recent breakthroughs in gene therapy have perhaps the most significant implications for the future of health care. Scientists have recently finished mapping the whole genome, and the implications for this knowledge in the future are beyond anything that we can imagine.

But while technology produces wonderful diagnostic tools, treatments, and occasional cures, it also brings to the forefront extraordinary ethical dilemmas. For example, there are widely differing opinions about the benefits and potential harms of genetic screening. Should we know about our gene makeup and our predisposition for disease? This type of information could be very useful for insurers or employers, but would we ever want them to have access to it? Can you imagine people having access to your medical records or your genetic makeup and how that could be used or misused in the future? Should health care reform include all those issues too? How can we effectively balance the positive use of technology with its potential for abuse? And finally, does our understandable love affair with technology adequately take into account its expense and its potential for further dividing the nation between those who have access to it and those who do not?

10. Id.
F. Demographic Challenges

Finally, in defining the problems and goals of health reform, it is important to determine if the inevitable financing and health delivery challenges associated with the retirement of the baby boom generation should be addressed. This demographic challenge is undeniable, as the population of Medicare beneficiaries will double from forty to eighty million by the year 2035. Although competitive reforms over the long term may achieve some limited savings, the fact remains that if you double the population of people on Medicare, the cost will likely double as well.

Linked to the demographic challenge is the need for updating the Medicare benefit to provide for long-overdue prescription drug coverage. It makes little sense to have a Medicare benefit that does not cover prescription drugs in the twenty-first century. The whole future of health care is largely reliant on pharmacological interventions, yet we do not cover an outpatient prescription drug benefit. Seniors and people with disabilities care passionately about this issue because they see the extent to which their health care is pharmacologically based. They are scared of not having access to their medications, and fear, as I will note later, is an incredibly powerful motivating force.

Long-term care is also a concern. Presently, we do not provide any type of significant coverage for chronically ill individuals of any age, who want to stay in their communities, and desire to be able to receive some sort of support for doing so. When we do provide care, it is generally through the welfare-oriented Medicaid program. As a consequence, we have tens of millions of Americans of all ages who are chronically ill who receive no meaningful assistance. While these demographic problems are undeniable, they also have great potential to be extremely expensive to address. Policymakers risk alienating a powerful constituency if they don’t address these

14. Id.
15. Democracy Compact, supra note 6.
17. Study Says 100 Million Americans Chronically Ill, Nov. 12, 1996, at http://www.dienmet.com/cnnhealth.html. Study, done by researchers at the University of California in San Francisco, reveals that over 100 million people who are chronically ill in America today.
issues, yet if they do take them on, they also risk weighing down any health care expansions with expensive, mostly governmental, interventions.

IV. DEVELOPING HEALTH CARE POLICY AND DESIGNING A STRATEGY FOR ENACTMENT

After effectively defining the problems in the health system that should be addressed and developing a general consensus on the goals for reform, it is necessary to design a policy that effectively achieves these goals. The importance of developing a sound policy cannot be overstated, as the policy will be forced to undergo extraordinary scrutiny by both objective policy validators and interests who oppose it. As important as the policy and the process by which it was developed is the subsequent strategy that is tapped to pass and enact such reform. My following comments address both of these essential components of a successful effort to reform the health care system.

A. Overall Policy Approach

Even before developing explicit policy, it is essential to determine whether the approach to health care reform will be comprehensive or incremental in nature. There are advantages and disadvantages to both. Obviously, a comprehensive approach requires a great deal of political capital and is much more difficult to develop and to advocate. However, a comprehensive approach can also much more efficiently expand coverage to a greater number of Americans and can do so while addressing the broad range of financing, insurance reform, quality assurance, and cost containment policies which are directly and indirectly impacted by any health reform. Conversely, a more targeted approach to health reform has the advantage of being easier to achieve consensus around and doing so with less political risk and capital expenditure. The downside, of course, is that while such incremental initiatives are more likely to be enacted into law, they almost inevitably cost more per individual assisted and are frequently more likely to incur unintended consequences.

B. The Policy Development Process

Developing viable policy—from both a structural and political perspective—is certainly one of the greatest challenges facing anyone advocating
health reform. It must be developed in a manner that a broad-based coalition of internal and external policy validators will conclude is workable. To the extent the policy design fails to work from either a financing or health care delivery perspective, the policymaker advocating it will almost inevitably receive merciless and devastating criticism that threatens the very survival of the proposal.

To achieve success in this area, the talented policy analysts that are familiar with financing, delivery, history, and practical application of health policy must be utilized to frame the proposal. If it is an Administration proposal, contributions to the policy must come from a broad array of internal power and policy centers such as the Department of Health and Human Services, the Treasury Department, the Department of Labor, the Office of Management and Budget, the Domestic Policy Council, and the National Economic Council. This is important not only so that policymakers can benefit from various sources of expertise, but also because these departments' investment in the policy is critically important to ensure a broad-based, Administration-wide commitment to the eventual proposal released by the White House. It is also critically important to receive such validation from elite outside experts that the media and the Congress tap as resources on questions of policy.

The last policy question that must be answered is whether the proposal that is released is detailed or general in design. A detailed approach has the advantage of being able to expedite outsiders' analysis of the proposal; for example, achieving a relatively certain budget estimate from the Congressional Budget Office. If there is already broad-based support for such a policy, these details can help accelerate Congressional progress on passing the legislation. The downside, of course, is that any detailed policy exposes itself to easier scrutiny and a greater likelihood of explicit and effective criticism. As such, it frequently becomes more appealing to delay the release of underlying details to avoid such criticism.

C. Timing and Trust in Government

Even the best of policies will have great potential to fail if they are not proposed during a time in which the political environment is open to reform. Generally, that means that there has to be a broad-based acknowledgement that the problems in the health care delivery system are great enough to justify legislative intervention. To advocate comprehensive reform, there almost needs to be a sense of crisis. Ironically, however, there also needs to be a general trust in the government's ability to intervene in a constructive
way. Concurrent with that faith, the public must feel that they can trust the leader advocating such change. These are all necessary prerequisites, as health care is so controversial and so complex that the public must trust that the leader advocating change has their best interest in mind in order to support reform. Lastly, any policy that is promoted cannot be pursued if there are too many other policy priorities also being advocated. In order to both promote and defend a viable health policy, the advocates of that proposal must be available to dedicate a significant amount of time to it.

D. Effective Policy Outreach and Rollout

Beyond securing external validation from the policy elite, it is imperative to develop and implement a strategy that incorporates a broad base of validators for the initiative. It is necessary to secure the agreement of outside validators to lobby the Congress and to illustrate broad-based support from interest groups that are influential with the public, and therefore the media. In addition to proving expert support for the policy, securing interest group involvement increases the number of defenders against the inevitable opposition to the policy. To achieve this end, it is necessary to understand the priorities of key health care interest groups, such as consumer groups, health care providers, insurers, manufacturers, and state and local interests, and integrate them into both the policy and the strategy for enactment.

Unfortunately, these different interest groups rarely have a uniform vision, and you often must choose who is going to be on your side from among these different groups. It is nearly impossible to push through any health reform without the validation of the consumer groups. The provider community is often supportive of reforms that do not include significant cuts to their current reimbursement rates. The insurers and the pharmaceutical companies are often opposed to reforms that mandate significant cost containment while the business community is very focused on promoting cost containment reforms.

Along with outreach to the various interest groups, there must be a carefully designed communications strategy that is developed both for the broader public message as well as the day-to-day press coverage of the proposal. The press can play a constructive or destructive role, but they frequently play a destructive role by default, as conflict is more newsworthy than common ground. That is why I think that you will find that the best reporters are those who recognize the conflict inherent in a reform debate while simultaneously educating the public as to why such a reform is important. It is necessary that they show what benefits can emerge with the pas-
sage of a piece of legislation, as well as to fairly portray the alternative, whether that be the status quo or another piece of flawed legislation.

In order to ensure a positive media relationship, it is essential to provide sufficient and accurate information to enable the media to write knowledgeably. The media need real evidence to support the contention that any proposed solution is worth pursuing, and they are more likely to accept such information if it is validated by independent sources.

No legislation can be enacted into law unless it is passed by the Congress. Anyone who desires any legislation to be passed must understand the role and the responsibility of the Congress. There is great interest in health care on Capitol Hill, and a strong belief that their role is to be the final legislator and compromiser of any initiative. Congress reacts harshly to any hint that this authority could be undermined. As such, a well-understood knowledge of the positions of key Members and Committees of Jurisdiction, as well as a close working relationship with them, is essential. At least initially, the role of the opposing party is frequently to raise serious concerns about the proposal. Thus, policymakers' goal should not necessarily be to achieve agreement at the beginning of the legislative process, but to provide room for an acceptable compromise at the end of the process. It matters little whether the compromise is something that the opponents want or fear opposing; it matters significantly that the perception from the public is that the final agreement is bipartisan in nature.

V. APPLYING THE CLINTON ADMINISTRATION EXPERIENCE

Applying the lessons outlined previously to the experience of the Clinton Administration helps explain why it failed to achieve success in enacting the Health Security Act, but succeeded in enacting or implementing a host of targeted health care reforms in the latter part of the Administration. Regardless of the success or failure of particular policy priorities, the Administration learned the importance of making health care a presidential priority, and succeeded in laying the groundwork for the health care agenda for years to come.

Applying these lessons to the Health Security Act, one can only conclude that despite an unprecedented effort, the outcome was, in retrospect, preordained. By taking a comprehensive approach to reform, it was necessary that almost all elements of the policy and the strategy be implemented flawlessly. Unfortunately, this was not the case, as we failed in attracting and retaining both internal and external validators that were critical to the press and public evaluation of the policy. While we defined the problem and
desired outcome quite well, we promoted a policy at a time when the trust in the federal government was perhaps at its lowest. There was great dissatisfaction with, for example, the government's inability to recognize the perceived failure of the welfare system. As such, the idea that the federal government would propose and significantly regulate health care was bound to be vulnerable to fair and unfair criticisms of the proposed policy. This helps explain why President Clinton now believes that in retrospect, it might have been better to precede with welfare reform prior to pushing such an ambitious health care initiative.

There were other timing problems, however. These included the fact that the Administration had already pushed for very tough votes from the Democratic Congress on deficit reduction and trade. We also were advocating a health care initiative at a time when the President and the First Lady were being criticized (I believe unfairly and inaccurately) for a range of so-called "scandals" such as Whitewater and Travelgate. Moreover, there were foreign policy challenges, such as Haiti, that understandably distracted the President. All this combined to undermine our traditional validators within the groups and on Capitol Hill, and made it much more difficult and eventually impossible to produce a working majority in support of our policy to secure universal coverage.

These factors, along with an overwhelming lobbying assault from opponents of health care reform, served to not only undermine trust in the government, but also trust in the President. The lesson here is that the greatest motivating force in American politics is fear, not hope. Americans are frequently more vulnerable to fear tactics designed to scare them into thinking that they will lose something good than they are open to being convinced that a new policy can improve their current lot in life. Republicans, recognizing that public support for reform was diminishing and fear of it was increasing, became less and less interested in making any compromise on health care.

It is imperative to acknowledge, however, that many of these problems outlined above were self-inflicted. We produced a policy that even some of our own Administration did not support, and said so publicly. The policy released was so detailed that it made it very susceptible to effective (yet frequently unfair) criticism. Our sense of timing to promote this policy perhaps could not have been worse. And our relationships with the Hill as a consequence suffered significantly.

In contrast, subsequent health care efforts by the Clinton Administration were much more successful. They occurred subsequent to the reform of the welfare system, and were targeted reforms that addressed insurance
reforms, patient protections, children’s health care, and Medicare and Medicaid modernization. They succeeded in making health care more accessible, expanding coverage, extending the life of the Medicare trust fund to historic levels, and producing the highest immunization rates and lowest infant mortality rates in the nation’s history. We also set the stage for future health care debates on the Patients’ Bill of Rights, expanding health insurance coverage, modernizing Medicare to include a prescription drug benefit, and reviving the public’s interest in long-term care. These incremental reforms were more inefficient than broader reforms would have been. Nevertheless, such targeted reforms and successes were important perhaps at least as much because they showed that government could develop and pass workable health policy than they were comprehensive health achievements. Perhaps most important, we succeeded in making health care a presidential priority, something that I believe every subsequent President will have to emulate.

VI. LIKELY HEALTH CARE POLICY REFORMS IN THE BUSH ADMINISTRATION

Now, in Washington, we have a Republican administration and a Republican Congress. Health care has not been their number one priority to this point. Instead, they have focused on other issues, such as tax cuts, defense, spending issues, and education (not necessarily in that order). Health care traditionally is not an issue that people often associate with the Republican Party. People have been skeptical of their commitment, and they feel that a lot of special interest groups are closer to them than they are to the Democratic Party.

I think, however, that President Bush took a page from President Clinton in the election. A lot of Republicans in the early 1990s were angry that President Clinton talked so much about crime and welfare reform, traditionally issues associated with Republican priorities. In fact, early in his first term, President Clinton spent a lot of time and resources to illustrate his commitment to these areas. He wanted to give the public a sense that he was not only committed to traditionally Democratic issues, but with any issues that frustrated the American people. These actions gave him common ground with the center of the American public. President Bush has made some early efforts to associate him with health policy reform, and has proposed an interim solution he calls the “Helping Hand” solution to the pre-

scripion drug benefit problem. This program is designed to help low income people obtain health care and prescription drug benefits.

Most Americans do not really focus on elections until election cycles. There are strong Democrats and strong Republicans, but the people in the middle are the ones who, in the end, influence elected politicians. So I anticipate that President Bush will continue to do what he has already done to a certain extent, both in the campaign and now, which is to acknowledge that President Clinton raised very real health care issues that need to be addressed and that there is an unfinished agenda that the American public wants very strongly to get done.

VII. CONCLUSION

I always say that health care is the sex, drugs, and rock and roll of the domestic policy scene. It is the fun issue. It has everything: it is complex, it is emotional, it is special interest laden, it is money laden, it is full of politics, and it is full of policy. As maddening as it can be, it can also be the most rewarding thing one can do. I can tell you personally from having done work in health policy for so many years, that I have been privileged to meet people, whether it is parents whose children did not have health coverage, and now do, or the person who had a preexisting condition who could not get health care before the implementation of the Kennedy-Kassebaum insurance reforms, and now can, to someone who is now able to take time off to care for a chronically ill spouse or parent because of the Family and Medical Leave Act, or individuals with disabilities who are now able to go back to work without the fear of losing their health coverage.

When you actually get policies enacted into law and see them making a real difference in people's lives, there really is nothing like it. So I welcome young, old, and committed new people to this field. I hope you will join the cause and work towards improving the nation's health care system. As Winston Churchill said, and I'm paraphrasing, "Americans will always do the right thing, but not until they've exhausted every other option first." Since we have tried almost every course of action, I have to believe we are

20. Id.
21. See Press Release, supra note 16.
about to get it right. With your help, I hope and expect that we will achieve the goal of assuring that every American has quality, affordable health care.

VIII. QUESTIONS AND ANSWERS

Student: I want to thank you for sharing some of the complexities of the issue, for this was a very enlightening lecture. I do not know if your definition of coverage expansion includes expansion of coverage for mental health services, or is that a totally different battle?

Mr. Jennings: I have spent a lot of time talking to Tipper Gore about those issues and we have succeeded in a number of important fields. First, we passed the Mental Health Parity Act, which mandated that there should no longer be inaccurate or discriminatory lifetime and annual caps on mental health coverage. We required, through executive order, that all federal employee health plans must have mental health parity in all benefits. The implementation of this policy proved that mental health parity in health coverage does not significantly increase health costs. This evidence may prove to be a great tool for those advocates striving to extend mental health parity to private health plans.

The Clinton Administration held a historic White House Conference on mental health. We released the first Surgeon General report on mental health. Tipper Gore served as a wonderful advocate for mental health, and I am confident that she will continue to work on these issues. When we passed the 1997 Balanced Budget Act we had to fight opponents of mental health parity to ensure that mental health benefits would be part of the CHIP program, which we succeeded in doing. I think that through the attention that has been focused on mental health services within the last several years, we are making real progress on these issues.

Student: On a pragmatic side, let's discuss finances. Incidents of fraud within the health care system always seem to involve big bucks. As a taxpayer, I say, okay, I am all for supporting those that need the assistance. When you design these systems, do you, at all, consider the back end? What are we going to do with those people caught abusing the system?

Mr. Jennings: That is a very good question. We have spent a lot of time over the past eight years working to control health care fraud. We spent a lot of time weeding out fraud in the Medicare program during the Clinton Administration and we did it very successfully. In the minds of many pro-
vider groups, we were too successful in this area. They feel that the Health Care Financing Administration was far too aggressive in their enforcement; they frequently felt that understandable compliance shortcomings resulting from confusing directives from Medicare were not criminal acts.

So, in order to effectively fight Medicare fraud, you have to find the right balance between strong enforcement and good communication with providers. It is true that many Americans believe that if you just cut back on the fraud, you would have all the money you need to take care of everyone. I wish that were true, but it is not. There is no question that there must be strong anti-fraud enforcement mechanisms to control fraud, and, also importantly, give yourself credibility on this issue. Americans must know that you are doing everything you can to stop fraud. But you also need to diffuse the public notion that no matter how successful you are, it will not be enough money to take care of the problems.

I must say that I am proud, however, that the Medicare actuaries and independent career analysts have concluded that the Clinton Administration's dedication to anti-fraud activities is one of the most important reasons why we significantly extended the life of the Medicare trust fund during the Administration. Additionally, I think our efforts have successfully changed provider behavior, making it much less common for providers to bill for services inappropriately.

Student: Sir, one other thing, also about financing. There is great concern about a potential recession. Realistically, what will that do for the efforts in Washington on health care?

Mr. Jennings: Well, it is interesting; sometimes in bad times you can end up having more of a focus on health care. A lot of the surveys that are most recently coming out are showing that people are concerned about job layoffs. When the job security issue gets raised, so does people's fear of losing their health care. When you lose your job you lose income, but it is much easier to replace an income source than to replace health care. People really fear losing health care.

In fact, in 1993, that was one of the driving forces for our attempt at major health care reform. The people who feared losing health care were a much more influential political force that those who were already uninsured. So, interestingly, bad times can lead to more action on big issues. Now, I do not anticipate that this recession would lead to discussions of universal health coverage, but you might make efforts to expand coverage in other ways. For example, one smaller policy that may become popular in a time of
economic downturn is subsidies for COBRA coverage. Individuals who leave or lose their jobs can opt to continue their health coverage by paying 102% of the premium their employer paid. However, many individuals cannot afford to pay these premiums, but if you can develop a six-month or year-long subsidy program for people who have lost their jobs, that stopgap period could make a real difference, in both reducing numbers of uninsured and creating a greater sense of security and trust in the government. So, in an ironic way, bad economic times can lead to positive developments.

It is interesting to note that as private sector health care expenditures have increased dramatically in recent years, we have succeeded in constraining health care spending to historic low levels. The outcome of this fact is that the large surpluses we now have are largely attributable to our success at moderating the growth of Medicare and Medicaid. I therefore believe that a strong argument can and must be made that a significant portion of federal surpluses should be dedicated to health care improvements. In the 1980s and 1990s, we always utilized health care savings to be the source of new financing for coverage improvements. While there no doubt will be an appropriate interest in dedicating some of the surplus to tax cuts, it should not be at the expense of long-overdue and needed investments in insurance coverage expansions and a new Medicare prescription drug benefit. It is my hope that the health care needs of the nation will not be bypassed by the tax cut fervor that will almost inevitably be promoted by the new President and the Republican Congress. Only time will tell.
Skin and Bones: Post-Mortem Markets in Human Tissue

R. Alta Charo*

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Immediately the human corpse rises to a dignity and importance in the commercial world which it may not have possessed in its lifetime. It is a commercium, a thing of value, a subject of political economies, perhaps to be bought, sold, and exchanged, and subject to the rules of supply and demand. . . . The whole foundation of law and custom is shaken. It becomes a serious question how it shall be rebuilt. A new civilization calls loudly for new definitions of the rights and duties of society to the dead body. Up to the present writing they have not been satisfactorily given.

I. INTRODUCTION

This rather modern sounding cry for examination of the market for human tissue actually dates to the late nineteenth century, when the supply of cadavers for medical education was dwindling. Whether one dates the transformation to the nineteenth or to the twentieth century, it is certain that "[f]or better or worse, we have irrevocably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell." Where once the value of the human body was seen exclusively in its ability to perform labor or to produce offspring or to bring sensual and other personal satisfaction, the potential of the human body as a source of transferable physical material has led some to see its value in medical and, if made available for sale, economic terms as well.

3. See generally, Boulier, supra note 1.
5. See Scott, supra note 4, at 179–97. Identifying a market value for the sum total of all human tissue is a popular intellectual exercise. In the early 1970s, for example, one student wrote on the possible tax consequences of organ sales, and relied on the figure of $653.50 as the market value of the constituent minerals in the body including blood serum.
This essay briefly describes the history of using various human non-organ tissues, whether obtained from living or deceased donors, so that the issues surrounding postmortem markets in bone, skin, and other tissues can be better situated within the context of the American market and regulation for tissue generally.

Human tissue is obtained in a variety of ways. Blood may be donated or sold by living persons for use in transfusion or basic research. Hair may be sold by living persons for wig makers, or placental tissue collected after childbirth for cosmetics manufacturers. Surgical procedures may result in pathological samples taken both for diagnostic purposes and for long storage for both clinical uses related to the patient and research uses going far beyond the patient's lifetime. These tissues may also be manipulated to create replicating cell lines that have characteristics resulting both from the underlying tissue and from the laboratory manipulation. Gametes (sperm and eggs) and fetal tissue from abortions and miscarriages can be collected from donors and transferred to others, usually with reimbursement although technically not with payment that would transform the transaction into a formal sale. While each of these forms of tissue transfer are interesting, this chapter will focus on a selection of human tissues—specifically, corneas, gametes, and cell lines—in order to illustrate some of the legal and market phenomena typically associated with tissue transfers.

Interestingly, there is relatively little law at either the state or federal level governing tissue transfers, whether with regard to how tissue is obtained, how it is transferred, or how it is manipulated and transplanted. In part, this may be due to the low economic value of most human tissue. In the absence of financially significant disputes, fewer cases come to courts for resolution and there is less pressure for legislative bodies to anticipate and regulate future disputes. In part, it is also due, to the complexities of property law, the primary area of law applicable to the recovery and transfer of human tissue, and its historical inability to reconcile the concerns of the market with the more emotional and spiritual concerns associated with the

See Paul McCarthy, Note, Tax Consequences of Transfers of Bodily Parts, 73 COLUM. L. REV. 842, 860 (1973) (citing CHEMICAL AND ENGINEERING NEWS, Nov. 13, 1972, at 60, col. 2). Today that figure would need radical adjustment to account for the potential economic value of gene sequences, rare tissue types, and reproductive material. See LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR (2001).


7. Id.
legal characterization of personal control over one's body, both before and after death. Thus, while there is a growing interest in health and safety based regulation of tissue manipulation and transplantation, and a body of rules governing the distribution of whole organs from cadavers, there is only spotty legal coverage of other areas of what might be termed "tissue law."

The essay begins with a look at the interplay of property law and personal autonomy, and at the origins of the law's treatment of the corpse. It is here that one finds the beginnings of still lively discussions about the relationship between ourselves and our bodies that, in turn, informs discussions about the law and regulation governing markets in human tissue. It turns next to some specific examples of markets in tissue, some in which people know they are releasing tissue for the use of others and some in which that knowledge may be absent. Finally, it summarizes the growing body of regulatory law that governs tissue manipulation and transplantation, an area of general application to many different kinds of tissue from many different sources.

II. PROPERTY AND PERSONAL AUTONOMY

The value of the body is intimately linked to the question of personal autonomy. Depending on which basis is chosen to explain notions of personal autonomy, the removal of cadaver tissue without consent, a frequent proposal in the area of "presumed consent" laws to foster greater availability of transplantable organs and tissue, will or will not violate notions of personal autonomy that run deep in the American legal system.

Autonomy can be promoted through many legal regimes. The value of the body is intimately linked to the question of personal autonomy. Such autonomy can be achieved through many legal regimes. In one, autonomy is premised on the notion that one's body is one's personal property, and that uninvited removal of tissue is a form of theft or trespass. In another, the body is not property, but personal autonomy is premised on liberty interests of the person within, and uninvited removal of tissue is a form of injury and a deprivation of liberty. The question of personal control over one's body is highlighted throughout civil and criminal law. An unwanted touching—whether by a criminal attacker or by a doctor who exceeds the scope of consent to surgery—is a battery. Bodily integrity is a highly protected legal and cultural value in the United States, and informed, uncoerced consent is

necessary before any bodily invasion. This conclusion can be reached whether or not one views the body as a form of personal property.

But while it is clear that a living, competent person's body parts cannot be removed without his or her consent, the law of bodily integrity is less clear after someone has died. Here, the question of whether the body is property becomes pertinent, as the liberty interests that support an alternative theory of personal autonomy are usually considered to have died with the person. Thus, by characterizing the body as property, personal control over the removal of tissues can continue even after death, by virtue of testamentary wishes in a will or ownership interests in heirs and next of kin. In the context of determining decision-making authority for research and clinical uses of organs and tissue, courts have tended to recognize that the source of the tissue has decision-making authority—even over interventions that will occur after death, or after the tissue has been removed—but at the same time to eschew a clear jurisprudence of the body as a form of property. The result is legal confusion in the market and quasi-market for human tissue. Adding to the confusion is the fact that questions of control are distinct from the issue of commercialization. Thus, in most cases, the donor of a cadaver organ for transplantation cannot be paid for the organ, but the living donor of certain types of tissue (blood, sperm, eggs, genes) may be compensated. And doctors or researchers who claim intellectual property rights in altered versions of other people's cell lines or genes can earn millions.

III. THE LAW OF THE CORPSE

The earliest Anglo-Saxon cases to consider ownership of human tissue, specifically corpses, were decided almost 1000 years ago by special ecclesiastical courts in England who were given complete jurisdiction over all matters concerning burials and disposition of corpses. With few


10. Genetic Engineering News publishes an annual list of "molecular millionaires." Prominent among them are researchers who have patented patients' genes. Brian O'Neill, Biotechnology Bay State has share of "Molecular Millionaires," BOSTON GLOBE, Apr. 21, 1999, at D4.

exceptions, control of dead bodies remained within the exclusive jurisdiction of the church courts until the nineteenth century, when the growth of medical schools and their need for cadavers for dissection created a challenge to ecclesiastical dominion over bodies.\textsuperscript{12}

In the earliest recorded treatise of the subject of property rights in the human body, Lord Edward Coke wrote: "[t]he burial [sic] of the cadaver (that is caro data vermibus) is nullius in bonis, [the goods of no one] and belongs to ecclesiastical cognizance, [sic]"\textsuperscript{13} a statement that became the foundation for the Anglo-American law that human body parts cannot be property.\textsuperscript{14}

In colonial America, the absence of ecclesiastical courts resulted in civil jurisdiction over bodies and the application of common law principles. There were no commercial rights in cadavers, no right for a decedent to direct the manner of burial, and no burial rights enforceable by the next of kin; common law courts were more focused on commercial disputes than sentimental concerns.

During the 1800s, however, common law doctrine was increasingly viewed as incapable of managing the real emotional distress associated with mismanagement of bodies, and courts began assigning to the next of kin an enforceable right to possession of a body for burial. To preserve the continuity of common law principles, the right was sometimes characterized as a "property right."\textsuperscript{15} This right became so well established that in 1891, a court suggested that the "fact that a person has exclusive rights over a body for the purposes of burial leads necessarily to the conclusion that it is his property in the broadest and most general sense of that term."\textsuperscript{16}

Judicial references to property rights in corpses were misleading, however.\textsuperscript{17} While common law property rights generally include the right to

\textsuperscript{13} 3 \textit{EDWARDO COKE, INSTITUTES OF THE LAWS OF ENGLAND} 203 (1644).
\textsuperscript{14} See Griffith v. Charlotte, Columbia & Augusta R.R. Co., 23 S.C. 25, 32 (1884). The Court noted that "Coke was understood to say that 'a dead body was the property of no one.' No matter what he did say; this understanding, or misunderstanding, has come down to us as law." \textit{Id.}
\textsuperscript{15} See \textit{JACKSON, supra} note 11.
\textsuperscript{16} Larson v. Chase, 50 N.W. 238, 239 (Minn. 1891).
\textsuperscript{17} Property is generally viewed not as a single indivisible concept but as a bundle of legally protected interests, including the right to possess and use, to transfer by sale or gift, and to exclude others from possession. Although the property concept can be invoked to protect various legal interests, one's right to use property is commonly limited to uses that do
possess and use, to transfer by sale or gift, and to exclude others from possession; few of these rights were applied to bodies. For instance, the theft of a cadaver was not larceny, the sale of a cadaver was not a common law crime, the heirs had no right to repossess a body wrongfully taken from them, and a cadaver could not be the subject of a lien. Recognizing the limited applicability of property law to corpses, twentieth century American courts retreated from the broad pronouncement of bodies as property and began referring to more limited "quasi property rights" vested in the next of kin and arising out of their legal duty to bury the dead. These rights include the right to possession and custody of the body for burial, the right to have it remain in its final resting place, and the right to recover damages for any outrage, indignity, or injury to the body of the deceased.

The family's interest in the dead body was subject to various interests of the state government, including concern for public sensibility, promotion of public health, identifying cases of murder, and protecting the economic interests of undertakers and insurers. Quasi property analysis became the prevailing rule in both the United States and England during the early twentieth century and continues to be applied to disputes over funeral arrangements.

In the 1930s, American jurists and legal scholars began questioning the applicability of property law concepts to cases involving wrongful conduct toward corpses. Gradually, the newly developing tort law framework of intentional infliction of emotional distress (also called "outrageous conduct") was viewed as a more appealing theoretical basis for a legal claim against anyone who wrongfully removes, mutilates, or operates on the body of a dead person, or who prevents its proper interment or cremation. The cause of action is a personal right of the survivor rather than a right of the decedent or his estate, as the courts are not primarily concerned with the extent of the physical mishandling or injury to the body per se, but rather

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with the effect of such improper activities on the emotions of the surviving kin.  

Even these rights, however, are tempered by the public interest. In American jurisdictions, a person may dictate the disposal of his or her remains through a will, and if she fails to do so, the decedent's family may exercise the power. This power, however, is subject to limitation by rights of coroners and medical examiners. If the state interest is compelling enough, the relatives of the decedent may lose any quasi-property right. 

Overall, courts have backed away from adopting a property theory for the body, for example by discussing and rejecting conversion claims with respect to corpses, in part because of the belief that the partial remains of a human body have no inherent value. On the other hand, they have conflated quasi-property rights in the corpse with torts claims for infliction of emotional distress due to improper handling of the corpse, leaving the extent to which there is a legally recognized property interest in the body still unclear.

22. Id.
24. See State v. Powell, 497 So. 2d 1188 (Fla. 1986) (holding that the state interest in providing sight to blind citizens is compelling enough to allow removal of corneas from a corpse without notice to the next of kin).
25. The essence of the tort of conversion is interference with the owner's right of possession or control. The plaintiff in a conversion suit must therefore show a right to possess the property or the suit will fail. Historically, establishing a property interest in a bodily part has been quite difficult. As discussed earlier, the sale or disposition of cadavers, cadaver tissues, or the cadaver organs has generally been restricted. In addition to demonstrating a property interest in the tissue, a successful suit for conversion must show that the plaintiff has suffered some injury through interference with the property. One form of injury is a diminution in the availability (and hence the value) of the property to the plaintiff, but "raw" tissues and cells have little pecuniary value in themselves.
27. Michelle Bourianoff Bray, Personalizing Personality: Toward a Property Right in Human Bodies, 69 TEX. L. REV. 209, 231 (1990). In a number of prominent scandals, crematoria and funeral homes have been the subject of class-action suits following disclosure of improper handling of corpses, including a $31 million suit in 1984 to the relatives of 5,000 people whose ashes were dumped on land instead of over the ocean; and $25 million suit in 1991 to relatives of people whose bodies were harvested for tissue and then cremated, with mixed ashes returned to the families; and, most recently, a suit for improper disposal of hundreds of bodies at a Georgia crematorium. Duane Stanford, Lawyers Target Funeral Homes, Not Crematory, ATLANTA J. & CONST., March 3, 2002, at 1A.
Without a clear notion of whether interference with the body is an interference with property or an invasion of privacy, it is difficult to develop a coherent and consistent set of rules governing control over the body and its tissues. While either theory can support rules that permit dispositive control to rest with the person, while alive, and with the person’s kin, after death, only a property theory can easily support a commercial market in tissues, whether taken from live donors (or, perhaps, better defined as sellers) or from cadavers now owned by those who inherit the body from its “owner.” In light of the existing markets and quasi-markets in tissue, and in light of the growing range of commercial uses of tissue, this lack of clarity poses a challenge to the orderly development and regulation of tissue transfers for research, transplantation, and other uses.

IV. THE LAW OF CADAVERIC TISSUE DONATION

The first phenomenon to put pressure on this lack of clarity in the status of human tissue arose in the mid-twentieth century, when scientific advances led to an increasing need for transplantable tissue. From 1947 until 1968, forty states enacted statutes permitting anatomical donations from cadavers for transplantation or scientific research. Variations among the statutes lead to the formation of a special committee of the Commissioners on Uniform State Laws to draft a uniform donation statute. The result of this effort is the Uniform Anatomical Gift Act (UAGA), which has been adopted throughout the fifty states and the District of Columbia.

The UAGA permits any competent adult to make a gift—to take effect upon death—of all or any part of his body for purposes such as medical education, research, and transplantation. Donations for research purposes may only be made to hospitals, physicians, medical and dental schools, and tissue banks. Post mortem donations of human tissues and cells to noncommercial biomedical researchers are therefore permitted, although transfers from noncommercial researchers to commercial researchers are not

28. Sideman, supra note 12, at 841.
30. Id. The UAGA supersedes only those areas of the common law of cadavers that are addressed by the act. Id. at 921–22.
31. Id. at 925.
32. Id.
addressed by the model law.\textsuperscript{33} It has been argued that the UAGA recognizes rights in the human body that may be classified as property rights, but the UAGA does not discuss inter vivos (during life) gifts, nor does it say anything about the sale of organs or other body parts.\textsuperscript{34} The chairman of the committee that drafted the UAGA has written that it was intended neither to encourage nor prohibit sales.\textsuperscript{35}

In 1984, Congress enacted the National Organ Transplant Act (NOTA).\textsuperscript{36} NOTA prohibits the sale of a human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin. Although the act makes it a felony to purchase specified human organs for transplantation, reasonable payments for a living donor’s expenses (e.g., travel, housing, and lost wages) are permitted.\textsuperscript{37} Despite this prohibition, there is a quasimarket in organs such as corneas.

V. PRESUMED CONSENT STATUTES AND CORNEAL TRANSPLANTATION

Corneal transplants have been done since 1905, and the Eye Bank Association of America (EBAA) estimates that 45,000 people around the world need such transplants each year.\textsuperscript{38} EBAA has 110 member eye banks operating in over 100 locations in forty-three states, the District of Columbia, Puerto Rico, Canada, Europe, the Middle East, and Australia.\textsuperscript{39}

Corneas are considered “organs” under NOTA and many state statutes, and many corneas are acquired by ordinary, voluntary donation practices, such as prior authorization from the deceased or donation by next of kin.\textsuperscript{40}

\begin{thebibliography}{99}
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\item[33.] Stason, \textit{supra} note 29, at 924. Gifts may be made either by will or by a gift document such as a donor card. In the absence of contrary instructions by a decedent, the next of kin may authorize a gift. \textit{id.} at 926.
\item[34.] \textit{id.} at 924.
\item[35.] \textit{id.}
\item[37.] The statute’s organ sale prohibition was based primarily on congressional concern that permitting the sale of human organs might undermine the nation’s system of voluntary organ donation. It was also driven by concern that the poor would sell their organs to the rich, to the detriment both of poor people who might feel economically coerced to become organ suppliers and those who need but cannot afford transplantable organs. It may also reflect congressional distaste for sales of human body parts generally.
\item[38.] The Eyebank Ass’n of Am., \textit{at} http://www.restoresight.org/pubscct.htm (last visited Nov. 8, 2001).
\item[39.] \textit{id.}
\end{thebibliography}
There is, however, an additional, lesser known process for gathering corneas for transplantation. Statutes in approximately twenty states permit a coroner to remove the corneas of a cadaver on which an autopsy is performed if there is no known objection from surviving relatives.\(^{41}\) Commonly referred to as “presumed consent” laws, these statutes were enacted in the 1960s, 1970s, and 1980s in order to ward off shortages.\(^{42}\)

Harvesting cornea tissue under presumed consent laws has resulted in several challenges to the constitutionality of state laws that would remove dispositional control over corneas from the next of kin. In a number of cases, the state courts first found that the laws were valid under the state constitutions and second, that there was no property interest in the deceased person’s body. Several courts held that the next of kin of the deceased has no property right in the dead body.\(^{43}\) One of these courts also rejected the argument presumed consent statutes invade a fundamental privacy right in a person’s body,\(^{44}\) holding that a right of privacy concerns the right to make decisions about one’s own body, and that this right dies with the person.\(^{45}\)

At the same time, however, these courts have acknowledged a quasi-property right in the surviving relatives of the decedent to possession of the body for purposes of burial. Indeed, two more recent cases in the federal courts have suggested that next of kin may have a stronger property interest in the dead body of a relative than these state cases would suggest, and that their dispositional authority might go beyond mere control over burial.\(^{46}\) The cases, however, do not develop this point enough to make it possible to generalize to other tissues or other forms of more purely voluntary donation.\(^{47}\)

According to Professor Julia Mahoney of the University of Virginia:

> The ability of coroners to harvest the corneas of corpses entrusted to them creates opportunities for market transactions, as coroners’

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41. Id.
44. Tillman, 360 N.W.2d at 275.
45. Id. at 277.
46. Whaley v. County of Tuscola, 58 F.3d 1111 (6th Cir. 1995); Brotherton v. Cleveland, 923 F.2d 477 (6th Cir. 1991).
47. Id.
offices sell the retrieved corneas to tissue "banks"... which serve an intermediary function, in turn reselling usable eyes to corneal transplant programs. Late in 1997, press reports documenting a series of such exchanges appeared in the Los Angeles Times. From 1992 to 1997, reported the Times, the Los Angeles County coroner's office delivered corneas to the Doheny Eye and Tissue Transplant Bank in exchange for total payments of over $1,000,000. Doheny paid the coroner's office $215 to $335 per cornea, then resold the corneas for significantly more.... Eye banks generally pay money to obtain corneas, whether obtained from morgues, hospitals, or otherwise, and in turn receive money from corneal programs. Corneal transplant programs in turn sell transplant services—which, of course, include a cornea as part of the deal—to patients.48

Viewed as a question of privacy rights, the use of presumed consent statutes to govern removal of corneas can be regarded as unproblematic for the deceased person, whose privacy interests have also died, leaving only the question of whether the public interest in ensuring adequate supplies outweighs the public interest in protecting the sensibilities of the family. The body itself becomes a kind of public resource, available for harvesting and use to serve public purposes. But if corneas are the private property of the deceased, property that should be controlled by will or the law of intestacy, then this removal constitutes a form of taxation on the estate, or worse, a taking, for which some argument about compelling public purpose must be made, and some form of compensation provided. Without a theory of the body as a public resource, this harvesting of corneas, especially when coupled with financial transactions among intermediaries, is easily perceived by the public as a rather ghoulish form of state-sanctioned theft, rather than as a benign form of human tissue recycling in order to aid the living.

VI. THE LAW OF GAMETE SALES

An example of another large-scale market for human tissue lies in the area of reproductive medicine, where sperm and ova are routinely obtained from donors whose reimbursements for the service of providing gametes strongly resemble a payment for the sale of their gametes. Gametes are retrieved from thousands of Americans every year for use in assisted reproduction. In many cases, the gametes are transferred to someone other than the gamete provider's partner, a phenomenon commonly referred to as

48. Mahoney, supra note 40, at 184–85 (citations omitted).
egg or sperm donation, even where the donors are reimbursed for the gametes. The Centers for Disease Control, for example, estimates that donor eggs were used in approximately ten percent of all Assisted Reproductive Technology (ART) cycles carried out in 1998, or 7756 cycles. A 1987 study by the congressional Office of Technology Assessment estimated the frequency of sperm donation as considerably higher.

Sperm and egg donors are sought by advertisement, sometimes as low-key as a flyer stuck on a billboard in a medical school and other times as noticeable as an advertisement in a major national newspaper. Ron’s Angels bills itself as “the most visited egg and sperm site in the world.” Whether or not that is true, the internet site offering to auction sperm and ova from physically attractive people has generated much greater public awareness of the market for human gametes.

Unlike most other developed countries, Americans can buy and sell gametes, although the transactions are sometimes labeled as something other than a sale, for example, where provision of a semen sample is rewarded with a cash payment for “services” as opposed to a product. Similarly, recipients will pay for a fertility service that includes the provision of the necessary gametes, thus avoiding the need to consider the transaction strictly as a purchase of gametes. Indeed, the American Society of Reproductive Medicine condemned the Ron’s Angels’ site in these terms:

The ASRM Ethics Committee states that reasonable compensation is justified for the time and trouble of both sperm and egg donors. Compensation should not vary based on attributes that a child may have. The “Ron’s Angel’s” website is essentially a donor egg ‘auction’ to sell human eggs to the highest bidder in the hopes of providing potential parents with more attractive—and therefore desirable—children. We believe that the “Ron’s Angels” website violates the ethical principles outlined by the Committee, promotes unrealistic expectations to potential parents, commercializes what is otherwise a voluntary donation process, offers undue enticement


to potential donors, and has great potential to exploit highly vulnerable people.\(^\text{52}\)

The amount offered to reimburse gamete donors has varied over the years. At the time of the 1987 congressional survey, men who met selection criteria (for health, absence of transmissible disease, freedom from family history of significant heritable disorders, and minimum height and physical fitness) appeared to receive between thirty dollars and fifty dollars for each semen sample provided, while egg donors (who must undergo a more arduous, unpleasant, and risk prone retrieval) would receive up to several thousand dollars. In 1998, however, an announcement by a New Jersey fertility clinic of plans to double the compensation offered to egg donors from $2500 to $5000 demonstrated that prices for egg donation were rising, and generated extensive press coverage and commentary.\(^\text{53}\) The New York Times reported that accounts of the price increase "put a spotlight on what is perhaps the touchiest issue in the egg donation process: are the eggs a gift or a free-market commodity?"\(^\text{54}\) In March 1999, the price offered for usable ova increased by an order of magnitude when an advertisement placed in the campus newspapers of several Ivy League schools offered a $50,000 "financial incentive" to an "Intelligent, Athletic Egg Donor."\(^\text{55}\)

Both the pricing regimes and some cases suggest that, regardless of rhetorical presentation, gametes are indeed treated as property. For example, because gametes can also be retrieved from the dead, occasionally widows, fiancées, girlfriends, and parents of men who recently died have requested sperm retrieval, raising the question of dispositional authority over gametes. In Hecht v. Superior Court,\(^\text{56}\) which concerned the validity of a provision in a man's will that his companion of five years be permitted to

\(^{52}\) ASRM Statement on "Ron's Angels" Website, Statement of R. Jeffrey Chang, M.D. President, American Society for Reproductive Medicine, at http://www.obgyn.net/infertility/articles/asrm_pr.htm (last visited Jan. 27, 2002).


\(^{54}\) Kolata, supra note 53, at A1.

\(^{55}\) Sydney Leavens, Yale U. Students and Professors React to Egg Donation Ad, YALE DAILY NEWS (New Haven), Mar. 4, 1999, at LEXIS, News Library (describing reactions among members of the Yale community).

use his semen, the appellate courts upheld the provision, treating the semen as if it were the property of the deceased and therefore eligible for disposition by testamentary provision. The status of sperm—and, by extension, other tissue—as the subject of property rights or personal rights also arises in cases where there is no testamentary wish. In the mid-nineties, for example, a newly married young man was killed in a quarrel with police. His widow requested his semen even though there was no prior indication of his wishes, in a will or by other means. Physicians acceded to her wishes, as they have on several other occasions to requests from girlfriends and parents.

Of course, the fact that courts have at times treated male gametes as if they are property does not necessarily tell us whether this if a form of property that ought to be bought and sold. In her analysis of the Hecht case, philosopher Bonnie Steinbock writes:

ownership does not settle the question of the scope of control—that is, what the owner may legally do with the stored sperm. Under certain circumstances one can own something one is not permitted to sell. For example, the Queen of England owns a great deal of land and many art treasures that she may not sell. However, since ordinarily one may sell one’s property, the identification of sperm as property creates a presumption that it may be donated, stored, sold, and bequeathed.

Of course, ownership of something, whether of a pet or a piece of land or one’s own tissue, should also convey the right to sell the property is not answerable merely by calling the item one’s “property.” “Too many incidents are lacking to say that persons own their bodies. Restrictions on transfer and the absence of a liberty to consume or destroy, for example, indicate that persons do not own their bodies in the way that they own automobiles or desks.”

57. Hecht, 20 Cal. Rptr. 2d at 276.
58. Id. at 290–291.
60. Id.
61. Id.
63. Id. at 62 (quoting STEPHEN MUNZER, A THEORY OF PROPERTY 56 (1980)).
Looking at the question of personal control over one’s body, it is helpful to distinguish between property rights in one’s body and personal rights over its treatment:

Property rights are body rights that protect the choice to transfer. Personal rights are body rights that protect interests other than the choice to transfer. To note that someone has dispositional authority over a body or body part is thus not necessarily to acknowledge a property right; dispositional authority may indicate a personal right instead.64

At the same time, the law’s tolerance of our decisions to donate or sell some of our body parts does suggest that some property rights clearly exist. Whether these property rights include the right of sale hinges on a more complex analysis of the social ramifications of such sales. Steinbock elaborates:

[One should distinguish also] between weak property rights, which involve only a choice to transfer gratuitously, and strong property rights, which involve a choice to transfer for value. Most countries permit the donation of organs, but forbid their sale. In these countries, people have weak property rights in their organs. In countries where the sale of blood and semen is legal, individuals have strong property rights in these bodily fluids.65

The question of whether sperm and ova should be available for sale in the United States, that is, whether they should be the subject of strong property rights, is periodically revisited whenever controversies arise over the scale of such sales or the connection of such sales to purportedly eugenic goals, such as the sale of gametes from intellectually or physically “superior” adults.66 But if we should ever conclude that such sales ought to be permitted, then we should be prepared to apply the entire body of the law of sales, as well as the body of tort law governing the sale of products.

VII. THE LAW OF TISSUES AND CELL LINES FOR RESEARCH

As mentioned in the introduction, many human tissues are obtained for use in research, commerce, and clinical care. While most of these tissues are

64. Id.
65. Id. at 61.
66. Steinbock, supra note 62, at 65.
obtained with the knowledge of the tissue source (if he or she is alive) or at least the consent of the kin (when the tissue source is dead), the use of tissues for research is characterized by a mix of both witting and unwitting "donation" for use.

While individuals in the United States may possibly be seen to have a strong property right in their gametes, no such strong property right has been identified in the other tissues of their bodies, even when these tissues are taken while the individual is alive. Human tissue is routinely excised in medical procedures and stored for both clinical and research purposes. Once stored, the tissues are then transferred among laboratories and researchers for work on such things as genetic epidemiology, but there is virtually no tradition of compensating the individuals from whom the tissues came. Indeed, in many cases these individuals have no knowledge that they have unwittingly made a gift of their human biological materials to the research world.

The medical and scientific practice of storing human biological materials is more than 100 years old. Human biological collections—which include DNA banks, tissue banks, and repositories—vary considerably, ranging from large collections formally designated as repositories to blood or tissue informally stored in a researcher's laboratory freezer. Large collections include archived pathology materials and stored cards containing blood spots from newborn screening tests (Gunthrie cards). Tissue specimens are stored at military facilities, forensic DNA banks, government laboratories, diagnostic pathology and cytology laboratories, university-and hospital-based research laboratories, commercial enterprises, and nonprofit organizations. Archives of human biological materials range in size from fewer than 200 specimens to more than 92 million. Conservatively estimated, at least 282 million specimens (from more than 176 million individual cases) are stored in the United States, and the collections are growing at a rate of over 20 million cases per year.

The most common sources of human biological materials are diagnostic or therapeutic interventions in which diseased tissue is removed or tissue and other material is obtained to determine the

67. Id.
68. Research Involving Human Biological Materials: Ethical and Policy Guidance, supra note 6, at 1.
nature and extent of a disease. Even after the diagnosis or treatment is complete, a portion of the specimen routinely is retained for future clinical, research, or legal purposes. Specimens also are obtained during autopsies. In addition, volunteers donate organs, blood, or other tissue for transplantation or research, and some donate their bodies after death for transplantation of organs or anatomical studies. Each specimen may be stored in multiple forms, including slides, paraffin blocks, formalin-fixed, tissue culture, or extracted DNA. Repositories provide qualified commercial and noncommercial laboratories with access to specimens for both clinical and research purposes.69

In addition to its future clinical use, a specimen of human biological material can be used to study basic biology or disease. It can be examined to determine its normal and abnormal attributes, or it can be manipulated to develop a research tool or a potentially marketable product. Just as a clinician chooses biological materials appropriate to the clinical situation at hand, a researcher's choice of such materials depends on the goals of the research project. The selected tissue can be used only once, or it can be used to generate a renewable source of material, such as by developing a cell line, a cloned gene, or a gene marker. In addition, proteins can be extracted, or DNA isolated, from particular specimens.70

There is substantial research value both in unidentified material (i.e., material that is not linked to an individual) and in material linked to an identifiable person and his or her continuing medical record.71 In the former, the value to the researcher of the human biological material is in the tissue itself and often in the associated

69. Id. at 2.
70. Id.
71. Id.

Human biological materials also may be used for quality control in health care delivery, particularly in diagnostic and pathology laboratories. In addition, these materials are used to identify an individual, such as in paternity testing and in cases of abduction or soldiers missing in action, as well as in other forensic matters for which biological evidence is available for comparison. The advent of technologies that can extract a wide array of information from these materials generally has increased the potential uses—in research and otherwise—of human biological materials that are unrelated to individual patient care.

Id. at 2–3.
clinical information about that individual, without the need to know
the identity of the person from whom it came. In such cases,
beyond knowing the diagnosis of the individual from whom the
specimen was obtained, researchers may not require more detailed
medical records, either past or ongoing.

Sometimes, however, it is necessary to identify the source of the
research sample, because the research value of the material de-
pends upon linking findings regarding the biology of the sample
with updated information from medical or other records pertaining
to its source.

By using the power of new DNA technologies and other molecular
techniques, scientists potentially can turn to millions of stored hu-
man biological materials as sources of valuable scientific, medical,
antropological, and sociological information. Indeed, these

72. Research Involving Human Biological Materials: Ethical and Policy Guidance, supra note 6, at 2. "For example, investigators may be interested in identifying a biological marker in a specific type of tissue, such as cells from individuals with Alzheimer's disease or specific tumors from a cancer patient." Id.

73. Id. The recently published regulations designed to protect the privacy of medical
records and other health information do not appear to affect tissue banks. The regulations,
published by the United States Department of Health and Human Services (DHHS) on
December 28, 2000, address not only medical records but also other individually identifiable
health information maintained by health plans, health care clearinghouses, and certain health
care providers. They give consumers access to their health information and control the
inappropriate use of that information. They limit non consensual use and release of private
health information and give patients new rights to access their records and to know who else
has accessed them. The regulations specifically exempt tissue banks, organ procurement
organizations, eye banks, and blood banks because they are not considered "health care
providers" within the meaning of the regulation.

74. Id. at 3.

The demonstrated use of these technical capabilities suggests that human tissue and
DNA specimens that have been sitting in storage banks for years—or even a cen-
tury—could be plumbed for new information to reveal something not only about
the individual from whom the tissue was obtained, but possibly about entire groups
of people who share genes, environmental exposures, and ethnic or even geo-
graphic characteristics. Clearly, the same is true for materials that may be collected
in the future. DNA, whether already stored or yet to be collected, can be used to
study genetic variation among people, to establish relationships between genes and
characteristics (such as single gene disorders), or, more generally, to conduct basic
studies of the cause and progression of disease, all with the long-term goal of im-
proving human health.

Id.
technologies are so powerful—even revolutionary—that they also hold the ability to uncover knowledge about individuals no longer alive.

- In 1997, [for example.] scientists at the University of Oxford announced that they had compared DNA extracted from the molar cavity of a 9,000-year-old skeleton (known as Cheddar Man) to DNA collected from 20 individuals currently residing in the village of Cheddar; this resulted in the establishment of a genetic tie between the skeleton and a schoolteacher who lived just half a mile from the cave where the bones were found. 75

- Scientists have used enzyme linked assays to analyze tissues more than 5,000 years old and to track the historic spread of diseases such as malaria and schistosomiasis, obtaining knowledge that can enlighten current efforts to control infectious disease. 76

- In early 1999, a United States pathologist and a group of European molecular biologists announced that they had found DNA sequences in the Y chromosome of the descendants of Thomas Jefferson that matched DNA from the descendants of Sally Hemings, a slave at Monticello. 77 The data establish only that Thomas Jefferson was the most likely of several candidates who might be the father of Eston Hemings, Hemings' fifth child, but also have raised a storm of controversy. 78

In light of these new uses for stored human tissue, academic and government bodies have begun to ask whether the tissues may only be used with permission of the individuals from whom they came—a position consistent with the notion that these tissues are the property of those

75. Id. See also Marriette DiChristina, Stone Age Kin, POPULAR SCIENCE, June 1997, at 90.


78. Research Involving Human Biological Materials: Ethical and Policy Guidance, supra note 6, at 3.
individuals—or whether the tissues are a kind of public resource that can be used with impunity, provided that no undue harm would befall these individuals by virtue of a release of tissue information to employers, insurers, or family members who might misuse or misunderstand its import. To date, it is this latter position that has guided federal policy, even while, in other respects, professional societies have called for recognizing that individuals do have an interest in the uses to which their body tissue is put.\textsuperscript{79} In addition, the AMA Code of Ethics requires that patients' consent must be obtained before their tissue is used for commercial purposes.\textsuperscript{80}

While federal human subjects research regulations and the 1999 report of the National Bioethics Advisory Commission both call for a practice of seeking consent from individuals in most cases, this practice is premised not on a theory of property, but on a theory of personal privacy; and since information revealed by studying the tissue may render these individual research subjects vulnerable, they ought to have the privilege of declining participation if they wish.\textsuperscript{81} Indeed, where risks are minimal and obtaining consent is unwieldy, both current regulations and NBAC's proposals for revised practices permit use of stored tissue without any authorization from the person whose body provided the materials.\textsuperscript{82} This is a sure sign that the tissues are not the subject of strong property rights. It is also consistent with the leading common law case on the question of property rights in excised tissue, \textit{Moore v. Regents of the University of California},\textsuperscript{83} in which the influential supreme court of California held that a patient whose cells had been removed and used by others to construct a valuable cell line did not have a cause of action for conversion, citing the lack of any precedent holding that an individual has a property interest in excised cells.\textsuperscript{84}

\textsuperscript{79} Ellen Wright Clayton, et al., \textit{Informed Consent for Genetic Research on Stored Tissue Samples}, 274 JAMA 1786 (1995). Ethical opinions, professional guidelines, and court decisions are increasingly recognizing the importance of an individual's control over his or her tissue outside of the body. A workshop of the National Institutes of Health and Centers for Disease Control developed a protocol for the collection of tissue samples that recognizes the personal and religious implications of tissue donation and allows people to control what use is made of the tissue removed from their bodies. \textit{Id.} More recently, the NIH adopted most of the NBAC recommendations concerning the management of research on stored human tissue. \textit{See} http://ohsr.od.nih.gov/info/ninfo_14.php3.

