Introduction: Remembering Stephanie Feldman Aleong

A Letter to Most Darling Steph
Remembering Stephanie
Stephanie F. Aleong: A Tribute to a Natural Leader
Memorial Dedication to Stephanie Feldman Aleong
Stephanie Aleong: A Friend, Colleague, and Inspiration
Stephanie Aleong: A Brief Recollection and Tribute
Stephanie Feldman-Aleong: A Legacy of Love and Loyalty
Professor Stephanie Aleong: More than My Professor and Mentor—My Friend

ARTICLES
The Impaired Physician: Medical, Legal, and Ethical Analysis with a Policy Recommendation
The Need for an Equitable Revolution to "Appropriately" Remedy Wrongfully Denied Benefits Under ERISA
Closing the Door: Mental Illness, the Criminal Justice System, and the Need for a Uniform Mental Health Policy

NOTES AND COMMENTS
Florida's Fight Against Prescription Drug Abuse: Prescription Drug Monitoring Program
Every Woman Deserves Her Own Pair of Genes: The Constitutionality of Patenting the BRCA Genes in Association for Molecular Pathology v. U.S. Patent & Trademark Office

VOLUME 34  SUMMER 2010  NUMBER 3
HEALTH LAW ISSUE
Dedication in Memory of Stephanie Feldman Aleong

Introduction: Remembering Stephanie Feldman Aleong.... Kathy L. Cerminara 565
A Letter to Most Darling Steph ................................................... Madison Gray 571
Remembering Stephanie ......................................................Susan Polsinelli 575
Stephanie F. Aleong: A Tribute to a Natural Leader .......... Carsten Evans 579
Memorial Dedication to Stephanie Feldman Aleong .......... Ani B. Satz 583
Stephanie Aleong: A Friend, Colleague, and Inspiration..... William E. Adams 585
Stephanie Aleong: A Brief Recollection and Tribute ......... Joel A. Mintz 587
Stephanie Feldman-Aleong:  
A Legacy of Love and Loyalty ...........................................Anthony Niedwiecki 589
Professor Stephanie Aleong: More than My  
Professor and Mentor—My Friend..................................Anthony M. Stella 593

ARTICLES

The Impaired Physician: Medical, Legal, and  
Ethical Analysis with a Policy Recommendation .......... Rebecca Sara Feinberg 595

Antitrust and the Biopharmaceutical Industry:  
Lessons from Hatch-Waxman and an Early  
Evaluation of the Biologics Price Competition  
and Innovation Act of 2009 ......................... Matthew J. Seamon 629

The Need for an Equitable Revolution to  
“Appropriately” Remedy Wrongfully Denied  
Benefits Under ERISA .................................................. Robert C. Sheres 679
Closing the Door: Mental Illness, the Criminal Justice System, and the Need for a Uniform Mental Health Policy .......................................................... Shane Levesque 711

NOTES AND COMMENTS

Florida’s Fight Against Prescription Drug Abuse:
Prescription Drug Monitoring Program ........................................ Ashley Dutko 739

Every Woman Deserves Her Own Pair of Genes:
The Constitutionality of Patenting the BRCA Genes in Association for Molecular Pathology v. U.S. Patent & Trademark Office .......................................................... Morgan Geller 765
In Memoriam

Professor Stephanie Feldman Aleong
1972–2008
INTRODUCTION: REMEMBERING STEPHANIE FELDMAN ALEONG

KATHY L. CERMINARA

I wish I were not writing this Introduction. As wonderful an issue of the Nova Law Review as this is—and it is indeed a tour de force—it commemorates the loss of my dear friend and colleague, Stephanie Feldman Aleong. I would gladly trade this publication opportunity to have Stephanie back. The tragedy of her unexpected death in 2008 at the age of thirty-six shook Nova Southeastern University’s Shepard Broad Law Center to its core, and we still sorely miss her. I’m sure we always will.

Nevertheless, we play the cards we are dealt in life, as no one knew better than Stephanie. A juvenile diabetic who coped with her disease and overcame past tragic events with sheer force of will and a huge personality, this tiny woman liked to credit her infinitely positive attitude to her father’s advice that “You have to fake it until you can make it.” Everyone who knew Stephanie knew how she incorporated this admonition into her life, consistently putting a positive spin on bad news and counseling others to look on the bright side of any situation. Stephanie faced bad news countless times as she battled melanoma this last time, from the day she first learned the diagnosis, throughout her research of treatment options, with her decision to enroll in a clinical trial, and while preparing for anticipated discomfort as she began the trial. Yet, “faking it until she could make it,” she found the silver lining in each cloud. Not long before she began the trial, only thirteen days before her death, she assured her friends, family, colleagues and students that “I am a tough little bird so I will undergo this therapy with a cheery heart and a smile . . . .”

The tributes at the beginning of this issue afford the reader some glimpse into why Stephanie was special to those of us who had the opportunity to know her. On personal notes, Stephanie’s friends Madison Gray and Susan Polsinelli offer snapshots of the roles that she played in their lives at

1. E-mail from Stephanie Feldman Aleong to Faculty at Nova Southeastern University Shepard Broad Law Center (Oct. 8, 2008) (on file with author).
2. See also James B. Levy, In Memoriam: Stephanie Feldman Aleong, 15 J. LEGAL WRITING INST. xiii (2009) (eulogizing her); Jennifer S. Bard, What We in Law Can Learn From Our Colleagues in Medicine About Teaching Students How to Practice Their Chosen Profession, 36 J. L. MED. & ETHICS 841, 848 (2008) (describing her as “a distinguished health law scholar and law professor whose remarkable commitment to innovative teaching is a model for us all”); Ani B. Satz, Disability, Vulnerability, and the Limits of Antidiscrimination, 83 WASH. L. REV. 513, 513 n.1 (2008) (dedicating article to her).
Vanderbilt University and in the Office of the State Attorney in Miami-Dade County, Florida. Assistant Dean Carsten Evans of Nova Southeastern University's College of Pharmacy explains the important role Stephanie played in the lives of countless Floridians as she and a team of investigators vanquished a major pharmaceutical counterfeiting operation when she was an assistant statewide prosecutor.\(^3\) After serving the state attorney general’s office in that capacity, Stephanie moved into teaching, heading to Emory Law School, where she was a colleague of Professor Ani Satz, whose tribute reflects great respect and affection. Finally, Stephanie came to our law school, where her colleagues and students found her *joie de vivre* and talent inspirational, as is evident from the tributes of Dean Bill Adams, Professors Joel Mintz and Anthony Niedwiecki, and alumnus Anthony Stella, once one of Stephanie’s students.

In part because of her juvenile diabetes, Stephanie felt strongly about using her academic scholarship to further combat drug counterfeiting. While teaching her beloved Criminal Law and Lawyering Skills & Values students, she influenced pharmacists and other health care professionals through her directorship of our Master of Science in Health Law program. She also researched and wrote about America’s flawed pharmaceutical supply chain.\(^4\)

When the editors of the *Law Review* and I planned this issue, however, it did not seem appropriate to narrowly focus on pharmaceutical regulation when remembering Stephanie. Far from one-dimensional, Stephanie could intelligently discuss, debate, and offer valuable comments on every subject ranging from bioethics to health care policy. Therefore, it seemed most fitting to include in this issue articles on a similarly broad range of health law topics. Thanks to hard work by the *Law Review* editors and staff, especially Alyson Sincavage and David Stahl, these articles address a variety of important topics. Stephanie would be proud.

Notably, although the following articles analyze a cross-section of legal issues in the health care industry, they all address matters that are of tremendous importance to patients. Stephanie would have liked that. Much as cost, quality and access comprise a “three-legged stool” underpinning health care policymaking,\(^5\) patients’ costs, the quality of care patients received, and

---

patients' struggles to access care concerned Stephanie. In this, she and I were kindred spirits, so I am especially thankful that this selection of articles reflects a patient-centric focus.

Professor Matthew Seamon, for example, attempted to choose a topic that "Professor Aleong would acknowledge as important," and he succeeded admirably by choosing one affecting the costs patients might bear for drugs in the future. While most patients would not know what "biologics" are, such drugs are of tremendous importance to them. A "biologic" is a drug "derived from a living organism or one of its products and . . . manufactured" through a genetic pathway. Such genetically tailored drugs could improve the lives of hundreds of thousands of patients, and Professor Seamon urges the development of an abbreviated path to their approval. As he himself says, this topic would "impact [patients'] wallets."

Stephanie also worried about the quality of care patients received. Her method of ensuring quality care was to ensure that patients received the prescription drugs they were supposed to receive, rather than counterfeits. Two of the authors in this issue, Rebecca Feinberg and Shane Levesque, propose health care system changes that would also improve the quality of care patients receive. Specifically, Ms. Feinberg addresses the problem of impaired physicians and suggests nationwide standardization of methods to prevent impairment, identify afflicted physicians, treat them, and follow up thereafter. Mr. Levesque focuses on improving care for mentally ill prisoners upon release from prison, in an attempt to break the cycle of recidivism. He proposes diversion programs, comprehensive discharge planning before release from prison, and pre-release enrollment in public benefits to help ensure continuity of care upon release. There can be no doubt that taking steps to ensure that physicians are functioning at peak levels and reforming the way the correctional system treats the mentally ill would improve the quality of care patients receive—patients of many different types in the first instance and a tightly circumscribed category of patients in the latter instance.

Finally, Stephanie shared my concern about the impact on patients of America's employer-based system of health care coverage. Within this area,

7. See id. at 649–650.
8. Id. at 629 n.1.
Robert Sheres takes on one of the more perplexing puzzles arising from litigation on the part of such patients under the Employee Retirement Income Security Act of 1974 (ERISA).\(^\text{10}\) Although Congress enacted ERISA with the stated goal of protecting employees in the wake of spectacular pension plan failures, the statute’s effect on employees who receive health care coverage through their employers has been far from protective. The United States Supreme Court has narrowly interpreted the list of statutory remedies available to patients alleging that their health insurers improperly denied payment for treatments. The result, as Mr. Sheres concludes after reminding the reader of the statute’s pro-employee goal, “contravenes this goal by refusing to allow participants and beneficiaries to be made whole by way of consequential damages.”\(^\text{11}\) His proposal that the Supreme Court revisit the issue is a sound one, while his suggestions to those representing such patients in the meantime are ingenious. Perhaps his article can help patients gain access to treatments by putting some weapons in the hands of attorneys representing them.

I cannot conclude this introduction without mentioning the contributions of two student authors about health law topics, for Stephanie loved her students. Here, Morgan Geller and Ashley Dutko join the four authors whose works I just described in addressing issues that could greatly impact patients in the future. Ms. Geller analyzes a case alleging that the United States Patent and Trademark Office acted unconstitutionally in granting patents on human genes to researchers, and Ms. Dutko writes about an important Florida statute intended to combat prescription drug abuse. Stephanie would have been glad to see student work of such quality.

In short, just as Stephanie aimed at improving her surroundings in every way possible during her short life, this issue of the \textit{Nova Law Review} is chock-full of scholarship aimed at improving the health care system in a variety of areas important to patients. It memorializes a terrific person who lives on in our minds and hearts. It also reminds us that Stephanie did nothing halfway and could juggle many different balls while smiling and inspiring others to be better and to achieve more than they ever thought they could. It reflects the variety of ways in which Stephanie continues to inspire others to improve the health care system through public service,\(^\text{12}\) to use the law as


\(^{12}\) In tribute to Stephanie, Nova Southeastern University’s College of Pharmacy and the Drug Safety Institute have created an award titled the “Stephanie F. Aleong, J.D., National Patient Safety Award” to recognize “individuals whose unique efforts have significantly advanced patient safety.” See News Release, Nova Se. Univ., Two Florida Drug Inspectors
an instrument of change,\textsuperscript{13} or simply to do the best job possible under any and all circumstances.\textsuperscript{14} It is something she would be glad to see in print. But I still wish I had not written this Introduction.


\textsuperscript{13} For example, when Stephanie and two of our colleagues teamed up to lead the Goodwin Symposium at the law school, they chose to focus on “the impact women have had on the law and legal profession and to outline what challenges lay ahead.” Stephanie Feldman Aleong, Olympia Duhart & Linda F. Harrison, \textit{Tilting the Scales: The Changing Roles of Women in the Law and Legal Practice}, 31 NOVA L. REV. 217, 219 (2007).

Dearest and Most Darling Steph:

You must be highly amused by my multiple efforts to draft a "Tribute to Professor Aleong" for an issue of the *Nova Law Review* to be dedicated in your honor.

Do the well-meaning editors realize that the friends you gathered close tended to be rather . . . eccentric? Do they realize that an eccentric will offer thoughts completely out of proportion from those that a colleague might? I suspect that my piece might be politely declined out of a discomfort for the edge of grief underlying every word. I suspect that the editors of the law review might be more comfortable if I could write safe sentences about finding closure regarding your absence.

It has been 508 days since your death. But enough about you . . .

How does one write a tribute anyway? Tribute is defined as "a gift, testimonial, compliment, or the like, given as due or in acknowledgment of gratitude or esteem" with synonyms such as "recognition, commendation, eulogy." 2

Do words exist that could express how loving and brilliant and sparkly and filled with laughter you will always be to those lucky enough to be in your inner circle?

Here's what I find unseemly about this tribute piece. It's so very . . . posthumous.

Not my authorship obviously, but your place as the individual worthy of honor. I celebrated you on a daily basis for the sixteen years that you were my friend. I fear that most of our readers missed out. Those who knew you surely do not need my awkward attempts to articulate how fabulous you were.

1. Should I let our readers in on the fact that "But enough about you . . ." was one of your standard lines?
The thing that I admired the most about you was your capacity to live with an open heart. The focus of your attention was on finding the joy in life—a pixie sprite sprinkling glitter and giggles as she danced by.

As a result, the quality of your life—and the lives of those around you—was illuminated. Is there a higher testimonial to offer on behalf of someone? This is my simple truth to offer up for posterity’s sake about Professor Aleong: She illuminated her little corner of the world.

You were buried on a Sunday, and I spent my flight back to Nashville that night paralyzed with grief. While driving to work the next morning, the radio played Bob Marley’s *Three Little Birds*! It had to be a message from you, yes?

How many times did we sing that song? I remember your little jazz-hands motion while you mouthed the lyrics to me behind the back of a tragically dull fellow at a disastrously dull cocktail party during law school; we laughed ourselves into asthma attacks on the way home that night. I remember holding hands in the backseat of the car and singing it to one another under our breath on the way to your bridal shower; your mother and grandmother were in the front seat.

I need to believe that the song the morning after your burial was a message from you.

For the consideration of our readers, I offer its lyrics to close this piece. If they choose to believe that the spirit of the song is a message from you then I am happy to share your message with them.

With unyielding love, Your Sabu

"Don’t worry about a thing,  
’Cause every little thing gonna be all right.”

Singin': “Don’t worry about a thing,  
’Cause every little thing gonna be all right!”

Rise up this mornin',  
Smiled with the risin' sun,  
Three little birds  
Pitch by my doorstep  
Singin' sweet songs

---

4. Also known as, Madison Gray. Steph called me Sabu. It was a thing.
Of melodies pure and true,
Sayin', "This is my message to you-ou-ou:"

Singin': "Don't worry about a thing,
'Cause every little thing gonna be all right."
Singin': "Don't worry about a thing,
'Cause every little thing gonna be all right!"\(^5\)

5. BOB MARLEY & THE WAILERS, supra note 3.
REMEMBERING STEPHANIE

Professor Aleong was a teacher long before she graced the halls of Emory Law School or Nova Southeastern. I know this because I was one of her first pupils. It was 1998 and I was Susan Schnell, a shiny new Assistant State Attorney for Miami-Dade County, Florida, fresh out of the University of Virginia, one of those law schools “up north.” She was Stephanie Feldman, one of the “Chiefs” of the DUI/Crimes Division, the training grounds for all new Miami ASAs. And although she was younger than I was (and shorter), that made her my boss.

As Steph would tell it, that fateful first day, she looked out into the room of forty plus eager new prosecutors, and somehow picked me out of the crowd. She said that in those first moments, although she should have been thinking about a thousand other things more pertinent to the job ahead, she was instead thinking to herself that she and I were going to be fast friends.

Stephanie was a woman of great faith, so I never doubted for a moment that she had a premonition about me and about our future. Those of you who knew her, or knew of her, would also know that she was also a woman of great determination. And so, whether it was destiny, determination, or just my good luck, I think I can fast forward in this story to tell you that we became dear and enduring friends.

For three years, we shared our daily lives. We worked together, we shopped (a bit too often given our salaries), we dined (lots of sushi), and listened to goofy 90s pop songs like Ricky Martin’s La Vida Loca (one of Steph’s favorites at the time). When I left Miami with my husband-to-be to move to Manhattan, we continued our friendship from a distance.

I loved and adored Steph as a friend, but what was more unusual about this friendship was how much inspiration I drew from her example. Even in her twenties Stephanie got more accomplished in a day than many of us get done in a week. She was energized from the tips of her toes to the top of her blonde head. Those who knew and loved her understood that her seemingly limitless energy was fueled by her passion—passion for her family, for her friends, and for the causes that she believed in.

As an Assistant State Attorney, Stephanie was a young, inexperienced lawyer who was in a position to exercise a great deal of discretion and have tremendous impact on the lives of hundreds of crime victims and criminal defendants. Stephanie approached her duties with unwavering professionalism, unyielding precision, and a flawless moral compass. Stephanie advocated ferociously on behalf of the crime victims that she helped, and more than any other lawyer I know, she became personally involved with the cause.
of improving lives and helping crime victims put shattered pieces back together.

The excellence of her work was rewarded at the State Attorney’s Office where she was offered (and gladly accepted) leadership positions that allowed her to move up the ranks with lightning speed (and grace). When she left the office in Miami to go to the Statewide Prosecutor’s Office, she had already amassed the skills, knowledge, and street-smarts to spearhead a task-force that was so effective in protecting the integrity of pharmaceuticals that her efforts were documented in the book Dangerous Doses.¹

I will leave it to her other friends and colleagues to tell you their accounts of her career as a law professor at Emory and Nova Southeastern. I observed these events only from a distance. But what I will mention, and what was most remarkable to me about her time as a law professor, was the seemingly endless array of students that she took under her wing. I have catalogued years of zany sitcom-like problems presented by her law students. Invariably, Professor Aleong was there to steadily guide them through these amusing (at least to me) events. I would note that she was also there for them when their lives and their families were truly in crisis.

In all of those years of conversation, I wasn’t at all surprised to hear about her level of engagement with her students. Stripping aside her brilliance and her accomplishments, Stephanie at her core was a wonderful friend and advocate, and I am sure that those qualities helped shape the direction of many lives and careers.

Stephanie’s professional accomplishments and impact are obvious when you look at tributes like the “Stephanie F. Aleong, J.D., National Patient Safety Award” that is given by the Nova Southeastern College of Pharmacy in her memory each year, or the publication of this volume of the Nova Law Review featuring articles on health law topics that were near and dear to Stephanie, or even the hundreds of friends, loved-ones, and admirers who packed her memorial service.

On a personal level, her memory is with me in the large and small moments of my life. At turning points, I find myself aspiring to her high-impact, activist approach to life. In the small moments, when I am exhausted and I don’t want to finish a tedious project for my work, I think of her endless energy. I think of her when I feel too drained to sit down on the floor with my boys to play a game or put together a puzzle. When a task seems too difficult or too intimidating, I conjure up my memories of Stephanie and

---

¹ KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA’S DRUG SUPPLY (2005).
I think about how quickly and methodically she would attack the situation and just get it done.

She is my siren in other ways too. Stephanie possessed boundless energy, enthusiasm, and a capacity to love that I have seldom run into in life. If you had been at her memorial service, you couldn’t have helped noticing how many of her beloved stood up to talk about how fiercely loyal, giving, and loving Stephanie was to all those who she took into her heart.

She was the woman who would drop everything to help a friend (and later, a student). She was the kind of person would drive miles out of her way without question if it meant that someone whom she cared about would have an easier time of it. And Steph would never skip a birthday or a holiday or any special occasion that would allow her to make a fuss and show her friends and family how much she cared.

Stephanie was exceptional in that she committed her heart and soul to her relationships. She never wavered for lack of time, energy, or focus. So, I often summon up my memories of Stephanie and her warmth and generosity. She is my emotional barometer, and her memory reminds me to be more selfless, more open, and more loving.

As she battled melanoma, Stephanie shared her extraordinary warmth and compassion with a new “family.” I met them when she invited me to log-in to her melanoma support community. Once there, I found that she didn’t just join the online group, rather she became entwined in the fabric of the community. I knew from speaking with her that Stephanie was drawing strength and comfort from her interaction with the other patients and their families, but when I read the community posts, I quickly realized that she was also very busy helping many of her friends in the melanoma community accomplish a wide variety of goals—finding ways to pay for travel and lodging for an endless succession of treatments and experimental studies, sharing information and research, giving advice on how to put financial and personal affairs in order.

And then there was the emotional support. She was so deeply connected to so many other individuals and families battling cancer. Even on days when I had spoken with her and knew her to be physically and emotionally exhausted to the core, she supported her friends with online posts that were brave and sincere and full of certainty and optimism.

When Stephanie wrote an e-mail or a post her closing was always “Love and Light.” So I will close with that: To you Stephanie, to your love and your light, and all of the goodness that came into this world and into our lives because of you. May you continue to inspire us to make an impact in our professions, communities, and in our personal lives. May your example help us to embrace our friends and families with your same warmth, passion, and compassion. And may we grow to embody your courage and optimism.
My heart is with your beloved Neil, your family, and all those who were lucky enough to share your friendship. You are missed terribly.
STEPHANIE F. ALEONG: A TRIBUTE TO A NATURAL LEADER

CARSTEN EVANS

It was April of 2005 when I entered the Barnes & Noble on South University Drive in Plantation. My eyes were immediately drawn towards the red-orange covered book on the top level of the promotional display counter for just-released books. The title screamed at me “Dangerous Doses!” Then the subtitle catch phrase, “How Counterfeiters Are Contaminating America’s Drug Supply,” squealed even. I opened it to find that it was not only about America, but more specifically how South Florida was contaminating America’s drug supply. The book would have a major influence over me regarding my profession—pharmacy—more than any other that I have read before or since. I even personally knew some of the good and bad characters in the book.

My job title is Assistant Dean in the College of Pharmacy at Nova Southeastern University in Ft. Lauderdale. One of my responsibilities includes educating working pharmacists through providing live, continuing professional education (CE) programs throughout the year. These programs are continuing education for mandatory license renewals. It is my incumbent responsibility to know what is happening within the profession and to provide speakers/forums with the focused vision to address the pertinent issues of current interest at scheduled CE offerings several times a year. To do this, I research the best topics and speakers for the subjects. This includes bringing speakers from Canada and from around the United States to our campus.

I found myself unable to come to a stopping point when I started reading this book, Dangerous Doses by Katherine Eban. How could I have missed hearing about all of this vital information regarding the safety of medications that were being dispensed all around my little world in South Florida? I was so embarrassed for my lack of knowledge, and yet, at the same time so thankful of learning about the knowledge so vital to all patients around the United States who potentially were taking counterfeit medications. This book had given me the idea for the keynote speaker for my next meeting—Katherine Eban, the book’s author.

After going back and forth with her New York agent, they settled on a $5,000 plus expenses fee for her one hour appearance (maybe not even a

lecture). My budget could bear a $2,000 honorarium, but not the big bucks of corporate America. I scanned my alternatives to Katherine. The likely choice would be the “star” of the book—the person whose courage and strength put the bad guys in jail—Stephanie Feldman.

According to the book, Stephanie Feldman was the five-foot nothing live character who coordinated the investigations of drug counterfeiting through her office, Florida Health Care Fraud. She was the statewide prosecutor and was described in the book as being a character like Dorothy in The Wizard of Oz. From the book I determined that she was the one person who felt the strong responsibility of making the medications in this country safe. As I found out later, this was one of her primary passions in life that drove her professionally every day. She took counterfeiting Americans with bad expensive drugs personally and could not understand why everybody did not fight or care about keeping medications from being laced with these contaminants. So Stephanie became my new “mark” for the keynote speaker for the upcoming CE program. Now I had to find her. The book ended with her leaving the Florida taskforce and moving to Atlanta to work at the Emory Law School. I felt good about this information and knew that it was going to be easy to locate her.

Two weeks after my first calls, I finally hit somewhat of a jackpot. I found a lady who used to work with Stephanie in the same department. She asked me to repeat my name and where I was calling from, while using a huge question mark-like statement. I knew something unusual was about to happen. When I repeated what she wanted to know, she laughed at me. She told me she knew Stephanie well and then stated, “She works at Nova Southeastern University—right where you are calling from.” For the second time since I found this book, I had this instant mixed emotion of being so embarrassed for my lack of knowledge, and yet at the same time so thankful of learning about the knowledge so vital to me. I thanked her and set out to meet Professor Feldman.

My first call to extension 6230 was to verify that Stephanie Feldman was there—now I learned that her name was Aleong—and to ask her if I could come over immediately and meet her. She said yes and I did. As I discussed who I was and what I wanted, I did not find a monster-like law enforcer who fought crime with the intimation and power of the legal system. Instead, I found an attractive young lady that had the largest heart and compassion for doing the right things in life. She articulated the need for pedi-gree documentation for drug management in this country. She was providing me with an instant learning curve and with a breath of professional fresh air. She was a great example of why students come to class on time. It also was apparent in this brief meeting why all the investigators that worked with her in the past wanted to adopt her. She was a winner in what I would call the
A TRIBUTE TO A NATURAL LEADER

“friend-for-life” club. People who are in this club are so good at what they do and believe in life that they seem unreal. That was Stephanie Feldman Aleong from the first time I met her.

Stephanie became a regular at our continuing education meetings in South Florida and eventually was recognized around the country as a safety expert through her articles and lectures at national safety meetings in various other professional circles. She lectured on medication symbology (e.g. bar-coding) methods that would enhance inventory control and safety. She served on advisory boards and wrote articles focused on pedigree enforcement. Stephanie visited with Florida Governor Jed Bush in Tallahassee on the subject and spent her own money, despite his political opposition to it. It was her passion in life to advance patient safety to the level where people could get the medication that they thought they were getting. How simple was that?

Regardless of the many unbelievable opposing factors, Stephanie had many supporters in her convictions. Cesar Arias and Dr. Gene Odin were two South Florida pharmacy inspectors who shared the exact same expectations of “doing the right things in life.” There were many others as well, especially those associated in “Operation Stone Cold.” This was her team and she was their hero. (Please read the book.) In her short lifetime, she gained the respect of all of those who understood and valued the word “integrity.”

For all the great safety awareness offerings that Stephanie Feldman Aleong brought to the healthcare profession, the College of Pharmacy created a recognition award in her honor one month after she died. The award honors those who reflect the attributes that Stephanie practiced in her passion to do the right things. The award reads, “Recognizing individuals whose unique efforts have significantly advanced patient safety,” and is housed in a showcase on the third floor of the College of Pharmacy. It is an annual award that is presented at the year’s largest gathering of pharmacists in South Florida.

The first “Stephanie F. Aleong, J.D., National Patient Safety Award” went to the two pharmacist inspectors who worked closely with her, Cesar Arias and Gene Odin. They shared the highest respect for each other in the most difficult of difficult times. The book outlines the many behavioral challenges they survived. The second award, this past November, was presented to Stephanie Shubat, who is responsible for the approval of all U.S. nonproprietary names through the United States Adopted Names Program (USAN). Her efforts synthesize the expertise of the American Medical Association (AMA), the United States Pharmacopeia Convention (USP), the American Pharmacists Association (APHA), and the Food and Drug Administration (FDA) in order to ensure that drug information is communicated accurately...
and unambiguously in an assigned drug name. Ms. Shubat also helps coordinate international nomenclature through close liaison with the World Health Organization's INN Program. During her tenure as Director of the USAN program, Ms. Shubat presided over modifications to the nomenclature schemes for up-and-coming biologics including monoclonal antibodies and cell therapies. Besides having the name Stephanie in common, many personality attributes (sense of urgency, doing the right thing) and mental attributes (integrity, honesty) were shared.

We like to teach "leadership" in the College of Pharmacy to all of our students. I am sure that goes on for all of the colleges within the Health Professions Division and around the campus, as we need leaders to get things done the right way. For a few people on earth "leadership" comes natural. Stephanie was a natural leader. Through her special efforts, she protected the people we love most in this world.
MEMORIAL DEDICATION TO STEPHANIE FELDMAN ALEONG

ANI B. SATZ

In October 2008, the legal academy lost Stephanie Feldman Aleong to melanoma. Stephanie was 36 years old.

Stephanie was an Assistant Professor at Nova Southeastern University, Shepard Broad Law Center, where she sagely directed the Masters in Health Law Program and taught doctrinal and legal practice courses. Under her leadership, the Masters Program attracted an increasingly impressive group of health care professionals from around the country.

Stephanie arrived at Nova by way of Emory University, where we first met. At Emory she was known as an extraordinary legal writing instructor and contributor to our Trial Techniques Program.

Stephanie’s scholarship and advocacy focused on the safety of the domestic prescription drug supply chain. This interest was cultivated during her six year tenure as a Florida state attorney specializing in the prosecution and investigation of racketeering in pharmaceuticals. In that capacity, Stephanie helped dissolve a federal crime ring and undoubtedly helped countless individuals avoid illness and death from counterfeit drugs. Her work is detailed in a novel, and a Hollywood director intended to create a film about her personal and professional story. Stephanie was a frequent consultant for the print and news media on drug safety and occasionally served as a consultant for television dramas addressing drug crimes.

Stephanie was a talented and passionate teacher. She was tirelessly devoted to helping her students succeed in their courses, careers, and more generally in life. Their successes were her successes. A well-written student paper made her beam; a poorly written one encouraged her to work harder.

Stephanie was also a wonderful colleague. She was one of the first people to welcome me to Emory. She was generous with her time and knowledge, worked to connect people with similar interests, and sought to advance the careers of others.

While Stephanie’s academic accomplishments are easy to describe, it is much harder to capture her personality. Stephanie was one of my closest friends, and part of the difficulty may be that I am still too close to the loss.

What I am able to articulate is that Stephanie was one of the most generous, thoughtful, and passionate people I have ever known. A good day

was measured by the happiness of those around her. A room in her house was dedicated to storing gifts for her family and friends—items she had discovered that reminded her of certain people. The impressive number of meticulously wrapped boxes stacked against the wall demonstrated in one more way that she always seemed to be thinking of others. Even while battling her terminal illness, she would ask me about my family, my career, and even whether I was being a “healthy” vegetarian.

She loved animals, and aside from her domestic pets of many years—Bubba (cat, now deceased), Molly (dog), and Monster (dog)—took care of a family of ducks that lived in a nearby lake (Larry, Curly, and Moe). She once saved an entire litter of newborn possums from certain death by erecting a tent over them to help keep them cool until a wildlife rescue arrived.

What made her enthusiasm for life and generous nature especially remarkable was that her own life had been quite difficult. She almost never spoke about these challenges. When Stephanie was a very small child, her mother perished in a car accident in which Stephanie was the only other passenger. Stephanie was a childhood diabetic who went misdiagnosed for many years, which caused her significant illness and distress. Many people did not know Stephanie had skin cancer until it reoccurred five years after her initial operation. Even at that point, she rarely discussed her illness and demonstrated an amazing resilience and optimism about the uncertainty of life that I suspect most could not garner under similar circumstances.

Stephanie symbolizes, in my view, what the legal profession should be about: passion for scholarship and teaching, determination to make an impact and further legal change, and service to one’s institution and other communities. Legal academia is often an atomistic enterprise. We are rewarded not for the lives we touch or the change we catalyze but for the quantity of articles generated in isolation behind closed doors. This is only part of our task. I believe that we all could learn from Stephanie’s example of what it means to be a scholar, a teacher, a colleague, and a friend.
STEPHANIE ALEONG: A FRIEND, COLLEAGUE, AND INSPIRATION

WILLIAM E. ADAMS

Professor Stephanie Aleong, like most of us, was a complex person with many aspects to her personality. I have previously discussed some of these facets in a eulogy I was privileged to present on behalf of the Law Center, which appears in an earlier version of this law review. This tribute will focus on Stephanie’s role as a teacher and administrator in her role as Director of NSU’s Master in Health Law Program. I was her supervisor in this job as Associate Dean for International, Online and Graduate Programs.

Stephanie assumed this position a few years after the creation of the program. A degree offered by a law school to persons not seeking a JD was still relatively unusual; therefore, there were few models upon which to draw guidance. Further, the degree was offered primarily in a distance learning format, something also quite rare at the time in law schools and still unfortunately so. To add to the challenge, the program needed to undergo a review of its learning outcome goals pursuant to the assessment regime required by regional accreditors, something that some universities had begun to practice, but almost unique to law schools. True to her personality, Stephanie was undaunted at undertaking such tasks. On the contrary, she loved challenges and tackled these with the energy and enthusiasm that she mustered for everything that she undertook.

The substance of the program was a natural for Stephanie. As a former prosecutor, she had zealously pursued those who profited from selling counterfeit drugs and, true to form, had developed a reputation of excellence, one that attracted the attention of journalists investigating the issue. Her commitment is a testament to Justice Holmes’ musing that “an individual must involve herself with the issues of her time or be ‘at peril of being judged not to have lived.’” Her interest, expertise and passion for matters of health law made her struggles with her own health issues even more poignant. She fought the latter with the same courage, strength and indefatigable energy that she approached everything.

As with any administrative job, this one involved many tasks that are, to say the least, tedious. There were the inescapable reports and forms that needed to be completed and filed, meetings to be attended and reminders to be sent to supervisors, supervisees, faculty and students. Unlike some who rise to managerial roles because of their creativity and intelligence, Stephanie did not neglect the mundane and boring parts of her job nor push them onto someone else over whom she had supervisory powers. In regard to the pre-
viously-mentioned learning outcome assessment review and reports, she was an invaluable partner in mastering the jargon, this of the educational variety, that seems an inevitable part of any new administrative review mandate. She patiently revised reports that seemed, when submitted, to completely comply with prior instructions. She displayed the same fortitude in explaining to experienced attorneys and teachers why they needed to document and quantify what they were doing in their classes and listened patiently to their complaints about this interference from distant bureaucrats.

Although she dutifully fulfilled these mundane tasks, she truly excelled as a teacher and as a creative and thoughtful administrator. As she was in the live classroom, she inspired in the online classroom as well. Always one to push students to dig deep and find what they were capable of achieving; she nonetheless was beloved by those lucky enough to study with her. Similarly, she was interested in assisting those teaching in her program, most of whom were new to teaching in an online format. The program flourished under her guidance and will miss her.

Those of us lucky enough to toil in the field of education often draw inspiration from past teachers and colleagues to inform what we do. There will be many things that I will remember and miss about Stephanie as a friend and colleague, and there will be many things that I will try to emulate as I go forward in my career. However, most of all, I can only hope that I can capture some of the passion and energy that will live on in those students lucky enough to have encountered her. Farewell again, Stephanie, I still miss you and am still inspired.
I met Stephanie Feldman Aleong in the fall of 2003, when she interviewed for a position as an assistant professor in our law school’s Lawyering Skills and Values Program. We were then looking for a candidate who was bright, hardworking, and enjoyed contact with students. We hoped that individual would be a good colleague, a positive role model for the students, and a benevolent influence in the school. My initial sense was that Stephanie would do well in all of those respects. I was wrong. Stephanie Aleong did not merely do good work in those—and all other—facets of her work. She was simply superb at them.

Stephanie was extraordinarily intelligent as a professor and lawyer. Her intelligence was not limited to her academic and legal abilities, however. She also possessed what is colloquially referred to as “people smarts:” an uncanny ability to hear what other people are saying, to understand what affects and motivates others, and to communicate directly (and helpfully) with everyone fortunate enough to come in contact with her.

Stephanie Aleong had remarkable energy and a great enthusiasm for working with her students. She cared, in sincere and inspiring ways, about their development and welfare, and she devoted immense amounts of her time to guiding them, both academically and (at times) personally, through their difficulties and travails. Stephanie’s door was always open to her students. They knew they could always go to her for valuable academic guidance, sound advice, and (where appropriate) a needed word of sympathy and support or a firm push in the right direction. Many students took advantage of her availability to them. All who did benefitted enormously.

In addition, Stephanie was a first rate classroom teacher. Although slight in stature, during class meetings her liveliness, learning, and passion for her subject matter always filled the room. She prepared doggedly for those learning sessions and she expected her students to do the same—consistently holding them to high standards, but never belittling those who were slower to grasp the points she was conveying.

Stephanie was also a highly skilled lawyer. Before entering academia, she had been a successful prosecutor who specialized in rape cases and matters involving counterfeit medications. In that role, she was notably tough but fair. Stephanie’s knowledge of the pharmaceutical business and the laws it is subject to was encyclopedic, and she used that knowledge to good effect, protecting many lives in the process. Indeed, Stephanie’s work to protect the
public from phony medicines was nationally known, and she was well respected for it by her allies and adversaries alike. Stephanie’s groundbreaking efforts in this area continued even after she left full time legal practice. She was a popular speaker and an influential writer on the topic throughout her all too brief academic career.

Stephanie Aleong was a marvelous colleague as well. She participated in both committee meetings and faculty gatherings thoughtfully and (sometimes) passionately. Although she was not diffident about sharing her views on various faculty matters, she also listened carefully to the views of others; and she was unfailingly respectful to those who disagreed with her perspective. It was always a delight to serve on faculty committees with Stephanie. She was someone you could always depend on to make helpful suggestions and to do at least her fair share of the work—and often far more than that. No task was too great or too small for Stephanie. She had a zest for getting the job done, and her cheerful willingness to stay on track, and see the work through, was very frequently contagious.

Beyond all of this, Stephanie Aleong was a warm and caring human being. She was devoted to her husband Neil and the other members of her family, who looked to her often for love and support. She loved her friends, her pets, good music, and good food. Her untimely passing left many who knew her with a deep and lasting sense of loss. Her memory remains an inspiration and a blessing.
STEPHANIE FELDMAN-ALEONG: A LEGACY OF LOVE AND LOYALTY

ANTHONY NIEDWIECKI

Stephanie Aleong was a teacher, scholar, lawyer, prosecutor, aunt, sister, wife, and daughter. But to so many of us, she was a friend. Stephanie was not the usual friend or acquaintance. She was a person who was constantly pulling for you, supporting you and fighting for you. Stephanie really represented what we all want in a friend—someone who is compassionate, loyal, and generous. Stephanie was all of these things to me, and she is sorely missed everyday because of it.

To say that Stephanie was compassionate is an understatement, but I can think of no other way to describe how she treated people. Stephanie was most compassionate when dealing with her students at Nova. Whenever a student had a crisis, regardless of whether the student had a real crisis such as an illness or a typical law school crisis of making a mistake in class, everyone knew they could go to Professor Aleong for advice, support, and help. I cannot count the times that I have heard students say how many hours she spent helping those who were in need. Many students saw her as a motherly figure, which is surprising given that she was one of the youngest faculty members at Nova! Her firm advice with that gentle touch was exactly what each student needed and sought from her. They knew that when they needed a shoulder to cry on or advice on how to deal with some problem at home, they could count on Professor Aleong to deal with them compassionately and without judgment.

Nowhere was Stephanie’s compassion more evident than when she was dealing with her own cancer. At a time when she should have focused on her own health and well-being, she reached out to others who were suffering from cancer. She was a regular on the cancer blogs and message boards, offering support and love to complete strangers. Stephanie provided quiet support to those in the Nova family that were also suffering from cancer. I did not know how much friendship and love she provided to so many people at Nova that were sick until after she passed away. To this day, I do not know how she had the time to help so many people, be the great professor and scholar she was, provide support for her family and friends, and still sleep! What’s more, she did it all with a smile. Stephanie believed that she

1. Anthony Niedwiecki, Associate Professor of Law, Director of the Lawyering Skills and Values Program, Nova Southeastern University. In addition to being a colleague, Professor Niedwiecki was a close friend of Professor Aleong.
was put on this earth to help others, and everything she did in her life was geared toward fulfilling that goal. Her life may have been short, but she did more to help people in those years than most people do in much longer lives.

Her compassion made her one of the most loyal people I know. I always knew that I would have Stephanie's support no matter how tough times got. If Stephanie disagreed with me, she would do so in her own sweet, but firm way without anyone else knowing. As soon as we were in public, she stood by me forcefully and strongly. I always knew she had my back. Again, her loyalty also extended to her students. I know of no stronger advocate for our students than Stephanie. She pushed them to do their best and had faith that everyone could succeed. The more difficult the student, the harder she pushed. She was truly a teacher and mentor to every student she encountered. Her loyalty to the Moot Court Honor Society is still an example of how any professor should help a student organization. She spent countless hours working with students and doing whatever she could to make the program the best it could be. Her imprint on the program will be felt for so many years to come.

Her compassion and loyalty are only overshadowed by her generosity. In fact, her compassion and loyalty were most likely developed by her generosity. I know of no other person in my life that has given more to so many without asking for anything in return. Again, the amount of time she spent with her students and colleagues went well beyond what anyone could possibly expect. The love she showed to each of her family members and friends was immeasurable. Each person who came into her life felt like he or she was the most important person to Stephanie because that is how she made each of us feel. When I was around Stephanie, I thought I was the only person who mattered to her. Stephanie would also give me small gifts that would capture a special or funny moment that we shared together. To this day, I chuckle when I see the tissue box she gave me that says “judicial relief,” knowing that we shared many stories about students crying in our offices around the middle of each semester.

I know of no story, however, that captures Stephanie’s compassion, loyalty and generosity more than when she helped me with a campaign event one day. Stephanie was one of my biggest supporters when I decided to run for office, but nothing compares to the day she walked with me in a parade only a couple weeks after having surgery to remove some of her cancer. I never asked her to come, but she heard me say how excited I was about my first parade as a candidate. The morning of the parade, she called and said that she was bringing her dogs to walk with me and my family at the parade. Before I knew it, Stephanie was at the parade wearing her campaign shirt and walking her dogs. We walked almost three miles in the sun and heat, with Stephanie constantly smiling and handing out candy to the children. Never
once did she complain, although I know that she was still very sore from her surgery. We tried to get her to ride in the car, but she refused. She just said that she wanted to support her friend. That is what captures this great woman—a loyal, compassionate and generous friend to all. I know I speak for so many people touched by Stephanie when I say: “Thank you Professor Aleong. We truly miss you, but your example of compassion, loyalty and generosity will always live on.”
PROFESSOR STEPHANIE ALEONG: MORE THAN MY PROFESSOR AND MENTOR—MY FRIEND

ANTHONY M. STELLA

Professor Stephanie Feldman Aleong taught me legal writing during my first year of law school. But, to me, and to most students she encountered, she was more than a professor. She was a mentor and friend.

Professor Aleong had an inexplicable ability to challenge her students’ minds and touch their hearts. She inspired her students to work hard and grow intellectually, while simultaneously encouraging them to chase their passions and follow their dreams. She also molded her students into both better attorneys and better people.

How did she accomplish this unbelievable feat? By example.

As a professor, her relentless work ethic exemplified the inexorable commitment to professional excellence she bestowed on her students. Without rue, she demanded her students study, study some more, and, if we had any free time, study something we liked. She accepted no excuse for laziness. It was not tolerated. Period.

She also deeply cared for the integrity of her students. She was a pundit of professionalism. To her, results mattered, but the means were as important as the end. She cautioned her students against losing sight of their moral compass and jeopardizing their ethical stature for the sake of individual accolades. She reminded us to balance our morality with our accomplishments, giving equal weight to both. She encouraged us to never lose sight of our humanity and to remember that we are people who should not only respect our fellow man, but ourselves.

In the end, it was Professor Aleong’s compassionate disposition for the personal well-being of her students that endeared her to so many. Please don’t misunderstand me. She was just as austere as the toughest professor when it came to her students’ grading and quality of work (my lowest grade during my first year of law school was in legal writing). But, unlike some professors, who are justifiably cautious when it comes to student relationships, she expressed a warm, heartfelt empathy for the many anxiety ridden law students whom she perpetually taught and advised. Her door was always open. With a warm smile and a bowl full of candy, she actively listened to student concerns, offering well-thought-out advice and feasible solutions. No problem was too big. No concern too small. Everything that mattered to you mattered to her. You mattered.

For me, Professor Aleong (“Professor A” as I came to call her) had a special place in my heart before her unexpected passing. Through divine
patience and perseverance, she helped mold me into the person and professional I am today. She never gave up on me, even when I disappointed her—although she never told me that and always said how proud she was of me. At my lowest moments, she was there to support and encourage me. I will miss her, as she was more than my professor and mentor—she was my friend.
I. INTRODUCTION

A young woman came in to see her obstetrician for an ultrasound during her prenatal treatment. This is her third child, so she knows what normal pregnancy is like. She informed the obstetrician that she has had cramping and some spotting, an abnormal occurrence during the first trimester of preg-
nancy. The doctor, who seemed harried and stressed, began the ultrasound and quickly viewed the machine’s monitor. The patient heard the fetal heartbeat and was placated by the doctor’s pronouncement that all seemed well. The doctor left as quickly as she had come in, calling over her shoulder that she would see the patient in three months. The patient dressed and went home. A week later the cramping became worse. The fallopian pregnancy, which the doctor had missed on her quick ultrasound and had been foreshadowed by the cramping, had progressed to a dangerous stage. The fallopian tube began to rupture under the pressure of the ectopic pregnancy. The patient was rushed to the emergency room where she was quickly transferred to emergency surgery. Because the fallopian pregnancy had not been diagnosed at an earlier stage and had not been treated in a timely fashion, an emergency hysterectomy had to be performed. The patient underwent three blood transfusions during her four-day hospital stay and returned home not only having lost the pregnancy, but also having lost the future capacity to have children.

A young man sat on the edge of an examining table in a hospital gown, waiting to be examined for minor back pain which began when he carried his child’s camp trunk up the stairs. When the doctor came in to perform the examination, he appeared disheveled and unkempt. After a brief disorganized examination, the doctor wrote a prescription for pain medication and moved on to the next patient. The pharmacist recognized the doctor’s signature. The doctor was an orthopedist highly respected in the medical community, and so the narcotic prescription was filled without question. The patient took the bottle of pills home and self-administered the medication. The pills, morphine, should have been one milligram each and the patient should have taken no more than two a day. The prescription had been written for ten milligram tablets and the doctor had simply instructed the patient to take them when the pain is bad. The patient woke in the middle of the night from the back pain. Following the doctor’s orders to “take them when the pain is bad,” the patient took two pills and laid back down. The two pills, a lethal dose of morphine, suppressed the patient’s respiratory drive and the young man never awakened.

A patient was wheeled into the operating room for coronary artery bypass surgery. The cardiac surgeon stuck his head in the operating room door and checked that the anesthesiologist was beginning to sedate the patient and gave him a ten-minute warning before the patient will be fully sedated. The cardiac surgeon is a seasoned physician who has earned the universal respect of his colleagues. He is tremendously popular with nurses and residents because he is a patient teacher, skilled surgeon, and has wonderful bedside manner, a skill many surgeons lack. On this morning he looked a bit ragged and seemed to be shaky. He excused himself to the doctor’s lounge to finish
his "breakfast." When he did not return to begin scrubbing for the operation, a resident was sent to retrieve him. The resident entered the lounge to find the doctor swigging from a silver flask before heading for the operating room. The resident, a direct subordinate of the surgeon, looked at him in shock. The surgeon responded to the resident's shock by flippantly replying that he just needs a little swig to steady his hands before surgery and he has done this for thirty years, there is no problem.