\textsuperscript{80} AMA CODE OF ETHICS, E-2.08 (2001).

\textsuperscript{81} \textit{Id.}

\textsuperscript{82} \textit{Id.}

\textsuperscript{83} 793 P.2d 479 (Cal. 1990).

\textsuperscript{84} \textit{Id.}
One strong public policy reason advanced for withholding property status to these excised tissues is the effect that would have on important research and on the protection of human subjects of research. If considered personal property, then much tissue could be used only with explicit permission, something logistically difficult to obtain for the many thousands of stored samples collected years ago from people who have since moved, changed names, or otherwise become difficult to locate. Given the important genetic and viral epidemiology that can be done on these stored samples, prohibiting all uses without explicit donor consent would be a major blow to public health and medical research. Of course, consent would be unnecessary in situations in which the tissue is considered abandoned, but under such an abandonment theory, the tissue could be used with impunity, and without regard for the potential invasions of privacy and social interests that might arise on occasion, when analysis reveals stigmatizing information about the person from whom the tissue was taken. By viewing the tissue not as property, but as an invasion of privacy interests, a more nuanced public policy can develop, in which tissue is used with permission where possible, and without permission when the public interest in use is significant and the possible dignitary or pecuniary harm to the individual is de minimis.

VIII. THE REGULATION OF TISSUE TRANSPLANTATION

Regardless of whether tissue is viewed as personal property, or whether as personal property it can be sold, it is nonetheless possible to comprehensively regulate tissue transactions for the purpose of ensuring minimum safety in transplantation settings.

Tissue banking, the term that describes the process of removing and then storing human tissue for future use, originated in the United States in the 1940s. The first tissue banks established were eye banks, which stored corneas, and bone banks, which stored bone removed during surgery for use in future patients. In 1950, the United States Navy established the United States Navy Tissue Bank, which pioneered techniques for recovering, processing, and preserving cadaver tissue. It was not until the late 1960s that the federal government became involved, when a group of American ophthalmologists approached the Division of Biologic Standards at the National Institutes of Health and suggested the implementation of federal

86. *Id.*
87. *Id.*
guidelines for corneal storage media.\textsuperscript{88} At the time, however, "[t]ransplantation was regarded as part of the practice of medicine or surgery, and no effort was made to regulate the procedure or the human organs and tissues being transplanted."\textsuperscript{89} The "FDA [merely] encouraged the development of voluntary guidelines by those who retrieved, processed, and stored human tissue intended for transplantation," which did indeed occur.\textsuperscript{90}

In 1976, the American Association of Tissue Banks (AATB) was established to develop standards and procedures and to assist new programs in complying with standards.\textsuperscript{91} The AATB's accreditation system "evaluates tissue banks for compliance with a comprehensive set of standards through document review and site visits."\textsuperscript{92} "The AATB standards cover acquisition, processing, preservation, storage, labeling, and distribution of tissue."\textsuperscript{93} As of 2002, the AATB's website lists seventy-four tissue banks in the United States operating under AATB accreditation.\textsuperscript{94} The Eye Bank Association of America (EBAA) serves a similar function for human eye banks.\textsuperscript{95}

Throughout the 1980s, the FDA continued its 1970s policy of encouraging the development of voluntary industry standards.\textsuperscript{96} In 1985,
amid growing concern regarding the Human Immunodeficiency Virus (HIV), FDA worked with the Human Milk Banking Association of North America to develop practices that would minimize the possibility of the transmission of HIV through donor breast milk. Then, in 1988, the FDA and the Centers for Disease Control and Prevention (CDC) published a joint statement outlining their views on what constituted safe sperm banking practices. The statement was endorsed by the American College of Obstetricians and Gynecologists, the American Fertility Society, and the AATB.

Despite its progress in encouraging self-imposed voluntary standards, the FDA’s position by 1990 on the regulation of human tissue was somewhat different from what it had been in 1976. Although it was still the FDA’s policy “to promote the development of voluntary standards; to remain constantly alert to any hazards to public health,” the agency also vowed “to promulgate regulations when needed and to publicize any regulatory intentions on the part of the FDA.” No longer would the FDA confine itself to acting only in the face of immediate need. The FDA, in accordance with the growing concerns over the safety of the human tissue supply, would take a more proactive attitude toward human tissue regulation.

The next six years witnessed several of the FDA’s regulatory attempts in the human tissue area, as well as a number of abandoned or unsuccessful
congressional attempts to regulate the field. The FDA’s initial attempts at regulation were not efforts designed to impose safeguards on the entire human tissue banking industry; rather, the FDA sought to regulate the industry with regulations targeted for specific tissues.\footnote{102} As the scope of its efforts increased, though, so did resistance from the industry, which identified legal and practical problems with the FDA’s actions.\footnote{103} This

\footnote{102. One approach the FDA took when promulgating these regulations was to define the tissue in question as a “medical device,” in spite of its 1983 statement to Congress. Gordon Johnson, Director of the Office of Health Affairs at the FDA’s Center for Devices Radiological Health, defined human tissue devices as “tissues of human origin—usually cadaveric—that have been processed, that have been changed or altered in some way, shape, structure, or character. They may be cut and sculptured, disinfect, sterilized, or freeze-dried. Any number of things may occur. These are tissues that have some structure or structural character.” Gordon C. Johnson, \textit{Regulating Tissues (and Organs?) as Devices}, 46 \textit{Food Drug Cosm. L.J.} 28 (1991) [hereinafter Johnson]. For example, the FDA classified human lenticules, a product derived from human cornea and applied to the cornea to correct vision problems, as post-amendment Class III devices, for which manufacturers of were required to obtain premarket approval for those “products.” \textit{Id.} at 30. In addition, the FDA determined that dura matter (the outer meningeal covering) allografts constituted pre-amendment devices. \textit{Id.} at 31. Those distributors who could not document having distributed dura matter allografts prior to May 1976 would have to file premarket notifications, and all distributing facilities were required to register as device manufacturers. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812).
}

\footnote{103. The piecemeal regulation that caused the most controversy was the decision to regulate human heart valves as medical devices. Johnson, \textit{supra} note 102, at 31. The origins of the controversy lay in a 1987 rule that required the filing of a premarket approval application, or a notice of completion of a product development protocol for the replacement heart valve, a medical device. \textit{Id.} This regulation attracted little controversy and the notice of proposed rulemaking prompted only one comment, which was not related to the FDA’s classification of replacement heart valves. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812). The FDA embroiled itself in controversy, however, when it published a June 1991 notice of applicability of a final rule (NAFR) stating that the 1987 regulation would apply not only to mechanical replacement heart valves, but to replacement human heart valves as well. Therefore, the premarket approval requirement would apply to replacement human heart valve allografts. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812). Pointing out that it was illogical to test a human heart valve to see if it works safely and effectively in humans, as it clearly does, the tissue banking industry argued that forcing companies to go through the lengthy and expensive process of obtaining premarket approval was wasteful and unnecessary because heart valves are already known to be the most effective replacement heart valves available.}
resulted in the FDA backing away from its initial approach, despite successfully resisting judicial challenges from the industry, and accepting instead an approach that regulated all tissues under a common regime focused on maintaining public health and safety.

Finally, at an October 16, 1991 FDA-sponsored public hearing on federal regulation of human tissue, the National Tissue Bank Council (NTBC), an organization comprised of nonprofit tissue banks, presented an alternative regulatory plan to the FDA. Under the NTBC's plan, public standards for dealing with different types or classes of tissues would be promulgated by the FDA, following consultation with the public and experts. Such a system, the NTBC maintained, would obviate the need for premarket approval.

On December 14, 1993, the FDA issued an interim rule "to require certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of AIDS and hepatitis through human tissue used in transplantation." Unlike the FDA's previous regulatory efforts in the area of human tissue, this rule applied not just to one type of tissue, such as heart valves or dura matter, but rather applied to all types of human tissue. The

104. The industry mounted an effort, ultimately successful, to push back the date by which FDA had mandated that investigational device exemptions (IDEs) or premarket approval applications (PMAs) must be in effect to continue marketing. Heart Valve Allograft Processors Ask Court to Prohibit FDA Call for PMAs; Non-Profit Tissue Bank Coalition Calls for "Monographs" for Tissue Products, M-D-D-I REP. ("The Gray Sheet"), Oct. 21, 1991, available in LEXIS, EXEC Library, GRAY File.

105. Six tissue banks filed suit against FDA, alleging that human heart valves were neither devices nor replacement heart valves within the meaning of FDA's prior regulations. Alabama Tissue Ctr. of Univ. of Ala. Health Serv. Found. v. Sullivan, 975 F.2d 373 (7th Cir. 1992). The Seventh Circuit rejected both of these claims, ruling that human heart valves are "implants" within the meaning of the applicable law. Id. at 378. The final rule notice was a reasonable interpretation of prior regulations and "[a]ccordingly, the [rule was] an interpretive rule not subject to appellate review." Id. at 379.

106. The FDA announced in October 1994 that it would no longer enforce the extension of the regulation to human as well as mechanical heart valves. In explaining its action, the FDA cited its belief that special controls effectiveness of heart valve allografts. The decision to abandon this interpretation of NAFR marked not only the end of the human heart valve controversy, but also indicated the end of the FDA's attempts to regulate human tissue using a piecemeal approach. Concluding that the piecemeal approach left too many questions unanswered, the FDA decided to take a broader approach to the regulation of human tissue, a decision that played a part in the agency's rescission of its rule on human heart valves as well. Id. at 373.


108. Id.
rule was a sweeping regulatory effort that encompassed the entire human tissue industry.

In explaining its reasons for adopting this approach, the FDA noted that its prior piecemeal efforts had resulted in incomplete coverage of the human tissue field in that they did not cover "bone, ligaments, tendons, fascia, cartilage, corneas, and skin that are used in the treatment of bone disease, orthopedic injuries, ligamentous and joint complaints, degenerative skeletal disease, blindness due to corneal opacification, and burn wounds." In addition, the FDA referenced the fact that AATB, EBAA, and American Red Cross all had expressed support for the notion of federal human tissue regulation. Finally, the agency expressed its concern over the importation of human tissue into the United States from unknown sources and of unknown quality, and discussed its investigation into that issue, stating, "[i]n a relatively brief period of time, the agency was able to ascertain, in a few isolated instances, the availability for importation and distribution of tissue materials that do not meet minimal screening standards for transmission of infectious diseases." The FDA concluded,

"donation has occurred, and continues to occur, when generally-accepted donor screening through medical history review is largely absent. The agency currently believes that these instances do not represent the predominant practice within the industry. Nonetheless, the traffic in tissue for transplantation without adequate testing or donor screening, whether domestic or imported, cannot be permitted to occur."

After explaining its legal basis for issuing the interim rule, the FDA explained further that the "FDA is issuing this interim rule because of an

109. Id. at 65,515.
110. Id.
112. Id. The FDA promulgated the interim rule not under the FDCA, but instead under the PHS Act, which authorizes the Secretary of the Department of Health and Human Services (DHHS) "to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable disease . . . ." Id. If the FDA were to classify human tissue as a drug or device under the FDCA, then a sponsor would have to demonstrate that the product was both safe and effective to obtain FDA approval. As it had been suggested by some that an effectiveness test is inappropriate for human products, and that the FDA should only be concerned with such products' safety, under the PHS Act, such a problem would be avoided.
immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of tissue from donors infected with or at risk of these diseases.\textsuperscript{113} In other words, the FDA did not intend that the interim rule serve as a long-term regulatory program; rather, the agency intended that more extensive and specific regulations would be proposed in the near future. When the FDA promulgated the final rule in 1997, more than three years subsequent to the issuance of the interim rule, it adopted some new definitions and imposed some procedural changes, but otherwise left the substance of the regulatory regime established by the interim rule essentially unchanged.\textsuperscript{114}

The FDA soon began to use the enforcement powers it had granted itself under the interim rule. For example, in February 1993, it ordered AlloTech, a tissue-processing firm that was engaged in the business of importing tissue from Eastern Europe, “to retain or destroy stored tissue and recall previously distributed tissue from about 180 donors.”\textsuperscript{115} This action was taken despite the fact that there was no evidence that any of the tissue was infected; the action was based on the FDA’s determination that the firm “lacked adequate documentation of medical history screening and disease testing for the tissue.”\textsuperscript{116}

In 1998, the FDA’s new approach described a comprehensive plan for regulating human cells, tissues, and cellular and tissue-based products.\textsuperscript{117}

\begin{itemize}
\item \textsuperscript{113} Id. Responding to the concern over the transmission of communicable diseases through human tissue transplants, the rule mandated that all tissue donors be tested for HIV-1, HIV-2, hepatitis B, and hepatitis C. Furthermore, the rule specified that the process for determining whether banked human tissue was suitable for transplantation must include ascertainment of the donor’s identity, as well as a determination that the donor’s relevant, accurate medical history “assures freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection.” Human Tissue Intended for Transplantation, 58 Fed. Reg. at 65,520 (codified at 21 C.F.R. §1270). The rule declared that records must be maintained as to the results and interpretations of tests, the destruction of unsuitable banked human tissue, and information on the identity and medical history of the donor. 21 C.F.R. §1270.33 (2001). The FDA chose not to require premarket approval of banked human tissue. As for enforcement provisions, the interim rule granted the FDA the power to inspect all establishments covered by the rule, and it also provided that, should the agency find tissue to be in violation of the rule, the FDA had the power either to order its destruction or seize and/or destroy it.
\item \textsuperscript{114} Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting, 21 C.F.R. §1.1 (2001).
\item \textsuperscript{115} John Henkel, Safeguarding Human Tissue Transplants, FDA CONSUMER 9, 11 (1994).
\item \textsuperscript{116} Id.
\item \textsuperscript{117} 21 C.F.R. §§ 207, 807, 1271 (2001).
\end{itemize}
Under its new tiered, risk-based approach, the FDA proposed to exert only the type of government regulation necessary to protect the public health,\textsuperscript{118} such as requiring cell and tissue banks to register with the FDA and submit a list of their human cellular and tissue-based products tissue banks,\textsuperscript{119} setting standards for suitability determination for donors,\textsuperscript{120} and outlining a general set of rules governing good facility management practices.\textsuperscript{121} Together, these rules, when finalized, would establish a comprehensive regulatory program for human cellular and tissue-based products, to be contained in part 1271 of the Code of Federal Regulations.\textsuperscript{122} In January 2001, the FDA published its final rule, the first of these topics, registering tissue banks and their products,\textsuperscript{123} even before finalization of the donor suitability and GTP proposed rules.

\textbf{IX. SUMMARY}

Human tissue is obtained from those who are dead and those who are alive. At times, the tissue is obtained with the full consent of the tissue source or next of kin, especially in the context of organs and other tissue for transplantation. At other times, it is taken without their knowledge, let alone their consent, as is often the case for corneas or tissue taken for research samples. In general, tissue sales are discouraged, as evidenced by some of the national laws in this area, but tissue such as gametes, hair and blood can be sold, albeit not always because of a coherent view of these tissues as the property of the people from whom they came.

This lack of consistency in the treatment of human tissues has made it difficult to propose models for comprehensive regulation of the human tissue

\begin{footnotesize}
\textsuperscript{118} 21 C.F.R. § 207.20. To accomplish this goal, it planned to issue new regulations under the communicable disease provisions of the Public Health Service Act (the PHS Act).

\textsuperscript{119} Id. Some human cellular and tissue-based products would be regulated only under these new regulations, while other human cellular and tissue-based products would also be regulated as drugs, devices, and/or biological drugs. Id.

\textsuperscript{120} Id. It also proposed modifications to current registration and listing requirements for drugs and devices under which cell and tissue establishments already regulated under the Federal Food, Drug, and Cosmetic Act (the Act) and/or section 361 of the PHS Act would register and list following the new procedures. Id.


\textsuperscript{122} 21 C.F.R § 1271 (2001).

\textsuperscript{123} Id.

\end{footnotesize}
market. In part, this is due to underlying jurisprudential concerns about treating the body and its parts as property, whether of individuals or of the state. It is also partially due to concerns that important scientific endeavors, such as research on banked tissue samples, would be slowed or halted should the samples be considered the property of the people from whom they came, and their use subject to voluntary and informed consent in all cases. It may also be due to the low economic value of most human tissue, at least in its raw form, resulting in relatively few conflicts arising to judicial or legislative attention.

Outside the area of whole organ donation, the only area in which comprehensive market regulation is appearing concerns the safety of the tissue transfers, especially with regard to transplantation. Here, an evolving federal policy has resulted in a new, comprehensive regulatory system that would set federal standards to ensure that transplanted tissue is adequately screened for infectious disease and competently handled and manipulated by the tissue banks that act as intermediaries between those who collect the tissue and those who use it.

A more robust form of national control over the market in human tissue, then, will probably depend upon resolution of political and legal views of the body, so that its treatment, whether as property or as some other thing, will be consistent with underlying political and legal views concerning personal autonomy and the appropriate respect to be paid to our bodies, whether living or dead.
A Conversation with Dr. Anne-Valerie Kaninda*

Anne-Valerie Kaninda, M.D.

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I. INTRODUCTION

I am going to talk to you about the Campaign for Access to Essential Medicine that has been launched by MSF, which stands for Médecins Sans Frontières, the French name for Doctors without Borders.1 This campaign was launched about three years ago.2 My focus today will be on AIDS, especially AIDS in Africa.

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* Kathy Cerminara: Our special guest today and, our Goodwin speaker is Doctor Anne-Valerie Kaninda, who is a medical advisor to Doctors without Borders: Médecins sans Frontières Access to Essential Medicines Campaign. Dr. Kaninda is an epidemiologist specializing in the control of emerging and reemerging diseases. She has worked with MSF since 1994, and has been with the Access to Essential Medicines campaign since April 2000. And I am sure most, if not all of you, know as an affiliate of MSF, she is with the 1999 Noble Peace Prize winning organization that is involved in sending more than 2000 medical volunteers all over the world, especially in developing countries to provide medical care.

Before we start, I would like to say just a few words about the current environment. Infectious diseases kill fourteen million people per year worldwide. Ninety-seven percent of these deaths occur in developing countries. Infectious disease is the leading cause of death worldwide.

If you look at essential drugs, there are 306 active substances today that governments list as such. To give you a point of comparison, there are more than 5000 products today approved by the Federal Drug Administration ("FDA") in the United States, so essential drugs are only a very limited subset. According to the World Health Organization (WHO), one-third of the population is denied access to these drugs and the cost of anti-retroviral drugs is approximately $35, the average monthly income in developing countries. So there is no way for the people, or even the government, to afford drugs to treat the people for whom it is medically required.

II. CURRENT ENVIRONMENT

Unfortunately, health care is not a priority in many developing countries. There is not a lot of money put in the health budget. In fact, a lot of developing countries have a health budget less than $10 per year, per person, sometimes even less than four dollars per year, per person. In addition, the regulatory authorities are very weak and there is a fear of using generics. For example, when the drugs are substandard, or counterfeit, people do not like to use generic even though there are high quality generics which are much cheaper than the brand name drugs and more readily available. There are no real counter-forces to either industry or government in these societies.

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4. Id.
Many of these countries have governments that are not as accountable as governments can be in wealthy nations like here.

If we look at the pharmaceutical industry in the last two decades of the twentieth century, there has been an incredible amount of consolidation within the industry, with increased competition, and an increased pressure for existing and new medicines to yield high returns. That means that the industry has turned increasingly into a big marketing machine, marketing their new products rather than taking a more health-oriented or research-oriented approach.

III. DRUG DEVELOPMENT

In general, drug companies focus their research and development in areas where the prospect of high returns on their investments is favorable. Between 1975 and 1997, among the 1223 new chemical entities that were brought into the market worldwide, only one percent treat tropical diseases. Out of those thirteen drugs, most were coming from army research on malaria, such as, the compounds from the Walter Reed Army Institute of Research, or from laboratories with public funding.

Now, if you look at the annual reports from the pharmaceutical companies in terms of market sales in 1999, the projected worldwide pharmaceutical market for Africa and Asia represented 10.6% of the total market. Approximately seventy-two percent of the population lives in Africa and Asia today, and they consume 10.6% of the pharmaceutical market. The pharmaceutical industry’s three largest companies are multinational, but they have headquarters in the United States. Considering these companies’ annual reports, they have revenues in the billions of dollars. When you compare the amount the companies spend on marketing versus the amount they spend on research and development, at least twice as much is spent on marketing than what is spent on research.

10. Id. at 364.
12. Bernard Pécoul, M.D. et al., supra note 9, at 364.
13. Id.
14. Id.
15. Id.
In 1994, 130 countries signed a General Agreement on Tariffs and Trade (GATT) agreement\textsuperscript{16} and created the World Trade Organization (WTO). This treaty included an agreement on intellectual property protection. All the countries that signed this agreement and are now members of this World Trade Organization, have to change their national laws to become compliant with the Trade-Related Intellectual Property Rights (TRIPS) agreement.\textsuperscript{17} In this agreement, pharmaceuticals are considered as any other goods, like Barbie dolls, CDs, etc. This means the countries that signed the agreement have to grant patents on pharmaceuticals. In many developing countries, pharmaceuticals were not covered by patents. In some countries, they were simply not patentable. Now, this all has to change. This agreement sets the minimum standard for intellectual property protection. It will have a negative effect on drug availability in developing countries because countries that have strong generic industries, such as India or Argentina, will no longer be able to make high-quality copies of medicine for a cheaper price until the patent expires. So this means the Agreement will delay the introduction of cheaper medicines into many developing countries.

In recent years, what we have seen is that the United States and European Union have lobbied poor countries to create national laws that restrict the safeguards included in this TRIPS Agreement. These safeguards include compulsory licenses and parallel imports.\textsuperscript{18} Compulsory licenses provide that if a country can not have access to a product because the patent order sets it at a price which does not make it available to the majority of the public, or the product is not available, and the country is in an emergency situation, then the government can issue a license. This, in effect, overrides the rights of the patent order and grants a license to a third party to locally produce the product or import it from a generic manufacturer from the outside in exchange for a reasonable royalty. Of course, pharmaceutical companies hate this safeguard because they see it as a threat to the intellectual property of their patent.

The use of parallel importing is another safeguard that allows governments to do some comparison shopping. If a company, the owner of a patent product, sells its product in country A for a certain price and in country B for a lower price, then the government of country A is allowed to go and buy it

\begin{enumerate}
\item InterAm Database, International Treaties—GATT (General Agreement on Tariffs and Trade), at http://www.natlaw.com/treaties/gatt.htm (last visited Jan. 27, 2002).
\item MSF Access Website, supra note 2.
\end{enumerate}
for the lower price in country B. This is another safeguard the pharmaceutical companies do not favor. Parallel imports, by the way, are not allowed here in the United States.

All of our amendments allow generic manufacturers to start preparing their file for registration to obtain a generic products license before the patent is expired, so that the very day the patent expires, the product is all ready to enter the market. The generic manufacturers do not have to wait until the day that the patent expires to start doing what is called reverse engineering: start work on the product; learn how to make the product; and provide all the necessary tests and records for the regulatory authorities to get the registration approved.

Moreover, what we have seen in the field so far is that our patients die because drugs become increasingly ineffective. When you use drugs, especially to treat infectious diseases, ultimately you will see resistance to the drug. That is the case with any drug, any antibiotic, antiparasitic or antiretroviral drug. Thus, we have drugs that were introduced in the first half of the last century that are increasingly ineffective. There are no new drugs brought on the market to replace these drugs. In some cases, the production of existing drugs is abandoned because they are not deemed profitable enough by the pharmaceutical companies, especially drugs which treat diseases affecting poor people in poor countries. These diseases include sleeping sickness, or types of meningitis that do not occur here, in Europe, or in Japan, and other diseases which occur in both the wealthy nations as well as the developing world.

There are new drugs but these drugs, are usually patented and expensive or inaccessible, so people do not have access to the drugs and they die. Over the years we have seen research decrease. That is why we launched this campaign. The objective of the campaign is to stimulate research and development into neglected diseases, to ensure the production of abandoned and endangered drugs, and also to establish a normal system that allows essential medicines to be cheaper in poor countries.

IV. AIDS

Out of the 36 million people infected with the Human Immunodeficiency Virus ("HIV") worldwide, ninety-five percent are in the developing world.\(^9\) Overwhelmingly, the majority of patients do not have access to

treatment; treatment for opportunistic infections, but more specifically anti-retroviral treatment. This is really the treatment that has made the difference in the last three years here, in Europe, and in other wealthy nations. As the Health Minister of Zimbabwe said at last year’s World Health Organization assembly, there are treatments in the north and the patients are in the south and there is no crossover.

Another paradox with AIDS, is that for the developing world and the majority of the people infected with the virus today, we have been stuck over the last ten to fifteen years with the promotion of “prevention-only” strategies. The ideal prevention would be not to get infected. That is the best way to stay healthy, but this strategy does not always work. Prevention-only methods have not been able to control the course of the epidemic. We still continue to say that the answer is prevention, but I am not sure that this is an ethical medical attitude to have. Another problem is that the newer anti-retrovirals, as of today, are not included in the World Health Organization’s model list of essential drugs. Of the anti-retrovirals, only zidovudine (AZT) and nevirapine were listed as essential drugs in 1999.

Finally, another paradox is that in the very few local initiatives, where treatment has been introduced—we have seen and witnessed this first-hand in our own projects in the field—when you start treating people, people come and get tested because there is hope for them. Each time you offer treatment, you maximize the effectiveness of your prevention activities. If you do not offer treatment to people, they do not want to know because it is a death sentence for them and then there is another stigma associated with this disease. That is, they are rejected and marginalized by their societies and families and they just end up in a miserable, destitute state and die. However, when you offer treatment, people are more open to the prevention messages that you give them, and they come to get tested.

Today, less than ten percent of the people infected with the virus know or suspect that they are infected with the virus. How can you do effective prevention if people do not even know that they are infected? Also, when you look for treatment, and especially if the treatment combination is highly active anti-retroviral therapy, you decrease the amount of virus that replicates in the bodies of people and they become less infectious and less likely to transmit the disease. So why not treat people? For the answer to this question, you have to look at the industry rhetoric on the issue.

V. INDUSTRY RHETORIC—HIV/AIDS

If you listen to the industry rhetoric, the pharmaceutical companies will say that patents are not the issue, rather, the rhetoric is that intellectual property protections are fundamental to the way the industry works because they have to invest a lot of money in research and development. Out of the several thousand compounds screened, only one will be brought on the market. Yet, so much money is spent on marketing that could be put to better use in research and development.

When we ask companies to decrease their price for poor countries, they are very reluctant to do so. At least until very recently, because they say that the money is needed for research and development. But if you look at it, what appears to drive their agenda is really the wealthy market. They actually recoup their costs and investments in this wealthy market.

So, what we are asking for is some extra production in markets where they do not sell anything anyway today, where they are not interested in selling anything. What is the point of protecting the intellectual property in these markets if they are not interested in selling? At least they should let other people, like the manufacturers of generics, sell the drugs. But, they argue that intellectual property protections are fundamental and patents are not the issue.

The pharmaceutical industry claims that with AIDS, the problem is not drugs, the problem is infrastructure. Even if you had the drugs for free, you would not be able to use them because you do not have transportation means, you do not have distribution systems, you do not have clean water, and you do not have human resources. You do not have the basic necessities. This is a blanket statement. There is a huge heterogeneity among different countries in the developing world, and there are countries today that are ready to start treating people if they had the drugs. Countries like South Africa and Thailand, for instance, could do a lot today.

Within these countries, too, there is a huge heterogeneity. Even in the least developed countries, in the large urban areas, there exists a minimum of laboratory facilities and health care. It is not in the best shape of course. If we had the drugs for free today, although we would not be able to cover 100% of the needs of the entire population of these countries, we could do something. We could start. We need not do nothing or everything; there is a significant something in between where we could start. That is what we should be doing today. Infrastructure is a constraint, but it is not an excuse for not doing anything.
Another issue is compliance. Some will argue that these are complicated regimens and poor people in poor countries will not be able to comply. They will not be able to take the drugs. This is simply not true. The evidence consists of really limited experiences. But in Brazil, or in Senegal, or in Uganda, for instance, it shows that if you offer drugs to people and they are sick they are going to take the drugs. Of course, if you use a drug-dumping program, just give the drugs and then leave, then people are not going to take their drugs. But if you have a quality program, rational use of drugs, and if you are careful with what you are doing, then people are as able to take the drugs in that setting as they are able to take the drugs in the United States.

Next, an issue which is often brought up is the issue of resistance. You are not going to have good compliance if you do not have the proper facilities to monitor the drugs. Then you are going to create super resistant germs that will spread from country to country. With respect to anti-retroviral drugs on a wide scale, of course we are going to create resistance, but what is the point of having effective drugs if you are not going to use them?

Today, there are more than 100 compounds which are in the pipeline; new drugs for AIDS. The drugs for which the virus is going to become resistant are going to be replaced by new compounds in the next year or so. In Europe, in the western world, we have started to create resistance by using the highly active anti-retroviral therapy. When protease inhibitors have been introduced we have seen a whole bunch of patients in which the viral load was starting to increase and be resistant, but who still had a clinical benefit and have been maintained on this therapy, just because the clinical benefit was still there. If we are accepting the creation of resistance here, why would we not accept it overseas in developing countries?

The final argument is that there is no political leadership in developing countries. That is true. There is no political leadership. However, wealthy nations lack political leadership on this issue as well. We have to push for strong political commitments. We cannot accept this as a reason or an excuse for doing nothing. We have to treat people. Today, needed drugs are prohibitively priced because of monopolies in other developing worlds. Monopolies are one factor responsible for the high prices of drugs. Patents in many of the developing countries, such as Thailand or South Africa, are responsible for monopolies. The anti-retrovirals are registered and patented, and in this case, it is an issue.

21. See generally Pérez-Casas et al., supra note 7.
22. Id. at 15.
Anti-retroviral drugs are not patented in most of the least developed countries; this is true. In many of these countries, they are not registered and they are not available. Pharmaceutical companies do not even bother to register their products in some of these countries. They are not interested in selling them there. Lack of information is always very important in terms of monopolies. In some countries, we see generics sold at the same price as brand name products. And when you look at it, they are the only ones, so you can have several sources of generic, but only one is registered there, so why would choose one generic over another brand?

For example, the generic form of an anti-fungal drug used in the treatment of cryptococcal meningitis is a sold at twenty-nine cents per tablet in Thailand. In South Africa, the price of the same brand product by Pfizer is approximately four or five dollars per tablet. Therefore, the cost of maintenance and treatment per year for 10,000 patients, if you buy the product from Thailand, would cost a little over $1,000,000. If you buy them in South Africa, you would have to spend almost $30,000,000 for exactly the same number of patients and the same treatment. Alternatively, if you look at the number of patients treated per year with a $1,000,000 budget, there are approximately 10,000 people treated with the Thailand product compared to 350 people treated with the Pfizer product in South Africa.

VI. THE AIDS PROGRAM IN BRAZIL

Brazil decided in 1997 that it would provide free anti-retroviral treatment for its population infected with HIV/AIDS when it is medically required. Today, that is almost 100,000 patients. They used local, generic production and the threat of compulsory licenses when the drugs were patented and no generic was available to decrease the price. They were able to decrease the price for triple combination therapy on average, to about

23. Id. at 12.
24. Id.
25. See id.
26. See supra note 21, at 12.
$3000 per year, per patient, compared to a cost of between $10,000 and $15,000 per patient, per year here. 29

The program has been quite successful. They have halved their death rate between 1997 and 1999. 30 They have decreased hospitalizations for opportunistic infections by sixty to eighty percent. 31 Between 1997 and 2000, the program has saved a little over $600,000,000 in hospitalization costs. 32 Furthermore, because these people are not hospitalized and continue to stay healthy for a while, they can still go to work and lead productive lives. This benefit is not even included in the savings.

Presently, the United States is taking Brazil in front of the World Trade Organization (WTO) to challenge their patent legislation. 33 The article they are particularly challenging states that Brazil will grant a patent to a product, but there is a local working requirement; the patent owner has three years to produce the drugs locally if they want the patent to continue to remain in effect. After three years, if the company is not able to produce the drug, or the company cannot prove that there is no way that it can produce the drug locally, the government can then issue a compulsory license and resort to generic production.

For Brazil, it is very important to have the local working requirement because it is a way to attract technology and knowledge in their country instead of granting patents to companies which are going to produce somewhere else and just import the product into the country. It is not clear-cut whether this is or is not allowed under the TRIPS agreement and this is why the dispute settlement has been initiated. The director of Brazil’s AIDS program is arguing that the country really needs this particular provision. In particular, the country wants to be allowed to issue a compulsory license after three years if the drug is not produced locally. Brazil also provides for compulsory licenses in case of a health emergency.

31. Id.
32. Id.
33. See Wadia, supra note 27.
VII. Cipla Offer

Recently, you may have heard, that there was an Indian generic manufacturer that offered to provide HIV treatment combination therapy for $600 per year, per patient, to the South African government. So far, that is the lowest that is available. This is good news because last year in Durban, at the International AIDS Conference, we set a target goal of $200 per year, per patient, for treatment combination therapy and we were far away from that. The lowest price at that time was approximately $1000 per person, per year, for a brand name product and then came this generic offer, which was really good news. Cipla even offered what they called a humanitarian price, for MSF of $350 per patient, per year.

We are not only campaigning for our programs, we are campaigning for everyone, other “NGOs,” or non-governmental organizations. Anyone involved in the treatment and care of people in the developing world should have access to these affordable prices. If the generic manufacturers can offer a lower price than the brand name industry, with it’s increased market share should be able to offer a lower price as well.

VIII. WHO Change of Position

Recently, there was an official breakthrough with the World Health Organization ("WHO") change of position. Dr. Gro Harlem Brundtland, the WHO Director-General, said in essence in an editorial in the international Herald Tribune that anti-retrovirals are essential drugs, which was really good news. In addition he said anti-retroviral drugs can be administered effectively in Africa without the Western standard of monitoring and follow up. This was really good news because one way you can kill the initiative for treating patients in Africa is by setting up very high standards for monitoring and follow up, knowing that there is no way that you can monitor a viral load every other week for patients who live in the middle of the bush, 1000 kilometers away from the center. The World Health Organization now also supports offering the drugs at lower prices in developing countries.

35. Id.
37. Id.
IX. PMA v. NELSON MANDELA

Then there was the South African lawsuit, PMA v. Nelson Mandela. PMA stands for Pharmaceutical Manufacturer Association.\(^{38}\) The Pharmaceutical Manufacturer Association is the South African brand name industry. First, you have to understand that the patent legislation for pharmaceuticals in South Africa was inherited from the apartheid era.

At one time, industries, not only pharmaceutical industries but all of them, were highly discouraged to invest in South Africa. So the South African government passed legislation in 1965 directed at the pharmaceutical industry which gave really sweet deals to brand name companies as an incentive to invest in South Africa.\(^{39}\) After the end of the apartheid, the South African government tried to rectify this legislation to allow the government access to cheaper drugs.\(^{40}\) The Medicines and Related Substances Control Amendment Act signed by Nelson Mandela in 1997 provides for things like parallel importation and compulsory licensing. Compulsory licensing was already possible under the previous law, but the new law gave it a broader scope.\(^{41}\) Generic substitution, or measures like that, would enable the South African government to increase access to cheaper drugs.

Two to four months after that legislation was signed, thirty-nine companies within the Pharmaceutical Manufacturer Association of South Africa sued the government over this legislation.\(^{42}\) In effect, this really blocked the enactment of the legislation.\(^{43}\) Since then, the legislation has been signed but it cannot be enforced until the lawsuit is settled. The case was finally starting to be heard on March 5th.\(^{44}\) On March 6th, the case was suspended again until April 18th, to allow companies to prepare information regarding pricing.

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41. § 15C of Medicines and Related Substances Amendment Act.
43. Id.
policies. What the AIDS activists in South Africa have done was to use the case of AIDS and use the focus on AIDS to demonstrate how the prior legislation was really affecting and hurting people living with HIV/AIDS. A group of activists, the Treatment Action Campaign or TAC of South Africa has presented evidence to the court that was not included initially and the pharmaceutical companies asked for more time to prepare the case.\(^{45}\)

On March 5th and 6th, the international media were present in Pretoria, and filed reports that really hit the news big time. So the reaction from the pharmaceutical companies came very quickly. On March 16th, the European parliament passed an emergency resolution calling all companies to drop the lawsuit in South Africa.\(^{46}\) The WHO also made a press release backing the South African policy on drug patents. So, there is a lot of political support for the South African government in that particular case.\(^{47}\)

X. INDUSTRY REACTION

These developments probably explain the recent industry reaction because they have been really bloodied in the press and public opinion is really not in their favor right now. So Merck, a large pharmaceutical company, came very quickly with the offer of decreasing the prices of two antiretrovirals that they produce in the market.\(^{48}\) Their offer is a little bit puzzling. For the first time it put forth a press release that said it will offer these products for $500 per year per patient, which is normally $600 per year per patient in developing countries.\(^{49}\) However, Merck said this is not for Brazil, so Brazil is excluded from the deal. It is only for Africa. With Asia, we do not know. So it appears they might be going one step in the right direction, but then two steps back.

Then you look at the price and they say they are offering it at cost, but it is really hard to tell if it is accurate. If you look at Cipla, it is offering a

\(^{45}\) Id.


\(^{47}\) The case was eventually dropped by all thirty-nine companies. See SA Victory in AIDS Drugs Case, supra note 42.


\(^{49}\) Id.
combination of three drugs for $600 per year, per patient. So, if Merck is offering one drug for $500 per patient, per year, it is a little hard to believe it is at cost. It is not clear what they include in calculating cost, but it is hard to believe Cipla is losing any money when they are offering $600 per year, per patient, on that triple combination therapy.

Then there are the raw materials. If you calculate the quantity of raw material needed per year per patient, then you come up with more than 1000 dollars for the treatment. They probably have discounts when they buy raw material, but it could be ten percent or ninety percent. We do not know since there is no price comparison. It is really hard to tell whether or not these drugs are really offered at cost.

Bristol Myers Squibb is another story. They have exclusive licensing agreements for two drugs and the patents are held by Yale University and the National Institute of Health (NIH). Since they have exclusive licensing agreements, they act as the patent owners and have monopolies. We asked them for a price decrease for many years for both of these drugs for Thailand and South Africa, but they have refused. They have refused, up until very recently. We hooked up with some Yale law school students and told them that their university owns the patent rights on these drugs, we need the drugs, and asked for their assistance. The students went to the Dean and asked to see the original contract. They started making some noise, and made the point that if a professor at the university develops a drug, in the licensing agreement there are usually fair pricing provisions that are not enforced. That is OK here, because this country is rich and can afford the higher price of the drugs, but that is not the case for other countries.

The South Africa media circus, combined with the investigation by the students, made Bristol Myers Squibb announce last week that they were giving an emergency relief patent right and they would make sure, finally, that no patent would stand in the way of access to drugs. In addition, Glaxo last week made a press release or short statement saying that they would provide one of the drugs for $2 per day, per treatment.

XI. WHAT'S NEXT?

So, what is next? Triple combination therapy is probably going to be made available for $500 to $600 dollars per patient, per year for the least developed countries. This is probably where we are headed, hopefully by the end of this year. The question is, who will pay for these drugs? At this price level, the least developed countries do not have the resources necessary to treat their patients, especially those who have between ten to twenty percent of their adult population infected. They do not have the resources, so wealthy nations have to come up with the money. Once you start implementing treatment programs, it is really a long-term commitment. You cannot start a treatment program and say, “Ok, I am going to put people on antiretroviral therapy,” and a year later say, “I am not going to pay anymore; I am not giving any money, find your treatment somewhere else.” Once you start treating people, it is for life.

XII. SO WHAT HAPPENS WITH GENERICS?

What about generics? Generic companies are in business to make money, exactly like the brand name, research-based pharmaceutical companies, but so far what has driven the prices down is public opinion and competition. It might be tempting for wealthy nations to say they are going to give money, but on the condition that you buy the drugs you need from companies that are in those countries. That policy favors the research-based companies. This would be a big mistake because the developing world has to be part of the solution, as well. Right now, the only pharmaceutical industry that is producing drugs in the developing world is the generic industry.

The generic industry serves as a tool to drive prices down and is needed even if we reach low drug prices today. What about tomorrow when the world’s drug needs are going to increase? We will still need to continue to drive the prices down. So, for this reason and because the developing world has to be part of the solution, generics should be included in the equation. Finally, what about the developing countries that are excluded as with the Merck offer? The pharmaceutical companies come up with something that

will make them look generous, but they immediately restrict it to poor African countries, not Brazil, not Thailand, and not South Africa.\footnote{In some cases aid comes with strings attached. See Michael Waldholz, \emph{Bristol-Myers's AIDS Relief is Hitting Hurdles in Africa}, WALL ST. J. (New York), July 7, 2000, \textit{at} http://www.aegis.com/news/wsj/2000/WJ000701.html.}

\section*{XIII. REASONS FOR HOPE}

There is, however, reason for hope. You have to understand that the United States is probably the only or one of the only countries on earth where there is no pharmaceutical prescriptive drug price control. In Europe, there is some level of prescriptive price control in all of the countries. Therefore the United States is the most profitable market for them. Here, we pay on average almost twice to ten times as much for the exact same drugs that are available in France. What industries worry about is if they engage heavily in these deferential pricing schemes, it could be used as a tool against them, forcing them to decrease their price in the wealthy markets, which is all they are concerned about.

In February, Oxfam launched a campaign for access to essential medicines. It is an international campaign, but for now, the UK has launched its campaign and its first target is Glaxo. They made it very clear to Glaxo that since they own some stock in the company, they made it very clear to them that they were going to attend the shareholders meetings and start challenging Glaxo on their pricing policy in the developing world. The same day or the very next Glaxo issued a press release saying yes, this was indeed a problem and they had some inconsistent policies so far but that they were working on a solution and they were a very responsible company. It is really good news to see that those companies can react quickly when the right argument is used.

Human rights advocacy groups are also interested in taking up the issue and domestic organizations have also expressed interest. So things are probably going to move this year. This campaign is not only about AIDS, it is really about what we call neglected diseases and essential medicines in the developing world.\footnote{For information about additional diseases, see generally MSF Access Website, \textit{at} http://www.accessmed-msf.org (last visited Feb. 17, 2002).}
A Conversation with Dr. Louis Sullivan:

Louis Sullivan, M.D.

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I. INTRODUCTION

What I thought I would talk about today for this midday session is the challenge, as well the promise, of addressing health disparities in the United States. By health disparities, I mean a number of things. First of all, we have as we look at various segments of our population, differences in life
expectancy, differences in incidence of diseases, differences in access to healthcare, and differences in health insurance coverage. So, a variety of factors infringe upon the health status of our citizens. Certainly, in a democratic society, the goal is to provide equal access to services provided for all of our citizens.

II. HEALTH CARE ACCESS DISPARITIES

First of all, I think the United States of America has the most advanced and sophisticated healthcare system in the world. How do I support such a statement? As you know the Nobel prizes in physiology and medicine worldwide are considered premiere scientific recognition awards. Although the United States has only 6% of the world's population, half of the Nobel prizes in physiology or medicine of the twentieth century were received by scientists in American laboratories. That is a measure of the quality of our scientific enterprise. Secondly, when a new pharmaceutical reaches annual international sales of one billion dollars or more, because of great acceptance and utility, it is then called a "blockbuster" pharmaceutical. Of the blockbuster pharmaceuticals of the twentieth century, more than 40% of them came from United States pharmaceutical companies: a measure of the effectiveness and efficiency of our pharmaceutical industry. Thirdly, as a nation we have the most highly trained health personnel, not only physicians and dentists, but also nurses, allied health personnel, and others.

It was not always that way. In fact, many of you have heard of the Flexner report, which was issued in 1910.1 This report was issued by Dr. Abraham Flexner, a microbiologist at Rockefeller Institute in New York at that time. This report was commissioned by the Carnegie Foundation, with their long interest in higher education. Over a two-year period of time Professor Flexner visited all 148 medical schools in the United States and Canada to assess their effectiveness. At that time Europe, not the United States, was the leading center for medical education, with such Universities as Bologna, Heidelberg, Edinburgh, London, and others considered to be the pinnacle of training in medicine. The Flexner report was a revolutionary and cataclysmic report. It is still available in medical libraries, and I would

invite you to read it because it has a brief description of every one of those medical schools.

Dr. Flexner recommended strengthening medical education. He recommended that some schools should be closed, and he was very critical of the quality of curriculum, or the absence of curriculum. Many institutions were proprietary institutions, where the owners were usually physicians who had simply obtained a license or charter from the state to operate a medical school. There were no accrediting bodies at the time. Because of Flexner's report, and his recommendation of the model that should be adopted, similar to Johns Hopkins Medical School, a number of changes occurred. By 1925, the number of medical schools had been reduced from 148 to 80 and remained at eighty over the next thirty years. Then in the mid-1950s, with federal, state, and private support, the United States began an expansion of medical education, including the development of forty-five new medical schools. The number of medical schools in the country grew to 125. With the number of improvements that have occurred, there is no doubt that we now have the most highly trained health care personnel in the world. We have people coming from around the world to the United States for care because it is often not available in their own countries.

Fourth, our technology is the most advanced, with medical devices, clinical treatment protocols, and diagnostic procedures that are readily available around the country. Fifth, as a nation we invest more dollars in biomedical research than any other nation. For the current year, that investment comes to seventeen and a half billion taxpayer dollars invested by the National Institutes of Health ("NIH"), not only in research carried on the NIH campus in Bethesda, Maryland, but research that is supported in medical schools and hospitals, and other health profession institutions around the country. That seventeen and a half billion is matched by twenty-six billion dollars invested in clinical and applied research by industry, that is, by medical devices industry and the pharmaceutical industry. The result is, virtually every week we read about some new system of biology which has been deciphered, such as, the genetic code; the discovery and use of stem cells; the ability to grow nerve cells in the laboratory; and many other advances that formerly were not thought possible.

Well, in spite of these advantages, our system also has some problems. Our healthcare system is the most expensive in the world. We spend more than $4000 dollars per capita in our healthcare system for every man, woman, and child in the country, virtually double that of most Western nations. In spite of our expenditures, some nations do better than we do in a number of health indicators, such as infant mortality. We rank around
twenty-two in infant mortality, and other indicators of health status. So we have a distribution problem in our country so far as health services and access to healthcare.

We have a paradox: not everyone has access to health services, because of economics and geography. We have forty-three million Americans without health insurance, and an equal number who are underinsured. Second, there is a geographic maldistribution of health professionals and health services. In many fields we have adequate or even excess number of physicians in such areas as ophthalmology or dermatology, but inadequate numbers in primary care fields such as family medicine, general pediatrics, and general internal medicine. There are also cultural barriers to healthcare, which is increasingly important with the expanding diversity of our country's population. There are also differences in education, which have an impact upon health status and access to health services.

III. MINORITY HEALTH DISPARITIES

Finally, there remain vestiges of discrimination, or often, even unconscious bias in the allocation of health services and resources. This bias has been shown, for example, in two studies. One study involved the Medicare population, showing that African-Americans in the Medicare system who have chest pain are less likely to have a comprehensive cardiovascular evaluation as are whites. A similar study, in the Veterans Administration Hospital system, showed that there were similar glaring gaps in the quality of health services that black veterans received. So we are faced with glaring gaps for decades in the health status between the white population on one hand, and the nation's minorities on the other. Now, poverty does play a major role in this, but poverty is not the total answer.

The result of all of this is that in this year 2001, black Americans have a life expectancy that is significantly shorter than that of white Americans. For white females born this year, life expectancy approaches eighty years. That compares to the life expectancy of black females of seventy-four years, a six-year difference. When we look at our male population we see that for white males, the life expectancy for a white male born this year is seventy-four years, whereas for black males it is sixty-six years. An eight-year difference in life expectancy. I was visiting a facility in the District of Columbia just a week ago when I learned that the life expectancy for black males in our nation's capital was only sixty-four years. The most striking gap is between white females of eighty years and black males of sixty-six years. An astonishing difference of fourteen years in life expectancy in this
most affluent technologically advanced country in the world. What this also means is that for black males, on average, they only draw about two years of social security retirement benefits, whereas for white females they draw an average of fifteen years in benefits from a system in which we all pay, according to our income during our working years.

IV. CAUSES AND CURES

A. Causes

What are some of the reasons for the disparities in health status affecting the American minority populations versus the white populations? As I mentioned, higher death rates in minority segments of our population are a result of many conditions. The long list of conditions include: infant mortality rates that are twice as high in the African-American population as the white population; and one and a half times as high in the Latino population as in the non-Latino white population; higher death rates from diabetes, heart disease, stroke, kidney failure, AIDS, prostate cancer, violence and other causes. Now, if you look carefully at all of these conditions there are certainly biological determinants that are very important. I maintain as well, that individual health behavior contributes significantly to health outcomes over a sustained period of time.

We also note, that the United States since its founding has always had a shortage of minority physicians. I remind you that during slavery in many Southern States it was illegal to teach slaves to read or write. Thus in 1864 with the Emancipation Proclamation, a number of illiterate adults were released to fend for themselves in our country. Although that was more than 135 years ago, some of the lingering consequences are still affecting our population. In 1950, 2.1% of all United States physicians were African-American, even though, African-Americans comprised 10% of the United States population at that time. In the mid-1950s, because of the projection by a number of groups of a pending shortage of doctors, our country began a unique and remarkable expansion of medical education.

This continued until 1981, resulting in the 125 medical schools we have now versus the fifty that existed in 1950. Some of those new schools include the University of South Florida in Tampa, affiliated with Nova Southeastern University today, and other schools around the country, of which my school, Morehouse School of Medicine, is one of those forty-five newer medical schools. We are now graduating nationally some 6000 physicians every year.
as opposed to 8000 physicians we were producing up through the mid-1950s in our country.

In spite of efforts over the past thirty or more years we have only increased the percentage of physicians who are African-American from 2.1% in 1950 to only 4% today, even though the African-American population is now 13% of the nation’s population. Less than 8% of today’s medical students are African-American, and less than 7% are Hispanic-American, even though Hispanics comprise 12% of the United States population. So, one of the lingering issues we have today is the continued shortage of health professionals from our nation’s minority population.

In 1995, Dr. Miriam Komoromy and her colleagues reported in the New England Journal of Medicine that those communities with a high percentage of African-Americans or Hispanic-Americans among their citizens had a lower number of physicians than did comparable white communities with similar socioeconomic indices, such as similar income status and education status. Dr. Komoromy also noted that Hispanic-American and African-American physicians were more likely to establish practices in such communities with high percentages of minority citizens. Thus, part of the answer for greater access to healthcare for the nation’s minority populations is an increase in the number of physicians from those groups.

A report released in May of 1999 in Washington D.C. by the Public Health Policy Advisory Board revealed that our nation is not addressing some of the prominent health issues confronting our children today. Those are primarily deaths from injuries, homicides, and suicides. The title of this report is Health and the American Child, Risks, Trends and Priorities for the 21st Century. This report is a result of a year long project and is the most comprehensive study of its kind. While many causes of childhood death are on the decline, the report finds alarming gaps in the progress of addressing other important and many preventable threats that claim the lives of children today. Adolescent suicides and homicides have increased dramatically in the past few decades and now represent the number two and number three causes of death in children between the ages of one through nineteen. Indeed, the report found that the top three causes of death in the age group one through nineteen years are unintentional injury, comprising 43% of the deaths; homicide, comprising 12% of deaths; and suicide comprising some

6% of deaths. All three together accounted for 63% or almost two-thirds of all deaths in childhood.

In addition to identifying the leading causes of child mortality, the report provides an important analysis of risk factors underlying those causes of death, such as substance abuse and handgun violence. The report also examines how social factors such as poverty and family structure affect children's health. The report also provides broad recommendations to serve as a catalyst for developing a better national framework for protecting the health of our children. Presently our nation's policies and programs designed to protect children's health are not as effective as they should be because there is no comprehensive national strategy. The solutions to these causes are multifaceted. They include improved access to healthcare, which means more availability of health insurance to diminish the geographic, economic, and cultural barriers as well as the improved health behaviors of our citizens themselves. Sustained vigorous education efforts including health promotion and disease prevention programs are needed to address these problems.

B. Cures

A little more than a year ago, I was pleased to participate in the release of Healthy People 2010 with the United States Public Health Surgeon General David Satcher. Also participating in the release of *Healthy People 2010*, the former Surgeon General Julius Richmond who served under President Carter and who released the first set of national health goals in the document called *Healthy People in 1979*. Having served as Secretary between 1989 and 1993, I released *Healthy People 2000* in September of 1990, which had some 298 health goals for the nation, which we hoped to reach during the decade of the 1990s. While our nation did make significant progress during the 1990s, including such gains as lowering infant mortality, increasing the rate of childhood immunizations, decreasing death rates

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related to heart disease, cancer, and stroke, we actually lost ground in other areas such as obesity in children and in adults. In spite of these setbacks, overall, the Healthy People 2000 movement was a success during the decade of the 1990s. Our new national health goals articulated a year ago with the release of Healthy People 2010 include almost twice as many objectives; 467 as compared to 298 in 1990. The essential goals of Healthy People 2010 are two firsts: 1) the increase of quality and years of healthy life and 2) to eliminate disparities in health status.

During the twentieth century our nation experienced remarkable improvement in the health of our citizens. An infant born in 1900 had a life expectancy of forty-seven years, whereas, today, an infant born has a life expectancy of seventy-eight years. Almost a doubling of life expectancy occurred during the twentieth century. This was due to multiple factors including: improvements in public health such as the provisions of safe drinking water; the availability of nutritious food; and improved sanitation as well as advances in medical care. If you go to many developing countries you will find that safe water is still not readily available. These are the things that we take for granted in our society today.

In 1900, leading causes of death included pneumonia, tuberculosis, diarrhea in infants, and diphtheria. In contrast, today, the leading causes of death are such things as heart disease, our number one killer; cancer at number two; and stroke, number three. Chronic obstructive pulmonary disease, kidney failure, diabetes, AIDS, and violence are also leading causes of death. Upon review of the ten leading causes of death, disease, and disability today among our citizens, it is clear that our health behavior does play a significant role with our biology and with our environment.

1. Promoting Healthy Behaviors

Health behavior will be increasingly important going forward into the new century. Individually, and as a community, the decisions we make not only shape our lives but they expand or limit our freedoms. They also influence the lives of others, particularly our children. Working together as a community, a state, or a nation can create a culture of positive values and healthy behaviors. We can continue to improve the health of our citizens as we improve the living conditions in our society.

Now, improvements in life expectancy over a twenty-year period, from 1970–1990, were calculated by a group of independent economists headed by Hugo Sonnenschein of the University of Chicago. The improvements in life expectancy have been estimated independently by these six economists
at various academic institutions around the country to have added fifty-seven trillion dollars, to our nation's economy through this twenty-year period or an average of almost three trillion annually. This is a result of the prevention of illness and injury as well as improvements in healthcare. This report is titled *Exceptional Returns: The Economic Value of America's Investment in Medical Research,*\(^6\) published in 1999 by Hugo Sonnenschein and other economists.