Each of the scenarios just described, and many more like them, are an all too frequent occurrence in the field of medicine. Physician addiction is taboo, but this silence injures both the physician and his patients. Alcohol and drug addiction interfere with multiple functions in daily life. There is no doubt, when the addicted individuals are physicians, the interference affects their ability to practice medicine, causing their patients to receive a lower standard of care than they would otherwise receive. In a retrospective study of impaired physicians performed by Murray, most impaired physicians admitted during the interviews that their impairment had negatively influenced their patient care. The cited lapses in care ranged from missing calls or rounds because they were intoxicated to negligently causing the death of a patient. The true surprise is in the number of physicians who are impaired by addiction. A research study performed by Birch and colleagues found that roughly two-thirds of young physicians drink in excess of recommended safe drinking limits. Some experts estimate the rate of addicted physicians to be between seven and twelve percent, similar to that found in the general population. Other experts state that a physician has a thirty percent greater risk of becoming addicted than a member of the general population.

---

3. Murray, supra note 1, at 1538.
4. Id.
problem must be addressed with a universal policy. Even one impaired phys-
ician who is left practicing medicine is one too many.

Despite the prevalence of physician addiction and subsequent impair-
ment, there is no universal approach to prevention, identification, treatment, or post-recovery follow-up. The purpose of this article is to address and ana-
lyze the issues of addiction that are distinct for physicians, culminating in a policy recommendation to address these problems. This policy recommend-
ation addresses current flaws in the system that allow impairment to occur and continue in the medical field. Prevention will be addressed with a tho-
rough education and continuing education requirement for all physicians. Identification, partially remedied by the education obtained in the prevention approach, must also include inducement for self-identification and greater protection for the identifying individual. Essential in both the treatment and follow-up stages of care is a universal approach. This must include confi-
dentiality, if not anonymity, for the individual being treated and individual-
ized care plans. These suggestions combine to create a policy recommenda-
tion believed to remedy the current problem of impaired physicians.

II. MEDICAL ANALYSIS

A. An Impaired Physician Is . . .

The impaired physician is a medical doctor who suffers from alcohol-
ism, drug addiction, or mental illness. Physicians, like other professionals who are responsible for the life of another individual, bear an additional burden in their impairment. The American Medical Association’s Council on Mental Health defines physician impairment as, “the inability to practice medicine adequately by reason of physical or mental illness, including alcoholism or drug dependency.” The ramifications of physician impairment go beyond the individual and his personal contacts, and place his patients at greater risk. It is this risk to patients that makes physician impairment in-
compatible with the practice of medicine. And it is this incompatibility that leads the impaired physicians to further conceal their addiction and continue to practice medicine while impaired. The nature of medicine as a profes-
sion emphasizes self-reliance and competence. These traits, ingrained in

9. Id.
12. See Gossop et al., supra note 6, at 162.
the physician from training and practice, make it more difficult for the physician to recognize or admit his own impairment. Impairment, particularly in the form of alcoholism and depression, inhibits the impaired physician’s insight. Additionally, the impaired physician often conceals his addiction because the stigma attached to physician impairment makes seeking help significantly more difficult than for the general population. Potential punitive responses may also play a role in incenting concealment. Compound- ing the problems of self-denial and concealment is the fact that physicians have difficulty recognizing and addressing early signs of addiction in their colleagues, though the diagnosis may have been obvious if the addicted individual had been a non-physician patient.

Physicians have both a higher prevalence of impairment and more difficulty obtaining treatment than non-physicians. The high rate of impairment is generally attributed to two sources: the high stress inherent in medical practice and the access to chemical substances. It is clear that the practice of medicine has an intrinsic level of stress greater than that found in most professions. This stress stems from bearing the responsibility for the lives of patients and accountability to both the patients and peer organizations. This stress coupled with relatively easy access to a gamut of pharmacologic substances creates a dangerous temptation for those physicians who feel overwhelmed by their obligations and responsibilities. Baird and Mor-

13. See Brooke, The Addicted Doctor, supra note 11, at 150.
15. See id. at 31, 35; Gossop et al., supra note 6, at 162.
16. See Gossop et al., supra note 6, at 162–63.
17. Blondell, supra note 7, at 210.
18. Id. In addition to impairment, physicians are at a greater risk for both physical and mental health problems, according to Higgs in his published work on the health of health care workers. R. Higgs, Doctors in Crisis: Creating a Strategy for Mental Health in Health Care Work, 28 J. ROYAL C. PHYSICIANS LONDON 538 (1994).
19. Blondell, supra note 7, at 210. Impairment as a result of occupational stress is a phenomenon that extends beyond the practice of medicine. See Bissell & Jones, supra note 2, at 1142–43. In general, greater responsibility in a chosen field is attributable in part to the attainment of higher education and there is correlation between the attainment of higher education and alcoholism. Id.
20. See Deborah Brooke, Editorial, Why Do Some Doctors Become Addicted?, 91 ADDICTION 317, 317–18 (1996) [hereinafter Brooke, Doctors Become Addicted?]. Included in the concept of “stress” is the understanding that physicians work uncommonly high number of hours per work week. See W.L.M. Baird & M. Morgan, Editorial, Substance Misuse Amongst Anaesthetists, 55 ANAESTHESIA 943, 943 (2000). Attempts to control excessive work hours have been instituted during training in residency and fellowship programs by the Accreditation Counsel for Graduate Medical Education (ACGME). Accreditation Council for Graduate Medical Education, ACGME Highlights Its Standards on Resident Duty Hours—May 2001, http://www.acgme.org/acWebsite/positionpapers/pp_oshaResponse.asp (last visited April 17,
gan describe an additional reason for the higher prevalence of impairment among physicians. They propose that physician substance abuse is not merely a result of access to opiates and other potent psychoactive drugs, but in part a result of the physician’s understanding of the intricacies of pharmacodynamics and pharmacokinetics.

Impairment affects the physician’s life both personally and professionally. The physician’s personal life is usually affected first, then his professional interactions with colleagues, and the last area to be affected by impairment is often the physician’s patient care skills. Impaired physicians who might recognize that their addiction is overtaking their personal life still might deny the existence of the problem in their professional life because they fear the stigma and disapproval of their peers, or loss of their ability to practice medicine. Loss of respect or approval by a physician’s peers may threaten their livelihood. One of the greatest fears cited by impaired physicians was the threat of loss of licensure. This is a realistic fear given the fact that the most common reasons for a doctor to appear before his professional disciplinary organization are alcoholism and mental disorder. The looming potential for formal discipline and stigmatization by peers leaves many impaired physicians feeling that they cannot seek help or treatment. The result is that the majority of physician suicides are attributable to alcoholism, drug dependence, and depression. In these and many other ways, impairment harms not only the physician, but also the physician’s family.

21. See Baird & Morgan, supra note 20, at 943–44.
22. Id. at 943.
24. Blondell, supra note 7, at 211.
25. Gossap et al., supra note 6, at 162.
26. Id.
27. Bohigian et al., supra note 23, at 1079.
30. Baird & Morgan, supra note 20, at 944.
31. See id.
B. Identification of the Impaired Physician

Identifying the impaired physician presents a tremendous challenge. The impaired physician resists identification because addiction carries stigma amongst his colleagues and, potentially, punitive action by the medical licensing body. Colleagues, too, will be reluctant to report an impaired physician because they are fully aware of the harsh ramifications of being labeled impaired. An impaired physician can be identified if his addiction leads to an interaction with law enforcement authorities. For physicians still in training, a supervisor may identify their impairment based on work performance. In most cases, the first people to become aware of the physician’s impairment are family and close friends.32

Many physicians hesitate to approach or identify a colleague. A suspecting colleague may question whether he is correct in assessing the impaired physician’s status. And more subtly, a colleague of an impaired physician does not wish to gain a reputation for “tattling.” In many cases, a colleague may hesitate to identify an impaired physician because he identifies with him, and can easily see himself in his colleague’s shoes. The reluctance to identify an impaired colleague is due in part to the attitude of the profession towards addiction. Only a short time ago in the history of medicine, smoking was socially acceptable despite the knowledge that smoking was unhealthy and even detrimental. Now, as smoking has fallen out of favor, few physicians would hesitate to tell a colleague not to smoke. The progression of alcohol in the attitude of medical professionals is following the same trend. It is progressively less acceptable to drink in excess, and it is not looked on favorably by colleagues.33 But attitudes have not yet progressed to the point where one colleague is likely to tell another that he should not have another drink.34 Although colleagues may hesitate to become involved or to meddle, the impaired physician often craves their assistance, fears asking for it, and wishes it were volunteered.35 A testimonial from one recovering physician states, “to help us the most . . . you must get to know us better and sooner.”36 Yet in the majority of documented cases, colleagues acted only

32. See Edwards, supra note 10, at 1297. As the addiction progresses the impaired physician’s symptoms will become more overt, to the extreme of endangering patients. See id. Before this point, the impaired physician will provide a progressively lower standard of clinical care. See id. This may manifest in forgetfulness, lack of effort, or apathy towards supervision of physicians in training. Id.
33. See Edwards, supra note 10, at 1297–98.
34. See Bissell & Jones, supra note 2, at 1145.
36. Id.
when the physician’s impairment posed great danger to patients. Gossop and his colleagues found that fifty-nine percent of the impaired physician’s colleagues knew of the addiction as a result of impairment at work.

The ramifications of addiction are not restricted to the impaired physician’s professional life. His addiction is likely to get him in trouble in all areas of his life. A physician who is caught driving under the influence may be arrested and convicted, but his trouble may not stop there. It is the practice of some court clerks to send a report to the medical licensing board for that state when there is any criminal proceeding that involves a physician. In some jurisdictions, such as California, the law provides that a physician who has been convicted of more than one alcohol offense is guilty of “unprofessional conduct.” In a study of ninety-eight recovered physicians, they “accumulated . . . 219 arrests and 170 jailings." Yet in this same sample of ninety-eight recovered physicians, only fifty-eight had been admonished by a colleague, twenty warned by a medical licensing agency, twenty had lost hospital privileges, and nine had their medical license revoked or restricted. These statistics show that the people and their law enforcement representatives are stricter in identifying impaired physicians than is the medical profession. Closing the gap in identification between law enforcement and medical regulatory agencies could be one of many steps taken to assist in early detection and treatment of impaired physicians.

Physician impairment often begins, or is at least foreshadowed, in medical school. Many coping mechanisms that are developed to handle the stress of practicing medicine are developed as a student when the rigors of medical practice are first imposed upon the individual. Most substance use begins in medical school and serves as an ominous predictor of future

37. Murray, supra note 1, at 1538.
40. Id. In many of the impaired physician testimonials, particularly those in rural atmospheres, the physicians recount being stopped for driving under the influence, but released without question because they were considered a prominent member of the community. Bissell & Jones, supra note 2, at 1145.
41. Rice, supra note 39, at 87.
42. Id.
43. Bissell & Jones, supra note 2, at 1142–43, 1145.
44. Id. at 1145.
45. Id.
46. A more complete discussion of the laws surrounding impaired physicians is to follow in Part IV, and the discussion of potential solutions will be continued in Part V.
47. Blondell, supra note 7, at 210.
abuse. Yet medical schools traditionally neglect to address substance abuse. There is unifying consensus that early detection and intervention are by far the best approach, yet medical school curriculum does not reflect this. Only twenty-two percent of medical schools have a policy of teaching preventive measures for physician impairment. In one study of emergency medicine residency programs, only thirty-six percent involved instruction on recognition, progression, and treatment of physician impairment. In the same study, thirty percent of program directors had no formal education regarding physician impairment. It would be a vast improvement simply to inform all program directors that every state medical society has a physician impairment program. Program directors cannot bear the full burden of identifying impaired residents because their impressions are based on work performance. A resident’s work performance is largely dependent upon medical knowledge and skill, making it easy to mistake an impaired resident for an unprepared resident. Possible impairment could be attributed to lack of understanding for a specific disease etiology or insufficient training in a specific locus. The impaired student, resident, or fellow will exhibit symptoms in his behavior and interaction with family and friends long before impairment manifests into the work environment.

Identification of an impaired physician should be done using an objective standard. Most commonly used to identify alcohol abuse is a four question assessment called “The CAGE questionnaire” which reads as follows:

1. Have you ever felt that you should cut down on your drinking?
2. Have people ever annoyed you by criticizing your drinking?
3. Have you ever felt bad or guilty about your drinking?

49. Blondell, supra note 7, at 218.
50. Id.
52. Id.
53. Id. at 1074.
54. When the term “impaired physician” or “physician” is used, it is intended to encompass medical students, residents, and fellows.
55. McNamara & Margulies, supra note 51, at 1074.
4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?

Answering yes to more than two questions is indicative of a serious alcohol problem. Identification of chemical abuse or addiction is most commonly based upon multiple symptoms in the following chart.

<table>
<thead>
<tr>
<th>EARLY SIGNS</th>
<th>LATE SIGNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic family members</td>
<td>Family dysfunction</td>
</tr>
<tr>
<td>Regular use of alcohol</td>
<td>Depression</td>
</tr>
<tr>
<td>Drinking while studying</td>
<td>Drinking while “on call”</td>
</tr>
<tr>
<td>Drinking to relax or to sleep</td>
<td>Auto accidents</td>
</tr>
<tr>
<td>Drinking alone</td>
<td>Poor hygiene</td>
</tr>
<tr>
<td>Frequent intoxication</td>
<td>Public intoxicication</td>
</tr>
<tr>
<td>Blackouts</td>
<td>Memory impairment</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td>Needle marks</td>
</tr>
<tr>
<td>No religious affiliation</td>
<td>Missed work</td>
</tr>
<tr>
<td>Likable personality</td>
<td>Negativism</td>
</tr>
<tr>
<td>Good health</td>
<td>Poor health</td>
</tr>
<tr>
<td>Good grades and patient care</td>
<td>Poor patient care</td>
</tr>
</tbody>
</table>

57. In the McNamara and Margulies study, these were the four criterion presented to the program directors. McNamara & Margulies, supra note 51, at 1074. The report states that a “substantial number of program directors reported no or only slight knowledge of four key areas regarding impaired physicians.” Id.

58. Blondell, supra note 7, at 211 (organizing data from David C. Clark et al., Alcohol-Use Patterns Through Medical School: A Longitudinal Study of One Class, 257 JAMA 2921, 2923 (1987)).
In order to utilize these two tools, medical institutions—medical schools, residency training programs, fellowship training programs, hospitals, and other medical institutions—must have policies and procedures in place to handle the impaired physician. These policies must include education on impairment, identification of the impaired individual, modes of intervention, requirements for treatment, policy on reporting to licensing agencies, and procedures for re-incorporating the recovering physician into the medical profession. Failure to have such a plan leads to an inappropriate response which ultimately results in an inferior outcome. 59

C. Intervention and Treatment of the Impaired Physician

There is no single right way to intervene and treat an impaired physician, but there are consistent elements that must be present in the treatment of every case. Each state has its own impaired physician program, all with similarities and differences. Many are affiliated with Alcoholics Anonymous or Caduceus, which aids continuity for the impaired physician when he completes the formal treatment program. 60 First and foremost is the understanding that identifying and treating the impaired physician earlier in the course of their addiction is the action that has the most influence over the outcome. 61 It is not adequate to wait until the impaired physician manifests the symptoms of full or severe addiction before intervening and treating. 62 The professionals who intervene and treat the impaired physician must exude hope and potential for recovery or the impaired physician may view continued substance abuse or suicide as better options. 63 It is essential that within the positive attitude there is no hint of condescension. 64 Confidentiality is another key element to successful intervention and treatment. The impaired physician is likely to fear exposure to colleagues and thus deny addiction or refuse treatment. 65 In general, the impaired physician does best when treated outside of the medical community in which he works. 66 This option removes the possibility of colleagues developing a protective collusion that hinders recovery. 67 Additionally, the impaired physician may be more comfortable attending a facility in which none of his colleagues treat him. 68

59. See Blondell, supra note 7, at 211–212.
61. Nelson et al., supra note 7, at 34.
63. Id. at 215.
64. Steinbicker, supra note 35.
65. See K. Rawnsley, Helping the Sick Doctor: A New Service, 291 BRIT. MED. J. 922, 922 (1985). It is commonly more effective to offer the impaired physician treatment outside of the medical community in which he works. Id. This option removes the possibility of colleagues developing a protective collusion that hinders recovery. Id. Additionally, the impaired physician may be more comfortable attending a facility in which none of his colleagues treat him. See id.
in an in-patient unit, particularly if the unit is dedicated specifically to the treatment of medical professionals so that the impaired physician is not being treated alongside non-medical professionals. The standard progression of treatment following the in-patient stay is a halfway house program that segue into an outpatient follow-up program.

There is universal consensus that early identification and intervention result in the best outcome. The first statewide diversion program officiated by the medical board began in 1989 in Oregon, and now serves as the model for other state medical boards to emulate. The Oregon diversion program “starts with a focus on early identification and active intervention.” British journals cite the American practice of early intervention to stress the urgency of halting addiction before it escalates to a chronic level. The early stages of impairment tend to correlate with the early stages of a physician’s career. It is during these early stages that physicians commonly adopt the habit of drinking in excess or using other chemicals as a means of escape. These students can be preliminarily identified by anxiety and stress during training. In the training period for a physician, which includes medical school, residency, and fellowship, the student is supervised and evaluated regularly. This observation by a senior physician provides a window of opportunity to identify and treat the impaired physician. If addiction is missed during training, the physician may progress through several years of medical practice and worsening addiction before the impairment is recognized by a colleague. Additionally, program directors are more likely to refer a physician-in-training to a treatment program than colleagues would be to refer another physician because the physician-in-training is not threatened with license sanctions or negative implications on their career. The hierarchy of medicine places an attending physician in a pedagogic position of authority, with little to no personal risk from reporting a subordinate as there would be.

67. Gossop et al., supra note 6, at 163.
68. Steinbicker, supra note 39.
69. Nelson et al., supra note 7, at 31–32.
71. See Gossop et al., supra note 6, at 160, 163.
72. Id. at 160.
73. Id.
75. Blondell, supra note 7, at 210–11.
76. Id.
77. Nelson et al., supra note 7, at 34.
THE IMPAIRED PHYSICIAN

if reporting a colleague. Despite these facts, the number of impaired residents being identified does not correlate to the number of residents who are impaired.\(^7\) McNamara and Margulies found that residency program directors identified one percent of their residents as impaired and intervened.\(^9\) The CAGE results for the same group of residents revealed that over twelve percent were either addicted or severely abusing chemical substances.\(^8\)

Thomas, Santora, and Shaffer demonstrated the ability to identify potential impaired physicians during training by their stress level.\(^8\) Their retrospective study demonstrated that those physicians who were mid-life drinkers exhibited significantly more stress and anxiety than physicians who in mid-life are non-drinkers.\(^8\)

An important, yet generally lacking, element of early detection is education. Physicians must be taught how to identify the signs and symptoms of addiction both in themselves and their colleagues. In addition they must be taught how to help the impaired colleague, or how to help themselves. This training should begin in medical school, be reinforced in residency and fellowship, and be continually discussed during continuing medical education. In addition, medical institutions should form an “Impaired Physician Committee” that would be charged with educating all members of the staff about identification, available resources and access to resources.\(^8\)

The initial hurdle in treating an impaired physician is actually getting him to commit to a treatment program.\(^8\) There are two ways an impaired physician enters a treatment program: voluntarily or by referral. Impaired physicians who choose to enter a program voluntarily are rewarded with anonymity. This allows them to arrest the progression of their addiction and recover without public exposure, disciplinary action, restriction of privileges, or loss of license.\(^8\) Voluntary entrance into a treatment program does not usually occur until a relatively late stage of addiction. This is in part because the impaired physician is often not able to recognize the progression of their chemical dependency, and also in part because denial is a classic companion

---

78. McNamara & Margulies, supra note 51.
79. Id.
80. Id.
81. C.B. Thomas et al., Health of Physicians in Midlife in Relation to Use of Alcohol: A Prospective Study of a Cohort of Former Medical Students, 146 JOHNS HOPKINS MED. J. 1 (1980).
82. Id.; Brooke, Doctors Become Addicted?, supra note 20, at 317.
83. Blondell, supra note 7, at 211–12.
84. In a study published in the British Medical Journal, a retrospective examination of impaired physicians in the follow-up stage of recovery demonstrated that the degree of cooperation in treatment did not affect the outcome. Murray, supra note 1, at 1537–39.
85. Bohigian et al., supra note 23, at 1078.
Thus, without external aid, the impaired physician is not likely to seek assistance “until late in the course of [his] illness.”

In cases of referral, knowledgeable physician colleagues are the preferred method of entering a treatment program. Often the referral of an impaired physician to a treatment program is either by a superior in his medical institution or by an accreditation or licensing board resulting from an investigation after a problem in the work environment. Approximately forty percent of referrals stem from poor work performance, and another thirty percent of referrals are catalyzed by some form of “disciplinary action or the threat of disciplinary action.” A referral, irrespective of the source or cause, must be kept confidential. Most medical association treatment programs have a strict policy to keep impaired physician’s information confidential. Some go so far as to not retain records and to identify impaired physicians by a given number and not by name. The British Medical Association, quoting success in American programs, reported that health care professionals in treatment are entitled to the highest standard of confidentiality.

The burden of treatment for impaired physicians falls not only on the impaired physician’s shoulders, but on the shoulders of the greater medical community. Impaired physicians must be treated individually. Their treatment and recovery program must contain certain universal necessities, but those involved in providing treatment must tailor the program to the individual patient. Society in general has an expectation that medical professionals will not abuse chemical substances. This stems from the understanding that physicians guide and lead their patients by example as well as by treatment. Physicians are expected to set a healthy example by not smoking, exercising regularly, and seeking regular medical check-ups. This example cannot be imposed as moral judgment and may not be presented in a fashion of moral superiority. Such a negative approach will not aid the impaired physician in treatment or recovery, and may inhibit other impaired physicians from seeking treatment. The illness of one health care professional affects and reflects on the greater health care community. Colleagues who

86. Blondell, supra note 7, at 213.
87. Id.
88. Id. at 209.
89. Gossop et al., supra note 6, at 161.
90. Baird & Morgan, supra note 20, at 943.
93. Edwards, supra note 10, at 1297.
are supportive and compassionate without being judgmental are all integral parts of a positive outcome for the impaired physician. 94

D. Prevention of Recovered Impaired Physician Relapse

Physical recovery from addiction is a quick and relatively small part of the impaired physician’s recovery; it is the mental recovery that lasts a lifetime. 95 Addiction is a progressive and chronic disease in which the impaired person uses and abuses chemical substances, despite personal knowledge of the negative ramifications. The chemical substance progressively controls the addicted, both physically and mentally. Cessation of use, depending on the chemical, may cause physical withdrawal. The nature of addiction leaves the impaired subject vulnerable to relapse during any stage of recovery. 96 Thus a significant portion of treatment effort must be funneled to ensuring that the impaired physician does not succumb to relapse.

Relapse is a significant concern, particularly when the impaired physician returns to patient care. Monitoring and follow-up care, like initial addiction treatment, does not have a specific recipe; rather, this stage must also be tailored to the individual in question. Shore studied the probationary periods of recovered impaired physicians and found that probation ranged in length from one month to one hundred and twenty months. 97 In a focus group of his study, eighteen of the thirty-four physicians experienced a total of forty relapses. 98 The Rand study, a study focusing on addicts with “serious dependency profiles,” reports a fifty-six percent relapse rate. 99 Baird, who focuses on impaired anesthesiologists, cites a forty percent relapse rate during the first two years of recovery. 100 He goes on to state that eighty percent of recovered impaired anesthesiologists successfully return to clinical practice. 101 Ulwelling found that forty-nine percent of impaired physicians relapsed at an average of twenty-two months. 102 The prognosis is not as dour

---

94. Baird & Morgan, supra note 20, at 944.
96. Blondell refers to relapse as a “common” occurrence. Blondell, supra note 7, at 209.
98. Id.
100. Baird & Morgan, supra note 20, at 944.
102. Ulwelling, supra note 70.
as it may seem; impaired physicians typically have more favorable outcomes than the general public.\textsuperscript{103}

Multiple factors contribute to the successful recovery of the impaired physician. Many impaired physician treatment programs cater directly to these needs, acknowledging that the ultimate goal is to reincorporate the impaired physician as a practitioner in the medical community. To attain and sustain this goal the impaired physician requires a combination of factors including, but not limited to, support of colleagues, support groups angled towards impaired physicians, outpatient follow-up care, and monitoring and advocacy during any probationary period of return to work.

The process of recovery is dynamic; the recovering impaired physician requires different resources as their recovery evolves.\textsuperscript{104} In the beginning, most impaired physicians require the guidance and support of professional health care providers.\textsuperscript{105} Ultimately, many recovered impaired physicians model their own practice of medicine to help and treat other addicts.\textsuperscript{106} In testimonials provided by recovered alcoholic physicians, Doctors’ and Dentists’ Group of Alcoholics Anonymous and general Alcoholics Anonymous groups were pivotal and invaluable components of their recovery.\textsuperscript{107} Alcoholics Anonymous provides continuity for the recovered impaired physician as they progress through the stages of recovery.\textsuperscript{108} This is particularly important for physicians who traveled to treatment facilities in another geographical location for treatment, for whom continued care is often a stumbling block. Additionally, Alcoholics Anonymous endorses camaraderie amongst the participants, creating an environment that can be warm and accepting.\textsuperscript{109} The comfort found in this environment is strikingly different from the more sterile and detached atmosphere found in most psychiatric facilities.\textsuperscript{110} Research demonstrates that a cohesive support system, such as that found in Alcoholics Anonymous, serves to reinforce good behavior.\textsuperscript{111}

Toxicology testing is another common element of follow-up care. One approach is to use Alcoholics Anonymous in conjunction with random tox-
Ulwelling found that random urine monitoring had a positive correlation with successful treatment outcome. He went on to show that if a recovered impaired physician does not relapse in the first four years, they are not likely to relapse. If the impaired physician arrived at treatment by referral, they will be followed upon release by the applicable medical board. Recovered impaired physicians who are followed closely in this manner have a high success rate. If a relapse occurs, close monitoring often allows detection before a positive drug screen demonstrates that relapse has occurred.

If the recovered impaired physician is returning to clinical treatment, medical facilities may institute additional requirements before granting practice privileges. Some examples are restrictions on access to controlled substances, and medications to be taken for any ailment must be done under the supervision of a physician who is aware of the individual’s recovery status. Some institutions may limit the scope of practice or the recovered impaired physician’s prescribing capacity. The arrangements between privilege granting facilities and the recovered impaired physician are similar to all the previous stages of treatment and recovery in that it must be individualized to each specific case.

III. LEGAL ANALYSIS

A. Impaired Physician Legislation

Every state in the union has an established treatment program for impaired physicians. In the early 1970s, the American Medical Association

112. Ulwelling, supra note 70, at 21. Many treatment programs, upon admittance to the facility, require the impaired physician to sign a contract of sorts which includes committing to follow-up care that may include random toxicology testing. Id.
113. Id.
114. Id.
115. Id.
117. Bohigian et al., supra note 23, at 1079.
118. See Blondell, supra note 7, at 217.
119. Bohigian et al., supra note 23, at 1078.
120. This is of particular importance when the prescriptions in question are narcotics. A common practice is to use a prescription pad that is sequentially numbered and creates a duplicate with each prescription.
121. Lynn Hankes & LeClair Bissell, Health Professionals, in SUBSTANCE ABUSE: A COMPREHENSIVE TEXTBOOK 897, 900 (Joyce H. Lowinson et al. eds., 2d ed. 1992); Gossop et al., supra note 6, at 160.
began to focus attention on the issue of impaired physicians.122 This began
the national transformation that culminated in an impaired physician treat-
ment program in each state.123 The first state medical board to establish a
 statewide impaired physician program was Oregon.124 The Oregon Senate, in
1989, passed Senate Bill 1032 which established funding and structure for
the Diversion Program Supervisory Council and its medical director.125 In
addition, the Accreditation Council for Graduate Medical Education man-
dates that program directors in certain medical fields, “identify impaired
physicians and intervene appropriately.”126 The effects of this obligation are
evident in the most recent surveys which indicate that eighty-two percent of
programs have a policy regarding impaired physicians.127

The impaired physician’s addiction has ramifications beyond their med-
ical practice. The impaired physician, like any other substance abuser, is
likely to come into contact with law enforcement.128 It is the practice in
some states, and is the law in others, that when a physician is convicted of a
criminal offense, the medical board is notified.129 In the year 2001, the Fed-
eration of State Medical Boards gave 335 disciplinary actions for non-
medical related offenses.130 In the majority of jurisdictions, a conviction for
driving under the influence will lead to a state board investigation to deter-
mine if the incident was isolated or evidence of impairment.131 Despite this
practice, the public response to impaired individuals132 is harsher and more

122. Ulwelling, supra note 70, at 21.
123. See Federation of State Physician Health Programs, History, http://www.fsphp.org/
History.html (last visited Apr. 17, 2010); Gossop et al., supra note 6, at 160.
124. John J. Ulwelling & John F. Christensen, Northwest Center for Physician Well-Being,
125. Id. The funding for the Diversion Program Supervisory Council and the medical
director is funded by medical licensees’ fees, which at time of publication were twenty five
dollars each year. Ulwelling, supra note 70, at 21. Cumulatively, these fees raised roughly
one hundred and sixty thousand dollars per year. Id.
126. Dubovsky et al., supra note 8, at 447.
127. McNamara & Margules, supra note 51, at 1072. The Accreditation Council for
Graduate Medical Education initially required this of emergency medicine residencies. Id.
128. Bissell & Jones, supra note 2, at 1145. Contact with law enforcement refers to inci-
dents such as driving under the influence and disorderly conduct.
129. See Rice, supra note 39, at 88. Some states go so far as to notify the medical board if
a physician is arrested. Id.
130. Id.
131. Id.
132. Public response refers to arrests, jailing, revocation or suspension of driver’s license.
Bissell & Jones, supra note 2, at 1145. Medical society’s response most often consists of
warnings with proportionally low amount of medical license suspensions or loss of hospital
privileges. Id.

Published by NSUWorks, 2010
frequent than the medical societies’ responses. In a study of 100 impaired physicians, only three had their license revoked, fifteen had their license suspended, and nineteen had restrictions placed on their practice. This means that more than half of the impaired physicians in this study received no reprimand from the medical society. Blondell, in his article on impaired physicians, concludes that physicians must address the lack of response to impairment by medical societies or the legislature will do it for them.

B. Legal Aspects of Reporting the Impaired Physician

Many impaired physician treatment programs offer anonymity as an incentive to enroll voluntarily. Impaired physicians who do so and successfully complete the program may never come into contact with the licensing agency or medical board. Although the promise of anonymity acts as incentive to enroll in the treatment program with the ultimate goal of physician recovery, there is a little-discussed negative. An impaired physician who completes the treatment program and returns to clinical practice may do so without anyone else’s knowledge. Specifically, it is possible for an impaired physician to voluntarily receive treatment and have none of his colleagues or superiors become aware that a problem existed. Given the high incident of relapse, significant risk to patients still exists. As noted in the discussion of treatment programs, follow up care and close monitoring are essential parts of a treatment and recovery program for an impaired physician. The impaired physician who maintains complete anonymity will not be followed or additionally supervised once he completes the treatment program.

Impaired physicians who self-refer to treatment programs may be required to expose themselves as impaired on license applications and renewals. Physicians must renew their license on an annual basis. One step in the license renewal process is answering a series of questions including ques-

133. Id.
135. Blondell, supra note 7, at 217–18. It is inherent in his writing that Dr. Blondell believes legislation, rather than response within the medical community, would not be a positive solution. Id.
136. Nelson et al., supra note 7, at 32.
138. As detailed in the previous section, multiple studies report the relapse rate for recovered impaired physicians is between forty and fifty-five percent in the first two to four years.
139. See discussion supra, Part II.C.
140. Peyser, supra note 137, at 517.
tions about substance abuse and treatment.\textsuperscript{141} The phrasing of the question and what information must be reported by mandate varies by state.\textsuperscript{142} Currently, many state psychiatric associations are lobbying to have the impairment and substance abuse questions reflect current impairment and not past history of impairment.\textsuperscript{143} This would allow the physician to move from state to state, receive license reciprocity in the new state, and then relapse. If the impaired physician continually enrolls in the treatment program voluntarily, it may be possible for him to transfer from state to state each time he relapses. This loophole has the potential to put patient populations at grave risk.\textsuperscript{144} The Federation of State Medical Boards has made a progression towards closing this loophole by creating the practice of information sharing between state medical boards.\textsuperscript{145} This progression, while a strong attempt to move in the right direction, does not address the full problem.\textsuperscript{146} State medical boards share information about disciplinary action taken against a physician, but as we have seen in the statistics, less than half the impaired physicians ever received formal discipline from their medical board.\textsuperscript{147} In addition, the extent of action taken may vary between states as well as the determination of what discipline is significant enough to report.\textsuperscript{148} Finally, most medical “boards do not report licensure denials.”\textsuperscript{149}

The American Medical Association’s Council on Mental Health in its report on physician impairment states, “[I]t is the physician’s ethical responsibility to take cognizance of a colleague’s inability to practice medicine adequately by reason of physical or mental illness including alcoholism and drug dependence.”\textsuperscript{150} Despite this ethical obligation, many physicians hesitate to report a colleague for two primary reasons. First is the general perception among physicians that the counseling programs for impaired physicians are inadequate.\textsuperscript{151} Second is the fear of liability.\textsuperscript{152}

\textsuperscript{141} \textit{Id.}
\textsuperscript{142} See \textit{id.}
\textsuperscript{143} \textit{Id.}
\textsuperscript{144} See Richard P. Kusserow et al., \textit{An Overview of State Medical Discipline}, 257 JAMA 820, 823 (1987).
\textsuperscript{145} \textit{Id.}
\textsuperscript{146} \textit{Id.}
\textsuperscript{147} \textit{Id.}
\textsuperscript{148} \textit{Id.}
\textsuperscript{149} Kusserow et al., supra note 144, at 823.
The fear of liability for third parties\textsuperscript{153} can influence the decision to report an impaired physician in either direction.\textsuperscript{154} Fear of liability for slander may prevent a person from reporting a physician's alleged impairment. To date, there is no record of a successful slander suit against a reporter whose report can be justified with evidence even if the alleged impairment is ultimately unfounded. This can be interpreted as the court system protecting the honest reporter or it could simply be a function of out of court settlements driven by social pressures on the parties involved. Opposing the fear of liability for slander is the fear of liability for negligence.\textsuperscript{155} The impaired physician's employer can be held liable for negligence if a patient injury results from the impaired physician's practice of medicine.\textsuperscript{156} Thus, there is incentive for colleagues and employers to refer an impaired physician to a treatment program.\textsuperscript{157}

Impaired physicians who are referred to treatment programs may have a greater potential for successful recovery.\textsuperscript{158} When the impaired physician enters a treatment program by referral, the appropriate medical board is notified.\textsuperscript{159} As detailed in the medical analysis section of this paper, impaired physicians fear losing their license to practice medicine.\textsuperscript{160} If the impaired physician is known to the medical board, the incentive to participate and succeed in the treatment program increases.\textsuperscript{161} Additionally, when the impaired physician completes the inpatient and halfway house portions of their treatment and begins to reintegrate into the clinical environment, the medical board participates in the follow up care to help ensure patient safety.\textsuperscript{162}

In addition to self-reporting and colleague/employer reporting, a patient who believes that his physician is impaired may take action.\textsuperscript{163} The patient


\textsuperscript{153} Id. Third parties refers to the impaired physician's colleagues, employer, and institution. Id.

\textsuperscript{154} See id.

\textsuperscript{155} Third-Party Liability, supra note 152.

\textsuperscript{156} Id.

\textsuperscript{157} Edwards, supra note 10, at 1297. Additional incentives for referral are discussed in the ethics portion of this paper.

\textsuperscript{158} Patrick G. O'Connor & Anderson Spickard Jr., Physician Impairment by Substance Abuse, 81 MED. CLINICS OF N. AM. 1037, 1038, 1048 (1997).

\textsuperscript{159} See id. at 1048.

\textsuperscript{160} See supra Part II.A.

\textsuperscript{161} See id.

\textsuperscript{162} See id. at 1047–48.

has two venues in which he can file his complaint. One option is for the patient to sue the physician for malpractice. In a malpractice suit the patient will have the burden to prove four elements: duty, breach, damage, and causation. Another option is for the patient to file a complaint with the licensing board, in which case the patient need only prove duty and breach for the board to take action. There are significant distinctions between a malpractice suit and a complaint filed with the licensing agency. To begin, the patient does not need to have suffered injury at the hands of the allegedly impaired physician to file a complaint with the licensing agency. This narrower scope of investigation makes a complaint to the licensing board significantly easier to verify than a malpractice suit. In the case of a successful malpractice suit, the patient will likely receive monetary compensation for their injury. To the contrary, a complaint to the licensing agency that is found to be meritorious does not provide any tangible compensation to the complaining patient. Instead the patient acts altruistically because the tangible benefit of the complaint is to protect future patients from harm. A complaint filed with the licensing board is arguably the most effective means of prevention because it is the licensing board’s primary goal to protect patients from unqualified physicians.

C. Impairment in the Context of the Americans with Disabilities Act

Individuals who are deemed disabled under the Americans with Disabilities Act (ADA) are afforded protection from discrimination based upon their disability. The general rule, as defined in 42 U.S.C. § 12112 states, “No covered entity shall discriminate against a qualified individual on the basis of disability in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other

164. See id.
165. In order to file a suit alleging malpractice, the patient must have the ability to claim some form of damage that resulted from the physician. See id. at 252.
166. Id.
167. Id. at 252, 254.
168. See Annas, supra note 163, at 254.
169. Id. at 252.
170. See id. at 254. A physician does not necessarily lose their license to practice medicine as a result of a successful malpractice suit. See id. at 253.
171. Id. at 254.
172. Annas, supra note 163, at 254.
173. See id.
terms, conditions, and privileges of employment." To establish a prima facie case of discrimination that violates the ADA, the McDonnell Douglas framework is used. The plaintiff must establish: (1) he is disabled or regarded as disabled within the meaning of the ADA; (2) he is qualified to perform the essential functions of the job; and (3) he was subjected to an adverse employment action solely on account of his disability.

In accordance with the McDonnell Douglas framework, the foundational question is whether or not alcohol or substance abuse/addiction qualifies as a disability under the ADA. The court in Burch v. Coca-Cola Co. determined that alcoholism is not a per se disability as defined by the ADA. Irrespective of a disability’s status under the ADA, the courts have held that if the employer treats the individual as though they are impaired, the disability automatically becomes considered a disability under the ADA. From this we must conclude that if an impaired physician is approached and offered the opportunity to self-refer or is referred to a physician wellness program, the impaired physician will necessarily be considered impaired under the ADA. Therefore the impaired physician would be protected from discrimination—in the form of termination, restricted privileges, etc.—based solely on his impairment.

175. Id.
177. Id. at 802; see, e.g., Holbrook v. City of Alpharetta, 112 F.3d 1522, 1525 (11th Cir. 1997) (where a police officer injured in an accident claimed he was discriminated against as a result of his disability and the district court granted the city’s motion for summary judgment because the officer was no longer able to perform the essential functions of the job but the city had maintained his job title, wages, and benefits); Aucutt v. Six Flags Over Mid-Am., Inc., 85 F.3d 1311, 1320 (8th Cir. 1996) (where the court granted summary judgment to employer because plaintiff failed to establish that he was disabled within the meaning of the ADA); Bacon v. Great Plains Mfg., Inc., 958 F. Supp. 523, 531 (D. Kan. 1997) (where a former employer was not held liable under the ADA because plaintiff did not show former employer knew of her disability, nor did she show that she had a disability that qualified under the ADA).
179. 119 F.3d 305 (5th Cir. 1997).
180. Id. at 316.
181. 42 U.S.C. § 12102(1)(C) (2006); see, e.g., Holihan v. Lucky Stores, Inc., 87 F.3d 362, 363 (9th Cir. 1996). Holihan acted in an abusive, hostile and threatening manner towards several employees. Id. at 364. Holihan’s supervisors inquired if he had any problems that they could help him with, which Holihan denied. Id. Holihan was transferred to a different store where he had multiple outbursts. Id. Holihan’s supervisors offered him the choice of suspension pending investigation or a leave of absence if he contacted the company’s employee assistance program. Id. The judge held that, “a reasonable jury could infer that Lucky regarded Holihan as suffering from a disabling mental condition that substantially limited his ability to work.” Holihan, 87 F.3d at 366.
The prohibition against employment discrimination based on disability in the ADA sets precedent for changing the questions asked in the licensing and credentialing process.\textsuperscript{182} The ADA prohibits questions about an individual’s past history of disability in the employment context because it is intrusive and would require an unnecessary disclosure of private information.\textsuperscript{183} The ADA does not apply directly to the licensing and credentialing process, but the rationale used when drafting the legislation lays the groundwork for changing the licensing and credentialing process to be held to the same standard as other employment activities.\textsuperscript{184}

D. Informed Consent and Disclosure of Prior Impairment to Patients

The doctrine of informed consent is the principle that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”\textsuperscript{185} This doctrine guides the physician-patient relationship. The physician must disclose a standardized amount of information before receiving consent to perform a procedure.\textsuperscript{186} The physician must disclose the diagnosis, including further tests and evaluations and their nature and purpose.\textsuperscript{187} The physician may emphasize which treatment modality he would recommend based on his expertise, but he must also disclose all the possible options.\textsuperscript{188} The physician must also disclose the risks associated with each treatment option.\textsuperscript{189} Informed consent is necessary prior to treatment.\textsuperscript{190} If informed consent is not obtained, the treatment may be technically considered battery, and the physician could be held liable.\textsuperscript{191}

The remaining question is whether an impaired physician has the obligation to disclose his addiction to a patient prior to performing a treatment. Some states have adopted a patient-centered standard for disclosure, requiring the physician to disclose any information that could be material to the

\textsuperscript{182} Peyser, supra note 137, at 517.
\textsuperscript{183} Id.
\textsuperscript{184} See id.
\textsuperscript{185} Schloendorff v. Soc’y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914).
\textsuperscript{186} Robert J. Boyle, The Process of Informed Consent, in INTRODUCTION TO CLINICAL ETHICS 81, 84 (John C. Fletcher et al. eds., 1995).
\textsuperscript{187} Id.
\textsuperscript{188} Id. at 83. Included in the treatment options must be the option to refuse care. See Truman v. Thomas, 611 P.2d 902, 906 (Cal. 1980).
\textsuperscript{191} Id. (applying the rule in Gray v. Grunnagle, 223 A.2d 663, 674 (Pa. 1966)).
THE IMPAIRED PHYSICIAN

patient's decision.192 Spielman states that "the test for determining whether a particular peril must be divulged is its materiality to the patient’s decision: all risk potentially affecting the decision must be unmasked."193 This standard is troublesome to many physicians who do not tend to share information on their own competence when discussing informed consent. Rather, physicians are accustomed to controlling the quantity and content of information flow between themselves and their patients.194 Physicians do not expect, nor do they want, the patient expanding the topics of discussion during informed consent.195 The closest analogy is physicians informing a patient of a mistake they have made that caused the patient injury.196

In Kaskie v. Wright,197 an alcoholic physician performed emergency surgery on an injured child without informing the child’s parents of his impairment.198 Although the statute of limitations had run before the case was filed, the court addressed the issue in their decision.199 The court, referencing Boyer v. Smith,200 stated that there must have been a “touching,” but that negligence is not necessary for recovery.201 It described consent to treatment as a contractual arrangement by which any “contact with the patient’s body must be agreed to.”202 The court followed the precedent set out in Boyer and refused to expand the doctrine of informed consent “to include matters not specifically germane to surgical or operative treatment.”203

In Ornelas v. Fry,204 a kidney transplant from one sibling to another failed.205 During the surgery, the kidney-receiving sibling “bucked,” an ac-

192. Bethany Spielman, Expanding the Boundaries of Informed Consent: Disclosing Alcoholism and HIV Status to Patients, 93 AM. J. MED. 216–18 (1992). Two states specified in this study are Louisiana and New Jersey. Id.
193. Id.
195. See Roger W. Shuy, Three Types of Interference to an Effective Exchange of Information in the Medical Interview, in The Social Organization of Doctor-Patient Communication 17, 24 (Sue Fisher & Alexandra Todd eds., 2d ed. 1993); Spielman, supra note 192, at 216–18.
196. The issue of disclosing addiction is akin to the issue of a physician disclosing his HIV status. Few, if any, physicians disclose to a patient if they themselves are HIV positive. Spielman, supra note 192, at 216–18.
198. Id. at 214.
199. Id. at 214–15.
201. Kaskie, 589 A.2d at 216.
202. Id.
203. Id. at 217.
205. See id. at 820.
tion akin to coughing. The motion tore stitches from the recently attached kidney, and emergency suturing had to be done. The kidney was removed a few days later; ultimately the transplant recipient died. The family alleged that the “bucking” was a result of negligent anesthesia. They brought suit against the anesthesiologist alleging that he did not disclose his status as an alcoholic, which they believed to have been the proximate cause of their son’s death. The court held that the anesthesiologist’s status as an alcoholic did not in itself prove the claim of negligence. The court went on to say that negligence could only be proven if his alcoholism translated to a lower standard of care. The court concluded that the plaintiffs had not demonstrated evidence that the anesthesiologist’s alcoholism played a relevant factor in the poor outcome of the surgery.

In Hidding v. Williams, the court found differently than the above cases. Mr. Hidding was operated on by an alcoholic physician. The physician neglected to disclose the risk of loss of control over bowel function. He also neglected to disclose his status as a chronic alcoholic. The court concluded that this doctor’s failure to disclose his impairment vitiated the patient’s consent to surgery. The court justified this decision by stating that had the patient known this piece of information, it is likely he would have elected to have the surgery performed by a different physician.

Different forms of physician impairment should be compared in the analysis of what information should be disclosed to a patient about the provider. A common comparison is made between an alcoholic physician and an HIV-positive physician. If a provider has the obligation to reveal his HIV-positive status to a patient because there is risk of transmission, does the same obligation exist for an alcoholic physician to reveal his addiction because there is an increased risk of error and/or complication? In Estate of

206. Id.
207. Id.
208. Id. at 820–21.
209. Ornelas, 727 P.2d at 821.
210. Id.
211. Id. at 823.
212. Id.
213. Id.
215. See id. at 1198.
216. Id.
217. Id. at 1196.
218. Id.
219. Hidding, 578 So. 2d at 1196.
220. Id.
Behringer v. Medical Center at Princeton, the Superior Court of New Jersey held that the Medical Center could suspend Dr. Behringer's surgical privileges based on his positive diagnosis of AIDS. The court went further to say that the Medical Center properly conditioned the return of Dr. Behringer's surgical privileges on the mandate that he obtain informed consent, "as a physician with a positive diagnosis of AIDS" from every surgical patient.

There is no clear consensus in the courts or in the medical literature about physician disclosure and the informed consent process. These opposing interests, the patient's interest in information and the physician's interest in privacy, are not calculable to an exact science. Just as each patient is treated individually, each physician and each informed consent process must be taken individually.

E. Policy for Impairment in Professions Outside the Medical Arena

Impairment from alcohol or drug addiction is a significant concern in any profession in which one individual is responsible for another human being. Physician impairment can be compared to pilot impairment and firefighter impairment, to name only a few. All professions which entail public safety share the same universal public policy initiative, to protect the public which the profession is there to serve. This shared goal creates a dichotomy of two competing interests—the interest of the public and the interest of the professional. In the case of impairment, these competing interests are multiplied.