2. More Research

The gap in health status between blacks and whites results in an estimated 73,000 excess deaths annually in the nation's African-American community. An effort to close the gaps in health status should reduce these excess deaths, as well as, result in significant economic returns as well, lower healthcare costs, increased wages, more tax revenues, and less demand for social services. This will result in a healthy working population as compared to a health-impaired disabled population. So, from a humanitarian perspective, as well as from an economic vantage point, efforts to address the disparities in health status and healthcare will show significant results for our society as a whole. We need more research into the underlying reasons for persistence of health disparities in our nation.

In 1989, an article in the Chronicle of Higher Education reported that less than 1% of grants from the National Institutes of Health, our public research agency, as part of the United States public health service, were awarded to minority scientists, whether those scientists were at minority or majority institutions. Ten years later in January of 1999, the Institute of Medicine found that the National Cancer Institute, the largest of our NIH with a three billion dollar budget funded studies specifically focused on the problems of cancer in the nation's minority populations, with grants of less than $150 million dollars in a three billion dollar budget.

3. The Center for Research in Minority Health Disparities

I attended hearings before the Subcommittee on Health and Human Services of the United States Senate Appropriations Committee headed by Senator Arlen Spector. We proposed that greater attention and resources be

given in our nation to addressing the issue of health disparities. We recom-
mended that the Office of Research in the Minority Populations of NIH be
elevated to a Center for Research in Minority Health Disparities. Now the
significance of that is as follows. First, a Center has direct grant making
authority, which an Office does not have. Secondly, the director of a Center
sits as a member of the policy-making body of the National Institutes of
Health, which the director of an Office does not. Finally, the profile of the
programs would be higher for a Center than an Office. Consequently,
legislation was introduced and passed by the Congress to establish such a
Center at the National Institutes of Health. That bill was signed into law in
December of 2000 by President Clinton. 7

The purpose of the Center is to develop and monitor the NIH strategic
plan to increase funds for research programs focused on health disparities
and minority health. Now this is an encouraging development, but the
Senate is still young and it is still organizing its programs and its personnel.
It is hoped that other health agencies in the United States Public Health
Services such as, the Centers for Disease Control, the Health Resources and
Services Administration, the Agency for Health Care Quality, and other
public health agencies, as well as, state agencies and private research organi-
izations, will join a comprehensive sustained effort to understand all the
reasons for disparities in health status and in healthcare for our coun-
try. This should be coupled with the development of programs to eliminate
these gaps in the health of our poor citizens and minority citizens. The
benefits to our nation would be not only improved health but greater produc-
tivity from the work of citizens, resulting in a significant increase in our
standard of living. It is primarily a question of political will and of commit-
ment.

V. CONCLUSION

My hope is that our leaders and our citizens will provide that commit-
ment for a greater, healthier nation in the new millennium. In the profes-
sions, we need you and your colleagues to provide your talents and your
leadership skills and your commitment to helping solve these problems.
Health is not simply a problem for health professionals. It is a problem for
all of our citizens. The challenge is great but so are the rewards. Never has

7. Minority Health & Health Disparities Research and Education Act of 2000, S.
the need, nor the promise, been greater for achieving significant changes to benefit those who have not been as well served by our system. I leave you with this challenge because it is an opportunity for leadership. Thank You.

VI. QUESTIONS AND ANSWERS

Professor Cerminara: Actually, if I may, take introduction prerogative and ask the first question. I am curious, with regard to access to care issues; it seems that we see a lot going on right now with the explosion of the Internet. We hear a lot of talk today about wireless technology and everybody being on the Internet. We see a lot going on with regard to consults over the Internet, medical records being shipped back and forth for information purposes. Just information becoming available on the Internet to anybody surfing around who can learn something about conditions, statistics, causes of death, possible stuff you could take to be in better health. Do you think that this increasing interaction of the Internet and medicine will help eliminate some healthcare disparities, or do you think it will perpetuate or deepen them?

Dr. Sullivan: Well, first of all, I think that there is no question that the Internet will contribute to improving the health of Americans. The challenge will be to see that it does not cause further widening of the divide between those that have and those that have not. There are many efforts under way around the country to be sure that we do not have that divide that widens. But I think the Internet certainly is playing a very positive roll, and it also fits with the fact that our citizens want to be more in charge of their healthcare than previously.

I have lived long enough to go from the phase where the typical patient would say “well doctor you do what you think is best, etc.” So the patient would not even bother to understand what the problem was but simply put it into the hands of the doctor. It is very different now. People want to know what is wrong, what is the diagnosis, and what does this mean in terms of my health, my ability, my ability to work, life expectancy. What are the treatment options? I would like to get a second opinion. I want to know what are the side effects of this drug. So people are taking a much more active role and certainly the Internet helps that very much. And of course, typically a patient comes into the doctor’s office already with a huge print out about what the symptoms are. So, certainly that is a part of it.

I think that it is healthy and as I have mentioned, with the healthy people movement, this is a process that does require it to be effective, active
participation by individuals themselves in preserving and affecting their health. There is more change in the profile of diseases that Americans are dying from today versus one hundred years ago. Many diseases are chronic conditions, which are affected by lifestyles, such as heart disease, our number one killer.

We have a little more than two million deaths a year, and of those, roughly three quarters of a million or 750,000 are related to heart disease. Well, heart disease is related to whether or not you are overweight, whether or not you exercise. Studies have shown repeatedly that people who are active, whether it is simply walking or playing tennis, or golf, or doing aerobics, those people have lower incidents of heart attack or stroke. They live longer; if they have high blood pressure, their blood pressure tends to come down. They may eliminate the need for medicine entirely.

So those are things that the patients themselves can do. People who are well educated or have access to the Internet can get that information. So clearly, it will have an overall positive affect. The problem that we have to address is making sure that everyone does have access to the Internet because those who do not could be left behind.

Student: Dr. Sullivan, can you tell us which specific causes of mortality have the largest discrepancy between black and white populations?

Dr. Sullivan: Well there are several. For example, deaths from stroke, for example, among African-Americans are twice as high as among Whites. Infant mortality again is twice as high. As you look at the various populations, you see other discrepancies. For example, deaths from diabetes are up one and a half times as high in African-Americans. But they are about five and six times as high among the Pima Indians of Arizona as among Whites. They are being investigated there because we do not understand all of the reasons why they are showing a higher incidence. Diabetes is one of those conditions that has an underlying genetic propensity. It tends to run in families, but it does not mean that if you have that tendency, you will develop diabetes. I am sure many of you know people who may be in their 40s or 50s and suddenly found that they have diabetes. They may have gained weight, or other risk factors may have developed. So, there are a number of other environmental factors that influence whether or not they indeed become overweight, which may bring out the diabetes tendency. Vietnamese women have a high incidence of cervical cancer compared to Whites. So there are a number of specific discrepancies when you look at different populations. However, the major discrepancies based upon size of the
population is between the African-American community and the White community.

Perhaps the worst discrepancies overall are really among the Native-American population. We do not have good data there. That is, we have enough data to know, but the data we do have is not as voluminous or as precise as that of the African-American population. Again, heart disease, stroke, and infant mortality are the greatest discrepancies.

Interestingly enough, when you look at such things as breast cancer you find that the rate of the incidence of breast cancer is about the same between African-American women versus white women. Nevertheless, deaths from breast cancer are higher; about 40% higher among black women. It is thought to be an access to care issue including the lack of health insurance.

It also can mean the attitudes of individuals. That is if you wait, if you do not come in early when you have a lump, discharge from the nipple, or other signs, and you come in six to nine months later, well you may have a disease that has progressed much further. Individuals need to be aware of the advantages that can accrue to them by early medical care and not ignoring a problem. Again, that is part of the individual's attitude. Does the health system benefit them? Because again, I maintain that the health transaction is a scientifically based but socially influenced transaction. The biology is there, but it depends on how the interaction occurs and of course the other thing that I mentioned, is that some of the unconscious bias that studies have shown in how patients are treated when payment for services is not an issue.

The Medicare studies and the Veteran studies of diabetic of black veterans with vascular problems in their legs, because vascular problems are common in diabetes, show that more had amputations rather than arterial grafts. Here again, we do not know how much of this is the attitude of the patient or the patient may just feel that the best thing is to get rid of the leg, where you have circulatory problems versus how much advocacy the health professional gives, in terms of arterial grafts.

Student: Regarding your comments about economics and insurance. Do you have any thoughts about the evolution of managed care in the last ten years and any predictions about where the American insurance system is going; more regulation or maybe more public sectors, or is the public sector thing really “in the tank” after Clinton’s initiatives?

Dr. Sullivan: Well, first as you know, we have a public/private healthcare system. Where the care is provided by public insurance such as Medicare
and Medicaid, a federal/state system. The other 60% is really primarily private sector employer-based insurance. In the end, the costs are quite significant. I should have made one other comment too about the Internet: one of the real challenges right now are the so-called Health Insurance Affordability Act Provisions of 1996, the Kennedy-Kassenbaum Act.

One of the requirements is that before information can be released we have to have the permission of the patient. Moreover, the question is what does that mean. Someone predicted that means that even getting a prescription filled is transferring information. What is consent? What does consent mean? In addition, the other thing is carrying on a number of clinical trials, which have been helpful in giving us better treatment.

There are a number of treatment protocols that are going around the country whether it is cancer or heart disease or diabetes or a number of things. You really have to collect a lot of information and sort it out. How do we do that while we protect patient confidentiality? If you are a physician and you are referring a patient to someone else for a consultation, does it mean you have to have written permission of the patient? So in other words, these are the regulations that go into effect at the end of this month that many in the health industry have asked that they be delayed, because of the complexity of them and adding to cost of the healthcare transaction.

We just spent $1.2 trillion dollars or almost 14% of the GNP last year on healthcare. People are saying: well this could really cause glitches in provision of care but send cost up tremendously. There is conflict here. How do we really provide security? Everyone agrees that no one should be compromised by learning that you have a tendency for diabetes. But how do we do this without interfering with the provision of care and without adding to the cost?

The other thing I should like to mention is we have 14% of GNP healthcare now; the percentage of GNP that the healthcare consumed in 1960 was 5.6%, so this is threefold and this is the very time that our economy has expanded. And that is an issue.

Now, on the issue of managed care I think that, first of all, managed care has contributed to our ability to control cost because in 1989 when I went to Washington it was predicted then that the healthcare system would consume 18%, even 20% of the GNP by the year 2000 if we did not bring cost under control. Well, we are at 14% now rather than at eighteen, perhaps

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even 20%. The significant part of that has been the contribution of managed care. However, managed care assistance are like anything else we have, it is like the differences in your choice of automobile mechanics. Some are very good and others you would not go to again.

Some of the managed care programs have been very restricted and more focused on cost containment rather than provision of quality services. There has been a backlash against a number of managed care programs. We have some loosening of programs, of greater growth of what we call point of service programs or PPO programs as opposed to strict managed care operations.

I think that we are going to see continued efforts, though more modest ones, than the Clinton effort to provide reform of the healthcare system. I think the Clinton effort fell of its own enormity, but that was not the only problem. Politically, I think, a serious mistake was made. As you try to reform a system that has a lot of moving parts, a lot of very bright people with dedicated constituencies and what happened with release of the plan by President Clinton was: the hospital industry was attacked; physicians were attacked as being greedy, insurance companies were attacked, and the pharmaceutical industry was also attacked. Furthermore, there was this “five hundred person secret committee,” which how can you, in Washington you cannot have a secret committee of three people let alone five hundred. The AMA for example was not invited, was not included. So it created a very powerful collection of adversaries.

In my view it would have been much smarter to bring everyone in and to debate the issues out here and perhaps they would have ended up with a less sweeping effort, but I maintain that with a more modest effort we would have succeeded. That would have put us in better shape today than we are. So, that was the problem. Such things as the Children’s Health Insurance Program that has been implemented is still not working as well as it should. The prescription drug debate that is well under way now is for our seniors.

**Student:** Do you think that we are going to get one this year?

**Dr. Sullivan:** I would not bet on it. No, it may happen but I think I am not seeing a galvanized effort to really bring that together yet. Because first of all, it is defined differently by different groups; as you know President Bush had a more modest prescription drug plan than some of the Democrats would want. So, with Congress being virtually evenly divided, still its slightly Republicans and Republican President the last thing that Congress wants to do would be to override the President. The chances are, we are going to get
a modest bill or not one at all. The key thing that existed in 1993, was a
general agreement with the public that we had a system that needed to be
fixed. We still have a lot of understanding there but not the level of public
agreement that we really needed to bring this about. So I think there will be
incremental changes here and again. Continued efforts like the Health
Insurance Affordability Act is designed not only to enhance the transaction
but also, by use of Internet and electronic systems, to reduce the cost of the
healthcare transaction. It is predicted, with full implementation of electronic
commerce, that over a period of four or five years we could save at least
forty-five billion dollars in administrative costs because of the cost of pa-
perwork. Therefore, I think that we are going to continue to see modest
efforts tinkering with the system. But I predict that it is going to be perhaps
two to three years or more before we see enough dissatisfaction to really
provide a political imperative for significant change. Hopefully, those
efforts will actually include the major players in the healthcare system, as
opposed to exclude.

**Student:** As far as the economic position of specific minorities, are they
affected by their ability to have access to higher levels of insurance with our
managed care system the way it is, and is that possibly the responsibility for
the disparity of the longevity between minority group and the Whites? And
if so, do minorities or anybody in general have rights to the same quality
care? And if so, do you foresee some kind of solution for the systems that
equalize that?

**Dr. Sullivan:** Well, first of all, so far as the lack of health insurance, it does
affect different groups differentially. Around 13% of the White population
is uninsured. 21% of African-Americans and 31% of the Latino population
lack health insurance. The absence of health insurance does not include the
percentage of people that are underinsured, they have an insurance policy
but really, it is very limited in what is actually provided. Another factor is
that our private system is based primarily on employer-based insurance.
Therefore, the unemployment rate affects our health insurance rates as well.

It is very expensive to have an individually purchased health insurance
policy, about 40% of what you pay in premiums are administrative costs.
Those are the two main contributing factors. A third factor involves choices
influenced by economics. The choice between paying for health insurance
or providing food and clothing for their children. I think that clearly, the
solution in my view is going to be a public and private system, and that is to
really help provide for poor people or low-income people in purchasing health insurance.

In fact, during the first Bush Administration, we proposed a bill that would have provided for people with low income levels, that is incomes up to 200 percent of the poverty level would receive a voucher provided by the taxpayers for purchase of health insurance. Today that voucher would have been worth $3750 a year. However, it was criticized for being insufficient. Some felt that it should probably be about a thousand dollars higher or more. That was during a time when there was a Republican President with a Democratic Congress. It was introduced in February of 1992 and we could not get congressional hearings that year. That was an election year, and if you have the White House and the Congress in different parties, from a political standpoint, you do not want to provide the other party with potential issues with which they could win. In other words, the timing for the introduction of that legislation was not good because we were getting into an election season.

That bill would have provided help towards health insurance and it had features in it that we estimated at that time, if enacted, the bill would have reduced the number of people without health insurance from thirty-seven million to between five and seven million. It was not perfect because there still would have been a significant number of people without health insurance. But we reason that the system would have been able to absorb that level of citizens without health insurance because right now in public hospitals, perhaps as many as 50% of the people seen at a hospital, like Jackson Memorial Hospital, are uninsured. Which means that Jackson Memorial and the taxpayers of Dade County are providing the dollars to pay for healthcare in less than ideal circumstances; people are having long waits, or missed appointments because again people do not have a quote, “friendly encounter” with the healthcare system. They come in and have to sit around and wait for hours and a lot of other things that happen to them.

I think that we will see a resurrection of some features, like the development of group purchasing cooperatives for health insurance, particularly for small businesses. A reason for this is that most of the people without health insurance are those in small businesses, because the cost of insurance in small businesses represents a greater cost than in larger groups. But in some parts of the country where you have group purchasing cooperatives, that has brought down the cost of insurance because you have a larger pool over which you spread your risk, and your administrative costs also come down on a per capita bases as a group gets larger.
Student: You mentioned the constitutional institutionalized legalities of young slaves being educated, and as a result we have fewer professionals out there than otherwise. Can you give me some numbers on African-Americans and other minorities being actively involved in a study program. And do you believe that the Tuskeegee study may have made an impact on their participation.

Dr. Sullivan: Yes, clearly the Tuskeegee study has had a negative impact that continues today. And for those who may not be familiar, the Tuskeegee study was a study that was started back in the 1930s looking at the natural history of syphilis in black men in Tuskeegee, Alabama, because in the 1930s there was no treatment for syphilis. Penicillin was introduced in 1941 and cured syphilis. But, in spite of that, the study was continued until 1972. When it was reported there was outrage. This was a study conducted with support from the United States government. This has had a profound impact on the level of trust that African-Americans and some others have on the healthcare system. That is, am I going to be experimented on? If I go there, will I be given the best treatment? So yes, there is a wariness.

Pharmaceutical companies today, for example, are really pressed very hard by the Food and Drug Administration ("FDA") to have a diverse population group to test new therapies, and among those groups, they include a significant number of minorities. The similar thing, but for different reasons, exists for women in studies. Women were excluded from clinical trials over the years for a number of different reasons. Primarily, one being that if a woman is pregnant she is unaware the experimental protocol that may do damage to the baby. Similar things for children, because of their rapid growth, accelerated metabolism, they were often not used for studies.

So even today, a lot of the drugs we use in children we have extrapolated our understanding of the drug from the use of adults to children. But the FDA now has over the last decade or so, changed that to say if the drug is going to be used in children or women, it should be tested in them. So there is a very different environment now for clinical testing of drugs.

But coming back to the African-American population, it is because of that as well as other encounters that African-Americans have had with the system that would account for their unpleasant view or distrust of the health professional. There is a great difficulty now in getting a significant number of African-Americans enrolled in clinical trials and that raises an ongoing problem.

Professor Cerminara: Thank you very much Dr. Sullivan.
The Born-Alive Infants Protection Act: Baby Steps Toward the Recognition of Life After Birth

Stacy A. Scaldo*

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I. INTRODUCTION

Two babies were born this morning. They are both premature—each of their mothers was only twenty-three weeks pregnant at the time of birth. Because they were born at such an early stage, it is clear that both of these babies will need neonatal care. However, only one will receive it. The first baby, named Sarah, will be taken to the Neonatal Intensive Care Unit ("NICU") where she will be given care and treatment to both comfort her and prolong her life. She will be held, fed, and examined to monitor her progress. The second baby will not be given a name. She will instead be taken to an empty room, a utility or laundry room, where she will be left alone to die. No care will be administered to her, not even the comfort of a warm blanket to surround her as she breathes her last breath. It will take her anywhere from forty-five minutes to eight hours to die, the whole time

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1. Babies born at this stage are at a severe disadvantage when it comes to long-term survival. Most of their lungs are underdeveloped and only adept at amniotic fluid intake. Air is, in a sense, poison to a child born at this stage of development and Respiratory Distress Syndrome (RDS) is a common condition.
gasing for the air her lungs cannot process. This unnamed infant will not have the chance to prove she can survive.

Why will these two babies receive such different treatment in the same hospital, by the same health care professionals? The answer sparks more questions than it resolves. Sarah is wanted, the second baby is not. Sarah was born premature to parents who were hoping for a healthy child. The second baby was born as a result of an abortion gone wrong. Despite the intent of each mother when she arrived at the hospital, both of these babies, regardless of their circumstances of birth, feel the same pain, struggle to breathe the same air, and fight for the same chance to live. That both of these babies are alive, moving their arms and legs and trying to breathe, does not result in equal treatment.

The question of when life begins is not exclusively linked to conception and gestational age. For some, the denial of personhood has been extended through birth to living, breathing infants. Instead of using medical or even common definitions to determine when a baby is alive, the standard has been reduced to a legal argument. Because it has become legally and politically popular to define a living baby in terms of whether that child is wanted, healthcare professionals have been forced to make medical judgments concerning aborted newborns based upon the simple fact that the baby is not welcomed into this world.

This article explores how courts and lawmakers in this country have extended a woman’s right to choose an abortion to a point beyond that of birth, and how there is an immediate need for legislation to protect the rights of an infant born alive during a botched abortion. Part two introduces the Born-Alive Infants Protection Act of 2000 ("the Act") and describes its intended purpose. Part three discusses the types of abortion procedures afforded to women and identifies those most commonly associated with the result of a live birth. Part four discusses the progression of case law and political thought that has fostered the deterioration of the right to life. Part five analyzes the arguments for and against the Act and why it is essential that this legislation is passed. Part six concludes this article.
II. A CRY FOR HELP OUTSIDE THE WOMB

A. The Born-Alive Infants Protection Act of 2000

The text of the Born-Alive Infant Protection Act of 2000\(^2\) basically has two parts. Section 8(a) states:

In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words "person," "human being," "child," and "individual," shall include every infant member of the species homo sapiens who is born alive at any stage of development.\(^3\)

Section 8(b) provides:

As used in this section, the term "born alive," with respect to a member of the species homo sapiens, means the complete expulsion or extraction from its mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.\(^4\)

The Act serves two main functions. Section 8(a) adds a baby who is born alive to the traditional definition of person, human being, child, and individual. Section 8(b) includes a baby who has survived an abortion as being born alive. The Act was proposed in the House of Representatives by then Representative Charles Canady.\(^5\) According to Representative Canady, the legislation "would provide legal protection to living, fully born babies who survive abortions."\(^6\) In Representative Canady's words, these babies are "tiny, helpless infants brought into the world through no choice of their own and struggling to survive."\(^7\)

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\(^3\) H.R. 4292 § 8(a).

\(^4\) H.R. 4292 § 8(b).

\(^5\) See H.R. 4292.


\(^7\) Id.
B. Care and Nourishment

In explaining why the Act is needed, Representative Canady focused on the notion that fully born babies entitled to full protection of the law is in serious jeopardy. Evidence that this fear is a reality was offered by Jill L. Stanek and Allison Baker, both registered nurses who work in the Labor and Delivery Department at Christ Hospital and Medical Center in Oak Lawn, Illinois. Stanek testified that the hospital performs abortions on women in their second and third trimesters, aborting both healthy babies and babies with severe disabilities. According to Stanek:

> In the event that a baby is aborted alive, he or she receives no medical assessments or care but is given only what the Christ Hospital calls “comfort care.” Comfort care is defined as keeping the baby warm in a blanket until he or she dies, although even this so-called compassion is not always provided. It is not required that these babies be held during their short lives.

Stanek told of an aborted Down’s Syndrome baby who was born alive and subsequently taken to a “Soiled Utility Room” in the hospital because neither his parents nor the attending nurse wanted to or had time to hold him. Stanek cradled and rocked him for the forty-five minutes that he survived. One baby actually lived for eight hours after being aborted. No care was offered to that child either. Many of the babies who survive abortions that late in the pregnancy are healthy babies who are aborted because they are misdiagnosed with birth defects and disabilities. Even though these babies are healthy, they are left to die simply because their birth is the result of an abortion. The most disturbing story that Stanek told concerned a healthy baby with a fetal age past twenty-three weeks:

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8. *Id.*
12. *Id.* at 15.
13. *Id.*
14. *Id.*
15. *Id.* at 14.
17. *See id.* One baby who was aborted weighed much more than expected and the attending nurse was “haunted because she [did not] know if she made a mistake by not getting
I was recently told about a situation by a nurse who said, “I can’t stop thinking about it.” She had a patient who was 23+ weeks pregnant, and it did not look as if her baby would be able to continue to live inside of her. The baby was healthy and had up to a 39% chance of survival, according to national statistics. But the patient chose to abort. The baby was born alive. If the mother had wanted everything done for her baby, there would have been a neonatologist, pediatric resident, neonatal nurse, and respiratory therapist present for the delivery, and the baby would have been taken to our Neonatal Intensive Care Unit for specialized care. Instead, the only personnel present for this delivery were an obstetrical resident and my co-worker. After delivery of the baby, who showed early signs of thriving, was merely wrapped in a blanket and kept in the Labor & Delivery Department until she died 2 ½ hours later.\textsuperscript{18}

In addition to Stanek’s testimony, Baker told of three separate instances where she witnessed babies left to die without even so much as a blanket to keep them warm.\textsuperscript{19} Recalling one occasion, Baker said:

I happened to walk into a “soiled utility room” and saw, lying on the metal counter, a fetus, naked, exposed and breathing, moving its arms and legs. The fetus was visibly alive, and was gasping for breath. I left to find the nurse who was caring for the patient and this fetus. When I asked her about the fetus, she said that she was so busy with the mother that she didn’t have time to wrap and place the fetus in the warmer.\textsuperscript{20}

Due in no small part to the testimony of Stanek and Baker, on September 26, 2000, the Act passed in the House by a margin of 380 to 15.\textsuperscript{21} The Act was then introduced as a bill in the Senate the very next day by Senator Rick Santorum.\textsuperscript{22} Despite bipartisan support, the bill died when Senator Kent Conrad objected to a request made by Senator Trent Lott to pass the bill by

\begin{itemize}
  \item[18.] Hearings, supra note 9, at 16 (testimony of Nurse Jill L. Stanek).
  \item[19.] Hearings, supra note 9, at 18 (testimony of Nurse Allison Baker).
  \item[20.] Id.
  \item[22.] See S. 3127, 106th Cong. (2000).
\end{itemize}
The Act was reintroduced into both houses of Congress on June 14, 2001. Senator Conrad is not the Act’s only opponent. The main argument against its passage is that it violates a woman’s right to choose to have an abortion. Political activists groups like the National Organization for Women (“NOW”) and the National Abortion Rights Action League (“NARAL”) argue that the Act is a direct attack on the Constitution. This belief stems from the perception that the sole determining factor in abortion decision making is the intent of the mother. However, the very purpose of the Act is to separate the rights of the baby from that of the mother at the moment of birth.

III. THE STAGES OF TERMINATION

As the purpose of the Act is to define a newborn who survives an abortion as a person, it is necessary to understand the stages of pregnancy and which abortion procedures have the potential of resulting in a live birth. The abortion procedure a doctor chooses to perform is determined by the age of the fetus, namely, whether the fetus has reached the point of viability. Viability is defined as “the capacity for meaningful life outside the womb, albeit with artificial aid,” and not just momentary survival.” It is presumed to exist after twenty-seven weeks of gestation but not before twenty weeks.

23. Id. See also ‘Born Alive’ Bill Fails in Senate, CHRISTIANITY TODAY, Jan. 8, 2001, at 20.
24. See Born-Alive Infants Protection Act of 2001, H.R. 2175, 107th Cong. (2001); S. 1050, 107th Cong. (2001). There have been no further hearings or votes concerning the Act since its reintroduction.
25. John Leo, Baby Saving Made Easy: Any Bill that Protects Against Infanticide Should Be Backed, U.S. NEWS & WORLD REPORT, Sept. 25, 2000. The NARAL announced that “this bill attempts to inject Congress into what should be a personal and private decision about medical treatment.” Id.
26. Id. Leo writes:

The intent of the mother is something of a frontier for abortion supporters. It shifts attention away from the reality of the baby, already born with rights, and back toward the purpose of the operation—to abort. Pro-choice literature is filled with suggestions that the developing life within a mother is an unborn baby if she wants it, simply discardable tissue if she doesn’t.

Id.
28. Id. Weeks of gestation are calculated “in terms of the first day of the last menstrual period. However, gestational age may vary depending on whether the stage of
The period between the twentieth and twenty-seventh week is considered to be the “gray zone” in which some fetuses may be viable and some may not.29 Pregnancy and fetal age are calculated by trimesters. The first trimester is measured from the start of the pregnancy to the thirteenth week, the second trimester is measured from the thirteenth week to the twenty-seventh week, and the third trimester is measured from the twenty-seventh week until the date of delivery.30 Ninety-five percent of abortions are performed in the first or very early second trimester, usually at or before fifteen weeks gestation.31 It is estimated that “two thirds of abortions beyond [twenty] weeks are performed between [twenty-one and twenty-two] weeks."32 Furthermore, the number of abortions that are performed after twenty-six weeks gestation is estimated to be between 320 and 600.33

In the first trimester, abortions are usually performed on an outpatient basis.34 Procedures which are used at this stage include vacuum aspiration, menstrual regulation, and prescribing Mifepristone ("RU-486").35 Vacuum aspiration, the predominate method, involves inserting a vacuum tube into the uterus to evacuate the fetus from the woman’s body.36 It is usually not required to use anesthesia or dilation at this time.37 Because the fetus is at the earliest stage of development and has not reached the point of viability, abortions performed in the first trimester do not result in a live birth. The Born-Alive Infants Protection Act would therefore most likely not apply in these situations.

Once a pregnant woman enters the second trimester her options change. The most common procedure used in the early second trimester is dilation and extraction ("D&E").38 This “is similar to vacuum aspiration except that the cervix must be dilated more widely (usually with osmotic dilators) because surgical instruments are used to remove larger pieces of tissue."39 Intravenous fluids, sedatives and a local anaesthetic may be administered to

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29. Id.
30. Id.
32. Id.
33. Id.
34. Id. at 726.
35. Id.
36. Gans Epner, supra note 27, at 726.
37. Id.
38. Id.
39. Id.

pregnancy is calculated from the first day of the last menstrual period, from the estimated time of fertilization, or from the estimated time of implantation.” Id.
the patient. After the fetus is removed, a curette is used to remove the tissue that remains on the uterine walls. Labor induction is sometimes used at this stage, but this procedure is usually more common in the mid second to third trimester. The most common abortion procedures performed in the mid second and third trimesters of pregnancy include D&E, intact dilation and extraction ("D&X"), labor induction, hysterotomy, and hysterectomy.

During a third trimester D&E procedure, "[b]ecause the fetus is larger . . . and because its bones are more rigid," a physician is more likely to use a destructive procedure to perform the abortion. Uterine and cervical perforation caused by medical instruments and fetal parts are more likely.

The risks involved in an abortion at this stage of pregnancy cause some doctors to perform D&X on patients who are in the third trimester. D&X, commonly known as partial birth abortion, consists of:

- deliberate dilation of the cervix, usually over a sequence of days;
- instrumental or manual conversion of the fetus to a footling bream;
- breech extraction of the body except the head; and
- partial evacuation of the intracranial contents of a living fetus to effect vaginal delivery of a dead but otherwise intact fetus.

Labor induction as a means to perform an abortion increases in conjunction with fetal age. The procedure has three steps:

First, the physician opens the cervix . . . using either prostaglandin E2 gel, Cytotec or laminaria (little match-like sticks composed of seaweed) . . . . He inserts one . . . or two . . . pills in or near the cervix, irritating it and causing it to open. Second, after the cervix opens, the small baby . . . literally drops out of the womb. Sometimes, the baby dies in the process. However, many are born

40. Id.
41. Gans Epner, supra note 27, at 726.
42. Id.
43. Id. Hysterotomy and hysterectomy are rarely used because of increase in maternal mortality and morbidity rate associated with these procedures. Id. These procedures involve the "surgical delivery of the fetus through an incision in the uterine wall and abdomen." Id.
44. Gans Epner, supra note 27, at 726.
45. Id.
46. Id.
47. Id.
alive—thus the name, "live-birth" abortion. In this case, the third step is letting the baby die. 48

Late term abortions are most often associated with the possibility of the baby actually surviving and, in essence, being born alive. This has created a confusing situation for health care professionals. If a woman comes into the hospital with the intent to have an abortion, is she entitled to that and nothing less? Because our legal and political systems have created a standard that choice is absolute, health care professionals are now in a quandary as to what to do when a child who was marked for abortion is born alive. At this point, the only two choices that they are left with is to let the baby die or finish the job. 49

IV. THE EROSION OF THE RIGHT TO LIFE

The right to have an abortion extends further than reproductive decision making as the concepts of abortion rights and of life's parameters are scientifically amorphous at best. Attempts to resolve this enigma have taken the debate from the delicate subject of determining when life inside the womb begins to an all out conclusion that a woman's intent controls. This progression, and the effect thereof, are the reasons why the Born-Alive Infants Protection Act has been proposed.

A. The Cases

In Roe v. Wade, 50 the Supreme Court found that a woman has a fundamental right to privacy established by the Fourteenth Amendment which is "broad enough to encompass [her] decision whether or not to terminate her pregnancy." 51 Because of this, the state must show a compelling interest in order to restrict this fundamental right. 52 According to the Roe Court, the state's interest in the life of the fetus becomes compelling

49. Hurlburt, supra note 48.
51. Id. at 153.
52. Id. at 155.
only at the point of viability. Therefore, before viability, the right of a woman to have an abortion overrides any interest of the unborn child. Despite this fundamental right, the Court was careful to note that the right to have an abortion is not unconditional. Both the life and health of the mother are parts of the equation that the physician should analyze when determining whether to perform an abortion post viability.

In order to balance both the interest of the mother in choosing an abortion and the interest of the state in protecting what it called “potentiality of life,” the Court established a trimester test. During the first trimester, the state may not regulate abortion. During that stage the decision to terminate a pregnancy should be left to a woman and her doctor. In the second trimester, the Court concluded, the state may only regulate abortions “in ways that are reasonably related to maternal health.” Finally, the Court ruled that in the third trimester, the state may regulate and even proscribe certain abortion procedures unless such procedure is necessary to preserve the life or health of the mother.

Despite occasional challenges in court and a plethora of scholarly dissatisfaction, the standard set forth in Roe remained in place for almost twenty years. Then, in 1992, the Court decided Planned Parenthood of

53. Id. at 163. In Roe, the court defined viability as the point that the fetus can survive independent of its mother. Id. at 160.
54. Roe, 410 U.S. at 164.
55. Id.
56. Id. at 153. In Doe v. Bolton, the companion case to Roe, the Court stated that a physician’s medical judgment may be exercised according to physical, emotional, psychological, familial, and age factors relating to the health of the mother. 410 U.S. 179, 192 (1973).
57. Roe, 410 U.S. at 162.
58. Id. at 163.
59. Id.
60. Id.
61. Id. at 164.
63. Cf. Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 64 (1976) (stating that “[t]he time when viability is achieved may vary with each pregnancy, and the determination of whether a particular fetus is viable is, and must be, a matter for the judgment of the responsible attending physician”); Webster v. Reprod. Health Servs., 492 U.S. 490, 515 (1989) (upholding a state statute creating a presumption of viability at twenty weeks which the attending physician “must rebut with tests indicating that the fetus is not viable prior to performing an abortion”); Colautti v. Franklin, 439 U.S. 379, 400 (1979) (clarifying a statute subjecting physicians who perform an abortion to potential criminal liability if they failed to attempt to preserve the life of a viable or potentially viable fetus); Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747 (1986) (striking down a provision in a statute
Southeastern Pennsylvania v. Casey. In Casey, the Court affirmed the fundamental tenets of Roe, but changed the legal standard. Instead of affirming the compelling state interest and trimester test of Roe, the Court held that "a law designed to further the State’s interest in fetal life which imposes an undue burden on the woman’s decision before fetal viability" is unconstitutional. The Court described an “undue burden” as a state regulation that “has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.”

Although the Casey Court disregarded the trimester test established in Roe, it quoted the language of Roe with regard to the health of the mother and noted that “subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment for the preservation of the life or health of the mother.”

This new standard, coupled with the Court's decision to uphold certain restrictions imposed by the state, brought dissatisfaction to both sides of the abortion debate. Although Casey did not overturn Roe like many had assumed it would, the new language used by the Court was an indication that the interest of the state would be more respected in the balancing analysis. At the very least, the Court moved away from the impression that abortion was an absolute right—a theory which brought outrage to some abortion advocates. However, because the Court upheld the legality of abortion, the mandate that every person performing an abortion to “exercise of that degree of care . . . ‘required . . . to preserve the life and health of any unborn child intended to be born and not aborted’”).

65. Id. at 870. The Court reaffirmed that, pre-viability, a "woman has a right to choose to terminate her pregnancy." Id.
66. Id. at 877.
67. Id.
68. Casey, 505 U.S. at 879 (quoting Roe, 410 U.S. at 164–65).
69. See id. The Court upheld four of five provisions imposed by the State including informed consent, twenty-four hour waiting periods, extensive reporting requirements, and the medical emergency exception. Id.
70. See Janet Benshoof, Planned Parenthood v. Casey: The Impact of the New Undue Burden Standard on Reproductive Health Care, 269 JAMA 2249 (1993). Benshoof wrote that “[w]hile the majority opinion reaffirmed a woman’s right to choose an abortion, the opinion opens the door to a multitude of new restrictive abortion laws, which diminish, and in some cases completely block, a woman’s ability to exercise that right.” Id. at 2249. She continued that “for the first time in a case that did not involve government funding, the Court abandoned the principle that the government must act with neutrality with regard to the woman’s decision whether to terminate her pregnancy.” Id.
burden remained on the pro-life side to lobby for change. Since a complete ban on abortion appeared to be a fruitless fight, the focus turned to time and manner—namely, partial birth abortion.

When *Stenberg v. Carhart*\(^7\) came before the Court in 2000, the focus was on the ability of a state to ban the late term D&X abortion procedure.\(^7\) The Court framed the issue as “whether Nebraska’s statute,\(^7\) making criminal the performance of a “partial birth abortion,” violates the Federal Constitution” as interpreted in *Roe* and *Casey.*\(^7\) The Court ruled that the statute was unconstitutional for “two independent reasons.”\(^7\) The first reason was that the “law lack[ed] any exception ‘for the preservation of the ... health of the mother.’”\(^7\) The second reason was that the statute “‘impose[d] an undue burden on a woman’s ability’ to choose a D&E abortion,\(^7\) thereby unduly burdening the right to choose abortion itself.”\(^7\)

The Court discussed the health exception prong first, intentionally emphasizing that the earlier undue burden test would no longer be the sole arbiter of statutory validity.\(^7\) As the Court discussed, this health exception prong applies to more than the ability to choose abortion:

\[
\text{[A] State cannot subject a woman’s health to significant risks both in [the context where the pregnancy itself creates a threat to health], and also where state regulations force women to use riskier methods of abortion. Our cases have repeatedly invalidated statutes that in the process of regulating the methods of abortion, imposed significant health risks. They make clear that a risk to a woman’s health is the same whether it happens to arise from regulating a particular method of abortion, or from barring abortion entirely.}
\]

72. *Id.* at 921–22.
75. *Id.* at 930.
76. *Id.* (quoting *Casey,* 505 U.S. at 880).
77. *See supra* text accompanying notes 37–40.
78. *Carhart,* 530 U.S. at 930.
79. *Id.* at 930–39. The Court extended the health exception prong to a previable fetus as well. Justice Breyer noted that because the “law requires a health exception in order to validate even a postviable abortion regulation, it at a minimum requires the same in respect to previability regulation.” *Id.* at 930.
80. *Id.* at 931.
This decision made clear what was unresolved in *Casey*—that the health of the mother stands on its own and is not to be balanced against the interest of the state.  

**B. The Language**

Although this case could have been decided by applying only the undue burden test, the Court split the previous test, which incorporated the concerns for the health of the mother in determining whether the state had imposed an undue burden on her choice, into a separate and distinct two-part test. In deciding that the statute posed an undue burden, the Court relied on a vagueness challenge. It held that the statute had the “effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.” The language of the statute, the Court reasoned, could have been interpreted to apply to the more commonly used D&E procedure as well as D&X because the procedures are similar in form. If this were the case, Nebraska and any other state would have had the opportunity to revise the statutory language and clarify that the ban only covered D&X abortions. The Court did not afford the State the opportunity to do this but instead promoted the health exception prong, a test that would virtually block any state from creating legislation to stop this procedure.

This *Carhart* decision came as a surprise to some who had presumed that the Court would uphold the Nebraska statute. In fact, prior to that decision, similar statutes had been interpreted by courts to apply only to the D&X procedure. After the *Carhart* decision, those courts were called to reconsider such decisions.

82. *Id.* at 226–27.
84. *Id.* at 939.
85. *See, e.g.*, Richmond Med. Ctr. For Women v. Gilmore, 144 F.3d 326 (4th Cir. 1998). The court in *Gilmore* noted that the “term ‘partial birth abortion’ in the statute appl[i]ed to the intact dilation and extraction procedure” and that the conventional dilation and evacuation procedures were not subject to prosecution. *Id.* at 331. That interpretation was also provided by the Attorney General of Virginia. *Id.* The court also relied on the interpretation of the AMA with respect to the federal partial birth abortion statute, an act similar in language to the Virginia statute as well. *Id.* at 332. The AMA said that the federal statute “clearly defines the prohibited procedure so that it is clear on the face of the legislation what act is to be banned . . . physicians will be on notice as to the exact nature of the prohibited conduct.” *Id.* In *Planned Parenthood of Wis. v. Doyle*, the court
Although the language of these decisions seem at first blush to be relatively harmless, the implications are of significance to the validity of the Born-Alive Infants Protection Act. With each passing abortion case, the language becomes more offensive to the rights and needs of the baby. For example, in Carhart, the Court completely disregarded the fetus' experience in a partial birth abortion and instead focused exclusively on the will of the mother. It relied upon information supplied by the American College of Obstetricians and Gynecologists ("ACOG") which provided that dilation and extraction "may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman." However, the same panel which released that opinion "could identify no circumstances under which [this] procedure... would be the only option to save the life or preserve the health of the [mother]."

In fact, more evidence supports the belief that intact D&X should be banned. The American Medical Association ("AMA") has recommended "that the intact [dilatation and extraction] procedure not be used unless alternative procedures pose materially greater risk to the woman" and that the abortions "not be performed in the third trimester except in cases of serious fetal anomalies incompatible with life." Furthermore, according to the AMA, there are no credible studies on intact D&X to attest to the

held that the "intentional removal of the fetus intact is what distinguishes an intact D&E procedure from a [conventional] D&E procedure." 9 F. Supp. 2d 1033, 1036 (W.D. Wis. 1998).

86. In Gilmore, the court vacated its stay order pending appeal after the Carhart decision. See Richmond Med. Ctr. For Women v. Gilmore, 219 F.3d 376 (4th Cir. 2000). In reluctantly vacating the stay, Judge Luttig stated:

As a court of law, ours is neither to devise ways in which to circumvent the opinions of the Supreme Court nor to indulge delay in the full implementation of the Court's opinions. Rather, our responsibility is to follow faithfully its opinions, because that court is, by constitutional design, vested with the ultimate authority to interpret the Constitution.

Id. at 378. Judge Luttig believed that the Supreme Court would hold the partial birth abortion ban to be constitutional, based on the "overlay of deference customarily afforded state statutes in facial challenges..." Id. at 377.


88. Carhart, 530 U.S. at 934.
89. Gans Epner, supra note 27, at 729.
90. Id. The AMA recommendations provide that "except in extraordinary circumstances, maternal health factors that demand termination of the pregnancy can be accommodated without sacrifice of the fetus, and the near certainty of the independent viability of the fetus argues for ending the pregnancy by appropriate delivery." Id.
procedure's safety.91 Finally, the AMA has argued that none of the risks associated with a D&X procedure are medically necessary because other procedures are necessary to doctors who decide that terminating the pregnancy that late in the term is necessary.92 The Carhart Court could have at least balanced the recommendations of these two agencies. However, instead of fairly weighing the two, the Court chose the statement that fit its intended result and concluded that the D&X procedure should remain an option. Furthermore, in speaking about the health exception prong, the Court reasoned:

the division of medical opinion signals uncertainty. If those who believe that D&X is a safer abortion method in certain circumstances turn out to be right, the absence of a health exception will place women at an unnecessary risk. If they are wrong, the exception will simply turn out to have been unnecessary.93

The problem with this line of thought is that it does not eliminate the fact that hundreds or thousands of babies will have been subject to excruciating torture all for the protection of a procedure which may or may not be necessary. If this reality were a legitimate concern, then the result may have been different.

Carhart set a new standard of denial which was quickly adhered to as a legitimate rationalization for the intended result to follow the will of the mother first, last, and only. In Planned Parenthood of Central New Jersey v. Farmer,94 the Third Circuit drew a distinction between a partial birth abortion and infanticide by reasoning that:

Positing an “unborn” versus “partially born” distinction, the [New Jersey] Legislature would have us accept, and the public believe, that during a “partial-birth abortion” the fetus is in the process of being “born” at the time of its demise. It is not. A woman seeking an abortion is plainly not seeking to give birth.95

91. Id. The partial birth abortion procedure is also not recognized in medical textbooks or taught in medical schools or residencies. Id.
93. Carhart, 530 U.S. at 916.
94. 220 F.3d 127 (3d Cir. 2000).
95. Id. at 143.
The language of this case is further evidence that the rights of the fetus have become obsolete.

C. The People

In addition to a twenty-eight year downward spiral in which the courts have continued to chip away at the minuscule interest in potential life granted to the state by Roe, political and philosophical thought has in many ways pushed our society into believing that an unborn or even newly born baby should not enjoy the rights of full personhood. Peter Singer, Professor at Princeton University, has argued that “birth is an arbitrary point for society to bestow personhood . . . .”96 He and other influential scholars “want parents to have some time to decide whether to dispatch the baby or keep it.”97 Jeffrey Reiman, professor at American University, has expressed that “infants do not possess in their own right a property that makes it wrong to kill them.”98 He has denied “that infants are members of the community who share equal worth, dignity, and rights, and explicitly [has concluded] that ‘there will be permissible exceptions to the rule against killing infants that will not apply to the rule against killing adults and children.’”99 Furthermore, Michael Tooley, a philosopher writing at the time of the Roe decision declared that fetuses and newborns do not have a right to life because they are not people.100 In other words, Tooley advocated the belief that infants do not qualify as human beings because “a human being . . . possesses a serious right to life only if it possesses the concept of a self as a continuing subject of experiences and other mental states, and believes that it is itself such a continuing entity.”101

This belief that infants are not entitled to full protection of the law has even permeated the Oval Office. In November, 2000, then President Bill Clinton’s Office for Civil Rights wrote that “protections against discrimination on the basis of age and disability [do not] require doctors to treat seriously ill newborns as long as the parents consider them aborted.”102 This statement is less than shocking considering the fact that Clinton twice vetoed a ban on partial birth abortion which was passed by both houses of Congress.

96. Leo, supra note 25.
97. Id.
98. Id.
99. Hearings, supra note 9 (testimony of Prof. Robert P. George).
100. Id.
101. Id.
Before the first veto the procedure was believed to be implemented in rare medical emergencies. This misconception was due not only to a lack of available information, but also intentional skewing of statistics. After Clinton vetoed the ban in April, 1996, conflicting information began to surface. The fact that the original statistics had been skewed for political purposes, and that the evidence concerning the effects of this procedure were by that time widely publicized did not stop the former president from vetoing the ban a second time. It is actions like these that signal the need for a clear and distinct determination that a baby born alive is entitled to personhood.

D. The Need

The cases, legal theories, and political arguments surrounding the abortion debate have enabled the intent of the mother to be paramount to any and all rights of the child. The thought that a baby aborted during the mid-second to third trimester can survive the abortion, be born alive, and feel the effects of the abortion have been consistently dismissed. Pain perception centers develop early in the second trimester of pregnancy. Infants of similar gestational age, that are born prematurely, are cared for with pain management as one of the tenets used in the NICU. The pain management practiced for a partial birth abortion would not meet the federal standards for the humane care of animals used in medical research. These views support the need for the Born-Alive Infants Protection Act.

In speaking in support of the Act, Representative Canady summarized the Supreme Court’s decision in *Carhart* as resting “on the pernicious notion that a partially-born infant’s entitlement to the protections of the law is dependent not upon whether the child is born or unborn but upon whether or not the partially-born child’s mother wants the child or not.” He also pointed to the decision in *Farmer* as holding that “an infant who is killed...”

103. Sprang, supra note 92. The circulated numbers were 450 to 500 per year. *Id.* at 744.
104. *Id.* For example, in November 1995, the National Coalition of Abortion Providers Executive Director Ron Fitzsimmons stated that “women had these abortions only in the most extreme circumstances of life endangerment or fetal anomaly.” *Id.* After President Clinton vetoed the bill, Fitzsimmons “admitted that his own contacts with many of the physicians performing intact D&X procedures found that the vast majority were done not in response to extreme medical conditions but on healthy mothers and healthy fetuses.” *Id.*
105. Sprang, supra note 92, at 745.
106. *Id.*
107. *Id.*
during a partial birth abortion is not entitled to the protections of the law because . . . a woman seeking an abortion is plainly not seeking to give birth." After reflecting upon these cases, Representative Canady demonstrated the potential consequences of this line of thought. He concluded that:

[under the logic of these decisions, once a child is marked for abortion it is not relevant whether that child emerges from the womb as a live baby. A child marked for abortion may be treated as a nonentity even after a live birth and would not have the slightest rights under the law; no right to receive medical care, to be sustained in life or to receive any care at all. Under this logic, just as a child who survives an abortion and is born alive would have no claim to the protections of the law, there would appear to be no basis upon which the government may prohibit an abortionist from completely delivering an infant before killing it or allowing it to die.]

Representative Canady was not hypothesizing when he told of the consequences of these decisions. The testimony of Nurses Stanek and Baker are proof that these practices are already in use.

V. BUT YOU’RE SUPPOSED TO BE DEAD

Senator Conrad is not the only opposition that the Born-Alive Infants Protection Act faces. During the hearings before the House, doctors, scholars, and lawmakers spoke out against the proposed law. The attacks stem from two systems of belief. First, there is the content neutral attack. This is the group which would base their resistance on the addition of a born alive infant to the list of those entitled to personhood, such as the Peter Singers of the world. They would essentially deny personhood to a newborn baby regardless of whether the baby was wanted by its parents or not. This argument is an across the board ban on recognition of a living baby.

The second attack is content based. The argument is that babies who are born alive as the result of an abortion are not entitled to personhood.

109. Id.
110. Id.
111. See supra pp. 488-89 and accompanying notes.
112. See supra note 23 and accompanying text.
113. See supra p. 500.
The proponents of this are groups like NOW and the NARAL. It is also fostered by the language of noted court opinions. This theory focuses solely on the woman’s determination that she will abort the baby. For the followers of this line of thought, once this decision has been made, the concept of being born alive ceases to exist.

Of the two lines of thought, the first grouping seems to make more sense. At least it does not discriminate on the basis of self-worth. However, as pointed out by its supporters, no argument for banning this Act can reconcile the distinction between a woman’s right to choose to have an abortion and the rights of a born alive infant. Opponents of the bill have yet to explain how the mother’s right to terminate her pregnancy extends through the birth of a live baby. There are several more concise arguments, upon which those opposing this Act rely. Each of these arguments, however, does not appear strong enough to deny personhood to a newborn baby.

The first argument against the Born-Alive Infants Protection Act is that it restates current law. Opponents contend that “[e]xisting federal and state law already provide adequate protection for the fetus.” It is true that more than forty states have laws that either grant a new born personhood or proscribe the killing of a baby born alive, but these laws only apply to babies who are born to mothers who either planned to have them or at least did not have an abortion. If the judiciary does not interpret those laws as applying to an aborted baby who is born alive, then the laws do not solve the problem that this Act would. Enacted laws are of no support to a class that is not protected by the legislation.

The second argument against the Born-Alive Infants Protection Act is that the language of the bill “would impose on doctors and parents a universal definition of life or ‘alive,’ which is . . . inconsistent with the harsh reality presented by a number of circumstances.” In other words, this bill would “significantly interfere with the agonizing, painful and personal decisions that must be left to parents in consultation with their physicians.” It would cause parents to prolong the life of a dying infant out of fear that choosing to discontinue treatment would be a “termination of life” instead of a termination of the “painful process of death.” What all of this means is that there are physicians who would be confused as to “whether this
bill would mandate that doctors provide care beyond what they would normally deem to be appropriate for newborns who have no possibility of survival.\textsuperscript{119} In addition to the testimony of doctors who analyzed the bill and concluded that the criteria of live birth as set forth in the Act is “unambiguous and easily discernible by any birth attendant,”\textsuperscript{120} it is common knowledge that a baby who is lying on a table, moving its arms and legs, and gasping for air is, in fact, alive.

Furthermore, any parent who was planning on giving birth and raising their child will not arbitrarily decide to stop life sustaining methods based on a legal definition of live birth.\textsuperscript{121} The Act is intended to apply to babies born alive as a result of a botched abortion. It is for the purpose of granting those children the same rights as children born to parents who want them. It is not meant to force parents and doctors to keep babies, who clearly have no vital signs, nor is it meant to force them to administer treatment that would be ineffective. When medical attention will no longer help the child survive, doctors are not required, under the Act, to keep the baby alive, regardless of the circumstances of birth.\textsuperscript{122} The effect of this Act is to define a baby who survives an abortion as a person, so doctors do not leave a baby to die, in an effort to fully perform their end of an abortion contract.

A third argument against the Born-Alive Infants Protection Act is that it is a back-door attempt to restrict a woman’s right to choose to terminate her pregnancy.\textsuperscript{123} However, there is a distinction between having an abortion and killing a living baby. Once a woman delivers her baby, there is no way she can terminate her pregnancy because the pregnancy has already been terminated through the birthing process.\textsuperscript{124} Because the Act defines born

\textsuperscript{120} Hearings, \textit{supra} note 9, at 59 (testimony of Dr. Watson A. Bowes, Jr.).
\textsuperscript{121} Parents who want their baby will fight until they feel that it is a losing battle.
\textsuperscript{122} Hearings, \textit{supra} note 9, at 59. Dr. Bowes testified:

\begin{quote}
It is my opinion that this definition of being born alive does not and will not have a detrimental effect on either maternal or infant health care. I am confident of this because this is the definition of live birth that is in effect in the state of North Carolina in which I practiced for 18 years. During this time, these criteria for defining live birth did not interfere with physicians making clinical judgments about providing appropriate care for newborn infants nor with parents being involved in those decisions. Importantly, this definition of live birth does not restrict a physician’s prerogative to recommend that medical care regarded as futile be withdrawn or withheld.
\end{quote}

\textit{Id.}

\textsuperscript{123} \textit{Id.} at 35 (testimony of Rep. Stephanie Tubbs-Jones).
\textsuperscript{124} \textit{Id.} at 56 (testimony of Prof. Gerard V. Bradley).
alive as "complete expulsion or extraction" from the womb, there is no conceivable way to abort a child who has already been completely expelled or extracted from a woman’s body.

The only chilling effect that this bill may have on a woman seeking an abortion is the thought that the woman who goes in for an abortion may, nonetheless, end up being a mother if the child is born alive. So, the issue boils down to determining whether a baby who survives an abortion can force a woman to be a mother. Roe spoke to this possibility:

Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it. In other cases, as in this one, the additional difficulties and continuing stigma of unwed motherhood may be involved.

As testimony before the House has indicated, these detriments that the court in Roe spoke of are "not of pregnancy, but of having and raising a child." Neither the text nor the spirit of the Born-Alive Infants Protection Act mandates that a woman is required to keep and care for the child that she aborted in the event that the baby survives the abortion. She has the same ability as any other mother who gives birth to terminate her parental rights and give the baby up for adoption. She never has to see the baby, know how it is progressing, or provide any care whatsoever.

While a woman who intends for an abortion to be successful can relinquish her rights as a parent, health care professionals should not be entitled or even forced to relinquish their obligations to a living human being based solely on the will of the mother. It is the very essence of a physician’s responsibility to care for a patient who is alive and in need of medical attention. That the mother did not intend to have the child should,
realistically, not be part of the equation for a doctor in deciding whether to care for a baby who has obvious signs of life. The answer is certainly not to ignore the baby until the intent of the procedure is achieved. The same standards that apply to any person who presents at a hospital for care should be applied to a baby who survives an abortion. The fact that this standard is not equally applied means that we have different levels of care for living people based upon whether they are considered valuable by others. If that is a legitimate criterion, then the most rudimentary theory of worth holds no authority.

The fourth argument against the Born-Alive Infants Protection Act is that it is vague and overbroad.\textsuperscript{130} According to its opponents, because the Act could affect over 70,000 sections of the United States Code ("the Code"), it would be impossible to predict all of its possible ramifications.\textsuperscript{131} Although this argument was presented as a serious problem that could emerge from enacting this bill, there have never been any examples provided of how this Act would negatively affect the Code. Surely, if this were a legitimate problem that could potentially redefine 70,000 sections of the Code, there could be at least one example provided of how these sections would be detrimentally affected.

Although no opponent stepped forward and offered evidence concerning the Act’s statutory effect, the House Subcommittee on the Constitution requested that two attorneys from the American Law Division of the Congressional Research Service discuss the possible statutory impact of the Act.\textsuperscript{132} The attorneys concluded that the "addition of [the] new language would have minimal effect on the prospective application of federal statutes."\textsuperscript{133} They analyzed the effect on tort, trusts and estates, and criminal law—the areas of law where the interests of those born alive are most often recognized.\textsuperscript{134}

They began with federal tort claims which are most commonly brought under the Federal Tort Claims Act (FTCA).\textsuperscript{135} The Act would not effect this practice because "the relevant portions of the FTCA do not use the terms 'person,' 'human being,' 'child,' or 'individual' in establishing damages

\textsuperscript{130}. \textit{Id.} at 35 (testimony of Rep. Stephanie Tubbs-Jones).
\textsuperscript{131}. \textit{Id.} at 36.
\textsuperscript{132}. \textit{See id.} at 48 (testimony of Ken Thomas, Attorney, American Law Division of the Congressional Research Service).
\textsuperscript{133}. Hearings, \textit{supra} note 9, at 50 (testimony of Ken Thomas).
\textsuperscript{134}. \textit{Id.} at 50–52.
\textsuperscript{135}. \textit{Id.} at 50.
For trust claims, state law and the trust instrument determine whether those born alive are considered beneficiaries. Therefore, these new definitions would have little effect on that area of the law. The most damaging effect to existing law that the attorneys found would be in the area of criminal law. They stated that the concept of born alive proposed by the Act is broader than that of common law because it appears to be intended to apply to fetuses which were born prior to viability. It also adds abortion to the common law definition which was previously limited to non-consensual fetal demise. Because of this, the attorneys concluded that:

[It is not clear if the statute would be limited to the situation where the cause of death was inflicted after the fetal expulsion, or whether it could be interpreted to cover injury inflicted in utero during an abortion. Application of the homicide statutes for damage[s] incurred during an abortion would raise constitutional issues based on a woman's liberty interests under the 14th Amendment. While the canon of constitutional doubt would lean against the application of a statutory ambiguity in a way that may violate the Constitution, it is not clear how this statute would be applied.]

The answer to whether this Act would affect the point of viability can be answered by responding to the fifth argument proposed by the opposition. The argument is that the Act defines viability—a task which the Supreme Court has consistently refused to do. This argument fails for three reasons. First, viability, like a woman's right to choose to have an abortion, is a concept only applicable to a pregnant woman. Once a baby is born, the definition of viability is extinguished. Either the newborn baby is alive or it is dead. Whether the baby lives or dies, there is no longer any need to calculate the potential for the baby to live outside of the womb. Second, even if the viability test were used once the baby was aborted, the test would not be altered by any significant amount of time. Because viability is measured by fetal age, it is more likely that an older fetus will survive a late term abortion. The gray area between the twentieth and

136. Id.
137. Id. at 51 (testimony of Ken Thomas, Attorney, American Law Division of the Congressional Research Service).
138. Hearings, supra note 9, at 51.
139. Id. at 51–52.
140. Id. at 52.
141. Id.
142. See id. at 44 (testimony of Rep. Stephanie Tubbs-Jones).
twenty-seventh week may be carved out to a clearer degree if a substantial number of twenty week old fetuses live, but administering aid to aborted babies that live is not going to automatically turn a pre-viable fetus into a viable fetus. This argument leaves out the most important part of the equation—the baby has to be born alive. Just because the Act applies to all stages of fetal development, does not excuse the fact that the baby has to be born alive to receive protection.

Third, the chances of a pre-viable fetus living through an abortion remain low due to both the age of the fetus and the abortion procedures that are used on fetuses that young. Early term abortion methods destroy the body of the fetus, ripping it apart. By the time the fetus exits the womb, it is reduced to tissue, and often times it is not expelled in full form. With a live birth abortion, not only is the child usually at the point of viability but the child is delivered in its entirety, similar to an actual birth in the ninth month. The chance of survival obviously increases dramatically when the child is delivered like a full birth as opposed to being removed like a tumor.

Furthermore, viability is determined inside the womb. The essence of this term is its potentiality. The Roe Court defined viability as the point when the fetus can survive independent of its mother, but that definition has changed over the years to now mean "the capacity for meaningful life outside the womb, albeit with artificial aid," and not just momentary survival.143 Once the child is born, there is no need to measure viability because potentials have become realities, and the reality is that there is now a living, breathing human being. Even if viability were the determining factor, the fact that the baby may need artificial aid to survive is meaningless. The definition explicitly allows for medical help in determining viability. The argument that the Act would have any effect on the definition of viability is simply untrue and irrelevant.

A related argument was provided by the NARAL. This organization claims that the Born-Alive Infant Protection Act is "yet another anti-choice assault on the basic tenets of Roe v. Wade."144 However, the point of birth

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143. See Gans Epner, supra note 27, at 724.
144. Stuart Taylor, Jr., When Does Abortion Become Infanticide?: Approval of RU-486 May Help Pull Us Back from That Line, 23 LEGAL TIMES 84 (2000). Another argument that has been offered, though not by the NARAL, is based entirely on statistical data and population counts. It provides:

"[B]irth has always been understood as the delivery of an infant who has at least some chance of living more than a few minutes. Since no baby has ever survived birth before 22 weeks of pregnancy (20 weeks since fertilization), a miscarriage or abortion during the first half of pregnancy is not considered to result in a live birth even if the embryo or fetus exhibits some signs of life after delivery. The reason for this definition
“marks the earliest possible time . . . when the interests of the [mother] can be separated entirely from the interests of the child.” Additionally, prosecutors and lawmakers are already injected into the medical decision making process. They have been involved since the profession began. Passing the Act may be the first step toward leaving this decision to health care professionals by providing a definition of “alive” based on heart beats and respiration instead of a convoluted interest-serving legal definition. In other words, maybe “[i]f we understand that we are dealing with a human being, reasons of convenience and self-interest [would] become radically inadequate in supplying a ‘justification’ for the killing of [a] child.”

While most of the arguments against the Born-Alive Infants Protection Act are based on the constitutional right of a woman to choose to have an abortion, no critic has provided any analysis of the Act’s validity under the current test. If the argument challenges the Act’s constitutionality under Roe, Casey, and now Carhart, then the opponents should at the very least be prepared to apply those standards to the present situation. Despite this retreat to the security of Roe and its progeny, implementation of this doctrine is incompatible with any form of relief under these circumstances. In other words, abortion rights and live children do not mix.

In order to strike down the Act under a right to choose analysis, a litigant would have to prove that either the law does not contain a vital

is obvious: [it is] important to know how many babies are born alive each year for all kinds of vital statistics and public health purposes. For instance, we want to know how many stillbirths and infant deaths there are as a percentage of live births, in order to address medical problems. Because the birth of a living child has tax consequences, we need to define birth in a reasonable way. Including miscarriages and induced abortions as births would make nonsense of these efforts.


145. Hearings, supra note 9, at 9 (testimony of Prof. Hadley Arkes). Arkes testified that:

Even if Roe v. Wade articulated an unqualified right on the part of a woman to end her pregnancy, the pregnancy would now be over. No right to end the pregnancy would require at this moment the death of the child. And of course no one, at that moment, claims to be suffering any doubt that we are dealing with a human being—as though the offspring of homo sapiens could have been anything less than human at any phase in its life. This is the first moment then, under our current law, when we should be able to declare, with unchecked conviction, that the law may extend its protections over that child.

Id.

146. Id. at 10.
exception for the preservation of the life or health of the mother, or it imposes an undue burden on a woman’s right to obtain an abortion. Proving either of these as a way of showing that born alive infants are not entitled to personhood is impossible. The argument is fundamentally flawed under both prongs, as once a baby is born alive, it is no longer a part of the mother. As soon as the baby leaves the womb, the privacy right becomes as important to the mother as the placenta is to the already born child.

The basic tenet behind the abortion rights analysis is that a woman should be able to do what she wants with her own body. But basic biology is cogent evidence that once it survives birth, the baby is its own separate, independent being. No health exception is needed because allowing the living, breathing baby to be considered a person has no correlation to a mother’s life or health. There is no undue burden imposed on the woman’s right to terminate her pregnancy because the pregnancy has already been terminated through the birth. Although this reality may be unpopular to those who would prefer that a woman retain total control over the life and death of her child, even through birth, it cuts right to the heart of this debate. Once a child is born, its mother does not have the right to a dead baby.

VI. CONCLUSION

How can what seems like such a simple theory be so complex? It would appear that within the most basic of thought processes that the evidence that a child is born alive is for all necessary purposes proof that it is a person. Politics has once again been injected into a formula where it does not belong. A child’s worth should not be placed on whether he or she is wanted by the person who gave birth to him or her. Although there is a right to prevent the birth of such a child, that right ceases to exist when the child is born. There is no clearer point of individualism than that of separation. When a child is born, it is its own being, no longer dependant upon its mother for food, shelter, and comfort. All of those essentials can be provided by another once the child leaves the womb. There are others who want to step in and take over the role that is often times so casually disregarded. But before that can happen, the child must be given the chance to survive. The Born-Alive Infants Protection Act would allow such a child to have that chance at life.

Cloning and the Constitution,
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Daniel Mark Cohen*

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INTRODUCTION

In form and fashion, in proposition and purpose, the breadth and depth of human culture ever demonstrates a remarkable diversity. The sundry peoples of the earth differ, not only in their appearance, clothing, and diet, but no less in their social systems, religious beliefs, and political philosophies. Yet whether king or commoner, aristocrat or pauper, notorious or anonymous, each human being shares with every other, one fundamental condition of life, as indeed human beings have throughout their history on

* Nova Southeastern University, Shepard Broad Law Center, 2001, J.D. Thank you to Professor Kathy Cerminara for her invaluable observations and insightful criticism; to Lori Bangor, Esquire, for her single but vital question on the issue of cloning and free speech; and to Sorraya Solages and Theresa Fontana for their exhaustive editorial labors.
earth. Each man, and each woman traces his or her origin to a mystifying, microscopic biological event: the fusion of male and female gametes that describes the process of sexual reproduction. Moreover, this nascent physiological occurrence is universally precipitated by, and generally subservient to, a greater, inexorable "carnal" desire of a man and woman, each for the other. It is a desire that oft constitutes not only a corporeal passion, but no less an emotional (some might say a spiritual) yearning that draws the two together for that ecstatic union of the sexes by which new human souls are conceived. Yet the aggregate result of recent scientific advances in physics, chemistry, biology, genetics, and medicine, has led humankind to the astonishing discovery that reproduction in animals, non-human in fact, and human in theory, may also be achieved asexually through a laboratory procedure known as cloning.\(^1\) Scientists have already successfully cloned animals, including frogs,\(^2\) salamanders,\(^3\) mice,\(^4\) sheep,\(^5\) cows,\(^6\) and monkeys.\(^7\) Many scholars and scientists working in related fields of biochemistry believe that it is just a matter of time before humankind acquires the knowledge needed to similarly procreate, or more precisely, replicate human beings.\(^8\) Indeed, in January 2001, a Kentucky infertility specialist informed the world he is forming a consortium, intending, he announced, to produce the first human clone.\(^9\) Remarkably, many scientists firmly believe that human beings have already been cloned clandestinely.\(^10\)

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1. Suggesting the horticultural origin of the term, the word "clone" is derived from the Greek word "klon," which means "twig." OXFORD ENGLISH DICTIONARY 342 (2d ed. 1989).


5. Id.


9. Id. at 1.

Cloning, even at the most rudimentary level, holds out the extraordinary promise for curing otherwise incurable diseases, perfecting the transplantation of life saving organs, eradicating defective lines of genes, forestalling the process of aging, as well as for what may be the most sophisticated use of cloning envisioned: a form of human reproduction that will one day incorporate all these achievements to produce a radically different, ostensibly superior form of human being. On the other hand, the prospect of human cloning holds out equally grave dangers: for the sacrilegious abuse of human embryos and fetuses, the mutation of human beings into monstrous, transgenic forms, gratuitous stillborn births and malformed...
infants, the promotion of some socially favored racial characteristics over others, and the cruel infliction of needless suffering on experimental subjects, human and nonhuman alike. As a result of the potential for both good and evil in cloning, advocates and opponents of the technology continue to compete with one another to define the ancillary issues, and in particular, they seek to do so through the assignment of legality or illegality to the propositions they respectively favor.

Part I of this paper constitutes a brief primer on the subject of human reproductive cloning. Section A consists of a discussion of the actual and anticipated benefits of cloning, while section B discusses the fears, myths, and the prospective dangers of the process. Part II evaluates cloning in the light of constitutional law and principles. Section A of Part II reviews the present legal status of cloning in the United States. Section B analyzes cloning as it relates to reproductive freedom and the right to privacy. Section C examines how anti-cloning legislation might violate the principles of Equal Protection, while section D discusses cloning and freedom of speech.

I. BASIC FACTS ABOUT HUMAN REPRODUCTIVE CLONING

A. Reproduction, Sexual and Asexual

Scientists tell us that each human being consists of literally trillions of cells. Each of these cells, though undetectable to the human eye, constitutes an entire world unto itself, an unimagined and unimaginable intricacy of activity that takes place in every moment, in every place where human cells thrive. Perhaps even more intriguing, almost every human cell contains the complete “genetic code” of an individual. The genetic code may be understood as a storehouse of sorts, a place in which all the information concerning a person’s physical composition and hereditary potential are maintained on a submicroscopic level. Through this genetic prodigiousness, whereby a person’s full genetic code exists in almost every

Technologies describing the successful cloning of a human embryo by inserting human DNA into a cow’s egg).

21. BOYCE RENSBERGER, INSTANT BIOLOGY 59 (Fawcett Columbine 1996).
one of his or her trillions of cells, it is, at least theoretically, possible to transform each one of those cells into a complete human being.\textsuperscript{23}

Though a human being consists of an incomprehensibly prolific number of cells,\textsuperscript{24} that singularly fantastic integration and complexity originates from a single cell, the ovum or egg, produced by the female of the species.\textsuperscript{25} By fusion with a male gamete, and subsequent progressive cell division and growth, an embryo forms that will eventually evolve into a fully-formed fetus.\textsuperscript{26} However, just before the male and female gametes unite, each possesses only twenty-three chromosomes, incomplete by half of the number needed to create a human being.\textsuperscript{27} Once united, a new cell is created possessing the full forty-six chromosomes required for human life.\textsuperscript{28} These forty-six chromosomes consist of segments of DNA molecules, known as genes, which carry and transmit the traits and attributes of each of the two parents.\textsuperscript{29} It is this process, at once mundane and miraculous, that is commonly referred to as \textit{sexual} reproduction.

Cloning, in contrast, is a form of asexual reproduction. That is to say, it requires neither a coupling of the sexes, nor the union of male and female gametes. In the prospective process of human reproduction wrought through cloning,\textsuperscript{30} the entire forty-six chromosomes of a prospective parent or donor are transplanted into a female’s enucleated egg. The resulting embryo is then implanted in the womb of the actual or surrogate mother where it can gestate. As with \textit{in vitro} fertilization, it is only the initial microscopic event of conception that occurs in a laboratory, outside of the female’s uterus. Scientists have already successfully performed this procedure with several species of mammals.\textsuperscript{31} The offspring of the process constitutes not a physically or biologically novel form of life, but a precise physical or genetic duplicate, a “delayed identical twin” of the parent.\textsuperscript{32}

In fact, cloning already takes place both in nature and in human culture. Plants reproduce through a form of cloning scientists refer to as “vegetative

\begin{itemize}
\item \textsuperscript{23} Id.
\item \textsuperscript{24} RENSBERGER, \textit{supra} note 21.
\item \textsuperscript{25} \textit{Embryology}, Compton’s Interactive Encyclopedia (Softkey Multimedia Inc. 1996).
\item \textsuperscript{26} Id.
\item \textsuperscript{27} Id.
\item \textsuperscript{28} Id.
\item \textsuperscript{29} Id.
\item \textsuperscript{30} Robertson, \textit{supra} note 12.
\item \textsuperscript{31} Scientists have succeeded in cloning mice, sheep, calves, and monkeys. \textit{See supra} notes 5–8.
\item \textsuperscript{32} \textit{Cloning Human Beings, supra} note 2.
\end{itemize}
propagation. In horticulture, cuttings of a single plant are cultivated to propagate desired botanical characteristics. It is through cloning that farmers cut and graft their crops, favoring the traits of some plants over the traits of others. Cloning also occurs naturally in higher animals, as when identical twins are born. Undertaken in the province of the scientific laboratory, cloning has resulted in such achievements as the artificial production of insulin, and the growth of vital cultures.

In sexual reproduction, a new form of life constitutes a convergence of the genetic identity of each parent. It is for this reason that a child carries physical traits of both parents, not only in the genotypes such as hair, eye, and skin color, but also in recessive traits that may later appear in the child’s offspring. In asexual reproduction, however, the new form of life is, in most cases, genetically identical, that is, an exact duplicate of the parent.

In what seems the most fundamental contradiction of reason and experience, many express fears that a clone will constitute not only a genetic duplicate, but also a spiritual or behavioral replication of the source of the cloned cell. That is to say, many people have expressed fears that a clone will duplicate a cloning parent’s evil personality, moral disposition, or political purpose, which expressions conjure up dystopic images of the conspiratorial cloning of armies of murderous dictators and criminals.

An appeal to simplest reason and reflection however, suggests that the determinant of a human being’s personality (alternately referred to as the “mind,” “soul,” “self,” “psyche,” and “spirit”) is not essentially, and certainly not exclusively, biological. Rather, it is shaped passively by the uterine environment during the term of gestation, and actively from the first moments of a person’s birth by his or her surrounding domestic and social environments.

In sum, the determinable biochemical causality of the brain’s formation does not necessarily imply a similar rudimentary, mechanical causality of the ideas and purposes forged by that mystery called the “mind,” even if the mind finds its corporeal foundation and physical correspondence in the brain. Men and women may find a natural appeal in the simplicity of the notion that all human beings may be reduced to a summation of microscopic, biochemical events. However, that simplicity is no more entitled to endorsement than the similar but mistaken appeal men and women found in past centuries in the notion that the planets must, of necessity, travel in perfect spheres, and not as they actually do, in inelegant ellipses, or in the notion that the earth must be flat. (For after all, how could it be round? How would it stay suspended in space? If the earth wasn’t flat, wouldn’t we all fall off the surface?)

Genetically identical twins raised in different cultures may possess some similarities, perhaps even striking similarities. However, the differences in the languages they speak, their dialects, interests, religious beliefs, and avocations are directly traceable to their
B. The Anticipated Benefits of Human Reproductive Cloning

Successful development of human reproductive cloning technology holds out visionary promise for the treatment and cure of otherwise untreatable and incurable diseases. Indeed, it is now conceivable that certain genetic diseases may one day be eradicated from the face of the earth. For example, if both partners in a marriage carry the gene for Tay-Sachs disease, through cloning they might be able, not only to conceive a child free of the disease, but they may be able to create that child free of the gene itself, so it would never be suffered by future generations. By creating an embryo from a cloned cell, scientists could supplant the flawed gene with a healthy one.

Perhaps equally remarkable with the prospect of conquering dread diseases, cloning technology offers the possibility of an entirely novel, unimagined, and heretofore unimaginable form of human reproduction. Cloning may provide a new means of reproduction for couples, or even individuals, who otherwise find themselves unable to procreate children. Thus, in the cases in which a couple is unable to conceive a child because of gametic failure, cloning technology may enable them to produce a child that is biologically related to one, and perhaps both parents. For example, if the man is the infertile partner, by cloning his DNA into his wife's enucleated egg, the DNA implant might be understood as an imperfect, genetically dominant substitute of sorts for the male gamete. Through this process, a child will be conceived that carries the traits of both parents. Both the process and the result of this form of cloning closely resemble existing treatments for reproductive dysfunction—*in vitro* fertilization and artificial insemination. In contrast, where the woman is the infertile partner, cloning could produce a child by implanting the woman's DNA within a donor egg, but the child would not carry any of the biological traits of her husband. In respective environments, that is, to the home, family, friends, and society, as well as some independent form of internal psychological engagement that describes the process of reflection, introspection, creation, and the application of one's reason from a uniquely relative perspective.

41. *Id.*
42. *Id.*
43. Robertson, *supra* note 12.
44. Gametic failure takes place when a woman cannot produce eggs or a man cannot produce sperm necessary to produce healthy offspring.
addition, where a person carries flawed recessive genes, such as those that transmit Tay-Sachs disease, sickle cell anemia, or cystic fibrosis, the asexual reproduction of cloning would provide a couple with the otherwise unavailable security of producing a physically healthy and genetically sound child.

C. Actual Fears and Prospective Dangers of Human Reproductive Cloning

As great as the anticipated benefits of cloning are, the fears and dangers are perhaps greater. Within weeks of the Roslin Institute’s publication of the paper describing the successful cloning of a sheep, members of Congress began drafting anti-cloning legislation. In addition, some countries in Europe declared human cloning to be illegal. Highly respected professional organizations within the scientific and medical communities, as well as more than two dozen recipients of Nobel prizes in science, agreed “there should be a moratorium on the creation of a human being through cloning.” So serious are the fears and dangers inspired by the technology, that in 1997, President Clinton’s National Bioethics Advisory Commission concluded, unequivocally, that human cloning should not be attempted. The Commission also expressed multiple concerns about the physical safety, the autonomy, the kinship, and possible objectification of the resulting children. Moreover, in the years since the announcement of the cloning of the first sheep, members of Congress have repeatedly held hearings and proposed bills expressly drafted in order to prohibit cloning.

As naturally occurs with the introduction of new ideas with the potential to transform human self understanding and the order of society, the discussion of cloning in the public arena has been accompanied by grave and

51. Id.
often highly imaginative fears.\textsuperscript{53} However, although some concerns may be freely dismissed as unfounded, cloning does indeed present genuine dangers


However, although a clone will indeed, in all cases, constitute an exact genetic duplicate of the parent cell, and possess a very strong (but not necessarily identical) physical resemblance, a clone will \textit{not} constitute an exact, or even necessarily, an essential behavioral or moral copy. The natural occurrence of identical twins in society provides an ideal form of proof of this fact. Though identical twins are genetically indistinguishable, both common experience and scientific studies demonstrate that, salient similarities notwithstanding, each twin is endowed with his or her own unique personality. \textit{See}, e.g., NANCY L. SEGAL, PH.D., \textit{ENTWINED LIVES} (1999). Not only do twins differ in the whirls of their respective fingerprints, studies of twins raised apart indicate their performance on intelligence quotient tests varies as much with environment as with genetic constitution. \textit{Id}. In other words, genes may provide the raw material for a person's intelligence, emotion, and purpose, but each person's necessarily different and distinct environment gives that material its unique form. The scientific ability to trace the causality of, and so, produce otherwise naturally occurring pigments in paint does not by any means imply the ability to similarly trace the causality of, and so, produce infinitely higher works of creative virtuosity produced with those paints, such as those produced by Rembrandt or Van Gogh.

Three factors insure that a clone will differ in fundamental ways from his or her parent:

1) The primary material from which a cloned human being is formed, the DNA from the somatic cell, must be supplemented by the contrasting mitochondrial DNA of the enucleated egg in which it is placed. Alexander, supra note 10, at 12 (quoting Infigen's Michael Bishop). The convergence of two different forms of DNA will result in necessary differences in the newly conceived child from its parent.

2) While the debate over whether nature or nurture determines human behavior may serve an invaluable heuristic purpose, it is a self-evident fact that the domestic and social environments within which a child develops shape his or her psyche in the most fundamental ways. Moreover, it is not only these extrinsic environments that determine a person's language, dialect, interests, beliefs, and aptitudes; the necessarily unique uterine environment in which a child gestates, as well as the home in which child development takes place, have been shown to play a key role in determining a child's biochemical, and so, neurological development. \textit{Id}. Thus, though a cloned child will possess the precise hereditary information of a parent cell, because the child gestates in a particular womb at a necessarily unique time in the surrogate or actual mother's life, and because it is further introduced to the experiences of life through a unique social place and historical time, a child's personality, in all instances will take an independent, differentiated form.
with which men and women must reckon if they are able to exploit the
technology at last for the public weal. All human invention, from the
artificial production of fire, to the generation of power through nuclear
fission, may be used for good or for evil; cloning, of course, is no different.

Expressly conceding the great inefficiency of current cloning
technology, the chief executive of the company that introduced the first
cloned sheep to the world advised that “it would take more than 400 eggs
and 50 surrogate mothers to produce a cloned baby.”\footnote{Robertson, supra note 12, at 43 n.1.} He noted that cloning
the first sheep required “277 reconstructed eggs, of which 29 developed into
normal embryos placed in 13 sheep, and that only one embryo resulted in
success.”\footnote{Id.} “Such a high failure rate will mean numerous malformed and
stillborn infants will be produced.”\footnote{Gilbert, supra note 18.} Thus, the genuine dangers to the health
and the life of the fetus, as well as to the welfare of prospective mothers,
whether natural or surrogate, must be properly addressed before the cloning
of human beings may be reasonably advanced.

Another concern is that “cloning is a harbinger of the genetic alteration
and control of human characteristics in offspring.”\footnote{Robertson, supra note 46, at 36.} Indeed, cloning is
closely related to “transgenic modification,” the ability to modify the genes
of a cell in order to predetermine the physical, and perhaps, behavioral
characteristics of the prospective offspring.\footnote{Id. at 39.} The notion of the progressive
genetic modification of a human being over generations suggests a change in
human self understanding perhaps as revolutionary as the Copernican
explanation of the heliocentric order of the solar system,\footnote{Nicolaus Copernicus,} and the Darwinian
proposition that man came into being not by a spontaneous act of Divine

3) A clone will differ fundamentally from his or her parent as a necessary
consequence of the indeterminable causality of gene activity. A person’s chromosomes
contain at least thirty-thousand genes. Philipkoski, supra note 10. Only some of the genes are
expressed; that is, only some of them unfold into actual characteristics of a person. Whether
or not a particular gene is expressed is a result of an ultimately indeterminable, sometimes
random, extraordinarily complex activity among different genes, and between genes and the
environment. Mark D. Eibert, Cloning: Myths, Medical Benefits, and Constitutional Rights

54. Robertson, supra note 12, at 43 n.1.
55. Id.
56. Gilbert, supra note 18.
57. Robertson, supra note 46, at 36.
58. Id. at 39. Scientists have already successfully altered the genes of laboratory
animals, creating models of human disease within mice. Kassirer, supra note 14. This
“transgenic modification” of mice allows scientists to study the role of genes in normal
development and disease. Id.
Will, but by a process of natural selection that transpired over the course of millenia. The social, legal, and moral implications of humankind's prospective self-transformation through cloning and genetic manipulation are so overwhelming as to be inassimilable. Thus, many discern in cloning the potential "to tamper with the 'moral and social' sense of what it means to be a human being."

It is also feared that the acceptance of asexual human reproduction will harm society by eliminating reproduction in its sexual form as an essential characteristic of human life, disrupting the traditional and conventional classification of human society by generations, and confusing parent-child relationships. Indeed, one wonders whether the source of a cloned child's DNA should be properly described as the child's parent, or as the child's twin. In addition, fears have been expressed that, with the acceptance of asexual reproduction of human beings, the diversity of the human gene pool will be diminished.

Indeed, it would seem that cloning, in conjunction with similarly revolutionary advances in genetics and biochemistry, has brought society one step closer to realization of the formerly fictional notion of eugenics, the highly controversial science that supposes to improve the human race through controlling inherited characteristics. Among the first attempts in the field of eugenics was undertaken by National Socialist Germany which, in paying tribute to the ideology of a glorified Aryan race, engaged in ineffably cruel and horrific experimentation on human subjects, and sterilized those considered racially undesirable or inferior. It is also most disturbing to learn that a eugenics movement existed in the United States,

60. CHARLES DARWIN, ON THE ORIGIN OF THE SPECIES BY MEANS OF NATURAL SELECTION (1859).
63. "[The donor of a cloned cell] is not the child's 'parent' in any biological sense, but simply an earlier offspring of the original parents." George J. Annas, Why We Should Ban Human Cloning, 339 NEW ENG. J. MED. 2 (July 9, 1998).
65. OXFORD ESSENTIAL DICTIONARY AMERICAN EDITION 342-43 (2d ed. 1998).
one that came into existence long before the National Socialists came to power in Germany.\(^{67}\) The theoretical potential of cloning and transgenic modification, and the historical record left by the governmental programs of Germany and the United States, demonstrate that the acute fears expressed by both scientists and laypersons are not properly dismissed as unfounded or fanciful.

Other somewhat less menacing, but nevertheless disturbing fears give cause for concern. Some worry that the wealthy and powerful may use cloning to replicate themselves,\(^{68}\) or that entrepreneurs might seek to market the DNA of a celebrated athlete, model, artist, or entertainer.\(^{69}\) In an alternate scenario, a person might seek to appropriate the DNA of a third party without that party's consent,\(^{70}\) and use the stolen genetic material to produce a clone.\(^{71}\)

The prospective capacity to reproduce human beings asexually through cellular vestiges that survive a person's death has inspired some rather confused and troubling ideals. In what is a startling, recurrent theme among those who advocate human cloning, the technology is endorsed for its apparent ability to resurrect a living replica of a dying or deceased child.\(^{72}\) In such instances, some people, it seems confuse the possibility of genetic replication with hopes of spiritual resurrection. In what seems a sadly misguided ideal, the surviving parents seek to create a new child, apparently to perpetuate the myth that their deceased child lives again. One may speculate that such parents misunderstand a clone as somehow constituting a reincarnation of their deceased child, or perhaps they seek to indulge the

\(^{67}\) Pelias, supra note 66, at 843; Mark D. Eibert, Cloning: Myths, Medical Benefits, and Constitutional Rights, Sept. 23, 1999, at http://www.humancloning.org/users/infer/f/ humancloning.html (observing that thirty-six states in the United States passed eugenics based sterilization laws in the early part of the twentieth century. California sterilized more than 30,000 of its citizens).

\(^{68}\) Robertson, supra note 12, at 119.

\(^{69}\) Id.

\(^{70}\) Cloning Human Beings, supra note 2.

\(^{71}\) Id. The commission of such an act, it seems, might give new meaning to the tort of conversion, and raises the question of whether a person can claim legally protected possessory rights in his or her DNA. See, e.g., Kojo Yelpaala, Owning the Secret of Life: Biotechnology and Property Rights Revisited, 32 McGeorge L. Rev. 111 (2000).

\(^{72}\) See, e.g., Gibbs, supra note 7, at 6 (noting that the Clonald project operated by the UFO Raelian sect, advertised its plans to clone a ten month old deceased infant; parents of six-year-old child who died in a tragic fall seek to clone the child, though they could procreate another child, and other children, through natural means of procreation); Alexander, supra note 10, at 3, 10; Annas, supra note 62, at 3; John A. Robertson, Liberty, Identity, and Human Cloning, 76 Tex. L. Rev. 1371, 1381 (1998); Thomas H. Murray, Even If It Worked, Cloning Wouldn’t Bring Her Back, WASH. POST, Apr. 8, 2001, at B1.
whim or vanity of creating another child with an appearance identical, or nearly identical, to the first. In fact, it is difficult to imagine a proposition that more greatly diminishes the sanctity of the memory of a deceased child than the confused supposition to blithely replace the child with a surrogate physical replica. Such a notion would seem to constitute a denial, indeed, annihilation of the unique place the late child held in time, and in the hearts, of those by whom he or she was loved. Moreover, because of the inherent danger in producing a human clone, it seems a profound irony that “in trying to make a copy of a child who has died tragically, one of the most likely outcomes is another dead child.”

Cloning has also produced fears concerning the psychological welfare of children born from the asexual process of reproduction. Questions have been raised whether such children will suffer psychological harm because of a “diminished sense of individuality and personal autonomy.” The National Bioethics Advisory Commission has expressed the fear that a child borne of cloning might be “severely harmed” by the knowledge that he or she possesses identical DNA to the source of his birth.

73. Gibbs, supra note 7, at 4.
74. Cloning Human Beings, supra note 2. If the sanctity of a human being is in his or her uniqueness, and men and women value what is distinctive, then it is reasonable to conclude that they will disregard, or diminish the worth, of that which is common. Thus, the less unique a person, the more he or she is likely to know a diminished sense of worth in the world, in the eyes of others, and consequently, in his or her own eyes.
75. Id. However, it might be reasonably argued in response that a child’s primary development, whether mental, emotional, or spiritual, will be complete by the time he or she is able to understand and assimilate the relatively abstract and subtle concepts of asexual biological origin. Such initiation, it is reasonable to suppose, would affect the child no more traumatically than does news learned by a child that he or she was adopted, rather than biologically conceived, by his mother and father. While such news potentially might confuse, or even disturb a person, it is hardly an event that, as some maintain, would properly bring into question whether he or she should have been born.

According to one observer, “the central problem of cloning [is] the devaluing of persons by depriving them of their uniqueness.” Annas, supra note 62, at 122. “The only reason to clone an existing human,” Dr. Annas suggests, “is to create a genetic replica.” Id. at 123 (It should be noted however that although in vitro fertilization and artificial insemination provide the means for procreation to many otherwise infertile couples, these processes do not work universally). See Alexander, supra note 10. Neither in vitro fertilization, nor artificial insemination, can help those couples in which one of the partners suffers from a condition of gametic failure that is perfect. (For couples seeking to sire a child that is biologically related to at least one of the parents, and for whom the notions of extra marital donors of eggs or sperm, like adoption, are unacceptable, cloning may indeed fulfill a need that cannot be dismissed as merely capricious, vain, or gratuitous). “The danger is that through human cloning, we will lose something vital to our humanity, the uniqueness (and therefore the value
According to the National Bioethics Advisory Commission ("NBAC"), the most real and immediate danger in the attempt to clone a human being would be to the fetus.\textsuperscript{76} Indeed, the NBAC observed, "at present, the use of this technique to create a child would be a premature experiment that would expose the fetus and the developing child to unacceptable risks."\textsuperscript{77} The identification of this prospective danger by the Commission back in 1997, has been supported by subsequent cloning research on animals. In March, 2001, scientists conceded that clones are often borne with "serious developmental problems," such as heart and lung defects and defective immune systems.\textsuperscript{78} In recent months, mice produced by cloning technology suffered what seems to be a spontaneous metabolic transformation.\textsuperscript{79} From a condition of apparent normalcy, the mice developed conditions of obesity in what seems to be random genetic errors that can emerge at any time in a cloned animal's life.\textsuperscript{80} Moreover, only two to three percent of efforts to clone mice, and only one percent of efforts to clone a cow succeed in producing live offspring.\textsuperscript{81} According to another source, "ninety-eight percent of embryos never implant, or die off during gestation or soon after birth."\textsuperscript{82} If the embryos do not die in fetal development, they may die shortly after birth; if they survive, they often suffer major developmental defects.\textsuperscript{83}
II. CLONING AND THE LAW: DO THE PRINCIPLES OF THE CONSTITUTION PROTECT OR PROSCRIBE REPRODUCTIVE CLONING?

A. The Present Legal Status of Reproductive Cloning

While fears, both justified and fanciful, have driven much of the opposition to the notion of asexual human reproduction, at present, only four of the fifty states have passed laws that prohibit human reproductive cloning. California, Louisiana, Michigan, and Rhode Island have enacted laws that ban attempts to create a human being through asexual reproduction. While the laws of three of the states threaten offenders with formidable financial and licensing penalties, Michigan’s anti-cloning statute is a criminal one, under which violators may be sentenced to ten years in prison. Moreover, Michigan’s criminalization of human cloning is enforceable against researchers, doctors, and their infertile patients. Mindful of the rapid advances in science, however, both Rhode Island and California included “sunset” clauses in their legislation; so the respective laws automatically expire after several years if they are not extended.

The federal government has prohibited the use of federal funds for embryo research since 1996. Reinforcing this prohibition, President Clinton issued an Executive Order forbidding the use of federal funds for human cloning research. However, although sundry anti-cloning bills have been proposed, no accommodation could be reached between Republicans

85. Id.
86. In Louisiana and Michigan, violators of the statute may be fined up to ten million dollars. LA. REV. STAT. ANN. § 1299.36.2 (West 2001); MICH. COMP. LAWS ANN. § 333.16274 (West 2001). In California and Rhode Island, an organization that violates the statute may be fined up to one million dollars. CAL. HEALTH AND SAFETY CODE § 24185 (West 2001); R.I. GEN. LAWS § 23-16.4-2 (1998).
87. MICH. COMP. LAWS ANN. § 750.430a (West 2000).
88. Id.
91. Cloning Human Beings, supra note 2.
who seek a comprehensive ban on human cloning, and Democrats who wish to protect those forms of nonhuman cloning research that are unrelated to human reproduction. Because biomedical researchers and interested patient groups have lobbied with intensity against anti-cloning legislation. Because their interests lie in nonreproductive, and so, noncontroversial forms of cloning, the constituents of those lobbyists are concerned that a blanket ban will outlaw established commercial and scientific enterprises. Thus, private research undertaken to clone human beings is legal in most of the United States. However, after controversial testimony before a House subcommittee in March of 2001, House members advised that they have acquired stronger conviction in favor of a national ban on human cloning. Through a White House press secretary, President Bush announced that he supports the idea of anti-cloning legislation: ‘The president believes that no research—no research—to create a human being should take place in the United States.’

Strangely, the Food and Drug Administration (FDA), presumably because of its power to regulate the pharmaceutical industry, declared that human cloning is subject to its authority. An official of the FDA stated that the agency can prohibit human cloning experiments based upon public safety concerns. Violators, according to the FDA, could face fines up to $100,000.00, and be sentenced to up to a year in prison. However, despite these assertions, the FDA does not seem to have statutory jurisdiction over the practice of medicine or cloning, and despite the agency’s assertion of such authority, even members of the House of Representatives have expressed doubts about the FDA’s jurisdiction over cloning.

93. Eibert, supra note 67; Gibbs, supra note 7. (The primary source of embryos for stem cell research is provided by in vitro fertilization clinics, whereas cloning of embryos, not to produce human beings but only to produce stem cells, would provide an almost infinite supply).


95. Id.

96. Id.

97. Id.


100. Weiss, supra note 94.

101. Id.

102. Id.
B. Cloning, Reproductive Freedom, and the Right of Privacy

The charter political document of the United States, the Declaration of Independence, proclaims that liberty stands premier among the inalienable rights of man. The charter legal document of the United States, the Constitution, seeks to ensure liberty through a separation of governmental powers, and a Bill of Rights that enumerates the comprehensive and fundamental rights of the individual. Despite the proclamation of the sanctity of freedom, and recurrent articulation of liberty's preeminence throughout the Bill of Rights, those very rights of freedom so fundamental to men and women, (tenuous perhaps by nature), have been ever under challenge since the Republic was founded. Thus, citizens of the United States have found themselves forced to resort to the judiciary to establish that the Constitution protects their rights to marry, to have children, to educate and raise their children, to marital privacy, to acquire and use contraception, to bodily integrity, and the right of a woman to choose to have an abortion. These and other decisions relating to the family and procreation form a constellation of sorts, establishing a right of privacy that, though formally not enumerated, finds its authority in the Constitution; indeed, these Supreme Court decisions confirm that the Constitution upholds an inherent right to privacy, most particularly where matters of the family and procreation are concerned. The Court has also observed that the Constitution protects "personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education," having stated unequivocally that such freedom concerns "the most intimate and personal choices a person may make in a lifetime." The right of privacy precludes governmental interference with an individual's decision on matters of his or her body. Moreover, in Eisenstadt v. Baird, the Court stated,
“if the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.” In addition, in more than one opinion, the United States Supreme Court has expressly identified a constitutionally protected right to reproduce, also referred to as “reproductive freedom.”

Some states assign even greater importance to the right of privacy; the Florida Constitution, for example, enumerates an express right to privacy. This provision states, “[e]very natural person has the right to be left alone and free from governmental intrusion into the person’s life...” Thus, a person in Florida has a right to be free from governmental intrusion into areas where he or she can demonstrate a reasonable expectation of privacy.

Considering then the strength of the federal and state recognition of the right of privacy, particularly as it relates to reproductive matters, one might suppose then that the right of a person to procreate through cloning cannot be gainsaid. Closer analysis requires the more cautious conclusion that the answer depends upon how the question is cast. If the question of human cloning is defined as a matter of reproductive freedom, the governmental proscription of human cloning will violate citizens’ “fundamental liberty to have and rear healthy, biologically related children.” Human cloning is, according to this point of view, sufficiently similar to other means of reproduction, whether natural, or artificial by in vitro fertilization and artificial insemination, to be classifiable as conduct protected by the principle of reproductive liberty. It is also worth noting that while in vitro fertilization is thoroughly legal and, some might say, now even conventional, it was illegal in many states a mere twenty years ago.

115. Id.
117. FLA. CONST. art. I, § 23.
118. Id.
121. Robertson, supra note 12.
122. Gibbs, supra note 7; Eibert, supra note 53, at 13.
In diametric opposition to such a view, however, it may be argued with equal vigor that a person’s right to clone him or herself is not a fundamental right entitled to constitutional protection. Based upon the principle that citizens universally enjoy a right to what the courts call “substantive due process,” the state cannot violate a citizen’s “fundamental rights” without a compelling, narrowly-tailored interest.\textsuperscript{123} Fundamental rights, in turn, have been juridically defined as those “deeply rooted in this Nation’s history and tradition”\textsuperscript{124} and “necessary to an Anglo-American regime of ordered liberty.”\textsuperscript{125} Because there is no tradition of asexual replication in the United States, and permitting asexual replication is not necessary to safeguard any existing concept of ordered liberty, staunch opponents of the technology argue conversely that there is no constitutional right to be cloned in the United States.\textsuperscript{126} Those who oppose human cloning have also drawn support from an unlikely source; Ian Wilmut, who cloned the first sheep, and so, is perhaps the scientist most associated in the public perception with cloning, has openly declared his opposition to attempts at asexual reproduction of human beings.\textsuperscript{127} Moreover, there already exist limits on citizens’ right to reproduce that are almost universally recognized: reflecting universal social mores, every state in the Union, if not every nation in the world, has adopted legislation criminalizing incestuous relations and marriages. Florida law, for example, prohibits a person from engaging in sexual relations, as well as marriage, with a parent, sibling, uncle, aunt, nephew, or niece.\textsuperscript{128} Thus, the right to privacy, and reproductive freedom, like all other rights and freedoms, are not absolute.

Dr. Annas suggests cloning human beings is not only redundant, but that it is also gratuitous.\textsuperscript{129} “Although it is possible to imagine some scenarios in which cloning could be used for the treatment of infertility, the use of cloning simply provides another choice for choice sake, not out of necessity.”\textsuperscript{130} Cloning, Annas states, is “a technique that can produce an indefinite number of genetic duplicates.”\textsuperscript{131} “It is the duplication,” Annas

\textsuperscript{126} John A. Robertson, \textit{Why We Should Ban Human Cloning}, 339 NEW ENG. J. MED. 21 (July 9, 1998).
\textsuperscript{127} Gibbs, \textit{supra} note 7.
\textsuperscript{128} FLA. STAT. § 826.04 (2001).
\textsuperscript{129} Annas, \textit{supra} note 62, at 3.
\textsuperscript{130} Id.
\textsuperscript{131} Id.
observes, “of an already existing person, who is replicated only and precisely to create a genetic duplicate (since this is all that cloning can do).”

While the cloning of individual cells may serve as an invaluable resource for treating and curing disease, because human beings already possess the capacity to reproduce sexually, whether naturally, or in the case of gametic failure, through in vitro fertilization, artificial insemination, or in the alternate, adoption, some might posit that there is no genuinely meaningful purpose for cloning human beings, in what is an essentially uncreative, asexual form of human reproduction. However, it is important to note that the success rate of in vitro fertilization is under thirty percent, and it is an expensive and onerous process as well. Moreover, because the infertile condition of some couples is complete, neither in vitro fertilization, nor artificial insemination are options.

Finally, some opponents of cloning advance the proposition that, while citizens may possess the constitutionally protected right to know freedom from governmental interference in matters that concern reproduction and procreation, child bearing itself is not a privilege, condition, or benefit to which citizens can suppose to claim entitlement at the government’s expense. “[T]he government does not have the obligation to ensure that each citizen who wants a child has a child.” According to this argument, the right to reproductive freedom to which the Supreme Court has identified both expressly and implicitly in multiple decisions, protects only those who have the capacity to reproduce through the traditional method of sexual reproduction.

C. Cloning and Equal Protection

The Fourteenth Amendment expressly, and the Fifth Amendment implicitly, provide each citizen with a constitutional right to a standard of legal protection that is equal to that known by all others. Thus, the Constitution prohibits the government from invidious treatment of one

132. Id.
133. Eibert, supra note 53, at 3; Alexander, supra note 10, at 6.
135. Robertson, supra note 46, at 37.
137. Id.
138. U.S. CONST. amend. XIV, V.
person, or class of persons *similarly situated* to others. In addition, if a law violates a citizen's right that the Supreme Court has identified as *fundamental*, that law may violate the principle of equal protection. The Supreme Court has already ruled that the freedom to procreate constitutes a fundamental right. Thus, if scientists attain the ability to clone human beings, any proposed governmental prohibitions against human cloning may have to withstand the legal test of strict scrutiny, the judicial standard by which the constitutionality of alleged violations of fundamental rights are measured. If a law infringes upon the rights of a so-called *suspect* class, one defined by race or national origin, the law must be necessarily related to a compelling governmental interest. If the law infringes the rights of an intermediate class, defined by gender or children borne out of wedlock, the law must be substantially related to an important state interest. Laws that infringe upon the rights of almost all other classes need only be rationally related to a legitimate governmental interest. Laws that prohibit reproductive cloning of humans, considered in light of current case law, would thus only need to be rationally related to a legitimate state interest. Even if the purpose of the law is considered legitimate, the means to achieve that aim must be reasonable. If the ban on cloning is a total one, the law would be significantly underinclusive, inasmuch as it would not similarly prohibit artificial forms of reproduction, such as *in vitro* fertilization, that share similar dangers to public safety and

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But even if underinclusive as well as overinclusive, the Supreme Court would not find sufficient reason to strike down the law if it is shown to be both rational and legitimate. Only if opponents of the law could demonstrate that the underlying purpose of the ostensibly legitimate state interest is insidiously biased or prejudicial, would the Court strike the law down as unconstitutional. Thus, a law that prohibits human cloning, denying infertile couples access to technology that might otherwise provide them with the freedom to procreate that is naturally known by others, and even if indisputably constituting a form of discrimination, still might not violate equal protection under the law. For if the state can demonstrate a rational relationship of the law (e.g., prohibition against reproductive cloning) to a legitimate state interest (e.g., protecting the health of unborn children and prospective mothers,) and no bias is established, the discriminatory law will still be upheld by the courts.

D. Cloning and the Freedom of Speech

At first blush, it would seem that the subject of cloning, would have no relationship to First Amendment speech issues. For the first amendment of the United States Constitution prohibits the state from violating citizens' sacrosanct right to speak freely, while cloning concerns the seemingly unrelated spheres of science, technology, and human reproduction. Yet other forms of human activity, not otherwise identifiable as speech, have in fact been so classified, thereby acquiring the First Amendment shield of invulnerability against governmental prohibition or intrusion. Indeed, it is

148. Id.
150. U.S. CONST. amend. I.
151. Among the forms of human expression the Supreme Court has classified as "speech," and so protected by the First Amendment include commercial advertising, expressive conduct, and symbolic speech. See Texas v. Johnson, 491 U.S. 397 (1989) (flag burning as a form of protest against governmental policies); Tinker v. Des Moines Sch. Dist. 393 U.S. 503 (1969) (wearing of black armbands as a form of civil protest); Spence v. Washington, 418 U.S. 405 (1974) (upside down display of the American flag with an attached peace symbol); West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943) (flag saluting as a form of utterance); Miller v. California, 413 U.S. 15 (1973) (classifying pornography as a form of speech that should be protected unless classifiable as "obscene")
primarily those who engage in speech that are deemed to pose an unequivocal danger or destructiveness by way of immediate incitement, conscious, willful calculation, or deception who can not look to the Constitution for protection.

Some proponents of cloning who seek to advance the notion that scientific research should be endowed with immunity from governmental prohibition, argue such research constitutes an alternate, unrecognized form of human speech. Even the National Bioethics Advisory Commission, appointed by President Clinton, observed in its report on cloning, "If the First Amendment protects a marketplace of ideas, it seems likely [that] it would protect the generation of information that would be included in that marketplace." On the other hand, the government is free to regulate according to a broad and complex legal definition; Pope v. Illinois, 481 U.S. 497 (1987) (extending the rule of Miller v. California, 413 U.S. 15 (1973)).

Chaplinsky v. New Hampshire, 315 U.S. 568 (1942) (fighting words); Cohen v. California, 403 U.S. 15 (1971) (fighting words that present "clear and present danger").


Central Hudson v. Public Serv. Comm., 447 U.S. 557 (1980) (ruling that the First Amendment does not protect commercial speech that is misleading).


Most of the cases cited in notes 149–53 concern speech as it is produced by, or effects individual citizens in their capacity as private and general members of society. Of course, the law also classifies, and restricts, the communication peculiar to society's many subcultures. For example, restrictions on speech, whether civil or criminal, are found in the realm of commerce in the prohibition against the revelation of trade secrets; in public broadcasting in proscriptions against "indecency;" amongst lawyers and judges on one hand, and doctors, hospitals, psychiatrists, psychologists, and social workers, on the other, in the confidentiality with which they are bound to hold client and patient records; in the courtroom, against lawyers from introducing evidence the court deems prejudicial; amongst journalists and newspapers, against publishing the names of rape victims and minors; against publishers as well as individuals from unauthorized copying of the creative works of others under copyright law; and against workers within governmental agencies, for speech disruptive to the agency's operation, or policy aims and objectives among others. These subcultural speech issues, as well as governmental regulation of the time and place of speech, irrespective of conduct, is beyond the scope of this discussion.

Cloning Human Beings, supra note 2, at F-6.
scientific research to protect and promote public health and safety.\textsuperscript{157} As one scholar has observed, "there are ample precedents for such restrictions, as in the case of regulation of experiments with new drugs and with nuclear materials and facilities."\textsuperscript{158}

One point of view suggests that scientific experimentation constitutes a form of expressive conduct, or symbolic expression, and so is entitled to First Amendment protection.\textsuperscript{159} Scientific research, according to these observers, can be classified as a constitutionally sanctioned type of \textit{symbolic speech}, comparable to students wearing black armbands or burning draft cards as an expression of protest.\textsuperscript{160} According to this proposition, scientific research is a form of protected speech, no different in essence from the creative expression of ideas by playwrights or musicians.\textsuperscript{161} Therefore, it is argued, research devoted to the end of cloning human beings is protected from governmental proscription by the First Amendment.

Such an argument, however, stretches the meaning of the word out of shape, causing it to collapse under the weight of the conduct wrongly assigned to it. Speech, in all the forms in which it has been deemed to be entitled to protection by the Constitution, concerns the conveyance of an idea or ideas, from a speaker to another listener or other listeners, whether those listeners are concurrently engaged, or merely prospective. All human speech, whether political, commercial, religious, social, or purely personal speech,\textsuperscript{162} whether expressed verbally in words, pictorially in images, or symbolically in conduct, shares the quality of constituting a message of some

\begin{thebibliography}{99}
\item 159. United States v. O'Brien, 391 U.S. 367 (1968); \textit{see Cantrell, infra} note 161, at 73; \textit{Green, supra} note 158, at 620; \textit{Foley, supra} note 147, at 682–87.
\item 161. \textit{Foley, supra} note 147, at 683–84.
\item 162. Remarkably, the category of \textit{personal} speech is not recognized by the courts. Thus, the mundane speech of the common man, certainly the most fundamental and practical use of speech by human beings, has been left unrecognized, and so, unprotected by the United States Judiciary.
\end{thebibliography}
kind, a message through which the speaker seeks to reach and communicate with another or others.\textsuperscript{163}

In contrast, while it is undisputed that scientific research should be entitled to broad protection, (albeit for entirely different reasons,) research consists of actions, actions that apply the scientist’s thought, examination, and inquiry.\textsuperscript{164} Scientific research consists of the \textit{application}, not the communication of ideas. The actions of the scientist, in the form of research, contrast with his or her ideas.\textsuperscript{165} Speech consists of the \textit{expression} of ideas, whether by voice, gesture, pen, or image, created by a person in order to communicate with another or others.\textsuperscript{166} Scientific research \textit{might} be classifiable as the expression, or exploration of the validity, of ideas. But the purpose of that expression is \textit{discovery}, not communication. Scientists, it is true, may invariably wish to communicate the consummating discoveries of their research to others. But the proposition that such purely physical action and engagement of the world constitutes a form of speech is simply invalid, advanced by its proponents, it seems, only in order to exploit the supreme legal protection afforded by the First Amendment. While no rational or caring soul can suppose to dispute the great virtue of science for its material improvement of the human condition, the cause of Truth in general, and science in particular, is not properly served by disingenuous definitions. Moreover, while some advocates of cloning may argue that prohibitions against the related research and procedures would inhibit

\textsuperscript{163}. How might the observations entered into a diary be classified? For, at least apparently, the diarist writes for his or her own self, and not to any consciously intended recipient. Shall we suppose as a result that the speech of the diarist is unprotected by the First Amendment? It would seem the diarist’s purpose does not include the intention to communicate the related ideas to another or others. And if the diarist affirmatively seeks to keep the diary private, the proposition becomes even stronger. However, diaries may be published posthumously as a historical, social, or familial record, a fact of which many serious diarists, certainly those more educated, may be aware. The fact that the diarist consciously creates a record might suggest eventual readers, absent express words or actions to the contrary. Moreover, many diarists, especially children, consciously indulge the conceit that the diary itself is a conscious, understanding recipient of the chronicler’s confessions, a fact manifest in the common practice of commencing entries with the salutation, “Dear Diary,” or alternately, addressing a fictional recipient by a given moniker. On the other hand, it may be equally argued that the maintenance of a diary provides a purely private, expedient means in which a person seeks to forge linguistic order on the chaos of his or her otherwise wordless experience of thought and feeling.