In the case of a pilot, physician, or firefighter who is impaired, the public that each profession serves is placed in a precarious situation. The passengers on a plane, the patient in pre-operative preparation, and the innocent victim in a burning building or car accident do not know or have control over the abilities of the professional who is there to assist them. Yet, the outcome is less likely to be positive because an impaired professional is providing substandard services. From the perspective of the service consumer, it seems logical to ban impaired professionals. On the other hand, the impaired professional is also a person with inherent self-worth who is suffering from an illness beyond his control. Removing him from the profession or even publicly acknowledging his impairment, even for the sake of treatment, may cause great harm. The impaired physician may be the sole provider for his

222. Id. at 1283–84.
223. Id. at 1255 (emphasis omitted), 1279.
224. See id. at 1254.
225. See id. at 1258.
family and removing him from work may adversely affect all the members of his family.\footnote{In addition to the potential economic hardship, the impaired physician may suffer as a result of the stigma his illness carries.}

Although many levels of assistance are available to the impaired professional, society ultimately places the public’s interests above the professional’s personal interests. We see this decision expressed in our legislative system with regulation of narcotics and opiates as well as age restrictions and activity restrictions on alcohol. In addition, a number of court cases have reiterated this point in decisions concerning impaired professionals.\footnote{Each of these cases abided by the public policy notion that the safety of the general public outweighed the interests of the impaired professional.}

IV. ETHICAL ANALYSIS

The ideal foundation for healthcare policy stems from the express values of society. In the field of bioethics, the predominant approach to the application of these values is through the theory of Principalism.\footnote{See generally NAT’L COMM’N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, DEP’T OF HEALTH, EDUC., & WELFARE, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at http://ohsr.od.nih.gov/guidelines/belmont.html#ethical [hereinafter BELMONT REPORT].} Princip
palism provides a framework with which all bioethics dilemmas can be analyzed based upon four principles: autonomy, nonmaleficence, beneficence, and justice.\footnote{Id. at Part B.} Medical society has held this ethos since the origin of the profession, a fact demonstrated by the persistent use of the Hippocratic Oath for nearly two and half millennia.\footnote{Id. at Part A-D.} Society has since reinforced the ethos of the four prima facie principles in a codification of the Belmont Report.\footnote{See id. at Part A-C.} Thus, Principalsm is the de facto standard for moral foundation in medicine.

Within the philosophical framework of Principalism, society values benefit to the patient over benefit to the physician.\footnote{See id. at Part B2.} This hierarchical ranking is demonstrated by the policies limiting the physician’s autonomy in areas such as human research, refusal to treat, and treatment protocols.\footnote{Id. at Part B2.} An impaired physician policy must be syntonic with these established policies. It must maximize the good for the patient within the framework of society’s chosen value system. Once the desired outcome is defined and the method of obtaining that outcome is determined, policy can be designed to ensure the desired outcome is reached. Thus it is essential to perform an ethical analysis of the potential responses to physician impairment prior to making a policy recommendation.

A. Autonomy

Autonomy, also referred to as “Respect for Autonomy,” is the principle of self-governance, the concept that an individual is free of controlling influence or limitations imposed by others on the individual’s decision making process.\footnote{See id. at Part A-D.} In the framework of physician impairment, the patient’s autonomy and the physician’s autonomy come into conflict. It must be clear in the policy that patient autonomy takes priority over physician autonomy. The physician may have the autonomy to self-destruct, namely to leave addiction untreated, but this right cannot be extended to be a right to damage a patient.

\footnote{Id. at Part B.}  
\footnote{See id. at Part B2.}  
\footnote{Id. at Part B.}  
\footnote{Id. at Part B.}
Patient autonomy infers that the patient be fully informed because there is no opportunity for autonomy without knowledge. This analysis does not favor protection of the physician, but rather implies that the patient must be informed that the physician suffers from addiction. The problem raised by this analysis is that it creates incentive for the physician to hide his addiction. Policy on physician addiction must recognize the potential for this behavior and the additional risk of patient harm created by this potential. Practical policy must therefore create incentive for the addicted physician to self-identify and seek treatment. If the incentives include the opportunity for full rehabilitation and return to practice upon remission of the addiction, then the physician is more likely to self-report, obtain treatment, and return to medical practice unimpaired. Incentive, even in a non-punitive form, does not allow autonomy for the physician, but does create greater benefit to both the physician and his patients.\textsuperscript{235}

B. Nonmaleficence

Nonmaleficence is the principle obligation to not inflict harm.\textsuperscript{236} This principle is a foundational concept universal to all ethical theories in medicine.\textsuperscript{237} It is summarized in the maxim, \textit{primum non nocere}, first do no harm.\textsuperscript{238} In the circumstance of physician impairment, the principle of nonmaleficence is simple: protect the patient from the impaired physician who would likely do harm. Any policy addressing physician impairment must address the need to prevent an impaired physician from injuring a patient.

C. Beneficence

Beneficence, the natural extension of nonmaleficence, is the obligation to do good.\textsuperscript{239} Within Principalism, a physician has four obligations: “1. [o]ne ought not to inflict evil or harm . . . ; 2. [o]ne ought to prevent evil or harm; 3. one ought to remove evil or harm; [and] 4. [o]ne ought to do or promote good.”\textsuperscript{240} The first obligation is nonmaleficence and the remaining three obligations are beneficence.\textsuperscript{241} Thus, beneficence builds off of nonma-

\textsuperscript{235} See id. at Part B2.

\textsuperscript{236} See id.; see also TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 114 (5th ed. 2001).

\textsuperscript{237} See BELMONT REPORT, supra note 228, at Part B2.

\textsuperscript{238} See id.

\textsuperscript{239} See id.

\textsuperscript{240} BEAUCHAMP & CHILDRESS, supra note 236, at 114.

\textsuperscript{241} Id. at 115.
leficence, taking the theory of first do no harm and extending it to preventing others from doing harm, removing the potential for harm, and ultimately doing good.242

The potential for beneficence in physician impairment is maximized by offering the impaired physician non-punitive treatment options.243 If physician impairment is approached in a punitive fashion, the risk increases that an impaired physician will obscure and hide his addiction, ultimately creating risk of harm to the impaired physician’s patients.244

Within the principle of beneficence the patient’s and physician’s interests are not in conflict. Incentivizing treatment for physician impairment fulfills a universal good. Beneficence is accomplished for the patient by removing risk of harm and replacing it with treatment by a non-impaired physician—i.e., doing good. Beneficence is accomplished for the physician, who in this case is also a patient, by obtaining treatment for the impairment.

D. Justice

The principle of justice is attributed to Aristotle who summarized it as, “Equals must be treated equally, and unequals must be treated unequally.”245 In the context of physician impairment, the comparison is best drawn as the rights of the individual—i.e., the physician—versus the rights of society—every member of society is a potential patient.246 As expanded upon before, the communal ethos in society is to place greater value on the rights of the members of society.247 Thus, society and the individual are not equals and are therefore not treated as equals. The needs of potential patients’ safety trumps the impaired physician’s needs, resulting in regulation of medical practice while impaired. Policy resulting from the principle of justice would emphasize its primary focus on removal of the impaired physician from practice, and secondarily address the treatment programs.

In the context of medicine, justice is often analyzed in the context of distributive justice.248 Distributive justice focuses on disparate levels of healthcare and health services for different groups within society.249 In the instance of physician impairment, there is no evidence that any one subset of

---

242. See id.
243. See id. at 116.
244. See id.
245. BEAUCHAMP & CHILDRESS, supra note 236, at 227.
246. See BELMONT REPORT, supra note 228, at Part B3; see also BEAUCHAMP & CHILDRESS, supra note 236, at 226.
247. See BELMONT REPORT, supra note 228, at Part B3.
248. See BEAUCHAMP & CHILDRESS, supra note 236, at 226.
249. See id.
society is at greater risk for treatment by an impaired physician. Theories of disparate impact can be made for different socioeconomic classes, but again there is no proof that either of these theories is accurate. The first theory is that the poor population is disparately affected by physician impairment because this population generally receives care in large institutions in which an impaired practitioner could more easily slip through the cracks. In addition, members of lower socioeconomic classes do not necessarily have knowledge of or access to patient advocates to assist them. The second theory is that the rich population is disparately affected by physician impairment because members of upper socioeconomic classes tend to receive care in elite institutions where a physician with status may be able to avoid being reported for impairment by use of clout and influence. In addition, many physicians who choose not to practice in this elite environment, but rather choose to serve the underprivileged communities, may have a communal ethos of altruism and idealism. These practitioners are less likely to tolerate an impaired colleague who puts their patients at risk.

V. POLICY RECOMMENDATIONS

Despite the prevalence of physician addiction and subsequent impairment, there is no universal approach to prevention, identification, treatment, or post-recovery follow-up. Each of these four elements must be standardized for all physicians practicing in the United States. For all physicians in the United States, their careers began in a standardized format. Every student took specific pre-med requirements, the MCATs, standard medical curricula, core rotations, medical board examinations, and the same accreditation exam for their specialty. This ecumenical approach to medical education and training produces a consistent caliber of physicians. Yet once a physician's official training years are complete, the national standard ends. Physicians are regulated by their state licensing agency. Each state sets its own requirements for continuing medical education and license renewal, and national continuity is lost. It is this loss of continuity in the system that allows impairment to occur and continue in the medical field. Creating a national standard for impaired physician programs and policies would return to the proven methodology of universal physician regulation.

This policy recommendation rests on a base of continuity. Each of the four elements of an impaired physician policy—prevention, identification, treatment, and post-recovery follow-up—must be standardized.

Prevention of physician impairment is the ideal approach to reducing the impaired physician problem. As the studies discussed in prior sections
have demonstrated, the majority of physician impairment starts during medical school. For this reason, it is essential that physician impairment be addressed during the first year of medical school. A standard curriculum should be taught in every medical school, the same way that anatomy and physiology are standardized in all medical schools. The curriculum must include key information such as how to recognize impairment in oneself and in others, what resources are available for an impaired physician, and what protection is afforded the impaired physician. After a detailed curriculum is taught in the first year of medical school, a truncated version of the course should be revisited at the end of second year, just before students begin to rotate on the wards. In addition to education during medical school, residency programs should incorporate at least one impaired physician lecture per year in the regular, mandatory conferences. Finally, all physicians must participate in a certain amount—varying by state—of continuing medical education to maintain their credentials and licensure. It should be mandatory that a portion of this education address physician impairment. This plan ensures that every physician is well versed in recognizing and addressing physician impairment and is knowledgeable about the resources available.

All the literature and studies are in agreement that the key to a successful recovery is the early identification of an impaired physician. The education discussed above will help physicians to recognize impairment in their peers. In addition, the continuing conversation about physician impairment throughout a physician’s career will help to remove the stigma attached to physician impairment. The combination of lowered stigma and knowledge of resources will help to raise the portion of physicians who self-report or who report a peer.

Universality is most important during the treatment stage. Rather than having an impaired physician program in every state, there should be a number of nationally run and regulated physician wellness programs. Having a national impaired physician treatment center would help to vitiate a number of the current treatment deterrents. National treatment centers would help the impaired physician to seek treatment outside of their professional circles. This is particularly important in small medical communities where anonymity may be far more difficult to maintain. Additionally, this would ensure that physicians are treated in physician-only settings, which are proven to be more successful for recovery than programs that mix physicians and non-physicians. Additionally, the healthcare providers at these national treatment centers would be specialists in physician impairment, and thus more apt in

250. See Blondell, supra note 7, at 210.
251. See supra Part II.C.
approaching the treatment hurdles that are unique to physicians. A national impaired physician treatment center would encourage self-reporting by providing anonymity in combination with the optimal treatment environment.

The post-recovery follow-up must also be standardized. Every recovering physician should be followed in the same manner, for the same length of time, and by the same physicians as the treating physicians. This continuity helps provide stability for the recovered physicians as they re-enter the work environment. Additionally, a standardized follow-up program allows the recovered physicians to know what to expect and to not feel singled out for additional attention.

These suggestions combine to create a policy recommendation believed to better diminish the current problem of physician impairment. Continuity in each of these four stages will provide the backbone of support necessary to minimize physician impairment.

Matthew J. Seamon**

I. Introduction ........................................................................... 630
II. Regulatory and Economic Overview ........................................ 633
   A. Antitrust Considerations ...................................................... 633
   B. Patents and Exclusivity ....................................................... 634
   C. Economic Framework ......................................................... 638
III. Industry Overview and Regulation ......................................... 640
   A. FDA Oversight .................................................................... 640
   B. Research and Development ................................................ 643
   C. Marketing Strategies Employed ............................................ 645
IV. Statutory Regulation of Drugs and Biologics ............................ 647
   A. Drug Regulation under the FDCA ...................................... 647
      1. New Drug Application (NDA) ......................................... 648
   B. Biologics Defined ............................................................... 649
      1. Biologic Regulation under Public Health Service Act ....... 652
         a. Biologic Licensing Application .................................... 653
V. Generic Drug Regulation / Drug Price Competition and
   Patent Term Restoration Act of 1984 .................................... 654
   A. Generic Drugs ................................................................. 656
   B. Abbreviated New Drug Application (ANDA) ...................... 657

* This article is dedicated to the memory of Professor Stephanie Aleong. Although I am honored to have met Professor Aleong, my interactions with her were modest. In choosing this topic, I looked for an issue that Professor Aleong would acknowledge as important. Although this topic is not on the forefront of patients, it does impact their wallets and is subject to exploitation by others and protection from caring and dedicated professionals like Professor Aleong.

** Dr. Seamon is Associate Professor, Pharmacy Practice at Nova Southeastern University College of Pharmacy and serves of Counsel to the firm of Fuerst Ittleman in Miami, Florida where he focuses his practice on Food and Drug Law. Dr. Seamon would like to thank Professor Kathy Cerminara and the Nova Law Review for the opportunity to provide this paper, to Professor Linda Harrison for peeking my interest in antitrust and to Professor Phyllis Coleman for her unwavering support and confidence in me as an attorney. The teacher who "is indeed wise . . . does not bid you [to] enter the house of his wisdom, but rather leads you to the threshold of your own mind." KAHLIL GIBRAN, THE PROPHET 56 (1973). All views expressed in this paper are solely of the author and do not reflect those of Nova Southeastern University or Fuerst Ittleman.
I. INTRODUCTION

In the movie Training Day, veteran police detective Alonzo Harris, played by Denzel Washington, tells rookie police officer Jake Hoyt, played by Ethan Hawke, “This shit’s chess not checkers.”1 Although Detective Harris was not talking about the biopharmaceutical industry, he might as well have been. Over the last couple of decades, the U.S. pharmaceutical marketplace has become a sophisticated gaming industry spawned by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as Hatch-Waxman.2 Financial success is predicated on anticipation, responsiveness, business shrewdness, legal adeptness, and industry acumen. Although complicity and collusion may be unlawful, the pharmaceutical industry has pushed the outer boundaries of behavior for profit and penetration. Consider the incentive—the average cost to develop a new biotechnology product is $1.2 billion and only one-third of drugs approved recoup research and development costs.3 The risk is high. However, the upside is substantial. Blockbuster drugs generate billions in sales annually with certain drugs earning in excess of ten billion dollars annually.4

1. TRAINING DAY (Warner Bros. 2001).
Biologics represent the evolving future of prescription drug therapy. They have already revolutionized the treatment of cancer, diabetes, hemophilia, and rheumatoid arthritis, among other diseases. As the human genome is mapped to completion, research and development is now identifying important genetic predispositions and novel targets for therapy that will further restructure medicine. We are truly at the threshold of a paradigm shift in drug therapy. Herceptin, a monoclonal antibody drug used to treat a deadly form of breast cancer, has been shown to reduce the risk of death by 33%. Nevertheless, the costs of biologics are immense. A single biologic can cost upwards of $200,000 annually. In 2007 Americans spent over forty billion dollars for biological drugs and they now account for approximately 20% of global drug sales. It is estimated that 50% of the pharmaceutical market is represented by biologics.

To confound the situation, there is a newly legislated, but not yet implemented approval pathway for generic biologics in the United States authorized under the Biologics Price Competition and Innovation Act of 2009 (BPCIA). Prior to this act, for a generic biologic to become available, the sponsor had to conduct lengthy and costly research; essentially the same requirements as an innovator drug. Thus, the research and development costs remained significant and the cost to the patient would be only marginally decreased. Additionally, as approval would only be considered a follow-up without significant cost-savings, many would be reluctant to “switch,” and sponsors were disinclined to develop these products. Accordingly, brand biologics had a functional patent life in perpetuity and the incentive to compete was trivial. For example, recombinant human insulin by Lilly was ap-

7. Engelberg et al., supra note 5, at 1917.
8. Id.
12. Engleberg et al., supra note 5, at 1918.
13. See id.
proved in 1982, and there remains no generic for this billion dollar drug.\textsuperscript{14} However, on March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, a health reform bill, which, in part provided statutory authority for biosimilar products, like Hatch-Waxman established for traditional drugs.\textsuperscript{15}

Although Hatch-Waxman is often viewed as a wide success, it has a number of important flaws that should serve instructional in the evaluation of the new regulatory framework for generic biologics.\textsuperscript{16} Additionally, Europe has a pathway in place to provide further insight and experience, and a Canadian system is approaching final implementation.\textsuperscript{17} There are important lessons to be learned and a properly structured approval pathway for generic biologics will prove to be advantageous.

Part II of this paper presents antitrust concerns in the current biopharmaceutical marketplace. It looks at the current system of patents and exclusivity and evaluates the economic framework that makes biopharmaceuticals so unique and susceptible to peculiar business practices. Part III of this paper presents the Food and Drug Administration’s (FDA) regulatory role in prescription drug regulation and then underscores the current business practices of the biopharmaceutical industry. It establishes that the future of medicine is biologically based and the need for a properly structured pathway for generic biologics. Part IV of this paper reviews the regulatory framework involving prescription drugs, including biologics. Part V deconstructs the Hatch-Waxman provisions to the Food, Drug, and Cosmetic Act of 1983 (FDCA) and surmises limitations to the amendment, serving as foundation for the evaluation of the BPCIA. Part VI of the paper reviews the current state of generic biologics and evaluates the new legislation in the U.S. using the E.U. legislation as a benchmark. Part VII assesses the future of follow-

\begin{itemize}
\item \textsuperscript{15} Id.
\item \textsuperscript{17} See Behnke et al., supra note 9, at 2.
\end{itemize}
up biologics in the U.S. in light of the evolving framework and provides concluding remarks on the topic.

II. REGULATORY AND ECONOMIC OVERVIEW

In order to appreciate the gamesmanship involving biologics and drugs one must need to understand the regulatory interplay between antitrust law and patents and the economic framework surrounding prescription drugs.

A. Antitrust Considerations

Antitrust involves the balance between government granted monopoly in the form of patents and other intellectual property rights, and the abuse of monopoly power to hinder competition. It serves to protect the integrity of the competitive process and enable consumers wide access to the best possible products at the lowest possible prices. It serves to try and level the playing field for all players in a market.

Antitrust legislation originated in the late 1800s while certain businesses, called trusts, controlled entire industries, most notably steel and oil. As expected, prices soared while quality and services diminished. In response to growing concern, President Theodore Roosevelt and Congress led the bust of these trusts, through pioneering antitrust legislation. Antitrust legislation has shown to lower prices, improve service and spawn vigorous competition. Amazingly, it is some of the most direct and succinct law on the books. It is elegant in its simplicity. Consider Section 1 of the Sherman Act is ninety-six words and outlaws "[e]very contract, combination or conspiracy in restraint of trade," Section 2 is eighty-two words and finds "[e]very person who shall monopolize, or attempt to monopolize... guilty of a felony." The impact of these 178 words has evolved an encyclopedia

22. Id. at 35–36.
of case law, has allowed U.S. businesses to develop new industries, and has provided U.S. consumers remarkable services and products at reasonable prices. Today, antitrust legislation remains a vital aspect to competition and affects such diverse industries as cable television, telephone service, internet search engines, and computer operating systems.

Antitrust legislation encompasses federal antitrust laws, enforced by the Department of Justice and state antitrust laws, enforced by state attorneys general. Antitrust cases involving drugs are primarily within the purview of the FTC Bureau of Competition, Health Care Services, and Products Division, which generally regulates the pharmaceutical industry. Antitrust legislation provides for suits by the injured party including State Attorneys General, and the award of injunctive relief. Antitrust law involving drugs is based primarily in Section 1 of the Sherman Act—trusts; Section 2 of the Sherman Act—monopolies; Section 2 of the Clayton Act, commonly referred to as the Robinson-Patman Act—prohibiting price discrimination; Section 3 of the Clayton Act—dealing with exclusionary practices, such as tying arrangements and predatory pricing; Section 7 of the Clayton Act— affecting mergers and acquisitions; Hart-Scott-Rodino—involving pre-merger notification; and Section 5 of the FTC Act—preventing unfair and deceptive business practices.

B. Patents and Exclusivity

Patent law involves “the right to exclude others from making, using, offering for sale, or selling [an] invention throughout the United States or importing [an] invention into the United States.” Patents are granted to products based on utility, novelty, and non-obviousness. Patent law is consti-
stitutionally based and within the federal purview. Article 1, Section 8 of the U.S. Constitution reads “Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Patent law serves to foster innovation by protecting the interest of the innovator and to prevent copycats that simply pilfer the reward. The United States Patent and Trademark Office (USPTO) is the federal agency responsible for granting patents and is an Agency in the U.S. Department of Commerce.

There are three types of patents available for prosecution. Drug patents primarily incorporate utility patents and typically involve the drug product, formulation, manufacturing process, and method of use. Theoretically, all patented drugs are subject to replication, including complex biologics. A properly filed patent, must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

When talking about drugs and biologics another important aspect to consider is exclusivity. Exclusivity refers to “exclusive marketing rights granted by the FDA upon approval of a drug.” Patents are granted by the U.S. Patent and Trademark Office based on statutory requirements, whereby

41. U.S. CONST. art. 1, § 8.
43. 35 U.S.C. § 1.
49. Id.
exclusivity is granted by the FDA upon a drug's proof of safety and efficacy. Patents are granted for twenty years. Exclusivity depends on the type of patent issued and is typically five years. Although an innovator drug may have no patent protection remaining, once it is approved by the FDA it gains a period of exclusivity, whereby the FDA cannot approve a generic competitor.

The interplay between patent law and antitrust law strikes an important and delicate balance between competing interests. Patents are government granted monopolies, while antitrust is government's bust of monopolies. The two are in complete philosophical opposition. Interestingly, however, both seek to accomplish the same end: increase innovation. Patents seek this by directly rewarding innovation and making public information on existing products to help promote further research and development, thus paying it forward. Antitrust seeks to promote innovation through a leveling of the competitive process, thus allowing new innovators to research and reward.

Trade secrets are another intellectual property right, like patents, but with critical differences. Trade secrets refer to “any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.”

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving ma-

52. 21 C.F.R. § 314.108(b)(2).
53. See id.
55. Id. at 1259.
56. See id.
57. Id. at 1260.
58. See id. at 1261.
59. See Leslie, supra note 54, at 1263–64.
60. See RESTATMENT (THIRD) OF UNFAIR COMPETITION § 39 cmt. c (1995).
61. RESTATMENT (THIRD) OF UNFAIR COMPETITION § 39.
Generally speaking, to be protected, a trade secret must be kept secretive, be of value, and provide a competitive business advantage. Trade secrets differ from patents in three important regards. First, a trade secret can survive indefinitely, unlike a patent which expires after twenty years. Secondly, a trade secret does not involve disclosure of any information and in fact requires the holder to conceal the practice. Thirdly, trade secrets offer no real protection against reverse engineering and copy. The classic example of a trade secret is the recipe for Coca-Cola. If Coca-Cola sought patent protection, they would have to disclose the recipe and then receive protection for only the statutory time. Not a great business practice for the Atlanta based company using a recipe from Pharmacist John Pemberton, developed over one hundred years ago. However, if at any point a competitor can legally determine the recipe, Coca-Cola is at a complete loss for compensation or harm.

The pharmaceutical marketplace does not typically rely on trade secrets to protect innovation. Although the protection afforded is expansive, the risk is too great. Pharmaceutical companies notoriously employ a number of competitive intelligence systems, and the technology used to reverse engineer drugs is rather simple for those in the business. Instead, the major pharmaceutical companies rely on patent protection and urbane marketing.
campaigns to maximize profits, as accountability to shareholders is an important obligation.  

C. Economic Framework

The pharmaceutical industry has a very unique economic framework based on the styles of competition, manufacturing issues, research and development costs, barriers to entry, and elasticity of demand.

Life saving therapies, and drugs in general, are said to have inelastic demand. Practically speaking this means as the price increases, the demand stays the same regardless of supply. In classic economic theory, a product's price is viewed as the equilibrium point between supply and demand in a perfectly competitive marketplace. However, in a situation like Type I diabetes where you need insulin to survive, the relationship between supply and demand is irrelevant to establish a price point. A diabetic will pay whatever price possible, independent of the supply.

Another important economic consideration involving drugs is pricing. There is no price regulation in the United States, although every other Westernized country has some regulation. For example, there are direct price regulations in Canada, France and Italy. Indirect regulations exist in Japan—insurance reimbursements—and the United Kingdom—profits. Pricing is extremely complex in the United States as insurance, managed care, and government payers confound the situation, and the inelasticity of demand supports high pricing. Drugs are further unique in that they involve important economies of scale. An established pharmaceutical manufacturing

74. See id. at 592–93.
77. See Neeraj Sood et al., The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries, 28 HEALTH AFF. (Web Exclusive) w125, w125 (2008).
78. See id. at w136.
79. See id. at w127.
80. See id. at w130–31.
facility can manufacturer drugs at a nominal cost. This does not hold as true for biologics, which may have a considerable cost associated with manufacture, but economies of scale still ring true as with all large scale productions and industries. 83 Once the facility is established, the cost to produce is rather low.

The pharmaceutical industry is inimitable in that it encompasses three types of competition, each with unique economic considerations. 84 First, there is brand/brand competition. 85 This typically involves drugs in the same class and drugs used for similar indications. 86 An example of this is Viagra and Cialis. The second type of competition is brand/generic. 87 This occurs when a drug loses its exclusivity and patent protection and a generic drug becomes available. 88 An example of this is Prozac and fluoxetine, manufactured by a generic company. The third type of competition among drugs is generic/generic. 89 As drugs lose their patents, generics become available. 90 An example of this might include fluoxetine—by Mylan Pharmaceuticals—and fluoxetine—by Teva Pharmaceuticals.

Barriers to entry are another essential concept in understanding the interplay between patent and antitrust with drugs. Drug development is considered to have a slow speed of entry and new players are at a considerable disadvantage. 91 It takes approximately eight years to develop a drug from initial research to market approval. 92 And this is for skilled players. A new company seeking to research and develop a drug would face a number of challenges, including necessary supplier agreements, specialized industry regulation and intellectual property right considerations, sunken costs, and susceptibility to predatory pricing.

83. See id.
85. See id.
86. See id.
87. See id. at xii–xiii.
88. See id.
89. See Cong. Budget Office, How Increased Competition From Generic Drugs, supra note 84, at xiii.
90. See id.
92. See Average Cost to Develop a New Biotechnology Product Is $1.2 Billion, supra note 3.
As a result of these factors, the pharmaceutical marketplace has evolved into a true oligopoly. As such, there is a great incentive for price fixing, conscious parallelism, tacit collusion and collusive pricing tendencies, along with heavy reliance on game theory.\(^\text{93}\) Not surprisingly, the industry has faced accusations of monopolization, agreements not to compete, agreements on price or price-related terms, predatory pricing, unlawful horizontal mergers between competitors, vertical mergers involving PBMs, potential competition mergers, illegal tying, and other arrangements.\(^\text{94}\)

### III. INDUSTRY OVERVIEW AND REGULATION

The pharmaceutical industry is a competitive and potentially very lucrative marketplace. Profits are measured in billions of dollars in annual sales and unexpected, sudden market collapses are not uncommon. One day Vioxx was a jackpot with sales of $2.5 billion annually; the next it was a liability estimated at $50 billion to Merck.\(^\text{95}\) Black-box warnings, other labeling revisions, and competing drug approvals incessantly threaten a drug's survival and profitability.\(^\text{96}\) One in five drugs will see a black-box warning or require market withdrawal in a twenty-five year life-span.\(^\text{97}\) Loss of patents protection is another critical issue. Within two months of losing patent protection, Prozac lost 70% of its multibillion dollar market share.\(^\text{98}\)

#### A. FDA Oversight

The FDA is one of eleven agencies of the Health and Human Services (HHS) which is the department responsible for "protecting the health of all Americans."\(^\text{99}\) The statutory functions of the FDA are formally delegated to

---

94. See FTC 2008 REPORT, supra note 25.
97. Id. at 2216.
the Secretary of the HHS, who is appointed by the President and is a member of the President’s cabinet. The FDA ensures safe and effective drugs to U.S. consumers, in addition to a myriad of other roles. The FDA also oversees food, veterinary medicines, dietary supplements, medical devices, radiation emitting devices, and cosmetics. The FDA has six product centers, one research center, and two offices within the agency that regulate its various responsibilities. The Center for Drug Evaluation and Research (CDER) is the largest center in the FDA and is charged with prescription and non-prescription drugs. The Center for Biologics Evaluation and Research (CBER) is responsible for biologics including some drugs.

Like all administrative agencies, the FDA has three essential functions: rulemaking authority, investigative/enforcement authority, and adjudicatory

100. FDA, FDA Staff Manual Guides, Volume II, Delegations of Authority: Regulatory Delegations of Authority to the Commissioner Food and Drugs, http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm (last visited Apr. 17, 2010).


103. Id.


Nevertheless, administrative agencies are often referred to as a headless, fourth branch of government as their rulemaking authority is granted by the legislature, their investigative and enforcement authority is accountable to the Executive branch, and their adjudicatory authority is subordinate to the court system. These inherent limitations have often inhibited the FDA and account for many of the claims made by its detractors.

The FDA regulates approximately $1 trillion worth of goods, with an annual budget of $3.2 billion. Approximately $828 million of this budget originates from user fees. These user fees were first established in 1992 in response to growing concern about the efficiency of the FDA’s review process when Congress enacted the Prescription Drug User Fee Act (PDUFA I). PDUFA reauthorizes every five years. PDUFA affords the FDA the opportunity to hire reviewers and expedites the drug approval process. The most recent enactment, PDUFA IV, was included in Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Under PDUFA, the FDA collects three types of user fees from the industry: application fees, establishment fees, and product fees. PDUFA has been heavily criticized as the regulators—the FDA—have now become very tight bedfellows with the industry, and the agency now relies on this funding for sur-

107. See JOHN P. SWANN, FDA’S ORIGIN, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George Kurian, ed. 1998)).
108. FDA, FAQs by Topic, http://www.fda.gov/AboutFDA/WhatWeDo/FAQs/default.htm (last visited Apr. 17, 2010).
109. FDA, Summary of the FDA’s FY 2010 Budget, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm153154.htm (last visited Apr. 17, 2010). The budget for 2010 specifically includes a section on generic biologics—referred to as “Follow-on Biologics.” Id.
110. Id.
113. Id.
vival, a very alarming proposition.\textsuperscript{116} User fees account for approximately fifty percent of drug review costs.\textsuperscript{117}

In determining which products are assessed user fees, the FDA widely utilizes a reference entitled Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.\textsuperscript{118} This reference includes all drug products approved by the FDA since 1984 including therapeutic equivalents, so called generic drugs.\textsuperscript{119} Drugs listed in the Orange Book are assumed to be marketed and thus qualify for user fees.\textsuperscript{120} The Orange Book also serves as the official compilation of patent and exclusivity listings of drugs recognized by the FDA.\textsuperscript{121}

B. Research and Development

The drug approval process is a costly, complex, and cumbersome one. In the screening and development phase, a myriad of laboratory compounds are thoroughly screened for activity.\textsuperscript{122} So called "hits" are then further tested for "leads" in a process coined hits-to-leads.\textsuperscript{123} Medicinal chemists work to identify and then (re)engineer the most active and stable compounds to focus further development, all in the hopes of finding the next blockbuster.\textsuperscript{124} Compounds, most active in vitro, are administered to rodents and then primates to assess plausibility in humans.\textsuperscript{125} Products appearing promising can then be administered to humans in a complex and closely monitored system of escalating doses and monitoring.\textsuperscript{126} Products are further tested for carcinogenicity, mutagenecity, and teratogenecity.\textsuperscript{127}

\textsuperscript{116} See FDA, White Paper, supra note 112.
\textsuperscript{117} Id.
\textsuperscript{118} Natalie M. Derzko, The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation, 45 IDEA 165, 169 (2005).
\textsuperscript{119} See id. at 167, 169.
\textsuperscript{120} See Dep't of Health & Human Servs., Approved Drug Products, supra note 14, at ix.
\textsuperscript{121} Id. at i.
\textsuperscript{124} Id. at 377.
\textsuperscript{125} See 21 C.F.R. § 314.50(d)(2) (2009).
\textsuperscript{126} See 21 C.F.R. § 312.21.
\textsuperscript{127} See 21 C.F.R. § 312.32(c)(B).
Before administering a so-called investigational drug to humans, the sponsor must seek an Investigational New Drug Application (IND). Technically, this serves as legal permission to move an unapproved, investigational drug into the stream of interstate commerce. The application has three focus areas: 1) animal pharmacology and toxicology; 2) chemistry and manufacturing; and 3) clinical protocols and investigator information. The FDA reviews this application with an eye on safety and future development, all the while understanding that drug development is inherently dangerous, but necessary. The FDA has a thirty-day window to issue a “clinical hold” on an IND, or else the application is deemed approved and the drug can then be administered to human subjects in the first of a series of research protocols.

Phase I studies are the first studies involving humans. The drug is typically administered to a small number of healthy male volunteers, usually between ages twenty and eighty. The drug is evaluated for the preferred route of administration, a tolerable dosage range, safety and side effects, and reviewed for its pharmacokinetic characteristics. Next, Phase II studies are conducted whereby the drug is administered to a population of interest, usually about 200 patients inflicted with the disease, but otherwise healthy. These studies establish preliminary efficacy data, identify the preferred dosing regimen and target dose, and further assess safety. Phase III studies are typically large-scale randomized, controlled and uncontrolled trials involving thousands of patients to substantiate efficacy, expand safety data, and confirm the optimal dose.

128. See 21 U.S.C. § 355(j) (2006); see also 21 C.F.R. § 312. IND is also referred to as “Notice of Claimed Investigational Exemption for a New Drug.” 21 C.F.R. § 312.3(b).
130. FDA, IND, supra note 122.
131. See id.
133. 21 C.F.R. § 312.21(a)(1).
135. 21 C.F.R. § 312.21(a). Pharmacokinetic characteristics refer to the body’s action on a drug. See 21 C.F.R. § 312.23(a)(5). That is, absorption, distribution, metabolism, and elimination/excretion. 21 C.F.R. § 312.23(a)(8)(i).
136. 21 C.F.R. § 312.21(b).
137. See id.
138. 21 C.F.R. § 312.21(c).
Overall, the research and development process is a risky endeavor. The top ten pharmaceutical companies bring an average of only 0.6 drugs to market per year. Only five out of five thousand compounds make it to human testing, of which only one is ultimately approved for human use. Then remarkably, only one-third of drugs approved generate sufficient earnings to recoup average research and development costs.

C. Marketing Strategies Employed

In response to the highly risky, yet lucrative business of pharmaceuticals, the industry has developed a complex multi-faceted approach to increasing sales, promoting widespread, and some would say indiscriminate use, and discerning themselves from the competition. Drug companies hire celebrity spokespersons and cheerleaders as sale associates. They utilize a sophisticated system of data mining to identify changes in market share and physician identifiable prescribing habits. The industry has even been accused of creating diseases and selling sickness. They have an infamous reputation for providing lavish incentives to physicians for the mere opportunity to detail them on the benefits of their product. They regularly masquerade marketing as “educational symposia and seminars.” Companies seed the market through the use of “free” drug samples and low cost in-hospital contracts. They use prominent physician names, along with ghost writers in medical publications and have even gone so far as to establish journals. Although these tactics may be facially legal, the ethical consid-
erations are notable. Direct-to-consumer advertising (DTCA) of drugs has become a great windfall for the industry since 1997 when the FDA issued a draft guidance that effectively enabled the use of broadcast ads for DTCA.\textsuperscript{150} Currently, only the United States and New Zealand allow DTCA of pharmaceutical products.\textsuperscript{151}

In addition to FDA regulation, the industry highly self-regulates. PhRMA, the pharmaceutical trade association, publishes a Code on Interactions with Healthcare Professionals, which provides ethical guidance on industry practice.\textsuperscript{152} The updated code took effect in January 2009 and includes a number of changes targeting some of the above mentioned practices.\textsuperscript{153} The other major regulatory guidance is published by the Office of the Inspector General of the Department of Health and Human Services and is called the Compliance Program Guidance for Pharmaceutical Manufacturers.\textsuperscript{154} It calls for drug companies to establish voluntary compliance programs within the company.\textsuperscript{155} Specifically, the program targets three risk areas: “(1) Integrity of data used . . . to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.”\textsuperscript{156} The document is intended for drug companies to gain insight and foster adherence to relevant laws, especially involving federal health care programs.\textsuperscript{157}

Another important business tactic widely impacting healthcare delivery involves off-label drug use.\textsuperscript{158} Off-label use refers to the delivery of a pharmaceutical distinct from its approved labeling.\textsuperscript{159} This can range from an

\begin{flushright}
\end{flushright}

\begin{itemize}
\item 150. FDA, Prescription Drug Promotion, \url{http://www.fda.gov/NewsEvents/testimony/ucm115206.htm} (last visited Apr. 17, 2010).
\item 153. \textit{See} Press Release, PhRMA, PhRMA Revised Marketing Code Reinforces Commitment to Responsible Interactions with Healthcare Professionals (July 10, 2008), \url{http://www.phrma.org/news_room/press_releases/phrma_code_reinforces_commitment_to_responsible_interactions_with_healthcare_professionals}.
\item 155. \textit{Id.}
\item 156. \textit{Id.} at 23,733.
\item 157. \textit{Id.} at 23,731.
\item 159. \textit{Id.}
\end{itemize}
increased dose to a shortened duration of treatment to a novel use.\textsuperscript{160} Once a drug is approved by the FDA, the actual use becomes part of the practice of medicine, and thus beyond the purview of the FDA.\textsuperscript{161} Off-label drug use accounts for approximately twenty percent, with certain drug classes approaching seventy-five percent.\textsuperscript{162} This use is considerable and has even landed a prominent physician in jail for unlawful promotion.\textsuperscript{163}

IV. STATUTORY REGULATION OF DRUGS AND BIOLOGICS

Drugs, including biologics, are regulated primarily under federal legislation via the interstate commerce clause of the United States Constitution. Traditionally, health, safety, and welfare, the so called police powers, are reserved to the states. However, as drugs “substantially affect interstate commerce,” their regulation is deemed a federal matter subject to federal purview.\textsuperscript{164}

A. Drug Regulation under the FDCA

Federal drug regulation occurs primarily through the Federal Food, Drug, and Cosmetic Act (FDCA).\textsuperscript{165} This Act was first legislated in 1938 in response to the tragic sulfanilamide incident and has since undergone a number of important revisions.\textsuperscript{166} In part, the act prohibits the movement in inter-
state commerce of a new drug without an approved application. Approval can arise from a New Drug Application (NDA), “paper NDA,” abbreviated NDA, or Over-the-Counter (OTC) Monograph.

Under the FDCA, a drug is defined as an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” This means the intended use, via the labeling of a product, dictates its status. The FDCA further regulates drugs through its misbranding and adulteration provisions. Adulteration refers, in part, to a drug product that is “filthy, putrid, or decomposed.” Misbranding involves a drug’s label. Any false or misleading labeling statements render the drug misbranded. Drugs found to be adulterated or misbranded are subject to seizure by the FDA and other enforcement mechanisms. The FDCA also authorizes the IND, which allows an unapproved drug to be researched. Historically, a number of biologics have been approved solely under the FDCA, including insulin and human growth hormone.

1. New Drug Application (NDA)

Under the FDCA, drugs require premarket clearance before they can be sold in the United States. Drugs that appear to have a positive risk to benefit ratio are then sought for marketing approval. This typically occurs through a New Drug Application (NDA), authorized under section 505(b)(1) of the FDCA. The NDA is the comprehensive collection of data and knowledge on a drug product. The goal of an NDA is to demonstrate to the FDA that a drug is safe and effective, the labeling is appropriate, and that

168. See FDA, Small Business Assistance, supra note 115.
173. Id.
174. 21 U.S.C. § 334. Although the FDA maintains enforcement authority for civil, criminal, and administrative actions, they maintain a cooperative working relationship with the U.S. Department of Justice involving many criminal matters. See 21 U.S.C. § 335. In fact, section 335 authorizes the FDA to report criminal violations to said department. Id.
175. 21 U.S.C. § 355(i); 21 C.F.R. 312.23 (2009).
178. See 21 C.F.R. § 314.2.
179. See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50.
180. See id.
the manufacturing ensures the drug's identity, strength, quality, and purity.\textsuperscript{181} The NDA even includes a section on environmental impact.\textsuperscript{182}

Drugs have to demonstrate safety and efficacy under a burden of substantial evidence.\textsuperscript{183} They also have to submit preclinical data—animal pharmacology and toxicology—to demonstrate current good manufacturing practices, compliant product packaging and labeling, and follow postmarketing requirements including reporting known adverse effects.\textsuperscript{184}

The NDA is assigned a Therapeutic Review Classification based on the importance of the drug, which dictates the FDA's timeline for review.\textsuperscript{185} The FDA typically then utilizes an advisory committee to help evaluate the drug and make a non-binding recommendation as to approval.\textsuperscript{186} Applications with deficiencies receive a "complete response letter" describing the agency's findings of concern.\textsuperscript{187} Drugs suitable for approval can then be approved and licensed under the FDCA to move in interstate commerce as long as they are not adulterated or misbranded.\textsuperscript{188} Any changes in indications, manufacturing procedures, labeling, dosage form, or dosing, require a supplemental application referred to as an NDA.\textsuperscript{189}

B. Biologics Defined

Biologic drugs are large molecule products, typically proteins, derived from a living organism or one of its products and manufactured through a

\textsuperscript{181} 21 U.S.C. § 355(b); 21 C.F.R. § 314.50(b).
\textsuperscript{182} 21 C.F.R. § 314.50(d)(1)(iii).
\textsuperscript{183} 21 U.S.C. § 355(d).
\textsuperscript{186} Drugs that provide a "significant improvement compared to marketed products," receive priority review within six months, and remaining drugs are reviewed within a ten month time frame. Id. at 1–2; FDA, Fast Track, Accelerated Approval and Priority Review, http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessstoImportantNewTherapies/ucm128291.htm (last visited Apr. 17, 2010).
\textsuperscript{187} See FDA, Advisory Committees, http://www.fda.gov/AdvisoryCommittees/default.htm (last visited Apr. 17, 2010). The FDA identifies forty-nine advisory committees. Id.
\textsuperscript{188} See 21 C.F.R. § 314.105.
\textsuperscript{189} 21 C.F.R § 314.7(b). Supplemental applications are differentiated based on minor changes to be described in an annual report, moderate changes which require a thirty-day premarket notification to the FDA, and major changes which must be approved prior to distribution of the drug. 21 C.F.R § 314.7(a)–(e).
DNA or RNA pathway. Biologics comprise a large and diverse group of products used in a myriad of diseases and conditions. Traditional drugs are small molecule products produced by chemical synthesis combining chemicals and reagents in inert reaction vessels. These drugs are well-defined and thoroughly characterized; whereby biologics are typically less thoroughly characterized as they are derived from living materials, susceptible to environmental conditions and are of greater complexity. Since biologics are protein based, they are typically administered via injection to bypass enzymatic destruction in the stomach, whereas drugs are typically administered orally. Biologics generally have less stability than traditional drugs and often require refrigeration.

Biologics are biochemically complex, exhibiting a primary structure (amino acid sequence), a secondary structure (disulfide bonding), tertiary structure (elaborate bending), and a quaternary structure (final aggregation of the compound). Additionally, many of these products are glycosolated having multiple shapes called isoforms. Thus, biologics exist in multiple conformations and may readily convert between each. It is possible, in fact, that all possible variants of a biologic are not fully characterized.

Manufacturing biologics is a highly sophisticated process, much different from traditional drugs. Biologics often utilize a specific cell line and require precise and consistent manufacturing involving highly developed

190. See Michael Kleinberg & Kristen Wilkinson Mosdell, Current and Future Considerations for the New Classes of Biologicals, 61 AM. J. HEALTH-SYS. PHARMACY 695, 697 (2004). In very basic terms a certain biologic (protein) is sought. See id. Scientists obtain the gene to code for the protein. See id. at 698. This gene is then inserted into a living system—typically bacteria, yeast or Chinese hamster ovary—which then produces the desired product, which then is highly purified. See id. at 699. Interestingly, the first recorded use of biological therapeutics involves the use of an antibiotic obtained from moldy soy in China, in 500 BCE, to treat boils. Philip E. Johnson, Implications of Biosimilars for the Future, 65 AM. J. HEALTH-SYS. PHARMACY S16, S16 (2008).

191. These drugs refer to typical organic-based drugs such as aspirin, Lipitor and Norvasc. See D.J.A. Crommelin et al., Shifting Paradigms: Biopharmaceuticals Versus Low Molecular Weight Drugs, 266 INTL. J. PHARMACEUTICS 3, 4 (2003).

192. See Kleinberg & Mosdell, supra note 190, at 696.


194. Johnson, supra note 190, at S20.


196. See id. at 6.

197. See Janet Woodcock et al., The FDA’s Assessment of Follow-on Protein Products: A Historical Perspective, 6 NATURE REV. DRUG DISCOV. 437, 438 (2007).

198. See id.

199. Johnson, supra note 190, at S16. Amazingly, bioengineering dates back to 4000 BCE, where yeast fermentation was used to produce alcohol for festivity. Id.
fermentation processes and purification methods. Even very slight deviations in the manufacturing process can result in an altered bioactivity changing the actions of the compound. Impurities and contaminants pose serious threats and some may contain intrinsic infectious agents.

The cloning technology required to manufacture biologics originated in the 1970s and is a highly complex and sequential process. The first biologic approved was recombinant insulin (Humulin, Lilly), in 1982. Since then more than 250 biologics have been approved and marketed in the United States. These products range from botulinum neurotoxin for wrinkles, to monoclonal antibody based therapies for colon cancer, to vaccines for chicken pox, to enzyme replacement therapy for Pompe disease.

As biologics are rather complex molecules, they carry risks not typically associated with traditional drugs. The most important of these risks is immunogenicity. Immunogenicity refers to neutralizing antibody formation against a foreign substance, in this case, a biologic. Biologics are inherently immunogenic because of their biochemical composition.