\textsuperscript{164}. Foley, \textit{supra} note 147, at 683.
\textsuperscript{165}. \textit{id}.
\textsuperscript{166}. \textit{id.} at 679.
scientific inquiry, there is no reason to suppose that all scientific goals or practices are proper, moral, or need be socially accepted.167

In Spence v. Washington, 168 the Supreme Court ruled that some conduct can be identified, at least legally, as expressive, and so entitled to First Amendment protection. 169 The first element of that test requires that the source of the conduct intend to "convey a particularized message."170 Though scientists naturally hope to share the fruit of their scientific labors with colleagues, if not with society in general, and to communicate the nature of the work in the publication of papers and the delivery of lectures at conferences, the research itself does not constitute speech. The manipulation of elements and compounds by chemists, the exacting measurement of anatomy and physiology by biologists, the studied calibration of the stars by astronomers, the search for the existence of subatomic particles by physicists, none of these activities constitute ideas that occur in the mind; nor do they constitute the communication of such ideas to another or others in the speech of the spoken, written, graphic, or symbolic kind. Rather, each of the respective scientific endeavors constitute an application of the scientist's internal idea to the external, physical world of matter and energy.

Consider the diagram below:

\[
\begin{align*}
\text{idea} & \quad \text{speech} & \quad \text{action} & \quad \text{matter} \\
\text{(spoken, written, graphic, symbolic)} & \quad \text{(manual, mechanical electronic, digital)} \\
\text{intent to communicate} & \quad \text{intent to alter or effect some aspect of the material world, through exertion capable of understanding}
\end{align*}
\]

167. Sophia Kolehmainen, Human Cloning: Brave New Mistake, 27 HOFSTRA L. REV. 557 (1999); see Declan Butler & Meredith Wadman, Calls for Cloning Ban Sell Science Short, 386 NATURE 8, 8 (1997) (discussing the concern of some scientists that legislating too quickly on cloning techniques may hinder innovative research).

168. 418 U.S. 405, 409–10 (1974) (holding that an inverted display of the American flag with a peace symbol affixed thereto is a form of communication protected by the First Amendment).

169. Id. See Foley, supra note 147, at 682.

170. Spence, 418 U.S. at 411; Foley, supra note 147, at 682.
Pure idea as it occurs in the human mind stands at one extreme of a greater spectrum; physical matter as it occurs outside the human mind stands at the other. When we refer to speech, we refer to the expression of the feelings and thoughts, whether spoken, written, graphic, or symbolic. When we refer to conduct, we refer to action taken by a person as a consequence of ideas.

Of course, this distinction can be obliterated by proposing to define ideas in physical terms as primarily or merely neural activity of the brain. In this way, one could suppose to blur the distinction between speech and action, defining speech as the residual effect of neural and oral physical activity. As a concomitant of this proposition, the distinction can be

171. For example, communicative gestures such as sign language employed among the deaf, or a mourner's self-attirement in black garments as a means of communicating his or her condition of bereavement.

172. Such a proposition is not nearly as far-fetched as the uninitiated reader might suppose. Behavioral psychologists, for example, enamored of the objective measurement that distinguishes science from other disciplines of human inquiry, early endorsed the absurd, nihilist notion that, in the endeavor to change human conduct, the attributes of thought, feeling, and speech should be entirely disregarded. See, e.g., the works of John B. Watson and B.F. Skinner. The great error of the behavioral psychologists, and indeed all who suppose to translate human or animal behavior in scientific terms, is their failure to recognize one fundamental fact: the universally determinable knowledge scientists acquire in their objective measurement of the world, as manifest in the disciplines of mathematics, physics, chemistry, and astronomy, exists not as a superior or supreme form of knowledge; to the contrary, it is an inferior form of knowledge, existing precisely to serve the greater purpose of individual sentient creatures in their several, necessarily unique, subjective engagement to the world. (This is one reason the mystery of human intelligence, of necessity, defies anything close to meaningful measurement.)

Doctors, insurance companies, and others in the health care industry have already committed a similar error. Despite the most grave and far-reaching social consequences, they essentially, and expediently, deny the historic, universal distinction drawn by human beings between the mind and body. Consider:

Throughout their lives, human beings suffer, as a natural and necessary condition of life, varying degrees of what may be called “psychic” pain. Such a condition is commonly described as “mental” or “emotional” suffering, and is invoked in such words as “unhappiness,” “discontent,” “distress,” “anger,” “grief,” “depression,” and “despair.” Such pain may be understood metaphorically as a herald of sorts, conveying to the recipient the existence of some form of internal discord, which condition calls for the sufferer’s recognition, appraisal, and resolution.

The psychic pain that men and women call “unhappiness,” in any of its myriad forms, may thus be understood to occur within human beings as a signal, in the same way that physical pain in one’s knee or one’s shoulder occurs in response to the suffering of some precipitating trauma. That signal informs the recipient of the fact of an emergent condition requiring immediate attention. Indeed, the more intense the signal, the greater the danger to
the person should he or she fail to heed it. Thus, the athlete who suffers a sudden, acute
tearing pain in his or her knee must urgently suspend the precipitating activity; failure to do so
will result in an aggravation of the pain and injury. Indeed, if the victim fails to heed that
urgent sensory warning, he or she may suffer the thorough destruction of the limb or organ’s
utility. The internal suffering identified as “psychic,” “mental,” or “emotional,” invariably
proceeds from some form of frustration—for example, the inaccessibility of food when
hungry, poor performance on a school exam, the infliction of a harsh reproach by one’s
employer. It may occur suddenly, as with the unexpected death of a loved one, or it may
transpire in a more subtle manner, as with the cumulative effect of a person’s protracted action
in compliance, not with his or her own internal needs, but rather, with the contrary desires of
family, friends, co-workers, employers, or society. Such frustration may be benign, as when
the quenching of one’s thirst is delayed a few moments. Or it may take far more serious
forms, as when a child is deprived of reliable affection, instruction, or security in his life, and
as a result, his or her sovereign ability to harmoniously engage the world is proportionately
impaired. In all but the most extreme cases, that is, in all cases in which a person’s ability to
function socially is not substantially impaired, relief from suffering may be found in careful
reflection and reason, integration of the consequent understanding, and the determination of
appropriate remedial action. In many cases, this process may take place naturally, with the
passage of time. In other cases, a more conscious and deliberate approach may be required.

Over the past decade or so, with successful penetration of the subvisual molecular
and atomic realm of human anatomy and physiology, scientists have succeeding in discovering
a neurochemical analogue that corresponds to the emotions. As a result, with the introduction
of certain chemicals into the body, scientists are now able to manipulate the neurochemical
composition of a person’s brain, and so, freely alter that person’s emotions. With the
successful commercial promotion of such drugs as Prozac, Xanax, and Elavil, the sale of anti-
depressants and mood stabilizers has grown into a powerful multi-million dollar industry.
Whether expressly by invoking “scientifically proven” truth, or implicitly by silent practice,
physicians now, it seems routinely, diagnose human distress and despair as constituting
something other than necessary conditions of life, properly resolved by a person through the
sovereign employment of his or her reflection and reason. Rather, human emotion is
commonly defined and understood in this, the dawn of the twenty-first century, as an
essentially biological, neurochemical aberration, an essentially physiological condition that,
when identified as the source of pain, is properly treated with the purported curative of
prescribed chemicals.

Physicians, and society as a whole, commonly recognize the legitimacy of grief
that arises in a person who suffers some sudden trauma, such as the death of a loved one.
Similarly, they usually recognize that the natural resolution of that condition, in most cases,
may be achieved with the mysterious but naturally therapeutic effect of time’s passage.
Strangely, however, they rarely recognize the grief that results from the cumulative effect
of some protracted trauma to the mind or soul, such as may occur in a more subtle manner with
the eventual failure of a more prolonged endeavor. The resulting “melancholy” or
“depression” is rather mis-defined in biochemical, rather than social, spiritual, or philosophi-
cal terms.

When a person suffers a failure of some protracted enterprise, such as may occur
in work, school, or marriage, the aspects of the world that formerly served to divert and
engage may become strangely muted and hollow. An amnesia of sorts may overcome the
person so that he or she can barely, if at all, recall ever having found any type of delight or uplift in the world. He or she may suffer a relentless despair, perhaps over past errors, whether real, exaggerated or imagined, or alternately, over some form of misfortune recalled or envisioned. He or she may suffer as well a perfect hopelessness towards any imagined course of action in the future that will bring desired but elusive relief. Unreason usurps the throne of reason in the person's attempt to conceive of ideals and goals towards which laboring is deemed worthy, as the sufferer commonly presumes an unfounded sense of omniscience and clairvoyance—omniscience in his or her certain conclusion that there is no good to be known in the world, and clairvoyance in his or her identical presumption concerning the perfect deficiency of goodness to be ever known again in the future. In most cases, a person can redress this tyranny of emotion over reason by withdrawal from those engagements that, previously unacknowledged, serve to oppress him or her, as well as tenaciously searching out affirmative, recreational engagements that will serve to please, restore, and uplift his or her mind. For if there is a neurochemical analogue, or biological seat to the emotions, then any putative imbalance caused by misfortunate events is surely redressable through fortunate ones. Simply put, if adverse events upset the balance of the body's emotional chemistry, then uplifting events should, in most cases, be able to restore it. The problem, indeed, the challenge, a person faces in seeking to overcome melancholy is the immobilizing inertia and delusive pessimism that so often accompany that condition, to search out and find those pleasing and restorative engagements that, in such a state, are so elusive. The word "recreation" is formed from the verb "to recreate." To recreate is "to restore to a good or normal physical condition from a state of weakness or exhaustion." OXFORD ENGLISH DICTIONARY 372 (2d ed. 1989). And it is ultimately, and precisely a want of that recreative engagement to the world, in sufficiently bounteous degree, that may prevent a person from overcoming the paralyzing melancholy he or she may suffer.

Of course, the mortality of human being has its limits. While the body possesses extraordinary resources for self-healing, an extreme physical trauma may require external intervention. Similarly, an extreme mental, spiritual, or emotional trauma can be so acute that a person's ability to function becomes impaired, or worse, the victim may find him or herself driven to self-destruction in the attempt to overcome unbearable psychic pain. In such cases, of course, medical intervention is redemptive. Just as the physician must at times concede the mysteriously curative power of non-physical agents such as a patient's positive outlook, or the unknown therapeutic agent animated by the so-called placebo effect, so too, the soul must at times rely upon physical intervention as the requisite means of survival. However, in conventional medical understanding and practice, one finds an institutional confusion of cause and effect, or translated into more apt metaphorical terms, a confusion of disease and symptom. The intense experience of discontent and frustration that may be described as distress, depression, or despair, as well as the physical, bio-chemical analogue thereto, do not constitute the cause of a person's pain; they constitute the pain itself. They constitute the effect that proceeds from an undiscerned, private (but perfectly accessible) psychic cause; in most cases, that cause is the failure to acknowledge and withdraw from oppressive engagement to the world, and concomitantly, to seek out more uplifting engagement. By supposing to prescribe medication to redress the corresponding neurochemical imbalance, doctors, (again, metaphorically speaking,) mistakenly treat the symptom rather than the disease. Where a person's pain is acute, where he or she is so overwhelmed that he or she cannot function, where he or she is self-destructive or suicidal, then resorting to chemical
treatment is, of course, justified. But even then, the conscious, greater goal, too often absent in contemporary practice, should be to prudently wean the patient off the medication, while helping him to re-organize the order of his life so he or she can recover his or her sovereignty, and exploit the natural and proper means of his or her restoration.

With the great, looming authorities of science, advertising, and social convention conjoined in purpose, the common man of the twenty-first century, afflicted by acute unhappiness, is just as likely as not, to conclude that his affliction proceeds, not from the discordant order of the purposes and aims of his life, but from an anatomic, neurochemical imbalance in need of medical treatment. But it is precisely the pain of sadness, of frustration, of grief, that provide the very foundation for the penultimate two questions of life: 1) What is meaningful? and 2) What is moral? Or put another way, ever vulnerable to finding him or herself ultimately oppressed by action undertaken in conformity with convention, habit, or impulse, a person must ever ask himself, 1) What must I do today to successfully sustain or improve my life? And 2) Does the prospective course of action raise any question of moral injury to others, or to myself? Despite the radical technological transformation of human society in the twentieth century, these questions abide, remaining undiminished in their primacy. In contrast, to suppose to eliminate a person’s psychic pain chemically is thus to block his or her access to the very means of his or her human growth, of his or her human being, now for the forging of faith in the fire of abiding despair, now for creative discovery of new realms, or an alternate path of uplifting engagement. Ironically, it is precisely because of the potential use of narcotics for such a socially subversive purpose that legislators rigidly require medical prescription for some drugs, and absolutely outlaw the acquisition, possession, or use of others. Moreover, neurochemical treatment leaves the problems that introduced the original condition of discontent unresolved, leaving that person’s mind, soul, or spirit, in a static, and so, ultimately frustrated condition.

As with the false proposition that scientific research constitutes a form of speech, the proposition that a chemical imbalance in the brain is the cause, rather than the effect of human unhappiness, constitutes a principle expediently fashioned out of self-interest: 1) The pharmaceutical industry enjoys, and stands to continue to enjoy, monumental profits with society’s adoption of the exotic notion that unhappiness is properly defined as the want of some form of medication. 2) Insurance companies endorse the proposition, false though it is, for it eliminates the enormous cost they would otherwise have to incur if they were required to provide the alternate treatment, (woefully flawed though it often is,) of more mystically-based forms of psychological consultation. 3) Physicians are served by this fiction simply because it is so expedient; they need not spend time listening and assigning significance to patients’ complaints when the routine, momentary dispensation of prescriptions provide instant, even if ultimately, only illusory resolution. And it is precisely the want of such significance that precipitates the suffering that impels patients to seek medical resolution or treatment for what is essentially a nonmedical condition. (Indeed, the ineffably radical transformation of society over the last century, wrought by television, computers, motion pictures, radio and recorded sound, in diminishing and displacing a person’s traditional engagements to family, friends, nature, and religion, has left the individual human soul thoroughly dislocated. As electronic, anonymous engagement of that which is remote has displaced the natural, familiar engagement of that which is at hand, the significance so deeply and vitally coveted by human beings, at one time naturally accessible, has all but vanished.) In a day and age in which physicians seem almost universally to aspire to schedule as many patients in a given hour as possible, any
similarly denied by supposing to define matter as sensory ideas, received, classified, and suffered within the mind. However, if there is to be a basis of agreement among human beings on any subject, a starting point must be established with certain primary principles, of which idea and matter, as well as speech and conduct, naturally, and to be sure, universally, are observed by human beings in the practical exigencies of daily life.

While some legal scholars may conclude that the First Amendment’s freedom of speech protects scientific speech, the Supreme Court has ruled that freedom of speech, while protected by the Constitution, is not absolute. And just as the definition of freedom is properly circumscribed, so equally the definition of speech should not be allowed to suffer the dilution, diminution, or distortion of indiscriminate or inappropriate employment.

CONCLUSION

Some strenuously advocate cloning based upon the Constitution’s protection of individual right of privacy and reproductive freedom. Others peremptorily oppose asexual reproduction because it is neither historically rooted nor necessary to the Anglo-American tradition of ordered liberty. Clearly, the fear of the unknown has driven much of the opposition to reproductive cloning as have legitimate fears and skepticism about scientific and medical abuse. Hence, should scientists develop the ability to clone human beings in a manner that is reliably safe for both mother and child, no course of action which reduces the time they must spend with patients will surely be welcome. In short, there is simply no material disincentive to deter those in the health care industry—pharmaceutical companies, insurance companies, and physicians, from endorsing and promoting a neurochemical definition of human emotion, and so, human being.

174. Cantrell, supra note 160, at 73; see CARMEN, supra note 160, at 35.
175. Cantrell, supra note 160, at 73; see CARMEN, supra note 160, at 36; see also Abrams v. United States, 250 U.S. 616, 627 (1919) (Holmes, J., dissenting) (“I do not doubt for a moment that by the same reasoning that would justify punishing persuasion to murder, the United States constitutionally may punish speech that produces or is intended to produce a clear and imminent danger that it will bring about forthwith certain substantive evils that the United States constitutionally may seek to prevent.”); Whitney v. California, 274 U.S. 357, 373 (1927) (Brandeis, J., concurring) (“But, although the rights of free speech and assembly are fundamental, they are not in their nature absolute.”); Near v. Minnesota, 283 U.S. 697, 716 (1931) (“the protection [of free speech] even as to previous restraint is not absolutely unlimited.”).
constitutional basis seems to exist for denying infertile couples access to such technology.\textsuperscript{176}

However, the ability to clone human beings has not yet been achieved. While politicians and philosophers debate how many clones can dance on the head of the proverbial pin, the immediate, practical considerations render the matter peripheral rather than primary in importance. A more practical issue that calls for immediate resolution concerns the disputed domain where research into reproductive human cloning takes place—the scientific laboratory. While science has radically transformed society through such revolutionary inventions as the airplane, the motion picture, antibiotics, and the computer, science has also amplified humankind's destructiveness by providing society with the means to construct hydrogen, atomic, and nuclear bombs, as well as the means to irrevocably pollute the land, sea, and air. Moreover, the burgeoning ideals of eugenics have already wrought

\textsuperscript{176} It may be a mistake to speak of a constitutional right to reproduce through cloning, just as it may be equally inaccurate to speak of a constitutional right to vote, to marry, or to raise and educate one's children. One speaks more accurately, perhaps, by asking whether the principles of the Constitution protect or proscribe the challenged speech or conduct. The Constitution's enumerated rights are finite, and relatively few in number. The application, of these rights, of course, are inestimably broad and diverse in scope. Rather, the more proper inquiry might be whether the Constitution, in some provision or aspect, prohibits the disputed aim or interest.

The transcendent authority of the Constitution, and the greater cause of Truth, are better served by discussion of citizen's rights, not in terms of affirmative or express constitutional articulation, which enumeration, of necessity, is quite limited. Rather, we more wisely speak in terms of whether or not citizen's interests are, by the principals of the Constitution, protected or constrained. That is, does any principle of the Constitution protect or prohibit a man or woman from engaging in the challenged activity?

All legitimate and just rights are bestowed upon men and women, not by human edict or pronouncement. Rather, they are endowed by Nature, and acquire entitlement to protection by natural law; the Constitution merely provides the political and legal mechanism by which men and women may protect themselves from insidious governmental encroachment. To defiantly demand, insist upon, or proclaim one's interests because, one asserts, they are not enumerated but no less sacrosanct constitutional rights, threatens to mistake both the condition of life bestowed by Nature, and human aptitudes endowed by Providence, as mortal in origin or justification. It is a person's right to speak his or her mind, to seek redress from those who govern, to marry, and to reproduce, not because the Constitution gives a person these or any other rights. For surely these are not enumerated anywhere in that document, transcendent though its contents may be. Rather a person is entitled to protection of these rights because the attributes of a person's mind, and the innocence of his or her purpose, are sustained by a source greater than mortal men, which men, politically, commercially, religiously, and interpersonally, are wont to enslave and oppress their brethren. The Constitution embodies a finite number of rights, but the principles determinable from those rights are not similarly bound by a finitude in application.
catastrophic results: the infliction of suffering in the cruelest, most incomprehensible terms by Nazi Germany during World War II,\(^\text{177}\) thus proving that those who fear the abuse of such discoveries are not rightly dismissed as hysterical Cassandras. Because of the consequent apprehension, and in particular, the immediate fear of the casual misuse of fetal tissue and embryos, governmental regulation of human cloning research constitutes a proper, and ultimately, necessary step in the advance of science.

The most immediate danger in the attempt to clone a human being would be to the fetus.\(^\text{178}\) Indeed, the National Bioethics Advisory Commission observed that presently, using this technique to create children would pose significant dangers to developing children and the fetus.\(^\text{179}\) Such statements may appear to some as little more than governmental cant, but even Ian Wilmut, the scientist famed for cloning the first sheep, has condemned human cloning attempts as “criminally irresponsible,” observing that ninety-eight percent of embryos fail to survive gestation or birth.\(^\text{180}\) Wilmut has further expressed certainty that cloned human children would be born with abnormalities, and be predisposed to die prematurely.\(^\text{181}\) Indeed, so serious are the fears, and so legitimate are the dangers, that the Commission concluded unequivocally that human cloning should not presently be attempted.\(^\text{182}\) Moreover, a series of bills have been proposed by Congress in the attempt to prohibit human cloning.\(^\text{183}\) The Commission has expressed concerns about physical safety, about eugenics, as well as about the individuality, autonomy, objectification, and kinship of the resulting child.\(^\text{184}\) Legislation proposed in Congress has followed the specific regulations of the National Bioethics Advisory Commission.\(^\text{185}\) The Commission recommended a federally legislated prohibition on any attempt “whether in a research or a clinical setting, to create a child through somatic cell nuclear transfer cloning.”\(^\text{186}\) However, in anticipation of imminent advances in existing research, the Commission qualified its ban with the suggestion that such legislation include a sunset clause to ensure that Congress will review

\(^{177}\) Pelias, \textit{supra} note 66, at 843.

\(^{178}\) \textit{Cloning Human Beings}, \textit{supra} note 2.

\(^{179}\) \textit{Id}.

\(^{180}\) Gibbs, \textit{supra} note 7, at 4.

\(^{181}\) \textit{Id}.

\(^{182}\) \textit{Cloning Human Beings}, \textit{supra} note 2, at 3.


\(^{184}\) Robertson, \textit{supra} note 126.

\(^{185}\) \textit{Cloning Human Beings}, \textit{supra} note 2, at iv.

\(^{186}\) \textit{Id}.
the issue after a specified period in order to determine if the prohibition should continue.\textsuperscript{187}

The reproductive technology of cloning, like all scientific processes that prescribe human ingestion, implantation, and transplantation, requires governmental regulation as the only means available to protect the powerless and unknowing. Such regulation will serve not only the prospective parents of a cloned child, and the cloned child him or herself from the moment of conception; it will also protect society as a whole by upholding the sanctity of human life. Governmental regulation of human cloning will serve to ensure the health of prospective children, the safety and well-being of the mother, and ensure the propriety of genetic diagnosis and therapy.

Later in this century, the ability to reproduce asexually may be regarded as an utterly pedestrian fact of life much as the instant generation regards the ubiquitous presence of mobile telephones and portable computers as unremarkable. It is a potential that nevertheless succeeds in disorienting the minds of most men and women in the current day, who never supposed to imagine a means of human procreation other than sexual reproduction. While politically, socially, and legally, America's commitment to human freedom must check any hint that the government might suppose to exploit its power to proscribe a safe and reliable, albeit scientific means to reproduce, in contrast, the scientific and medical procedures themselves, precisely because unchecked, they may be abused with potentially disastrous effects, must be subject to governmental regulation. It is only with prudent and proper governmental regulation that society will be able to properly exploit cloning to achieve such heretofore unimaginable visionary ideals such as the finding of cures for disabling and horrific diseases, and defeating the continued hereditary transmission of defective genes.

\textsuperscript{187} \textit{Id.}
State v. North Florida Women’s Health & Counseling Services, Inc.: The Constitutionality of the Parental Notice of Abortion Act

Jesse Lieberman

I. INTRODUCTION

Christy is a seventeen-year-old pregnant girl. She is a junior in high school and in the top of her class. Christy plans on going to college and law school and eventually becoming a lawyer. Christy has never been as stressed as she is now. She has her SATs coming up in one month, a math test on Friday, and must make the toughest decision of her life—whether she should get an abortion.

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Jesse Alan Lieberman gives special thanks to his fiancée Andrea for her support and inspiration in writing this article. He would also like to thank his parents Evelyn and Eugene Lieberman and his dear friend Rachele Sannino for their encouragement and support.

I. This story is fictional, however, it demonstrates the practical effects of Florida’s Parental Notice of Abortion Act.
She definitely does not want to have this baby. If she becomes a mother now, she will not be able to live the life she was planning to live. She will not be able to go to college because she will have to get a job to support her child. Christy will not even get to go on her junior trip to Disney World because she will have to stay home and take care of her child. She simply is not ready to become a mother!

In order for Christy to obtain an abortion, under Florida law, the physician performing the abortion must first notify one of Christy’s parents. Christy knows her parents hold strong views on the subject of abortion and will force her to carry the pregnancy to term against her will. She fears they will do whatever they can to prevent her from having an abortion, including confining her to the house. She fears the significant medical risks that carrying a pregnancy to term poses on minors. Such risks include, “hemorrhage; infection; worsening medical complications, such as a seizure disorder or hypertension; risks associated with a caesarian section; and aggravation of chronic diseases, such as bowel problems, colitis, and anemia.”

Christy has no idea what to do. The longer she delays this decision, the greater the risks in obtaining an abortion. She is now thirteen weeks pregnant. Her risk of mortality from an abortion is now nine times as great as it was five weeks ago. She knows that she must make a decision soon before it is too late to obtain an abortion. Christy is considering either going to another state that does not have this notice requirement or obtaining an illegal abortion in Florida.

Jennifer is Christy’s friend and feels that she is in an even greater predicament. Jennifer is also a seventeen-year-old pregnant girl who has her SATs in a month, a math test on Friday, and wants to have an abortion. Jennifer fears that if one of her parents is notified that she is pregnant, her parents might force her to leave the house and will terminate financial support. She also fears that her parents will physically and emotionally abuse her if they find out that she was sexually active.

Tragically, the stories of Christy and Jennifer will be very similar to the stories of many minor girls in Florida if Florida’s Parental Notice of Abortion Act (“Act”) is ultimately found constitutional. The Act provides:

4. § 390.01115.
termination of pregnancy may not be performed or induced upon a minor unless the physician performing or inducing the termination of pregnancy has given at least 48 hours actual notice to one parent or to the legal guardian of the pregnant minor of his or her intention to perform or induce the termination of pregnancy.5

The Act further provides that notice is not required if: 1) an immediate abortion is medically necessary; 2) a parent or guardian waives notice; 3) the minor is "married or has had the disability of nonage removed;" 4) the minor has a minor child dependent on her; or 5) the minor has had the notice requirement removed through a judicial bypass procedure.6

This Act was supposed to become effective on July 1, 1999.7 However, on June 15, 1999, physicians who perform abortions, clinics that provide abortion services, women's rights organizations, and some minor female members filed a complaint presenting a facial challenge to the Act, along with a motion for a temporary injunction enjoining the enforcement of the Act.8 The circuit court granted the plaintiffs' motion for a temporary injunction on July 27, 1999.9 On May 12, 2000, the circuit court granted a final judgment granting a permanent injunction and concluded that the Parental Notice of Abortion Act was unconstitutional.10 On February 9, 2002.

5. § 390.01115(3)(a).
6. § 390.01115(3)(b)(1)–(5). In order for the notice requirement to be removed through a judicial bypass procedure, the minor must petition the court through clear evidence that she is sufficiently mature to decide whether to terminate her pregnancy, that there is parental abuse, or that notice is not in her best interest. The court shall hear evidence relating to the emotional development, maturity, intellect, and understanding of the minor. If the court does not make a ruling within forty eight hours after the petition is filed, the petition is granted and the notice requirement is waived. The minor has a right to appointed counsel, confidential proceedings, a full transcript of the proceedings, and an expedited appeal if necessary. § 390.01115(4).
7. Appellants' Initial Brief at 1, N. Fla. Women's Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D419.
8. N. Fla. Women's Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D420. Ordinarily only a person or family whose privacy rights are infringed or threatened has standing to assert the rights. But a "recognized exception" (citations omitted) applies where enforcement of a challenged restriction would adversely affect the rights of non-party, and there is no effective avenue for them to preserve their rights themselves. Id. at D420–21. This exception applies to physicians in the present case because physicians' own interests are at stake here. They are subject to discipline if they violate the notice provisions of the Act.
9. Id. at D420.
10. Id.
This article discusses whether Florida's Parental Notice of Abortion Act is constitutional under the Florida Constitution by analyzing the case of State v. North Florida Women's Health & Counseling Services, Inc. Section II of this article explores the circuit court's opinion, which found the statute to be unconstitutional. Section II also discusses the case of In re T.W., since the circuit court held that case was controlling precedent. Section III focuses on the appellants' arguments. Section IV addresses the appellees' arguments. Section V examines the opinion of the First District Court of Appeal of Florida, which found the statute constitutional and reversed the circuit court's ruling. Section VI discusses why the first district's holding should be reversed. Finally, Section VII concludes this comment.

II. THE CIRCUIT COURT'S RULING

On May 12, 2000, the circuit court ordered a final judgment granting a permanent injunction and concluded that the Parental Notice of Abortion Act was unconstitutional. The circuit court based its conclusions of law on the seminal case of In re T.W. In In re T.W., the Supreme Court of Florida ruled that a parental consent to abortion statute violated the Florida Constitution's right to privacy. The circuit court applied the same legal principles in the present case as were discussed in the case of In re T.W. This section examines the legal principles applied in the case of In re T.W.
After reviewing *In re T.W.*, the Appellants' Arguments section, summarizes the reasons why appellants in the present case feel that the circuit court's holding should be reversed.

In *In re T.W.*, the Supreme Court of Florida first discussed how the United States Supreme Court has, for the most part, left the issue of privacy to the states, like protection of a man's property and his own life. The court stated that "[w]hile the federal Constitution traditionally shields enumerated and implied individual liberties from encroachment by state or federal government, the federal court has long held that state constitutions may provide even greater protection." The court then held that the Florida citizens opted for a greater protection of the right to privacy when they approved, by a general election in 1980, Article I, Section 23, of the Florida Constitution: "Every natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law." The court further discussed how the drafters of the amendment rejected the words "unreasonable" or "unwarranted" before the phrase "governmental intrusion," making the right to privacy an even stronger right for the citizens of Florida.

After discussing the right to privacy in Florida, the court entertained the issue of whether this right is implicated in a woman's decision to continue her pregnancy. The court found that the right is in fact implicated and held that "[t]he Florida Constitution embodies the principle that 'few decisions are more personal and intimate, more properly private, or more basic to individual dignity and autonomy, than a woman's decision... whether to end her pregnancy. A woman's right to make that choice freely is fundamental.'"

The next question the court addressed was whether this freedom of choice concerning abortion extends to minors. The court concluded that it does, based on the language of the amendment: "[t]he right of privacy

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21. *Id.* at 1191.
23. *In re T.W.*, 551 So. 2d at 1191. At the time this opinion was written, Florida was one of the few states in this country having its own express constitutional provision guaranteeing an independent right to privacy. *Id.* at 1190.
25. *In re T.W.*, 551 So. 2d at 1191.
26. *Id.* at 1192–93.
27. *Id.* at 1193.
28. *Id.*
extends to "[e]very natural person." The court held that minors are natural people and, therefore, the amendment clearly applies to them. Even though the court held that the right extends to minors, a person’s right to privacy is not absolute. A governmental intrusion into a person’s private life is lawful, only if the following standard is met:

> [s]ince the privacy section as adopted contains no textual standard of review, it is important for us to identify an explicit standard to be applied in order to give proper force and effect to the amendment. The right of privacy is a fundamental right which we believe demands the compelling state interest standard. This test shifts the burden of proof to the state to justify an intrusion on privacy. The burden can be met by demonstrating that the challenged regulation serves a compelling state interest and accomplishes its goal through the use of the least intrusive means.

In applying this standard, the Supreme Court of Florida reviewed every state interest that is implicated in a minor’s abortion decision to determine whether any of these interests were compelling. The court found two interests implicated in a minor’s abortion decision, “the health of the mother and the potentiality of life in the fetus.” To determine whether these interests would be deemed compelling, the court used the same analysis that was used by the Supreme Court in Roe v. Wade. Under Roe v. Wade, the mother’s health does not become a compelling state interest until immediately following the end of the first trimester and the potentiality of life in the fetus first becomes a compelling state interest when the fetus becomes viable. The court in In re T.W. discussed how the parental consent to abortion statute intrudes upon the privacy of the pregnant minor from conception to birth. The court thus concluded that the health of the mother

29. Id.
30. In re T.W., 551 So. 2d at 1193.
31. Id.
32. Id.
33. Id. at 1192 (quoting Winfield v. Div. of Pari-Mutuel Wagering, 477 So. 2d 544, 547 (Fla. 1985)). This standard applies to everyone, regardless of age. In Winfield, this standard was applied to adults, and in In Re T.W., the standard was applied to a minor.
34. In re T.W., 551 So. 2d at 1193–95.
35. Id. at 1193.
36. Id.
38. Id. at 163.
and the potentiality of life in the fetus were not compelling state interests, because the statute’s “invasion of a pregnant female’s privacy by the state for the full term of the pregnancy is not necessary for the preservation of maternal health or the potentiality of life.”

The T.W. court found that two more state interests were implicated in a minor’s abortion decision, “protection of the immature minor and preservation of the family unit.” To determine whether these interests were compelling, the court examined section 743.065 of the Florida Statutes. The court then noted that “under this statute, a minor may consent, without parental approval, to any medical procedure involving her pregnancy or her existing child—no matter how dire the possible consequences—except abortion.” The court concluded:

[i]n light of this wide authority that the state grants an unwed minor to make life-or-death decisions concerning herself or an existing child without parental consent, we are unable to discern a special compelling interest on the part of the state under Florida law in protecting the minor only where abortion is concerned.

40. Id. at 1194.
41. Id.
42. See id. at 1195. Section 743.065 of the Florida Statutes provides:
Unwed pregnant minor or minor mother; consent to medical services for
minor or minor’s child valid.—
(1) An unwed pregnant minor may consent to the performance of medical or
surgical care or services relating to her pregnancy by a hospital or clinic or by
a physician licensed under chapter 458 or chapter 459, and such consent is
valid and binding as if she had achieved her majority.
(2) An unwed minor mother may consent to the performance of medical or
surgical care or services for her child by a hospital or clinic or by a physician
licensed under chapter 458 or chapter 459, and such consent is valid and
binding as if she had achieved her majority.
(3) Nothing in this Act shall affect the provisions of s. 390.001 [the abortion
statute].

43. In re T.W., 551 So. 2d at 1195.
44. Id. In N. Fla. Women’s Health & Counseling Serv., Inc., the circuit court also
found that sections 384.30 and 394.4784 of the Florida Statutes were inconsistent with the
Parental Notice of Abortion Act. Final Judgment Granting Permanent Injunction at 11–12,
State v. N. Fla. Women’s Health & Counseling Serv., Inc., 26 Fla. L. Weekly D419 (1st Dist.
Ct. App. Feb. 9, 2001). These statutes provide that physicians, health care professionals, and
health facilities “may examine and provide treatment for sexually transmitted diseases to any
minor” without any parental involvement, and a minor age 13 or over may obtain mental
health diagnostic and evaluative services and outpatient crisis intervention services without
Since the court found none of these interests compelling, the court held the statute requiring parental consent to abortion unconstitutional.45

III. APPELLANT’S ARGUMENTS

The appellants in North Florida Women’s Health & Counseling Services, Inc. first argued that the case of In re T.W. was not precedent, and therefore, the circuit court had no right holding the case of In re T.W. as controlling precedent.46 The appellants argued that “under the Florida Constitution, both a binding decision and a binding precedential opinion are created to the extent that at least four members of the Court have joined in an opinion and decision.”47 The appellants argued that In re T. W. was a plurality opinion and “[t]he views of the justices in T. W. were divided into five separate opinions, none of which garnered the four votes necessary to constitute a precedential ‘opinion’ under the Florida Constitution.”48

The appellants next argued that even if In re T. W. is precedent, “[t]he T. W. holding should be limited to the parental consent statute under consideration by the Court in that case.”49 In making this argument, the appellants cited to mainly federal law.50 Appellants argued that the courts have recognized a critical distinction between parental consent and parental notice statutes.51 Appellants then quoted a United States Supreme Court opinion:

[T]he difference between notice and consent [requirements] was apparent to us before and is apparent now. Unlike parental consent laws, a law requiring parental notice does not give any third party the legal right to make the minor’s decision for her, or to prevent her from obtaining an abortion should she choose to have one performed. We have acknowledged this distinction as “fundamental”

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45. In re T.W., 551 So. 2d at 1196.
47. Id. (quoting Santos v. State, 629 So. 2d 838, 840 (Fla. 1984)).
48. Id. (quoting Jones v. State, 640 So. 2d 1084, 1091 (Fla. 1994)).
49. Id. at 23.
50. Id. at 23–25.
Appellants stated that, unlike a consent statute, "a parental notice statute has neither 'the purpose nor effect of placing a substantial obstacle in the path of a woman seeking an abortion.'"\(^{53}\)

A third argument of appellants was that the circuit "failed to give deference to the Legislature's findings and conclusions as to the 'compelling state interest' for the Act."\(^{54}\) They argued that legislative determinations of public purpose and facts should not be ignored and are presumed correct and entitled to deference, unless clearly erroneous.\(^{55}\)

[52. Appellants' Initial Brief at 23–24 (quoting Hodgson, 497 U.S. at 496).]
[53. Id. at 24 (quoting Planned Parenthood v. Casey, 505 U.S. 833, 877 (1992)).]
[54. Id. at 20.]

The legislature made the following specific findings:

1) "immature minors often lack the ability to make informed choices that take into account both immediate and long-range consequences;" 
2) the "unique medical, emotional and psychological consequences of abortion are sometimes serious and can be lasting, particularly when the patient is immature;" 
3) the "capacity to become pregnant and the capacity for mature judgment concerning the wisdom of an abortion are not necessarily related;" 
4) parents ordinarily possess "information essential to a physician's exercise of his or her best medical judgment concerning the child;" 
5) parents who are "aware that their minor daughter has had an abortion may better ensure that she receives adequate medical attention after her abortion;" 
6) "parental consultation is usually desirable and in the best interests of the minor;"

As to the compelling state interests in the Act, the statute provides as follows:

The Legislature's purpose in enacting parental notice legislation is to further the important and compelling state interests of protecting minors against their own immaturity, fostering family unity and preserving the family as a viable social unit, protecting the constitutional rights of parents to rear children who are members of the household, . . . reducing teenage pregnancy and unnecessary abortion, . . . and ensur[ing] that parents are able to meet their high duty to seek out and follow medical advice pertaining to their children, stay apprised of the medical needs and physical condition of their children, and recognize complications that might arise following medical procedures or services, to preserve the right of parents to pursue a civil action on behalf of their child before expiration of the statute of limitation if a facility or physician commits medical malpractice that results in injury to a child, and to prevent, detect, and prosecute batteries, rapes, and other crimes committed upon minors.

Id. at 20–21.

55. Appellants' Initial Brief at 21 (citing State v. Division of Bond Fin., 495 So. 2d 183 (Fla. 1986); Miami Home Milk Producers Ass'n v. Milk Control Bd., 169 So. 541
Finally, appellants argued that minors do not share the same degree of privacy as adults and, therefore, the state may impose restrictions on minors’ privacy interests less intrusive than that of parental consent. They argued that “the right to privacy of an unemancipated minor is more limited than that of an adult.” Appellants asserted that the

Florida Legislature has in numerous areas prohibited or restricted a minor’s ability to make choices implicating privacy, including marriage without parental consent (§ 741.04(1), donating body parts (§ 381.0041), consenting to sexual intercourse with an adult (§ 800.04), receiving a permanent tattoo (§ 877.04), obtaining a driver’s license (§ 322.09), using a tanning facility (§ 381.89(7)), entering into contracts (Chapter 743), or remaining in public places during certain hours (§ 877.22).

IV. APPELLEE’S ARGUMENTS

Among the appellants’ arguments against the circuit court’s holding was the claim that the circuit court should not have held the case of In re T.W. as controlling precedent, since In re T.W. was only a plurality opinion. In response, appellees argued that all the legal principles applied by the circuit court in North Florida Women’s Health & Counseling Services, Inc. were espoused by a majority of the justices in In re T.W.

60. Appellees’ Answer Brief at 20–21, State v. N. Fla. Women’s Health & Counseling Serv., Inc., 26 Fla. L. Weekly D419 (1st Dist. Ct. App. Feb. 9, 2001). These legal principles include:

1. Florida’s State Constitution, . . . establishes a right of privacy that is stronger and more broad in scope than the right to privacy found in the federal constitution. [See In re T.W., 551 So. 2d 1186, 1190–92, 1197 (Fla. 1989)]

2. This right to privacy protects a woman’s right to freely choose whether or not to continue her pregnancy without interference from government or third persons. [See id. at 1192–93,1197]

3. This right to choose to terminate extends to minors. [See id. at 1193, 1197]

4. It is a right so fundamental that the State may intrude upon it only if it can demonstrate (a) a compelling state interest in doing so; and (b) seeks to accomplish it through the least intrusive means. [See id. at 1192, 1197]
Furthermore, appellees contended that the Supreme Court of Florida has repeatedly recognized the precedential weight of the *In re T.W.* decision, and therefore, the circuit court was correct in applying this decision as controlling precedent.  

Another argument of the appellants was that even if *In re T.W.* is precedent, "[t]he T.W. holding should be limited to the parental consent statute under consideration by the Court in that case." Appellees responded to this argument by claiming "that the parental notice law intrudes upon minors’ right to choose abortion and is similar in effect to a consent law." Appellees averred that:

Under both notice and consent laws, minors fear that telling their parents about an impending abortion will result in abuse, being expelled from the home, disturbing an already dysfunctional or troubled family situation, or a parent exercising a de facto veto power over the minor’s decision by, for example, confining her to the house or threatening punishment.

A third argument of the appellants was that the circuit court failed to give deference to the legislature’s findings and conclusions as to the “compelling state interest” for the Act. In response to this argument, appellees claimed that the legislative findings contained in the Act do not satisfy the state’s burden of demonstrating that the Act furthers a compelling state interest. Appellees asserted that declaring a certain objective a

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5. Neither the health of the mother nor the potentiality of life in the fetus can be a compelling state interest justifying an intrusion on the right to choose if it applies to terminations of pregnancies within the first trimester. [See id. at 1193–94, 1197–98]
6. The State’s interests in protecting an immature minor and fostering the integrity of the family, while important and worthy, do not justify restricting a minor’s right to choose abortion where similar restrictions are not imposed on comparable choices or decisions. [See id. at 1194–95, 1198–99]

*Id.*

61. Appellees’ Answer Brief at 22 (citing B.B. v. State, 659 So. 2d 256, 258 (Fla. 1995); Jones v. State, 640 So. 2d 1084, 1086–87 (Fla. 1994); Post-Newsweek Stations v. Doe, 612 So. 2d 549, 552 (Fla. 1992)).
62. Appellants’ Initial Brief at 23.
63. Appellees’ Answer Brief at 27.
64. *Id.* at 27–28.
65. Appellants’ Initial Brief at 20.
compelling state interest is not enough. It must be demonstrated through comprehensive and consistent legislative treatment. Appellees then stated that "[i]f the state could meet the compelling interest standard by inserting the word 'compelling' into legislative findings, the protection of fundamental rights under Florida law would be eviscerated, because any statutory restriction on privacy could satisfy this standard by legislative self-proclamation."

Finally, appellants argued that minors do not share the same degree of privacy as adults, and therefore, the state may impose restrictions on minors' privacy interests less intrusive than that of parental consent. In reply, appellees contended that "whether minors have the same right to privacy as adults, and whether the state may have compelling state interests that allow it to intrude on minors' privacy rights although not on the rights of adults," are two separate concepts. Therefore, the fact that many laws prohibit or restrict a minor's ability to make choices implicating privacy, does not mean that a minor does not have a right to privacy. It simply means that each of those statutes furthers a compelling state interest through the least intrusive means.

V. THE FIRST DISTRICT COURT OF APPEAL'S RULING

The court began its analysis by pointing out that the Florida constitutional right to privacy has been interpreted more broadly than any right to privacy guaranteed under the federal Constitution. The court then cited to In re T.W. for the proposition that the "Right to Privacy is implicated when the Legislature imposes restrictions on the ability, even of minors, to obtain abortions." The court also cited the plurality opinion of In re T.W. for the proposition that while minors' rights to privacy include "freedom of choice concerning abortion," they are not coextensive with adults' rights to privacy and "that a minor's rights are not absolute."

67. Id. at 29.
68. Id.
69. Id. at 30.
71. Appellees' Answer Brief at 24.
73. Id. at D421.
74. Id. (citing In re T.W., 551 So. 2d at 1193).
The court then noted that since the Act requires that a minor’s parent or guardian be notified that [the minor] intends to undergo an abortion, the Act plainly interferes with “the right to be let alone and free from governmental intrusion into the person’s private life.”\(^{75}\) The court therefore concluded that in order to withstand a constitutional challenge, the Act must serve a compelling state interest and do so by the least intrusive means practicable.\(^{76}\) The court then discussed whether the Act does in fact serve a compelling interest.\(^{77}\) The court noted that it does not have the authority to strike down the Parental Notice of Abortion Act even if the state only establishes that one interest is a compelling state interest and the Act furthers that interest by the least intrusive means.\(^{78}\) The First District Court of Appeal then held that the Act does establish at least one compelling state interest and accomplishes this interest through the least intrusive means:

> [b]y facilitating the ability of parents and guardians to fulfill their duty to provide appropriate medical care for their daughters or wards, the Act serves a compelling state interest. Parents are legally responsible for their minor children’s health insofar as it is in their power to foster it. They have a duty to stay alert to their minor children’s medical needs, and to secure appropriate medical assistance if they are able to do. See § 827.03(3)(a)1., Fla. Stat. (1999) (defining neglect as including the failure to provide necessary medicine and medical services); see also Finn v. Finn, 312 So. 2d 726, 730 (Fla. 1975) ("[A] parent has the obligation to nurture, support, educate, and protect his minor children and the child has the right to call on him for the discharge of this duty.")\(^{79}\)

In coming to this conclusion, the First District Court of Appeal cited In re T.W., and held that "[a]n important step in gauging whether an interest should be deemed compelling is ascertaining whether the Legislature has acted consistently in protecting the interest."\(^{80}\) The court then held that, since it is necessary for a minor child to obtain consent before that child can receive medical treatment (and therefore the parent must receive notice), the

\(^{75}\) Id.
\(^{76}\) Id.
\(^{77}\) N. Fla. Women’s Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D421.
\(^{78}\) Id. at D422.
\(^{79}\) Id.
\(^{80}\) Id.
The legislature has acted consistently in protecting the state's general interest in facilitating adult assistance in managing medical problems.\textsuperscript{81}

It is the subject of the state's compelling interest that causes the difference in opinion between the First District Court of Appeal and the circuit court. The lower court noted that, according to the Parental Notice of Abortion Act, notice is required to a parent or guardian of a minor before that minor may obtain an abortion.\textsuperscript{82} Yet, the circuit court also noted that under Florida law, notice is not required to a parent or guardian of a minor before that minor may obtain pregnancy treatment other than an abortion.\textsuperscript{83} Further, the circuit court held that, under Florida law, notice is not required to a parent or guardian of a minor before that minor may obtain treatment for sexually transmitted diseases.\textsuperscript{84} The circuit court thus concluded that the legislature's treatment of a minor's decision to choose an abortion is inconsistent with its treatment of comparable decisions by a minor; hence, it found the Parental Notice of Abortion Act unconstitutional.\textsuperscript{85} The First District Court of Appeal rejected the contention that the laws regarding pregnancy related treatment and treatment of sexually transmitted diseases substantiate a legislative discounting of the importance of adult assistance in managing minors' post-surgical care.\textsuperscript{86} The court stated that "[t]here are obvious and important differences between sexually transmitted diseases, pregnancies that go to term, and abortions and these differences logically account for the differential statutory treatment."\textsuperscript{87}

The court noted that the incidence of sexually transmitted diseases is rising at an alarming rate.\textsuperscript{88} The court further stated that

rather than risk a (larger) epidemic, the Legislature has made a clearly rational decision to minimize barriers to treatment for sexually transmitted diseases. Not requiring minors to notify their parents or guardians in order to obtain medical treatment for sexually transmissible diseases evinces a public policy which in no way undermines or discredits the state's interest in trying to assure the

\begin{thebibliography}{9}
\bibitem{81} Id.
\bibitem{82} Final Judgment Granting Permanent Injunction at 1, State v. N. Fla. Women's Health & Counseling Serv., Inc., (Fla. 2d Cir. Ct. 2000) (No. 99-3202).
\bibitem{83} \textit{N. Fla. Women's Health & Counseling Serv., Inc.}, 26 Fla. L. Weekly, at D422.
\bibitem{84} Id.
\bibitem{85} Id.
\bibitem{86} Id.
\bibitem{87} Id.
\end{thebibliography}
adequacy of minors' care while they are recovering from surgery, including abortions.\textsuperscript{89}

The First District Court of Appeal of Florida then gave its reason why it felt that pregnancies that go to term were treated differently by the legislature than abortions.\textsuperscript{90} The court reasoned that absent abortion, pregnancy-related treatment is by no means always surgery.\textsuperscript{91} "Such surgery as is necessary commonly occurs at the time of birth. By then most minors' pregnancies are likely to be known to a parent or guardian so that a formal, legal requirement to give notice would not meaningfully advance any state purpose."\textsuperscript{92}

VI. THE SUPREME COURT OF FLORIDA SHOULD REVERSE THE HOLDING OF THE FIRST DISTRICT COURT OF APPEAL

The first district agreed with the circuit court that: 1) the Florida constitutional right to privacy is greater than the federal constitutional right to privacy;\textsuperscript{93} 2) the right to privacy is implicated when the legislature imposes restrictions on the ability to obtain abortions;\textsuperscript{94} 3) minors also enjoy rights to privacy under the Florida Constitution;\textsuperscript{95} 4) in order to withstand a constitutional challenge, the Act must serve a compelling state interest and do so by the least intrusive means practicable;\textsuperscript{96} and 5) an important step in gauging whether an interest should be deemed compelling is ascertaining whether the legislature has acted consistently in protecting the interest.\textsuperscript{97} The first district only disagreed with the circuit court in that the circuit court found that the Act does not serve a compelling state interest and the first district found that it does.\textsuperscript{98} Therefore, the first district reversed the circuit court's holding solely because the first district found that the Act serves a compelling state interest. Consequently, the first district's holding should be reversed if its reasoning that the Act serves a compelling state interest is

\begin{itemize}
\item \textsuperscript{89} Id.
\item \textsuperscript{90} Id.
\item \textsuperscript{91} Id.
\item \textsuperscript{92} Id.
\item \textsuperscript{93} N. Fla. Women's Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D421.
\item \textsuperscript{94} Id.
\item \textsuperscript{95} Id.
\item \textsuperscript{96} Id.
\item \textsuperscript{97} Id.
\item \textsuperscript{98} N. Fla. Women's Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D421.
\end{itemize}
illogical. With that in mind, the following discussion attempts to show that the court's reasoning here is, in fact, illogical.

In the first district's opinion, the court cited to the case of In re T.W. on numerous occasions and clearly recognized the precedential weight of the In re T.W. decision. However, the first district ruled completely against the Supreme Court of Florida when it found that the Act serves a compelling state interest. In In re T.W., the Supreme Court of Florida found that the Parental Consent to Abortion Act was unconstitutional, because the legislature had not acted consistently in protecting the immature minor and the family unit.\(^{99}\) The Supreme Court of Florida found that, under Florida law, a minor may consent, without parental approval, to any medical procedure involving her pregnancy, except abortion.\(^{100}\) The court then found that:

In light of this wide authority that the state grants an unwed minor to make life-or-death decisions concerning herself or an existing child without parental consent, we are unable to discern a special compelling interest on the part of the state under Florida law in protecting the minor only where abortion is concerned.\(^{101}\)

In the present case, the first district held, in complete contrast to In re T.W., that "[f]or parental notification purposes, the legislature also has a legitimate basis for distinguishing between abortion and other pregnancy-related medical treatments."\(^{102}\) The court reasoned that, absent abortion, pregnancy-related treatment is by no means always surgery.\(^{103}\) "Such surgery as is necessary commonly occurs at the time of birth. By then most minors’ pregnancies are likely to be known to a parent or guardian so that a

100. Id.
101. Id. In N. Fla. Women's Health & Counseling Serv., Inc., the circuit court also found that sections 384.30 and 394.4784 of the Florida Statutes were inconsistent with the Parental Notice of Abortion Act. Final Judgment Granting Permanent Injunction at 11–12, State v. N. Fla. Women’s Health & Counseling Serv., Inc., 26 Fla. L. Weekly D419 (1st Dist. Ct. App. Feb. 9, 2001). These statutes provide that physicians, health care professionals, and health facilities "may examine and provide treatment for sexually transmitted diseases to any minor" without any parental involvement, and a minor aged thirteen or over may obtain mental health diagnostic and evaluative services and outpatient crisis intervention services without parental involvement. Fla. Stat. §§ 384.30, 394.4784 (2000).
102. N. Fla. Women's Health & Counseling Serv., Inc., 26 Fla. L. Weekly at D422.
103. Id.
formal, legal requirement to give notice would not meaningfully advance any state purpose."\textsuperscript{104}

The first district also held that the state has an interest in encouraging minors to seek treatment for sexually transmitted diseases, but has no such interest in encouraging abortions.\textsuperscript{105}

These alleged differences are no different now than when \textit{In re T.W.} was decided and the Supreme Court of Florida in \textit{In re T.W.} obviously considered them insignificant when the court held that the Florida Legislature had acted inconsistently in protecting the immature minor and the family unit.\textsuperscript{106}

For the foregoing reasons, the holding of the First District Court of Appeal of Florida is inconsistent with the Supreme Court of Florida's holding in \textit{In re T.W}. Furthermore, it is illogical, and therefore, should be reversed.

\textbf{VII. CONCLUSION}

The issue of the constitutionality of the Parental Notice of Abortion Act is far from over. There are many possibilities of what the future may hold. One slight possibility is that the plaintiffs will choose not to do anything at all and, in effect, surrender. If this happens, trial courts throughout the state will have to obey the first district's holding that the Act is constitutional.\textsuperscript{107}

\begin{itemize}
  \item[104.] \textit{Id.}
  \item[105.] \textit{Id.}
  \item[106.] Final Judgment Granting Permanent Injunction at 12, \textit{N. Fla. Women's Health \& Counseling Serv., Inc.}, 26 Fla. L. Weekly at D419.
  \item[107.] This will be the result, because the issue of whether the Parental Notice of Abortion Act is constitutional has not been addressed by any other District Court of Appeal in Florida. \textit{State v. Hayes} was the first case in Florida to address this issue. This case held that in absence of a contrary Fourth District Court of Appeal opinion a Palm Beach County circuit court was bound to follow an opinion of the First District Court of Appeal.
\end{itemize}

In Florida the District Courts of Appeal are courts of final appellate jurisdiction except for a narrow classification of cases made reviewable by the Florida Supreme Court (citations omitted). The District Courts of Appeal are required to follow Supreme Court decisions. As an adjunct to this rule it is logical and necessary in order to preserve stability and predictability in the law that, likewise, trial courts be required to follow the holdings of higher courts District Courts of Appeal. The proper hierarchy of decisional holdings would demand that in the event the only case on point on a district level is from a district other than the one in which the trial court is located, the trial court be required to follow that decision (citations omitted). Alternatively, if
A more likely possibility is that plaintiffs will file a motion to stay the issuance of the mandate from the First District Court of Appeal, pending review by the Supreme Court of Florida. If the first district grants a stay pending review by the Supreme Court of Florida, then the Parental Notice of Abortion Act will not become effective until the Supreme Court of Florida has made a ruling on the case. However, the Supreme Court of Florida might make a ruling not to make a ruling. In other words, they might deny certiorari. This is unlikely, and the Supreme Court of Florida will most likely hear this case, because it raises questions of great public importance that are likely to recur.

It is hard to make a prediction on how the Supreme Court of Florida will rule, but if it affirms the decision of the First District Court of Appeal, this case is most likely over. Even if the United States Supreme Court would decide to hear this case, it would most likely hold the Parental Notice of Abortion Act constitutional. The reason for this is that in Lambert v. Wickland, the United States Supreme Court upheld a Montana notice statute that is very similar to the statute in the present case.

No matter what happens in the future of this case, the issues raised will forever be debated. This is because, in some cases, it is extremely beneficial for a parent to receive notice before his or her daughter obtains an abortion, while in other cases, it is very detrimental. This makes it very hard for us to decide on the constitutionality of a law that requires notice for the whole state of Florida. Fortunately, we do not need to make this decision. We leave this to the courts, for judges have and will continue to struggle with cases involving such difficult issues.
Charitable Choice: The Ramifications of Government Funding for Faith-Based Health Care Services

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I. INTRODUCTION

In 1996, Congress passed the federal welfare reform bill to help move millions of Americans from welfare to work. Primary in this bill is a provision, known as Charitable Choice, that authorizes faith-based organizations to compete alongside secular organizations to provide a wide range of federally funded welfare, health, and social services. The term “faith-based organization” includes at least three different types of organizations: 1) national denominations with social service arms like Catholic Charities and Jewish Family Services; 2) community development corporations that are incorporated separately from


2. Gretchen M. Griener, Charitable Choice Welfare Reform: Collaboration between State and Local Government and Faith-Based Organizations, 4 Welfare Information Network 1 (Sept. 2000), at http://www.welfareinfo.org/issuenotecharitablechoice.htm. The term “faith-based organization” includes at least three different types of organizations: 1) national denominations with social service arms like Catholic Charities and Jewish Family Services; 2) community development corporations that are incorporated separately from
The First Amendment, in the language of its clauses, erects a boundary between the federal government and religious institutions by ensuring that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . . ." The two clauses of the amendment guarantee two distinct forms of religious liberty. "The Establishment Clause prevents the government from imposing religion on people," and the Free Exercise Clause prevents government from interfering with the religion people choose to exercise. Because Charitable Choice allows pervasively religious organizations to compete for federal funding to provide services to the needy, potential conflicts with the separation of church and state guaranteed in the First Amendment may arise.

This article will explore Charitable Choice and its practical implications, as well as its possible constitutional conflicts. It argues that despite well crafted language, which may allow Charitable Choice legislation to pass constitutional muster, profound issues are raised when the states extend Charitable Choice laws as a new national social policy. These policies, particularly in regard to providing healthcare services for the poor through religious outreach, appear to be designed primarily as an effort to shift more responsibilities currently filled by government to the private sector.

congregations but with a religious base, and; 3) congregations and churches. Id. There is no agreement as to what specifically defines a faith-based organization. See id.


6. Id. at 40. "Pervasively sectarian" institutions are defined as those where "religion is so pervasive that a substantial portion of its functions are subscribed in the religious mission." Id. In such an institution, even aid designated for secular purposes "may nonetheless advance the pervasively sectarian institution's 'religious mission.'" Id. "The risk of such inappropriate grants, however, did not justify striking down the act as unconstitutional . . . ." Id. See also Bowen v. Kendrick, 487 U.S. 589, 610 (1988) (quoting Hunt v. McNair, 413 U.S. 734, 743 (1973)).

7. See Rebecca Carr, Leader of Faith-Based Proposal Is a Fighter, PALM BEACH POST, Apr. 8, 2000, at 21A. John DiIulio is now the director of the new White House Office of Faith-Based and Community Initiatives. Id. He promotes Charitable Choice legislation to give religious organizations more "access to federal money to deliver social services." Id. Appointed by President George W. Bush, DiIulio says he first realized the power of African-American churches on his community growing up in his Catholic blue-collar Philadelphia neighborhood. Id. DiIulio stated, in a recent White House interview, that much of America's social capital is thriving in churches, mosques, and synagogues that government should support those efforts. Id. "To work around these organizations as if they are somehow
First, the nature and history of Charitable Choice on the federal and state levels will be discussed. Second, the article will examine the legal evolution of the boundary between church and state, and analyze the relevance of that boundary to Charitable Choice legislation. Third, since there has been no Supreme Court case that has ruled directly on the constitutionality of Charitable Choice, a real-life scenario involving the proposed closing of a hospital in West Palm Beach, Florida will be studied. This example will highlight some possible ramifications in the event that a community faces the choice of providing its safety net healthcare through pervasively religious groups rather than providing no healthcare access for their poor.

II. WHAT IS CHARITABLE CHOICE?

A. Definition of Faith-Based Services

The 1996 federal welfare reform bill restructured the federal welfare system. This legislation, formally entitled the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), replaced the former federal entitlement program known as Aid to Families with Dependent Children (AFDC) with a block grant program, Temporary Assistance to Needy Families (TANF), to be administered by the states. This block grant to the states provides cash assistance to needy families within a five-year lifetime limit. When the welfare reform law

8. The controversy is clear in the comments of Marvin Olasky, senior fellow at the Acton Institute and editor of World magazine, who was President George W. Bush’s chief architect for the “compassionate conservative” philosophy. Olasky criticizes John Dilulio’s approach to open up federal money to “fringe” religions. Olasky says Dilulio should avoid controversies and stick to promoting less controversial faith-based proposals like regulatory reform, tax code incentives, and non-discrimination in grant making. The controversy is further underscored in a recent poll for the People and the Press and the Pew Forum on Religion and Public Life, which found seventy-five percent of Americans favored the president’s faith-based initiative, but only thirty-eight percent favored giving money to Muslim mosques or Buddhist temples. See Kingsley Guy, Cult Status As Much Political As Theological, SUN-SENTINEL (Pt. Lauderdale), Apr. 20, 2001, at 23A.

passed as H.R. 3734, Medicaid might also have been reorganized along similar lines. However, Medicaid’s entitlement status was not changed, despite an initial attempt to restructure Medicaid as a block grant as well. Instead, the bill delinked welfare and Medicaid eligibility, narrowed Medicaid eligibility for disabled children in the Supplementary Security Income (SSI) program, terminated access to Medicaid for some legal immigrants through loss of SSI, and barred most future legal immigrants from Medicaid.

Basically, the welfare reform law reduced the number of people covered and lowered federal expenditures by a projected $4 billion over six years, through 2002, while giving the states more flexibility in structuring their welfare and health insurance programs. Yet, the former welfare population could still qualify for Medicaid health insurance coverage under separate standards. Within this welfare reform law, in section 104, is a key provision called Charitable Choice. This provision is designed to stimulate

11. Ku, supra note 9, at 14. The major policy goal of the new welfare law was to provide more flexibility to states in both welfare and Medicaid, albeit with fewer dollars. Id. But counties and cities that maintain public or safety net hospitals that serve large numbers of indigent and uninsured patients would need to tap other local or state revenue sources to cover the uncompensated care costs. Id. Most affected will be hospitals and clinics in high immigrant areas such as South Florida, South Texas, or New York City. Id. at 5.

The specific sections of § 604(a) provide:
(a) In general
(1) State options
A State may—
(A) administer and provide services under the programs described in subparagraphs (A) and (B)(i) of paragraph (2) through contracts with charitable, religious, or private organizations; and
(B) provide beneficiaries of assistance under the programs described in subparagraphs (A) and (B)(ii) of paragraph (2) with certificates, vouchers, or other forms of disbursement which are redeemable with such organizations.
(2) Programs described
The programs described in this paragraph are the following programs:
(A) A State program funded under Part A of title IV of the Social Security Act (as amended by section 103 (a) of this Act).
(B) Any other program established or modified under title I or II of this Act, that—
(i) permits contracts with organizations; or
(ii) permits certificates, vouchers, or other forms of disbursement to be provided to beneficiaries, as a means of providing assistance.
(b) Religious Organizations

The purpose of this section is to allow States to contract with religious organizations, or to allow religious organizations to accept certificates, vouchers, or other forms of disbursement under any program described in subsection (a)(2) of this section, on the same basis as any other nongovernmental provider without impairing the religious character of such organizations, and without diminishing the religious freedom of beneficiaries of assistance funded under such program.

(c) Nondiscrimination against religious organizations

In the event a State exercises its authority under subsection (a) of this section, religious organizations are eligible, on the same basis as any other private organizations, as contractors to provide assistance, or to accept certificates, vouchers, or other forms of disbursement, under any program described in subsection (a)(2) of this section so long as the programs are implemented consistent with the Establishment Clause of the United States Constitution. Except as provided in subsection (k) of this section, neither the Federal Government nor a State receiving funds under such programs shall discriminate against an organization which is or applies to be a contractor to provide assistance, or which accepts certificates, vouchers, or other forms of disbursement, on the basis that the organization has a religious character.

(d) Religious character and freedom

(1) Religious organizations

A religious organization with a contract described in subsection (a)(1)(A) of this section, or which accepts certificates, vouchers, or other forms of disbursement under subsection (a)(1)(B) of this section, shall retain its independence from Federal, State, and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) Additional safeguards

Neither the Federal Government nor a State shall require a religious organization to:

(A) alter its form of internal governance; or

(B) remove religious art, icons, scripture, or other symbols; in order to be eligible to contract to provide assistance, or to accept certificates, vouchers, or other forms of disbursement, funded under a program described in subsection (a)(2) of this section.

(e) Rights of beneficiaries of assistance

(1) In general.

If an individual described in paragraph (2) has an objection to the religious character of the organization or institution from which the individual receives, or would receive, assistance funded under any program described in subsection (a)(2) of this section, the State in which the individual resides shall provide such individual (if otherwise eligible for such assistance) within a reasonable period of time after the date of such objection with assistance from an alternative provider that is accessible to the individual and the value of which is not less than the value of the assistance which the individual would have received from such organization.

(2) Individual described

An individual described in this paragraph is an individual who receives, applies for, or requests to apply for, assistance under a program described in subsection (a)(2) of this section.

(f) Employment Practices
new collaborations between government and faith-based organizations (FBOs), particularly in regard to spending Temporary Assistance for Needy Families (TANF) funds, the new name for federal welfare money provided as block grants to the states to administer.

Pursuant to section 104 of PRWORA, state governments which opt to contract with social service providers cannot legally prevent FBOs from competing for contracts simply because they are pervasively sectarian. The Charitable Choice provision, authored by Senator John Ashcroft of Missouri, prior to his recent appointment as Attorney General, has three basic goals: 1) to encourage states to expand the involvement of community and faith-based organizations in providing local services; 2) to protect the religious character of participating faith-based organizations; and 3) to protect the religious liberty of the individuals they may serve.

The theory behind Charitable Choice relies on three statutory principles: 1) to provide a nondiscrimination provision against religious providers; 2) to protect the rights of faith-based providers to keep their institutional autonomy; and 3) to provide choice through the free exercise rights of beneficiaries to say “no” to the services provided by a religious provider. By stating that beneficiaries who object to receiving faith-based services have the choice of which service provider to utilize, section 104 codifies the constitutional requirements for governmental interaction with faith-based providers in a way that intends to honor United States Supreme Court decisions.

A religious organization’s exemption provided under section [702 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-1a)] regarding employment practices shall not be affected by its participation in, or receipt of funds from, programs described in subsection (a)(2) of this section.

(g) Nondiscrimination against beneficiaries

Except as otherwise provided in law, a religious organization shall not discriminate against an individual in regard to rendering assistance funded under any program described in subsection (a)(2) of this section on the basis of religion, a religious belief, or refusal to actively participate in a religious practice.

13. The term “faith-based” organization or provider of services is used here very broadly to include whatever is generally construed to mean a religious organization under the Establishment Clause of the United States Constitution.

14. See http://www.fed-soc.org/Publications/practicegroupnewsletters/PG%20Links/charchoice.htm (last visited Jan. 27, 2002). Carl Esbeck, Director of the Center for Law and Religious Freedom, described these goals in a panel debate with Elliot Mincberg, Policy Director for the People for the American Way Foundation sponsored by the Federalist Society, a conservative group. Id. Esbeck, one of the chief architects of Charitable Choice, argues that it is consistent with the Establishment Clause, while Mincberg argues that it is unconstitutional. Id.

15. Id.
Court precedents for government neutrality. How the Supreme Court will ultimately decide the constitutionality of Charitable Choice remains unclear, but it seems likely from President Bush’s track record in Texas on Charitable Choice, and his proactive stand on the concept since entering the White House, that the federal government will avidly embrace the concept of working with faith-based organizations.

Since the Charitable Choice law is designed to make social service grants available to religious groups without impairing the religious character of those groups, the very essence of these faith-based organizations seems to lie in the strength of their religious message. Since this is emerging territory for the boundaries between church and state, and moves the boundary line, it is likely to stimulate defining litigation in at least four areas which may pose concerns: proselytizing beneficiaries; employment discrimination on the basis of religion; government entanglement; and adverse effects on religious missions. But key to any court analysis on how far to go in deregulating religion will be whether Charitable Choice truly provides choice to beneficiaries to avoid religious coercion as a condition of getting government-funded services.

The language of section 104 requires the states to provide an alternative to a religious provider if there is objection, and the alternative must be both timely and of comparable service. The Charitable Choice provision got little attention when it was first adopted as part of the welfare overhaul in 1996. Nor did it appear on many radar screens when it was expanded to cover drug treatment and community development grants in 1998. However, when President Bush created the White House Office of Faith-Based and Community Initiatives in late January to launch his plan to use government money to fund religious charities providing social services, new attention focused on this existing provision of the law.

16. Agostini v. Felton, 521 U.S. 203, 230–31 (1997). The neutrality principle inherent in the Establishment Clause does not bar the government from providing public funds to religious organizations, provided the purpose is interpreted as neutral. Id. The Agostini Court held that public school teachers could provide federally funded remedial education to disadvantaged students in parochial schools. Id. Agostini assumes public funding distributed in a neutral fashion is “less likely to have the effect of advancing religion.” Id.

17. See Julie A. Segal, Welfare for Churches: Buyers and Beneficiaries Beware, 5 GEO. J. ON FIGHTING POVERTY 71 (Winter 1997). The writer is a policy analyst for Americans United for Separation of Church and State, which argues against the constitutionality of Charitable Choice. Id.

18. Laura Meckler, Bill Expands ‘Charitable Choices,’ SUN-SENTINEL (Ft. Lauderdale), Mar. 4, 2001, at 1B.
Presently, members of Congress are pressing ahead with legislation to allow religious groups to compete for government money, including a major expansion of charitable choices, which allows groups to qualify for grants without divorcing their programs from religion. Senator Rick Santorum, (R-Pennsylvania), along with Representatives J.C. Watts, Jr. (R-Oklahoma), and Tony P. Hall, (D-Ohio), plan to introduce expanded legislation later this year, which translates President Bush's plans into future law. Faith-based providers held an organizational summit for Congress in Washington on April 24–25, 2001, to further advocate for legislation to expand the plans.

But legislators have recently slowed down the effort to give more time to fine-tune the proposals, which ran into controversy and were unexpectedly criticized by religious conservatives, as well as civil libertarians. Critics on the right reportedly fear the program could cause churches to become dependent on government funds, and objectionable sects could be funded. On the left, opponents fear an expanded program would chip away at the separation between church and state and permit government funded hiring discrimination. President Bush said at a press conference on February 22, 2001, defending his plan: "I believe that so long as there's a secular alternative available, we ought to allow individuals who we're helping to be able to choose a program that may be run by a faith-based program."

19. Elizabeth Becker, Bill on Church Aid Proposes Tax Incentives for Giving, N.Y. TIMES, Mar. 18, 2001, at 18. These bills will include tax credits to help low income workers open savings accounts at banks, charitable contribution deductions for people who do not itemize deductions on their income tax returns, and full deductions for donations of food to charities for restaurants and grocers. Id. Interestingly, this suggests that private, profit-making organizations like banks, restaurants, and grocers are the first in line to get tax breaks from faith-based initiatives.

20. Dana Milbank, Senators Slow Action on 'Faith-Based' Aid, WASH. POST, Mar. 14, 2001, at A11. Sen. Rick Santorum (R-Pa.) will wait several months to a year now to act on Charitable Choice in order to build consensus for his proposal and will likely split the bill in two. Id. The first bill will focus on tax incentives for charitable giving which has broad-based support. Id. The second part will likely be an incremental approach to charitable choice which he hopes to expand to five Cabinet agencies. Id.


President Bush’s comment stresses the choice factor inherent in the charitable choice provision. However, a central question is not being raised. What occurs under Charitable Choice provisions when, in terms of practical applications, there is no alternative choice available?

B. Background

Throughout America, healthcare is undergoing a major structural transformation. According to the Robert Wood Johnson Foundation, “one-third of all hospitals in the United States are failing financially, an equal percentage is [approaching fiscal failure], and the other third is barely making it.”23 As healthcare in the United States faces a significant financial crisis resulting in aggressive managed care and changing government policies, hospital markets around the country face declining occupancy rates and inpatient activity. These declines suggest many markets will face the continuing shrinkage of their healthcare providers through merger and consolidation. Such a scenario assures many markets fewer choices for healthcare and may undercut the implicit promise in Charitable Choice, that there will be alternative providers if needed.

Charitable Choice legislation represents a significant change from the historical practices and approaches of government in funding religious groups. Faith-based providers have long provided services to the poor.24 In the past, the government often would contract with religious groups to provide certain services, but safeguards were typically kept in place to protect the integrity of the groups and the interests of taxpayers.25 Previously, religious institutions had to create separate secular entities, (separate 501(c)(3) organizations), or sanitize its religious nature to receive public


25. See ACLU Briefing Paper Number 3—Church and State, at http://www.lectlaw .com/files/con07.htm (last visited Jan. 12, 2002). The ACLU believes government funding of services within religious facilities is constitutional only if: 1) the program is run by a nonreligious group; 2) the nonreligious group’s staff has no association with the religious facility; 3) the program has no religious content; 4) no religious symbols are displayed; 5) children are admitted on a nondiscriminatory basis, and; 6) government pay only to rent the religious facility. Id. This view contrasts sharply with the Charitable Choice provision. Id.
funds. Theoretically, these separate corporations allowed government to ensure that tax money was used for secular purposes, such as health services only, rather than for religious worship or proselytizing.  

Charitable Choice removes the safeguards, allows groups to evangelize while providing publicly financed services, and permits groups to discriminate in hiring on religious grounds. There may be significant, if not radical changes in the way healthcare is funded in the future. Since the welfare reform bill passed, millions of people were moved from welfare to the job market, but needed transitional healthcare benefits, paid for by Medicaid, to do so. Medicaid, the joint federal-state government-funded healthcare program for low income citizens, insures forty-one million Americans through a federal-state partnership. The Charitable Choice provision applies when states enter into purchase-of-service contracts or voucher arrangements with independent sector organizations under the Temporary Assistance for Needy Families program (TANF).

TANF provides states with grants to be spent on time-limited cash assistance. TANF generally limits a family’s lifetime cash welfare benefits to a maximum of five years and permits states to impose a wide range of other requirements, such as employment. If a person was eligible for AFDC, he or she would still be eligible for Medicaid, but although most persons covered by TANF will receive Medicaid, it is no longer required by law—in essence, Medicaid and welfare eligibility are no longer linked.

26. Bowen v. Kendrick, 487 U.S. 589, 631 (1988) (Blackmun, J., dissenting). In discussing pervasively sectarian environments and proselytizing, the case described these issues as terms of art with roots in the “Court’s recognition that government must not engage in detailed supervision of the inner workings of religious institutions . . . .” Id.

27. See generally Americans United for Separation of Church and State, (Apr. 11, 2001), at http://www.au.org/press/pr41101.htm (opposing the Watts-Hall bill, (H.R. 7) as subsidizing religious discrimination and citing a poll released by the Pew Forum showing that 78% of Americans say government-funded religious groups should not be able to hire only people who share their beliefs to staff programs, a key component of the Bush plan).

28. Interview with Louis Sullivan, M.D., Goodwin Seminar Speaker, Shepard Broad Law Center, Nova Southeastern University in Ft. Lauderdale, Fla. (Apr. 16, 2001). According to Dr. Louis Sullivan, former head of HHS, current HHS Director Tommy Thompson may be creative in forging national healthcare policy for the poor through transitional healthcare waivers now being crafted through welfare reform. Id.

29. Letter from Timothy M. Westmoreland, Director of Health Care Financing Administration, to State Medicaid Directors (Jan. 6, 2000).


31. Id.

32. Id. AFDC was codified at 42 U.S.C. § 601 et seq. (repealed by § 103(a) of DRWORA).
Charitable Choice also applies to the Supplementary Security Income (SSI) program, and therefore can be read to include food stamps and Medicaid programs, to the extent that states administer these programs using contracts or vouchers with non-governmental providers. Broadly interpreted, faith-based providers could offer everything from maternity homes, medical and health services that include drug and alcohol treatment, and primary healthcare. Since states may also contract with faith-based providers to administer social services, this could encompass setting eligibility standards for beneficiaries. Medicaid spending rose nine percent nationally last year, the largest increase in seven years, and now costs the states more than $200 billion a year. Legislators are scrambling to find ways to cut these costs and to provide more flexibility for shifting the costs of government programs to local providers.

C. The National Situation

On the national level, Charitable Choice has become one of the key struggles in church/state legislative activities with many special interest groups lining up on both sides of the issue. Its supporters include the Center for Public Justice, the Christian Legal Society, the National Association of Evangelicals, and the Union of Orthodox Jewish Congregations, to name but a few. Groups opposed include the American Civil Liberties Union, the American Jewish Committee, Americans United for the Separation of Church and State, and many conservative religious groups. These groups

33. In 1996, the State of Texas asked the Clinton Administration to approve their plan to contract out welfare, Medicaid, and food stamps. See Barbara Vobejda, Privatization of Social Programs Curbed; Texas Is Told Firms Can't Determine Medicaid, Food Stamp Eligibility, WASH. POST, May 10, 1997, at A9. Clinton approved only the welfare waiver, but not Medicaid and food stamps. Id. But under President Bush, new interest in broader waivers seems likely.

34. According to the analysis of the Congressional Research Service, these additional programs are the SSI program, and probably the food stamps, and Medicaid programs. See CRS memo, "Questions Re Section 104 of P.L. 104–193 (H.R. 3734) Concerning Services Provided by Charitable Religious or Private Organizations," Sept. 1996 (from the American Law Division), and CRES memo "Application of Section 104 of P.L. 104–193" Oct. 18, 1996 (by the Education and Public Welfare Division).


36. Id.


perceive that funding and regulation in the long run are inescapably intertwined, and it is unwise to allow religious organizations to become financially beholden to government. They see great risk in allowing government funds to go to pervasively religious institutions without adequate safeguards.

These groups hold that Charitable Choice chips away at the wall between church and state, and unconstitutionally permits government advancement of religions, while risking a general weakening of religious autonomy and integrity. Some social policy advocates also fear that government reliance on faith-based organizations for social services could weaken the social safety net, by allowing the government to retreat from its traditional role as a health and social service provider, and to shift the social and financial burden to private institutions. Whether this shift of services from public to private providers is a realistic possibility is questionable given the current amount of social services provided by the private sector. There have been major efforts to document how much aid church-related groups give to the poor.

In 1994, private contributions to the six largest faith-based organizations totaled $1.67 billion. This sum included $644 million to the Salvation Army; $315 million to the Union of Gospel Missions; $250 million to Jewish Federations; $204 million to Catholic Charities USA; $106 million to Christian Social Service Agencies; and $15 million to the YMCA. The percentage of funds that goes to social services is hard to determine because many of the major denominations, including the Evangelical Lutherans, the Southern Baptists, the United Methodists, and some Catholic archdioceses do not keep records on what social services its churches or parishes provide.

39. Id.
40. Id.
41. Id.
43. There is no common definition as to what comprises a faith-based or religious institution. President Bush has talked about Chuck Colson’s prison ministry. But such a mainstream concept may be quite different in operation than the street ministry of Minister Louis Farrakhan’s Nation of Islam or the beliefs held by the Church of Scientology, all of which could likely qualify to compete for tax money. See Griener, supra note 2; Mark Chaves, Religious Congregations and Welfare Reform: Who Will Take Advantage of Charitable Choice? AM. SOC. REV. 836–46 (Dec. 1999) (noting few clerics understand the issue yet, but black churches are more likely than white to participate in government faith-based contracts). Id.
The American Association of Fund Raising counsel estimates about twelve percent of the amount raised by churches and synagogues “annually goes to ‘direct social service provision by congregations.’ [which] [i]n 1995 would have amounted to $12.6 billion.” Since 1996, Congress has passed additional legislation involving Charitable Choice provisions. These include: the Welfare-to-Work program (1997); the Community Services Block Grant program funded by the Health and Human Service Reauthorization Act (1998); the drug treatment programs funded by the Substance Abuse and Mental Health Services Administration (2000); and the Community Renewal and New Markets Act of 2000. The purpose of President Bush’s aforementioned Executive Order of January 29, 2001, which authorized the establishment of an Executive Department Center for Faith-Based and Community Initiatives, is to expand Charitable Choice legislation, and to ensure that states, local government, and its contractors comply with the law. He estimates it would cost $8 billion in the first year of his administration.

Proponents continue to attach Charitable Choice provisions to popular legislation. In the last session of Congress, several acts of health-related legislation included the provisions. The American Community Renewal Act (H.R. 815), could require substance abuse beneficiaries to “actively participate in religious practice, worship and instruction.” The Adoption Awareness Act of 1999 was marked up as part of the Child Health Act of 2000, but not included. Other pieces of legislation include a Safe and Drug Free Schools and Communities bill, the Substance Abuse Mental Health Reauthorization Act (SAMHSA), and the Faith-Based Drug Treatment Enhancement Act, which explicitly allows religious organizations to receive federal funds for substance abuse treatment and rehabilitation, and requires beneficiaries to actively participate in religious practice, worship, and instruction.


Faith-based models for rehabilitating inner-city drug addicts abound, and popular support for church-state partnerships seems to be on the rise. A poll for the Democratic Leadership Council in 1999 found seventy-two percent of Americans favor close collaboration between government, religious, and charitable organizations to address the nation's problems, and "[t]he Pew Forum on Religion and Public Life reports even higher support among minorities and low-income families for such collaborations."

These trends suggest a climate which would welcome the shift of social services and costs to the private sector.

Already, Congress has jumped on the idea of a market-based system for healthcare delivery. A market-based system, in which economic market forces regulate healthcare provisions, has been the pet project of conservative groups such as the Heritage Foundation for some time. Senator John Breaux (D)-La. and Senator Bill Frist (R)-Tenn. introduced their version of a market-based bill to reform Medicare in which private insurance companies compete to provide healthcare coverage for the elderly and disabled.

Section 104 authorizes two types of governmental financial arrangements with independent providers. One method includes purchase-of-service contracts by which government pays providers to deliver specified services. Such contracts are a means for the government to deal directly with providers. The other type of financial arrangement consists of government-provided certificates, vouchers or other forms of disbursement, which are redeemable with the providers. This government relationship

48. Larry Lipman, Market-Based System Not Cure for Medicare Woes, PALM BEACH POST, Feb. 12, 2001, at 1E. The Breaux-Frist proposal allows companies to compete to offer plans at least equal to current Medicare levels and to offer a separate option plan to include prescriptions. Id. Based on bids, a government board determines how much Medicare would pay. Id.
49. It is noted that Senator Bill Frist's brother is Dr. Thomas F. Frist, chairman of HCA/Columbia, the nation's largest for-profit healthcare provider.
51. § 604(a)(2).
52. Id.
53. Id.
Goodman

with the provider is indirect, as the assistance goes to the beneficiary before passing to the provider. Both forms can be used in a market-based system.

In the case of TANF, states are authorized to use both "direct" and "indirect" means of paying for services provided by independent organizations. Section 104 leaves it up to the states whether to involve independent sector providers of social services or to provide all services through government agencies. If a state elects to involve any independent sector providers, then it may not exclude religious providers from consideration. Certainly there may be other ways to indirectly provide government funds to faith-based charities such as channeling funds through intermediary organizations; the federal tax credit is another vehicle that could provide government assistance indirectly. Unlike the existing tax deduction for charitable contributions, a tax credit would allow a greater sum to be given to charity since the amount would be directly subtracted from the total tax bill.

President Bush’s proposal calls for easing regulations that make it difficult for religious-based charities to work with government agencies. The Bush plan offers “a $500-per-person tax credit for charitable donations and a charitable deduction for the 70 percent of Americans who do not itemize tax returns; . . .” In addition, “it allow[s] religious charities to compete for government grants on equal footing with secular organizations.”

On September 21, 2000, Bush wrote in USA Today that he would allocate $80 billion over ten years in tax incentives to help churches provide services. Such unabashed plans certainly underscore why the Charitable Choice laws have been described by the Center for Public Justice, as an equal employment opportunity plan for faith-based providers. Bills already filed in the 107th Congress put private sector profit-making organizations

55. Id.
56. Id.
59. Id.
60. See Stem, supra note 38.
like banks, restaurants, farmers, and grocers, all in line for tax breaks-in-waiting for the blessings of faith-based initiatives.61

On the federal level, much legislation has now been enacted with charitable choice provisions but on the state level, only about 125 new initiatives emerged in nine states since 1996.62 Of these collaborations, fifty-four were with traditional agencies and seventy-one were with faith-based organizations, not traditionally involved in federal welfare programs, suggesting Charitable Choice provisions do attract and increase competition.63

Most states are not yet in compliance with the law. Few seem well educated or even seem to know about the law. According to the Charitable Choice Compliance Report Card issued by the Center for Public Justice, a majority of states have failed to put the new rule into effect by eliminating old restrictions and restructuring contracts.64 At this point, only Texas, Indiana, Wisconsin, and Ohio have begun codifying Charitable Choice provisions into their formal contracts.

"Indiana has become a leader in . . . implementing government–faith-based collaborations."65 In November 1999, FaithWorks Indiana began to develop partnerships.66 The initiative has awarded $5 million in contracts to forty-four different faith groups, using a large private accounting firm, Crowe-Chizek, as the independent contractor to develop the connections, but the Indiana Family and Social Services Administration distributes the TANF money to the efforts.67 In California, the state-level Office of Community Relations screens the applicants but Shasta County’s FaithWorks! acts as the intermediary for training the church members in best practices, using

62. See The Pew Forum on Religion and Public Life, supra note 42.
65. Greiner, supra note 63.
66. Id.
67. Id. at 6–7.
Catholic Charities as its fiscal agent for administering to the TANF clients appropriately.\textsuperscript{68}

In Texas, TANF funds are divided between the Department of Human Services and the Texas Workforce Commission.\textsuperscript{69} They use a contract group called Texas Family Pathfinders to match TANF families with services.\textsuperscript{70} Texas Family Pathfinders involves 174 active teams, 122 that are faith-based.\textsuperscript{71} Apparently, most other states have not yet begun the work to bring government procurement policies and procedures into sync with the law on Charitable Choice, perhaps mistakenly believing these guidelines are optional, when in fact, they are required.\textsuperscript{72}

D. The Florida Situation

In Florida, over the past three years, as more people were moved from welfare to work under the welfare reform bill, they too needed transitional health benefits paid for by Medicaid. As more children applied for state sponsored, low-cost healthcare, they discovered their families were poor enough for Medicaid too.\textsuperscript{73} These factors, on top of swelling drug prices and faulty Medicaid growth estimates made by state economists, have led to an estimated $944 million deficit in Medicaid this year in Florida.\textsuperscript{74}

With an unexpected $944 million hole to fill this legislative session, program cuts loom and proposals to eliminate prenatal care for thousands of pregnant women and to move Medipass clients to a Medicaid HMO all have surfaced in the legislature. The Agency for Health Care Administration proposes to move 107,689 people in twenty-eight Florida counties from its Medipass program into Medicaid health maintenance organizations to save the agency about $17 million, since Medipass pays more money than the HMOs.\textsuperscript{75} The National Governors' Association is also proposing radical

\textsuperscript{68.} Id.
\textsuperscript{69.} Id.
\textsuperscript{70.} Id.
\textsuperscript{71.} Greiner, supra note 63.
\textsuperscript{72.} See Welch, supra note 47.
\textsuperscript{74.} Linda Kleindienst, Proposals for Budget Cuts Hurt Poor, Needy, SUN-SENTINEL (Ft. Lauderdale), Mar. 11, 2001, at 17A.
\textsuperscript{75.} Sanjay Bhatt, State Plan Could Hurt Local Health Clinics, PALM BEACH POST, Feb. 15, 2001, at 5B.
changes in Medicaid to allow states to have greater flexibility to cover more people, but with fewer benefits.\textsuperscript{76}

Some Florida legislators clearly intend to bring Charitable Choice to this state in a far more comprehensive way, since $630 million has been “tucked away in the Florida House’s budget” this legislative session to be earmarked for social programs modeled upon Charitable Choice law.\textsuperscript{77} If it survives, it will open the door for the state to begin codifying charitable choice accountability rules in its contracts.\textsuperscript{78}

Concurrently, it was announced on April 6, 2001, that Florida will get further leeway in how it spends certain Medicaid dollars and receive at least another $159 million from the federal government to spend on the state’s major healthcare centers, where the poor are served and charity care is provided.\textsuperscript{79} Seventy Florida hospitals, most of which are not state run, including Jackson Memorial, Broward General, Imperial Point, South Florida State, North Broward Hospital District, Columbia Hospital, St. Mary’s Hospital in West Palm Beach, and A.G. Holley State Hospital will benefit.\textsuperscript{80}

Governor Jeb Bush said that “[t]his is part of a strategy with the new administration, [his brother’s], to trust states,”\textsuperscript{81} and “Florida is among a handful of states suddenly winning approval for Medicaid spending changes” under the first waiver to a state for its Medicaid programs.\textsuperscript{82} Four more waivers are expected to be granted shortly.\textsuperscript{83} This appears to be a clear signal that the federal government is poised to help Florida avert its healthcare budget crisis. Undoubtedly this can be viewed as a political favor from the President, underscored even more by the recent appointment of Ruben King-Shaw, the Secretary of the Florida State Agency for Health Care Administration that oversees Medicaid, to become the second-in-command

\textsuperscript{76}. See Segal, supra note 17.
\textsuperscript{77}. Rep. Johnnie Byrd, R.-Plant City, “is the sponsor of legislation to make no-strings grants to churches legal” in Florida and the GOP members of the House are supporting it. Editorial, \textit{House Tithes Taxpayers on Behalf of Churches}, PALM BEACH POST, Apr. 6, 2001, at 18A.
\textsuperscript{78}. \textit{Id.}
\textsuperscript{79}. Mark Hollis, \textit{U.S. Frees up Medicaid Cash for State}, SUN-SENTINEL (Ft. Lauderdale), Apr. 6, 2001, at 5B.
\textsuperscript{80}. \textit{Id.}
\textsuperscript{81}. \textit{Id.}
\textsuperscript{82}. \textit{Id.}
\textsuperscript{83}. Florida has had Medicaid waiver requests pending before the federal Health Care Financing Administration for nearly three years. In less than three months, President Bush acted on his brother’s request. \textit{Id.}
It also suggests much work has already gone on behind the scenes to prepare the state for entering the Charitable Choice era. The Medicaid waivers give Florida more power to experiment with new healthcare delivery systems and to offer care to uninsured people who otherwise would not be eligible for the program. Charitable Choice provisions in federal law already cover certain medical and healthcare services, including operation of health clinics, drug and alcohol treatment, and abstinence education programs.

The radical changes proposed for Medicaid warrant further scrutiny as the potential long-term effects on healthcare for the poorest and most vulnerable population are affected by expanding Charitable Choice. As government moves forward in its attempt to shift more of these services to the local communities' religious providers, there also appears to be an influx of private entrepreneurial providers lining up at the gates in wait. Many of these efforts represent a philosophical shift or paradigm in how best to revitalize urban neighborhoods, which many believe have seemingly failed to thrive under traditional government entitlement programs.

84. Robert Pear, Lobbyist Top Contender to Run Medicare, Medicaid, SUN-SENTINEL (Ft. Lauderdale), Mar. 4, 2001, at 6A. King-Shaw will be deputy to Thomas A. Scully, a lobbyist for the hospital industry. Scully will be nominated to be administrator of the Health Care Financing Administration, of the Department of Health and Human Services, that runs Medicare, Medicaid and the Children’s Health Insurance Program. If Scully and King-Shaw are both confirmed, market-based health care delivery seems likely to continue. Id.

85. Jena Heath, Governors Want More Freedom with Medicaid, PALM BEACH POST, Feb. 26, 2001, at 3A. The National Governors Association has proposed radical changes in Medicaid with less generous benefits because healthcare costs are rising at the same time tax revenues are declining. Id. The proposed plan would allow states to combine Medicaid with private health insurance and use it to pay for part of the employee share of premiums under employer-sponsored health plans. Id.

86. African-American churches are more likely to respond to charitable choice than any other denomination according to a study by Mark Chaves, associate professor at the University of Arizona. Mark Chaves, Congregations’ Social Service Activities, Policy Brief No. 6 (Dec. 1999). Urban Institute, Center on Nonprofits and Philanthropy, available at http://www.urban.org/periodcl/cnp_6.html (last visited Nov. 15, 2001) (on file with author).


88. See generally Alliance for Redesigning Government, available at, http://www.alliance.napawash.org/alliance/index.html (last visited Oct. 31, 2001). This advocacy group acts as a catalyst in neighborhoods looking to revitalize. Governor Jeb Bush operates Front Porch Florida, a faith and community-based concept which intends to jump-start black neighborhoods. In its first eighteen months of operation it has failed to attract sustainable
III. CHARITABLE CHOICE AND THE FIRST AMENDMENT

A. Background

To prevent the Charitable Choice provision from violating the Establishment Clause of the First Amendment, its proponents have carefully crafted its language to offer "choice" to potential beneficiaries who may choose not to accept faith-based services when offered. The language in the proposed bill carefully tries to avoid potential ramifications on the separation of church and state. Specifically, it describes that the state has the option to and may administer its services "through contracts with charitable, religious, or private organizations."

The current language of the bill states that if a potential beneficiary objects to the religious character of the organization from which he or she would receive assistance, the appropriate federal, state, or local governmental entity shall provide that individual with alternative assistance of equal value within a reasonable time period. The crux of whether Charitable Choice programs will succeed constitutionally lies in its actual field implementation. In other words, constitutionality is based upon whether the government can truly provide an alternative of equal value to accessible providers in a timely fashion. This requirement appears to be a challenging one in light of proposals for radical changes in Medicaid that would allow states to offer significantly less generous benefits than are now guaranteed to the poor.

If current and proposed government healthcare policies succeed in significantly cutting back government spending in favor of shifting costs to non governmental organizations, particularly local faith-based providers, this shift may alter the long term effects of providing the healthcare "safety net" for vulnerable populations. If such a result also interferes with the doctrine of separation of church and state, such a change raises the question of whether the states have gone beyond constitutional boundaries. As each state wrestles with how it will change its procurement policies and practices

partnerships with churches and companies due to lack of training and personality clashes. See Brittany Wallman, State's Front Porch Falling Down, SUN-SENTINEL (Ft. Lauderdale), Apr. 15, 2001, at 1A, 17A.

91. Id.
92. Id.
93. See Ku, supra note 9.
to comply with these new provisions, Section 104 is a new law untested in the courts and applicable constitutional law is developing. At this time, only some isolated trial court litigation in Texas, California, Kentucky, and Wisconsin has been filed. 94

B. The Legal Evolution of Church/State Relations

A wall has been built between church and state since the time of the Founding Fathers. In 1802, Thomas Jefferson wrote on the subject in a letter to the Danbury Baptists:

Believing . . . that religion is a matter which lies solely between man and his God, that he owes account to none other for his faith or his worship, that the legitimate powers of government reach actions only, and not opinions, I contemplate with sovereign reverence that act of the whole American people which declared that their Legislature should "make no law respecting an establishment of religion, or prohibiting the free exercise thereof." 95

The dilemma confronting legislators and the judiciary lies in the degree to which one builds the wall of separation between church and state. Much of the case law on the matter comes out of a long tradition of suspicion of government funding for religious education, not for the religious provision of social services. Most case law on church and state issues is about education. These cases may be helpful in understanding the court's thinking over time, but education cases also may not be quite on point.

The United States Supreme Court's most significant modern interpretation of the wall between Church and State stems from Everson v. Board of Education of Ewing Township, 96 which relies on a strict separationist interpretation of the Establishment Clause. In Everson, the Court held that

95. See Eyler Robert Coates, Sr., Thomas Jefferson on Politics & Government: Freedom of Religion at http://etext.lib.virginia.edu/jefferson/quotations/jeff1650.htm (last visited Jan. 27, 2002). The "wall of separation" metaphor used by Justice Hugo Black in the 1947 Everson case came from a letter Thomas Jefferson wrote to the Danbury Baptists, during his presidency, explaining his view of the meaning of the religion clauses. Jefferson's concern was likely as a way to prevent religion from interfering with government, rather than the reverse. Id.
state reimbursement for bus fares to attend religious schools was constitutional.\footnote{Id. at 18.} The Court acknowledged that the First Amendment was intended to erect a wall of separation between church and state; however, the Court found that the plan to reimburse parents for bus transportation benefits the child, and can therefore be differentiated as a more neutral purpose.\footnote{Id. at 17.}

Voting five-four, the Court rejected the contention that no aid was necessary, and appeared to distinguish between money going to parochial schools for secular functions like busing, and money going for religious purposes.\footnote{Id. at 16.} While the dissenters believed free transportation to religious schools was aiding religion,\footnote{Id. at 18.} the majority differentiated the specific purpose for which the money was used.\footnote{Everson, 330 U.S. at 20.}

The Court’s opinion in \textit{Everson} states:

Neither a state nor the Federal Government can set up a church. Neither can pass laws which aid one religion, aid all religions, or prefer one religion over another. . . . No tax in any amount, large or small, can be levied to support any religious activities or institutions, whatever they may be called, or whatever form they may adopt to teach or practice religion.\footnote{Id. at 15–16. Justice Black delivered the opinion of the Court. Id.}

Thus, \textit{Everson} sets some judicial precedent for beginning to define the wall of separation as something which might be viewed more neutrally or equally if the money’s purpose did not aid religion specifically.

There was a proliferation of religious freedom cases in the courts after the incorporation doctrine made the religion clauses applicable to all government entities and the chance for conflict multiplied. This was no doubt accentuated by changes in perspective since the 1960’s that brought into constitutional question many long standing government practices, such as school prayer.\footnote{See COUSER, supra note 5.}

Stricter separation case law is developed in \textit{Lemon v. Kurtzman},\footnote{403 U.S. 602 (1971).} when the Court found it unconstitutional to augment parochial school

\begin{thebibliography}{10}
\bibitem{97} Id. at 18.
\bibitem{98} Id. at 17.
\bibitem{99} Id. at 16.
\bibitem{100} Id. at 18.
\bibitem{101} Everson, 330 U.S. at 20.
\bibitem{102} Id. at 15–16. Justice Black delivered the opinion of the Court. Id.
\bibitem{103} See COUSER, supra note 5.
\bibitem{104} 403 U.S. 602 (1971).
\end{thebibliography}
teachers’ salaries with state funds.\textsuperscript{105} The Court held that such a plan caused excessive entanglement of civil authority and religion.\textsuperscript{106} \textit{Lemon} puts forth a three-prong test for determining when government violates the Establishment Clause: 1) the statute must have a secular legislative purpose; 2) the principal effect of the statute must neither advance nor inhibit religion; and 3) the statute must not foster "an excessive government entanglement with religion."\textsuperscript{107} For a law to be forbidden under \textit{Lemon}, the government, itself, must have advanced religion through its own activities and influence.

This separatist test sufficed for nearly a generation until \textit{Bowen v. Kendrick}.\textsuperscript{108} signalled a shift in policy by allowing the Adolescent Family Life Act to provide federal funding to religious organizations for services and counseling in the area of premarital, adolescent, sexual relations, and pregnancy.\textsuperscript{109} The Act in \textit{Bowen} did not violate the Establishment Clause because the Court found on its face that the Act did not have the principle purpose or effect of advancing religion, an accommodating view.\textsuperscript{110} Chief Justice William Rehnquist, writing for the majority, noted that it met the three-prong test for aid to parochial schools established in \textit{Lemon}.\textsuperscript{111} Grants went to religious organizations to fund a sincere and legitimate secular purpose in dealing with problems of adolescent sexuality.\textsuperscript{112} While the act encouraged grant recipients to involve religious organizations, among others, in addressing the problem, it was considered too incidental to advance religion in a way to be a constitutional problem.\textsuperscript{113} The act was neutral.\textsuperscript{114} It was determined that the use 1) had a valid secular purpose; 2) did not have the primary effect of advancing religion; and 3) did not create an excessive entanglement of church and state.\textsuperscript{115} The Court held that it was not a violation of the Establishment Clause for a religious organization to participate in the state program even when certain religious goals were furthered.\textsuperscript{116}

\textsuperscript{105} \textit{Id.} at 612. This case consolidated First Amendment challenges from Rhode Island and Pennsylvania that provided state aid to parochial schools. \textit{Id.} at 606–07.
\textsuperscript{106} \textit{Id.} at 625.
\textsuperscript{107} \textit{Id.} at 612–13.
\textsuperscript{109} \textit{Id.} at 622.
\textsuperscript{110} \textit{Id.} at 617.
\textsuperscript{111} \textit{Id.}
\textsuperscript{112} \textit{Id.} at 593.
\textsuperscript{113} \textit{Bowen}, 487 U.S. at 617.
\textsuperscript{114} \textit{Id.} at 617.
\textsuperscript{115} \textit{Id.}
\textsuperscript{116} \textit{Id.} at 622.
Even in *Bowen*, however, one finds an educational component in teaching sexual responsibility to teenagers, which may take it outside the narrower focus of Charitable Choice. Perhaps the most interesting message in *Bowen* is Justice O'Connor's concurring opinion, where she noted that funding for the moral issue of teenage sexuality was "inevitably more difficult than in other projects, such as ministering to the poor and sick." Accordingly, O'Connor's view suggests that government funding for health needs and hospitals that include faith-based providers would be constitutional.

Not surprisingly then, there are no Supreme Court cases specifically restricting government financing of church-affiliated social services, so the case law on this issue is not particularly clear. In fact, there is a long history of government funding going to church hospitals and other non-educational social services starting at the turn of the century.

In *Bradfield v. Roberts*, a Catholic-run hospital in Washington, obtained a capital improvement grant from the government, with the Supreme Court indicating that organizations devoted to social welfare activities, such as this Catholic hospital, should not be otherwise denied governmental money on account of the First Amendment. The Court then held that the secular charter granted to the hospital, and controlled by Congress, made the hospital a secular corporation, regardless of the Catholic sisters that operated it, which can be seen as a rather neutral holding. Arguably, religion has long played a part in religious health ministries from the early days of alms houses to religious drug and alcohol treatment centers which revolve around twelve-step recovery programs based on calling upon higher powers of the spiritual kind.

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118. Characterizing Justice O'Connor's controlling votes on the Supreme Court in Establishment Clause cases, Bret Kavanaugh, a partner at Kirkland and Ellis in Washington, moderated a panel on Charitable Choice at the conservative Federalist Society which described O'Connor's influence to be most significant. *See* http://www/fed-sco.org/2%20esbeck%20%20REVISED.html.

119. 175 U.S. 291 (1899).

120. *Id.* at 298.


C. Judicial Action: The Establishment Clause and Health and Social Services in Trial Cases

While there are no Supreme Court rulings specifically on the constitutionality of Charitable Choice, the Supreme Court has spoken on the issue of the use of tax money for religious purposes in *Mitchell v. Helms*. In *Mitchell*, in a 6-3 decision, the Court upheld a program giving library and media materials, such as computer software and hardware, to mostly Catholic schools in Louisiana. In *Mitchell*, the secular, neutral, and non-ideological nature of the aid was perceived as being within the law. The aid was allocated on private choices and with permissible content.

The opinion by Justice Thomas on behalf of a four-justice plurality held that in assessing such cases, the Court should no longer attempt to determine whether such aid goes to a pervasively sectarian school. Justice Thomas noted that "nothing in the Establishment Clause requires the exclusion of pervasively sectarian schools from otherwise permissible aid programs..." There are several pending trial court cases that will bear watching in light of *Mitchell* as they will test what that decision means for healthcare.

In July 2000, the American Jewish Congress and the Texas Civil Rights Project filed a suit in Texas state court. *American Jewish Congress and Texas Civil Rights Project v. Bost* will consider the constitutionality of "welfare to work" funds flowing to the Jobs Partnership of Washington County, an organization whose evangelical Christianity, according to the petitioners, "permeates their curriculum." In April 2000, Americans United and the American Civil Liberties Union filed suit against the State of Kentucky and the Kentucky Baptist Homes, alleging discrimination on the basis of religion in hiring for publicly funded positions, in its welfare-to-work programs, representing a violation of the Constitution’s Establishment

123. 530 U.S. 793 (2000).
124. Id. at 836.
125. Id. at 828.
126. Id. at 829.
127. See Becker, *supra* note 19, at 18.
129. See *Charitable Choice Lawsuits*, *supra* note 128.
Clause.\textsuperscript{130} It attempts to test a principle embodied in Charitable Choice, which allows religious institutions that receive government funds, to discriminate in their employment practices at least on the basis of religion.\textsuperscript{131}

The American Jewish Congress filed suit January 5, 2001, in the Superior Court, State of California, in San Francisco.\textsuperscript{132} It charges that the California Employment Development Department solicited proposals for five million in funding out of TANF funds from the 2001 California state budget, designated solely for faith-based groups\textsuperscript{133} The Freedom from Religion Foundation sued the governor of Wisconsin alleging a Christian twelve-step course for addicted fathers is "pervasively sectarian."\textsuperscript{134}

If there were a doctrinal shift underway, it would appear to be about recognizing secular activities as government-fundable through indirect aid such as vouchers and tax deductions, because the nature of indirect aid underscores the individual's choice to receive the aid and spend it in different places. This premise was taken even further in \textit{Mitchell v. Helms}\textsuperscript{135} where the Supreme Court ruled that providing educational equipment to religious schools with taxpayer money meets constitutional muster.\textsuperscript{136}

Clearly, this decision altered the current law, which allowed local school boards to have the power to decide how the federal money allocated for Title VI block grants for technology would be spent. From the school

\begin{itemize}
  \item \textsuperscript{130} Eyal Press, \textit{Faith-Based Furor}, \textsc{New York Times Mag.}, April 1, 2001 at 62–65.

  \item \textsuperscript{131} This case centers on a therapist terminated because her "homosexual lifestyle is contrary to [Kentucky Baptist Homes for Children's] core values," according to the termination letter she received from her employer. \textit{Id.}

  \item \textsuperscript{132} "Participating faith-based organizations, notwithstanding their receipt of Federal funds, retain their exemption under Title VII of the Civil Rights Act of 1964, which permits employment discrimination on the grounds of religion. Organizations with fewer than 15 full-time employees are not subject to the nondiscrimination requirements of Title VII." \textit{See Faith Communities, supra note 46, at 4.}

  \item \textsuperscript{133} American Jewish Congress, \textit{AJCongress Asks California Court to Invalidate Job Training Program Limited to Faith-Based Providers only}, available at http://ajcongress.org/pases/RELS2001/JAN_2001/jan01_06.htm.

  \item \textsuperscript{134} \textit{Id.}

  \item \textsuperscript{135} \textit{Id.}

  \item \textsuperscript{136} \textit{See generally Bowen v. Kendrick, 487 U.S. 589 (1988).}

  \item \textsuperscript{137} 530 U.S. 793 (2000).

  \item \textsuperscript{138} \textit{Id.} at 835–36. According to University of Texas law professor Douglas Laycock, there are six theories espoused by various justices from time to time on how money can be allocated from government to religious groups. \textit{See} Douglas Laycock, \textit{A Survey of Religious Liberty in the United States}, 46 \textsc{Ohio St. L. J.} 409, 443–46 (1986). They include: 1) no-aid theory; 2) purchase-of-services theory; 3) equal-treatment theory; 4) child-benefit theory; 5) tracing theory where the money is traced to be sure it only goes to a secular expenditure, and; 6) little-bit theory, where a little bit of money going to a religious school is all right. \textit{Id.}
\end{itemize}
boards' perspective, this decision further chips away at the wall of separation, as they have no way of monitoring whether the computers will be used for religious purposes or not. 137

It is this background of neutrality and its nexus with individual choice that forges the entry to the era of Charitable Choice. While the Supreme Court did not rule on the constitutionality of Charitable Choice per se, it clearly indicated a plurality would likely find a voucher approach to government funding constitutionally acceptable. Judge Clarence Thomas wrote, "It is the students and their parents—not the government—who, through their choice of school, determine who receives Chapter 2 funds. The aid follows the child." 138

Thus, the principle that emerges in the context of Charitable Choice legislation is that the public purpose is for the government and the private sector to work together to address beneficiaries' needs for services. If the private sector providers are religious, and they perform a neutral service, the government's interest ends. Healthcare is neutral as to religion. Thus, Charitable Choice would presume to meet any constitutional test as long as the beneficiaries have a choice as to where they can obtain services, to ensure there is no religious coercion. The neutrality of healthcare then, sets the stage for health vouchers and health contracts based upon choice. Whether there is a real choice becomes the central issue of concern.

Some experts on Charitable Choice, notably Stanley Carlson-Thies of the Center for Public Justice and Carl Esbeck of the University of Missouri at Columbia, believe the Charitable Choice law strongly protects faith-based charities against government intrusion. 139 But others, such as the conservative Heritage Foundation's Joe Loconte and Baylor University law professor Derek Davis, believe the religious nature of faith-based groups will ultimately compromise Charitable Choice, a view many in the conservative community have also recently voiced. 140 Marvin Olasky, a University of Texas professor who is a close adviser to President Bush and the author of


his book on compassionate conservatism, does not think the Founders wanted the country to give preference to either secularism or atheism.\textsuperscript{141}

It would seem for now that Charitable Choice has been crafted in a way that will pass First Amendment scrutiny. The greater concerns lie in the question raised in situations when there may be no viable alternative service provider, a situation that could easily result from the closing of community non-profit or public safety net hospitals, leaving only faith-based providers. How will they be monitored?

IV. CHARITABLE CHOICE IN ACTION: SOUTH FLORIDA

A. Background: Catholic Health Care

Clearly, there is nothing inherently wrong in adding a religious aspect to healthcare; indeed, religion provides a strong belief system and the positive effects of spiritualism and prayer are certain. In addition, a religious healthcare provision certainly is not new. Traditional religious providers, whether Catholic, Jewish, Methodist, or Baptist, all have long and successful hospital traditions. The Robert Wood Johnson Foundation, a preeminent healthcare charitable group, for example, has 1100 faith-based healthcare programs up and running with the support of nearly forty million in private charitable funds.\textsuperscript{142}

Catholic healthcare provides an interesting example of the traditional religious provider. The Sisters of Charity founded Catholic healthcare in this country 150 years ago.\textsuperscript{143} Today, the Catholic system boasts 601 hospitals in forty-eight states that collectively admit sixty-five million patients per year.\textsuperscript{144} "In nineteen states, more than twenty percent of hospital


\textsuperscript{142} See \textit{About Faith in Action}, A National Program of The Robert Wood Johnson Foundation, 2001, \textit{at} http://www.interfaithcare.org/about/index.htm. This is the nation’s largest philanthropy devoted solely to improving health and healthcare for Americans. \textit{Id.} It created the Faith in Action program to fund community efforts in 1993 and since then, their Interfaith Volunteer Caregivers program has helped build over 1100 faith-based volunteer programs nationally with two thousand more partnerships planned. \textit{Id.} These projects are privately supported with foundation charitable dollars.


admissions are to a Catholic facility.... In 1997, Catholic hospitals generated thirty-five billion in net patient revenues."145 Including respite, rehabilitation, and skilled nursing care, Catholic facilities collectively comprise the single largest provider of institutional care in the country.