202. See Woodcock et al., supra note 197, at 438.
205. Id.
209. The Successful Effort to Develop Myozyme for Pompe Disease at Genzyme FAQs, The Successful Effort to Develop Myozyme and Bring New Hope for to Families Affected by Pompe Disease, http://www.genzyme.com/pompemovie/pompe-movie-faq.htm (last visited Apr. 14, 2010). This drug is based on the research of a father with "two children with Pompe disease." Id. The story is depicted in the movie, Extraordinary Measures. Id.
210. Giezen et al., supra note 204, at 1888.
211. Id.
212. Id.
213. Id.
confound the issue, biologics are almost universally injectable and thus pose increased immunogenic potential.\textsuperscript{214} Immunogenicity tends to render a drug ineffective and may cause allergic type reactions that could be fatal.\textsuperscript{215} Biologics may also pose an increased risk of infection and cancer compared to traditional drugs.\textsuperscript{216} Traditional drugs may also be immunogenic, although the concern is that biologics pose a greater risk.\textsuperscript{217}

It is important to differentiate biologics from gene therapy and other fields of biotechnology. Although these areas may ultimately merge, the current state of technology is separate and regulation involving gene therapy is at its infancy and beyond the scope of this paper.\textsuperscript{218}

1. Biologic Regulation under Public Health Service Act

Biologics are a subset of drugs regulated primarily under Section 351 of the Public Health Service Act (PHSA) and part 600 of title 21 of the Code of Federal Regulations.\textsuperscript{219} The PHSA was established in 1944 and served to revise and consolidate the existing public health legislation including the Biologics Control Act of 1902.\textsuperscript{220} Under the PHSA, biologics are defined as “any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.”\textsuperscript{221} Biologics further intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are regulated as drugs and therefore subject to the requirements of the FDCA and the PHSA.\textsuperscript{222}

\textsuperscript{215} Giezen et al., \textit{supra} note 204, at 1888.
\textsuperscript{216} \textit{Id.}
\textsuperscript{217} See \textit{id.}
\textsuperscript{218} See Johnson, \textit{supra} note 190, at S19–20.
\textsuperscript{219} Public Health Service Act § 351, 42 USC § 262 (2006); 21 C.F.R pt. 600 (2009).
\textsuperscript{220} David M. Dudzinski & Aaron S. Kesselheim, \textit{Scientific and Legal Viability of Follow-on Protein Drugs}, 358 NEW ENG. J. MED., 843, 844 (2008). In 1901, thirteen deaths of children by tetanus were traced back to a diphtheria antitoxin obtained from the blood of local horse named Jim. Linda Bren, \textit{The Road to the Biotech Revolution: Highlights of 100 Years of Biologics Regulation}, FDA CONSUMER, Jan.–Feb. 2006, at 50, 51. At the same time, a similar tragedy occurred in New Jersey. \textit{Id.} These events prompted Congress to regulate biologics with the passage of the 1902 Biologics Control Act, also known as the Virus-Toxin Law. \textit{Id.}
\textsuperscript{221} 21 CFR § 600.3(h) (2009).
\textsuperscript{222} Gottlieb, \textit{supra} note 214, at S3–S4.
Interestingly, biologics are regulated within both CBER and CDER.\textsuperscript{223} Under the current regulatory framework, some "therapeutic biologic products" are reviewed and regulated by CBER, while others are reviewed by CDER.\textsuperscript{224} Effective June 30, 2003, CDER regulates monoclonal antibodies and proteins for therapeutic use, which comprise a rather significant proportion of biologics.\textsuperscript{225} CBER regulates cellular products, gene therapy, vaccines, allergenic extracts, blood and blood products, and certain fibrinolytics.\textsuperscript{226} Drugs licensed under the PHSA are exempt from the licensing requirements of the FDCA.\textsuperscript{227}

a. \textit{Biologic Licensing Application}

Biologics are developed similarly to traditional drugs and are subject to the same rigors of pre-market clearance.\textsuperscript{228} Their research and development follows a very similar pathway including preclinical evaluation and clinical testing involving Phase I, Phase II, and Phase III studies.\textsuperscript{229} Biologics almost universally have some Phase IV requirements based on the anticipated risks in large-scale populations.\textsuperscript{230}

Unlike traditional drugs, biologics are reviewed and approved under a Biologic License Application (BLA).\textsuperscript{231} An approved BLA is analogous to an NDA and provides the legal authority to move a biologic in interstate commerce.\textsuperscript{232} Generally speaking, a BLA is approved on the basis of safety, purity, and potency of a biologic.\textsuperscript{233} Additionally, the application must con-

---

\textsuperscript{223} Due to "historical vagaries," a number of recombinant biologics were approved under an NDA and regulated by CDER. See Dudzinski & Kesselheim, supra note 220, at 844.


\textsuperscript{225} See FDA, Transfer of Therapeutic Products to the Center for Drug Evaluation and Research, supra note 224. These include such drugs as cytokines—e.g. interferons—and enzymes—e.g. thrombolytics. See id.

\textsuperscript{226} Id. These include such drugs as immunoglobulins and antivenins. Id.


\textsuperscript{229} See id. at 435–36.

\textsuperscript{230} See id. at 436.

\textsuperscript{231} 21 C.F.R. § 601.20 (2009).

\textsuperscript{232} See 21 C.F.R. § 601.20(b)(1), (d).

taint data on chemistry, manufacturing, and controls; non-clinical pharmacology and toxicology; patent information; and labeling. The requirements for approval of a biologic are often more challenging than traditional drugs since any small deviation in manufacturing can result in a significant impact on the bioeffectiveness, and the risk of unanticipated problems is a greater threat.

V. GENERIC DRUG REGULATION / DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

During the 1970s and 1980s, drug prices began to increase rather dramatically. To complicate the issue, the wide availability and acceptance of generic drugs was not to be found. Most states do not substitute laws for the pharmacist, and generic manufacturers had to undergo costly and time-consuming full-scale studies to gain approval. Moreover, generic companies had to wait for a patent to expire before ever commencing research and production, thus effectively extending the innovator's patent. Suffice it to say, the generic drug industry was not bountiful and brand companies enjoyed lengthy patent protections.

Seeking to streamline this concern, increase the availability and use of generic drugs, all while protecting innovation and patents, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984. This landmark legislation, commonly referred to as the Hatch-Waxman Amendments to the FDCA, sought to strike a balance between two important competing interests: increased availability of generic drugs and en-

HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited Apr. 17, 2010). Potency of biologics is essentially synonymous with the term efficacy as it relates to drugs. See 21 C.F.R. § 601.20(c).

234. See 21 C.F.R. § 601.20.

235. See Underwood, supra note 228, at 436.


237. See id. at 102–03.


enhanced patent protection for branded products. The Act consists of two titles. Title I amended the FDCA and established an abbreviated approval pathway for generic drugs under an Abbreviated New Drug Application (ANDA). It also provides exclusivity for brand drug approvals. Title II authorizes the extension of patent terms for approved new drug products. Brand drugs receive "an extension term equal to one-half of the time of the investigational new drug (IND) period . . . plus the NDA period . . . [with a] maximum extension [of] five years and the total market exclusivity time cannot exceed fourteen years." Hatch-Waxman requires all drug applications under the FDCA to file patent information with the FDA. This way, the agency has clear direction in granting exclusivity for brand drugs and approving generic drugs. Hatch-Waxman only applies to drugs and the FDCA, and did not include provisions to allow for an abbreviated approval pathway under section 351 of the PHSA.

In order to fully appreciate Hatch-Waxman, one must grasp the drug approval process for generics. There are currently three mechanisms by which a generic drug can enter the prescription market when a patent expires on a brand product—NDA, ANDA, and Paper NDA. All three are available under the FDCA. The use of an NDA for a generic drug is not commonly used, based on the cost and complexity of the information included. The ANDA is a much more efficient and cost effective route and is the most commonly employed pathway. Another abbreviated approval mechanism is the Paper NDA, more technically referred to as 505(b)(2) approval. The Paper NDA is similar to an NDA but allows the FDA to rely on published data and previously determined assessments of safety and efficacy in its approval. Although a paper NDA can apply to a generic drug, it is typically reserved for minor changes of an existing drug, such as formulation or dosing.

243. Id. Before the approval of this act, generic drugs were required to undergo the same rigorous clinical trials as branded drugs. FTC 2002 STUDY, supra note 238, at 3. These were typically large scale randomized controlled efficacy and safety trials. Id. Needless to say, this research was cumbersome, costly, and complex. It was also unnecessary.
245. Id. § 201.
247. See id. at 189.
A. Generic Drugs

The generic drug industry is a true boon by all social accounts.251 Generic drugs represent almost seventy percent252 of all prescriptions filled, yet account for only sixteen percent of the expenditure.253 The average brand drug costs $120 per month and the average generic drug costs less than $35.254 Over the past ten years, the United States healthcare has saved approximately $700 billion dollars through the use of generic drugs.255 Generic utilization occurs as follows. Physicians can prescribe a brand drug or a generic.256 If the prescriber writes out a prescription for a brand drug, the pharmacist typically substitutes a generic, if available.257 In fact, under Medicare law, pharmacists are typically required to substitute.258 Alternatively, many insurance companies may only pay for a generic if available.259 If a patient insists on a brand product or there is no generic available, the patient receives and pays for the brand drug.260

Despite the considerable impact associated with generic drugs, the economic framework remains somewhat musing and the full cost savings is often delayed and slow to materialize.261 The first generic to market is typically priced at about ninety-four percent of the brand drug’s price, thus offering a very nominal cost-savings.262 It is not until a second generic comes to mar-

251. See FTC 2002 STUDY, supra note 238, at 9.
252. This is “up from 19 percent in 1984 when Hatch-Waxman was” approved. Id. at i.
254. Id.
257. See id. “Generic drug substitution is only possible when a health care provider pre-
scribes a multisource drug (i.e., a brand name multisource drug or its associated equivalent),” Id.
258. See id. at 4.
259. See id. at 3.
260. See DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECT. GEN., supra note 256, at 3.
262. Id. Although this seems outrageous, it is actually quite logical. When a first generic comes to market, insurers almost always require the generic drug over the brand drug, thus significant market share is almost guaranteed. Nevertheless, once a second generic comes to market, the less expensive product receives the great lion’s share of market push, thus poten-
ket that a substantial, fifty percent cost savings is seen, and it takes approximately seventeen generics competing until a ninety percent cost-savings is realized.\footnote{Id.}

B. **Abbreviated New Drug Application (ANDA)**

Hatch-Waxman codified an abbreviated approval pathway for generic drugs via 505(j) of the FDCA.\footnote{See Federal Food, Drug, and Cosmetic Act § 505(j), 21 U.S.C § 355(j) (2006).} The general requirements of an ANDA are chemistry, manufacturing, labeling, and proof of bioequivalence.\footnote{Id.} Collectively this is termed Therapeutic Equivalence.\footnote{Id.} The ANDA is considered abbreviated because it does not require proof of preclinical or clinical data, both of which are required in an NDA.\footnote{Id.} Since generic drugs do not require this information, the cost to bring a generic to market is greatly reduced. Instead of relying on clinical data, the sponsor for a generic drug has to prove bioequivalence to the brand drug.\footnote{Id.} Bioequivalence is established when “the rate and extent of absorption of the test drug do not show a significant difference from the rate and extent of absorption of the reference drug.”\footnote{DEP’T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS, supra note 14, at v.} This is essentially a surrogate marker used to demonstrate safety and efficacy of the drug. In place of preclinical data, the sponsor submits only a section on chemistry allowing the FDA to rely on the reference listed drug approval as underpinning.\footnote{21 U.S.C. § 355(j)(9).}

An ANDA also has to include information on patents. The generic sponsor must “certify” the status of the patent they are copying.\footnote{21 U.S.C. § 355(j)(2)(A)(vii).} There are four types of certification available.\footnote{Id.} Paragraph I certifies the challenged drug has not been patented.\footnote{21 U.S.C. § 355(j)(2)(A)(vii)(I).} Paragraph II certifies the patent has already expired on said drug.\footnote{21 U.S.C. § 355(j)(2)(A)(vii)(II).} Paragraph III certifies the date the patent will expire.
Paragraph IV certifications are the most controversial and contentious. The first generic to successfully file Paragraph I certification receives a 180-day marketing exclusivity.\textsuperscript{277} This very clever provision is intended to promote immediate filing of an ANDA by creating a monopoly within a monopoly for the first generic approved. This incentive appears to be very intelligently calculated and provides sufficient reward to increase generics without too much hindrance on the overall market. Paragraph IV certifications receive a lot of press and have spawned a number of tactical business practices and legal maneuverings.\textsuperscript{278}

The filing of a Paragraph IV certification also triggers a peculiar thirty-month stay provision preventing the generic drug to market.\textsuperscript{279} A generic company that files an ANDA must notify the FDA and the brand company who then has forty-five days to file an infringement action, if so desired.\textsuperscript{280} If no suit is filed and the application is complete and approvable, the FDA can license the drug for immediate market.\textsuperscript{281} If the brand company does file an infringement action, the FDA stays “approval of the ANDA until the earliest of: 1) the date the patent[s] expire[s]; 2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or 3) the expiration of 30 months from the receipt of notice of the Paragraph IV certification.”\textsuperscript{282} Practically speaking, by simply filing an infringement action, the brand company receives a thirty-month stay of approval of the generic; the theoretical approximate of the time to litigate the matter. Amazingly, two and a half years of additional exclusivity comes with low risk and nominal costs—a noticeable incentive. This automatic stay frustrates the system and further increases the gaming strategy employed in drug development.

\textsuperscript{279} Id.
\textsuperscript{280} Id.
\textsuperscript{281} See id.
\textsuperscript{282} FTC 2002 STUDY, supra note 238, at 39.
C. Paper NDA and the Case of Omnitrope®

In addition to 505(j) approval with an ANDA, Hatch-Waxman also authorizes 505(b)(2) pathway for abbreviated approval, the so-called paper NDA. This application allows for a sponsor to rely upon previously published literature for certain aspects of the application, including the FDA’s determination of safety and efficacy. Data on the reference listed drug is then used for the remaining requirements such as pharmacology and toxicology. Drugs approved under a paper NDA are not necessarily substitutable for the comparator product and not AB listed in the Orange Book. The paper NDA is considered a potential source of approval for a generic biologic, although the impediments seem overwhelming and the framework is not intended to regulate such actions and has never been used. Technically speaking, there is no paper BLA and the authority for approval of a generic biologic under the current regulatory system is uncertain.

Interestingly, the paper NDA has been used to approve one biologic, despite vigorous opposition and extensive legal wrangling. On May 30, 2006, the FDA approved Omnitrope® for marketing, despite a citizen’s petition from Pfizer, Biotechnology Industry Organization, and Genentech urging otherwise. Omnitrope® was approved, in part, through reliance of the FDA’s determination of safety and efficacy of the reference listed drug,
Genotropin manufactured by Genetech, approved under an NDA.\textsuperscript{292} FDA review found the drug was “sufficiently similar . . . to warrant [such] reliance” despite strong protest.\textsuperscript{293} The application also included clinical data obtained by Genentech.\textsuperscript{294} The FDA found a relative lack of complexity of the hormone and the availability of sufficient analytical techniques to approve the drug.\textsuperscript{295} The FDA was clear this route of approval would not apply to biologics licensed under the PHSA or to products lacking a well-documented history of use.\textsuperscript{296}

D. Exploitation of Hatch-Waxman

Practically speaking, Hatch-Waxman accomplished its aim. By most, if not all accounts, Hatch-Waxman increased access to generic drugs while providing sufficient protection and incentives for brand companies to continue to be innovative. However, like most if not all legislation, Hatch-Waxman is riddled with loopholes that have undermined some of its intent and has been subject to exploitation and abuse by brand companies seeking to maintain patent protection and prevent competition.\textsuperscript{297} The legality of many of these strategies is made on a case-by-case basis and a number of settlements and decrees have occurred.\textsuperscript{298}

The loopholes center around two provisions of the Paragraph IV certification: 180-day exclusivity and thirty-month stay.\textsuperscript{299} Brand company manipulation of the 180-day exclusivity center around payments to generic companies not to market and the manufacturer of so called, “authorized generics.”\textsuperscript{300} Brand companies have been accused of filing baseless infringement actions to trigger the thirty-month stay provision and even file inequitable patent applications to delay market entry.\textsuperscript{301} Lastly, brand companies can delist a patent after successful Paragraph IV certification to cause recertifica-

\textsuperscript{292} See Segal et al., supra note 288, at 2. Genotropin was approved under a NDA and not a BLA although biochemically it is a biologic drug. FDA, Drug Details, Genotropin, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (last visited April 17, 2010).

\textsuperscript{293} Letter from Steven K. Galson, supra note 284, at 8.

\textsuperscript{294} See Gottlieb, supra note 214, at S4.

\textsuperscript{295} See Dudzinski & Kesselheim, supra note 220, at 845.

\textsuperscript{296} Id.

\textsuperscript{297} FTC 2002 STUDY, supra note 238, at 39–40.

\textsuperscript{298} See id. at 16–17.

\textsuperscript{299} Avery, supra note 16, at 179.

\textsuperscript{300} Id. at 181.

\textsuperscript{301} Id. at 179–80.
tion under Paragraph I and the subsequent loss of exclusivity by the generic.\textsuperscript{302}

The FTC has investigated a number of agreements not to compete between a brand company about to lose patent protection and the generic company awarded 180-day exclusivity.\textsuperscript{303} These "pay for delay" agreements often involve a "reverse payment," whereas the brand company simply pays the generic company to not compete during the exclusivity period.\textsuperscript{304} Interestingly, courts have been inconsistent as to the legality of this practice and some "pay for delay settlements" have been deemed legal.\textsuperscript{305} The Sixth Circuit has ruled that reverse payments are a per se violation.\textsuperscript{306} Meanwhile, the Eleventh Circuit approaches the issue using an analysis somewhere between per se and rule of reason.\textsuperscript{307} Using a three part analysis the court looks to "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."\textsuperscript{308}

Authorized generics refer to drug products manufactured by a brand company, identical to the brand product, but sold—i.e. authorized—as a generic.\textsuperscript{309} The brand company can either sell the drug directly or license it to another company to label and sell.\textsuperscript{310} Brand companies often introduce authorized generics during the 180-day exclusivity period as a first generic.\textsuperscript{311} Although this clearly undermines the intent of Hatch-Waxman, is anticompetitive, and diminishes the incentive for generic companies to compete, it appears fully legal.\textsuperscript{312} To date, the courts have upheld the legality of authorized generics through two appellate cases.\textsuperscript{313} In fact, the United States Court of Appeals, District of Columbia Circuit, affirmed the decision to not even hear a citizen's petition made by a generic company, Teva.\textsuperscript{314} Additionally, the United States Court of Appeals, Fourth Circuit, found no legal sufficiency to

\textsuperscript{302} Id. at 198.
\textsuperscript{303} See FTC 2008 REPORT, supra note 25.
\textsuperscript{304} Avery, supra note 16, at 181.
\textsuperscript{305} FTC 2009 REPORT, supra note 184, at i.
\textsuperscript{306} In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).
\textsuperscript{307} See Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1311 & n.27 (11th Cir. 2003).
\textsuperscript{308} Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).
\textsuperscript{309} John M. Rebman, Dr. Strange Drug, or: How I Learned to Stop Worrying and Love Authorized Generics, 12 DePaul J. Health Care L. 159, 159 (2009).
\textsuperscript{310} Id.
\textsuperscript{311} Id. at 160.
\textsuperscript{312} See id. at 160, 181.
\textsuperscript{314} Teva Pharm. Indus. Ltd., 410 F.3d at 51, 55.
disallow the entry of an authorized generic by the NDA holder as they were within their statutory right.\footnote{315.}{Mylan Pharms., 454 F.3d at 276–77.}

The thirty-month stay provision of Hatch-Waxman has been a real lure for brand companies, who have in turn sought inventive ways to trigger the stay.\footnote{316.}{See, e.g., FTC 2009 REPORT, supra note 184, at 57, 71.} A number of these techniques have been tried in court. For example, in the case of \textit{In re Neurontin Antitrust Litigation},\footnote{317.}{No. 02-1390, 2009 WL 2751029 (D.N.J. Aug. 28, 2009).} Pfizer, the brand manufacturer of Neurontin, was accused of filing sham litigation against the generic company, submitting false and fraudulent patents for inclusion in the Orange Book, and misconduct of patent prosecutions to impair competition.\footnote{318.}{Id. at *1, *4; see FTC 2002 STUDY, supra note 238, at 40.} In \textit{Aventis Pharmaceuticals v. Amphastar Pharmaceuticals, Inc.},\footnote{319.}{525 F.3d 1334 (Fed. Cir. 2008).} the court found incontrovertible evidence of inequitable conduct by the brand company with intent to deceive the U.S. Patent and Trademark Office in failing to disclose information in a patent application.\footnote{320.}{Id. at 1349.}

The FTC stands in strong opposition to tactics aimed at undermining the integrity of Hatch-Waxman.\footnote{321.}{See FTC 2008 REPORT, supra note 25; see also John R. McNair, Note, \textit{If Hatch Wins, Make Waxman Pay: One-Way Fee Shifting as a Substitute Incentive to Resolve Abuse of the Hatch-Waxman Act}, 2007 U. ILL. J.L. TECH. & POL’Y 119, 126.} In fact, in 2008 the Commission issued a report detailing these practices, describing their anti-competitive effects.\footnote{322.}{Id. at 1349.} The report was instrumental to changes in the original act that helped close some of the loopholes at the time. Additional legislation has been proposed to further close loopholes, but the system still remains open to manipulation and exploitation.\footnote{323.}{For example, the Preserve Access to Affordable Generics Act (S. 369) prohibits generic companies from entering into agreements with brand companies to delay or cease from offering a generic option to the market. \textit{See PRESCRIPTION ACCESS LITIGATION FACT SHEET: THE PRESERVE ACCESS TO AFFORDABLE GENERICS ACT (S. 369)/ THE PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2009 (H.R. 1706)}, July 22, 2009, http://www.prescriptionaccess.org/docs/Fact Sheet HR 1706 S369.pdf [hereinafter FACT SHEET: H.R. 1706/S. 369].}

The transcendent value of Hatch-Waxman is grounded on its impact on competition and, ultimately, drug prices. Although not perfect, the Act spawned an entire generic drug industry, while maintaining and rewarding innovation, which is no easy task.
VI. CURRENT STATE OF GENERIC BIOLOGICS

Hatch-Waxman established a mechanism for generic drugs in the United States. However, this act did not predict the role of biologics and a void was created. Meanwhile biologics, constitute a rising market share, and as patents continue to issue and expire, the need to substitute products in attempted cost-savings is a major policy concern. In the aughts, there were a number of failed attempts to regulate generic biologics; however, each measure was systematically defeated in Congress.

In June 2009, the Federal Trade Commission released a comprehensive analysis on generic biologics. The report found that competition between a biologic and its generic counterpart is more likely going “to resemble brand-to-brand competition, rather than [the traditional] brand-to-generic competition,” because of the cost and complexity of bringing a generic biologic to market. The report claimed that even in the presence of a generic biologic, the brand product would retain seventy to ninety percent of its market share, which is quite different than the current system, where erosion is immediate and glaring. The report further asserted generic biologics would provide a cost-savings of approximately ten to thirty percent. Overall, the report is clear that existing incentives provided for in Hatch-Waxman are sufficient for biologics, signifying that anything longer than five years of exclusivity will be anticompetitive.

A. Generic Biologics Defined

The BPCIA defines a generic biologic as “a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biolog-

326. See FTC 2009 REPORT, supra note 184.
327. Id. at iii.
328. Id. at v.
329. Id. at v. The Congressional Budget Office estimates that generic biologics will be priced at a twenty to twenty-five percent reduction initially and increase to forty percent by the fourth year. CONG. BUDGET OFFICE, COST ESTIMATE: S. 1695, BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2007 7 (June 25, 2008), available at http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf [hereinafter CONG. BUDGET OFFICE, COST ESTIMATE].
330. FTC 2009 REPORT, supra note 184, at 57.
N ical product licensed under section 351 of the Public Health Service Act. \textsuperscript{331} Biosimilarity is defined as a product “highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency.\textsuperscript{332}

Technically speaking, generic drugs refer to products manufactured without trademark protection.\textsuperscript{333} Scientifically speaking, the term has come to mean a drug that has the same dosage, safety, strength, route of administration, quality, performance, and intended use as a brand drug—essentially an exact copy.\textsuperscript{334} A generic drug is considered an identical copy to a brand drug with an associated cost-savings.\textsuperscript{335}

Many claim the term “generic biologic” is a fallacy and inappropriate to use.\textsuperscript{336} It is claimed that independently manufactured biologics should not be considered identical to each other based on a number of manufacturing variances and resulting subtleties.\textsuperscript{337} Biologics are manufactured in living systems and fluctuations inevitably occur.\textsuperscript{338} Instead, these copies are only considered similar and follow-on to a brand drug.\textsuperscript{339} Accordingly, the choice term represents a meaningful characterization of the issue and driver of some of the legal, social, and scientific discussions.

Developing a generic biologic involves identifying the target drug, establishing duplicative or similar methods of production and product characterization to validate similarity. Generic biologics are referred to by a myriad of terms including: biosimilars, biogenerics, follow-on biologics, follow-on proteins, and subsequent entry biologics (SUB). There is no officially accepted scientific nomenclature, although the term biosimilars appears to have become vernacular in the United States with the passage of the BPCIA. Biosimilar is the preferred term in Europe, whereas Canada utilizes SUB to refer to these products. An all encompassing and adequate term may not exist.

\textsuperscript{332} Id. § 7002(b).
\textsuperscript{334} Id.
\textsuperscript{335} Id.
\textsuperscript{338} Gottlieb, supra note 214, at S4.
\textsuperscript{339} See id. at S2.
Nevertheless, for the sake of discussion, generic biologic may be appropriately defined as a biological drug product with the same biochemical structure and function as a trademarked product with equivalent purity, potency, and safety.

1. Challenges with Generic Biologics

The primary goal of generic biologics involves product safety. As with all drugs, safety is paramount and the production of an equivalent product with an equivalent safety profile is essential. The practical goal, meanwhile, is to establish a system that supports substitution of the generic biologic at the pharmacy level with an associated cost-savings to the payor.

Based on the complex biochemical nature of biologics, the creation of an equivalent generic poses a myriad of challenges before it can be widely produced and accepted. First, there must be a system to define and establish structural equivalency. Replication must be feasible based on the patent and there must be a method to characterize the product as equivalent. Next, there must be a method to assure functional equivalency of products, namely safety, purity, and potency. Practitioners and patients must then have confidence in the substitution of these products and payors must realize an actual cost-savings.

The requirements for establishing equivalency are going to vary by the drug involved. While certain classes of biologics may only require general guidelines to establish equivalency, other, more complex agents may require very specialized and particular approaches to demonstrate both structural and functional equivalency. The establishment and inclusion of Compendium standards should be sought. Any variances determined will then have to be supported by evidence of no effectual difference for equivalency to be established.

Structurally, generic biologics are thought to be extremely difficult to produce an exact replica, unlike small molecule generics which are rather easy to replicate and produce. Differences in cell lines, manufacturing practices, temperature, pH, finishing and storage conditions, and protein ag-

340. Gottlieb, supra note 214, at S3.
341. See id.
342. See Crommelin et al., supra note 191, at 14.
343. See id.
345. See Crommelin et al., supra note 191, at 14.
346. See Woodcock et al., supra note 197, at 438.
aggregation, can all affect product structure. Another challenge involves analyzing these products for structural equivalency. Traditional drugs are considered easy to characterize, whereas characterization of biologics is extremely difficult. Crystal studies only capture the current confirmation of a biologic, which can exist in multiple states. Highly advanced analytical techniques such as X-ray crystallographic diffraction, MRI, and reversed-phase high-performance liquid chromatography are going to be required to establish structural equivalence, if at all possible under the current state of technology. Orthogonal methods will be needed and multiple techniques may be required.

Batch to batch variability inevitably occurs with biologics and impurities may be present. Brand companies have argued information on variability is a trade secret and confidential commercial information is available only to the FDA. They argue that any use of protected information would require the FDA to pay just compensation under the Fifth Amendment’s Takings Clause.

Establishing functional equivalency will also pose some challenges. Even though we have reliable biomarkers to assess equivalence with most drugs, the physical complexity of biologics and the various confirmations of isoforms are problematic. For instance, a biologic could have the same response in a pharmacodynamic measure such as blood pressure with its comparator, but have other, unanticipated responses, i.e. side effects, based on its folding characteristics and the way it binds to a certain receptor.

As immunogenicity is a concern with all drugs, it becomes a greater concern with generic biologics, especially when interchangeability is consi-

347. See Crommelin et al., supra note 191, at 14.
348. See id.
349. Gottlieb, supra note 214, at S4.
350. See Crommelin et al., supra note 191, at 6.
352. See Shacter, supra note 344.
353. See Crommelin et al., supra note 191, at 14.
355. See U.S. CONST. amend. V, XIV. Specifically, information on chemistry, manufacturing, and controls are believed to be widely protected. See Letter from Kathy J. Schroher, supra note 354, at 6 & n.9.
356. See Crommelin et al., supra note 191, at 14.
357. Gottlieb, supra note 214, at S4.
dered. Since biologics are complex proteins, they can elicit a number of immune responses, depending on a number of factors. Although very similar, two inexact biologics can elicit very different immune responses.

Overall, biologics represent a very diverse complexity of products, and thus many of these considerations do not apply equally and the FDA will have to deal with many of these issues on a case-by-case basis, at least initially. The FDA has not yet developed a formal system to evaluate equivalence and is going to have to have an open approach, likely involving a consensus of the professional and scientific communities. Only when structural and functional equivalencies are truly established with confidence, can we begin talking about product substitution and cost-savings.

The FDA will have to compile some system that supports substitution for biologics, like the Orange Book’s AB rating system for conventional drugs. Once equivalency is established, it is likely that physicians and pharmacists will be amenable to product substitution as the current system of generics has demonstrated. Legislators can then move to require substitution. Opposition is expected with lobbying efforts by the Biotechnology Industry Organization (BIO), and PhRMA, the biologic and drug trade associations respectively, leading the way. Payors, concerned with the bottom line, will likely push for substitution, helping advance the system and promote acceptance.

The cost of developing a generic biologic is large, estimated at $100-$200 million; much greater than a traditional generic drug. There will be a need for particular cell lines and highly specialized manufacturing processes, the availability of which may prove a tough find. A full biogeneric industry does not currently exist as the need has not arisen. The review process is going to be extremely challenging and may ultimately require a significant amount of data, and may thus be costly to the generic company. Nevertheless, once the regulatory framework is established, companies will step forward as it remains a highly lucrative industry and drug prices should be expected to fall over time.

359. See Crommelin et al., supra note 191, at 11.
360. See id.
361. See id. at S4, S7.
363. See id.
365. See Engelberg et al., supra note 5, at 1917–18.
366. Id. at 1918.
B. **International Regulatory Approach**

Australia does not categorize biologics separate from drugs, so their position is less problematic. Canada issued a Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) and Related Documents on January 30, 2008. The draft document was revised and republished on March 27, 2009, and is amidst review and further development.

Canada does not plan on establishing a new regulatory framework, but will instead rely upon its existing statutory authority for Health Canada to review and approve these products. SEBs will be analyzed on a case-by-case basis and reviewed as new drugs. They will not follow the abbreviated approval pathway available for generic drugs nor be substitutable. They will have no exclusivity, per se. Nevertheless, the appeal is that the submission can rely, “in part, on prior information regarding the authorized innovative biologic drug in order to present a reduced clinical and non-clinical package.” Additionally SEBs can be submitted for innovator biologics not approved in Canada.

Overall, the Canadian approach appears to be a reasonable approach to the issue. As technology further advances, costs continue to rise and patents fall, Health Canada may need to reassess the issue and consider substitutability.

---


369. See id. at a–b.

370. See id. at 2.

371. Id. at 4–6.

372. Id. at 4.


374. Id. at 1.

[A] suitable reference biologic drug exists that: a) was originally authorized for sale based on a complete data package; and b) has significant safety and efficacy data accumulated such that the demonstration of similarity will bring into relevance a substantial body of reliable data; the product can be well characterized by a set of modern analytical methods; and the biologic drug, through extensive characterization and analysis, can be judged similar to the reference biologic drug by meeting an appropriate set of pre-determined criteria. Products employing clearly different approaches to manufacture than the reference biologic drug (for example, use of transgenic organisms versus cell culture) will not be eligible for authorization as SEBs.

Id.

375. Id. at 3, 6. This is made upon request of the Minister and “must include sufficient information to explicitly explain the link.” Id. at 6.
ity at the pharmacy level, the possibility of a reduced review time for the agency and incentives for manufacturers to produce and market these products. The first drug approved under the subsequent entry biologic review system was Omnitrope® on April 20, 2009.376

The European Regulatory Union maintains the benchmark regulation for biosimilar review and approval in the world.377 This pathway was established in June 2003 through modification of the EU’s medical products statutes.378 The European Agency for the Evaluation of Medicinal Products (EMEA), the European equivalent to the FDA, oversees the implementation of the review process. The regulations approach generic biologics as distinct from traditional generic drugs based on complexity, thus requiring a different approach to an abbreviated approval.379 Review and approval occurs on a case-by-case basis using product specific guidance documents issued through an open and public process.380 The system calls for “[a]n appropriate comparability exercise . . . to demonstrate . . . similar profiles in terms of quality, safety, and efficacy.”381 Although the system can approve a biosimilar drug, it leaves the determination of substitution to national authorities.382 France and Spain recently enacted legislation that prohibits automatic substitution of a generic biologic, and the system as a whole is still in its infancy.383

Under EMEA review, a biosimilar application contains non-clinical data, as well as clinical data.384 The section on non-clinical data is meant to identify changes in response between the two products and is based on in vitro studies, toxicokinetic measurements, etc.385 The clinical section is in-

379. See Gottlieb, supra note 214, at S3, S7.
380. Id. at S7.
381. EMEA 2006, supra note 378, at 3.
383. Id.
385. Id. at 4.
tended to demonstrate clinical comparability, including efficacy and safety.\textsuperscript{386} The EMEA guidelines also require a full chemistry evaluation.\textsuperscript{387} Guidance documents suggest that comparability efficacy studies may be needed, although they are not required.\textsuperscript{388} The extent of abbreviation varies and some approvals will be akin to the brand drug’s approval with rigorous data requirements.\textsuperscript{389} Additionally, class-specific guidelines can be established for product reviews.\textsuperscript{390} The EMEA system provides for an exclusivity period of ten years for an innovator reference product.\textsuperscript{391} Moreover, the applicant can obtain another year of exclusivity, for a total period of eleven years, if the biologic gains a new indication in the first eight years of its exclusivity which provides a “significant clinical benefit in comparison [to] existing therapies.”\textsuperscript{392} The regulations also require post-approval surveillance to monitor such things such as immunogenicity.\textsuperscript{393}

The first drug approved under the biosimilar review process in Europe was Omnitrope\textsuperscript{®} in January 2006.\textsuperscript{394} In 2007, the world’s bestselling biologic, erythropoietin, saw the approval of two biosimilar drugs in Europe, although market penetration has been slow to transpire.\textsuperscript{395} The true impact of biosimilars in practice has not yet come to fruition and in many ways the system is still in its early infancy. Advances in technology, experience, and legislation will refine the system over time.

C. Proposed U.S. Legislation

In the United States, the FDA approves drug products for marketing under authority of the FDCA and the Public Health Services Act.\textsuperscript{396} It has been “argued that the FDA has the authority to approve generic” biologics under...
an abbreviated follow-on pathway using the current regulatory framework. Nevertheless, the FDA has taken no action on the issue and has left the issue to Congress to legislate.

Over the last few years, there have been a number of proposed, and defeated, bills dealing specifically with generic biologics in the United States. It was not until the push for a national healthcare reform bill gained momentum did the prospect of legislation authorizing generic biologics become increasingly apparent and the chance of success elucidate. Despite strong opposition and quarrel, Congress maintained a steadfast move toward approval of a healthcare bill under the unwavering persistence of President Obama. One measure passed in the Senate and one in the House, thus setting the stage for bicameral national health reform. These two bills each included a provision authorizing generic biologics.

On November 7, 2009, H.R. 3962, the Affordable Health Care for America Act, passed in the House of Representatives by a 220 to 215 vote. Division C, Title V, Subtitle C, Part 2 dealt exclusively with Biosimilars. The bill amended the PHSA and established a framework to approve a generic biologic. A drug was considered “biosimilar” by evidence of analytical studies, animal studies, and clinical data that show no clinically meaningful differences in safety, purity, or potency from the reference (brand) product. It also included a provision, whereby the HHS Secretary can waive the requirement for clinical data; although this matter will need to be further considered either by legislation or regulation. It includes a section

397. Id. at 442.
400. Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009) (enacted). This was originally a House bill, but was co-opted by the Senate, as all revenue bills have to start in the House. Id.
404. H.R. 3962 § 2575.
405. H.R. 3962 §§ 2575(a)(2), (b)(3).
406. H.R. 3962 § 2575(a)(2).
on guidance documents, and empowers the FDA (HHS Secretary) to issue product class-specific guidance in approving biosimilar drugs.407

The bill provided for an exclusivity period of twelve years for innovator products.408 There are no further exclusivity provisions for changes in indications, dosage form, or route of administration, unlike Hatch-Waxman.409 The bill includes a rather complex process for patent disputes and includes a provision whereby agreements between the brand and generic company relating to manufacture, marketing, or sale of biosimilar products must be reviewed by the Assistant Attorney General and Federal Trade Commission.410 It provides a mechanism, whereby a generic biologic can be established as substitutable.411 The first biologic considered “interchangeable” receives a one year exclusivity to incentive filing, like Hatch-Waxman, authorized for traditional drugs.412 Additionally, the bill provides for an additional six-month exclusivity period for testing in a pediatric population and charges user fees to the manufacturer, like those authorized under PDUFA.413

The Senate bill dealing with generic biologics was H.R. 3590, the Patient Protection and Affordable Care Act.414 On December 24, 2009 this bill passed in the Senate by a vote of sixty in favor, thirty-nine opposed, and one present/not voting.415 Title VII, Subtitle A was entitled “Biologics Price Competition and Innovation Act of 2009” and was a close reflection of the House bill.416 It provided a similar framework to approve a generic biologic drug product through the PHSA.417 Under this act, a biologic is deemed biosimilar to a reference biologic if analytical studies, animal studies, and clini-

---

407. Id.
408. Id.
409. See Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2575 (2009).
410. See Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2575(a)(2).
411. Id. (for biologics that are administered more than once the application must demonstrate safety of switching back and forth).
412. Id. (interchangeability is established if the two products are biosimilar, expected to provide the same clinical results, and there is no increased risk by alternating between the two products).
413. Id.
415. Pear, supra note 403 (Not a single Republican voted in favor of this bill.). “Senator Jim Bunning, Republican of Kentucky, did not vote.” Id.
cal data show no clinically meaningful differences in safety, purity, or potency from the reference (brand) product. Also like the House bill, it provided for an exclusivity period of twelve years for the innovator product, granted a one-year marketing exclusivity for the first product deemed interchangeable, and included a six month pediatric exclusivity provision. Importantly, the bill did not consider pay-to-delay agreements like the House bill. Lastly, the bill required a determination on the savings to the federal government be calculated.

D. Patient Protection and Affordable Care Act and Biologics Price Competition and Innovation Act

On March 21, 2010, the House of Representatives voted in support of the Senate-approved H.R. 3590 by a vote of 219-212, setting the state for President Obama to sign into law landmark legislation involving healthcare and for the first time authorizing generic biologics in the United States. On March 23, 2010, the Patient Protection and Affordable Care Act became Public Law 111-148.

The Act establishes a user-fee supported pathway for approving generic biologics through the PHSA. The Act includes a section providing for product class-specific guidance documents to facilitate approval, as are utilized in Europe. It also provides a six month pediatric exclusivity provision which is a valuable social incentive. There is no Orange Book reliance for sharing of patent information, and instead the law details an information sharing process between the brand and the generic company on intellectual property.

The generic company does not have to certify any of the brand holder patents and there is no automatic thirty-month-stay provision, under the law which effectively closes the problematic loophole of Hatch Waxman. Instead, the law delineates a multi-step process for patent infringement con-

418. H.R. 3590, § 7002(a)(2).
421. H.R. 3590 § 7003(a).
422. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119 (2010). This bill was decided on strong partisan lines with 219 Democrats voting in favor and 34 voting against. All 178 Republicans voted in opposition.
423. See id.
424. See id. §§ 7001-03.
425. Id. § 7002.
426. Id.
427. See Patient Protection and Affordable Care Act § 7002.
cerns and requires the generic company to notify the brand company 180 days prior to marketing.\textsuperscript{428} This preserves the brand company's ability to seek a preliminary injunction.

The exclusivity period is twelve years from the date of brand drug approval.\textsuperscript{429} The debate on this issue was one of the most polarizing. BIO had sought fourteen years.\textsuperscript{430} Generic trade associations sought eight years.\textsuperscript{431} The White House and President Obama were somewhere in between, seeking exclusivity of ten years.\textsuperscript{432} Clearly a significant exclusivity period is a requisite requirement. This issue has been a vital component to the widespread success of the generic industry. Generic drugs often become available the same day the FDA exclusivity period ends on the brand drug and the wide spawn of generics has been notable. As the future of medicine is going to be biologically based, pioneering companies must be confident in the ability to recoup research, development costs, and make a significant profit on their discoveries. However, based on the FTC report and the success of Hatch-Waxman, twelve years seems overly generous and may in fact stifle competition.\textsuperscript{433}

The Law provides a one-year exclusivity for the first interchangeable product, which is greater than 180 days authorized under Hatch-Waxman.\textsuperscript{434} This provision should help incentivize development and provide reward for generic manufacturers. Nevertheless, the Law failed to bar the use of authorized generics by brand companies to undermine generic development. The law also failed to prohibit pay-to-delay agreements. This has been a conten-

\textsuperscript{428} Id.
\textsuperscript{429} Id.
\textsuperscript{432} \textit{Id.}
tious issue for the industry and the courts, and Congress missed a ripe opportunity to voice its concern.

VII. CONCLUSIONS

In Francisco's Money Speech, as Ayn Rand wrote in Atlas Shrugged, "[w]ealth is the product of man's capacity to think." 435 We are at the dawn of landmark legislation geared to modernize the generic pharmaceutical industry and spawn the next era of lower cost medications. A properly structured abbreviated pathway will enhance existing research and discovery, award generic companies the opportunity to compete and decrease the financial burden on the U.S. healthcare system. Clearly, there is a need for generic biologic legislation in the United States and the time has finally arrived. The marketplace for biologics continues to expand, the price for prescription drugs continues to surge, patents for existing products have begun to expire, and analytical technology has reached a sufficient juncture. All the key players are at the table and our elected officials accomplished the task. Now the pressure is on the FDA to deal with the next set of challenges the law will provide.

Undoubtedly, the FDA faces an enormous challenge with the passage of an abbreviated pathway for biologics. As always, the FDA must assure that patient safety trumps all. The FDA can then establish some equivalency system to support product substitution, like the current system whereby some products are substitutable, and others are not. 436 Then, stakeholders such as managed care organizations and pharmacy benefit managers can establish protocols and clinical guidelines to drive practice and decrease costs. 437

Once generic biologics become available, the market influence and penetration will be unique compared to the current system of traditional generics. Early competition will likely resemble brand-to-brand competition and prices may not be as low as some may anticipate. 438 The four dollar co-pay

436. Individual states, regulating the practice of pharmacy, may establish a negative drug formulary whereby pharmacists will have a list of drugs that, by law, they cannot substitute, although the FDA finds them interchangeable. See FLA. ADMIN. CODE ANN. r. 64B16-27.500 (2010) (Florida's example of a negative drug formulary). This is a public policy issue where a Board of Pharmacy has made a determination in opposition to the FDA. See id.
437. See id.
438. FTC 2009 REPORT, supra note 184, at iii; see also Emerging Health Care Issues: Follow-on Biologic Drug Competition: Hearing Before the H. Subcomm. on Health Comm. on Energy and Commerce, 111th Cong. 9 (2009)
may be some time off.439 Additionally, in vast contrast to traditional generics, some early generic biologic companies may have to utilize unprecedented marketing campaigns to try and drive market share.440 Ultimately the market acceptance to generic biologics will be similar to traditional drugs over time and patients will see a significant increase in cost savings. Moreover, because the U.S. Government is the largest payor of prescription drugs in this country, government acceptance of these products will have a profound effect on market acceptance.441

The likely players to emerge from the generic biologic marketplace are biotechnology companies, big pharmaceutical companies,442 and large generic houses.443 Currently, it is traditional generic companies being the most aggressive in developing biologics, especially those with a strong European influence.444 Generic companies in India will also emerge as early players, especially as that country is slow to respect U.S. patent law.445 Some claim that the approval of a generic biological approval pathway will deter venture capitalism.446 This is short sighted. The generic industry in this country has blossomed since Hatch-Waxman and competition only works to make a system more efficient and robust.

439. See Milt Freudenheim, Side Effects at the Pharmacy, N.Y. TIMES, Nov. 30, 2006, at C1 (describing Wal-Mart's four dollar generic program and how it prompted its competition like Target to also institute such a program).
440. See Moran, supra note 382, at 5.
441. Prescription Drugs: Overview of Approaches to Control Prescription Drug Spending in Federal Programs: Hearing Before the Subcomm. On Federal Workforce, Postal Service, and the District of Columbia of the H. Comm. On Oversight and Government Reform, 111th Cong. 2 (2009) (Statement of John E. Dicken, Dir., Health Care, Gov't Accountability Office). The Federal Employees Health Benefits Program is the largest employer-sponsored health insurance program in the country covering about eight million federal employees, retirees, and their dependents. Id. This includes Medicare, VA, DOD, and Medicaid. Id. at 1–3.
443. Behnke et al., supra note 9, at 2.
444. Id.
The passage of the BPCIA is essential to the future of healthcare and cost containment in the United States. Expectedly, any legislation of this complexity will open unanticipated loopholes. No system is perfect and the law may need further revision and amendments over time. Nevertheless, the future of medicine is upon us and the need for generic biologics is overdue. Science continues to blaze its path, while the corresponding policy inevitably lags. Meanwhile, we are only at the tip of the iceberg. Biobetters and tailored gene therapy are evolving and will pose additional generic considerations that will have to be dealt with. Remember, "[t]his shit’s chess, [it ain’t] checkers."

447. Biobetters refer to new versions of existing brand drugs with enhanced characteristics such as improved delivery, safety, or efficacy. Behnke et al., supra note 9, at 2. Frequently, a basic manipulation of a single amino acid sequence or other biochemical change in an existing drug can provide an improved profile. See id.

448. See generally W. Kalow, Pharmacogenetics and Pharmacogenomics: Origin, Status, and the Hope for Personalized Medicine, 6 Pharmacogenomics J. 162 (2006).

THE NEED FOR AN EQUITABLE REVOLUTION TO “APPROPRIATELY” REMEDY WRONGFULLY DENIED BENEFITS UNDER ERISA

ROBERT C. SHERES*

I. STRUCTURES OF HEALTH INSURANCE ............................................ 680
   A. The Private Insurance Model ............................................ 681
   B. The Structure of Employer-Sponsored Health Plans .......... 682
II. EMPLOYER SPONSORED BENEFIT PLANS UNDER ERISA .......... 684
   A. ERISA Generally .......................................................... 684
   B. ERISA Preemption ....................................................... 685
   C. ERISA’s Civil Enforcement Provision .............................. 687
   D. ERISA’s Relationship to Trust Law ................................. 689
   E. ERISA Plan Sponsors, Fiduciaries and Providers ............... 690
III. AN ERISA FIDUCIARY’S DISCRETIONARY ROLE IN PROVIDING BENEFITS .............................................................. 691
   A. “Medically Necessary” and “Experimental” Treatments .... 692
   B. Conflict of Interest Resulting from a Fiduciary’s Dual Role ... 693
   C. Litigating the Denial of Benefits .................................... 694
IV. REMEDIES FOR WRONGFULLY DENIED BENEFITS .......... 697
   A. Contrasting State Law and ERISA Remedies for Wrongfully Denied Benefits .................................................. 697
V. JUDICIAL INTERPRETATION OF “OTHER APPROPRIATE EQUITABLE RELIEF” BEFORE SEREBOFF .............................................. 699
   A. The Law Before Knudson ............................................ 699
   B. Knudson and Where the Court Went Next ................. 701
   C. Flaws in the “Typically Equitable” Definition ............. 703
   D. A Step in the Right Direction ..................................... 704
VI. PROPERLY DEFINING “OTHER APPROPRIATE EQUITABLE RELIEF” ... 704
   A. Typically Equitable and Appropriate Remedies .......... 705
      1. Injunction ......................................................... 706
      2. Equitable Restitution ........................................... 709
VII. CONCLUSION ........................................................................ 710

* The author earned his J.D., summa cum laude, from Nova Southeastern University, Shepard Broad Law Center and his Bachelors in Business Administration from the University of Miami. Mr. Sheres currently practices with the DuBosar Law Group in Boca Raton, Florida and previously served as a judicial law clerk to the honorable Judge Gary M. Farmer in Florida’s Fourth District Court of Appeal.
The inherent ambiguity in defining what constitutes a "medically necessary" or "experimental" treatment has been the center of much controversy in the realm of employer-sponsored health benefit plans. These uncertain terms, which are found in almost all such plans, classify the types of medical care that the insurer will or will not cover. Insurers will generally cover only "medically necessary" treatments and deny coverage for "experimental" treatments. As a result, insured participants and beneficiaries, whose only interest is their own health, argue that the term "medically necessary" should be interpreted broadly enough to cover any and all treatments ordered by their physician. Insurers, however, contend that the term must be construed very narrowly, so that coverage is limited and profit margins remain high.

When benefits are denied based on an insurer's conclusion that a requested treatment is not "medically necessary" or is "experimental," courts must decide whether the denial was justified or wrongful. If a court concludes that covered benefits were wrongfully denied and as a result, a participant or beneficiary was harmed, then that individual is entitled to "appropriate equitable relief" under the Employee Retirement Income Security Act (ERISA). The next question becomes: What constitutes relief that is both "appropriate" and "equitable"? When the United States Supreme Court has been faced with this question, it has focused almost exclusively on ERISA's use of the words "equitable relief," giving little credence to Congress's intent of providing relief that is not only equitable but also "appropriate." This article considers the Court's interpretation of this issue and suggests an interpretation that reconciles precedent with Congress's underlying intent of providing "appropriate" relief to those aggrieved.

I. STRUCTURES OF HEALTH INSURANCE

Due to the complex nature of our health system, this article requires a basic understanding of how health insurance is currently structured and pro-

2. See id.
3. See id.
5. See Phyllis C. Borzi, Ctr. for Health Servs. Research & Policy, ERISA Health Plans: Key Structural Variations and Their Effect on Liability 3 (2002).
7. See id.
vided in the United States. The two basic insurance models are private insurance and public insurance.8 Under the private insurance model, individuals and groups pay premiums related to that individual’s or group’s “risk of requiring medical care and the likely expense of that care.”9 The insurer’s main concern here is earning a profit for its shareholders.10 On the other hand, public insurance is a system whereby individuals pay a predetermined fixed sum to be included in the program, regardless of the individual’s actual or expected medical care needs.11 Under this model, the insurer’s main concern is assuring that all members in the community have access to health care.12 In the United States, public insurance programs provide substantial benefits to the elderly, poor, and disabled.13 This article, however, focuses exclusively on private insurance provided to employee-groups by their employers.

A. The Private Insurance Model

Under the private insurance model, individuals pay relatively small premiums, usually on a monthly basis, in return for the insurance company’s promise to pay for any costs the participants or beneficiaries (the insured) of the plan incur, resulting from covered illnesses or injuries.14 Some participants will suffer from severe illnesses which will require the insurer to cover treatments that far exceed those individuals’ premiums, while other participants will remain healthy, costing the insurer very little or nothing.15 Due to this disparity, insurers reduce their risk of suffering devastating losses by insuring large numbers of people, so that the healthy participants essentially subsidize the treatment of those participants requiring frequent or expensive care.16 Insurers safeguard their economic viability by categorizing participants based on their “risk classification” and deciding whether they are worth

9. Id.
10. See id.
11. Id. at 110–11. The government’s provision of police services is analogous to the public insurance model in that its citizens pay the same amount for police protections regardless of where they live or what they own. Id. at 111.
12. Ford, supra note 8, at 110.
13. GOSTIN & JACOBSON, supra note 4, at 336.
15. Id.
16. Id.
the risk of insuring. This decision making process is commonly referred to as underwriting.

In the underwriting process, insurers have broad discretion and use several tools such as applications, forms, reports from physicians, and medical examinations. If an applicant is approved, the insurer will offer coverage at a specified monthly premium. The premium is based on the risk or probability of the applicant requiring covered treatment.

The risk analysis mentioned above is determined differently depending on whether the applicant is an individual or a group. When insurance is sold to an individual, the insurer will take into account only that individual’s health risks in order to determine the premium amount. When, however, a plan is offered to a group, such as employees, the insurer will assess the characteristics of the group as a whole and charge each member of that group the same premium.

B. The Structure of Employer-Sponsored Health Plans

Employer-sponsored health plans are an important part of the United States’ health system. In fact, approximately ninety percent of Americans receive their health insurance through their employer. Because employers providing these benefits must tailor their plans to meet the needs of their employees, as well as their own financial incentives, employers have substantial flexibility in designing the plan that they will purchase for their employees. As further discussed below, the Employee Retirement Income Security Act of 1974 (ERISA) governs the administration of employer-

17. Id. at 665–66.
18. Id. at 666.
20. See id. at 665–66.
21. Id.
22. Id.
23. Id. at 666. The particular characteristics that insurers will look at include “gender, age, industry of the group’s employer, geographic area, . . . family composition, and group size.” Hoffman, supra note 14, at 666. “In many states, insurance providers are not required to disclose the criteria they use in making insurance decisions, and . . . state statutes provide only vague guidelines.” Id. at 666–67; see, e.g., Fla. Stat. § 627.062 (2009) (prohibiting the rates from being “excessive, inadequate, or unfairly discriminatory”).
24. GOSTIN & JACOBSON, supra note 4, at 334 (estimating that in 1999, ninety-three percent of privately insured Americans received their insurance from their employers); Timothy S. Jost, Pegram v. Herdrich: The Supreme Court Confronts Managed Care, 1 YALE J. HEALTH POL’Y L. & ETHICS 187, 187 (2001) (estimating that eighty-eight percent of Americans with private health insurance have employment-based coverage).
25. See BORZI, supra note 5, at 2.
sponsored health plans by establishing uniform minimum standards and lia-

ability for those in charge of carrying out the plans. 26

The structure of these ERISA plans often vary based on several fac-

tors. 27 For instance, while some plans are sponsored by only a single em-

ployer, other plans have multiple sponsors. 28 In all cases, however, the spon-

sor(s) must make certain important decisions in designing the appropriate plan. Such factors include the extent of the sponsor's insurance risk, the sponsor's level of involvement in the administration of the plan, the types of benefits offered, 29 "the methods by which benefits are delivered," 30 "the form of the plan and the nature of the employer subsidy," 31 and "the funding arrangement for self-insured plans." 32 Although all of these factors are important, only the sponsor's insurance risk and administrative involvement are pertinent to this discussion.

With respect to insurance risk, a plan might be "fully insured," "self-

insured," or some type of combination of the two. 33 In a fully-insured plan, the employer transfers the entire risk of payment to an outside insurance company. 34 Sponsors of "self-insured" plans, however, retain the full insurance risk, except in those cases where the risk is shared through stop-loss insurance or another type of reinsurance. 35 Along with retaining the insurance risk, some self-insured plans provide that the sponsor fully administer the plan. 36 In self-administered plans, the sponsor makes all coverage deci-

sions and retains all fiduciary obligations to participants and beneficiaries under ERISA. 37 If a sponsor is unable or unwilling to bear this burden, it

27. BORZI, supra note 5, at 2.
28. Id. The different types of plan sponsors include "single-employer plans," "multi-

employer plans," and "multiple employer welfare arrangements." Id.
29. See id. at 3. A sponsor may decide to offer one package of comprehensive health benefits to its employees or put together different plans offering different benefits. Id. at 3–4.
30. BORZI, supra note 5, at 4. Different benefit delivery methods may include "fee-for-

service," health maintenance organizations (HMOs), preferred provider organizations (PPOs), or a combination of any of these. Id. at 5. Any discussion of the details of these different methods is beyond the scope of this article.
31. Id. at 4. "[T]he form of the plan and the nature of the employer subsidy" determines how much of the cost or financing of the insurance will be shared by the employer. Id.
32. Id. at 5. Self-insured plans may set aside funds to pay for claims in a tax-exempt trust, usually a "voluntary employees' benefit association" (VEBA) or the employer may not set aside any funds and pay claims from the general assets of the employer. BORZI, supra note 5, at 5.
33. Id. at 3.
34. Id.
35. Id.
36. Id.
37. BORZI, supra note 5, at 3.
may outsource the plan administration and relieve itself of some obligations. 38

Unless otherwise noted, the ERISA plans discussed in this article are presumed to be fully insured and administered by the insurer. Meaning that the sponsoring employer paid an additional premium to an insurer so that the insurer makes all coverage decisions, bears all of the risk, and the employer’s liability is limited. 39

II. EMPLOYER SPONSORED BENEFIT PLANS UNDER ERISA

In order to fully appreciate the issues analyzed herein, a basic understanding on ERISA, its history, remedial scheme, and foundation in trust law is necessary. Section A of this part gives an overview of what ERISA is and why it was enacted. Section B discusses ERISA’s preemptive authority over state law. Section C identifies the remedies provided for by ERISA. Section D outlines ERISA’s foundation in trust law. Finally, section E defines the roles of certain individuals subject to ERISA’s provisions.

A. ERISA Generally

In 1974, 40 Congress enacted ERISA 41 in response to the mismanagement and failure of many employer-sponsored pension funds. This sequence of statutes was necessary to protect employees who were receiving only a small percentage of their promised benefits or none at all. 42 Although Congress’s primary purpose for enacting ERISA was to protect employees through the regulation of pension funds, 43 its coverage expanded to include all employer-sponsored benefit plans. 44 In order to remedy the abuse in plan

38. Id. at 3–4.
39. See id.
43. EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974, PUB. L. NO. 93-406, §2, 88 Stat. 829, 833. “It is hereby further declared to be the policy of this Act to protect . . . the interests of participants in private pension plans . . . .” Id. §2(c); H.R. REP. NO. 93-533, PT. I, AT 1 (1973), REPRINTED IN 1974 U.S.C.C.A.N. 4639, 4639. “The primary purpose of the bill is the protection of individual pension rights . . . .” Id.
44. 29 U.S.C. § 1003(a) (2000). This Act “shall apply to any employee benefit plan.” Id.
WRONGLY DENIED BENEFITS UNDER ERISA

administration, the drafters applied the "rules and remedies similar to those under traditional trust law, [which] govern[ed] the conduct of fiduciaries." These rules and remedies were intended to further Congress's goals of developing a uniform federal common law, ensuring the solvency of employee-benefits plans, and encouraging employers to provide fringe benefits to their employees. Notwithstanding these goals, ERISA does not mandate that any particular set of benefits or even that any benefits at all be provided to employees.

The two sections of ERISA that embody its purposes and goals are section 514 and section 502. Section 514 outlines ERISA's preemptive effect on state laws and section 502 outlines ERISA's exclusive remedial scheme.

B. ERISA Preemption

Section 514, often referred to as the "preemption clause," provides that ERISA "shall supersede any and all [s]tate laws insofar as they may now

45. H.R. REP. No. 93-1280, at 295 (1974), reprinted in 1974 U.S.C.C.A.N. 5038, 5076; see also 120 CONG. REC. 29,932 (1974) (explaining that "[t]he objectives of these provisions are to make applicable the law of trusts... and to provide effective remedies for breaches of trust").

46. See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 657 (1995); see also Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 11 (1987). It is thus clear that ERISA's pre-emption provision was prompted by recognition that employers establishing and maintaining employee benefit plans are faced with the task of coordinating complex administrative activities. A patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation, which might lead those employers with existing plans to reduce benefits, and those without such plans to refrain from adopting them. Pre-emption ensures that the administrative practices of a benefit plan will be governed by only a single set of regulations.

Fort Halifax Packing Co., 482 U.S. at 11.


48. See H.R. REP. No. 93-533, pt. I, at 1–2. The bill was designed to promote the expansion of these plans and increase the number of employees receiving them. Id. at 2.


52. 29 U.S.C. § 1144.

53. Id. § 1132.

or hereafter relate to any employee benefit plan." Although this "relates to clause" expresses ERISA's preemptive intent, it does not indicate how close of a relationship is required to satisfy the "relate to" language. In 1987, the United States Supreme Court applied a "broad common-sense meaning," to the phrase "relate to" and concluded that it meant having "a connection with or reference to." In 1995, the Court narrowed its definition in New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co. when it held that although Congress intended the provision to be applied broadly, it did not intend for it to preempt state laws that have only an indirect economic effect on the subject matter of an ERISA plan.

Even though the Court's definition of "relates to" does not offer much guidance, the "Savings Clause" in § 514 limits the scope of ERISA from being read too broadly. This clause provides that "nothing in this subchapter shall be construed to exempt or relieve any person from any law of any [s]tate which regulates insurance, banking, or securities." Moreover, section 514's "Deemer Clause" clarifies that self-insured employee benefits plans do not constitute "insurance companies" that are exempt from ERISA. In other words, an employer that acts like an insurance company by providing a set of benefits to its employees—such as promising to pay medical expenses—is governed by ERISA and not state insurance regulations.

55. 29 U.S.C. § 1144 (emphasis added). ERISA further defines an "employee benefit plan" as any plan "established or maintained: (1) by any employer engaged in commerce or in any industry or activity affecting commerce; or (2) by any employee organization or organizations representing employees engaged in commerce or in any industry or activity affecting commerce; or (3) by both." Id. § 1003(a).


58. See id. at 661–62.


60. 29 U.S.C. § 1144(b)(2)(B). Section 1144(b)(2)(B) states the following:

Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

Id.

The plan described above fits into the category which ERISA defines as an "employee welfare benefits plan," and in fact defines the type of plan through which ninety percent of Americans receive their health coverage. Therefore, the vast majority of health plans in America are all covered by ERISA and not the different and perhaps conflicting state and local insurance regulations. This furthers Congress's goal of creating a uniform federal common law. It should be noted that § 514 also has the effect of complete federal preemption, meaning that a defendant may remove any lawsuit brought against it, relating to an alleged violation of an ERISA plan, from state court to federal court, even if the plaintiff did not plead a separate federal law violation.

C. ERISA's Civil Enforcement Provision

Section 502, commonly referred to as ERISA's "civil enforcement" provision, enumerates the exclusive remedies available in ERISA actions. It states as follows:

(a) Persons empowered to bring a civil action

A civil action may be brought (1) by a participant or beneficiary

...
(B) to recover benefits due to him under the terms of his plan, to
enforce his rights under the terms of the plan, or to clarify his
rights to future benefits under the terms of the plan;

... 

(3) by a participant, beneficiary, or fiduciary (A) to enjoin any act
or practice which violates any provision of this subchapter or the
terms of the plan, or (B) to obtain other appropriate equitable re-

lief (i) to redress such violations or (ii) to enforce any provisions of
this subchapter or the terms of the plan;

... .

(g) Attorney’s fees and costs; awards in actions involving delin-
quent contributions

(1) In any action under this subchapter . . . by a participant, benefi-
ciary, or fiduciary, the court in its discretion may allow a reasona-
ble attorney’s fee and costs of action to either party. 68

As a result of three separate five-to-four Supreme Court majority op-
inions—two of which were written by Justice Scalia—ERISA’s remedial
scheme has been interpreted in such a way as to prevent those who were in-
jured as a result of wrongfully denied benefits from being “made whole.” 69
The Court did so by interpreting the “other appropriate equitable relief”
language in § 502(a)(3)(B) to exclude entitlement to consequential or puni-
tive damages. 70 As a result, injured employees are limited to recovering from
the insurer who wrongfully denied their benefits, only the monetary amount
of the denied treatments—plus costs and attorney’s fees—regardless of ac-
tual injuries or costs resulting from the denial. 71 In light of the purposes for
enacting ERISA, ERISA’s foundation in trust law, and even Justice Scalia’s
own words, it is apparent that the Court’s interpretation of the civil enforce-
ment provision is flawed.

68. 29 U.S.C. § 1132 (emphasis added).
69. See generally Great-West Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204 (2002);
70. See Mertens, 508 U.S. at 255 (emphasis added) (noting that § 502(a)(3)’s provision
for other appropriate equitable relief does not permit the recovery of consequential damages);
see also Russell, 473 U.S. at 144 (asserting that the language of ERISA does not support “a
private right of action for compensatory or punitive relief”).
71. See 29 U.S.C. § 1132(g) (2000); see, e.g., Hahnemann Univ. Hosp. v. All Shore, Inc.,
514 F.3d 300, 314 (3d Cir. 2008) (authorizing the award of reasonable attorney's fees and
costs to the prevailing party).
D. **ERISA’s Relationship to Trust Law**

As Professor Langbein explained, the Supreme Court’s interpretation of ERISA’s remedial scheme is inconsistent with its roots in trust law. After a review of ERISA’s legislative history, it is beyond peradventure that its remedial scheme was drafted with the principles of trust law in mind. In fact, ERISA even imposes a rule of mandatory trusteeship, requiring that “all assets of an employee benefit plan shall be held in trust by one or more trustees.” These trustees are subject to strict fiduciary duties, such as the duty of loyalty and prudence. For instance, § 404(a)(1) of ERISA, which mandates that a fiduciary discharge his duties “solely in the interest of the participants and beneficiaries,” mimics the loyalty rule in the *Second Restatement of Trusts*, requiring trustees to “administer the trust solely in the interest of the beneficiary.”

Most notable is the correlation between ERISA remedies and the remedies available in trust law for breach of trust. First, the *Second Restatement of Trusts* provides that in an action for breach of trust, the injured party may recover for “any loss” incurred. This is analogous to § 502(a)(1), which authorizes a participant and beneficiary to recover their initial losses, which are generally the benefits that were wrongfully withheld by the fiduciary.

Second, an injured trust beneficiary is entitled to “any profits” that the trustee made in breaching the trust. This is analogous to § 502(a)(2), which entitles the plan to recover for any losses or profits resulting from the fiduciary’s breach of the ERISA plan. Although § 502(a)(2) entitles “the plan” to recover and not the participant, this distinction is illusory as recovery by

---


73. See id. at 1331. “The Conference Committee explained that the drafters wanted to ‘apply rules and remedies similar to those under traditional trust law to govern the conduct of fiduciaries.’” Id.

74. 29 U.S.C. § 1103(a). Note that § 1103(b) exempts a few categories of plans. Id. § 1103(b).

75. See 29 U.S.C. § 1104(a)(1) [hereinafter referred to in text as § 404]. Section 404 of ERISA is also printed in the United States Code under § 1104; the two provisions are used interchangeably. See ERISA: THE LAW AND THE CODE, supra note 42, at xviii.


77. *Restatement (Second) of Trusts* § 205 (1959).


79. *Restatement (Second) of Trusts* § 205 cmt. a.

the plan is essentially the same as recovery by plan participants and beneficiaries who receive their benefits from the plan.

Finally, the third breach of trust remedy includes any gains that would have accrued but for the breach. 81 This remedy is analogous to the § 502(a)(3) "catchall" provision which "act[s] as a safety net, offering appropriate equitable relief for injuries caused by violations that § 502 does not elsewhere adequately remedy." 82 Professor Langbein explains that this third remedy should be interpreted broadly enough to achieve the core principle of trust law, which is to "restore[] the victim to the position that he or she would have had 'if there had been no breach of trust.'" 83

E. ERISA Plan Sponsors, Fiduciaries and Providers

In addition to preempting state law and providing an exclusive remedial scheme, ERISA mandates that every health benefits plan be established and maintained by a "plan sponsor," 84 such as an employer providing health-benefits to its employees. The role of the ERISA plan sponsor is analogous to the role of a settlor in trust law. 85 Similar to a settlor's ability to structure the terms of the trust, a sponsor decides how it will structure the plan that it offers.

ERISA further requires that every plan be in writing and have a "named fiduciary." 86 The fiduciary may be any individual, corporation or other entity—even the plan sponsor—that has control over the management, operation, and administration of the plan and its assets. 87 This fiduciary is responsible...

81. RESTATEMENT (SECOND) OF TRUSTS § 205 cmt. a.
83. Langbein, supra note 72, at 1335 (quoting RESTATEMENT (SECOND) OF TRUSTS § 205(c)).
84. 29 U.S.C. § 1002(16)(B) (2006). A "plan sponsor" under ERISA includes (i) the employer in the case of a "plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, or (iii) . . . [the] joint board of trustees or other similar group of representatives" in a multi-employer plan. Id.
86. 29 U.S.C. § 1102(a) (2000) [hereinafter referred to in text as § 402]. Section 402 of ERISA is also printed in the United States Code under section 1102; the two provisions are used interchangeably. See ERISA: THE LAW AND THE CODE, supra note 42, at xviii.
87. BORZI, supra note 5, at 18; 29 U.S.C. § 1102(c). Note that in addition to the named fiduciary, another person or entity will be considered "a fiduciary to the extent that the person: (1) exercises any discretionary authority or control over the management of the plan or disposition of its assets, (2) renders investment advice regarding plan assets for a fee for other direct or indirect compensation or has the authority or responsibility to do so, or (3) has any discre-
for ensuring that the plan is properly administered and must discharge its duties "solely in the interest of the participants and beneficiaries and for the exclusive purpose of" paying benefits and incurring "reasonable" administrative expenses. 88 Pursuant to § 402(b)(2) of ERISA, a named fiduciary may delegate fiduciary responsibilities to other fiduciaries or hire professional advisors to help carry out its duties, so long as the delegation is permitted by the health plan documents. 89 These duties are analogous to those of a trustee who protects the trust assets for the benefit of the trust beneficiaries. 90 In the event that an insured is injured by a fiduciary’s breach of any of its duties, ERISA’s civil enforcement provision, § 502, specifies the manner in which the insured may recover. 91

Finally, for the purposes of this article a “provider” is the entity or individual that actually provides the medical care to the insured, such as the doctor or hospital, and who is compensated for such services by the insurer. 92 Although generally a provider owes a fiduciary duty to the insured, its patient, providers that do not participate in the administration of the plan or decide whether treatment is covered by the plan, are not subject to liability under ERISA. 93

III. AN ERISA FIDUCIARY’S DISCRETIONARY ROLE IN PROVIDING BENEFITS

Similar to a trustee, ERISA fiduciaries generally have certain discretionary decision making powers, one such power includes the determination as to whether certain benefits are covered or denied. This determination is often guided by the specific terms defined in the ERISA policy. Section A below discusses the terms often found in policies which limit the types of benefits a fiduciary will deem covered. Section B explains how a fiduciary’s
discretionary authority or control over plan administration.” Borzi, supra note 5, at 18 (citing 29 U.S.C. § 1002(21)(A)).
88. 29 U.S.C. § 1104(a)(1) (2006). ERISA fiduciaries are held to the standards of care of a prudent person, which requires them to act “with the care, skill, prudence, and diligence under the circumstances . . . that a prudent man acting in a like capacity” would use in similar circumstances. Id.; see Donovan v. Mazzola, 716 F.2d 1226, 1232 (9th Cir. 1983) (applying the prudent person standard); Borzi, supra note 5, at 21.
89. See 29 U.S.C. § 1102(b)(2).
90. The trustee is the person who holds the title of the trust property, in trust for the beneficiary of the trust. Bogert, supra note 85, at § 1.
role may give rise to certain conflicts of interest, and the final section discusses how this conflict has been addressed by the Supreme Court.

A. "Medically Necessary" and "Experimental" Treatments

As noted earlier, ERISA mandates that all health insurance contracts be evidenced in writing.\(^{94}\) Although the drafters intended the terms of a plan to be in black and white, inherently ambiguous terms have turned them grey. For instance, ERISA plans generally limit coverage to benefits and treatments that are "medically necessary."\(^{95}\) The term "medically necessary," however, has a different meaning to physicians than it does to health plan administrators or even among administrators and physicians.\(^{96}\) For instance, "medically necessary" could "mean that a procedure or test is simply not appropriate or effective for addressing a patient’s condition" or it could "mean that the marginal value of a test or treatment ... over the next best test or treatment for the same condition is ... minimal in comparison to the marginal cost of the test or treatment over the next best test or treatment."\(^{97}\)

Moreover, ERISA plans usually exclude "experimental" or "investigational" treatments.\(^{98}\) The interpretation and application of these terms has caused some disagreement among different courts.\(^{99}\) For example, in Chambers v. Coventry Health Care of Louisiana, Inc.,\(^{100}\) the ERISA policy defined "‘experimental or investigational procedures’ as those services that do not have ‘a demonstrated value based on clinical evidence reported by peer-review medical literature or by generally recognized academic experts.’"\(^{101}\) In this case, the patient offered expert testimony from two doctors that a "PET fusion scan [was] widely accepted in the scientific community and in the relevant medical literature," while the administrator offered testimony


\(^{95}\) See Hall & Anderson, supra note 1, at 1640–41.


\(^{98}\) See e.g., Hall & Anderson, supra note 1, at 1637–40.

\(^{99}\) See e.g., Chambers v. Coventry Health Care of La., Inc., 318 F. Supp. 2d 382 (E.D. La. 2004); Harris v. Mut. of Omaha Cos., 992 F.2d 706 (7th Cir. 1993).

\(^{100}\) 318 F. Supp. 2d 382 (E.D. La. 2004).

\(^{101}\) Id. at 391.
from another doctor\textsuperscript{102} that PET fusion scans were experimental.\textsuperscript{103} Fortunately for the insured, the court found that the participant had provided sufficient evidence to prove that there was a substantial likelihood that the treatment was not experimental and therefore covered.\textsuperscript{104} In \textit{Harris v. Mutual of Omaha, Cos.},\textsuperscript{105} however, the court affirmed a ruling that a cancer treatment was experimental.\textsuperscript{106} The court based its decision on an appendix of articles that had been published several years prior, notwithstanding expert testimony that the treatment was no longer in its experimental phase and was in fact "medically necessary."\textsuperscript{107} This unpredictability is compounded by the fact that ERISA plans often grant plan administrators absolute discretion to initially determine whether requested benefits are "medically necessary," "experimental," or "investigational," regardless of the treating physician recommendation.\textsuperscript{108}

B. \textit{Conflict of Interest Resulting from a Fiduciary's Dual Role}

In most cases, insureds cannot afford to undergo treatment that is not covered by their ERISA plan.\textsuperscript{109} Therefore, the insurer's determination of whether a treatment is "medically necessary" or "experimental" will generally decide whether the treatment will ultimately be provided. As such, many argue that the insured's treating physician who is most familiar with the medical needs of the insured is in the best position to determine whether a treatment is "medically necessary."\textsuperscript{110} Others, however, argue that the administrator who analyzes a vast number of cases and is more familiar with the particular terms of the plan is best suited to make this determination.\textsuperscript{111} There is even a third group that believes that an unaffiliated third party professional should have the final say as to whether benefits are covered.\textsuperscript{112}

\begin{thebibliography}{9999}
\bibitem{102} Id. at 386. Note that the expert offered by the administrator worked as the Chief Medical Officer and Senior Vice President of the administrating company. \textit{id.} at 387.
\bibitem{103} Id. at 386–87.
\bibitem{104} \textit{Chambers}, 318 F. Supp. 2d at 391. This was a case in which the patient sought a preliminary injunction in order to prevent the administrator from denying coverage of the PET fusion scan. \textit{id.}
\bibitem{105} 992 F.2d 706 (7th Cir. 1993).
\bibitem{106} \textit{id.} at 707.
\bibitem{107} \textit{id.} at 709.
\bibitem{108} \textit{See Hall & Anderson, supra} note 1, at 1669–70.
\bibitem{109} \textit{See id.} at 1637–39.
\bibitem{110} \textit{id.} at 1649–50.
\bibitem{111} \textit{id.} at 1665.
\bibitem{112} \textit{See id.} at 1674.
\end{thebibliography}
Unfortunately, most plans bestow this discretionary power on the plan administrators who, in the case of fully insured and self-administered plans, are the same entities that will ultimately be required to pay for the treatments. It goes without saying that such administrators have a “financial incentive to deny benefits” in order to avoid the direct expenses they would incur from approving requested treatments. Therefore, an administrator “benefits directly from the denial or discontinuation of benefits.” This financial incentive to deny benefits appears to directly conflict with the administrator’s fiduciary duty to discharge his duties “solely in the interest of the participants and beneficiaries.”

C. Litigating the Denial of Benefits

Due to the potential danger to one’s health resulting from the denial of requested benefits, insureds will often appeal a denial. Generally, before an insured is entitled to a judicial determination, ERISA plans require that the insured first exhaust all of the insurer’s internal appellate procedures. All the while, the insured may be incurring additional injuries from passage of time or the financial burden of employing legal counsel. Although § 502(g)(1) of ERISA provides for reasonable attorney’s fees in litigation, courts have consistently interpreted this provision to exclude those fees incurred in pre-litigation administrative processes. If the denial of benefits is affirmed and the insured still believes that the requested benefits are covered, only then may he or she file suit in a court of law.

Although Congress did not specify a particular standard for reviewing the denial of benefits, in Firestone Tire & Rubber Co. v. Bruch, the United States Supreme Court focused on ERISA’s purpose of protecting employees and its basis in trust law to establish the appropriate standard. In Fire-
Wrongfully Denied Benefits under ERISA

Stone, it concluded "that a denial of benefits is to be reviewed under a de novo standard, unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan," in which case, abuse of discretion review applies. Under the abuse of discretion standard, an administrator's decision "will not be disturbed if reasonable." The Court noted that in cases where the fiduciary has a conflict of interest, such as a financial incentive to deny benefits, conflict should be considered as a factor in determining whether the insurer abused its discretion. Unfortunately, the Court in Firestone did not specify exactly how these conflicts of interest should be weighed or how to determine whether a conflict in fact exists. As a result, disagreement among the Federal Circuits ensued.

Recently, the Supreme Court reviewed the issue and stated as follows:

Often the entity that administers the plan, such as an employer or an insurance company, both determines whether an employee is eligible for benefits and pays benefits out of its own pocket. We here decide that this dual role creates a conflict of interest; that a reviewing court should consider that conflict as a factor in determining whether the plan administrator has abused its discretion in denying benefits; and that the significance of the factor will depend upon the circumstances of the particular case.

122. Note that the Court referred only to challenges under § 502(a)(1)(B) for benefits due. Id.

123. Reviewing these decisions de novo requires an analysis which is similar to construing trust provisions "without deferring to either party's interpretation." Id. at 112. Instead, the court would interpret the terms of the policy in light of all the circumstances and other evidence of intent. Id.

124. Firestone, 489 U.S. at 115.

125. This standard requires an assessment of whether the refusal of coverage is arbitrary and capricious, reversing the insurer's decisions only if it appears to be "without reason, unsupported by substantial evidence or erroneous as a matter of law." Fay v. Oxford Health Plan, 287 F.3d 96, 104 (2d Cir. 2002) (quoting Pagan v. NYNEX Pension Plan, 52 F.3d 438, 442 (2d Cir. 1995)); see also Firestone, 489 U.S. at 102. This standard is rooted in principles of trust law, because the insurer's discretion in determining what is medically necessary is analogous to a trustee's discretionary powers. See id. (noting that when a trustee is conferred with certain powers the exercise of that power is "not subject to control by the court except to prevent an abuse").

126. Id.

127. Id. at 115.


Justice Scalia, however, wrote a scathing dissent primarily attacking the majority’s “totality of the circumstances” approach. He contends that in light of ERISA’s roots in trust law, courts should apply a similar standard to that of a trust fiduciary with a conflict. Succinctly, he asserts that the conflict described above should not be considered “unless the conflict actually and improperly motivates the decision.” Justice Scalia reconciles this conclusion with the opinion in Firestone by disregarding, as “throwaway dictum,” the language indicating that conflicts should be weighed as a “factor.”

Regardless of whether the conflict factor is used, if a court ultimately concludes that an administrator has wrongfully denied covered benefits, the injured participant is entitled to some relief under ERISA’s remedial provisions.

It should be noted that some states have attempted to eliminate the conflict of interest altogether. For instance, in Standard Insurance Co. v. Morrison, Montana’s Commissioner of Insurance denied an insurer’s application for approval of “proposed disability insurance forms which contained discretionary clauses.” This denial was based on a state law that gave the Commissioner the authority to deny insurance forms that contained “inconsistent, ambiguous, or misleading clauses or exceptions and conditions which deceptively affect the risk purported to be assumed in the general coverage of the contract.” The insurer argued that the Commissioner was without authority to do so based on ERISA preemption. The court, however, ultimately concluded that ERISA’s savings clause applied to exempt the state law from preemption. It noted that both factors of the savings clause were met because the law was “specifically directed toward entities engaged in insurance” and “substantially affect[ed] the risk pooling arrangement between the insurer and insured.”

---

130. See id. at 2357 (Scalia, J., dissenting).
131. Id. at 2357–58.
132. Id. at 2357.
133. Id. at 2357–58.
135. See, e.g., Standard Ins. Co. v. Morrison, 584 F.3d 837, 849 (9th Cir. 2009) (affirming the denial of insurance forms containing discretionary clauses); Am. Council of Life Insurers v. Ross, 558 F.3d 600, 609 (6th Cir. 2009) (upholding a rule prohibiting insurers from marketing products containing discretionary clauses).
136. 584 F.3d 837 (9th Cir. 2009).
137. Id. at 841.
138. Id. at 840 (quoting MONT. CODE ANN. § 33–1–502 (2009)).
139. Id. at 841.
140. Id.
the one in *Morrison*, which prohibit insurers from making discretionary decisions is that in the event an insured appeals the denial of benefits, the court will have de novo review instead of the insurer-friendly abuse of discretion standard.\(^\text{142}\)

## IV. REMEDIES FOR WRONGFULLY DENIED BENEFITS

### A. Contrasting State Law and ERISA Remedies for Wrongfully Denied Benefits

As noted in section II.B above, the vast majority of Americans receive their health insurance from their employers; and as a result, their potential remedies are governed by federal law. Those who receive benefits from sources not governed by ERISA, however, play by a different set of rules.

If an individual is injured as a result of wrongfully denied benefits under a plan that is not covered by ERISA, he or she may seek relief under the appropriate state law and potentially recover an array of monetary damages, which are typically unavailable to ERISA insureds.\(^\text{143}\) For instance, a plaintiff might recover compensatory damages, including past and future physical and “emotional pain and suffering, as well as medical expenses, lost wages, and . . . other . . . form[s] of economic damages.”\(^\text{144}\) Such economic relief might include necessary and reasonable medical expenses to correct or mitigate an insured’s injuries, future nursing care, hospital care, laboratory tests, medicines, or therapy.\(^\text{145}\) Some plaintiffs may even recover damages for mental anguish, anxiety, or depression caused by the harmful effects of their injury.\(^\text{146}\) Finally, under certain circumstances plaintiffs recover “attorneys’ fees, costs, punitive damages, and prejudgment interest.”\(^\text{147}\) The potential awards under state laws have sometimes proven to be enormous, ranging upwards of $80 million.\(^\text{148}\)

\(^{142}\) Id. at 840.


\(^{144}\) Stephanie L. Schaeffer, *Cause of Action Against a Health Maintenance Organization Under State Tort Law, in 17 CAUSES OF ACTION 2D 193, § 18 (2009).*

\(^{145}\) See *id.*

\(^{146}\) *Id.*

\(^{147}\) *Id. ; see also* Williams v. Superior Court, 36 Cal. Rptr. 2d 112, 113 (Ct. App. 1994).

\(^{148}\) *See, e.g.,* Humana Health Ins. Co. of Fla. v. Chipps, 802 So. 2d 492, 495 (Fla. 4th Dist. Ct. App. 2001) (awarding nearly $80 million against Humana for terminating coverage for a special therapy program for a child with cerebral palsy). Note, however, that the award was set aside for improper jury instructions and evidentiary errors. *Id.* at 496–97.
In contrast to the wide array of potential avenues of recovery under state laws, § 502 of ERISA limits the available remedies that can be recovered for wrongfully denied benefits. First, § 502(a)(1)(B) provides that a participant may “recover benefits due to him,” “enforce his rights,” or “clarify his rights to future benefits under the terms of the plan.”

This provision is relatively straightforward and means that: (1) if an insured believes that covered benefits were wrongfully denied, then that individual is entitled to bring suit to recover the cost of those denied benefits; or (2) if there is a dispute over the meaning of precise terms of the plan, the court will clarify those terms.

Second, § 502(a)(3)(A) provides that an insured may seek “to enjoin any act or practice which violates . . . the terms of the plan.” This provision is also straightforward, authorizing a participant to ask a court to prevent the plan administrator from further violating the terms of the plan.

The main controversy arises with respect to the interpretation of § 502(a)(3)(B). This subsection provides that an insured is entitled “to obtain other appropriate equitable relief . . . to redress such violations.” In analyzing this provision, the Supreme Court held that it precludes any right to consequential or punitive damages. This means that if an insured was wrongfully denied benefits, such as a necessary surgery, and as a result his arm had to be amputated, that individual would be able to recover only the cost of the surgery, but no money for the loss of his arm. This would be the case even if the plan administrator knew that the surgery was covered under the plan and denied the benefits anyway.

Accordingly, the Court’s interpretation appears to leave those injured as a result of wrongfully denied benefits without a sufficient remedy and may even encourage some administrators to arbitrarily deny benefits. Without a doubt, this directly contravenes Congress’s intention of protecting employees and “replicat[ing] the core principles of trust remedy law, [which include] the make-whole standard of relief.”

152. Id. § 1132(a)(3)(B) (emphasis added).
154. Langbein, supra note 72, at 1319.
V. JUDICIAL INTERPRETATION OF "OTHER APPROPRIATE EQUITABLE RELIEF" BEFORE SEREOFF

ERISA’s remedial scheme limits the remedies that are available to insurers as well as the insured. Although both sides have sought monetary relief under the other appropriate equitable relief language, for the most part, neither has been successful.155 Section A provides a brief synopsis of the Supreme Court’s initial attempts to define the subject language in breach of fiduciary duty cases brought by insureds. Section B discusses how the provision was similarly applied to an insurer’s attempt to recover monetary relief. Section C points out some apparent flaws in the Court’s interpretation of the language, and section D identifies the Court’s most recent step in the right direction.

A. The Law Before Knudson

In Massachusetts Mutual Life Insurance Co. v. Russell,156 the Supreme Court set the stage for its current interpretation of § 502(a)(3)’s other appropriate equitable relief language.157 In Russell, a beneficiary of an ERISA health benefits plan brought suit to recover consequential and punitive damages for the improper processing of her claim for disability benefits under sections 409158 and 502(a)(2) of ERISA.159 The Court reversed the lower court’s ruling that pursuant to § 409, a beneficiary is entitled to compensatory damages “‘that [would] compensate [her] for all losses and injuries sustained as a direct and proximate cause of the breach of fiduciary duty,’ including ‘damages for mental or emotional distress.’”160 The Court also reversed the ruling that pursuant to § 409, punitive damages were recoverable under ERISA when a fiduciary “‘acted with actual malice or wanton indifference to the rights of a participant or beneficiary.’”161 Because these types of

155. See Langbein, supra note 72, at 1318–19.
156. 473 U.S. 134 (1985). Note that this case was decided by a five to four majority opinion. Id. at 135.
157. See id. at 150.
158. 29 U.S.C. § 1109 (2000) [hereinafter referred to in text as § 409]. Section 409 of ERISA is also printed in the United States Code under § 1109; the two provisions are used interchangeably. See ERISA: THE LAW AND THE CODE, supra note 42, at xviii.
161. Id. (quoting Russell I, 722 F.2d at 492).
damages were not expressly enumerated in § 502, the Court held that they were non-recoverable. 62 This conclusion was based on the Court’s assertion that because ERISA remedy law was so carefully and comprehensively drafted, any omission of a particular remedy must have been deliberate. 63 The Court supported its conclusion with the pronouncement that in enacting ERISA the drafters “were primarily concerned with the possible misuse of plan assets, and with remedies that would protect the entire plan, rather than with the rights of an individual beneficiary.” 64

In his concurrence, Justice Brennan identified portions of the majority opinion which he believed were “both unnecessary and to some extent completely erroneous.” 65 Although he agreed with the Court’s decision that § 409 provides remedies only for the plan as a whole and not individual participants or beneficiaries, he noted that beneficiaries “must look elsewhere in ERISA for personal relief.” 66 For instance, he explained that the Court did not decide the issue of whether a fiduciary may be held personally liable under § 502(a)(3)’s other appropriate equitable relief language. 67 He also noted that the main architect of ERISA, Jacob Javits, intended for § 502(a)(3) to be used by the courts to work out appropriate remedies in light of the purposes of ERISA. 68

Seven years later, in Mertens v. Hewitt Associates, 69 the Supreme Court addressed the issue of whether § 502(a)(3) authorizes money damages for the breach of a fiduciary duty. 70 In analyzing the provision, it noted that the term other appropriate equitable relief could mean one of two things, either: (1) “whatever relief a court of equity is empowered to provide in the particular provision was only intended to provide relief to the plan itself, not beneficiaries or participants. Id. at 138–140.

62. Id. at 146.

63. Russell, 473 U.S. at 146–47 (stating that “[t]he six carefully integrated civil enforcement provisions . . . provide strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly”) (emphasis omitted).

64. Id. at 142.

65. Id. at 155 (Brennan, J., concurring).

66. Id. at 150.

67. Id.


70. See id. at 249–50. In this case, the ERISA beneficiaries sought damages from non-fiduciaries who knowingly participated in the fiduciary’s breach of fiduciary duty. Id.
lar case at issue;” or (2) “those categories of relief that were typically available in equity (such as injunction, mandamus, and restitution, but not compensatory damages).”"171 The majority opted for the second interpretation primarily based on Justice Scalia’s assertion that the first meaning was too broad and would render the word “equitable” superfluous.172 In the dissenting opinion, however, Justices White, Rehnquist, Stevens, and O’Connor argued that the first definition should apply.173 The dissenting Justices insisted that the drafters of ERISA intended the term other appropriate equitable relief to be interpreted with respect to its roots in trust law.174 Specifically, they focused on the remedy for breach of trust, which includes the right to compensatory damages.175

B. Knudson and Where the Court Went Next

In Great-West Life & Annuity Insurance Co. v. Knudson,176 decided in 2002, the Supreme Court once again tackled the interpretation of other appropriate equitable relief.177 The issues in Knudson differed significantly from those in Russell and Mertens. In Knudson, an ERISA insurance company sought reimbursement from a plan beneficiary pursuant to a reimbursement provision in the ERISA policy.178 This provision entitled the insurer to repayment for medical expenses paid on the beneficiary’s behalf out of the settlement proceeds the beneficiary received from the third-party tortfeasor responsible for her injuries.179 In delivering the Opinion of the Court, Justice Scalia reiterated the Mertens rationale and applied the typically equit-

171. Id. at 256.
172. Id. at 257–58. Another reason why the majority chose the “typically equitable” definition is that elsewhere in ERISA and other federal statutes, Congress indicated its intention to broaden available remedies by using the terms “legal” or “remedial” in addition to “equitable.” See Mertens, 508 U.S. at 257–60.
173. See id. at 263–74 (White, J., dissenting).
174. Id. at 265–66 (stating that “[t]he traditional ‘equitable remedies’ available to a trust beneficiary [for breach of trust] included compensatory damages”). The dissent further emphasized that making victims of fiduciary breaches whole by providing monetary relief avoids the “anomaly of interpreting ERISA [in such a way that] leave[s] those Congress set out to protect—[ERISA participants and beneficiaries]—with ‘less protection . . . than they enjoyed before ERISA was enacted.’” Id. at 266–67 (quoting Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 114 (1989)).
175. Id.
177. See id. at 209–10.
178. Id. at 207–09.
179. Id. at 207.
The Court concluded that the insurer could not prevail due to the fact that it was seeking to impose personal liability on a beneficiary “for a contractual obligation to pay money-relief that was not typically available in equity.” In support of this conclusion, Justice Scalia cited the following portion from his dissenting opinion in *Bowen v. Massachusetts*.

Almost invariably... suits seeking (whether by judgment, injunction, or declaration) to compel the defendant to pay a sum of money to the plaintiff are suits for “money damages,” as that phrase has traditionally been applied, since they seek no more than compensation for loss resulting from the defendant’s breach of [a] legal duty.

Based on this rationale, Justice Scalia rejected the insurer’s claim that its cause of action for reimbursement should be classified as injunctive relief, a typically equitable remedy. The Court noted that only in rare cases, such as those that would avoid future losses, would the Court of Equity specifically enforce a contract to transfer funds. The Court also rejected the insurer’s argument that it was seeking the typically equitable remedy of restitution. As dicta, the Court stated that in order to seek equitable restitution, one must ordinarily do so “in the form of a constructive trust or an equitable lien, where money or property identified as belonging in good conscience to the plaintiff could clearly be traced to particular funds or property in the defendant’s possession.” Finally, the Court concluded that the “restitution” sought by the insurer is not equitable but a “freestanding claim for money damages.”

Justice Ginsburg and Justice Stevens wrote strong dissenting opinions. Justice Stevens emphasized that he agreed with Justice Ginsburg that it is unlikely that the 1974 Congress “intended to revive the obsolete distinctions

---

180. *Id.* at 209–10 (stating that “[e]quitable relief must mean something less than all relief.”... [It] must refer to ‘those categories of relief that were typically available in equity’”) (quoting Mertens v. Hewitt Associates, 508 U.S. at 256, 258 n.8 (1993)).


183. *Id.* at 918–19 (Scalia, J., dissenting).

184. See *Knudson*, 534 U.S. at 210–11. The insurer argued that it was seeking to enjoin the beneficiaries from refusing to perform as required by the reimbursement provision in the contract. *Id.*

185. *Id.*

186. *Id.* at 212–18.

187. *Id.* at 213.

188. *Knudson*, 534 U.S. at 219 n.4.
between law and equity . . . for defining the remedies” under ERISA.\textsuperscript{189} Further, he noted that he understood § 502(a)(3)(B) to authorize any appropriate order that would remedy a violation of an ERISA plan, regardless of what was available in English chancery courts.\textsuperscript{190} Justice Ginsburg elaborated on how unreasonable it was for the majority to focus on ancient classifications and emphasized that principles of equity are flexible and were introduced to accommodate the changing needs of society.\textsuperscript{191}

C. Flaws in the “Typically Equitable” Definition

As a result of Russell, Mertens, and Knudson, relief available under § 502(a)(3)(B) has been limited to the specific classes of remedies that Justice Scalia would consider typically equitable, such as mandamus, injunction, and restitution.\textsuperscript{192} This narrow interpretation of typically equitable remedies excludes the possibility of recovering compensatory damages primarily because Justice Scalia believes that suits for money are essentially actions at law and therefore not equitable.\textsuperscript{193} There are several flaws in this interpretation. First, as Professor Langbein explained, mandamus was exclusively a common law remedy and never typically equitable.\textsuperscript{194} Second, although the Court asserted that restitution is typically equitable, the law of restitution was only created after the fusion of the courts by the American Law Institute in the Restatement of Restitution (1937), by integrating the equitable rule of constructive trusts and common law rule of quasi-contract.\textsuperscript{195} Finally, and most significantly, Justice Scalia’s interpretation erroneously excludes monetary damage awards because he considered them to be the “classic form of legal relief.”\textsuperscript{196} This interpretation ignores the fact that the payment of money is in fact a “classic form of equitable relief” for trust beneficiaries seeking equitable redress for a fiduciary’s breach of trust.\textsuperscript{197} In fact, the Uniform Trust Code clearly states that in order “[t]o remedy a breach of trust, . . . the court may . . . compel the trustee to redress a breach of trust by paying money.”\textsuperscript{198} Keeping in mind that ERISA was drafted based on trust law and the
fact that an ERISA fiduciary's breach of its duty is analogous to a breach of trust, Congress likely intended § 502(a)(3)(B) to include monetary relief.

D. A Step in the Right Direction

Four years after Knudson, the Supreme Court decided Sereboff v. Mid Atlantic Medical Services, Inc. In Sereboff, the Court once again took on ERISA's other appropriate equitable relief language. The facts of Sereboff were essentially the same as those in Knudson. Without abrogating or overruling Knudson, however, the Court enforced an ERISA plan's reimbursement provision based on the typically equitable theory of constructive trust. The Court distinguished the two cases on a fact that seems arbitrary and may actually encourage fraudulent and unethical conduct. In essence, the Court enabled an insurer to enforce a monetary reimbursement provision of an ERISA plan based on semantics and quick thinking. Succinctly, because the typically equitable definition of § 502(a)(3)(B) would not permit the insurer to assert a cause of action for reimbursement under the terms of the plan, the insurer merely re-classified the remedy sought as one for a constructive trust over the specific trust in which the settlement proceeds were deposited.

The result in Sereboff is bitter-sweet. The Court took a step in the right direction by permitting the recovery of money to be considered other appropriate equitable relief. The method used to achieve this result, however, will be difficult for insureds to take advantage of when seeking money for wrongfully denied benefits. This is due to the fact that when an insurer denies a request for benefits, it generally does not earmark and deposit money that would make an injured insured whole into a separate fund over which a constructive trust may be imposed.