The impact of Roman Catholic healthcare is particularly interesting because all Catholic hospitals are governed by a single, unifying set of religious principles known as the "Ethical and Religious Directives for Catholic Health Care Services."146 Developed and issued by the National Conference of Catholic Bishops, the directives contain seventy rules that spell out which health services can and cannot be provided based on whether or not they are deemed "morally and spiritually harmful."147 Contraception, sterilization, abortion, and infertility services are among the types of healthcare which are specifically disapproved.148 There have been problems in communities across the country in acceptance of these restrictive policies.

As collaboration and demographic trends have affected the healthcare ministry, consolidation of Catholic healthcare has increased under its New Covenant Initiative and has called for sponsoring religious congregations to work together in furtherance of the Church.149 Twelve separate Catholic religious community sponsors have merged to form single governance and management structures, such as Catholic Health East, Catholic Health West, and Catholic Health Care Partners.150 "[I]n some markets, Catholic healthcare finds itself aggressively growing, and in many instances converting heretofore nonsectarian non-profit facilities to Catholic facilities."151

B. Hospital Consolidation in West Palm Beach

One such proposed consolidation by a Catholic organization attempted to join two hospitals, St. Mary’s and Good Samaritan, in West Palm Beach, Florida. On March 23, 2001, Intracoastal Health Systems agreed to sell its two non-profit hospitals in West Palm Beach, to Tenet Healthcare Corporation, the nation’s second largest for-profit chain. This proposed sale ended more than a year of intense media scrutiny, public criticism, and a

145. Singer, supra note 143, at 301
146. Uttley, supra note 144, at 12–13.
147. Id. at 13.
148. Id.
149. Singer, supra note 143, at 302.
150. Id. at 302–03.
151. Id. at 303.
lawsuit by Florida’s Attorney General to prevent Intracoastal from closing its unionized St. Mary’s Medical Center, or from consolidating St. Mary’s acute care, emergency, and trauma services at the non-unionized Good Samaritan campus, two and one-half miles away.

For thirty-eight years, St. Mary’s Medical Center was a Catholic-owned hospital run by the Franciscan Sisters of Allegany. St. Mary’s operates the largest emergency room in Palm Beach County, including one of two county trauma centers that specialize in treating accident victims. Licensed to operate 460 beds, St. Mary’s Medical Center had formed a jointly operated health system in 1994, with secular, Good Samaritan Hospital, hoping to reap combined efficiencies in a changing healthcare reimbursement environment.

The entity created under this Joint Operating Agreement, called Intracoastal Health Systems, was organized on a parity basis (50/50), but like many other attempted mergers across the country, failed to bring together its two disparate cultures. While the merger agreement had contemplated an unwinding if certain objectives were not met, the board did not act upon that. Instead, they subsequently approved one of the two parity sponsors, Catholic Health East,152 to become the primary creditor, holding approximately $150 million in tax-exempt bonds through its master trust indenture.153

By the end of fiscal year 2000, losses including one-time write-offs totaled $88 million. Clearly, this was not a sustainable scenario.154 To stem the losses, Intracoastal proposed to consolidate all of its acute, trauma, and emergency room services at its more compact, lakeside 341-bed Good Samaritan site. The proposed plan set off a firestorm of intense community reaction. The hospital system blamed reduced reimbursements and the rising costs of treating the uninsured and poor for its predicament, but critics blamed the hospital’s failed billing system, its inability to sign up eligible uninsured for coverage, and management missteps, for the river of red ink that administrators predicted would cause the hospitals to run out of cash by May 2001.155

152. The Franciscan Sisters of Allegany merged as a sponsor with Catholic Health East (CHE) in 1998; they consider themselves an owner of CHE.
154. Id. at 55.
155. Id. I served on a twelve-member community board that commissioned six nationally recognized experts in healthcare to form a consulting team to study the problems facing the West Palm Beach hospitals. The consultants studied whether both hospital campuses could be maintained without consolidation. The Consulting Team included Apache National Health Advisors for strategy; SMG Marketing Group for marketing assessment;
The process the hospital system used to make its consolidation decision was deemed inadequate. It did not seek community input until forced to do so; discussions took place largely behind closed doors; and its decisions were perceived as politically motivated to favor a demographically upscale location over the needs of the minority community, which identified almost exclusively with the St. Mary’s campus.\textsuperscript{156}

Further, a crisis of credibility grew within the community over what was perceived as a disastrous decision to move the trauma system, coupled with no real transition plan to meet the needs of the nearly 90,000 people who visit the St. Mary’s emergency room annually.\textsuperscript{157} Community activists came together to push for an independent study of the situation.\textsuperscript{158} A local healthcare conversion foundation granted $500,000 toward such a study and national consulting experts were hired to analyze the situation. That study determined there was insufficient political will to create a public trust hospital, but as a compromise, consolidation could proceed if there was a major redesign of the St. Mary’s campus to convert it to ambulatory and specialty care uses, with urgent care capabilities there.

Community outcry attracted the attention of Florida Attorney General Bob Butterworth, who filed suit in January to block the plan.\textsuperscript{159} After court-ordered mediation failed, Intracoastal abandoned its consolidation plan and agreed to sell its hospitals to Tenet,\textsuperscript{160} a move that for some triggered concerns that the “grass-roots” community activism that had fanned the controversy, was really a purposeful strategy all along, designed to push the hospitals into the private, for-profit sector.\textsuperscript{161}

\begin{itemize}
\item Hamilton HMC for facilities assessment; Gill/Balsano consulting for physician issues; McDermott, Will and Emery for legal issues; and Kaufman Hall for financial analysis.
\item Id. at 14. Of the nearly 90,000 who visited the emergency room, only 12,000 were admitted.
\item See Laycock, supra note 121.
\item Both Tenet and HCA were bidders for the hospitals and are members of the Federation of American Hospitals, a powerful healthcare advocacy group which supports
\end{itemize}
But the hospital’s financial predicament could be a microcosm for what is happening to safety net hospitals across the United States. St. Mary’s payer mix had changed over the years to include seventy percent of the Medicaid and non-paying patients in Palm Beach County. St. Mary’s central location in the northern part of West Palm Beach, in close proximity to inner city neighborhoods right off the interstate highway, ideally situates it geographically to serve as an access point of entry to the lower income population. Its Catholic tradition also made it welcoming to immigrants and people of color who were historically made to feel unwelcome at Good Samaritan Hospital, which did not even accept Medicare patients until 1964.

Good Samaritan Hospital sits on the Intracoastal Waterway overlooking the island of Palm Beach. The decision to do a wholesale consolidation on the Good Samaritan site seemed to many in the Palm Beach County community as counter-intuitive. The Good Samaritan site was only twenty-three acres, landlocked on the Intracoastal Waterway. St. Mary’s campus, on the other hand, was 105 acres, with good access from the interstate and with an approved, intact trauma system.

The average per capita income of Good Samaritan’s immediate area exceeds $88,000 per year. St. Mary’s Hospital sits adjacent to an urbanized area where the per capita income is $17,889 per year. Perhaps most striking is the payer mix between the two hospitals, for the uninsured are not evenly distributed. Medicaid covers 6.1% of Palm Beach County residents and 16.1% of Palm Beach County residents are uninsured (compared to 13.5% for Florida and 14% nationally).

St. Mary’s Medical Center has 40% of the Medicaid market and 67% of the Medicaid HMO market in the county. About 80,000 people qualify for Medicaid in Palm Beach County. The people who qualify for Medicaid must fall at or below 150% of the poverty level and meet designated criteria

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market-driven initiatives and runs a grassroots advocacy center. During the crisis, there was some workforce speculation that there were also “grass-tops” at work, “AstroTurf” groups that a number of healthcare coalitions front, that are actually public relations tactics or groups that pose as community-based organizations to promote a product or political aim.

163. Id. at 10.
164. Id. at 17.
165. Id. at 8.
167. Interview with Dwight Chenette, Deputy Director of Health Care District of Palm Beach County (Apr. 4, 2001) [hereinafter “Chenette”] (on file with author).
on income, assets, residency, and identification. There are fourteen Medicaid HMOs run in Palm Beach County, one of which is run by the public Health Care District of Palm Beach County (HCD). The reason the HCD set up its own Medicaid HMO was to ensure a safety net if the private insurers were to ever decide to exit the market due to insufficient margins. There are about 3000 enrollees in the HCD-run Medicaid HMO currently.\textsuperscript{168}

The taxpayer-supported HCD raises more than $80 million annually through its 1.05 millage rate.\textsuperscript{169} It has built up a surplus equity reserve of nearly $100 million which they intend to fund down in the future. This is a purposeful strategy intended to smooth out any millage hiccups to avoid any unexpected major increases for taxpayers. The HCD formerly ran two hospitals but consciously got out of that business to focus its mission on financing healthcare. There are policy implications in whether it is doing enough to have amassed an equity surplus of $100 million while the safety net hospitals suffer significant losses.

The HCD, however, believes that hospitals should not be bailed out from their own management missteps.\textsuperscript{170} More importantly, it perceives that it should run more like a healthy insurer than like a provider. To be able to pay out claims, it intends to assure an adequate surplus. At this time, the HCD Board, which is politically appointed, has tabled any consideration for increasing eligibility rates above 150% below poverty. However, the board is working on improving its ability to reach the target market it currently serves through easier sign-up procedures and improved data management. Five of its seven members turned over in the past year with some additional gubernatorial appointments.\textsuperscript{171} Yet, St. Mary’s share of the Medicaid market is three times the share of the next highest provider and five times the Medicaid HMO share of the third highest provider. Furthermore, demographics do not suggest there will be fewer poor people in the future.

In many respects, private not-for-profit St. Mary’s functioned like a government hospital or a hospital of last resort, accepting non-paying

\textsuperscript{168.} \textit{Id.}

\textsuperscript{169.} The Health Care District of Palm Beach County serves as an unregulated health insurance company for low income residents. Three programs serve these populations including Medicaid, Florida Healthy Kids and the Health Care District’s Coordinated Care program which runs through the Health Department at five clinics. The voters approved up to 2 mils in 1987. However, the District almost went bankrupt in 1992 when they discontinued services at 1.47 mils due to poor eligibility decisions. They reinstated the program the next year at 1.25 mils. They have rolled back the millage rate during the subsequent years as they gained operating experience. \textit{Id.}

\textsuperscript{170.} \textit{Id.}

\textsuperscript{171.} Chenette, supra note 167.
patients, even as referrals from joint-venture activities on their own campus. For all practical purposes, St. Mary's became the public safety net hospital for Medicaid and indigent patients from a wide geographic area, but without adequate financial assistance from others. Even though nearly 90,000 Palm Beach County residents use the St. Mary's emergency room annually, and even as the hospital faced closure, not one additional dime of public subsidy was forthcoming from county officials, city officials, or the Health Care District of Palm Beach County. The main source of uncertainty, perhaps, which chills public health safety net providers to augment its involvement, lies in the threat of losing Medicaid revenues because of the push to enroll beneficiaries in managed care.

C. Managed Care and the Shift to Market-Based Systems

Florida has moved the majority of its TANF population into Medicaid managed care, and the state has been among the leaders nationwide in moving elderly and disabled Medicaid enrollees into managed care as well. An estimated 205,000 non-elderly people with disabilities, or 66.4% of the total caseload of that type, were in Medicaid managed care in Florida in 1998. Florida continues to shift to a managed care model.

With a shift away from the model that there is only one provider with an entitlement to the money, (such as the role Jackson Memorial Hospital provides in Miami-Dade County), there will likely be a shift to the new market-based systems. Jackson is a public hospital with 1567 licensed beds and is affiliated with the medical school at the University of Miami. Medicaid and charity cases account for 44% of Jackson Memorial’s gross patient charges, compared with only 14% at Cedars and 6% at Baptist, the next highest providers in Miami-Dade County. Charity care is negligible

172. Id.

173. The HCD limited their support to only their regular $9 million a year contract for trauma services and ongoing support through their Medicaid HMO, the Florida Healthy Kids project, and their Coordinated Care program through the Health Department. They may increase penetration levels for those who qualify at 150% poverty level, or consider raising their hospital in-patient reimbursement rates, which have not increased since 1993. Id.

174. Larry Lipman, Bush Picks Brother’s Nominee, PALM BEACH POST, Mar. 31, 2001, at 8A. Ruben King-Shaw, Jr. will become deputy administrator of Health Care Financing Administration based upon his leadership record of moving people into managed care. This may bode well for Florida in structuring Medicaid waivers or other future policy decisions.

175. See J.P. Bender, Seven Hospitals Sue Miami Dade, SOUTH FLA. BUS. JOURNAL, Apr. 5, 2001, at 51A. Seven hospitals in Miami-Dade County have filed a lawsuit over Jackson Memorial Hospital’s exclusive use of county general revenue and a half-penny sales
at all other hospitals in Miami-Dade County; all thirty-five hospitals combined provide only 29% of what Jackson does in one year. Jackson has unusually secure sources of external funding to cover an operating loss that is relatively small to begin with, at about 25% of expenses. 176 But even Jackson must factor in the threat of losing Medicaid revenues because of the push to enroll beneficiaries in managed care.

Much of the market-based approach to cost-effective healthcare strategy features early intervention, outreach, and primary care structured in a community-wide strategy. In such a solution, providers like Jackson would have to compete for funds, by responding along with other institutions, to a Request For Proposals (RFP) developed by the County. Jackson would have to make its competitive case on how it would help Miami-Dade County fulfill its public health goal. It is likely that as the state complies with its requirement to allow faith-based providers a chance to compete for provision of services in lower-cost facilities, faith-based providers will gain many of these contracts, particularly since the most vulnerable residents often live in urban neighborhoods far from the hospitals.

The distance factor, combined with a lack of public transportation, and poor English proficiency on the part of the beneficiaries, present a significant barrier to care. While Jackson runs a network of clinics designed to involve community outreach, other operators that are more familiar with these satellite communities could provide a competitive threat. 177 There are also equity concerns about letting each county in Florida fend for itself in devising ways to treat its indigents. While Miami-Dade chooses to fund a public hospital, the 1.5% hospital revenue tax collected by Florida from all providers, which is redistributed on a county-specific basis tied to indigent care, proves to be disadvantageous to Palm Beach County.

From the four million dollar Intracoastal Health Systems paid in hospital revenue tax in fiscal year 1999, less than $400,000 comes back in return, because Miami-Dade County providers apparently soak up the distribution. 178 While there may be advantages to distribution by counties,
this equity concept has not moved forward. There are many differences in access to care for many lower-income households. Access to care depends on the generosity of local taxpayers, and the priorities placed on indigent healthcare. The need for greater access is pressing. In Palm Beach County, few private doctors accept Medicaid; in fact, in the West Palm Beach service area, only six out of seventy-four family practitioners accept Medicaid or Health Care District clients.\textsuperscript{179} Thus, while Miami-Dade and Broward County both tax its residents to meet healthcare needs of the indigent with a hospital care subsidy, other counties, such as Palm Beach County, deal with the burden differently.

Palm Beach County's philosophy mirrors national policy. According to national healthcare public policy adviser Christopher Jennings,\textsuperscript{180} there are two possible solutions to the St. Mary's situation and other situations like it around the nation. First, the burgeoning cost of uninsured indigent care, particularly in the efforts to fill the deficits at specific safety-net hospitals, can be covered with public subsidy, a solution many find to be inefficient.\textsuperscript{181} Alternatively, the income threshold of eligibility for Medicaid insurance coverage can be raised to include more people, allowing them to obtain coverage from various providers under prevailing market forces. The latter type of plan is the more efficient solution in a changing market according to Jennings.\textsuperscript{182}

Discussions with local healthcare planners at the Palm Beach County Healthcare District suggest that the latter strategy is more appealing to them as well.\textsuperscript{183} The potential closing of the St. Mary's emergency room showed that out of 90,000 annual emergency room visits, only 12,000 converted to admissions to the hospital, meaning 78,000 patients were treated and released, and could arguably therefore be more appropriately cared for in an Urgi-Care Center were such a system to be redesigned to improve delivery

\textsuperscript{179}. Letter from Edwin W. Brown, President, Florida Community Health Centers, Inc., to Bureau of Primary Health Care (Jan. 5, 2001) seeking Federally Qualified Health Center application for St. Mary's Campus, (on file with author).

\textsuperscript{180}. Interview with Christopher Jennings, former Clinton Health Care Policy adviser and Goodwin Seminar speaker at Shepard Broad Law Center, Nova Southeastern University (Jan. 26, 2001) (on file with author).

\textsuperscript{181}. See Bender, \textit{supra} note 175. While Jackson Memorial continues to use this strategy, to understand its effect on other hospitals in its region. \textit{Id.}


\textsuperscript{183}. Chenette, \textit{supra} note 167.
through greater access. In fact, local funders and social providers proposed a comprehensive redesign of the St. Mary's campus if the consolidation had occurred. These plans were conceptual and revolved around attracting a federally qualified health center. It is unclear whether the collaborations and leveraging of the 120-acre St. Mary's site for new community uses might also have provided opportunities under Charitable Choice for new types of religious or social service provider entrepreneurs to step in. But leaving it all to the marketplace may be dangerous, as can be seen in this real-life example of what can be proposed by the marketplace if left entirely to its own design.

D. The Initial Intracoastal Plan: Faith-Based Clinics

In Palm Beach, healthcare planners seem to support the increasing involvement of faith-based providers. At the time that the plans to close St. Mary's were first announced, the solution offered by Intracoastal Health Systems was to moderate demand by getting people to more appropriate care, and that much of the care provided today in hospitals can be moderated by greater access to lower-cost ambulatory facilities. Specifically, the more appropriate care that Intracoastal initially believed would be the best solution for the 90,000 people annually, who would no longer be served by closing its emergency room, was to offer a partnership with a faith-based provider clinic. Intracoastal proposed to create walk-in clinics in poor neighborhoods. Initially, the company ran full-page newspaper ads in June 2000 that cited its partnership with First Baptist Church as its model for those community clinics.

Intracoastal spokesmen said then that its board began studying the concept in 1998, and began to partner with First Baptist Church in opening its first clinic, which offers basic medical, dental, and vision care in February 2000. There is also a Pregnancy Resource Center and a Christian Care Center housed on the church grounds offering food, clothing, and services to the poor. Teen mothers and their children are housed at the site for up to a year. The First Baptist Church clinic offers walk-in care in its office suites on two weeknights. When a prospective patient arrives, there is "a video about Jesus playing on the television, framed Scripture hung on the walls, and patients [are provided] little pamphlets titled Steps to Peace with

184. See Consultants Study of Intracoastal Health Systems, supra note 156.
185. Id.
186. Id.
God." The patients also get a free gift along with their free healthcare, "The New Believer's Bible," courtesy of the First Baptist Church of West Palm Beach, where the clinic sits on its grounds.

Before getting the free care and gift, the clinic also uses a "spiritual history" questionnaire during the intake process, after the patients' eligibility is determined, before they see a doctor. The spiritual survey is intended as a tool to ensure evangelism "gets done" in the frantically busy office, the director says. "The most important reason we're there is ministering to them and sharing our love of Jesus Christ," said the clinic's medical director, Dr. Tom Rose. The questionnaire asks: "If you were to die today, do you know for certain whether you would go to Heaven or Hell?" and, "Do you consider yourself a Christian?"

Nonprofit healthcare funders, like the Quantum Foundation, who paid for dental equipment in the clinic, found the proselytizing unseemly. "They're saying it's optional, but this is a very vulnerable population they're serving; people know how they should answer," said Quantum health policy director Tim Henderson. "To have that questionnaire literally as a first step in the process and the questions, it's inappropriate." "God? I love very, very much God," said Haitian immigrant Alexandre Magloire, at the clinic for the first time after hearing through the grapevine that he'd see a doctor for free.

Intracoastal has abandoned its consolidation proposal by settlement agreement with the Attorney General and its proposed hospitals' sale to Tenet. Any future role for the First Baptist Clinic as the model for the community's safety net provider is now unclear. Under the new Charitable Choice provisions, such a scenario as described in the First Baptist Church Health Clinic is apparently fine. Religious organizations, with a contract for services as described under section 104 may operate with total religious autonomy.

188. Marian Dozier, Church Clinic Ministers to Body and Soul, SUN-SENTINEL (Fl. Lauderdale), June 18, 2000, at 1B.
189. Id.
190. Id.
191. Id.
192. Id.
193. See Personal Responsibility & Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, 110 Stat. 2161, (codified at 42 U.S.C. 604a (1996)). Under section 104(a)(2)(A), states that accept certificates, vouchers, or other forms of disbursement under subsection (a)(1)(B) shall retain their independence from federal, state, and local governments, including any governmental control over the definition; development, practice, and expression of the organizations' religious beliefs. In addition, neither the federal government nor a state...
Beneficiaries of assistance, such as Mr. Magloire, may object if he has an objection to the religious character of the organization and must be offered an alternative provider of equal value. But, is it reasonable to assume that an indigent person, with limited English skills, and possibly alien status, feeling vulnerable due to sickness, would not feel a subtle coercion to be dependent upon those who offer him comfort at the time of his affliction? The subtle manipulation of this kind of exchange, with its generally one-way communication, strikes some as inappropriate, even if the person is not turned away for not listening, and lies at the heart of the religious coercion issue central to the debate as to how far government should go in deregulating religious providers.

Here, a Baptist church clinic is not a government actor, even if it receives its funding indirectly from the government, through tax exemption, vouchers, or directly through contract. If the state elects to use federal welfare funds to provide services solely through its own governmental agencies, not utilizing any independent providers, then it has not violated the antidiscrimination requirement of section 104, by not involving faith-based providers.

The question arises of whether the federal Charitable Choice law can even be applied to the State of Florida. Florida’s Constitution actually expressly prohibits such uses of funds:

There shall be no law respecting the establishment of religion or prohibiting or penalizing the free exercise thereof. Religious freedom shall not justify practices inconsistent with public morals, peace or safety. No revenue of the state or any political subdivision or agency thereof shall ever be taken from the public treasury directly or indirectly in aid of any church, sect, or religious denomination or in aid of any sectarian institution.

shall require a religious organization to (A) alter its form of internal governance; or (B) remove religious art, icons, scripture or other symbols. Id.

194. In Employment Division v. Smith, 494 U.S. 872, (1990), the Supreme Court eliminated the requirement that government justify burdens on religion imposed by laws neutral toward religion and the compelling interest test in prior federal court rulings is a workable test for striking sensible balances between religious liberty and competing government interests.

195. See Section 104(g) Nondiscrimination Against Beneficiaries—“Except as otherwise provided in law, a religious organization shall not discriminate against an individual in regard to rendering assistance funded under any program described in subsection (a)(2) on the basis of religion, a religious belief, or refusal to actively participate in a religious practice.” Id.

196. FLA. CONST. art. I, § 3.
The State Constitution specifically forbids use of state or county revenues to directly or indirectly aid churches, but it has not posed a roadblock to Charitable Choice proponents.\textsuperscript{197} While Charitable Choice does not preempt state constitutions which restrict or prohibit disbursement of state funds to religious organizations, Charitable Choice applies to federal funds.

Proponents claim federal Charitable Choice legislation provisions trump state constitutional rights.\textsuperscript{198} Actually, all federal welfare funds are subject to the Charitable Choice provision, and states choosing to involve nongovernmental providers must follow the provision's rules regarding nondiscrimination against faith-based organizations. In states which commingle state and federal welfare funding, in order to comply with its own constitutional provisions, a state must segregate state funds from federal grants. If necessary, a state may keep its own funds separate to expend in accordance with its own constitutional provision, while allowing federal funds to flow to religious organizations to serve the poor.\textsuperscript{199} This conclusion follows from the Supremacy Clause of the United States Constitution, which provides that rights granted by congressional action are exempt from any state or local laws to the contrary.\textsuperscript{200}

There seems to be nothing to prohibit a state from choosing to contract with a faith-based organization to be the sole provider of services in a particular area, other than the requirement that there be an alternative provider available, if requested. In essence, Charitable Choice grants all religious organizations a statutory right to be eligible to contract with a state to administer social service. This right can be enforced with a lawsuit against the state.\textsuperscript{201} It stands to reason, however, that in areas where there are few providers and to obtain greatest efficiency, it will, for practical purposes, be impossible to find nonfaith-based providers in certain circumstances. In this situation, where nonfaith-based providers are not available, certain issues must be considered. Since there is no specific time framework for the alternative provider to be set up, and no limits on where the alternative might be geographically provided, alternatives provided might be totally impractical if offered some distance away.

\textsuperscript{197} Id.
\textsuperscript{199} 42 U.S.C. § 604a(k) (Supp. 1999).
\textsuperscript{200} U.S. CONST. art. VI.
\textsuperscript{201} See Chenette, supra note 167.
Florida certainly has encouraged contracting out and providing grants to faith-based and religious organizations. The Florida Pregnant Women Act\(^\text{202}\) for example, authorizes five county health departments including those in Miami-Dade, Broward, and Palm Beach County to contract with “faith-based organizations... and other social-services related entities.”\(^\text{203}\) This legislation targets outreach to high-risk pregnant women who may not seek proper prenatal care, who suffer from substance abuse, or who are infected with HIV, in order to provide services to them.\(^\text{204}\)

E. Concerns About Charitable Choice and Its Operation

The issues that Charitable Choice raises are far ranging. Currently, there are three different federal revenue streams that pick up Charitable Choice—TANF, Welfare to Work, and Community Services Block grants—and many more are planned. But in the broader sense, these concepts represent a shift in the political thinking about whether faith-based organizations might deliver more and more social services that previously were delivered by state and local governments. The wall of separation began to collapse in the 1980s with the increasing political development under Ronald Reagan and George Bush of the privatization of the public sector. Liberals and conservatives alike both lost confidence in the ability of government to provide welfare and education services in the inner cities. African-Americans grew tired of no improvements coming and turned increasingly to help from black churches.\(^\text{205}\)

The central thrust of Charitable Choice is to involve faith-based providers in providing services to the poor, while protecting the religious integrity of the organizations. Building on the work of Marvin Olasky and other religious liberty scholars, the policy shift reflects a view that government welfare programs have failed, and should be replaced by private and religious charities. Faith-based organizations have literally “fed the hungry, clothed the naked, sheltered the homeless, cared for the sick, visited the imprisoned, counseled and recovered the addicted, trained the unem-

\(^{202}\) FLA. STAT. § 381.0045 (2000).
\(^{203}\) § 381.0045(5).
\(^{204}\) Id.
\(^{205}\) South Florida's Donors Forum has for five years run its Philanthropy and the Black Church project for private funders to fund faith-based programs addressing problems such as affordable housing, foster care, and child care availability in low income neighborhoods.
ployed, educated the ignorant, protected the weak, and advocated for the powerless.”

Faith-based organizations have carried on their works of mercy, love, peace, and justice, with and without government money because of a divine mandate. The key questions are these: who are the credible partners and stakeholders in the local communities that genuinely care? Who has the capacity to deliver the services? And do American citizens let government off the hook of responsibility by caring for its needy citizens by transferring that responsibility to faith groups?

On the surface it would seem that the key consideration for capacity is whether the program has a secular purpose and that the organizations selected for service delivery be effective and efficient. This is a capacity question that seems to beg for compliance mechanisms whether they be monitoring, self-reporting, audits, or regulatory actions. This then opens up the question of whether state agencies will now write rules of accountability into their contracts, opening up religious providers to a scrutiny they may not be willing to accept.

Some Christian conservatives are leading the charge against Charitable Choice in that they see how problematic it might be. They fear an adverse effect on religious mission. If a state were to completely shift government social services for a certain area or a type of service to a religious institution, one can foresee the possibilities that beneficiaries may be subjected to religious indoctrination while they are attending the religious organization to obtain their government benefits. There is no way one can detect this unless one is on the scene. It stands to reason that this kind of governmental monitoring could lead to the type of excessive entanglement prohibited currently.


207. Id.

208. Id. (quoting Reverend Ana Price, Universal Truth Center, speaking on Faith-Based Initiatives at the Donor Forum, “Government grants to faith-based organizations will have a better chance of success and continuity if they require infrastructure, written proposals, evaluation criteria, budget plans and other criteria . . . .”).

209. Id. Charisse Grant, Dade Community Foundation, stated that, “Churches must not lose sight of their conviction or mission if they accept federal funding for social service work . . . . It will be important not to let the availability of money detract from that power.”

210. Reverend Donna Schaper, Address at the donor Forum’s Media Breifing, Coral Gables Congregational Church, (Mar. 1, 2001), “Will faith-based organizations be able to
It is interesting how closely the positions of some of the justices correspond to their own religious backgrounds. Three of the four most ardent supporters of equal treatment for religion, Antonin Scalia, Anthony Kennedy and Clarence Thomas, are practicing Catholics, while Stephen Breyer and Ruth Bader Ginsburg, are both Jewish, and maintain more separationist instincts. President George W. Bush, who has described himself as a born-again Christian, has allied himself with the pro-prayer camp. Since he may have the chance to appoint one or more justices who could make a majority shift in the Court, this could usher in a largely privatized public sphere in which education and welfare services are contracted out to religious organizations on a far broader scale.

In relation to Medicare and Medicaid, many are projecting that we are just a heartbeat away from seeing churches directly administer the Medicaid program. What churches will those be? Only about three percent of the congregations surveyed in a recent study of 1200 churches receive government funds today. Catholic and moderate Protestant denominations were more likely to apply for government funds than conservative or evangelical congregations. But sixty-four percent of African-American congregations expressed interest in bidding for charitable choice contracts. This shift could likely turn religious groups into social service providers with multimillion dollar budgets, and the risks of corruption and patronage speak freely about government policy if they are receiving vital federal grants?" Id. This concept was further expanded at the same seminar by Rick Englert for Project Teamwork when he said, "An intermediary organization can help a church to stand by its principles while also acknowledging and meeting government expectations. It is also important for churches to know when to part company with government programs if they do not suit the church's principles or mission." Id.

212. Id.
213. Id.
214. Rev. Barry Lynn, Americans United for Separation of Church and State, is quoted on whether Medicare and Medicaid would ever be administrated directly by faith-based providers:

I would not be surprised to see that as a proposal somewhere down the line, if this concept becomes emboldened by more and more presidential candidates supporting it. But I do not want to see the local church on the corner compete with the synagogue on the corner, and the temple on the third corner to decide who is going to be the administrators of the Medicaid program. I think that is exactly where you go if you let this concept fester.

See Debate, supra note 21, at 20.

216 Id. at 2.
217. See Chaves, supra note 43.
that inevitably accompany large government grants will also likely loom. There are already signs of the entrepreneurial types that have lined up to take advantage of school vouchers to also be in line to make money off government contracts as religious providers.

V. CONCLUSION

Prospectively, the pendulum has swung to such a degree that Charitable Choice legislation—similar to the programs being broadly developed in Indiana, Texas, and California—seems inevitable for Florida as the trend in public policy continues. Justice Thomas' analysis for the plurality in *Mitchell v. Helm*\(^{218}\) and the likelihood of President Bush moving the Supreme Court more to the right, suggest Charitable Choice programs will be upheld constitutionally, even if doing so means moving well beyond its current view of the legal interpretation of the Establishment Clause. In recent years the Court has increasingly shown accommodation of religious organizations, even pervasively sectarian ones.

It is increasingly likely that the Court will reflect the trend supporting a shift toward a more market based system and away from government provision in social services. This is really a redirection of money, and likely not an expansion. It suggests the Court will permit public monies to go to organizations that mix secular and sectarian activities together for neutral purposes like healthcare. In essence, this is taking a limited pot of money and diverting some of it to religion, to shift more services to the private sector and weaning the responsibility for entitlement programs from government.

Such a shift will require more attention in implementation. There is reason to believe that the field implementation may be significantly flawed. It is likely that there will not be adequate provider capacity. Particularly in the poorer inner city neighborhoods, where black churches are more likely to want to fulfill this charge, without there being a further blurring of the line between church and state. As Charitable Choice develops, there will need to be more government regulation to monitor and support its implementation.

To minimize problems like the civil rights employment discrimination disputes in Kentucky and the religious liberty disputes in California, or the blatant over the top proselytizing or coercion that went on in the West Palm Beach health clinic, there will need to be certain technical assistance packages and workshops for faith-based organizations (FBOs). These

\(^{218}\) 530 U.S. 793 (2000).
training programs will need to make sure government staffs understand Charitable Choice guidelines, how to reform their procurement procedures, and how to market and subcontract these joint ventures to best ensure a broad variety of vendors, particularly in communities faced with only one choice of faith-based provider.

There will need to be a far greater strategy to reach out to congregations that are not part of the human services network, in order to initiate meetings, advertise, and to provide dialogue, partnership environments, and mentoring for these FBOs prior to monitoring its efforts. States will need to change their internal rules on procurement, update contract language, and delete religious prohibitions on hiring decisions. FBOs will need to mandate noticing requirements to give choice to providers, and beneficiaries, as well as to draft and codify formal contracts.

There will need to be fiscal audit monitoring, tracking projects, performance based bill or invoice submission systems, and receipt of vouchers. There could also be extensive rulemaking on the provision of vehicles, machinery, office space, and other outside reference, referral, and outsourcing policies. There will need to be help in attracting working capital, to finance the administration of these contracts, originate requests for proposals, and initiate some kind of on-site field monitoring to detect religious proselytizing. There will also need to be case management to monitor contract performance, documentation in keeping eligibility for attendance, work requirements and volunteer requirements intact, as well as a willingness to accept government sanctions. It all needs to be developed and operationally monitored.

If a client is not comfortable with a religious aspect, it is the responsibility of the program designers to provide the service in another way, or withdraw their religious messages in order to retain certain clients. In rural areas, where there are no alternative providers, or in communities where the provider inventory has shrunk due to market place factors, government will need to keep an alternative, such as a government run HMO, and to provide services through private providers. For Charitable Choice to be effective, the boundaries between church and state must be respected to the degree that the beneficiary feels that its choice has been adequately served and properly protected.

Judith B. Goodman
NICA—Florida Birth-Related Neurological Injury Compensation Act: Four Reasons Why This Malpractice Reform Must Be Eliminated

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I. INTRODUCTION

The Florida Birth-Related Neurological Injury Compensation Act1 was part of the Florida Legislature’s efforts to manage both the spiraling medical malpractice costs and diminishing liability insurance availability during the 1970s and 1980s.2 During that period, medical liability insurance had become so expensive that, although “technically available”, it was “functionally unavailable.”3 In trying to ferret out the causes of the malpractice situation, the legislature determined that there was an identifiable group of physicians that disproportionately accounted for medical liability claims, both in number of claims and amount of payout.4 There were multiple specialties in this group, but it was not hard to realize that obstetrician-gynecologists (“ob-gyns”) were important contributors.5 Therefore, in 1986,

3. Id. at 547 n.90.
4. Id. at 552.
5. Id. (noting that these physicians paid claims that were two to three times as high as the remainder of physicians). Obstetricians are defined as physicians (medical doctors or osteopathic physicians) who diagnose, care, and treat pregnancy and associated disorders.
the legislature created a special academic task force to study the Florida malpractice problem and to assist the ob-gyns in particular.\footnote{6}

The task force evaluated the rising insurance costs. It reported that "litigation costs and attorney's fees" had increased from 1975–1986, yet there was no particular change in the relevant substantive law to account for it.\footnote{7} While it was true that the tort environment had shifted in favor of the plaintiff with the change to a national medical standard and the use of \textit{res ipsa loquitur}, these changes alone should not have accounted for the increases.\footnote{8} As the marketplace would allow, the skyrocketing medical liability insurance costs were being partly passed on to increasingly dissatisfied patients and their insurance companies.\footnote{9}

Cost alone was not the sole problem. Some patients became nearly disenfranchised as physicians resisted treating high-risk patients; in fact, physicians resisted practicing in certain high-risk specialties altogether.\footnote{10} The more litigious patients became even more disillusioned with medical care, possibly as a result of poor medical performance of physicians or hospitals, and possibly, it was suggested, as a result of "incompetence or...\footnote{11}

\footnote{6} Tedcastle, \textit{supra} note 2, at 544.

\footnote{7} Id. at 550.

\footnote{8} Id. at 550–51. \textit{Res ipsa loquitur} is a tort doctrine whereby the plaintiff need only prove that the defendant had exclusive control of the instrumentality that caused the injury and that the type of accident is one that would not ordinarily occur in the absence of negligence on the part of the party in control of that instrument. McDougald v. Perry, 716 So. 2d 783, 785 (Fla. 1998) (proving a defendant's negligence regarding a wayward automobile wheel by using the doctrine of \textit{res ipsa loquitur}). Because \textit{res ipsa loquitur} allows for a common sense inference of negligence where hard evidence is wanting, it is self-evident that it is a plaintiff-friendly doctrine.

\footnote{9} Tedcastle, \textit{supra} note 2, at 554. Physicians who practiced or trained in that era recall that it was a difficult time. Interview with Harvey Schoenbrum, M.D., Board Certified Urologist, in Palm Beach County, Fla., (June 20, 2001). Patients blamed physicians for their skyrocketing fees, and physicians blamed the insurance companies for their rapidly increasing premiums. Id. Physicians were angry that the insurance companies were happy to collect premiums in Florida when there was no malpractice crisis, but leave the state when times got tough. Id.

inattentiveness, negligence or neglectfulness, faulty diagnosis or faulty equipment.\textsuperscript{11} The stage was set. There were increased medical care costs, increased liability insurance costs,\textsuperscript{12} "overly generous jury awards,"\textsuperscript{13} and difficulties in obtaining insurance.\textsuperscript{14} Patients and physicians were angry and, irrespective of where one wanted to place the blame, what had started as a malpractice epidemic had become a malpractice crisis.\textsuperscript{15}

The ob-gyns were a dramatic part of the malpractice crisis. Astonishingly, in 1985, ob-gyns in Florida paid an average medical malpractice liability premium of $185,460, compared to a national average of $23,300.\textsuperscript{16} The Florida Legislature correctly realized that ob-gyns were a subset of physicians that had a disproportionate, if not unbearable insurance liability, but without whom our society would not function.\textsuperscript{17} They also believed that the newborn was a subset of these physicians' patients who were apt to be injured catastrophically, and because of them, they decided to delve into what could only be called a medicolegal, insurance experiment.\textsuperscript{18}

The Florida Birth-Related Neurological Injury Compensation Act, ("NICA"), was Florida's contribution to the idea of a hybrid no-fault and tort medical liability system. This comment will first develop the historical perspective that led to this legislation. It will next review the NICA statute and goals in detail. From there, it will focus on whether NICA has met its stated and implied goals, and discuss some of the problems involved in reaching those conclusions. Lastly, this comment will analyze four important issues that NICA has faced. It will detail how it faced those issues and further explain why these four miscues, along with its marginal success, prove that this malpractice reform law should be repealed.

\begin{itemize}
  \item[11.] Gellhom, \textit{supra} note 10, at 170.
  \item[12.] Malpractice insurance rates for ob-gyns reportedly increased 113% during the four-year period from 1982–86, and there were more lawsuits involving these specialists than any other. Falkner, \textit{supra} note 10, at 1–2.
  \item[16.] Gellhom, \textit{supra} note 10, at 173.
  \item[17.] FLA. STAT. § 766.301 (2001) (indicating the legislative findings and intent for the NICA statute).
  \item[18.] \textit{Id}. NICA has been called the "most significant experiment with compensation for medical injury yet undertaken in the United States." Studdert, \textit{supra} note 15, at 500.
\end{itemize}
II. NICA IS BORN

The academic task force, along with outside recommendations, ultimately recommended NICA as a solution to the uniquely severe situation of the ob-gyns.\(^{19}\) The legislature found that ob-gyns were a high-risk, essential specialty that had suffered rapid advances in their malpractice liability costs.\(^{20}\) They found that any birth of a child that did not go well would usually be accompanied by litigation.\(^{21}\) One should realize, however, that there is not necessarily a \textit{quid pro quo} between a physician's errors and litigation. For example, in a traditionally low insurance risk medical specialty like dermatology, although it is self-evident that skin cancer patients unfortunately suffer iatrogenic injuries, they sue relatively infrequently; therefore, dermatologists enjoy relatively low insurance premiums.\(^{22}\) The reasons are speculative, but possibly the generally older group of patients the dermatologist treats may have a greater tolerance and patience for error or poor result. One might infer also that obstetrical injuries are worse, although not every obstetrical error is expected to be horrible. Regardless of the reason, the Florida Legislature intended to stabilize, or possibly reduce, the ob-gyn's insurance premiums.\(^{23}\) They concluded that the birth-related neurologically injured were an especially high risk and expensive tort subset, and they therefore required a dramatic new mechanism to deal with that problem.\(^{24}\) Their solution was to carve out these claims and provide compensation irrespective of fault.\(^{25}\)

\begin{itemize}
\item \(^{19}\) Tedcastle, \textit{supra} note 2, at 556–57.
\item \(^{20}\) \textit{Id.} at 583.
\item \(^{21}\) \textit{Id.} The medical consumer appears to have very little tolerance for obstetrical accidents. Every mother expects a "perfect" baby, and when an adverse birth happens, litigation frequently results. When a neurologically injured newborn is delivered, nearly all will sue, independent of whether their doctor was at fault.
\item \(^{22}\) Bruce L. Allen, M.D. & Josef E. Fischer, M.D., \textit{Caps on Malpractice Awards: Update}, HIGHLIGHTS BULL. AM. C. SURGEONS, June 1999, available at http://www.facs.org/dept/hpa/proliab/0699a.html (generally showing the relationship of dermatology malpractice fees to other medical specialty fees). For example, dermatology malpractice fees for the State of Florida ($1 million/$3 million coverage) is quoted as $35,440 per year compared to ob-gyn which is quoted as $140,346 per year. \textit{Id.}
\item \(^{23}\) Insurance premiums amounted to an average of eleven and six-tenths of one percent of gross practice revenues in 1986–87 for physicians in general, but they amounted to twenty-three and one-tenth percent of gross practice revenues for ob-gyns in the same time period. Tedcastle, \textit{supra} note 2, at 553 n.122.
\item \(^{24}\) \textit{Id.} at 557.
\item \(^{25}\) \textit{Id.}
\end{itemize}
The legislature decided "to provide [a] compensation [plan], on a no-fault basis, for a limited class of catastrophic injury that result[ed] in unusually high costs for custodial care and rehabilitation." The situation had become so severe, that in addition to that laudable goal, part of the legislative goal was to stabilize or reduce insurance costs to ensure that obstetricians would not be forced out of practice due to the malpractice crisis.

Toward their goal, the Florida Legislature’s first foray into no-fault compensation, NICA, was narrowly written to include only birth-related neurological injuries. This was not the only option available in terms of malpractice reform, however. For example, the legislature could have plunged medical negligence in toto into a no-fault, workers’ compensation-like system. Instead, the not yet functioning “Virginia Plan” became the model upon which NICA was patterned, and this plan was and still is limited to the birth-related neurologically injured.

III. THE NICA STATUTE

Both the Virginia Plan and NICA were to be strict liability workers’ compensation type plans, where the claimant did not need to establish fault and the claim was taken out of the tort system and managed administra-

28. § 766.302(2).
29. Randall R. Bovbjerg & Frank A. Sloan, No-Fault for Medical Injury: Theory and Evidence, 67 U. CIN. L. REV. 53, 76-79 (1998). Workers’ compensation exclusively provided compensation to those workers who suffered a disabling injury or illness on the job. Id. at 76. Most states (forty-seven) require employers to purchase or self-insure. Id. Workers may be unhappy with the relatively low compensation as opposed to that available in tort. Id. at 78. Therefore, workers have frequently tried to circumvent the exclusivity provision. Id. Other problems include the real or perceived lack of high quality care in some cases due to the various plan limitations. Id. See Richards, supra note 13, at 103 (describing a 1996 Utah tort reform plan that calls for wholesale abandonment of the existing tort system in favor of no-fault).
30. Tedcastle, supra note 2, at 582. See also Virginia Birth-Related Neurological Injury Compensation Act, VA. CODE ANN. § 38.2-5000-5021 (Michie 1999).
31. The Virginia Plan became the country’s first malpractice reform effort that adopted the no-fault method of compensation. Bovbjerg, supra note 29, at 56.
tively. In reality, there was a significant difference between NICA and workers’ compensation. With workers’ compensation, if the employee was injured on the job, he did not need to prove anything else in order to obtain compensation. With NICA, the claimant not only needed to have been injured during birth, but he also had to prove that the injury was related to oxygen deprivation or mechanical failure. The definition under the NICA was as follows:

“Birth-related neurological injury” means injury to the brain or spinal cord of a live infant weighing at least 2,500 grams . . . at birth caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired. This definition shall apply to live births only and shall not include disability or death caused by genetic or congenital abnormality.

Reading the statute, one can appreciate its restrictive details. For example, an obstetrician delivering an injured baby physically outside of a hospital could fall outside the criteria. Similarly, a “bad baby” that

32. Tedcastle, supra note 2, at 590. The similarities between workers’ compensation plans and NICA were that in both of these plans, purportedly in return for a relatively assured compensation handled through an administrative solution, the injured party gave up his common law tort rights. Bradford v. Fla. Birth-Related Neurological Injury Comp. Ass’n, 667 So. 2d 401, 403 (Fla. 4th Dist. Ct. App. 1995).

33. Tedcastle, supra note 2, at 590 n.424.

34. Id. Because of this proof requirement, NICA was neither pure tort nor pure no-fault.


37. This is not inconceivable. Although no cases of this nature are yet reported, an expectant mother might deliver a catastrophically injured baby at home or on the way to the hospital. The issue might arise whether the obstetrician who had delivered prenatal care is eligible to receive NICA protection, or whether he or she loses that benefit because the mother failed to make it to the hospital. In a related scenario, there is an issue as to whether an ob-gyn would receive the benefit of NICA protection if he or she cared for a pregnant woman who negligently abused illicit drugs or alcohol during the pregnancy and unexpectedly delivered at home. But see Fluet v. Fla. Birth-Related Neurologic Injury Comp. Ass’n, 788 So. 2d 1010 (Fla. 2d Dist. Ct. App. 2001). In Fluet, a mother of a neurologically injured baby who died was denied NICA benefits by the administrative law judge because she was delivered by a midwife, and her ob-gyn was not physically in the hospital when he ordered medication for her telephonically. Id. at 1010–11. The appellate court reversed, finding there was no specific
weighed 2400 grams or an infant that was the result of a genetic accident would not be covered, yet potentially are just as injured. NICA was meant to be the sole and exclusive remedy for an infant who satisfies the above criteria of a birth-related neurologically injured infant. A hospital and mandate that the physician be physically present in the delivery room. Id. at 1013. The holding discussed the difference between delivering the baby and the delivery of obstetrical services and concluded that NICA refers to the delivery of obstetrical services. Id. The statement of facts, however, do not tell if the physician was present in the hospital or out of the hospital when he telephoned his medication order. Id. This too may influence a court.

Also, consider the situation where a NICA-participating physician emergently delivers a mother in a migrant labor camp situation rather than in a hospital, and that mother has not had the benefit of prenatal care. While the statute provides for no notice in a situation like this, it does not speak directly to the “out of hospital” instance. This physician, who fully paid his or her assessment, might not be covered in the event of a birth-related neurological injury. If that same infant weighed slightly less than 2500 grams at birth, the ob-gyn would not be covered despite the fact that he paid his or her assessment into the program and notified the pregnant patient that he participated in NICA. These hypotheticals make the hazards of NICA’s restrictive statutory definition clear.

38. A “bad baby” is medical jargon for an obstetrical accident that results in a neurologically defective infant. See generally Cavanaugh, supra note 27, at 1299–1300 n.3 (giving a graphic example and discussion of the “bad baby” syndrome).

39. In order for an infant to be covered, the infant must meet the statute’s criteria. If a newborn infant is neurologically impaired, there may be questions as to whether the infant’s impairment resulted from hypoxemia (oxygen deprivation) or mechanical injury, and therefore covered, versus undiagnosed genetic injury or even maternal drug use, and therefore not covered. The no-fault aspect is already suspect since it will be a “my expert says this versus your expert says that” argument from the beginning. It has the potential to resemble traditional tort actions in medical negligence. Cavanaugh, supra note 27, at 1312–13 (describing the uncertain and complex interrelationship between events during pregnancy and perinatal events that lead to neurologically injured infants). It is not always certain whether the physician’s actions caused the injuries. Id. See Studdert, supra note 15, at 519–21; Bovbjerg, supra note 29, at 53–123 (discussing in detail the “no-fault” alternative to the medical malpractice crisis and propounding it as a substitute for the current system in tort). They explain in general that the central premise of no-fault is to “make third-party insurance for medical injuries more like first-party health or disability insurance.” Bovbjerg, supra note 29, at 64.

40. Cavanaugh, supra note 27, at 1321.

The rights and remedies granted by this plan on account of a birth-related neurological injury shall exclude all other rights and remedies . . . against any person or entity directly involved with the labor, delivery, or immediate postdelivery resuscitation during which such injury occurs, arising out of or related to a medical malpractice claim with respect to such injury[.] FLA. STAT. § 766.303(2) (2001). The same subsection of the statute also states that one may pursue a tort action if there is clear and convincing evidence of bad faith or malice on the part of the provider. Id.
physician must provide specific and timely notification to their pregnant patients in order to claim the protection of NICA's no-fault benefits, except in certain defined emergent circumstances. The statute initially provided that when a claimant filed a claim, it was to be reviewed by a panel of physicians selected by the Division of Workers' Compensation. That nonbinding, advisory panel is composed of three appropriately skilled physicians whose review determines whether the infant meets NICA's statutory criteria. If the infant's injuries are found to be noncompensable, then the claimant may pursue her remedy in tort. On the other hand, if the infant has suffered compensable injuries, NICA provides for as much as $100,000 in damages to the parents, plus actual expenses for medically reasonable bills related to the infant's medical care, rehabilitative care, training, and custodial care. Excluded from these listed covered expenses

41. Cavanaugh, supra note 27, at 1320. The Florida Statutes state that each hospital that has a participating physician and each participating physician shall:

provide notice to the obstetrical patients as to the limited no-fault alternative for birth-related neurological injuries. Such notice shall be provided on forms furnished by the association and shall include a clear and concise explanation of a patient's rights and limitations under the plan. The hospital or the participating physician may elect to have the patient sign a form acknowledging receipt of the notice form. Signature of the patient acknowledging receipt of the notice form raises a rebuttable presumption that the notice requirements of this section have been met. Notice need not be given to a patient when the patient has an emergency medical condition as defined in s. 395.002(9)(b) or when notice is not practicable.


42. Cavanaugh, supra note 27, at 1320–21. Due to dissatisfaction with claims handling, the Division of Workers' Compensation was replaced by the Division of Administrative Hearings in May 1993. Bovbjerg, supra note 29, at 87.

43. Cavanaugh, supra note 27, at 1320–21. Section 766.308(1) of the Florida Statutes states:

Each claim filed with the division under ss. 766.301–766.316 shall be reviewed by a medical advisory panel of three qualified physicians appointed by the Insurance Commissioner, of whom one shall be a pediatric neurologist or a neurosurgeon, one shall be an obstetrician, and one shall be a neonatologist or a pediatrician. The panel shall file its report, with its recommendation as to whether the injury for which the claim is filed is a birth-related neurological injury, with the division at least 10 days prior to the date set for the hearing. . . . The administrative law judge shall consider, but not be bound by, the recommendation of the panel.

FLA. STAT. § 766.308(1) (2000). It is the administrative law judge of compensation claims of the Division of Workers' Compensation that makes the final determination. FLA. STAT. § 766.309(1) (2001).

44. FLA. STAT. § 766.31(1)(b)1. (2001).
are various payments made to the claimant, such as from the government, various health care plans, or other insurance policies.\textsuperscript{45}

The Act provides for attorneys’ fees as well,\textsuperscript{46} although the restrained attorneys’ fees under NICA will not be as attractive as the usual contingency tort fee.\textsuperscript{47} Additionally, section 766.306 of the \textit{Florida Statutes} state that “[t]he statute of limitations with respect to any civil action that may be brought by, or on behalf of, an injured infant allegedly arising out of, or related to, a birth-related neurological injury shall be tolled by the filing of a claim.”\textsuperscript{48} Strictly read, it would appear that this provision grinds civil actions to a halt while the administrative action is settled, allowing time for the claimant to pursue her common law remedy later should the injuries prove to be noncompensable under NICA. However clear this language appears, in \textit{Humana of Florida, Inc. v. McKaughan},\textsuperscript{49} the court found and discussed the uncertainties that it perceived.\textsuperscript{50}

\textbf{IV. HAS NICA BEEN SUCCESSFUL?}

Gauging the success of a program like NICA is not easy. First of all, in general, it is hard to agree as to which parameters indicate success. The stated legislative goal was “provid[ing] compensation, on a no-fault basis, for a limited class of catastrophic injur[y] that result[ed] in unusually high costs for custodial care and rehabilitation;”\textsuperscript{51} this goal has no easily monitored and quantifiable parameters. In general, it is problematic to be highly confident in the value and interpretation of physician oriented information due to medical and legal complexities.\textsuperscript{52} Additionally, Studdert

\begin{itemize}
\item[\textsuperscript{45}] § 766.31(1)(a)1–4.
\item[\textsuperscript{46}] § 766.31(1)(c). \textit{But cf.} Fla. Birth-Related Neurological Injury Comp. Ass’n \textit{v.} Carreras, 633 So. 2d 1103 (Fla. 3d Dist. Ct. App. 1994) (showing that an attorney’s fee of $300 per hour was excessive and that any time the attorney spent in researching whether the patient’s claim should be filed in tort was not compensable as an attorney’s expense).
\item[\textsuperscript{47}] Studdert, \textit{supra} note 15, at 521 (noting that plaintiffs’ attorneys have an economic incentive to go around NICA and file in tort).
\item[\textsuperscript{48}] § 766.306.
\item[\textsuperscript{49}] 652 So. 2d 852 (Fla. 2d Dist. Ct. App. 1995), \textit{certifying question to} 668 So. 2d 974 (Fla. 1996).
\item[\textsuperscript{50}] This ambiguity meant to this court that when a malpractice defendant invokes NICA as an affirmative defense, the malpractice action did not necessarily automatically abate. \textit{Id.} at 861.
\item[\textsuperscript{51}] § 766.301(2).
\end{itemize}
noted how hard it is to isolate the forces that account for any causal change given the complexity of the medical malpractice arena. Thus, no real clarity evolves out of any method of gauging NICA's success.

For example, one might realize it would not be difficult to measure the cost of today's medical malpractice premiums and compare them in relative dollars to the premiums ob-gyns paid during the height of the malpractice crisis. However, the factors that may have affected those premiums are practically impossible to quantify given the dramatically changing health care climate over the relevant period. Consider that prior to the Clinton presidency, it would have been a rare American who understood what "managed care" was. Today, to the contrary, managed care is pervasive, and it would be a rare American who does not know what an HMO is. Any change in either the malpractice premiums, the availability of insurance, or the generally quieter malpractice climate might have resulted from any cause or combination of causes. However, it is at least as likely that the natural progression of managed care, rather than the effects of NICA, has been most influential. The end result is that NICA proponents will rave about NICA, and managed care proponents will rave about managed care.