VI. PROPERLY DEFINING "OTHER APPROPRIATE EQUITABLE RELIEF"

Without regard to the plan administrator's underlying motivation, the fact remains that courts have and will continue to conclude, from time to

200. See id. at 361.
204. See id.
205. For a detailed discussion on Sereboff, see Sheres, supra note 201.
time, that covered benefits were wrongfully denied. The type of benefit denied and the resulting injuries vary from case to case. For instance, an insurer might deny coverage for extended hospital stays, prescription drugs, or crucial surgeries. As a result of the denial, the insured might incur injuries ranging from allergic reactions, to the loss of a limb, or even death. In spite of the devastating losses and injuries that may result from a wrongful denial, insureds under an ERISA plan are limited to relief under § 502, which currently precludes consequential and punitive damages. As a result, injured participants and beneficiaries are without appropriate relief to redress the damages caused by plan administrators.

This unjust result stems from the Supreme Court’s unbalanced emphasis on Congress’s use of the word “equitable” in § 502(a)(3)(B) and disregard for the fact that such relief must also be “appropriate.” If Justice Scalia was correct, then every word used in ERISA’s remedial scheme was deliberate, including the word “appropriate.” Although the Court has stated that when considering the meaning of “appropriate” equitable relief, courts should “keep in mind the ‘special nature and purpose of employee benefit plans,’” it does not appear to have done so itself. The primary purposes of ERISA are to provide benefits to and protect employees. Therefore, the remedies available to those employees should redress the specific injury incurred by the employee.

A. Typically Equitable and Appropriate Remedies

The current interpretation of other appropriate equitable relief limits the remedies available to those typically equitable remedies identified by the Court which include injunction and equitable restitution. Courts are given a “high degree of discretion” when awarding these remedies, enabling them to be flexible and “measure, shape or tailor relief to fit [the court’s] view” of

207. See, e.g., Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1322 (5th Cir. 1992).
208. See, e.g., Aetna Health Inc., 542 U.S. at 205.
210. See, e.g., Aetna Health Inc., 542 U.S. at 205.
215. See Mertens, 508 U.S. at 256.
what is fair in a particular situation. As such, courts should use the flexibility of these equitable remedies to alleviate the damage caused by the wrongfully denied benefits.

1. Injunction

An injunction is a command from the court to a defendant requiring the defendant to act or avoid acting in a certain way. Due to their flexible nature, injunctions have been used in a variety of ways to prevent violations of rights, restore "rights that have already been violated," and even "establish rights" that did not otherwise already exist. Because there is no general limiting principal, an "injunction is a potential remedy in any case in which it may provide significant benefits that are greater that its costs or disadvantages." The following are a few examples on how injunctive relief may be fashioned to "appropriately" remedy wrongfully denied benefits in particular situations.

In Wickline v. State, Mrs. Wickline, a plan beneficiary underwent several major surgeries on her nerves and arteries. After the surgeries, the plan administrator rejected the surgeon’s determination that Mrs. Wickline should remain in the hospital for eight additional days. As a result, she was discharged. While at home, her leg became infected and ultimately had to be amputated. The surgeon concluded to a medical certainty, that had Mrs. Wickline remained in the hospital for the entire eight days, as he suggested, she would not have lost her leg. Therefore, in this instance, the wrongful denial of benefits resulted in the loss of Mrs. Wickline’s leg. Even though a court could not award compensatory damages to Mrs. Wickline or a similarly situated insured for their loss, perhaps it could use its injunctive powers to fashion an appropriate remedy. For instance, it might issue an injunction requiring the plan administrator to provide Mrs. Wickline with a

217. Id. § 2.9(1), at 162.
218. Id. § 2.9(2), at 165.
219. Id. at 166.
220. 239 Cal. Rptr. 810 (Ct. App. 1986).
221. Id. at 812–13. Note that although this was not an ERISA case, the same concept would apply.
222. Id. at 813–15.
223. Id. at 815.
224. Id. at 816.
225. Wickline, 239 Cal. Rptr. at 817.
prosthetic leg and rehabilitative therapy. Of course the administrator will argue that requiring the plan to pay for such relief is essentially the same as awarding consequential damages. This argument should fail in light of the Court’s ruling in Sereboff, which permitted an insurer to recover money by fashioning a method in which the money was recovered as equitable.

In Jacobs v. Kaiser Foundation Health Plan Inc., an ERISA plan beneficiary was bulimic, however the administrator refused to pay for any out-of-plan treatment because it considered alternative treatments available from the plan provider to be reasonable. The court ultimately determined that the treatment provided by the plan provider was not reasonable and therefore benefits for the requested out-of-plan treatment were wrongfully denied. If a court was faced with a similar situation, its injunctive power could be used to order the plan to adopt a form of bulimia treatment that is reasonable. Because bulimia is often a lifelong struggle, this prospective remedy may be “appropriate.”

In Nolte v. BellSouth Corp., the plaintiff brought a class action suit for breach of fiduciary duty, under ERISA §502(a)(3)(B), against the plan administrator for improperly denying benefits under a Short Term Disability Plan (STDP). She alleged that the administrators failed to apply the correct definition of the term “disability.” As an appropriate equitable remedy, the plaintiff asked the court to order the removal and replacement of the alleged breaching fiduciaries, . . . further enjoin the violation of the fiduciary duties owed to Plaintiff, . . . [and] appoint an “independent neutral body to substitute for those removed fiduciary[ies],” . . . which would reopen “each [STDP] claim” and determine whether the claim warranted an award of disability benefits.

226. Note that the administrator will likely argue that requiring the plan to pay for these additional treatments is the same as giving the patient the money and therefore essentially the equivalent of awarding her consequential damages. The administrator might also argue that this type of remedy does not serve ERISA’s purposes because the funds would be taken out of the plan’s account and therefore cause all plan members to bear the cost, possibly raising premiums.

227. 265 Fed. Appx. 652 (9th Cir. 2008).
228. Id. at 653–54.
229. Id. at 654.
231. Id. at *1.
232. Id. at *2.
233. Id.
The plaintiff further requested “an order establishing an administrative committee to audit and review” the administrator’s compliance with the previous order and disgorging all profits realized from past violations. Although the court dismissed the plaintiff’s case, it did not refute that this type of injunctive relief could be “appropriate equitable relief.” In fact, in Russell, the Supreme Court specified that the phrase “other equitable or remedial relief” as used in § 409(a) of ERISA is similar to “other appropriate equitable relief” in §502(a)(3)(B) and includes the “removal of [a breaching] fiduciary.”

Another potential equitable remedy might be an order requiring administrators who have previously been found to have wrongfully denied benefits to refer all future benefit disputes for external review at the administrator’s cost. “External review is a formal process to resolve disputes between health plans and patients by submitting those disputes to expert decision makers, independent from either the health plan or the patient.” It has been shown that external review uncovers that approximately fifty percent of the reviewed decisions by administrators were incorrect; therefore, this would likely be a very effective way of preventing future wrongful denials.

It should be noted that courts have used their injunctive power to award monetary relief in an effort to make whole those aggrieved. For example, in Dunnigan v. Metropolitan Life Insurance Co., the court held that prejudgment interest on late benefit payments does not constitute an award of compensatory damages. In fact, the court held that if “interest is sought to make the plaintiff whole by eliminating the effect of a defendant’s breach of

234. Id.

235. See Nolte, 2007 WL 120842, at *6, *7. The Court dismissed the plaintiff’s case asserting that pursuant to Varity Corp. v. Howe, a plaintiff cannot seek remedies under §502(a)(3) when other remedies are available through another specific provision of ERISA such as § 502(a)(1)(B). Id. at *6. Note, however, that other courts have interpreted Varity Corp. differently. See, e.g., Devlin v. Empire Blue Cross & Blue Shield, 274 F.3d 76, 89–90 (2d Cir. 2001) (“Varity Corp. did not eliminate a private cause of action for breach of fiduciary duty when another potential remedy is available; instead, the district court’s remedy is limited to such equitable relief as is considered appropriate.”).

236. Mass. Mut. Life Ins. Co. v. Russell, 473 U.S. 134, 142, 150 (1985) (It is abundantly clear that ERISA’s “draftsmen were primarily concerned with the possible misuse of plan assets”).


238. See id. at 311.

239. See id. at 327.

240. 277 F.3d 223 (2d Cir. 2002).

241. Id. at 229.
a fiduciary duty, [there is] no reason why such interest should not be deemed 'appropriate equitable relief' within the scope of § 502(a)(3)(B).”

2. Equitable Restitution

In addition to its injunctive power, a court may also use the remedy of restitution to assist in making an injured participant or beneficiary whole after being wrongfully denied benefits.243 Dan Dobbs explains that although in some cases restitution may provide compensation for a plaintiff, the goal of restitution, “is to prevent unjust enrichment of the defendant by making him give up what he wrongfully obtained from the plaintiff.”244 There are several different types of equitable restitution including: “(1) the constructive trust, (2) the equitable lien, (3) subrogation, (4) . . . accounting for profits,” (5) equitable rescission, and (6) reformation of instruments.245 Due to the flexible nature of equitable remedies and the court’s discretionary power, it is likely that several of these restitutionary remedies could be used in creative ways to address wrongful denials of benefits. This portion of the article will discuss the possible use of reformation and equitable rescission to achieve this goal.

Reformation is a traditionally equitable remedy which enables the court to alter a contract so that it more accurately meets the agreement of the parties.246 This remedy, however, may also be used to reform or alter a contract to meet other legal standards such as the doctrine in insurance law which requires insurance policies to meet an insured’s reasonable expectations.247 Such expectations may have arisen from brochures or other representations by the insurer or administrator, despite contrary provisions in the written policy.248 Therefore, if in a particular case the court finds that as a result of a plan administrator’s representations, a participant or beneficiary reasonably expected certain benefits to be covered, a plan that excludes these benefits should be reformed to meet the expectations of that participant or beneficiary.

Equitable rescission is a court order that causes a contract to be “un-made,” meaning that all benefits received under the contract are restored to

242. *Id.*
243. See *DOBBS*, supra note 216 § 1.1, at 4.
244. *Id.*
245. *Id.* § 4.3(1), at 391–92.
246. *Id.* at § 4.3(7), at 416.
247. *Id.* at § 4.3(7), at 418 (citing Roger C. Henderson, *The Doctrine of Reasonable Expectations in Insurance Law After Two Decades*, 51 Ohio St. L.J. 823, 825 (1990)).
248. *DOBBS*, supra note 216 § 4.3(7), at 418.
their original party. Generally, the benefits received by the plan administrator are the premiums paid by the participant, and the benefits received by the participant would be the medical services rendered. Therefore, if the participant has paid more in premiums than he has received in benefits before being wrongfully denied, perhaps a court would award the difference to the insured. Of course, the participant would now no longer have any insurance, which may not be the most desirable result.

VII. CONCLUSION

In Knudson, while referring to the majority’s interpretation of other appropriate equitable relief, Justice Ginsburg notes in her dissent that “[i]t is particularly ironic that the [Court] acts in the name of equity as it sacrifices congressional intent and statutory purpose to archaic and unyielding doctrine.” This emphasizes the fact that ERISA was enacted to protect employees and provide them with “appropriate remedies, sanctions, and ready access to the Federal courts.” The current interpretation of § 502(a)(3)(B) contravenes this goal by refusing to allow participants and beneficiaries to be made whole by way of consequential damages. What makes this fact even more troubling is that an award of consequential damages was in fact a traditionally equitable remedy for breach of trust, the theory upon which ERISA’s remedial scheme is based. Although the decision in Sereboff required that the compensatory damages awarded be cloaked as equitable relief, hopefully courts will view that decision as the beginning of equitable revolution relieving ERISA insureds from the Court’s flawed and archaic limitations on available remedies.

For the time being, it appears as though counsel for the insured will need to be creative in fashioning the relief they seek so that it will be considered traditionally equitable. This author suggests, however, that a clear declaration by the Supreme Court that the proper interpretation of other appropriate equitable relief is the one that Justice Scalia and the majority in Mertens disposed of as too broad. Until this is done, courts should use their discretionary power to mold the currently permissible remedies such as injunction, restitution, and rescission to provide equitable relief that appropriately addresses the injuries caused by the wrongful denials of covered benefits.

249. Id. at § 4.3(6), at 414.
CLOSING THE DOOR: MENTAL ILLNESS, THE CRIMINAL JUSTICE SYSTEM, AND THE NEED FOR A UNIFORM MENTAL HEALTH POLICY

SHANE LEVESQUE*

I. INTRODUCTION ................................................................. 711
II. THE REVOLVING DOOR OF MENTAL HEALTH CARE IN AMERICA’S PRISONS AND JAILS ..................................................... 713
   A. Rates of Mental Illness in the U.S. Correctional System .......... 714
   B. The Road to Transinstitutionalization ................................. 716
   C. Opportunities for Psychiatric Intervention in the Criminal Justice System ................................................................. 720
      1. Incarceration as a Unique Opportunity for Psychiatric Intervention ......................................................... 720
      2. Psychiatric Treatment and Relapse in America’s Prisons and Jails ........................................................... 721
   D. The Loss of Psychiatric Stability upon Community Reentry ..... 724
III. EFFORTS TO CLOSE THE DOOR: COMMON PROPOSALS FOR ENDING THE CYCLE OF RECIDIVISM ........................................... 726
   A. Diversion ................................................................. 727
   B. Discharge Planning ...................................................... 728
IV. ACCESS TO MEDICAID BENEFITS AS A SOLUTION .................... 729
   A. The Effects of Incarceration on Medicaid Benefits ............... 730
   B. Pre-Release Enrollment in SSI as a Means of Ensuring a Continuum of Care ..................................................... 733
V. CONCLUSION ........................................................................ 738

I. INTRODUCTION

Following the deinstitutionalization of the American mental health care system, which transferred the locus of psychiatric care from public inpatient institutions to community-based treatment facilities, the nation’s prisons and

* J.D., Saint Louis University School of Law, 2009. Doctoral student in Bioethics, Saint Louis University. This paper would not have been possible without the mentorship of Professor Sydney D. Watson, the generous guidance of Susan Stefan, Zita Lazzarini, and Elizabeth Pendo, and the excellent research assistance provided by Lynn Hartke.
jails became filled with mentally ill offenders. Instead of being diverted into mental health systems, and unable to conform their behavioral symptoms to the societal norms that comprise lawful activity, these individuals slipped through the holes of a ragged safety net into the criminal justice system. Today, although mentally ill prisoners have a constitutional right to basic mental health care, shortfalls in the identification of those in need of these services, as well as the punitive, stressful nature of the penal system, often exacerbate or even create additional symptoms of mental illness.

Despite this, prisons may nonetheless present a unique opportunity for meaningful psychiatric intervention. However, to the extent that some mentally ill offenders may achieve psychiatric stability while incarcerated, that stability is threatened when they are subsequently released to the streets with no home, no source of income, no social network, and no access to the medications and other care needed to maintain their newfound psychiatric stability. As a result, these individuals, who disproportionately experience addiction, may decompensate to the point of psychiatric crisis, triggering additional contact with the criminal justice system, and eventually succumbing to drug addiction, homelessness, and recidivism. This is the revolving door of America’s correctional system, through which the nation’s seriously mentally ill cycle over and over again.

Mental health advocates argue that two strategies in particular—diversion and discharge planning—are the best ways in which to combat this revolving door problem; however, both strategies are of little help to the vast numbers of America’s seriously mentally ill who, destitute and without access to public benefits, are completely unable to procure community-based psychiatric treatment. Instead, policy makers should focus on instituting programs that make Medicaid and other social benefits immediately available to seriously mentally ill offenders upon their release. And while mental health advocates have for years championed this particular strategy, an ex-

2. GOIN, supra note 1, at 2–3.
3. See id. at 3–4.
ploration of the legal framework that makes it possible has not received significant attention in legal literature.

Part II of this Article discusses the origins of the revolving door problem, paying specific attention to the individuals trapped within its turning, how they got there, and why they cannot escape. Next, Part III addresses some of the more common strategies advanced by mental health advocates for stopping the door’s revolution. Finally, Part IV identifies timely access to Supplemental Security Income and Medicaid as one strategy for ending the revolving door cycle, ultimately concluding that mentally ill offenders residing in prisons could most directly benefit from this strategy, which requires both state administrative action and stakeholder buy-in for the creation of a uniform mental health policy.

II. THE REVOLVING DOOR OF MENTAL HEALTH CARE IN AMERICA’S PRISONS AND JAILS

Empirical data suggest that over half of the men and women incarcerated in prisons and jails throughout the United States suffer from some form of mental illness. Ten percent to twenty-three percent of these mentally ill offenders suffer from psychotic symptoms, such as those with schizophrenia or who experience certain forms of bipolar disorder. This disproportionately high population of mentally ill inmates housed in correctional facilities has made the U.S. penal system the nation’s largest provider of mental health services.

Because of the criminal justice system’s new, de facto role in the provision of mental health services, incarceration may present a unique opportunity for psychiatric intervention. Many mentally ill offenders are poor, uninsured, and eligible for Medicaid prior to their incarceration. However, many have never signed up for public benefits; consequently, their inability to pay

6. See id. at 3. The report found that 15.4% of prisoners with mental health problems in state prisons, 10.2% in federal prisons, and 23.9% in state jails exhibited symptoms of psychotic disorders. Id.
7. See GOIN, supra note 1, at 2.
8. HEATHER BARR, CORR. ASS’N OF N.Y. & URBAN JUSTICE CTR., PRISONS AND JAILS: HOSPITALS OF LAST RESORT iii (1999), available at http://www.urbanjustice.org/pdf/publications/mentalhealth/PrisonsJails.pdf (stating that “prior to incarceration, very few [of New York’s mentally ill prisoners] were employed; most relied on public benefits or had no income. The vast majority received Medicaid or had no insurance at all.”).
for psychiatric services translates into a similar inability to address mental illness in any meaningful way prior to serving a criminal sentence.\textsuperscript{9}

But even to the extent that individuals do achieve stability resulting from psychiatric care received while incarcerated, that stability is often destroyed when seriously mentally ill offenders are released to the streets following the completion of their sentences, without the resources necessary to continue the very treatment that allows them to conform their behaviors to the societal norms that comprise lawful activity; as a result, they recidivate.\textsuperscript{10} This is often because of the unavailability of immediate federal entitlement benefits upon release from incarceration, as well as the delays inherent in re-enrollment and other application procedures.\textsuperscript{11}

This Section will provide information regarding the rates of mental illness in U.S. prisons and jails, pointing out that the population of incarcerated mentally ill offenders is disproportionate to rates of mental illness in the public at large. It will then discuss the deinstitutionalization of the U.S. mental health care system and the subsequent "transinstitutionalization" of the mentally ill from public, inpatient mental hospitals to the country's correctional facilities, with the result that America's prisons and jails have become the nation's largest provider of mental health services. Finally, it will explain how any stability resulting from psychiatric intervention during incarceration may be threatened by discharge to the streets without insurance benefits following the completion of a term of imprisonment.

A. Rates of Mental Illness in the U.S. Correctional System

The specific rates of mental illness represented among inmates of U.S. prisons and jails have, historically, been difficult to accurately determine.\textsuperscript{12} This may be due to the fact that there is high turnover among mentally ill offenders,\textsuperscript{13} whose sentences generally result from conviction for nonviolent offenses warranting relatively short terms of incarceration.\textsuperscript{14} However, in a


\textsuperscript{11} Id. at 7; see also BARR, supra note 8, at 34–35 (explaining the labyrinthine structure of the Medicaid re-enrollment process for those with mental illnesses).


\textsuperscript{13} Id.

\textsuperscript{14} See GOIN, supra note 1, at 2.
recent report, the Bureau for Justice Statistics issued new data confirming
that over half of all inmates in U.S. prisons and jails experienced mental ill-
ness. Consequently, rates of mental illness within correctional facilities
have been shown to far outweigh rates of mental illness represented in the
country’s general population, and may be as much as four times that of the
general public. Estimates place the total number of mentally ill offenders
contained in prisons and jails at more than 1.2 million. Of that number,
approximately one in five may experience a serious mental illness. This
classification typically includes major depression and manic conditions, such
as bipolar disorder, as well as schizophrenia and other psychotic conditions.

The prevalence of specific symptoms sufficient to support diagnosis of
a serious mental illness, when considered individually, places the dispropor-
tionately high rates of mental illness in the U.S. criminal justice system into
greater perspective. Approximately forty-three percent of state prisoners and
fifty-four percent of those in state jails meet the criteria for mania. Roughly
twenty-three percent of those incarcerated in state prisons and thirty percent
of those in state jails report symptoms consistent with a diagnosis for major
depression. Further, some fifteen percent of state prison inmates and twenty-
four percent of those in state jails present symptoms that satisfy the crite-
ria for psychotic disorder. One report concluded that, every day, as many
as 100,000 inmates throughout the prison system may be actively psychot-
ic.

15. JAMES & GLAZE, supra note 5, at 1. The report found that, in 2005, “705,600 inmates
in State prisons, 78,800 in Federal prisons, and 479,900 in local jails” experienced some form
of mental illness. Id. These numbers accounted for 56% of state, 45% of federal, and 64% of
local jail populations. Id.
16. See Ronald C. Kessler et al., Prevalence, Severity, and Comorbidity of 12-Month
DSM-IV Disorders in the National Comorbidity Survey Replication, 62 ARCHIVES OF GEN.
PSYCHIATRY 617, 619 (2005) (showing that 26.2% of adults in the general population expe-
rience some form of diagnosable mental illness); JAMES & GLAZE, supra note 5, at 3 (showing
that the rate of mental illness within the prison system is more than double that among Ameri-
cans generally).
17. See Jeffrey L. Metzner et al., Treatment in Jails and Prisons, in TREATMENT OF
18. See JAMES & GLAZE, supra note 5, at 1.
19. AM. PSYCHIATRIC ASS’N, PSYCHIATRIC SERVICES IN JAILS AND PRISONS xix (2d ed.
2000).
20. See, e.g., Fellner, supra note 9, at 135.
21. JAMES & GLAZE, supra note 5, at 1.
22. Id.
23. Id.
24. Fellner, supra note 9, at 135–36.
Because mentally ill prisoners have a constitutional right to receive minimally necessary medical treatment for serious mental health conditions, the high rates of these illnesses in prisons and jails pose particular challenges for criminal justice systems, which were not designed to address meaningfully the delicate work of treating this population. Perhaps more importantly, these rates pose significant challenges to communities, which are forced to address the continuing needs of the formerly imprisoned mentally ill offender, released into the community without immediate access to the benefits necessary to access treatment.

B. The Road to Transinstitutionalization

Beginning in the mid 1950s and continuing throughout the 1980s, the United States saw a shift in the locus of mental health care from public, inpatient institutions to community-based treatment facilities. The effects of the "deinstitutionalization" of the American mental health care system, although gradual, were vast: The population of state-run mental health hospitals declined from 559,000 in 1955 to 49,000 in 2006.

The deinstitutionalization of mental health care within the U.S. came as the result of several factors working in tandem, resulting in "a mass migration of persons with mental illness out of mental hospitals and into the community-based treatment facilities." In Bowring v. Godwin, the court held that prison inmates are entitled to psychological or psychiatric treatment if a physician or other health care provider, exercising ordinary skill and care at the time of observation, concludes with reasonable medical certainty (1) that the prisoner's symptoms evidence a serious disease or injury; (2) that such disease or injury is curable or may be substantially alleviated; and (3) that the potential for harm to the prisoner by reason of delay or the denial of care would be substantial.
munity.30 First, new pharmaceutical therapies proved effective in the treatment of mental illness, thus offering alternatives to traditional methods that were best administered in inpatient settings.31 These drugs were accompanied by "the belief that mental illnesses could be better treated in communities than in hospitals that were often more warehouses than therapeutic institutions."32

Second, the federal government's formal push for the deinstitutionalization of mental health care, which began in 1961, began to exert financial pressure on the institutional framework.33 That year, the Joint Commission on Mental Illness and Health, created to examine the state of the American mental health care system, issued to Congress a report recommending the funding and implementation of a federally based program to shift mental health care from public hospitals to community-based treatment facilities.34 In 1965, Congress responded by passing a law authorizing the construction of community mental health centers (CMHCs),35 and then amending that law to fund the staffing of those centers.36 Deinstitutionalization had begun in earnest.

Third, litigation in the federal courts produced decisions that both strengthened the procedural requirements and the criteria for achieving the involuntary civil commitment of mentally ill individuals.37 It also affirmed the constitutional right of mentally ill individuals to live in and be members of a community, regardless of whether they choose to receive psychiatric

30. GOIN, supra note 1, at 2.
31. See Ralph Slovenko, The Transinstitutionalization of the Mentally Ill, 29 OHIO N.U. L. REV. 641, 644–45 (2003) (describing how "the development of anti-psychotic medication resulted in a decrease in the use of physical restraints, psychsurgery, electroshock, hydrotherapy, insulin coma, and other physical means of treatment."); see also GOIN, supra note 1, at 2; LEARNING FROM HISTORY, supra note 1, at 4.
32. GOIN, supra note 1, at 2.
33. See LEARNING FROM HISTORY, supra note 1, at 4; Slovenko, supra note 31, at 646–47.
37. See Lessard v. Schmidt, 349 F. Supp. 1078, 1093 (E.D. Wis. 1972) (holding that involuntary commitment was only appropriate when "there is an extreme likelihood that if the person is not confined he will do immediate harm to himself or others"), vacated and remanded on other grounds, 421 U.S. 957 (1975), reinstated on remand, 413 F. Supp. 1318, 1321 (E.D. Wis. 1976); see also Addington v. Texas, 441 U.S. 418, 432 (1978) (holding that the Fourteenth Amendment requires proof by clear and convincing evidence in civil commitment procedures).
These decisions resulted in an increasingly large population of both treated and untreated mentally ill individuals residing within communities. However, this increase was not accompanied by the funding necessary to implement adequate community-based treatment. Thus, while federal deinstitutionalization policy envisioned the withdrawal of federal funds from public mental health institutions and the reinvestment of those funds in community-based treatment programs, that funding never came “close to approaching the early promises or projections of need.” Further, the average state contributions to the operation of public mental health institutions were not fully shifted to these programs. Adjusted for inflation, these contributions amounted to thirty percent less in 1997 than in 1955. As a result, those mentally ill individuals who do wish to find treatment for their conditions while living within their communities are more likely to be denied access because of either the scarcity of treatment programs or their inability to pay.

Additionally, the increased community presence of mentally ill individuals was not accompanied by a concurrent rise in their acceptance by other community members. To the layman observer, many behavioral symptoms of mental illness can be perceived as “bizarre,” “disruptive,” or “danger-

---

38. See O'Connor v. Donaldson, 422 U.S. 563, 587–88 (1975) (holding that states may not confine non-dangerous individuals with mental illnesses when it has been demonstrated that the individual is capable of living in the community with the willing support of others); Rennie v. Klein, 720 F.2d 266, 272 (3d Cir. 1983) (holding that, absent an emergency, an involuntarily committed patient who had been found competent had a right to refuse psychotropic medication); Rogers v. Comm'r of Dep't of Mental Health, 458 N.E.2d 308, 314, 323 (Mass. 1983) (holding that committed mental patients, both voluntary and involuntary, cannot be forcibly medicated except in emergency situations, and therefore have a right to refuse treatment).


40. See LEARNING FROM HISTORY, supra note 1, at 7–8; see also Teplin, supra note 39, at 795; Goin, supra note 1, at 2; Paul F. Stavis, Why Prisons Are Brim-Full of the Mentally Ill: Is Their Incarceration a Solution or a Sign of Failure?, 11 GEO. MASON U. CIV. RTS. L.J. 157, 157 (2000).

41. See JOINT COMM’N ON MENTAL ILLNESS & HEALTH, supra note 34, at xiii–xiv.

42. LEARNING FROM HISTORY, supra note 1, at 11.

43. Id.

44. ROBERT BERNSTEIN & CHRIS KOYANAGI, BAZELON CTR. FOR MENTAL HEALTH LAW, DISINTEGRATING SYSTEMS: THE STATE OF STATES’ PUBLIC MENTAL HEALTH SYSTEMS (2001).

45. Teplin, supra note 39, at 795.

46. Id.
As a result, law enforcement officers are often the very first called upon to address community concerns regarding these behaviors.48

Once engaged, police officers may conclude that, because the process of civil commitment is filled with procedural hurdles, and because many of the available community-based treatment programs will not accept patients who are perceived as "dangerous," charging that individual with a crime is "a less cumbersome and more reliable way of removing the person from the community."49 Or, the responding officer may simply not have sufficient training to recognize the symptoms of mental illness, which may appear very similar to intoxication.50 Regardless of the reason for the diversion of mentally ill people into the criminal courts, the criminal justice system's lack of sufficient criteria for excluding those individuals, and its ready acceptance of any individual whose actions do not conform with the law, may very well make it the only institution, aside from hospital emergency rooms, that "cannot say no" to the treatment of mentally ill persons.51

This is compounded by the fact that there has been a trend among the states throughout the past two decades to increase the criminal penalties for "lifestyle crimes," which are typically nonviolent offenses that do not cause direct harm to others, but do create feelings of unease among community members.52 These crimes are most often related to drug and alcohol use, the rates of which are especially high among the mentally ill, who, in many cases, use them in a desperate attempt to self-medicate.53

The net effect of these factors is that seriously mentally ill individuals, who, prior to deinstitutionalization, would have been diverted into the public mental health system, now receive the bulk of their long-term care from prisons or jails.54 This phenomenon, which has come to be known as "transinstitutionalization," is particularly troubling to mental health advocates, who assert that the criminal justice system is neither designed nor equipped to

47. Id.
48. Id.
49. Id.
50. Goin, supra note 1, at 3.
51. Teplin, supra note 39, at 795.
53. See Goin, supra note 1, at 3; JAMES & GLAZE, supra note 5, at 5–6; Slovenko, supra note 31, at 657.
54. Teplin, supra note 39, at 795.
handle the job,\textsuperscript{55} and that “formerly hospitalized patients” have “needlessly become prisoners.”\textsuperscript{56}

C. \textit{Opportunities for Psychiatric Intervention in the Criminal Justice System}

A determination of the quality of the psychiatric treatment provided in the criminal justice system is too broad an undertaking to be addressed in any meaningful way in this article; however, there is significant evidence, described \textit{infra}, indicating that it is less than adequate. But regardless of whether U.S. prisons and jails were ever intended to be providers of psychiatric treatment to the mentally ill, or whether that treatment can be considered adequate, penal institutions have become the largest “purveyor” of mental health services for the seriously mentally ill.\textsuperscript{57} To that extent, they are uniquely positioned to intervene in the psychiatric disorders of those mentally ill offenders who become incarcerated.\textsuperscript{58}

1. Incarceration as a Unique Opportunity for Psychiatric Intervention

Incarceration may itself present an opportunity for many mentally ill offenders to meaningfully address their psychiatric conditions.\textsuperscript{59} The potentially unique opportunity for psychiatric intervention presented by incarceration is likely due to the fact that the mentally ill experience poverty and homelessness in disproportionately high numbers, making them unable to pay for the treatment they need.\textsuperscript{60} Because of the scarcity of charity mental health care programs, the burden of paying for that care has been shifted largely to the patient.\textsuperscript{61} Considering that an estimated one in twenty Americans with a

\begin{itemize}
\item \textsuperscript{55} Slovenko, \textit{supra} note 31, at 641; Stavis, \textit{supra} note 40, at 157. \textit{See generally Human Rights Watch, \textit{supra} note 4.}
\item \textsuperscript{56} \textit{See Stavis, \textit{supra} note 40, at 158.}
\item \textsuperscript{57} E. Fuller Torrey, \textit{Editorial: Jails and Prisons—America’s New Mental Hospitals,} 85 \textit{Am. J. Pub. Health} 1611, 1611 (1995) (describing how “jails and prisons are replacing public mental health hospitals as the primary purveyors of public psychiatric services for individuals with serious mental illnesses in the United States”).
\item \textsuperscript{58} \textit{See GoIn, \textit{supra} note 1, at 4.}
\item \textsuperscript{59} \textit{See generally Christopher G. Hudson, Socioeconomic Status and Mental Illness: Tesis of the Social Causation and Selection Hypotheses,} 75 \textit{Am. J. Orthopsychiatry} 3, 16 (2005) (finding a “remarkably strong and consistent negative correlation between socioeconomic conditions and mental illness”); \textit{James \& Glaze, \textit{supra} note 5, at 4–5 (finding disproportionately high rates of homelessness and unemployment among mentally ill prison and jail inmates).}
\item \textsuperscript{60} \textit{See Human Rights Watch, \textit{supra} note 4, at 21.}
\end{itemize}
severe mental illness is homeless, accessing the resources to pay for private psychiatric care can be exceedingly difficult, if not totally impossible.\textsuperscript{62}

And while there are undoubtedly some mentally ill Americans who have sufficient social resources, such as family members, who are capable of footing the bill, those who need public mental health services the most are all too often unable to attain them until their symptoms have deteriorated to the point that they "are deemed a danger to themselves or to others," at which point they can be committed to a public hospital.\textsuperscript{63} However, at that point, because the few existing community-based treatment programs typically employ admissions criteria that exclude individuals whose behavior appears "dangerous," or who have been previously incarcerated, the most severely mentally ill members of the community may have no options for treatment other than that provided in prison.\textsuperscript{64}

2. Psychiatric Treatment and Relapse in America’s Prisons and Jails

In addition to government-run psychiatric institutions, America’s jails and prisons are perhaps the only places where individuals have a constitutional right to receive basic mental health care.\textsuperscript{65} However, only one-third of state prisoners, one-fourth of federal prisoners, and less than one-fifth of jail inmates with mental health problems actually receive mental health treatment while incarcerated.\textsuperscript{66} This treatment is most often provided in the form of prescription medication, although many of those who do receive mental health treatment during incarceration have some access to professional mental health therapy.\textsuperscript{67}

Although some seriously mentally ill prisoners receive psychiatric treatment while incarcerated, the punitive environment inherent to prisons and jails may actually exacerbate mental illness.\textsuperscript{68} Prisons and jails are...
"tense and overcrowded places in which all prisoners struggle to maintain their self-respect and emotional equilibrium despite omnipresent violence, exploitation, and extortion; despite an utter lack of privacy" and "stark limitations on family and community contacts." These conditions make it challenging enough for prisoners without mental illness to cope with the traumas of imprisonment; but, for the seriously mentally ill offender, these conditions can be debilitating.

The problem of overcrowding in U.S. prisons has long been documented, with some estimates showing that they operate at 150 to 200 percent beyond capacity. Cells often measure eight feet by six feet, and are occupied by two individuals, requiring one inmate to sit on a bunk when the other must access the toilet. These close quarters, and the consequent loss of privacy, can cause the seriously mentally ill to decompensate to the point of psychiatric relapse. Even those who were not mentally ill prior to incarceration can develop psychiatric symptoms for the first time, resulting in increased rule breaking, violence, and suicide.

In addition to the challenges to creating psychiatric stability that are inherent to the prison and jail environment, there are impediments created by the very structure of the mental health programs within these facilities. First among these is that, as a general matter, correctional officers are typically not trained mental health professionals, with the knowledge and expertise necessary to recognize and react appropriately to the behavioral symptoms of mental illness. As a result, the officers may mistake a bona fide psychiatric episode that makes it impossible for an inmate to conform his or her behavior for aggression, manipulation, or willful disobedience. The consequence of most of these mistaken assessments, especially when the misunderstood behavior can be construed as "violent," is that mentally ill prisoners "are met with more and harsher punishment instead of treatment." This is reflected by statistics showing that mentally ill state prison inmates are far more likely to be charged with rule violations than other prisoners, and on average serve

---

69. HUMAN RIGHTS WATCH, supra note 4, at 53.
70. Sultan, supra note 68, at 366.
71. KUPERS, supra note 68, at 47.
72. Id.
73. Id. at 48.
74. Id. at 47-48.
75. See Sultan, supra note 68, at 365.
76. See id. at 371.
77. Id.
four months longer.\(^7\)

One of the common forms of punishment imposed on mentally ill offenders is solitary confinement, which itself has been shown to exacerbate the symptoms of mental illness.\(^7\)

Another barrier to achieving adequate psychiatric services in prisons and jails is the chronic understaffing of mental health programs.\(^8\) Current staffing trends do not come near the levels proposed by experts, not only because correctional facilities are chronically underfunded for psychiatric care, but also because that already inadequate funding has failed to increase in relation to growing prison populations.\(^8\)

Pay for these positions is low, and turnover is high, largely because the work is difficult, often unpleasant, and commonly requires a lengthy commute.\(^8\) As a result, “counselors” who are typically not required to hold any formal credentials, overwhelmingly outnumber licensed mental health professionals.\(^8\)

This has huge clinical and ethical implications regarding the care of mentally ill offenders, because “under-trained, and under-qualified personnel end up making clinical decisions about appropriate treatment strategies and crisis interventions for seriously mentally ill prisoners.”\(^8\)

Further, comprehensive policies and programs designed to screen for mental illness are missing from most prisons and jails, contributing to the inefficacy of their mental health programs.\(^8\)

This may be part of the reason that so few seriously mentally ill prisoners actually receive treatment. As a result, mental disorders may be inadvertently allowed to decompensate, resulting in full psychiatric crisis.\(^8\)

Or, prison officials may erroneously conclude that a prisoner’s symptoms are an attempt to earn special treatment, or to otherwise manipulate the system.\(^8\)

However, even when mentally ill inmates are properly diagnosed, consistent delays in the delivery of psychiatric treatment may further inhibit the achievement of stabilization.\(^8\)

The interplay of these factors—the trauma associated with the loss of personal space and privacy, the severe punishment of uncontrollable behavior, and the inaccessibility of adequate psychiatric services—may have the cumulative effect of exacerbating mental illness, or even creating it. Either

\(^{7}\) James & Glaze, supra note 5, at 9–10.
\(^{7}\) Kupers, supra note 68, at 53.
\(^{8}\) See Human Rights Watch, supra note 4, at 95.
\(^{81}\) Id. at 96.
\(^{82}\) Id.
\(^{83}\) See id. at 99.
\(^{83}\) Id. at 100.
\(^{85}\) Human Rights Watch, supra note 4, at 101.
\(^{86}\) See id. at 106.
\(^{87}\) Id.
\(^{88}\) See Am. Psychiatric Ass’n, supra note 19, at 4.
way, the mentally ill offender runs the serious risk of exiting the criminal justice system far worse off than when he or she entered it. As a result, the Eighth Amendment guarantee that prisoners are entitled to adequate medical treatment while in the state’s custody becomes, in many ways, no more than an empty promise.

D. The Loss of Psychiatric Stability upon Community Reentry

Although there is no empirical data relating to actual rates of psychiatric stabilization among mentally ill offenders during periods of incarceration, it is reasonable to assume that some do become stabilized by the time they are released from prison or jail. However, any newfound stability is lost when those individuals are released into the community without adequate discharge planning, and without access to the resources they need to prevent an interruption in their treatment. With no access to medication, and with significant stressors associated with readjustment to community life, many mentally ill former inmates turn to alcohol and drugs as a form of self-medication, become homeless, and eventually recidivate. Thus begins again the turning of the cycle between incarceration, release and psychiatric crisis, in which the most serious of America’s mentally ill too often find themselves.

Long periods of incarceration can have a detrimental effect not only on one’s mental health, but also on virtually every other facet of one’s life. Thus, even when mentally ill former inmates achieve stabilization and are released into the community, they may face other challenges that threaten their ability to continue the treatment necessary to protect their mental health, and increase the possibility of recidivism. These challenges are most often associated with loss of housing, unemployment, frustration of social relationships, and access to adequate mental health care. Without assistance in connecting with community services to assist in making a successful reintegration, many mentally ill former inmates may simply slip through the holes of a ragged safety net.

89. Sultan, supra note 68, at 372.
90. See BARR, supra note 8, at 40.
91. See id.; HUMAN RIGHTS WATCH, supra note 4, at 192; Sultan, supra note 68, at 373.
92. BARR, supra note 8, at 36; Sultan, supra note 68, at 378.
93. See COUNCIL OF STATE GOV’TS, HOW AND WHY MEDICAID MATTERS, supra note 65.
94. See id.
95. BARR, supra note 8, at 31–35.
Social relationships can easily suffer when an individual is incarcerated, especially when that imprisonment is for an extended period. This can be attributed to a host of reasons, including limitations on the time allotted for visitation, the tendency to assign an inmate to a facility geographically distant from his or her home, the commonplace harassment of visitors by prison staff, and the excessive screening of personal correspondence. In fact, the maintenance of relationships may be intentionally frustrated by the correctional system as part of the punishment for having committed a crime. Evidence suggests, though, that social relationships are an incredibly important part of maintaining stability upon release, and indicates that the same policies seeking to isolate prisoners from society in fact exacerbate psychiatric crisis, not only behind bars, but also once the former inmate has reentered the community.

Similarly, incarceration brings about a necessary interruption of employment, which in turn amounts to an interruption of income. Many of the mentally ill offenders who are incarcerated were, prior to their imprisonment, already poor. Following release, they may not be able to find immediate employment, because of their criminal record. They may therefore find themselves completely unable to afford the costs of housing, food, and purchasing the medications they need to remain stabilized.

Although many mentally ill offenders are homeless at the time of their incarceration, many more become homeless after being discharged from prison or jail. Even a small period of incarceration can result in eviction or foreclosure. If these individuals no longer have a social network to fall back on, they may have little choice but to attempt to find temporary housing in a shelter. However, "[s]helters are not funded or staffed to provide ongoing psychiatric and substance abuse treatment." Furthermore, because most shelters operate on a first-come basis, there is no guarantee that there will be a bed available on any given night. Instead, the recently discharged individual may find herself sleeping on the streets, which are dangerous, violent

97. BARR, supra note 8, at 31–32.
98. KUPERS, supra note 68, at 162–63.
99. Id. at 163.
100. Id. at 162–63, 172–73.
101. BARR, supra note 8, at 33–34.
102. Id. at iii.
103. COUNCIL OF STATE GOV'TS, HOW AND WHY MEDICAID MATTERS, supra note 65.
104. BARR, supra note 8, at 33.
105. See id.
107. Id. at 364.
places that "invite[] backsliding" because of the availability of drugs and alcohol.\textsuperscript{108} And, once homeless, it may become even more difficult to find work.

Access to mental health services may also be affected by the kindred problems of unemployment, homelessness, and the destruction of social relationships. It can also be linked to the lack of available charity mental health programs.\textsuperscript{109} However, lack of access to needed psychiatric treatment is most often traced to the loss of, or difficulty in acquiring, public benefits such as Supplemental Security Income (SSI), Social Security Disability Insurance (SSDI), and Medicaid.\textsuperscript{110} What’s more, even if these individuals do find a treatment program that can help them, those services typically employ enrollment policies that exclude those with a history of dangerous behavior, a criminal record, or several previous hospitalizations.\textsuperscript{111}

Without access to housing, income, necessary mental health care or safety net programs, the mentally ill former inmate will almost certainly be re-incarcerated, typically within the first six months following release.\textsuperscript{112} Recent statistics not only confirm this, but also paint a grim picture of the possibility that a mentally ill offender will escape this cycle: In 2004, approximately half of mentally ill state prisoners and forty-two percent of mentally ill jail inmates had three or more incarcerations or probations.\textsuperscript{113}

\section*{III. EFFORTS TO CLOSE THE DOOR: COMMON PROPOSALS FOR ENDING THE CYCLE OF RECIDIVISM}

Advocates for the mentally ill have tended to suggest two primary ways in which states may curb the cycle of recidivism plaguing this population.\textsuperscript{114} The first of these is "diversion," by which the seriously mentally ill escape conviction for low-level, nonviolent offenses, and are instead routed into the mental health system in order to get the psychiatric care they need.\textsuperscript{115} The second of these is discharge planning, through which mentally ill offenders are connected with community-based housing, employment, and health services prior to their release in order to maintain a continuum of care.\textsuperscript{116}

\begin{footnotesize}
\begin{itemize}
\item[108.]\textit{Id.} at 363.
\item[109.]\textit{See id.} at 369–72.
\item[110.]\textit{BARR, supra note 8, at 34–35.}
\item[111.]\textit{See Teplin, supra note 39, at 795.}
\item[112.]\textit{HUMAN RIGHTS WATCH, supra note 4, at 193.}
\item[113.]\textit{JAMES \\& GLAZE, supra note 5, at 8.}
\item[114.]\textit{See BARR, supra note 8, at 42–56.}
\item[115.]\textit{See HUMAN RIGHTS WATCH, supra note 4, at 26.}
\item[116.]\textit{See id. at 192–93.}
\end{itemize}
\end{footnotesize}
A. Diversion

Diversion strategy, in addition to being promoted for mentally ill offenders, has also been implemented in relation to substance abusers, with the creation of "drug courts" to divert low-level offenders into drug and alcohol abuse treatment programs. Because of the close relationship between substance abuse and mental illness, and a consequent overlap of services, these voluntary drug courts may already be somewhat effective in diverting the mentally ill from the criminal justice system.

Today, mental health courts are becoming increasingly more common. In 2004, there were roughly 111 mental health courts in operation throughout thirty-two states. These courts operate by diverting individuals with mental illnesses into community-based programs that are supervised by the courts. Participation by the defendant is voluntary, incentives and sanctions are offered to encourage compliance, and social service and mental health professionals review treatment plans regularly.

While mental health courts have been shown to both reduce recidivism and to be cost-effective, the creation of a mental health court system that diverts a majority of mentally ill offenders out of prisons and jails is unlikely. First, because of the problem of "functional siloing," whereby actors within a system become so focused on their own performance and needs that they become increasingly unaware of how their action—or inaction—affects detrimentally a larger issue. The problem of functional siloing may be best illustrated by an example of its common operation: An administrative agency is asked to determine whether it should forgo funding in order to allow another agency, which may arguably be better suited to the task, to assume that particular responsibility. Because the loss of these funds is likely undesirable to the agency, the prospect of that loss may have the effect of skewing the agency's view of its efficacy. Translated into the immediate context, to the extent that prisons and jails receive funding based on the number of in-

120. Id. at 13.
121. Id.
122. Human Rights Watch, supra note 4, at 27.
mates housed within those facilities, those prisons and jails may resist the removal of those inmates and funds, and their redistribution to other programs. Secondly, because the mentally ill in general and mentally ill offenders in particular lack political power, they may not be capable of creating the momentum required to effectuate this type of immense bureaucratic shift. 124

B. Discharge Planning

These reasons make it more likely that the second suggested strategy—the provision of comprehensive discharge planning by correctional facilities prior to release—may be the most immediate way of combating the revolving door problem faced by the mentally ill who become entangled in the criminal justice system. Because discharge planning is conducted while an individual is incarcerated, it is possible to avoid the problem of functional siloing, since the point of service could remain within correctional facilities. 125 As a result, there need be no withdrawal or redistribution of federal and state funds from these facilities, and consequently far less political friction than that which may arise in regard to proposals for diversion.

Although approximately 600,000 men and women are released from prisons every year, many states do nothing in the way of providing discharge planning services to assist mentally ill offenders with reintegration into society, despite significant evidence showing that doing so reduces the risk of recidivism. 126 The mentally ill, who face greater challenges in transitioning from incarcerated life, are particularly susceptible. 127

While referrals to housing, employment and mental health services are all extremely important to the mentally ill former inmate, it is the connection with needed psychiatric services that is arguably the most important. However, almost thirty-five percent of prisons and jails do nothing to connect mentally ill offenders with community-based treatment once they are released. 128 Mentally ill offenders are seldom released with a sufficient supply of medication to carry them through until they procure community-based services. 129 Furthermore, the quality of the referral services provided by those facilities that do assist in linking mentally ill offenders with commu-

124. See Fellner, supra note 9, at 141.
125. HUMAN RIGHTS WATCH, supra note 4, at 194–96.
126. See id. at 192–93.
127. Id. at 192.
129. HUMAN RIGHTS WATCH, supra note 4, at 192.
ty-based treatment, as well as the number of referrals made annually, has gone unreported. Thus, there is no reliable data by which society may evaluate the adequacy and the efficacy of the discharge planning services that do exist.

The call for comprehensive discharge services by advocates and scholars has recently begun to echo in the halls of our nation's courts. In 2000, fueled by anecdotal accounts describing how seriously mentally ill inmates in New York were released from Riker's Island with nothing more than $1.50 in cash and $3.00 in subway tokens, unable to procure the medication needed to treat their conditions, the Supreme Court of New York ruled in Brad H. v. City of New York that the state's prisons and jails must provide adequate discharge planning. Similarly, in Wakefield v. Thompson, the Ninth Circuit held under similar facts that California must provide to mentally ill inmates on release a supply of psychotropic medication sufficient to ensure that their treatment is not interrupted during the time reasonably necessary to procure a new source for that treatment. Today, some states do, as a matter of course, provide mentally ill prisoners with psychotropic medications when they are discharged.

But even mere discharge planning may not be enough. The fact that correctional facilities provide mentally ill offenders with a short supply of medication and a referral for mental health services does not mean that individuals are regularly capable of accessing those services. Without an income, or some other means of paying for treatment, the mentally ill are left walking a psychiatric tightrope, poised to fall, and with only a tattered safety net.

IV. ACCESS TO MEDICAID BENEFITS AS A SOLUTION

Medicaid is a means-tested, public insurance program designed to shoulder the costs of medical care for the nation's poorest and its disabled citizens. States are free to "opt out" of participation in Medicaid; however,

130. See id.
132. 712 N.Y.S.2d 336 (Sup Ct. 2000).
133. Id. at 339–40, 345.
134. 177 F.3d 1160 (9th Cir. 1999).
135. Id. at 1164.
136. Nebraska provides a two-week supply; Arkansas provides a one-week supply; and both Virginia and North Carolina provide a one-month supply. Human Rights Watch, supra note 4, at 194–95.
if they choose to receive federal matching funds, state Medicaid programs are required to cover a number of specific services. In addition to this mandatory coverage, states have the discretion to fund further "optional services," as well as to increase eligibility. Further, states may add other home- and community-based services not outlined in the federal statute by seeking a waiver from the Secretary of Health and Human Services, who maintains broad approval authority. And while levels of coverage vary from state to state, every state offers comprehensive mental health care services for those individuals with severe mental illnesses.

Those mentally ill offenders who are enrolled in Medicaid at the time of their discharge from prison or jail are far more likely to be able to access available community-based services. Formerly incarcerated mentally ill offenders receive far more outpatient care than their counterparts without coverage, and their actual rate of using community-based mental health services double. Additionally, those with immediate Medicaid coverage upon release access services far more quickly than those not enrolled in Medicaid. They are less likely to be arrested or detained once enrolled, and more likely to remain within their communities for more than one year.

A. The Effects of Incarceration on Medicaid Benefits

Many mentally ill prisoners may be, immediately prior to their incarceration, eligible for Medicaid coverage. This makes sense in light of the

139. Id.; Watson, The View from the Bottom, supra note 96, at 405.
140. Watson, The View from the Bottom, supra note 96, at 405 n.12.
143. Id. at 13. This is based on a Washington State study showing that the average use of outpatient health services by mentally ill offenders with Medicaid was forty-six days versus the twenty-eight day average of those without Medicaid. Id. Further, ten percent of those outpatient days were used for mental health care among Medicaid enrollees, while those without Medicaid only sought mental health services five percent of the time. Id.
fact that homelessness, extreme poverty, and severe mental illness are so closely linked. But the fact that an individual is eligible for Medicaid coverage does not necessarily mean that the individual is actually enrolled in Medicaid. However, even to the extent that a significant number of mentally ill offenders may be enrolled in Medicaid at the time of their incarceration, far fewer complete their sentences with their enrollment intact.

Whether an inmate loses his or her Medicaid benefits while incarcerated depends on the length of the incarceration, whether the individual’s Medicaid benefits are linked to Supplemental Security Income (SSI), whether the state’s Medicaid laws allow for suspended enrollment, and whether the individual’s Medicaid card is lost during the incarceration period. Generally, federal law mandates that states may not receive matching Medicaid funds for medical services provided to qualified individuals during periods of incarceration. However, it does not require states to drop those otherwise qualified individuals from the rolls for the mere fact of their incarceration. Therefore, in principle, an individual who went into prison with a Medicaid card need only have benefits suspended, and should be able to immediately access those benefits upon his or her release.

Despite this, incarcerated Medicaid enrollees are, in reality, often immediately dropped from Medicaid programs because: 1) federal guidelines allow states to adopt more stringent policies than the federal government for maintaining Medicaid eligibility; and 2) limitations to state information management infrastructure make it impossible for many states to keep track of suspensions. Thus, even though states are authorized to merely suspend Medicaid benefits during incarceration, shortcomings in the state information management technology make it far easier for the state to simply terminate benefits entirely. Things can even be more difficult for those inmates whose Medicaid benefits are tied to SSI benefits: They always lose Medica-

---

148. Id. at 403.
id coverage if their SSI eligibility is terminated, and almost always do if it is suspended. 155

If, during an incarceration, an individual loses Medicaid coverage for any reason, the reapplication process can take months to complete. 156 Further, that individual may have to “jump through many administrative hoops” before Medicaid coverage is reinstated. 157 That is because the application process itself is “bewildering even for people who are not dealing with mental illness and the upheaval of having recently left jail or prison.” 158 For example, one description of the application process in New York City explains:

For example, to apply for Public Assistance, Food Stamps and Medicaid, an applicant must first figure out which Income Support Center to go to. The closest Income Support Center is not necessarily the right one; Income Support Centers are downsizing and merging, and Income Support Centers’ overworked staff sometimes tell new applicants that the Center is not taking any more applications. Once the appropriate center is located, the applicant must arrive before 9 a.m., complete a complicated application form, present identification and documentation of rent expenses and/or lack of cooking facilities, and be interviewed by a case-worker.

The applicant will then be directed to the Eligibility Verification Review office in Brooklyn Heights for a painstaking interview intended to detect fraud. Then, Eligibility Verification Review will send the Front End Detection System workers, who carry badges and announce themselves as “the FEDS,” to visit the applicant’s house and verify residence. If, after three visits, the FEDS have not found the applicant at home, the case will be closed. 159

This stressful set of events, and the inherent delay between the application for and the conferral of benefits, prevents recently released mentally ill offenders from tending to their most basic needs, or accessing psychiatric care other than emergency room services. 160 Without access to needed treatment, or the stability of knowing where he or she will be eating and sleeping, these individuals run the risk of undoing “any stabilization the in-

155. Id. States are not required to terminate the Medicaid eligibility of individuals whose SSI eligibility is merely suspended, but they almost always do. Id.
156. See BARR, supra note 8, at 35.
158. BARR, supra note 8, at 34.
159. Id. at 34–35.
160. GRIFFIN ET AL., supra note 153, at 1.
divid individual gained while in jail, placing the individual at risk of . . . return[ing] to the criminal justice system." 161

B. Pre-Release Enrollment in SSI as a Means of Ensuring a Continuum of Care

To reiterate, there is compelling evidence suggesting that the revolving door cycle of the arrest, release, and re-arrest of severely mentally ill offenders can be meaningfully addressed through the provision of comprehensive discharge planning. Discharge planning can be an incredibly powerful tool in combating recidivism within this population, by linking mentally ill inmates with the housing, employment, and necessary medical services that are instrumental in the reintegration of these individuals into society. And though social insurance benefits make access to care far more likely, former inmates very seldom receive timely enrollment. 162 As shown, access to Medicaid is often frustrated by state policies that create lengthy delays in the application process, and that generally favor termination versus suspension of Medicaid eligibility during periods of incarceration. 163 Further, because states overwhelmingly deny initial determinations of eligibility to those who are incarcerated, it can be very difficult for the mentally ill offender to procure needed medical care for months following release. 164 The inaccessible nature of public benefits is perhaps best illustrated in regard to mentally ill offenders incarcerated in prisons, because their longer periods of incarceration are more likely to disrupt Medicaid and other social benefits. 165

Although the provision of housing has itself proven effective in increasing the likelihood of successful community reentry among those with psychiatric disabilities, 166 referrals to prospective living arrangements and employers may mean nothing to those who experience severe mental illness and are incapable of paying for the psychiatric care and medication they need to maintain stability. Similarly, medical coverage is little to the person who is unsure where he or she will live, or where his or her next meal will come from. Consequently, it is imperative that mentally ill prisoners be given access not only to the medical benefits they need to remain stabilized, but

161. Id.
162. See id.
163. See id.
164. See id.
165. See BARR, supra note 8, at 34.
166. See Sam Tsemberis et al., Housing First, Consumer Choice, and Harm Reduction for Homeless Individuals with a Dual Diagnosis, 94 AMER. PUB. HEALTH 651, 654–55 (Apr. 2004) (concluding that access to stable housing may positively influence successful community reentry for individuals experiencing mental illness and substance abuse disorders).
also to the funds necessary to procure housing, food, and other essentials. This is especially true for those mentally ill offenders serving prison sentences—arguably, their longer sentences are the result of more severe offenses or a higher frequency of violating criminal statutes. Luckily, this can be accomplished in most states by the pre-release enrollment of mentally ill prisoners in SSI.

SSI is a federal program designed to provide a “minimum level of income” to the nation’s elderly and disabled “who do not have sufficient income and resources to maintain a standard of living at the established Federal minimum income level.” Consequently, to obtain benefits, applicants must show that they: (1) meet the income requirement; and are, (2) disabled, (3) blind, or (4) over sixty-five years old. The significance of this program is that, in addition to monthly financial support, SSI eligibility also confers immediate Medicaid eligibility in most states. This is because the Social Security Act allows states the attractive opportunity to authorize SSA to make Medicaid eligibility determinations in tandem with SSI determinations, which has the effect of reducing state administrative costs. But, as a general matter, residents of “public institutions,” including prisons, are presumptively ineligible for SSI. As a result, benefits are suspended for periods of incarceration lasting more than one month, and are terminated when the period of incarceration lasts for one year or more.

However, in a 1995 amendment to the Social Security Act, Congress charged the Social Security Administration (SSA) with “develop[ing] a system under which an individual can apply for supplemental security income benefits . . . prior to the discharge or release of the individual from a public institution.” SSA implemented just such a system, amending its own Program Operations Manual System (POMS) in 1996 to allow correctional insti-

168. Id.
169. Council of State Gov'ts, The Consensus Project, supra note 141, at 400. Pursuant to 20 C.F.R. § 416.2101, states may confer on SSA the ability to make Medicaid eligibility determinations based on the application for SSI. 20 C.F.R. § 416.2101 (2009); see Council of State Gov'ts, The Consensus Project, supra note 141, at 400. Nearly all states grant SSA that authority, and thus grant immediate enrollment in Medicaid to those individuals who are deemed SSI-eligible. Id. The states that do not are: “Connecticut, Hawaii, Illinois, Indiana, Minnesota, Missouri, New Hampshire, North Dakota, Ohio, Oklahoma and Virginia.” Id. at n.3.
171. 20 C.F.R. § 416.211.
172. 20 C.F.R. § 416.1325.
173. 20 C.F.R. § 416.1335.
tutions to enter into prerelease agreements with the agency.\textsuperscript{175} As a result, despite the presumptive ineligibility that exists for the incarcerated, otherwise qualified individuals who are residents of public institutions may now apply for SSI months in advance of his or her prospective release date,\textsuperscript{176} so long as the individual: (1) "appear[s] likely to meet the criteria for SSI eligibility when [he or she is] released from the institution;" and, (2) "may potentially be released within 30 days after notification of potential SSI eligibility."\textsuperscript{177} However, because SSA also instituted a policy of accepting all "application[s] under the prerelease procedure without regard to whether an agreement exists with the institution,"\textsuperscript{178} such agreements may not be the most fundamental component of an effective prerelease enrollment plan. Although it is doubtless that they do, and will continue to, play an important part in the prerelease enrollment process, it may be that the most important piece of these programs is that eligible prisoners be provided access to both the necessary paperwork and to the assistance they need to make a complete submission.

If, through these prerelease procedures, eligibility is determined prior to release, SSI benefits are suspended until the date of the prisoner’s reentry.\textsuperscript{179} And, since benefits are immediately payable to individuals whose eligibility has merely been suspended, and not terminated, it is possible for mentally ill offenders to walk out of prison and into benefits.\textsuperscript{180} In states that confer immediate medical eligibility in tandem with SSI eligibility, or that allow a simplified Medicaid application process for those who are SSI-eligible, this can mean immediate access to the funds necessary to pay for basic needs, and the medical coverage necessary to create a continuum of care.

Additionally, it makes logistical sense for prisons to deliver this service to mentally ill prisoners. Because prisons are charged with the treatment of the mentally ill prisoners that are incarcerated there, they ostensibly have on hand the very medical information used as evidence in state and federal determinations of disability. Ostensibly, through the provision of treatment, the prison’s medical personnel will have become familiar with the applicant.

\begin{flushright}
\textsuperscript{175} SOCIAL SECURITY ADMINISTRATION PROGRAM OPERATIONS MANUAL SYSTEM (POMS) § S1 00520.900 (2009).
\textsuperscript{176} Id. § S1 00520.900(A).
\textsuperscript{177} Id. § S1 00520.900(B).
\textsuperscript{178} Id. § 00520.900(C)(1).
\textsuperscript{179} 20 C.F.R. § 416.1325 (2009).
\textsuperscript{180} See id.
\end{flushright}
And, because the full application is relatively short, and can for the most part be completed online, it does not consume an inordinate amount of time.\textsuperscript{181}

Prerelease enrollment in SSI and Medicaid has, over the years, increasingly become an integral part of the plans promoted by mental health advocacy groups seeking to address the revolving door problem of mental illness in the criminal justice system.\textsuperscript{182} For example, the Judge David L. Bazelon, Center for Mental Health Law, has drafted a model act in which the provision of prerelease enrollment services plays the central figure.\textsuperscript{183} And this focus on prerelease planning is beginning to pay off. Now, almost half of the states have in place programs for assisting prisoners with establishing or reinstating social entitlements and other benefits for which they are eligible.\textsuperscript{184}

However, it remains troubling that more than half of the states do not assist mentally ill prisoners in accessing the benefits they need to remain stable, successful members of communities when they are released from incarceration.\textsuperscript{185} In order to close the revolving door for good, the states must be willing to implement policies that favor suspension of Medicaid eligibility during periods of incarceration as opposed to termination.\textsuperscript{186} To be successful, these policies must also mandate that prisons implement programs for assisting eligible mentally ill offenders in applying for SSI in time to receive those benefits upon release. Furthermore, states must grant SSA the authority to make Medicaid eligibility determinations in tandem with SSI determinations. But, arguably most importantly, the states must implement performance measures designed to determine to what extent prisons are successfully enrolling eligible mentally ill offenders in these programs.

To be successful, states will have to acquire the universal buy-in of all stakeholders, necessitating the fostering of communication between various state agencies, and the encouragement of agreements between those depart-

\textsuperscript{181} The application is filled out online, and consists of short answer questions. See Social Security Online, Apply for Disability Benefits, http://www.ssa.gov/applyfordisability/ (last visited Apr. 17, 2010).


\textsuperscript{183} See id. at 1–2.


\textsuperscript{185} Id.

\textsuperscript{186} Bazelon Ctr., Building Bridges, supra note 182, at 15.
ments to promote administrative efficiency. This could be best accomplished through the creation of a central agency to coordinate the state’s efforts, and by restructuring informational technology infrastructures as necessary to allow greater ease of interagency data sharing.

Recent legislation introduced to the United States House of Representatives seeks to encourage states to adopt policies favoring Medicaid suspension over termination for those inmates incarcerated for periods of one year or more. The Recidivism Reduction Act, introduced in June 2009, would require the provision of Social Security benefits for those individuals who file a Request for Reinstatement and were “eligible . . . on the basis of disability” but were thereafter “ineligible for such benefits because the individual was an inmate of a jail, prison, penal institution, or correctional facility for a period of 12 or more consecutive months.” Further, the Act would ensure that those former prisoners who were enrolled in Medicaid prior to their incarceration, but whose coverage was suspended as a result of their incarceration, would have coverage “reinstated upon release . . . unless and until there is a determination that the individual is no longer eligible to be so enrolled.” Finally, the Act, by pledging to increase federal matching rates over the course of one year for those states who update their information technology systems so that they are capable of administering a reinstatement program, would incentivize the institution of benefits suspension policies.

While the revision of state correctional health policy as it relates to those with mental illnesses will undoubtedly present a significant up-front cost to government in the form of Medicaid expansion, it must be noted that those funds may present an incredibly wise long-term investment. For years, scholars have attempted to solve the puzzle of cost-effectiveness in health care, including the provision of mental health services in communities rather than in prisons. Studies have shown, though, that locating psychiatric treatment in communities rather than in prisons has a positive increase on cost-effectiveness. States may, therefore, rightly consider it a prudent fiscal move.

187. See COUNCIL OF STATE GOV'TS, ENSURING TIMELY ACCESS, supra note 146.  
188. See id.  
194. Id. at 411.
Although diversion and comprehensive discharge planning are necessary components of a new mental health policy, they are not alone sufficient to carry the day. Instead, policy makers must focus on the reason why many of the severely mentally ill recidivate in the first place: the unavailability of the funds and medical coverage necessary to remain stabilized after they have been released from incarceration. Programs diverting mentally ill offenders into community-based programs mean nothing to the patient who cannot pay. Similarly, while discharge planning may assist with housing, employment, and may net a referral to an outpatient treatment facility, it does nothing to ensure that the mentally ill offender is able to afford the medication and treatment he or she needs to maintain psychiatric stability.

The starting point in the creation of a uniform correctional mental health policy is the enactment of legislation ensuring timely access to Medicaid and other public benefits for mentally ill offenders. This can, in most states, be accomplished through the pre-release enrollment of mentally ill offenders in SSI, which generally carries with it a presumption of Medicaid eligibility. This is especially important for those mentally ill offenders living in state prisons, who arguably warrant particular consideration, since they have arguably committed a greater number of offenses which are likely more serious in nature than those held in jails.

To succeed, states must necessarily procure the buy-in of all stakeholders. And while the resultant broadening of state mental health policies would require an up-front fiscal investment, that investment is likely sound considering the cost-effectiveness of community, as opposed to correctional, health care. In the end, unless Medicaid, or other safety net programs, are made immediately available to seriously mentally ill offenders, they will continue to cycle in and out of the criminal justice system, presenting not only a self-perpetuating monetary cost to taxpayers, but also an immeasurable human cost to society.
FLORIDA’S FIGHT AGAINST PRESCRIPTION DRUG ABUSE: PRESCRIPTION DRUG MONITORING PROGRAM

ASHLEY DUTKO*

I. INTRODUCTION ................................................................................... 739

II. HISTORICAL BACKGROUND ............................................................... 741
   A. Prescription Drug Abuse ............................................................. 741
      1. Doctor Shopping ...................................................................... 743
      2. Pill Mills ................................................................................. 744
   B. Florida: A Magnet for Doctor Shoppers and Pill Mills ............... 745
      1. Intrastate Problem ................................................................... 745
      2. Interstate Problem ................................................................... 745
   C. The Need for Regulation ............................................................... 747
      1. Prescription Drug Monitoring Programs .................................. 747
      2. How Florida Measures Up ....................................................... 748

III. SECTION 893.055 ............................................................................. 750
   A. Legislative History ..................................................................... 750
   B. Prescription Drug Validation Program ........................................ 751
   C. Rulemaking Authority ................................................................ 754

IV. OPPONENTS OF SECTION 893.055 ................................................. 754
   A. The Critics’ Perspectives ............................................................ 754
      1. Virginia Hacker ....................................................................... 755
      2. Other Potential Loopholes in Section 893.055 ....................... 757
   B. Alternative Options: Biometric Identification ............................ 758

V. LOOKING FORWARD ........................................................................... 760

VI. CONCLUSION .................................................................................... 762

I. INTRODUCTION

“Joe Druggie” visits Pain Clinic X complaining of minor back pain. A prescription is written. Within minutes, he arrives at Pain Clinic Y with the

* The author is a 2011 J.D. Candidate at Nova Southeastern University, Shepard Broad Law Center. Ashley Dutko graduated from Florida State University in May 2008, summa cum laude, with a B.A. in Psychology. She wishes to thank her family, in particular her parents Mike and Bettie Dutko, for their continued support and encouragement. The author also wishes to recognize and thank Michael McManus for his valuable insight and guidance in the development of this article. Finally, the author thanks her colleagues on Nova Law Review for their hard work and dedication in the editing of this article.
same "pain" complaints. Another prescription is issued. After filling the two prescriptions at different pharmacies, he walks into Pain Clinic Z, which is owned by a non-doctor with a criminal record, and receives an on-site distribution of pain medication. Can this type of "doctor shopping" happen in Florida? For now, yes. However, strict enforcement of new legislation may help control such widespread "doctor shopping" in Florida.3

On June 18, 2009, a hopeful Charlie Crist, Governor of Florida, signed legislation designed to halt the rising problem of prescription drug abuse in the State of Florida.4 Section 893.055 of the Florida Statutes—Prescription Drug Monitoring Program—requires the Department of Health to design and implement a comprehensive state-wide electronic database system "to prevent the inadvertent, improper, or illegal use of controlled substances."5 After a decade of increasing prescription drug misuse and abuse, Florida became the thirty-ninth state to implement such a system.6

Providing a general analysis of section 893.055 of the Florida Statutes, this article will trace the rise of prescription drug abuse in Florida and give insight into Florida's fight against this problem. Part II of this article will begin by familiarizing the reader with a background of prescription drug abuse, and introducing the specific prescription drug diversion methods of doctor shopping and pill mills. Part II will then address how Florida, in par-

---

2. Id.
4. See FLA. STAT. § 893.055 (2009); see also Bob LaMendola, Governor Signs Law to Rein in Pain Clinics—New Database Aims to Curb Pill Shopping, SUN-SENTINEL, June 19, 2009, at 1A [hereinafter LaMendola, Governor Signs Law]. Codified as section 893.055 of the Florida Statutes, Senate Bill 462—Prescription Drug Monitoring Program—declares:
   WHEREAS, while the importance and necessity of the proper prescribing, dispensing, and monitoring of controlled substances, particularly pain medication, have been established, controlled prescription drugs are too often diverted in this state, often through fraudulent means, including outright theft, phony pharmacy fronts, loose Internet medical evaluations, and inappropriate importation; in addition, there is a criminal element that facilitates the prescription drug abuse epidemic through illegal profitmaking from the diversion of certain controlled substances that are prescribed or dispensed by physicians, health care practitioners, and pharmacists... Ch. 2009-198, 2009 Fla. Laws at 1980.
5. Fla. S. Comm. on Controlled Substances/Prescription Monitoring, CS for SB 462 (2009) Staff Analysis 1 (Mar. 6, 2009), available at http://www.flstate.gov/data/session/2009/Senate/bills/analysis/pdf/2009s0462.hr.pdf [hereinafter CS for SB 462 Staff Analysis]. As "part of a prescription drug validation program," the system will contain data regarding controlled substance prescriptions provided to it by pharmacies and dispensers. Id.
6. See LaMendola, Governor Signs Law, supra note 4.
ticular, contributes substantially to the dismal statistics of prescription drug abuse. By the end of Part II, this article will illustrate why strong measures need to be implemented to regulate prescription drug abuse in Florida. Then, Part III will introduce the reader to the legislative history and enactment of section 893.055. Specifically, the article will discuss the purpose and components of the new legislation designed to combat the prescription drug war. Part IV of this article will then view section 893.055 from critics’ perspectives, including alternative measures and possible downsides to the new legislation. Part V of this article will discuss what the future holds for those affected by section 893.055. Finally, Part VI will conclude the analysis of section 893.055.

II. HISTORICAL BACKGROUND

A. Prescription Drug Abuse

According to the National Institute on Drug Abuse, the Nation’s rising drug problem lies not merely in the use of illegal substances, but even more so in the illegal misuse and abuse of legal prescription drugs for nonmedical use. According to a 2008 drug report from the Florida Medical Examiners Commission, lethal amounts of prescription drugs are found in deceased persons more often than illicit drugs. Although managing pain through narcotics is a legal medical practice and can be done responsibly, excessive use of prescription drugs alters brain activity, leading to abuse, addiction and dependence. The National Institute on Drug Abuse lists the three most commonly abused classes of prescription drugs: opioids, central nervous system depressants, and stimulants. More commonly referred to by their “street names,” these drugs include OxyContin, Vicodin, Demorol, Valium, Xanax,

9. See NIDA, supra note 7, at 1; see also Scott Hiaasen, Inside Broward’s Pill Mills, Miami Herald, Apr. 5, 2009, at 1A [hereinafter Hiaasen, Inside Broward’s Pill Mills].
10. NIDA, supra note 7, at 1.
11. Id.
and Ritalin.12 Long-term abuse of opioids, typically prescribed to manage pain, and depressants, prescribed to treat anxiety and sleep disorders, leads to physical dependence and addiction.13 Similarly, high doses of stimulants may lead to compulsive use, paranoia, “dangerously high body temperature, and an irregular heartbeat.”14

A recent survey from the Substance Abuse and Mental Health Services Administration indicates that “7.0 million . . . persons aged 12 or older . . . used prescription-type psychotherapeutic drugs nonmedically in the past month.”15 Nonmedical use is defined by the Substance Abuse and Health Services Administration to mean “the use of prescription-type drugs not prescribed for the respondent by a physician or used only for the experience or feeling they caused.”16 Second only to marijuana use, nonmedical prescription drug use is one of the most common forms of drug abuse in the United States.17 With percentages of the population using such prescription drugs for nonmedical purposes starting at a low of 2.48% in the District of Columbia, that number climbs to 7.92% in Florida.18

Aside from the staggering number of prescription drug abusers, the amount of deaths from the misuse and overuse of these drugs is quickly becoming equally astounding, particularly in Florida.19 Experts note a “107 percent jump in oxycodone deaths [in Florida] in two years.”20 According to the Florida Medical Examiners Commission, “Some traces of oxycodone were found in 1253 overdoses in 2007. Oxycodone-related overdoses continued to climb in . . . 2008.”21 With deaths from prescription drugs averaging about 8.6 deaths per day, prescription drug abuse has become a grave problem.22

12. See id. at 2–4.
13. See id.
14. Id. at 4.
16. NSDUH REPORT, supra note 15.
17. Id.
18. Id.
20. Id. George Hime, the Assistant Director of Toxicology for the Miami-Dade County Medical Examiner’s Office called the rate of overdoses “incredible” and warned, “It is the new epidemic of drug abuse.” Id.
21. Id.
22. See CS for HB 897 Staff Analysis, supra note 15, at 5.
What is the reason for this increasing “diversion of prescription drugs for illegal purposes or abuse”? According to Dr. Nora D. Volkow, the Director of the National Institute on Drug Abuse, “[A]ccessibility [to prescription drugs] is likely a contributing factor.” While prescription drug diversion activities can come in many forms, the two most common sources of the problem are doctor shopping and pill mills.

1. Doctor Shopping

Through a method known as doctor shopping, drug users continuously switch physicians, obtaining excessive amounts of prescription drugs. After obtaining the prescription drugs, doctor shoppers either take the medication themselves or sell the pills for a lucrative profit. Doctor shoppers sometimes start out with legitimate medical needs, but become dependent on the drugs, thereby seeking more and more drugs to feed their addiction. Other doctor shoppers may fraudulently obtain prescription drugs for non-medical recreational use. In doing so, the drug seekers use forged medical records, fake test results, or fake identification to justify their needs for prescriptions. Finally, the purely profit-driven doctor shoppers may obtain prescriptions only to turn around and sell them to other drug users for a higher price. Regardless of the motive, without a record of the prescriptions, prescribing doctors or pharmacists may be unaware of the patient’s additional active prescriptions. Thus, addicts and drug dealers posing as patients with legitimate medical needs are able to take advantage of the system.

23. Prescription Drugs Hearing, supra note 7, at 1.
24. NIDA, supra note 7, at 1 (emphasis added).
25. See CS for HB 897 Staff Analysis, supra note 15, at 3.
26. Id. According to the United States General Accounting Office, “[d]iversion activities can include ‘doctor shopping’ by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, prescription forgery, and purchasing drugs from Internet pharmacies without valid prescriptions.” Prescription Drugs Hearing, supra note 7, at 1.
27. See Vanessa Blum, These ‘Tourists’ Seek Pain Drugs, ORLANDO SENTINEL, Dec. 4, 2006, at B7. Prescription pills like oxycodone can sell for “almost 10 times what they cost at a pharmacy.” Id.
28. See CS for HB 897 Staff Analysis, supra note 15, at 3.
29. Id. at 3–4.
30. Scott Hiaasen, Pills from S. Fla. Flood Appalachian States, MIAMI HERALD, Apr. 6, 2009, at 1A [hereinafter Hiaasen, Appalachian States].
31. Id.
32. See CS for HB 897 Staff Analysis, supra note 15, at 3.
33. See id.
2. Pill Mills

Adding to the Black Market sale of illegal prescription drugs are pain clinics that deal out prescriptions without thoroughly examining patients. Adding to the Black Market sale of illegal prescription drugs are pain clinics that deal out prescriptions without thoroughly examining patients. At these pill mills, doctors—"dispensing practitioners"—have special authority to dispense the controlled substances directly to the patients, without any pharmacist intervention. Describing a typical "pill mill," investigators say that many are now "disguised as independent pain-management centers." Furthermore, certain "signs" make pill mills distinguishable: cash only, no physical exams, treatment with pills only from "their" pharmacy, and huge crowds of people waiting to be seen.

As an example, in Deonarine v. State, the defendant, a physician, was convicted of drug trafficking in a controlled substance after evidence revealed that he wrote multiple prescriptions for controlled substances in bad faith. Following the death of one of the defendant’s patients from a drug overdose, suspicious law enforcement officials reviewed the pharmacy and medical records of the patient and began investigating the defendant. One patient’s testimony revealed that the defendant “did not review her general medical history, . . . did not inquire about her limitations in activity, and did not discuss alternatives to pain medication.” Subsequently, after severing the doctor-patient relationship with the patient, the defendant continued to write regular prescriptions for the patient, even increasing the patient’s prescription doses. Furthermore, evidence showed that the defendant was aware that the patient “was using multiple pharmacies to fill the prescriptions.” This incident, which occurred in South Florida, reveals the “dangers of prescription drug abuse.” Furthermore, although Deonarine exemplifies Florida’s awareness and efforts to restrain prescription drug abuse, how successful are these measures in curbing such illegal activity?

34. Hiaasen, Inside Broward’s Pill Mills, supra note 9 (discussing how investigators predict many of these pill mills “feed narcotics to 65 patients a day or more”).
35. Id.
37. Id.
38. 967 So. 2d 333 (Fla. 4th Dist. Ct. App. 2007).
39. Id. at 335–36.
40. Id. at 334.
41. Id. at 335.
42. Id.
43. Deonarine, 967 So. 2d at 335.
44. Id. at 334.
45. Id.
B. Florida: A Magnet for Doctor Shoppers and Pill Mills

   1. Intrastate Problem

While abuse of prescription drugs is a nationwide problem, the Drug Enforcement Administration specifically notes the high concentration of doctor shopping and pill mills in Florida. The Drug Enforcement Administration estimates that in the past year, the number of pain clinics in Florida—South Florida in particular—has skyrocketed from 60 to 150. Furthermore, within six months in 2008, Broward County doctors dispensed upwards of 6.5 million oxycodone pills, which equals roughly “four pills for every Broward resident.” According to additional data from the Drug Enforcement Administration, Florida distributes more oxycodone than any other state. Mark Trouville, a Drug Enforcement Administration special agent, discussed how just forty-five doctors in South Florida dispensed about nine million oxycodone pills in six months. Dr. Charles Grudem, a board member of the Florida Society of Interventional Pain Physicians, calls this behavior “[t]otally suspicious.”

Furthermore, prescription drug overdoses in Florida alone climbed from 2780 in 2006, to 3317 in 2007, to about 4000 in 2008. According to experts, “[T]he growth in unscrupulous pain clinics is contributing to a rise in prescription drug overdoses.” Furthermore, police reported that over “4,000 Floridians died from prescription drug overdoses last year, about 11 a day, up by 20 percent over the year before.”

   2. Interstate Problem

Florida pill mills and doctor shopping do not stop at state borders. Rather, “travelers come [to Florida] by the thousands, narcotics investigators

46. What’s a Pill Mill?, supra note 36.
47. Hiaasen, Inside Broward’s Pill Mills, supra note 9. With Broward County alone having eighty-nine pain clinics, Hollywood Police Captain, David Siegel, stated, “Broward County has become the Colombia for pharmaceutically diverted drugs.” Id.
48. Id.
49. Id.
50. Id.
52. Bob LaMendola, Profiting from Pain: Clinics Face Scrutiny, SUN-SENTINEL, Apr. 7, 2009, at 1A [hereinafter LaMendola, Profiting from Pain].
53. Id.
54. Id.
55. See Hiaasen, Appalachian States, supra note 30. Rick Zenuch, an agent with the Florida Department of Law Enforcement, stated, “We’ve seen people coming from all over

Published by NSUWorks, 2010
say, from Kentucky, Ohio, West Virginia, Massachusetts and other states because of Florida’s “lax oversight of prescription drugs.” This “‘drug run’ phenomenon in South Florida” contributes to the “startling rise in prescription-drug overdose deaths in Florida, including [the] 107 percent jump in oxycodone deaths in two years.”

In April 2009, a sting operation dubbed “Operation Pill Crusher,” involving both state police and officers from the Drug Enforcement Administration, resulted in the arrest of two dozen alleged drug dealers who traveled from Kentucky to Florida to obtain prescription drugs from Florida’s pill mills. Charged with “trafficking in a controlled substance,” these individuals are only a handful of the thousands of Kentuckians suspected of traveling to South Florida to obtain prescription drugs.

A recent Miami Herald article reported that “Dr. Roger Browne was once one of Kentucky’s most popular pain doctors.” No startling fact—however—until one considers that Dr. Browne’s office was over eight hundred miles away from Kentucky. In fact, Dr. Browne’s pain clinic, American Health and Rehabilitation, was located in Coral Springs, Florida. Dr. Browne’s pain clinic is just one of the many Florida pain clinics that has become popular with out-of-state patients. For instance, some Florida pain clinics post signs boasting such obvious tip-offs as “Out of State Patients Welcome” and “No Wait for Walk-Ins.” These pill mills lure drug seekers with promises of on-site drug dispensing, “with coupons and discounts advertised in the back pages of alternative weekly newspapers, or on bus benches and billboards,” and even with gasoline vouchers for travelers. With such sales tactics as these, it is no wonder why out-of-state drug seekers and addicts travel across the country to obtain prescription drugs from Florida pain clinics.

57. Blum, supra note 27.
58. Blum, supra note 27. Furthermore, “[t]he unwanted tourism alarms state officials who have watched deaths from prescription pain medication skyrocket in recent years.” Id.
61. Id.
63. Id.
64. Id.
65. Id.
67. Id.
C. The Need for Regulation

With the rampant spread of prescription drug abuse, many states have implemented strict monitoring programs or criminal punishments for doctor shoppers and pill mill participants. Concerned not just with the overdosing of particular prescription drugs, experts are also worried about the dangerous effects of combining different prescription drugs, such as Methadone, Xanax, Valium, and Oxycodone. The improper dispensing, misuse, or diversion of prescription drugs can be deadly, especially when a pharmacist or practitioner is unaware of a patient’s prescription drug medication history.

1. Prescription Drug Monitoring Programs

Although prescription drug abuse and deaths have become a major problem in Florida, until recently, Florida lacked a prescription drug monitoring program. Sergeant Lisa McElhaney of the Broward Sheriff’s Office commented, “We are source-supplying many other states. This is literally embarrassing.” The [Florida] system has enabled this. Before June of 2009, Florida was one of only twelve states that lacked a database to regulate prescription drugs. Many individuals postulate that the reason drug dealers are making thousands of dollars for each trip to Florida is because Florida lacks a tracking system. Representative Kelly Skidmore of Boca Raton, Florida, one of the co-sponsors of a proposed drug monitoring bill, commented, “Shame on us for letting it get this far. . . . We don’t want every other state to view Florida as the pharmacy for illegal pain medications.” Additionally, prescription drug abuse and “diversion hurts [Florida] significantly in terms of lost lives, increased crime, human misery from addiction,
and ballooning health care costs connected to treatment, medical expenses, and Medicaid fraud that all Floridians ultimately bear.\footnote{77} In the thirty-eight other states that have enacted prescription-drug-monitoring programs, prescription data is electronically monitored and available for review and analysis for educational, public health, and investigational purposes.\footnote{78} While each state’s systems enact slightly different rules and procedures, the drug-monitoring programs’ “primary goal[s] [are] to identify forged prescriptions and to expose so-called doctor shoppers who visit multiple physicians and pharmacies seeking drugs . . . [by requiring] doctors to submit [prescription] information . . . to a centralized database.”\footnote{79}

2. How Florida Measures Up

Chapter 893 of \textit{Florida Statutes}, the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances “into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.”\footnote{80} Section 893.04, pertaining to pharmacists, authorizes pharmacists “in good faith and in the course of professional practice only, [to] dispense controlled substances upon a written or oral prescription of a practitioner” under specified conditions.\footnote{81} Furthermore, prescriptions for controlled substances must include the date, signature of the prescribing practitioner, and other relevant information about the patient and the prescription.\footnote{82} A similar section, section 893.05, pertaining to practitioners, allows such practitioners “in good faith and in the course of his or her professional practice only, [to] prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.”\footnote{83}

\footnote{79} Blum, \textit{supra} note 27.
\footnote{80} CS for HB 897 Staff Analysis, \textit{supra} note 15, at 2.
\footnote{81} FLA. STAT. § 893.04(1) (2009).
\footnote{82} \textit{Id.} § 893.04(1)(a)–(b). Such information includes the name and address of the patient, the name and address of the prescribing practitioner, the name, strength, quantity, and directions for use of the controlled substance, and the number of the prescription. \textit{Id.} § 893.04(1)(e)1–6.
\footnote{83} \textit{Id.} § 893.05(1).
Furthermore, Chapter 893 specifically targets doctor shoppers in section 893.13. For instance, section 893.13(7)(a) declares it unlawful for any person:

[t]o withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

In *Limbaugh v. State*, a widely recognized talk show host, Rush Limbaugh, was put under investigation for violating Florida’s “doctor shopping” statute. Police received information that individuals “had sold [Limbaugh] ‘large quantities’ of Hydrocodone and Oxycontin ‘over the course of many years.’” Police investigations then revealed that Limbaugh had received controlled substance prescriptions “from four different physicians within a five-month period.” With this information at hand, police officers acquired a search warrant and obtained Limbaugh’s medical records. Objecting to the seizure of his medical records, Limbaugh claimed that the police violated his “right of privacy in personal medical affairs.” However, in response, the Fourth District Court of Appeal held that in this situation, “the constitutional right of privacy in medical records is not implicated by the State’s seizure and review of medical records.” Such strict enforcement of section 893.13 reveals the State’s eagerness to prevent the widespread prescription drug problem.

However, although Chapter 893 does impose certain limitations and restrictions on controlled substance prescriptions, it has often been viewed as useless—lacking any type of prescription drug monitoring database. While

84. See id. § 893.13.
85. FLA. STAT. § 893.13(7)(a)8. Section 893.13(7)(a)9 further declares it unlawful for any person to “acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.” Id. § 893.13(7)(a)9.
86. 887 So. 2d 387 (Fla. 4th Dist. Ct. App. 2004).
87. Id. at 389.
88. Id.
89. Id.
90. Id. at 390.
91. Limbaugh, 887 So. 2d at 390.
92. Id. at 398.
93. See id.
94. See Blum, supra note 27. Dr. Miguel, a University of South Florida professor of pain medicine, called such legislative inaction, “infuriating and depressing,” stating, “You have to
Bill Janes, director of the Florida Office of Drug Control, discussed that, a “prescription-tracking system is not a cure-all,” he nevertheless stated that it “could help prevent doctors and pharmacists from unwittingly aiding addicts and drug dealers.” Other Florida lawmakers and supporters of stricter regulations have made prescription drug monitoring a top priority. Furthermore, non-Florida residents have also expressed their desire for a drug monitoring program in Florida in order to control the rampant drug trafficking link between Florida and their own states. Discussing how important a Florida prescription database is to the State of Kentucky, David Mongiardo, Kentucky Lieutenant Governor, stated, “This is a major piece of legislation that we have to have in order to protect our [own] citizens.”

III. SECTION 893.055

A. Legislative History

After rejecting similar prescription drug monitoring bills for years, the Florida Legislature passed Senate Bill 462—Prescription Drugs Act—in June of 2009. The new legislation requires the State to create a prescription drug monitoring database. Sponsored by Senator Mike Fasano, among others, Senate Bill 462 creates section 893.055 and is designed to combat Florida’s problem with pill mills and doctor shopping. One of the bill’s supporters, Representative Marcelo Llorente of Miami, Florida, commented, “[T]he legislation will eliminate pill mills or pain clinics that are dispensing drugs in a ‘reckless manner and enabling the tragic deaths of countless people.’”

Included in the text of the bill are several “whereas clauses,” provide Florida doctors with tools so they can safely prescribe these medications and know they’re in the right hands.” However, in Dr. Miguel’s opinion, “Right now, doctors are being made unwilling and unknowing participants in the drug trade.”

95. Id. Furthermore, “if criminal activity were suspected, police could get evidence much faster.” Id. 96. See Blum, supra note 27. 97. See Honeycutt, Virginia Hacker, supra note 78. 98. Id. According to Kentucky officials, drug addicts and dealers in Kentucky swarm to Florida to avoid the Kentucky All Schedule Prescription Electronic Reporting System, KASPER. Id. 99. See LaMendola, Governor Signs Law, supra note 4. 100. See FLA. STAT. § 893.055(2)(a) (2009). 101. See CS for SB 462 Staff Analysis, supra note 5, at 1; Editorial, A Bill Crist Can Sign Easily, PALM BEACH POST, June 9, 2009, at A8 (noting that Senate Bill 462 passed unanimously in the Senate and 110 to 10 in the House). 102. Deborah Circelli, State Targets ‘Doctor Shopping’, NEWS JOURNAL (Daytona Beach), June 9, 2009, at C1.
explaining the purpose for creating the prescription drug monitoring system.\textsuperscript{103}

WHEREAS, it is the intent of the Legislature to encourage patient safety, responsible pain management, and proper access to useful prescription drugs that are prescribed by a knowledgeable, properly licensed health care practitioner who dispenses prescription drugs and that are dispensed by a pharmacist who is made aware of the patient’s prescription drug medication history, thus preventing, in some cases, an abuse or addiction problem from developing or worsening, making such a problem possible or easier to identify, and facilitating the order of appropriate medical treatment or referral.\textsuperscript{104}

After passing unanimously in the Senate and 100 to 10 in the House, Senate Bill 462 was sent to Florida Governor, Charlie Crist, for approval.\textsuperscript{105} Despite the cries of opponents who believed that the proposed measures would do little to “solve Florida’s pill-mill problem,” Governor Crist signed the legislation on June 18, 2009.\textsuperscript{106}

B. Prescription Drug Validation Program

Subsection 893.055(2)(a) requires the Department of Health, by December 1, 2010, to

design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient’s health care practi-
As "part of a prescription drug validation program," the monitoring system will provide prescription information for "controlled substances in order to prevent the inadvertent, improper, or illegal use of controlled substances." More specifically, subsections 893.055(3)(a)–(g) require that each time a controlled substance is dispensed to a patient, the prescription information—such as the name of prescribing practitioner, date, method of payment, patient’s name, patient’s address and date of birth, and pharmacy information—must be reported through the database system. This reporting must be done as soon as possible, "but not more than 15 days after the date the controlled substance [was] dispensed," unless there is an approved exception.

Additionally, the Florida Office of Drug Control, along with the Department of Health, "may establish a direct-support organization to provide assistance, funding, and promotional support for activities authorized for the prescription drug validation program." Once "the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription drug monitoring program," the Department of Health will adopt the specific rules for "reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system." Aside from


108. CS for SB 462 Staff Analysis, supra note 5, at 1. However, this system must not interfere with good faith controlled substance prescriptions made by prescribing or dispensing practitioners or dispensing pharmacists. Id.

109. FLA. STAT. § 893.055(3)(a)–(g).

110. Id. § 893.055(4).

111. CS for SB 462 Staff Analysis, supra note 5, at 8.

112. FLA. STAT. § 893.055(2)(b). "All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. . . . The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding." Id. § 893.055(10).
providing funding, the direct-support organization will also assist and support promotions for the prescription drug monitoring system.113

The system must comply with the standards of the American Society for Automation in Pharmacy—ASAP—and with the Health Insurance Portability and Accountability Act—HIPAA—along with any additional state and federal privacy or security laws.114

Furthermore, subsection 893.055(9) declares it a first degree misdemeanor offense for individuals who “willfully and knowingly fail[] to report the dispensing of a controlled substance as required by” section 893.055.115 However, subsection 893.055(5)(a)–(f) provides a list of those who are exempt from the reporting requirements.116

Pharmacies, prescribers, or dispensers will have access to the information on the database relating to a specific patient of that pharmacy, prescriber, or dispenser.117 However, other access to the database is limited to the prescription drug program manager or staff in furtherance of managing the monitoring program.118 Upon approval from the program manager, certain other entities such as the Department of Health, the Attorney General, a “law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft [of] prescribed controlled substances,” or a patient or legal guardian may have direct access to the information on the monitoring database.119

113. Id. § 893.055(11)(d)7.
114. Id. § 893.055(2)(a).
115. Id. § 893.055(9).
(a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session. (b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital ... which is licensed in this state. (c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections. (d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital. (e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16. (f) A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.
Id.
118. Id.
119. Id. § 893.055(7)(c)1–4.
C. Rulemaking Authority

Along with creating section 893.055 of the Florida Statutes, Senate Bill 462 amended sections 458.309 and 459.005. The new legislation requires “[a]ll privately owned pain-management clinics, facilities, or offices” engaged in prescribing or dispensing controlled substances for pain treatment to register with the Department of Health by January 4, 2010, unless the facility “is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.”

The amendment to section 458.309 subjects pain clinics to annual inspections by the Department of Health to ensure proper compliance with the Board of Medicine. Furthermore, the amendment requires the Board of Medicine to adopt rules and standards of practice for physicians involved in pain treatment. Although not limited to these subjects, the rules created by the Board of Medicine must, at a minimum, address: “(a) Facility operations; (b) Physical operations; (c) Infection control requirements; (d) Health and safety requirements; (e) Quality assurance requirements; (f) Patient records; (g) Training requirements for all facility health care practitioners who are not regulated by another board; (h) Inspections; and (i) Data collection and reporting requirements.”

A very similar amendment to section 459.005 provides for the same rules and regulations, but it applies to the Board of Osteopathic Medicine, rather than the Board of Medicine.