Stewart notes just how difficult it is to understand malpractice trends and relates a relevant example. A slight alteration of her example would compare two physicians with different policy limits, one at $200,000 and

54. Id.
56. Whether the premiums are inflating, deflating, or stable, any statistical analysis would be hard pressed to accurately interpret the dramatic health care delivery changes that have coincidentally accompanied the birth and adolescence of NICA.
57. Stewart, supra note 52, at 977-78. In the Stewart scenario, there are two physicians, one with $1,000,000 and one with $200,000 in malpractice insurance policy limits. Id. Stewart hypothesizes that where there is a nuisance suit (non-negligent physician) of $200,000, the insurer for the $1,000,000 holder will be willing to settle because litigation costs will exceed that amount. Id. at 978. When the other physician clearly commits an act of malpractice, his or her insurer will be quick to settle to the policy limit knowing that their client will probably lose. Id. The question posed is how will these similar insurer settlement actions be classified for analysis. Id. In one case, the payment compared to coverage ratio is twenty-five percent; in the other, it is 100%. Id. Therefore, this frequently used ratio provides little analyzable data: both cases settled, one physician was negligent, and the ratio does not indicate who it is. Id. Stewart also points out that effective classification may be obfuscated because it might be analyzed in terms of the type of injury or the type of physician. Id. She convincingly shows that use of these statistics may not be probative. Id.
one at $1,000,000. Even nonculpable conduct on the part of the physician with the lower policy limit might cause his or her insurer to settle because defending against the claim might cost more that the policy limit. On the other hand, the high policy limit holder's insurer might defend "to the hilt" even culpable conduct, and bring in the crème de la crème of defense attorneys in order to avoid a judgment. A certain number of these high policy limit cases are going to be won, while the lower policy limit cases will be settled out of court. The result is a skewed and irrational view of malpractice trends, depending on the particular variable studied. Consequently, if physicians by chance or design over the relevant time period decide to increase or reduce their policy limits, then this might confound the understanding of the results of malpractice trend curves. Thus, one sees how medical and legal complexities may make one less confident in the integrity of possible causative parameters.

In addition, the Florida malpractice climate had calmed, and more insurers were looking to reenter the Florida market. The reality was, though, malpractice premiums had stabilized and decreased around the entire country over the time period NICA has been in effect, not just in Florida. 58 Even administrators from the Florida Department of Insurance, like William Bodiford, admit that it is thereby unreasonable to attribute this improved malpractice climate as one of NICA's successes. 59 As Richards noted, "[t]he effectiveness of these limited [no-fault] plans ... is dubious—both in their ability to adequately compensate injured newborns and in restoring insurance coverage to obstetricians." 60 Nevertheless, there was additional access to health care in Florida during the 1990s, even though "there is no empirical evidence that no-fault caused these improvements." 61 More recently, though, medical malpractice insurance is once again difficult to come by and increasing in cost. 62 These data suggest that

58. Richards, supra note 13, at 109 n.39; Studdert, supra note 15, at 500 (commenting that it is hard to isolate the forces that account for any change given the complexity of the medical malpractice insurance market).
59. Richards, supra note 13, at 109 n.39 (detailing a telephone interview between Richards and Bodiford where Bodiford himself opined that Florida's "social insurance program' [was] not deserving of any 'rave reviews'").
60. Id. at 109.
61. Bovbjerg, supra note 29, at 110.
62. Letter from Jenan L. Ariff, Vice President Aon Healthcare Practice, to Sandy Martin, M.D. (July 17, 2001) (explaining the generally worsening malpractice insurance situation and expected premium increases, as part of a mailing to all physician clients renewing medical malpractice insurance). The letter also notes mergers along with the pullouts. Id. This type of consolidation is rarely market friendly. Id.
even with NICA in existence for over a decade, there may be another medical malpractice crisis in the near future.

The absolute number or relative trend of malpractice suits for birth-related neurologically injured patients might be an appropriate measure of NICA success. Proponents might argue that if NICA does an excellent job, there would be fewer NICA claims and fewer payouts than anticipated. Detractors might look at the same data and lament that NICA is not doing its share or that the advisory panel is refusing to certify appropriate injuries. Other proponents might look to the reduced frequency and size of obstetrical malpractice suits in general and claim victory for NICA since it occurred since NICA's inception. However, this improvement can hardly be attributed to NICA, and even the improvement appears to be waning.

While it is difficult to arrive at a number, studies suggest that NICA should have approximately twenty-seven to fifty-three certified claims per year. Yet, from 1989 through 1997, a total of eighty-six claims were approved. The reasons for this are not clear, but it is not likely to be because of a sudden improvement in health care itself. Perhaps it may have had something to do with a reduced "claiming behavior" pattern or that some of these cases are simply just "lost[t] to tort."

Studdert conducted a statistical, empirical investigation and concluded that with respect to data as of 1998, "the annual frequency of tort claims did not undergo a statistically significant change after 1989 in either the $250,000+ or $500,000+ group of cases." Given that there are weaknesses with the statistical data, Studdert admits anyway that high cost tort claims, of

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64. Id. at 516. The authors note, however, that NICA has been relatively efficient at distributing the money it did distribute (approximately $12,000,000 of $15,700,000 went to the injured and their parents during the 1989–1997 interval). Id. at 503–04. Also, NICA's staff has been a source of advice and counsel, as well as money, to its beneficiaries. Yet, a significant number of patients who were denied compensation under NICA did receive compensation in tort, several at levels beyond the $1,000,000 level. Id. at 515. This leaves one with the gnawing question as to why the statute did not foreseeably include these birth-related injuries. Id. at 503.
65. Ariff, supra note 62.
66. Studdert, supra note 15, at 504.
67. Id. at 503–04.
68. Id. at 504–05.
69. Id. at 505. For example, Plaintiff's attorneys may have steered their clients away from NICA given the sparse attorney remuneration compared to tort recovery; or, for example, even some confusion as to NICA's role. Id.
70. Id. at 506.
71. Studdert, supra note 15, at 509.
the type that the no-fault NICA was designed to eliminate, persist. Ultimately, if there is a persistence of the type of high cost malpractice claim that NICA is designed to eliminate, then absent an increased number of actions of this kind, NICA’s benefit is less than convincing.

In some articles, investigators seemed to have concluded that a firm indicator of NICA’s success might be efficiency, defined as speed of resolution and level of administrative cost compared to tort. When these parameters were evaluated, as best as they could be, the authors concluded that NICA was a resounding success. Unfortunately, the devil is in the details. They note that while the program was intended to be restrictive, it is more narrow than intended; that there are still tort remedies leading to a manipulation of the program based on “perceived benefits” to both the claimants and their attorneys; and that a small program such as this leads to inefficiencies that perhaps could be overcome by a larger program. Some might claim that the exceptions defeat the conclusion, particularly when just about the same number of high claim injured infant tort actions occur now as before NICA.

V. THE REALITY OF NICA HAS NOT MET ITS EXPECTATION

There are expected advantages of a no-fault system. For example, one would expect reduced lawyer costs, one of the highest of overhead costs of the tort medical malpractice system; presumably less time delay in monetary recovery and time involvement by the defendants; and less need for the practice of defensive medicine due to the strict liability nature of the harm. The reality of the system, however, does not seem to have matched

[72. Id. (noting the “lively persistence” of these high cost tort claims).]
[73. Randall R. Bovbjerg et al., Administrative Performance of “No-Fault” Compensation for Medical Injury, 60 LAW & CONTEMP. PROBS. 71, 73 (1997).]
[74. Id. at 106–08.]
[75. Id.]
[76. Studdert, supra note 15, at 517.]
[77. Kirk B. Johnson et al., A Fault-Based Administrative Alternative for Resolving Medical Malpractice Claims, 42 VAND. L. REV. 1365, 1374 (1989); Bovbjerg et al., supra note 73, at 84. “Defensive medicine” refers to the practice of physicians ordering many tests and procedures that they would ordinarily not consider necessary, all because they consciously or subconsciously realize that they may be sued and have to take the witness stand to defend why they didn’t perform that esoteric test. See generally Michael C. Thornhill et al., Health Care Reform: Perspectives from the Clinton Campaign, 15 WHITTIER L. REV. 3, 7–8 (1993) (relating that physicians on a panel discuss the amount of defensive medical care they administered during their previous twelve-hour shift). The result of this is a general increase]
the promise, at least in Florida. Studies show that there is over a three-fold increase in Florida tort activity with respect to the types of claim NICA is designed to compensate, as compared to Virginia, where the other no-fault birth-related neurologically injured program is in effect.

The reasons for the increased litigious nature of the Florida patient are speculative, but practicing Florida physicians intuitively sense that Florida is a different type of medical environment. The older patient relocates from “up north” where they have spent their lives with a given set of physicians. They are suddenly faced with the situation of securing a new team of physicians to guide them through many of life’s most difficult problems. They are at a point in their lives when more medical problems develop, problems that never occurred when they were “up north” and younger. Maybe because it is human nature to search for a cause for these new problems, they often blame their Florida physicians. Also, perhaps they may be agitated into malpractice action by the plethora of attorney advertising on television, on the radio, and on the front and back covers of their local “Yellow Pages.” Obviously, as a group, they do sue, but the preceding speculation more accurately pertains to the elderly than it does to the younger obstetric group, who are more or less twenty or thirty-something. How the older group influences the obstetrical group toward their proclivity to sue in tort is ill defined; but even at twenty or thirty-something, it is not unreasonable to believe that they have acquired their parents’ and relatives’ opinions concerning their health care and their physicians. Then, if something goes awry, they are ready to pull the malpractice trigger. It is a fact that even among no-fault claimants, the large majority does not believe that the cause of their medical injury was accidental, but rather name a “provider” as being at fault.

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See also Cynthia J. Dollar, Note, Promoting Better Health Care: Policy Arguments for Concurrent Quality Assurance and Attorney-Client Hospital Incident Report Privileges, 3 HEALTH MATRIX 259.261-62 (1993) (noting that the “proliferation of medical malpractice suits, which began in the 1980s, has caused physicians, nurses, and other hospital personnel to practice defensive medicine...to ward off potential liability”). More tests and procedures along with more paperwork which occupy a greater percentage of health care time are all incident to this. Id.

78. Frank A. Sloan et al., The Road from Medical Injury to Claims Resolution: How No-Fault and Tort Differ, 60 LAW & CONTEMP. PROBS. 35, 48 (1997).
79. Id.
80. Stewart, supra note 52, at 979 (explaining the litigious nature of the Florida patient).
81. In defining a “provider,” the Florida Statutes state:
It is interesting to note that in a 1989 article, during the height of the malpractice crisis, proponents of an alternative fault based system of tort reform said that their proposed alternative "responds directly to the flaws in the current [tort] system... [and would] permit more injured parties to be compensated than does the current system." If one considers this a laudable goal of tort reform, there is no evidence that the no-fault NICA has been able to reach this goal. The authors also looked forward to an enhanced predictability of claim compensation, but there is no evidence that this goal, as applied to NICA, has been reached. After all, it is nearly impossible to predict whether a neonate will be adjudicated to be both physically and mentally impaired, as is required by the statute's definition. The authors thought that their alternative no-fault based system would lead to a larger number of meritorious claims because recovery would not be limited to those claims that were high enough to attract a contingency paid attorney. Once again, if one assumes that this is a laudable goal, NICA has not reached it. Parents and guardians will generally seek out the assistance of counsel when a "bad baby" situation arises. The first goal of counsel is going to be to prove that this baby did not meet the restrictive criteria of NICA, in order that he can go forward in tort. The authors of the article believe that a NICA type of no-fault plan "offend notions of justice and

The term "health care providers" means physicians licensed under chapter 458, osteopathic physicians licensed under chapter 459, podiatric physicians licensed under chapter 461, optometrists licensed under chapter 463, dentists licensed under chapter 466, chiropractic physicians licensed under chapter 460, pharmacists licensed under chapter 465, or hospitals or ambulatory surgical centers licensed under chapter 395.


This term insidiously entered the insurance vernacular in the late 1970s and early 1980s, as physicians began to receive insurance letters that began: "Dear Provider" instead of "Dear Doctor." Most practicing physicians abhorred that tendency to depersonalize their professional lives, but they could do nothing. It may have represented the beginning of the managed care "push," where physicians became interchangeable commodities as patients purchased health care plans rather than made appointments for personal physicians. Patients were no longer life-long patients of their doctor, but were consumers of their insurance plans' products.

82. Sloan, supra note 78, at 48.
83. Johnson, supra note 77, at 1389–90.
84. Id. at 1390.
85. § 766.302(2).
86. Johnson, supra note 77, at 1390.
87. Humana of Fla., Inc., v. McKaughan, 652 So. 2d 852 (Fla. 2d Dist. Ct. App. 1995) (presenting just such a case where the claimant’s goal was to prove he was not eligible for NICA).
individual accountability by imposing liability on health care providers even when they have done everything humanly possible to treat a patient but were unable to prevent a bad outcome.  

Although this article was not directly analyzing NICA, it is applicable because it was nevertheless discussing fault versus no-fault principles.

Perhaps NICA has excelled in other areas that outweigh its lukewarm performance in claims management. For example, in addition to the goal of compensation, Cavanaugh states that another goal of tort law that a no-fault program should attempt to accomplish is to deter poor medical practice. If the no-fault NICA program were to be completely successful, it would be successful at reducing the frequency and severity of birth related injuries, but that implies that these variables are within the control of the physician. Some variables are within the physician's control, such as the clumsy obstetrician who drops the neonate and breaks its spine or incorrectly uses extraction forceps and causes neurological damage. However, it is intuitive that a no-fault system would not deter poor medical practice in the same way a tort system would, where the accused physician sits in the courtroom and listens to the zealous advocacy of the plaintiff's attorney as he or she describes in embarrassing detail his or hers each and every mistake. This ego deflating fear is what deterrence is about. A no-fault system simply cannot address this with equal force.

The above analysis shows that while there have been some successes to NICA, the reality is that NICA simply has not lived up to its expectation. Whether it has been harmful is speculative. Perhaps it has been harmful because it has deterred consideration of a more meritorious plan.

During its evolution, NICA has faced four legal hurdles that have molded the statute, its construction, and effectiveness. The following four sections of this comment will present and analyze each of these legal problems in detail. The first section concerns the nature of NICA's funding mechanism. Both claimants and nonparticipating physicians, whether ob-gyns or nonobstetrical physicians, dislike the funding mechanism, although the funding has been adjudicated constitutional. It fails to meet the most basic tenet of an assessment of any kind, which is to allow the payer to see and reap the benefit of the tax. The second section concerns the notice requirement, which is burdensome and unfriendly to both the patient and physician. The notice requirement was added to avoid constitutional

88. Johnson, supra note 77, at 1376.
89. Cavanaugh, supra note 27, at 1338.
90. Id.
91. Bovbjerg, supra note 29, at 98 n.224.
weakness, yet it may ultimately lead either the patient or the physician to inadvertent loss of benefit. The third section of this comment will look at the ongoing jurisdictional struggle between the judiciary and the legislature. This comment will provide insight into how that struggle parallels the plaintiff and defense bars’ struggle for tort versus no-fault causes of action. The last section of this comment will analyze how the narrow medical definition of the potential claimant has often times eliminated the very party most in need of assistance.

A. The Oppressive Nature of NICA’s Funding

Section 766.314 of the Florida Statutes defines the assessments to the NICA program. It provides that all licensed physicians, exclusive of participating physicians, shall pay an initial assessment of $250 per year. If the physician became licensed after January 1, 1989, the physician would not be able to get away with a lower initial assessment since he or she would need to pay an initial assessment equal to the most recent assessment. With respect to those physicians who deliver obstetrical services, if the physician elected to become a participating physician, then the physician would pay an initial assessment of $5000, as well as the various annual

92. “Participating physician” means:
   a physician licensed in Florida to practice medicine who practices obstetrics or performs obstetrical services either full time or part time and who had paid or was exempted from payment at the time of the injury the assessment required for participation in the birth-related neurological injury compensation plan for the year in which the injury occurred. Such term shall not apply to any physician who practices medicine as an officer, employee, or agent of the Federal Government.

§ 766.302(7).

93. § 766.314(4)(b)(1).

94. § 766.314(4)(b)(3).

95. Before December 1, 1988, physicians who wish to participate:

shall pay an initial assessment of $5,000. However, if the physician is either a resident physician, assistant resident physician, or intern in an approved postgraduate training program, as defined by the Board of Medicine or the Board of Osteopathic Medicine by rule, and is supervised by a physician who is participating in the plan, such resident physician, assistant resident physician, or intern is deemed to be a participating physician without the payment of the assessment. Participating physicians also include any employee of the Board of Regents who has paid the assessment required by this paragraph and paragraph (5)(a), and any certified nurse midwife supervised by such employee. Participating physicians include any certified nurse midwife who has paid 50 percent of the physician assessment required by this paragraph and paragraph (5)(a) and who is supervised by a participating physician who has paid the assessment required by this paragraph and
assessments indicated above. There are exceptions to the assessments, which include certain classes of physicians such as residents in training, those who work for the Veterans Administration, and those with limited licenses.  

The Florida Statutes also provided that each hospital had to pay an assessment that was equal to fifty dollars per infant delivered in the hospital during the previous calendar year. The statute also provides for additional assessments to the hospital entities, if needed.

In addition to the above, in order to maintain the plan on "an actuarially sound basis," the statute also provides that up to $20,000,000 in additional money may be transferred from the Insurance Commissioner's Regulatory Trust Fund and, in certain instances, from casualty companies.

A source of contention from the receipt of the first NICA assessment, Florida physicians, in a class action, challenged the constitutionality of the funding mechanism. The class of physicians that did not practice paragraph (5)(a). Supervision shall require that the supervising physician will be easily available and have a prearranged plan of treatment for specified patient problems which the supervised certified nurse midwife or physician may carry out in the absence of any complicating features. Any physician who elects to participate in such plan on or after January 1, 1989, who was not a participating physician at the time of such election to participate and who otherwise qualifies as a participating physician under ss. 766.301-766.316 shall pay an additional initial assessment equal to the most recent assessment made pursuant to this paragraph, paragraph (5)(a), or paragraph (7)(b).

§ 766.314(4)(c).  
96. § 766.314(4)(b)4.a.-f.
97. § 766.314(4)(a).
98. § 766.314(7)(a). These are based upon actuarial calculations and valuations, provided that at no time the premium shall be greater than one quarter of one percent of the net direct written premiums. Id.
100. § 766.314(5)(b). "If the assessments collected ... are insufficient to maintain the plan on an actuarially sound basis, there is hereby appropriated for transfer to the association from the Insurance Commissioner's Regulatory Trust Fund an additional amount of up to $20 million." Id.

Taking into account the assessments collected pursuant to subsection (4) and appropriations from the Insurance Commissioner's Regulatory Trust Fund, if required to maintain the plan on an actuarially sound basis, the Department of Insurance shall require each entity licensed to issue casualty insurance as defined in s. 624.605(1)(b), (k), and (q) to pay into the association an annual assessment in an amount determined by the department pursuant to paragraph (7)(a), in the manner required by the plan of operation.

§ 766.314(5)(c)(1).
101. McGibony, 564 So. 2d at 178.
obstetrics argued that they were no more likely to receive a benefit from this assessment than any other member of the general public.\(^\text{102}\) They maintained that their rights to due process and equal protection under both the Florida and Federal Constitutions were violated.\(^\text{103}\) They saw the assessment as nothing more than an ill-conceived tax against the profession in general.\(^\text{104}\) The class asserted that there was “no rational basis for singling [them] out” to pay this tax,\(^\text{\textsuperscript{105}}\) except based upon an arbitrary and discriminatory action.\(^\text{106}\)

Because the Supreme Court of Florida agreed that “[o]nly clear and demonstrated usurpation of power will authorize judicial interference with legislative action,” the burden was on the class to prove that there was no conceivable basis to support the disliked tax.\(^\text{107}\) Unfortunately for the plaintiff physicians, their class was not a protected class,\(^\text{108}\) and the court stated that the tax would be constitutional so long as the state had a rational basis for its taxation decision and the decision was not arbitrary.\(^\text{109}\) Nonparticipating, nonobstetrical physicians (the majority of the physicians in Florida) complained, in effect, that it was unfair to lay a tax upon them selectively when all they did to “deserve” the tax was be a physician.\(^\text{110}\) One can assume from the class action that those that never delivered obstetrical services or had anything to do with labor and delivery could not believe that it was fair, or constitutional, to force them to selectively finance a malpractice problem in which they had no specific interest. By way of example, if a colo-rectal surgeon had a malpractice problem or indeed if colo-rectal surgeons as a group had a malpractice problem, the ob-gyns were not offering to pay toward their increased insurance premiums.\(^\text{111}\) This feeling amongst physicians became a near

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\(^\text{102. Id. at 179.}\)
\(^\text{103. Id. at 178.}\)
\(^\text{104. Id.}\)
\(^\text{105. Id. at 179.}\)
\(^\text{106. McGibony, 564 So. 2d at 179.}\)
\(^\text{107. Id.}\)
\(^\text{108. To fall within the construction of the equal protection provision of the Florida Constitution, “a ‘suspect class’ is any group that has been the traditional target of irrational, unfair and unlawful discrimination.” Coy v. Fla. Birth-Related Neurological Comp. Plan, 595 So. 2d 943, 945 (Fla. 1992).}\)
\(^\text{109. McGibony, 564 So. 2d at 179.}\)
\(^\text{110. Id.}\)
\(^\text{111. Interview with Harvey Garber, M.D., Board Certified Colo-Rectal Surgeon, in Palm Beach Co., Fla. (June 30, 2001).}\)
revolt, as nearly 17,000 physicians did not pay their NICA assessment early in NICA’s history.\textsuperscript{112}

The court studied the legislative intent of the Florida Legislature and determined that there was a malpractice crisis in Florida and a severe stress on the efficient delivery of health care, which ultimately affected all physicians in the state.\textsuperscript{113} They relied upon the concept of a team approach to medicine, and thus the court held that the legislature’s decision to selectively tax all physicians, but not the public at large, was not arbitrary, unreasonable or capricious and was therefore constitutional.\textsuperscript{114} The court used the syllogism that all doctors rely upon efficiently operated hospitals, and when the delivery of obstetrical care is disrupted as a result of the malpractice crisis, hospitals will not be efficiently operated.\textsuperscript{115} As a result, all physicians will be negatively impacted. Thus, physicians alone should pay the assessment.\textsuperscript{116}

To the dismay of the nonobstetrical physicians, the court stated precisely the opposite of what the Florida physicians had been thinking: "[w]e are convinced that all physicians, regardless of whether they practice obstetrics, derive a benefit from this legislation that is greater in degree than that derived by the general public."\textsuperscript{117} Thus, in general

\begin{itemize}
  \item 112. Coy, 595 So. 2d at 945.
  \item 113. McGibony, 564 So. 2d at 179.
  \item 114. Id. In addition, the Coy court was extremely concerned about the system-wide disruption that could ultimately befall the citizens, hospitals and physicians of Florida as a result of the malpractice crisis. Coy, 595 So. 2d at 946. The following exchange occurred:
  
  Question: “Hypothetically, let’s assume for a moment that all of the obstetrical physicians on that staff, because of malpractice premiums and because of—frankly, because of the problems associated with malpractice, including having to come to the courthouse and testify, and so forth, decided they had had enough. And they had decided that they have had enough so much that they decided to stop either treating indigent patients, which are sometimes a common problem pregnancy, or otherwise just stop practicing OB. Based on that hypothetical I gave you and your small knowledge of Jackson, would that have an effect on that hospital’s operations?”

  Answer: “It would be disastrous.”

  Question: “That disaster would permeate that hospital; wouldn’t it?”

  Answer: “I presume, yes.”

  Id.

  115. Coy, 595 So. 2d at 946.

  116. Id. at 946–47.

  117. Id. at 947.
\end{itemize}
constitutional terms, the legislature's methods were rationally related to legitimate governmental objectives and were constitutional, and, not being a protected group, the physicians would have to pay a tax they considered spiteful. It was a close four to three decision, and the dissent echoed the feelings of every one of those 17,000 physicians who did not pay their assessment.

Speaking for the dissent, Justice Kogan wrote, "I can find no rational basis for imposing much of the burden of this program primarily on physicians as a class . . . particularly . . . in light of the fact that obstetricians are not obliged to join the plan, and many have exercised this option." He said that this was nothing more than a "status tax" based on one's station in life, and, unless there was a nexus between that status and the goal the tax was designed to achieve, it would not pass even rational basis scrutiny. He believed that imposing this tax denied equal protection because similarly situated persons were not being treated similarly. Also, in this case, there was no quid pro quo—the nonobstetrical physicians were paying a tax and they received no specific benefit that the public at large did not receive.

A different consideration was accepted without challenge by all of the justices. This consideration was whether the assessment was a tax at all or was it a user fee. That the justices agreed the assessment was a tax allowed them to rapidly decide that rational basis, or severe deference, would be appropriate. Had the court instead decided that the assessment was a user fee, this jump would not have been so clear. For example, a user fee is one in which the fee is collected for a specific benefit, and thus the collecting entity must show that the fee fairly approximates the benefit received. Based upon this, some critics, however, have disagreed with the tax interpretation. They point out that although the assessment superficially resembles a tax, the court presented an analysis that was more along

118. Id. at 948.
119. Id.
120. Coy, 595 So. 2d at 948.
121. Id. at 947.
122. Id.
124. Id. at 329.
125. Id. at 333.
126. Id. at 329.
127. Id. at 331–33.
the lines of a “benefits-received” analysis.\textsuperscript{128} The absolute value of the difference between what the obstetrical physicians had to pay as opposed to the nonobstetrical physicians was meant to indicate the legislature’s construction as to the difference in value ($250 versus $5000) between the two groups.\textsuperscript{129} The ob-gyns were to receive this value benefit for their pecuniary burden, and it was appropriate for them to pay more.\textsuperscript{130} Other courts, however, have found that “benefits-conferrered” principles did not govern taxes but were appropriate instead for user fees or special assessments, thereby creating a constitutional question as to the funding mechanism.\textsuperscript{131}

Therefore, they opined, where assessments were for specific government provided services, the assessment was not a tax, but a special assessment or a user fee.\textsuperscript{132} “Similarly, the physician’s fee is not a tax . . . [and] [t]he court should have looked beyond the literal tax definition because a charge which superficially satisfies the definition might still be governed by [user fee] principles.”\textsuperscript{133} Therefore, it was concluded that the court incorrectly applied user fee principles and labeled the physician assessment as a tax.\textsuperscript{134} This is an important observation. With such a narrow majority and new members of the court, should this issue come before the court again they might find this assessment a user fee. In that case, the statute would not be presumptively valid, and the extreme deference accorded the legislature would not be automatic.\textsuperscript{135}

\textsuperscript{128} Liebman, \textit{supra} note 123, at 331–33.
\textsuperscript{129} \textit{Id.} at 331.
\textsuperscript{130} \textit{Id.}
\textsuperscript{131} \textit{Id.} at 332. \textit{See also} Alamo Rent-A-Car, Inc. v. Sarasota-Manatee Airport Auth., 906 F.2d 516, 518 (11th Cir. 1990) (following the reasoning that for a user fee to not violate the commerce clause, it must be a fair approximation of the value of the benefit conferred); City of Naples v. Moon, 269 So. 2d 355, 358 (Fla. 1972) (differentiating ad valorem taxes and special assessments); State \textit{ex rel.} Clark v. Henderson, 188 So. 351, 354 (Fla. 1939) (explaining that a tax and a special assessment are similar, but a special assessment is an enforced contribution that is imposed on a segment of the community as a result of special or peculiar benefit).
\textsuperscript{132} Liebman, \textit{supra} note 123, at 332.
\textsuperscript{133} \textit{Id.}
\textsuperscript{134} \textit{Id.}
\textsuperscript{135} \textit{Id.} at 335.
B. The Notice Requirement or How Not to Win Friends and Influence People

The NICA statute requires that each hospital with a participating physician and each participating physician shall give notice to their patients. The notice will advise the patient that a limited no-fault compensation program covers their provider in the event of severe neurological birth-related injury and the provisions of this insurance represent their only remedy in the event of a severe birth-related injury. The features of the notice requirement include that it shall be clear and concise; that the notice shall be given on a specific NICA-provided form; that the providers may elect to have the patients sign a receipt indicating they signed the form (in order to benefit from the rebuttable presumption clause that notice has been given); and that notice need not be given in the event of an emergency that meets the State of Florida’s statutory definition or when it is not practicable. If the physician or hospital fails to provide such notice, neither they nor the claimant will obtain the benefit of NICA protection in the event of birth-related neurological injury.

136. FLA. STAT. § 766.316 (2001). The full text is as follows:
Each hospital with a participating physician on its staff and each participating physician, other than residents, assistant residents, and interns deemed to be participating physicians under s. 766.314(4)(c), under the Florida Birth-Related Neurological Injury Compensation Plan shall provide notice to the obstetrical patients as to the limited no-fault alternative for birth-related neurological injuries. Such notice shall be provided on forms furnished by the association and shall include a clear and concise explanation of a patient’s rights and limitations under the plan. The hospital or the participating physician may elect to have the patient sign a form acknowledging receipt of the notice form. Signature of the patient acknowledging receipt of the notice form raises a rebuttable presumption that the notice requirements of this section have been met. Notice need not be given to a patient when the patient has an emergency medical condition as defined in s. 395.092(9)(b) or when notice is not practicable.

Id.

134. § 766.092(9)(b).
135. § 766.316.
136. Id.
137. Id.
138. Id.
139. Id.
140. Id.
141. Id.
In *Braniff v. Galen of Florida, Inc.*, the plaintiff filed a malpractice action and alleged that the negligent delivery of their daughter led to a severe neurological birth-related injury. The defendant claimed that he gave proper and adequate notice but that in any case, the statute did not mandate pre-delivery notice and that the exclusivity feature was not conditional upon pre-delivery notice. The trial court agreed and dismissed the civil malpractice action holding that the plaintiff could not recover any more than what the administrative action allowed.

The appellate court reversed, however, finding that the defendant had not properly given notice to the plaintiff. The defendant had not been successful in proving that the purpose of the notice requirement was just to inform patients of the procedures they needed to go through in order to file a claim. Had this been the legislative intent of the notice requirement, it would have made sense to be able to provide this notice even post-delivery. However, the court noted that the statute's language speaks of “the limited no fault alternative” which indicates a choice between health care alternatives (limited no-fault vs. traditional tort); hence, the intent of the notice was more than simple claim procedure. At the same time, the court stated that it made even less sense to have a pre-delivery notice requirement if that notice was not a condition precedent to benefiting from the exclusivity of a NICA lawsuit.

The court of appeal found that notice only became an issue when the defendant sought to shield himself against a tort claim. As a result of this ruling, the case was remanded for jury trial because there was a factual disagreement as to whether notice was actually given. Because the court considered this issue to be of great public importance, it certified the following question to the Supreme Court of Florida: "WHETHER SECTION 766.316, FLORIDA STATUTES (1993), REQUIRES THAT HEALTH CARE PROVIDERS GIVE THEIR OBSTETRICAL PATIENTS

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143. *Id.*
144. *Id.* at 1052.
145. *Id.*
146. *Id.*
147. *Braniff*, 669 So. 2d at 1052.
148. *Id.*
149. *Id.* at 1052–53.
150. *Id.* It would not have made sense to discuss alternatives in a notice when the patient might have already received the medical service and could no longer effectively choose an alternative. It only made sense that the notice was a pre-delivery notice. *Id.*
151. *Id.*
152. *Braniff*, 669 So. 2d at 1053 n.2.
PRE-DELIVERY NOTICE OF THEIR PARTICIPATION IN THE
FLORIDA BIRTH RELATED NEUROLOGICAL INJURY COMPENSA-
TION PLAN AS A CONDITION PRECEDENT TO THE PROVIDERS'
INVOKING NICA AS THE PATIENTS' EXCLUSIVE REMEDY? 153

The Supreme Court of Florida held that in order for the provider to
claim NICA as the exclusive remedy for his or her obstetrical patient's
catastrophic delivery, the provider must have given predelivery notice in a
reasonable time in advance of the required obstetrical services, where
practicable.154 The court stated that what would constitute reasonable
advance notice and "when practicable" would vary from circumstance to
circumstance.155 The court reviewed the legislative history of the NICA
statute and found that the academic task force that originally recommended
the adoption of a limited no-fault compensation plan was concerned that the
Virginia Plan did not have a notice requirement.156 The cause for the
concern was that patients who elected to be treated by an ob-gyn participat-
ing in the Virginia Plan had ostensibly given up their ability to sue in tort,
perhaps without adequate due process.157 The task force, therefore, included
the notice requirement in the Florida law to avoid any such question of
unconstitutionality.158

"The Task Force obviously believed that because not all health care
providers [were] required to participate in the NICA plan, fairness require[d]
that the patient be made aware that she has limited her common law
remedies by choosing a participating provider."159 If limiting one's remedies
was an unacceptable method of dealing with the malpractice crisis, the
legislators could have avoided the whole issue by mandating the limited no-
fault plan to all providers and therefore all patients. With the composition of
the Supreme Court of Florida at the time, it is likely that they would have
found that action rationally related to a legitimate Florida interest. Instead,
they saddled another bureaucratic burden on providers, which left another
loophole through which either the physician or the claimant could find
himself or herself unwittingly uncovered. Most distressing was the
uncertainty, because after the physician or hospital had paid their increased
assessment to provide NICA coverage, they could find themselves "bare" to

153. Id. at 1053.
155. Id. at 310.
156. Id.
157. Id.
158. Id.
159. Braniff, 696 So. 2d at 310 n.1.
face a malpractice action in common law tort anyway. 60 The logic of the Supreme Court of Florida, which mandated pre-delivery notice, is less than compelling when compared to the logic of the dissent in another important case, Bradford v. Florida Birth-Related Neurologic Injury Compensation Ass’n. 61

In Bradford, the parents of a birth-related neurologically injured child were successful in their “end run” around NICA. 62 They applied for NICA administrative benefits and then claimed that because their physician had not complied with the notice requirement, they were not eligible for NICA benefits. 63 Although the trial judge disagreed, the Fourth District did agree with the parents. Judge Klein’s dissent is more lucid and logical and may yet hold the day. He stated that when the legislature intends to make a statutory provision a condition precedent, it does so with clarity. 64 He gives the example of the medical malpractice statute pre-suit provision. 65 After the prospective plaintiff complies with the provision, he is given explicit directions on how to notify the soon-to-be defendant. This includes when to notify the defendant, the mandated use of certified return receipt mail, and what must be included in the notice. 66 In the NICA notice section, on the other hand, the hazy procedure is only generally stated and does not say when the notice must be given. 67

Judge Klein also makes an excellent point as to the meaning of the statutory definition of “participating physician.” He notes that the statute defines participating physician as:

a physician licensed in Florida to practice medicine who practices obstetrics or performs obstetrical services either full time or part time and who had paid or was exempted from payment at the time of the injury the assessment required for participation in the birth-

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60. Id. at 312.
62. Id. Studdert, supra note 15, at 520 (discussing the concept of the “end run” around the no-fault program).
63. Bradford, 667 So. 2d at 401-02 (implying they were not limited to an administrative solution by NICA but could pursue their common law remedy in tort).
64. Id. at 403.
65. Id.
66. Id.
67. Id.
related neurological injury compensation plan for the year in which
the injury occurred.\textsuperscript{168}

The judge said that from his point of view, any physician who would read
that definition would properly think that all they would need to do to be
completely covered would be to elect to participate.\textsuperscript{169} It would then be
within reason for the physician to discontinue their malpractice coverage for
this type of event.\textsuperscript{170}

Generally accepted canons of statutory construction suggest that it is
unreasonable to make the notice requirement a condition precedent if the
legislature did not expressly indicate it.\textsuperscript{171} Judge Klein stated that courts
should be reluctant to add words to statutes unless the word has obviously
been omitted, the context of the statute is clear and unequivocal, and adding
the word will assist the intent.\textsuperscript{172} As to the notice provision, there are no
missing words (i.e., condition precedent) and none should be added.\textsuperscript{173}

The notice provision can be onerous or burdensome in a number of
ways. If a parent has a child that fits the statutory definition of birth-related
neurologically injured, but there has been no common law negligence, the
parent would be able to collect from NICA, if the provider remembered to
supply predelivery notice.\textsuperscript{174} If a negligent physician had absentmindedly
allowed his liability insurance to lapse, with a suitable injury the parent
could be covered by NICA, but only if the physician remembered to give
predelivery notice. If a child suffers an obstetrical injury of a suitable type,
one can argue the parent might not receive NICA benefits if the physician
did not provide the prescribed NICA form. If a child suffers a qualifying
injury and the physician did not give notice, there is uncertainty as to
whether the parent could waive her right to notice.\textsuperscript{175} Also, if a NICA
physician without liability insurance failed to give adequate notice, and
negligently caused such an obstetrical injury, one might wonder if his or her
entire career could be jeopardized. The Supreme Court of Florida apparently
thought so.

\textsuperscript{168} Bradford, 667 So. 2d at 403.
\textsuperscript{169} Id.
\textsuperscript{170} Id.
\textsuperscript{171} Id. at 403-04.
\textsuperscript{172} Id. at 404.
\textsuperscript{173} Bradford, 667 So. 2d at 402.
\textsuperscript{174} Id.
\textsuperscript{175} E.g., O'Leary v. Fla. Birth-Related Neurological Injury Comp. Ass'n, 757 So. 2d
624 (Fla. 5th Dist. Ct. App. 2000).
C. The Jurisdictional Squabble: From McKaughan to O'Leary

NICA threatened to self implode because of other matters beyond the funding and notice issues. The issue of jurisdiction is an important example. It was critical to clarify whether it was the courts or the administrative framework of NICA or some combination of both that was to determine the inclusion or exclusion of various types of birth-related neurological injuries. Failure to do so would leave NICA in even more confusion. In one convoluted case, a plaintiff found themselves being forced to prove their child did not meet NICA requirements in order to prevail in their civil malpractice action. The confusion over NICA's jurisdictional underpinnings brought that case all the way to the Supreme Court of Florida.

In McKaughan, the infant son was the product of a breech delivery, at which time the infant was intubated. The child suffered injuries that eventuated in the filing of a medical malpractice lawsuit. The defendants answered affirmatively that the exclusive remedy provision of NICA covered the birth-related injuries. The parents did not believe that their son's injuries fit the narrow definition of NICA-injured. The circuit court ordered the malpractice action stayed while the parents sought an administrative determination by the Division of Administrative Hearings ("DOAH") as to whether the child was covered or not. Hence, the parents filed a petition to prove that their son was not covered because the injury did not occur "in the course of labor, delivery, or resuscitation in the immediate postdelivery period."

The parents asked DOAH to send the case back to the circuit court since they were not truly "claimants" seeking NICA benefits. DOAH held that the parents had not filed a claim suitable for administrative resolution.
and, in fact, dismissed the parent's petition, sending the case back to the circuit court. 186 DOAH stated that the health care providers should not have the ability to force administrative resolution on the plaintiff. 187 On appeal, the district court agreed and certified a question of great public importance which in essence was what "procedure to follow or... [what the] hearing officer's duty [is] when a claimant who denies having a NICA-covered injury is forced by the circuit court into the administrative forum." 188

Things were topsy-turvy with NICA. Instead of parents seeking coverage by NICA, they were trying to figure out how to prove that their child was not covered by NICA. Instead of NICA protecting the physician that paid an assessment for coverage, the DOAH was saying that these parents were not claimants so there could be no coverage and DOAH could have no jurisdiction. Just who had jurisdiction over the whole situation remained to be clarified.

The Supreme Court of Florida agreed that NICA legislation did not hold that the administrative hearing officer had exclusive jurisdiction to decide whether an injured infant was to be covered under NICA, a question that would arise when NICA is being used as a shield to a medical malpractice action. 189 So, the administrative judge was correct, at least temporarily, when he determined that he did not have jurisdiction and sent the case back to the courts for further action. 190 The court saw no clear legislative intent to prevent a plaintiff who believed their birth-related injury

186. Id.
187. Id.
188. Respondent's Answer Brief, supra note 178, at 4. The full text of the certified question was:

DOES AN ADMINISTRATIVE HEARING OFFICER HAVE THE EXCLUSIVE JURISDICTION TO DETERmine WHETHER AN INJURY SUFFERED BY A NEW-BORN INFANT DOES OR DOES NOT CONSTITUTE A "BIRTH-RELATED NEUROLOGICAL INJURY" WITHIN THE MEANING OF THE FLORIDA BIRTH-RELATED NEUROLOGICAL INJURY COMPENSATION PLAN, SECTIONS 766.301-.316, FLORIDA STATUTES (1993), SO THAT A CIRCUIT COURT IN A MEDICAL MALPRACTICE ACTION SPECIFICALLY ALLEGING AN INJURY OUTSIDE THE COVERAGE OF THE PLAN MUST AUTOMATICALLY ABATE THAT ACTION WHEN THE PLAN'S IMMUNITY IS RAISED AS AN AFFIRMATIVE DEFENSE PENDING A DETERMINATION BY THE HEARING OFFICER AS TO THE EXACT NATURE OF THE INFANT'S INJURY?

McKaughan, 668 So. 2d at 975.
189. McKaughan, 668 So. 2d at 978.
190. Id. at 977.
fell outside of NICA, even if incorrect, to prevent them from litigating their complaint in court.\(^{191}\)

Now NICA was squarely open for the courts to second-guess the administrative law judge’s compensability decisions,\(^{192}\) making things somewhat of a free-for-all. Therefore, the legislature faced their prior miscue and changed the law.\(^{193}\) The significant change was that now the administrative law judge had the exclusive jurisdiction to determine whether an injured infant satisfied the NICA statute or not.

The 2000 case of *O’Leary v. Florida Birth-Related Neurological Injury Compensation Ass’n*\(^{194}\) concerned an emergency obstetrical delivery of a pregnant woman who had been in an automobile accident.\(^{195}\) The baby was delivered but had complications and suffered neurological defects.\(^{196}\) The baby died a little over two years later, and the parents filed a malpractice

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191. *Id.*
193. Section 766.301(1)(d) of the *Florida Statutes* (1993) was amended in 1998 to read:

The Legislature makes the following findings:

The costs of birth-related neurological injury claims are particularly high and warrant the establishment of a limited system of compensation irrespective of fault. The issue of whether such claims are covered by this act must be determined exclusively in an administrative proceeding.

*FLA. STAT. § 766.301(1)(d) (2001).* *But cf. FLA. STAT. § 766.301(1)(d) (Supp. 1988)* (showing that the last sentence was not in the original language). Similarly, section 766.304 of the *Florida Statutes* (Supp. 1988) was amended as follows:

The administrative law judge shall hear and determine all claims filed pursuant to ss. 766.301–766.316 and shall exercise the full power and authority granted to her or him in chapter 120, as necessary, to carry out the purposes of such sections. The administrative law judge has exclusive jurisdiction to determine whether a claim filed under this act is compensable. No civil action may be brought until the determinations under s. 766.309 have been made by the administrative law judge. If the administrative law judge determines that the claimant is entitled to compensation from the association, no civil action may be brought or continued in violation of the exclusiveness of remedy provisions of s. 766.303. If it is determined that a claim filed under this act is not compensable, the doctrine of neither collateral estoppel nor res judicata shall prohibit the claimant from pursuing any and all civil remedies available under common law and statutory law.

*FLA. STAT. § 766.304 (2001)* (emphasis added). The original statute read: “The deputy commissioner shall hear and determine all claims filed pursuant to ss. 766.301–766.316 and shall exercise the full power and authority granted to him with respect to workers’ compensation claims, as necessary, to carry out the purposes of such sections.” *FLA. STAT. § 766.304 (Supp. 1988).*

194. 757 So. 2d 624 (Fla. 5th Dist. Ct. App. 2000).
195. *Id.*
196. *Id.* at 624–25.
action. The defendants sought to abate the malpractice action while the plaintiffs sought a determination from the administrative judge as to whether NICA benefits applied or not, although they maintained they had not received adequate NICA notice. The administrative law judge ruled that the issue of whether notice had been given was not in his jurisdiction and dismissed it back to the circuit. The defendant physicians appealed, which was the basis of this action.

The Fifth Circuit took note of the 1998 amendments to the NICA statute, done in recognition of the dual jurisdiction issue left open in McKaughan. Under the new law, the administrative law judge had exclusive authority to determine whether the injury was compensable under NICA and that any medical malpractice action was stayed until such time as the decision was made. The court reversed the administrative law judge's decision (that he lacked authority) and remanded back to him for determination of whether notice was given or waived.

It was a long road from McKaughan to O'Leary, but the final jurisdictional chapter may not yet be written in this battle between the judiciary and the legislature. However, there has already been one acceptance of O'Leary during the current year (2001). In University of Miami v. M.A., the court denied the medical malpractice defendant's request to abate the civil action while the administrative judge made his NICA determination so the defendants appealed. The district judge found that the trial judge erred in denying their motion to abate because now the administrative judge had exclusive jurisdiction to determine the compensability under the amended sections of the Florida Statutes.

The jurisdictional confusion spills over to both attorneys' bars. Previous to NICA, plaintiff attorneys essentially had one obstacle to overcome. They had to prove that a preponderance of the evidence showed that their client was injured and these defendants negligently caused that injury. With NICA, a new dimension is added, that of having to prove that

197. Id. at 625.
198. Id.
199. O'Leary, 757 So. 2d at 625.
200. Id.
201. Id. at 626.
202. Id.
203. Id. at 628.
204. 793 So. 2d 999 (Fla. 3d Dist. Ct. App. 2001).
205. Id. at 999–1000.
206. Id. at 999–1000 (citing to O'Leary, 757 So. 2d 624). The amended subsections were 766.301 and 766.304 of the Florida Statutes (1993).
their client does not have a NICA injury that would literally suck the claim out of tort and into no-fault. Similarly, defense attorneys who previously concentrated on proving their clients were not negligent or the plaintiff was not injured, now make every gasp at proving that the plaintiff was injured—and injured badly enough to be covered by NICA. This extra layer of bureaucracy would all be fine, if the end result was an improved system with reduced costs, and better coverage for all. However, the evidence above does not show that to be the case.

D. The Swiss Cheese Narrow Medical Definition

In McKaughan and in M.A., the underlying issue upon which thejurisdictional tangle operated was whether the injured infants met the narrow statutory definition of injury. In both of these cases, the plaintiffs were anxious to show that their injured child did not meet it. It is not difficult to imagine the situation where a defendant might not have adequate malpractice insurance (to cover multiple incidents, for example) and where the narrow definition precludes coverage for a family because their child, although severely neurologically injured, is not physically injured as well.

Studdert contends that the criterion used to determine whether an injured infant will be covered by NICA are restrictive, and their study provides both direct and indirect evidence. For example, they show that there is a high rate of dismissal of NICA claims. They proved their point by showing that fifteen of eighteen NICA dismissed claims ended successfully for the plaintiffs in tort, thus demonstrating the relative restrictiveness of NICA. They acknowledge that since a portion of these claims were settled as opposed to tried by a jury, their evidence that NICA criteria are stricter than negligence criteria is somewhat “circumstantial.”

However, they also looked at the clinical information; based upon that, twice as many claimants met negligence criteria as met NICA criteria. As they noted, this clinical disparity helps explain the indirect results noted

207. See discussion supra note 39.
208. The definition requires that the injured child be both mentally and physically impaired. Therefore a child who was substantially mentally impaired due to birth-related trauma but who did not have a substantial degree of physical impairment would not qualify.
210. Id.
211. Id.
212. Id.
213. Id.
above. On a more practical basis, it is clear that there are catastrophically injured claimants who are not qualifying for the restrictive NICA definition and whose providers were found to be not negligent. If the stated intent of the program is to "to provide compensation, on a no-fault basis, for a limited class of catastrophic injuries," it is surprising that these catastrophically injured patients should be left out.

When one says that the statute is restrictive or narrow, it is hard to envision how damaging that can be upon a family. A heartbreaking example is found in Florida Birth Related Neurological v. Florida Division of Administrative Hearings, where the infant was a product of a difficult labor and delivery complicated by asphyxia that led to damage to the basal ganglia area of the brain. The ob-gyn was a NICA participating physician. The infant, Eric, did not develop normally. He had severe physical problems, which led to tongue problems and inability to talk; by four and one-half years of age, he was unable to stand, walk or crawl. Experts believed he would never be able to clothe, feed or toilet himself. Tests showed, however, that despite the profound physical defects, measurements of his cognitive skills surprisingly were not much below average and the school board anticipated placing him in a mainstream class. The cause of his injuries was an umbilical cord wrapped around his neck at birth causing asphyxiation, hypoxemia and brain damage.

NICA found that this child did not suffer a compensable injury because his mentation was fairly good despite the profound and catastrophic birth-related neurologic and physical injury that he suffered. His argument sounded like an English lesson concerning how the word "or" and how the word "and" should and could be construed. First of all, the hearing officer states that although NICA wants the statute construed narrowly because the statute is in derogation of common law rights, the

215. 664 So. 2d 1016 (Fla. 5th Dist. Ct. App. 1995), certifying question to 686 So. 2d 1349 (Fla. 1997).
216. Id. at 1017.
217. Id.
218. Id. at 1018.
219. Id.
220. Fla. Birth Related Neurological, 664 So. 2d at 1018.
221. Id. at 1019.
222. Id.
223. Id.
224. Id. at 1020.
family wants the statute construed liberally because it is remedial. 225 The hearing officer concludes the statute should be construed to maximize the legislative intent, and the statute reads that an injury is one "caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired." 226 The hearing officer then delves into a Clintonesque interpretation of whether "and" really means "and" or does it mean "or:"]

In ascertaining the meaning and effect to be given in construing a statute the intent of the legislature is the determining factor. Although in its elementary sense the word 'or' is a disjunctive particle that marks an alternative generally corresponding to 'either' as 'either this or that;' a connective that marks an alternative. There are, of course, familiar instances in which the conjunctive 'or' is held equivalent to the copulative conjunction 'and,' and such meaning is often given the meaning 'or' in order to effectuate the intention of the parties to a written instrument or the legislative intent in enacting a statute when it is clear that the word 'or' is used in the copulative and not in the disjunctive sense. 227

He considered the policy reasons for NICA and stated that if the policy was to cover "catastrophic injuries that result in unusually high costs for custodial care and rehabilitation" in order to reduce insurance costs, there was no suggestion that even if this infant was more mentally impaired that the costs of care could possibly be any higher. 228 He concluded by saying that sometimes "[c]ircumstances may require courts to construe the word 'and' to mean 'or' whenever such a conversion is mandated by the context of the words" or where it is needed to make legislative intent clear, as in this case. 229

The court recognized the severe impact this would have on NICA, so they certified a question of great public importance to the Supreme Court of Florida. 230 The question essentially asked whether the NICA injury must include physical and mental defects or may either defect alone suffice. 231

225. Fla. Birth Related Neurological, 664 So. 2d at 1019.
227. Fla. Birth Related Neurological, 664 So. 2d at 1020.
228. Id.
229. Id. at 1021.
230. Id.
231. Id.
The Supreme Court of Florida made a hash of the whole matter by agreeing that the child suffered a NICA compensable injury, but by that, they meant that this child was, in fact, both physically and mentally injured as a result of his catastrophic delivery. The court reasoned the circuit court did not take certain factors into consideration. For example, "Eric will not be able to translate his cognitive capabilities into adequate learning in a normal manner. Moreover, as a direct consequence of his injuries, Eric's social and vocational development have been drastically impaired. Consequently, it is concluded that Eric is permanently and substantially mentally and physically impaired..."

However, as far as interpreting "and" as "or," the court was having nothing to do with that.

The court stated "[t]he Statute is written in the conjunctive and can only be interpreted to require permanent and substantial impairment that has both physical and mental elements." This slams a door in the face of certain catastrophic birth-related neurological injuries or at the least requires the family to run the gauntlet of litigation—precisely what the no-fault benefit was supposed to avoid.

VI. CONCLUSION

The Florida Birth-Related Neurological Injury Compensation Act, section 766.301–316 of the Florida Statutes, was born in an era of rapidly accelerating malpractice costs and was specifically designed "to provide compensation, on a no-fault basis, for a limited class of catastrophic injury that resulted in unusually high costs for custodial care and rehabilitation." Its underpinning was to insure that ob-gyns were not forced out of business by these excessively high insurance costs. It was designed to carve out the most severe of the birth-related neurologically injured patients, in part so that malpractice insurance companies would not be so fearful of doing business in a litigious Florida environment. This comment has presented evidence that shows that NICA has been only moderately successful in reaching its stated goals and cannot be credited with the

233. Id.
234. Id. at 1355–56.
235. Id. at 1356. The conjunctive operationally means that it is requires both physical and mental injuries. Id. The alternative was called the disjunctive and would have been an "either/or" condition. Id. at 1355.
236. FLA. STAT. § 766.301(2) (2001).
generally improved malpractice climate that some physicians now enjoy. In
fact, there is evidence that the malpractice environment is once again
hardening despite NICA’s existence. In addition, there is a high rate of
NICA claim dismissal that will end up in tort anyway.\textsuperscript{237} Lawyers game the
no-fault system by doing an “end-run” around NICA when it serves their
purposes.\textsuperscript{238}

Early on, the state’s physicians challenged the funding mechanism but
as of this writing, it is constitutional. Yet it depends on the correctness of
the interpretation by the Supreme Court of Florida that the assessment to all
nonobstetrical physicians is a tax and not a hidden user fee. This is dubious
because there is very little correlation between the amount paid and the
benefit received. In the best of circumstances, nonobstetrical physicians
resent paying a fee for the benefit of one particular specialty without their
consent, when the rest of Florida’s population is exempt. In the worst of
circumstances, it is illegal taxation.

The statute has had two severe structural difficulties that undermined
the faith one might have developed in the program. First, predelivery notice
was written into Florida’s version of limited obstetrical no-fault in the hopes
that NICA could survive a due process attack. Erstwhile, it puts the
provider’s family and livelihood on the line, directly contradicting one of the
main legislative intents. Second, the narrow, restrictive definition of birth-
related injury also threatens the very beneficiaries it was ostensibly designed
to assist. The exceptions to coverage poke so many holes in NICA’s
availability that the coverage ends up resembling Swiss cheese. It invites
litigation where some of the primary benefits of a partial no-fault system \textit{viz a viz} NICA is to avoid litigation and speed up solutions.

Jurisdictional infighting between the judiciary and the legislature is
even today not resolved. As discussed, the Supreme Court of Florida put its
foot down and showed that there was concurrent, contingent jurisdic-
tion.\textsuperscript{239} However, the legislature was not to be outdone, and they amended
the statute to provide that the administrative law judge would have exclusive
jurisdiction in NICA determinations and that no civil actions would proceed
until this was resolved. This has been followed in the Third Circuit recently,
but the judiciary may not yet have fired their final salvo.

A statute that is written to correct a specific problem and that fails to
accomplish its stated goal after more than ten years is one that should be
examined closely. In particular, where a statute has significant flaws—such

\textsuperscript{237} Studdert, supra note 15, at 519.
\textsuperscript{238} Id. at 520.
\textsuperscript{239} Id. at 517–18.
as its funding mechanism, its notice requirements, its limiting definitions, and its jurisdictional authority—it should be more than examined closely, it should, in fact, be repealed. Limited no-fault liability for obstetrical catastrophes is an idea whose time has come and gone.

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