IV. OPPONENTS OF SECTION 893.055

A. The Critics’ Perspectives

Representative Carl Domino of Jupiter, Florida was among the ten Florida State Representatives who voted against Senate Bill 462. Representative...
tive Domino, the sponsor of a competing bill, House Bill 143,\textsuperscript{128} feels that section 893.055 is "designed not to work," and that the legislation "creates a false sense of security."\textsuperscript{129} Joining in the fight against Senate Bill 462 are many vocal lawmakers, drug experts, and citizens who have expressed similar concerns.\textsuperscript{130}

Chief among the critics’ concerns with the new legislation is the potential for security breaches.\textsuperscript{131} Although section 893.055 gives the Department of Health until December 1, 2010 to design the specific requirements for the electronic database system, the legislation does list certain minimum information that \textit{must} be included in the database.\textsuperscript{132} It is the personal and medical information—name, address, date of birth, method of payment, prescription quantity and strength, for example—that has people worried about violations of privacy rights and the potential for abuse.\textsuperscript{133} Representative Domino warned, "Think of the consequences of an out-of-control state employee who chooses to access this database and make public highly sensitive personal information. Even more troubling is the potential for hackers to infiltrate."\textsuperscript{134}

1. Virginia Hacker

Ironically, amidst a push for Governor Crist to veto section 893.055, these very same privacy concerns became reality for the citizens of Virginia.\textsuperscript{135} According to reports, "the records of 8 million patients were stolen from Virginia’s prescription-monitoring system when a computer hacker

\textsuperscript{128} Domino/Aronberg Prescription Drug Validation Plan Saves Lives, Protects Privacy, Costs Less, PR NEWSWIRE, Mar. 24, 2009 [hereinafter Prescription Drug Validation Plan]. Senate Bill 614, sponsored by Senator Dave Aronberg of Greenacres, Florida, is the analogous Senate version of Representative Carl Domino’s House Bill 143. \textit{Id.}

\textsuperscript{129} Editorial, \textit{A Bill Crist Can Sign Easily}, supra note 101.

\textsuperscript{130} \textit{See} Circelli, \textit{supra} note 102.


\textsuperscript{132} \textit{See} Fla. STAT. § 893.055(3)(a)-(g) (2009).

\textsuperscript{133} \textit{See} id.; \textit{see also} Letter from Ellyn Bogdanoff et al., to Charlie Crist, \textit{supra} note 131.


\textsuperscript{135} \textit{See} Honeycutt, \textit{Virginia Hacker}, \textit{supra} note 78. "[O]n April 30, the same day that the Florida General Assembly passed legislation to create a monitoring system, [a] hacker posted a message on Virginia’s monitoring system saying he had stolen millions of prescription records." \textit{Id.}
broke into it and demanded a $10 million ransom.”  

Although it is reported that the Virginia database contained no patient medical histories, the database “does list names, addresses, and in some cases, Social Security numbers of patients who received prescriptions for painkillers, such as OxyContin.”

Prompted by the hacking incident in Virginia, thirteen Florida lawmakers urgently sent Governor Charlie Crist a letter on May 7, 2009, expressing their concerns.

We respectfully request that you veto Senate Bill (SB) 462 entitled Prescription Drugs/Electronic Monitoring/DOH. This request is based on a well founded fear that the sensitive personal and medical information contained in such a database would be susceptible to cyber terrorists and criminals who would use such information against the citizens of Florida. . . . Unfortunately, our fears were reinforced this past week when hackers broke into a Virginia database, similar to the one proposed by SB 462, used to track prescription drug abuse. . . . While proponents of SB 462 promise a secure database, any online security expert will tell you there is no such thing as a completely secure database. . . . By allowing Senate Bill (SB) 462 to become law . . . you will expand government further into the private lives of our citizens, and seriously undermine the safety and security of Floridians’ personal and private medical records.

However, Representative Kelly Skidmore of Boca Raton, Florida, who co-sponsored Senate Bill 462, addressed these concerns and discussed how under the proposed system, the names of the buyers, the drugs, and the dates

136. Id. Furthermore, the hacker threatened that if he didn’t get the money, “he would sell the information to the highest bidder.” Id.
137. Id. The Virginia database “has not been operational since” the incident. Honeycutt, Virginia Hacker, supra note 78.
138. See Letter from Ellyn Bogdanoff et al., to Charlie Crist, supra note 131.
139. Id. (emphasis added). Representative Carl Domino, one of the individuals who signed the letter to Governor Crist, sent a similar e-mail to Bill Janes, Director of Florida Office of Drug Control, and supporter of Senate Bill 462. See E-mail from Carl Domino, Florida State Representative, Dist. 83, to Bill Janes, Director, Florida Office of Drug Control (May 7, 2009, 3:46:21 PM), available at http://www.postonpolitics.com/wp-content/uploads/2009/05/from-rep-carl-domino-district-83.pdf. In this e-mail, Representative Domino pleas:

I am now asking you to join me in asking the Governor to veto [Senate Bill] 462 as it clearly poses a significant risk to constitutionally[ic] guarantees of privacy for our citizens. If you still feel that the bill should go into law please advise me why and what steps you propose to take to ensure that the Florida data base does not have similar risks.

Id.
would be separate. Representative Skidmore stated, "Even if someone hacked the system . . . they could get only one piece."  

2. Other Potential Loopholes in Section 893.055

Aside from the possibility of invading one’s privacy, section 893.055 of is thought by some to be deficient in other areas as well. For instance, although the bill went into effect July 1, 2009, the Department of Health has until December 1, 2010 to create the rules and procedures for implementing the electronic database. Paul Sloan, a Venice pain clinic owner and organizer of the Florida Society of Pain Management Providers, says, "The bill is useless as it is now . . . [and] will be ineffective in shutting down pill mills. Pill mills will be completely unaffected." Additional time-related concerns stem from the fact that "[e]ach time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department . . . not more than 15 days after the date the controlled substance is dispensed." With this delay, critics warn that "[s]ellers have 14 days to [log] a prescription, giving abusers plenty of time to make the rounds obtaining drugs before anyone can catch on."  

Also, critics worry that the legislation does nothing to prevent buyers from using fake identification to obtain and hide multiple buys. Furthermore, the penalty for a seller who skips entering prescriptions into the database is a mere misdemeanor. 

Lastly, patients with legitimate medical needs fear the effects this new legislation will have on the availability and accessibility of treatment.

141. Id.
142. See Prescription Drug Validation Plan, supra note 128.
143. See Fla. STAT. § 893.055(2)(a) (2009).
144. LaMendola, Governor Signs Law, supra note 4.
145. See Fla. STAT. § 893.055(4); see also LaMendola, Governor Signs Law, supra note 4.
146. LaMendola, Governor Signs Law, supra note 4.
147. Id.
148. Id.; see also Fla. STAT. § 893.055(9).
149. See Blum, supra note 27. However, addressing these concerns, a "whereas clause" from Senate Bill 462 states:

[The intent of this act is not to interfere with the legitimate medical use of controlled substances; however, the people of this state are in need of and will benefit from a secure and privacy-protected statewide electronic system of specified prescription drug medication information created primarily to encourage safer controlled substance prescription decisions that reduce the number of prescription drug overdoses and the number of drug overdose deaths . . . .

Because pain treatment is often impossible to measure objectively, critics worry that the new legislation may inadvertently prevent those who truly need the drugs from being able to obtain a prescription.\textsuperscript{150}

B. \textit{Alternative Options: Biometric Identification}

Although supporters and opponents of the bill share a common goal—the monitoring and regulation of prescription drug abuse—they disagree about the best method to achieve this goal.\textsuperscript{151} Florida House Bill 143, Monitoring the Dispensing of Controlled Substances,\textsuperscript{152} proposes an alternative to Senate Bill 462.\textsuperscript{153} Under House Bill 143, the database system would use biometric identification technology to immediately monitor the dispensing and purchasing of dangerous drugs.\textsuperscript{154} Although House Bill 143, sponsored by Representative Carl Domino of Jupiter, died in Committee on Health Care Regulation Policy, its innovative technological approach to the prescription drug war opens the doors for discussion.\textsuperscript{155}

The biometric identification system proposed under House Bill 143 would “require dispensers to use . . . biometric scanning devices—fingerprints or retinal scans, for example—to biologically identify people attempting to fill prescriptions for . . . controlled substances.”\textsuperscript{156} A Florida Department of Health database would “assign a unique identification number to the biometric scan” while simultaneously “convey[ing] this information back to the prescriber.”\textsuperscript{157} This unique identification number would provide pharmacists or dispensers with immediate detection of prescription conflicts, overlaps, and fraud.\textsuperscript{158} Because the encrypted information in the biometric database would be assigned a number rather than a name, proponents feel this measure fights fraud and ensures patient safety more efficiently than section 893.055.\textsuperscript{159} Furthermore, supporters of the proposed bill assure that

\textsuperscript{150} See Blum, supra note 27.
\textsuperscript{151} See Domino, supra note 134 (discussing an alternative proposal for prescription drug monitoring).
\textsuperscript{152} H.R. 143, 2009 Leg., Reg. Sess. ( Fla. 2009).
\textsuperscript{153} See id. Proposed by Senator Dave Aronberg, Senate Bill 614 was the analogous version of House Bill 143. LaMendola, Profiting from Pain, supra note 52.
\textsuperscript{154} See Domino, supra note 134.
\textsuperscript{155} See Fla. H.R. 143.
\textsuperscript{156} Prescription Drug Validation Plan, supra note 128.
\textsuperscript{157} Id.; see also Fla. H.R. 143.
\textsuperscript{158} Prescription Drug Validation Plan, supra note 128.
\textsuperscript{159} Dara Kam, Lawmaker’s Measure Would Drive Drug ID Business to One Firm, PALM BEACH POST, Feb. 6, 2009, at A1. Calling the alternative legislation, section 893.055 of the Florida Statutes, “old-fashioned,” Representative Domino stated, “Our stronger approach precludes the filling of multiple prescriptions. The biometric identification would be re-
even if someone hacked into the database, the advanced technology of the biometric system would prevent individual identities from being revealed.\textsuperscript{160}

However, looking beyond the novelty of this proposed method, opponents such as pharmacists are troubled by the costs to implement the biometric database.\textsuperscript{161} The biometric identification equipment could cost anywhere “from $300 to $700 per unit,” along with the regular “monthly software subscription service” which could cost between $50 and $150.\textsuperscript{162} But, supporters believe this is but a small price to pay for the lives that will be saved:

Well-heeled supporters of the old technology have thrown up roadblocks against the new state-of-the-art system. Some have argued that the small cost would cripple their profits. It amazes me that anybody would fight for profits while people are dying. Lives are on the line. It’s critical for Florida to get this right. We can choose the worn-out approach and, after more people die and privacy is compromised, come back in a couple of years and fix it. Or we can take the right path, protect privacy, curb doctor shopping and save lives.\textsuperscript{163}

According to Senator Aronberg, “Patients shouldn’t have to fear the prescriptions they are taking to make them well. This legislation creates a 21st century safety net to ensure the drugs they are given are just what the doctor ordered.”\textsuperscript{164} Similarly, Representative Carl Domino commented, “New technology is less costly, protects consumer privacy, and is in real time and cannot be defeated by a false identification.”\textsuperscript{165} However, despite the pleas from advocates urging lawmakers to adopt this alternative biometric identifying database system, section 893.055 of the \textit{Florida Statutes} went into effect on July 1, 2009.\textsuperscript{166}
While some critics remain skeptical about the new legislation, others are satisfied that at least some measures have finally been taken to combat the prescription drug war. Daytona Beach Police Chief, Mike Chitwood, mentioned that he would prefer the fingerprinting system, “but [he will] take anything [he] can get [his] hands on now.” Similarly, Senator Aronberg stated, “We need to ensure that Florida’s system uses top-of-the-line technology to eliminate the threat from hackers. The bill I proposed would have done so, and the bill that ultimately passed, can do so as well.” Former Governor of Florida, Jeb Bush, applauded lawmakers for passing the bill and commented that he had not “seen the details, . . . but if it is comprehensive and implemented correctly, it will save lives.”

V. LOOKING FORWARD

With the Department of Health having until December 1, 2010 to design and establish the comprehensive electronic database system, what will happen in the meantime to the tourist-friendly pill mills and drug-seeking doctor shoppers? On July 27, 2009, just weeks after the legislation went into effect, local Florida newspapers reported that pain clinics already began experiencing a drop in business. After P.S. Drugs, a Fort Lauderdale pharmacy, posted notices that it would “no longer fill certain prescriptions for out-of-state visitors,” Bruce Derby, the manager of the pharmacy, reported that “[b]usiness has dropped about 20 percent in the past month.” However, for vigilant law abiders like Derby, the drop in business is worthwhile if it prevents prescription pill traffickers from coming to Florida to obtain drugs.

Although many other pharmacies have adopted similar policies barring out-of-state residents from obtaining prescriptions, this practice may too have its drawbacks. For instance, Florida is home to many winter residents and extended-stay tourists who may have no other access to prescrip-

168. Circelli, supra note 102.
170. Id.
172. Id.
173. See id. Derby stated, “It’s about having a feeling of comfort about not filling those prescriptions.” Id.
174. See id.
175. See Santana, supra note 171.
Also, not every out-of-state tourist who visits a Florida pain clinic has doctor shopping in mind; some tourists have legitimate medical needs. Furthermore, without servicing non-Florida residents, the smaller “mom-and-pop pharmacies” may find it hard to compete with the larger national chain pharmacies.

However, not all pain clinics have experienced a drop in business since the enactment of section 893.055. In early March, 2010, agents from a regional task force raided three South Florida pain clinics that brought in over fourteen million dollars in cash within the past year. While agents seized truckloads of reports, computers, and pain clinic paraphernalia, confused drug seekers continuously arrived and quickly left throughout the day.

Recognizing that it may be years before section 893.055 of the Florida Statutes takes full effect, some cities, like Dania Beach, are currently in the process of adopting and implementing city rules to discourage future pill mill pain clinics from opening. In Dania Beach, the proposed law would prevent future pain clinics from opening in redevelopment areas of the city, mainly tourist and shopping areas. Furthermore, the law would prevent on-site dispensing of pain medication—a service typically geared towards doctor shoppers. While awaiting the effects of the proposed law, Dania Beach already issued a moratorium, or freeze, on pain clinics in April of 2009. Other cities, like Coconut Creek and Oakland Park, appear interest-

176. Id.
177. Id.
178. Id. For some struggling, smaller, and independent pharmacies, “the only way they’re surviving is by putting out oxycodone,” stated Broward Sheriff’s Office Sergeant, Richard Pisanti. Id.
179. See Santana, supra note 171. After passing unanimously in the Senate and 100 to 10 in the House, Senate Bill 462 was sent to Florida Governor, Charlie Crist, for approval. Editorial, A Bill Crist Can Sign Easily, supra note 101. Despite the cries of opponents who believed that the proposed measures would do little to “solve Florida’s pill-mill problem,” Governor Crist signed the legislation on June 18, 2009. LaMendola, Governor Signs Law, supra note 4.
180. Bob LaMendola, Pain Pills Worth Millions to 3 Clinics, SUN-SENTINEL, Mar. 5, 2010, at 1D.
181. See id.
182. See lhosvani Rodriguez, Dania Expected to OK Pain Clinic Curbs Today – Measure Would Prohibit the Dispensing of Pills and Restrict Locations, SUN-SENTINEL, July 28, 2009, at 1B. According to the Sun-Sentinel, Dania Beach would “become the first [city] in Broward [County] to pass a law clamping down on pain clinics, limiting where they may open and prohibiting them from dispensing pills.” Id.
183. Id.
184. Id.
185. Id.
ed in taking similar measures.\textsuperscript{186} Dania Beach Mayor, Anne Castro, believes that "everyone is going to start adopting these laws soon."\textsuperscript{187}

Furthermore, although the Department of Health must wait until sufficient funds have been raised to set up the electronic database system, the Department has already begun implementing other aspects of the law.\textsuperscript{188} The Florida Boards of Medicine and Osteopathic Medicine recently appointed seven Florida doctors\textsuperscript{189} to handle the rule-making procedures, specifically, designing the state-wide registration requirements for pain practitioners.\textsuperscript{190} The new legislation requires all privately owned clinics advertising pain-management services, or employing physicians that treat pain by prescribing or dispensing controlled substances, to register with the state and undergo regular inspections.\textsuperscript{191} Not only will the panel develop the applications for pain clinics to register with the state, but also "[i]t will decide health and safety requirements, the kinds of data clinics will have to report, how inspections will be conducted and what the fees will be."\textsuperscript{192} As of January 2010, about four hundred pain clinics had registered with the Florida Department of Health, disclosed their owners, and prepared for inspection.\textsuperscript{193} Chairman of the state panel, Fred Bearison, optimistically reported, "[t]hey are going to get inspected every year, and the inspectors can make sure they are following the new guidelines we set up—and that's going to help keep them in line."\textsuperscript{194}

VI. CONCLUSION

Following the grim statistics from the past decade, Florida lawmakers and officials had no choice but to take stronger action against prescription drug abuse. With the enactment of section 893.055 of the \textit{Florida Statutes}, it appears that Florida has made progress in its fight against the prescription drug abuse crisis.

\textsuperscript{186} Rodriguez, supra note 182. In September, officials in Coconut Creek will evaluate a previously imposed moratorium on similar pain clinics. \textit{Id.} Meanwhile, Oakland Park, home to "18 pain clinics within a two-mile radius," considered a moratorium, but decided against it because of the difficulty in distinguishing between pill mills and legitimate medical clinics. \textit{Id.}

\textsuperscript{187} \textit{Id.}


\textsuperscript{189} \textit{Id.} The seven doctors include: Fred Bearison, Robert Cline, Onelia Lage, Steven Rosenberg, John Beebe, Allan R. Escher, and Robert McCann. \textit{Id.}

\textsuperscript{190} \textit{Id.}

\textsuperscript{191} \textit{Id.}

\textsuperscript{192} Gentry, supra note 188.

\textsuperscript{193} Bob LaMendola, \textit{Pain Clinic Clean-Up Begins-400 Join Registry, but Many Don't Bother}, \textit{SUN-SENTINEL}, Jan. 6, 2010, at 1D.

\textsuperscript{194} \textit{Id.}
drug problem. Although the critics of this legislation have expressed legitimate concerns, many nonetheless remain hopeful that section 893.055 is a step in the right direction. Joined by a common goal—the control of prescription drug diversion—supporters and opponents of the new legislation agree that something needed to be done to end the prescription drug war in Florida. Critics and supporters alike recognize that section 893.055 will not automatically fix prescription drug abuse. Palm Beach County Sheriff’s Office narcotics agent, Robert Banuchi, stated, “It’s not a cure-all, and we still have to get it up and running.” It may take weeks, months, or even years for section 893.055 to make a substantial impact on Florida’s prescription drug problem. However, section 893.055—if nothing else—provides a stepping stone for the proactive measures that Florida must continue to take to stop prescription drug abuse.

EVERY WOMAN DESERVES HER OWN PAIR OF GENES:  
THE CONSTITUTIONALITY OF PATENTING THE BRCA  
GENES IN ASSOCIATION FOR MOLECULAR PATHOLOGY V.  
U.S. PATENT & TRADEMARK OFFICE

MORGAN GELLER*

I. INTRODUCTION ........................................................................................................ 766

II. HISTORY AND CONSTITUTIONAL PRINCIPLES OF PATENT LAW,  
DNA, AND THE BRCA GENES ................................................................................. 769
   A. Defining and Interpreting Genes and Patentable Subject  
      Matter ............................................................................................................... 769
   B. Myriad Problems .............................................................................................. 771
   C. Impeding the Progress of Science and the Useful Arts .................. 773
      1. The Need for Dynamic Constitutional Interpretation ...... 776

III. NOVEL LEGAL CHALLENGES: GENE PATENTS AS A CIVIL  
LIBERTIES ISSUE ................................................................................................. 776
   A. Granting Exclusive Licenses Infringe on First Amendment  
      Rights ........................................................................................................ 777
      1. Self-Realization Values and the Attainment of Truth in  
         the Marketplace of Ideas .................................................................. 778
      2. Chilling Effects Doctrine and the Public’s Right to  
         Know .................................................................................................. 781
   B. Fourteenth Amendment, Fundamental Rights, Privacy, and  
      Informed Consent .................................................................................. 784
      1. Reproductive Liberty and Gender Discrimination ........ 785
      2. Family Rights .................................................................................... 787
      3. Equal Protection as a Basis for Discriminatory Genetic  
         Testing Quality .............................................................................. 787

IV. CONCLUSION: CASE IMPLICATIONS AND SUGGESTIONS FOR  
FUTURE APPROACHES ......................................................................................... 788

* Morgan Geller is a 2011 J.D. Candidate at Nova Southeastern University, Shepard  
Broad Law Center. She graduated magna cum laude from the University of Florida in 2008,  
and received her B.S. in Journalism and Communications. The author would like to thank her  
family, most importantly her mother, Leslee Geller, for her guidance, undeniable support, and  
advice throughout the years. Finally, she acknowledges her fellow members of Nova Law  
Review for their hard work and time spent editing this article.
I. INTRODUCTION

Every person's body contains an array of complex and unique information, known as DNA. These segments of proteins and molecules instruct the body how to develop and function, and are the most basic ingredients of every person's individuality and distinct life experience. Genetic discoveries and identification of specific mutations have even contributed to the academic, corporate, and health communities in uncovering secrets and insight into the human body, health, and disease. An example of a recent genetic breakthrough was the identification of the human genes associated with hereditary breast and ovarian cancer, known as BRCA1 and BRCA2, which can help patients gain insight as to whether they are at risk of developing these diseases. In maximizing the benefits and possibilities of genetic discoveries for public health, ease of access "is crucial if basic research is to be expeditiously translated into clinical laboratory tests that benefit patients in the emerging era of personalized and predictive medicine."  

In an effort to reward and protect this new wealth of information and scientific advancements, the U.S. Patent and Trademark Office (USPTO) has granted thousands of patents on human genes, including BRCA1 and BRCA2, which give patent holders "the right to prevent anyone from studying, testing or even examining a gene." While the public can in fact benefit

1. See AMERICAN CIVIL LIBERTIES UNION, LEGAL CHALLENGE TO HUMAN GENE PATENTS 2 (May 27, 2009), available at http://aclu.org/pdfs/freespeech/brca_qanda.pdf [hereinafter LEGAL CHALLENGE TO HUMAN GENE PATENTS].
3. See Laurie L. Hill, The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs, 11 TEX. INTELL. PROP. L.J. 221, 222 (2003) ("In order to understand health and battle disease, scientists seek an understanding of [human] genes, hoping to improve our lives and cure the diseases that plague us. The complete sequencing of the human [genes] offers unprecedented opportunities for scientific advancement and medical breakthroughs.").
5. Complaint, supra note 2, at 2; see also Hill, supra note 3, at 228 (Proliferation of diagnostic genetic testing "will undoubtedly aid physicians in diagnosing patients and in practicing more effective preventative medicine.").
7. LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 1. Because patent holders have exclusive rights over the genes themselves, they essentially have "a monopoly over the patented genes and all of the information contained within them." Id.

Published by NSUWorks, 2010
from an efficient patent system, unsound patents or "government sanctioned restraints on freedom and competition" can also "harm the public by making products and services more expensive, if not completely unavailable, by preventing scientists from advancing technology, by unfairly prejudicing small businesses, and by restraining civil liberties and individual freedoms."  

Association for Molecular Pathology v. United States Patent & Trademark Office was originally filed on May 12, 2009 by the American Civil Liberties Union (ACLU) and the Public Patent Foundation, on behalf of numerous patients and researchers; and it is a new demonstration of concern for the non-patent holding public, whose interests and voices have been absent in the decision-making about the current patent system. One of the plaintiffs, Genae Girard, was diagnosed with breast cancer at the age of thirty-six, and in an effort to gain information about treatments and medical decisions, she stated:

I . . . decided to be diligent about getting second opinions along the treatment path . . . [but] one company has a monopoly on genetic testing of the BRCA genes. After I was diagnosed with cancer, I was tested for hereditary risk for breast and ovarian cancers. Mutations on [those] genes can show if you are at higher risk for these cancers. I tested positive. . . . Only one company . . . has the ability to sequence them. I can't get a second sequencing done at a different company to validate my results. I am thinking about having my ovaries removed . . . . It is uncomfortable making such an important decision based on only one test. . . . Having . . . your ovaries removed [is a] serious procedure[ ] that cannot be undone. Patents on human genes should not block patients' ability to get second opinions.  

10. Id. at 369–72; see American Innovation at Risk, supra note 8, at 2 ("[T]he patent community culture tends to dismiss and exclude the opinions of those it sees as unsophisticated outsiders, but it is mostly because the general public does not yet realize how much the patent system actually affects them.").
12. Id. (statement of Genae Girard). Genetic studies "will likely continue to identify many . . . genetic risk factors for common diseases. To continue translating these genetic discoveries into improved health and quality of life, it is critical to ensure that affordable,
The federal case of Association for Molecular Pathology, filed in the Southern District of New York, attempts to attack genetic patenting through theories and policies behind patent law, medicine, science, breast cancer activism, and "unusual civil liberties argument[s] in ways that could make it a landmark case."\textsuperscript{13}

With the advent of technology, patent law addresses many things which the Framers of the Constitution surely did not anticipate. Nevertheless, "[p]atent law should not trump [c]onstitutional rights nor be used to impede its own goal of advancing technology."\textsuperscript{14} This article will analyze the validity of DNA patents, specifically the patent on the genes associated with breast cancer, by applying the novel legal arguments raised in the pending case of Association for Molecular Pathology, as well as suggest the need for an exemption from infringement liability for exercising constitutional rights such as freedom of speech, expression, privacy, and bodily integrity. Section II of this article will begin with background information and history behind patent law, its constitutional purpose, and how it has been applied to DNA. It will also discuss the formation and opposition to the BRCA gene patents by explaining the causes of action in the Association for Molecular Pathology complaint. Furthermore, Section II will address the need for a new interpretation of gene patents by addressing the problems with the current laws and precedents, as well as the controversy and debate of patenting something which is naturally part of the human body. Section III will look to theories and interpretations of the First and Fourteenth Amendments as new grounds for attacking patents on human genes. Finally, Section IV will conclude by discussing the recent cases and how they have changed the analysis of patent claims in the Federal Circuit courts. It will also anticipate the defenses the patent holder of the BRCA may raise, as well as the implications of the Association for Molecular Pathology lawsuit and how patent law might be affected in the future.

\footnotesize{interpretable clinical genetic tests will be available to all Americans.}}\textsuperscript{\textit{Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 110th Cong. 2 (2007) [hereinafter Hearing: Stifling or Stimulating] (statement of Wendy Chung) (submitted in connection with statement of Marc Grodman, CEO, Bio-Reference Labs, Inc.).}}


14. \textit{American Innovation at Risk, supra note 8, at 16.}
II. HISTORY AND CONSTITUTIONAL PRINCIPLES OF PATENT LAW, DNA, AND THE BRCA GENES

A. Defining and Interpreting Genes and Patentable Subject Matter

Under section 101 of the Patent Act, there is no specific subject matter proscription on what is patentable.\(^\text{15}\) “[L]aws of nature, physical phenomena, and abstract ideas” are not patentable subject matter.\(^\text{16}\) While a mathematical formula is not a patentable invention, a patent may exist where there is a new function produced with the aid of knowledge of such a mathematical formula.\(^\text{17}\) Consequently, patents may be obtained for any new or useful process, machine, manufacture, or composition of matter.\(^\text{18}\) However, it is not always clear how to distinguish an unpatentable principle from a patentable process.\(^\text{19}\) Because of the lack of legislative guidance, courts have extreme difficulty in determining “what a patent does and does not cover,” and the discretionary “broadest reasonable construction’ standard” is often used to evaluate the validity of a patent claim.\(^\text{20}\) As a result, quality of patent law has suffered, and private patent holders have the potential ability to deny the American people of significant advances that may benefit and address the needs of the public.\(^\text{21}\)

Underlying the constitutional tests and congressional conditions for patentability is the balancing of two interests—the interest of the public in being protected against monopolies and in having ready access to and use of new items versus the interest of the country, as a whole, in encouraging invention by rewarding creative persons for their innovations. By declaring a constitutional

\(^{18}\) See Flook, 437 U.S. at 588–89.
\(^{19}\) Id. at 589; see also Lab Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 134 (2006) (per curiam) (Breyer, J., dissenting) (“[M]any a patentable invention rests upon its inventor’s knowledge of natural phenomena; many ‘process’ patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process.”).
\(^{20}\) American Innovation at Risk, supra note 8, at 6, 14.
\(^{21}\) Id. at 15. “That fundamental limitation on the scope of what can be patented is needed to protect the public domain of science and nature from being appropriated through private property rights.” Id. at 17.
standard of patentability, however, the Court, rather than Congress, will be doing the ultimate weighing.\textsuperscript{22}

Currently, the USPTO awards patents on human genes,\textsuperscript{23} usually meaning that the patent holder prevents laboratories from analyzing "the gene for mutations in order to diagnose the presence of a disease or condition, such as breast cancer," without permission and a high priced licensing fee.\textsuperscript{24} Approximately twenty percent of all human genes are patented, including those associated with Alzheimer's disease, asthma, and some forms of colon cancer.\textsuperscript{25} Ever since the Supreme Court held that a genetically altered bacterium could be patented in the case of \textit{Diamond v. Chakrabarty},\textsuperscript{26} courts have interpreted patent law to "include anything under the sun that is made by man."\textsuperscript{27}

The Supreme Court has recognized the danger of granting patents that cover broad subject matter through application—especially in areas that are vast and unknown.\textsuperscript{28} Defining the term "gene patent" and what it encompasses is not an easy task, and is open to interpretation.\textsuperscript{29} With the increase in knowledge regarding genes, the term "gene" does not only cover the genetic material that encodes a protein in the human body, but also would include that broad sense of genetic sequencing of the entire segment of the relevant DNA.\textsuperscript{30} Some argue that gene patents cover molecular constructions that do not exist in nature and are corresponding structures that are derived from naturally occurring genes.\textsuperscript{31} The debate over patenting genes derives from the fact that "naturally occurring genes as they exist in their native state—as they exist in the human body—are unpatentable... raw genetic sequence information;" but the irony of precedent is that the isolation and "purification of a natural product from its native environment can confer patentability on the purified [gene]."\textsuperscript{32}

\begin{itemize}
\item \textsuperscript{22} S. Doc. No. 108-17, at 315 (2004).
\item \textsuperscript{23} \textit{LEGAL CHALLENGE TO HUMAN GENE PATENTS}, supra note 1, at 3.
\item \textsuperscript{24} \textit{Hearing: Stifling or Stimulating}, supra note 12, at 3 (statement of Marc Grodman). "[E]xcept when blocked by exclusive licenses, clinical laboratories compete. We compete on service. ... We compete on quality. ... We compete on price. ..." \textit{Id}.
\item \textsuperscript{25} \textit{LEGAL CHALLENGE TO HUMAN GENE PATENTS}, supra note 1, at 3.
\item \textsuperscript{26} 447 U.S. 303 (1980).
\item \textsuperscript{27} \textit{Id.} at 309 (quoting S. Rep. No. 1979, at 5 (1952); H.R. Rep. No. 1923, at 6 (1952)).
\item \textsuperscript{28} See Brenner v. Manson, 383 U.S. 519, 534-35 (1966).
\item \textsuperscript{30} \textit{Id}.
\item \textsuperscript{31} \textit{See id.} at 313 (emphasis added).
\item \textsuperscript{32} \textit{Id.} at 311. \textit{Compare} Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 WL 878910, at *9 (S.D. Cal. Mar. 28, 2008), rev’d, 581 F.3d
When patent claims are drafted so that they cover any "recombinant or isolated form of naturally occurring gene sequence, . . . they would appear to cover any biotechnological product or process making or using the claimed sequence," thereby having a patent over the gene per se. In this way, courts are treating genes "as products in and of themselves, instead of guides to future product discovery." Accordingly, many argue that granting private property rights over "such a fundamental aspect of our common human heritage strikes some as an affront to human dignity."

B. Myriad Problems

[A] "useful" invention is one "which may be applied to a beneficial use in society, in contradi distinction to an invention injurious to the morals, health, or good order of society, or frivolous and insignificant"—and upon the assertion that to do so would encourage inventors . . . to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge.

The patent over the BRCA genes held by Myriad Genetics, a private biotechnology company in Utah, is an example of a detrimental broad patent claim. As researchers around the world were getting closer to isolating the first gene to be associated with hereditary breast cancer, researchers from Myriad applied for the patent, claiming they were the first to discover the genetic sequencing. The patent relates "generally to the field of human genetics," covers "methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene," and "also relates to the therapy of human cancers which have a mutation in the [patented] gene, including

1336 (Fed. Cir. 2009) (recently noting that "claims do not gain patentability simply by including man-made compositions"—such as gene isolation or purification), and Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (if there is to be a patent for an invention from a discovery of unknown natural phenomenon, "it must come from the application of the law of nature to a new and useful end"), with Holman, supra note 29, at 311.

33. Holman, supra note 29, at 313.

34. Melissa E. Horn, DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests, 50 CLEV. ST. L. REV. 253, 264 (2003); see also News Release, Pub. Patent Found., supra note 4 ("'Genes isolated from the human body are no more patentable than gold extracted from a mountain.'").

35. Holman, supra note 29, at 297.


37. See Horn, supra note 34, at 269.

38. Id. at 269 & n.162.
gene therapy [and] protein replacement therapy." Unfortunately, Myriad's broad patent claim also covers the ownership over the rights to screening for drugs relating to cancer therapy, as well as screening for gene mutations, which are essential to understand a person's predisposition to breast and ovarian cancer.

The suit filed against the USPTO and Myriad asserts that the patent over the naturally occurring genes should not be patented simply because they are "'isolated from their natural state and purified.'" A gene that is isolated and removed from a human body functions the same exact way as does a non-isolated gene inside the body. Therefore, removing the gene—a product of nature—does not change the fact that it still remains and functions as a product or law of nature. Furthermore, by patenting a correlation of certain mutations with a high risk of breast or ovarian cancer, Myriad has an unlawful patent over an abstract idea or principle, which allows them to gain a monopoly over a scientific fact.

Because the patent is over the actual genes, rather than a genetic test, scientists and laboratories are prevented from performing alternative testing on the genes. Breast cancer is not a rare disease, but instead is one of the leading causes of death among women. Right now, there are about two thousand different mutations along the BRCA genes, but because of Myriad's broad patent claim and its incomplete genetic testing, little is known

40. See id.
41. Complaint, supra note 2, at 19.
42. Id.
43. Id.
44. See LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 4. Laboratory Corp. of America Holdings involved the natural relationship between elevated hormone deficiencies in B vitamins in human blood, but Justice Breyer and the dissent would have held that such a correlation is merely an observable aspect of biology and the human body. See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 135 (2006) (per curiam) (Breyer, J., dissenting). The patent merely covered instructions for reading and understanding the significance of numbers in light of already acquired medical knowledge. Id. at 137.
45. LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 3.
about this vast array of information which may be vital to a woman deciding to undergo preventative surgery.\textsuperscript{48}

Researchers and clinicians cannot develop or implement new tests for breast/ovarian cancer linked to BRCA1 or BRCA2 if development or implementation involves looking at \([\text{the genes}]. \) Women cannot give their blood or DNA to a researcher or clinician and obtain a second opinion. The effect is to infringe on quality medical practice and to compromise quality assurance and improvement of testing.\textsuperscript{49}

\section*{C. Impeding the Progress of Science and the Useful Arts}

Article I, Section 8 of the Constitution gives Congress the broad power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."\textsuperscript{50} Patent law, therefore, is aimed at fostering productive efforts by providing inventors exclusive rights as an incentive for their research and intellect.\textsuperscript{51} The rationale behind the purpose and efficiency of patents is that competitors will be encouraged "to 'invent around' the patented invention, avoiding wasteful duplication of efforts, and insuring the eventual dedication of invention to the public with the expiration of the patent."\textsuperscript{52} Particularly in the field of diagnostic testing, competition is "critical to protection of the public health."\textsuperscript{53} The Framers of the Constitution, therefore, were concerned with "promoting certainty" in addition to the federal policy objectives.\textsuperscript{54}

\textsuperscript{48} See Timothy J. Ohara, Note, Patenting the Diagnosis of a Disease: The Scope of Patentable Subject Matter Based on Labcorp v. Metabolite Labs, 38 \textsc{Golden Gate} U. L. Rev. 139, 169–73 (2007); Horn, supra note 34, at 269.

With the breast cancer test, \ldots more reliable laboratory tests will enable better treatments or at least enable more rational decisions about electing experimental treatments. \ldots There is a large number of diseases that could be potentially diagnosed and treated more effectively through improved diagnostic testing \ldots However, researchers [cannot improve a genetic test] if broad diagnostic claims are allowed to remain valid, even when there is a[n] \ldots unmet need for such an improvement.

\textit{Id.} at 172–73.

\textsuperscript{49} Complaint, supra note 2, at 18–19.

\textsuperscript{50} U.S. CONST. art. 1, § 8, cl. 8.


\textsuperscript{52} Hill, supra note 3, at 236.

\textsuperscript{53} Hearing: Stifling or Stimulating, supra note 12, at 3 (statement of Marc Grodman).

The underlying policy behind patent law is that discoveries and inventions should be used fully and freely. Genes are at the forefront of public interest, considering that many of them may hold the keys to life-saving medical and scientific discovery and innovation. Unlike other patents on more tangible and concrete inventions, genetic discoveries have been publicly funded through initial research, but private biotechnology companies, such as Myriad, and the pharmaceutical industry are those that perform private research under a patent in order to strive towards a commercially viable use. However, some argue—that these privately funded patent holders are usually not interested in making any further end product, or do not have the capability of doing so. When this happens, further development is prevented because intellectual property rights in genes and diagnostic testing are being protected too early in the research process.

In a survey of clinical laboratory directors that perform DNA-based genetic tests—including members of the Association for Molecular Pathology—a study analyzing the effects of patents on genetic testing revealed that laboratories were being prevented from continuing already developed genetic tests because of gene patents. Because genetic laboratories have the ability and knowledge to perform and translate clinical tests without the publication of data supplied by gene patents, there is the argument that these gene patents are not necessary to provide the incentive for others to develop new innovations in genetic discoveries. On the contrary, when a genetic variant is discovered and sequenced, such as the BRCA genes, patents are not crucial for the development of the initial invention.

The patent held by Myriad makes ease of access to genomic discoveries restricted, and the BRCA genes have been underused in medical and scientific breakthrough as a result of the over-exclusive use of the patent holder. If the potential uses and benefits of these genetic discoveries are not made available to the public, access to personalized and predictive medicine is

55. See id. at 338.
56. Horn, supra note 34, at 262.
57. See id. at 263.
58. See id. at 265.
59. See id.
61. See id. at 8.
62. See id.
63. See Complaint, supra note 2, at 2; see also American Innovation at Risk, supra note 8, at 14 ("There does come a point at which over rewarding patent holders can in fact retard technological development.").
Because the BRCA genes are not the only genes or factors associated with breast cancer, there is still a lot to be uncovered about the disease in order to maximize the benefits of genetic testing and technology. However, because Myriad can decide how many tests will be done, and who is entitled to receive and perform the tests, only a limited number of individuals are using and testing the new information. In a statement regarding the danger of patents on patients' rights by prohibiting medical innovation, the American Society for Clinical Pathology reported:

[Myriad's] gene patents limit the broad availability of diagnostic tests due to the simple fact that laboratory scientists are prohibited from performing genetic tests because of patent enforcement and the threat of litigation. As a result, the market is dominated by a single provider, eliminating competition and scientific diversity, which ultimately drives up costs. ... Such patents stifle the innovative process, negating further refinement in test methodology, improvements in quality, and access to testing. ...

Perhaps the most disturbing effect of the Myriad patent over the BRCA genes is that because there is little incentive for competition due to fear of litigation, there is little incentive to improve the quality of testing performed by Myriad. As a consequence, the company continues to deliver confusing and ambiguous results. Because of the limited avenues of testing provided by Myriad, women and their families are left without knowing whether they should make a life-altering decision affecting their bodies, health, and value of life.

65. See Horn, supra note 34, at 272–73 ("Science has moved away from thinking that one gene is responsible for each disease. ... Multiple genes work in coordination; therefore, in order to treat or cure a disease, research and experimentation upon many genes and their functions is necessary.").
66. Id. at 269, 275.
67. Plaintiff Statements, supra note 11. "In breast cancer genetic testing, ... we have seen no innovation in the past five years—since Myriad Genetics introduced its most recent test." Id. (statement of Dr. Harry Ostrer).
68. Hearing: Stifling or Stimulating, supra note 12, at 4 (statement of Dr. Wendy Chung).
69. See id.
70. See id.
I. The Need for Dynamic Constitutional Interpretation

As those in the medical profession continue to be cooperative and open about their intellect and ideas within their studies, the case against Myriad demonstrates the need to interpret gene patent claims through a new alternative means of constitutional purpose.\(^ {71} \) When the Framers of the Constitution drafted the provision regarding congressional authority over patents, the science of genetic sequencing was surely not in their field of thought or imagination.\(^ {72} \) Therefore, like the Constitution itself, patent claims are drafted broadly to adapt to current social and legal issues in light of precedents that are already understood and well known.\(^ {73} \) Patent holders should not be able to construct their own claims and laws in order to fulfill their own private interests; rather, only Congress holds the broad power to grant patents to fulfill the constitutional intent of “promoting the sciences and useful arts.”\(^ {74} \)

When patents no longer function as the Framers intended, patents are unconstitutional. As the plaintiffs in Association for Molecular Pathology contend, patent law affects many fundamental rights.\(^ {75} \) Awarding a patent for a human gene, such as those associated with breast cancer, prevents scientific advancement and intellectual freedom by obstructing the free exchange of information that is vital to the workings of democracy.

III. Novel Legal Challenges: Gene Patents as a Civil Liberties Issue

In order to uphold the validity of the plaintiffs’ unprecedented constitutional challenges against patenting genes in Association for Molecular Pathology, one must understand the inner workings of the relationship between patent law and constitutional rights in order to appreciate these novel arguments, keeping in mind that the Constitution, as a political invention, and patents, as a physical invention, are both, in some sense, a source of intellectual, social, and human development.\(^ {76} \) Because Congress’ power over patents derives from the Constitution itself, “constitutional interpretation must be freed from the [past] circumstance[s] of the Framers,” in order to allow

---

71. See Katopis, supra note 54, at 387.
72. See Thomas K. Landry, Constitutional Invention: A Patent Perspective, 25 Rutgers L.J. 67, 92–94 (1993) (“It has been necessary to adapt the Constitution to our advancing technologies . . . . The case for accommodation of progress without originalist objections . . . is supported by the interpretative accommodation of progress in patent law.”).
73. See id. at 90–91.
75. See generally Plaintiff Statements, supra note 11.
76. See Landry, supra note 72, at 97 (emphasis added).
modern interpreters and judges to accommodate the changes caused by the new unknown realm of intellectual property that is engraved in genetic sciences.\textsuperscript{77} The power granted to a patent holder is created by constitutional power.\textsuperscript{78} Thus, constitutional law demands the flexibility and endurance of protections of fundamental liberties and core principles of a democratic society. To achieve the constitutional requisites of patent law, one must develop new conceptions of constitutional rights as exemptions from governmental power.\textsuperscript{79} Patents exist only for a limited lifetime.\textsuperscript{80} The Constitution lives forever. The enumerated power granted to Congress in Article I "is not an end in itself for the typical citizen in whose name the Constitution was ratified as supreme law."\textsuperscript{81}

A. Granting Exclusive Licenses Infringe on First Amendment Rights

Although the First Amendment states, "Congress shall make no law . . . abridging the freedom of speech, or of the press,"\textsuperscript{82} the text also applies to other forms of conduct and communication, such as expression of ideas and knowledge, self-expression, and the dissemination of information.\textsuperscript{83} Patent law serves the same purpose as does the First Amendment—to place knowledge and innovation on an equal playing field in order to develop new ideas based on actual merit and effort, and not based on what is dictated by more powerful organizations and the government.\textsuperscript{84} Therefore, if a gene patent prevents the progress of scientific and medical breakthroughs and innovations, the First Amendment is inevitably implicated because the federal government has awarded the patent holder with the exclusive rights to deny others from researching the genetic sequences, which results in the silencing of future knowledge, ideas, and expression.\textsuperscript{85} After all, "[t]he first amendment is there so as to enrich the gene pool of ideas."\textsuperscript{86}

\textsuperscript{77.} Id.
\textsuperscript{78.} See U.S. CONST. art. I, § 8.
\textsuperscript{80.} See Hill, supra note 3, at 233.
\textsuperscript{81.} BARBER, supra note 79, at 106.
\textsuperscript{82.} U.S. CONST. amend. I.
\textsuperscript{83.} See DANIEL A. FARBER, THE FIRST AMENDMENT 1 (1998) ("[T]he bare text of the First Amendment provides only a hint of the ultimate contours of legal protection.").
\textsuperscript{84.} Paul Heckel, Patents, Ecology and the First Amendment, PANDAB, July 6, 1998, http://www.pandab.org/patents-ecology-first-amendment.html. ("The role of patent laws plays in encouraging innovation is the same role as the first amendment plays in encouraging open political discussion and thus change: they make it possible to challenge entrenched and powerful established interests.").
\textsuperscript{85.} See generally FARBER, supra note 83. It is important to "preserve a predominantly free enterprise economy, [and] the allocation of our resources . . . will be made through nu-
In the case of Association of Molecular Pathology, the patent for the BRCA genes is drafted in such a way that it gives Myriad not only exclusive rights but also exclusive license, which makes it more difficult for others to express opinions and share ideas regarding the breast cancer enigma. If patents such as the one held by Myriad are an unconstitutional private ownership of a basic idea or human knowledge, then the gene patent therefore infringes on the First Amendment rights of researchers, doctors, patients, and the American public, who have a fundamental right to access known, beneficial public information. There are thousands of physicians, researchers, pathologists and scientists who are able and willing to look at and sequence a person’s BRCA genes and determine whether a mutation exists that would increase that person’s risk of breast or ovarian cancer. Genes contain the necessary information towards developing cures and therapies for diseases; however, “[t]he only thing that prevents those doctors and scientists from looking at the human BRCA1 and BRCA2 genes is Myriad’s patents.”

1. Self-Realization Values and the Attainment of Truth in the Marketplace of Ideas

Intrinsic in the First Amendment is the importance of attaining truth through the exchange of facts and personal fulfillment. “If people lack
access to a wide range of ideas, they are prevented from imagining the full range of possibilities in their lives."92 From the viewpoint of those wishing to study and research BRCA genes, and other genetic disorders and treatments related to them, the repressive nature of the patent system can confine their ability to express their perspectives, thereby taking a sense of self-ownership away from them.93

The Supreme Court once said that "[o]ur [n]ation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment . . . ."94 For those who have devoted their lives and studies to uncovering the endless possibilities in the field of genetic science, the patent law system seems to work against their devotion for their work and desire to acquire knowledge.95 Patents are economically driven, but in the world of science and research, personal wealth often takes a back seat to recognition among peers and self-gratification.96 Therefore, in the case of the plaintiffs opposing the BRCA gene patent, the patents are unnecessarily restrictive in that they deny the personal quest for scientific truth and progress in answering a usually narrow question with a specific answer.97 By patenting the BRCA genes, the government is sanctioning the patenting of useful scientific information and the abstract idea that mutations occur outside of the body.98 In fact, little is known to certainty regarding

92. Id.
93. See id.; see also Brian C. Murchison, Speech and the Self-Realization Value, 33 HARV. C.R.-C.L. L. REV. 443, 446 (1998) (explaining that the freedom to participate in decisions is a necessary ingredient to a democratically-governed society).
95. See generally Plaintiff Statements, supra note 11. There is a "strong disincentive to perform translational research, [which] applies to many other academically based genetics testing laboratories, thus depriving patient populations from the active research involvement of some of the best scientists and institutions in the world." Id. (statement of David H. Ledbetter, Ph.D.).
96. See Hill, supra note 3, at 243. Although there might be some underlying economic incentive behind genetic sciences, the foremost goal of scientists is defining individual achievement. Id. (citing John M. Golden, Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System, 50 EMORY L.J. 101, 147-49 (2001)).
97. See id. at 244. The validation of scientific findings, which are confirmed by others in the field, are vital in searching for scientific truth among different techniques and ways of approaching the scientific enigma in question. Id. (citing Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1048-53 (1989)).
98. See Complaint, supra note 2, at 23 (What is patented is that the two forms of the BRCA1 and BRCA2 genes have been made different because of nature—an abstract idea not known to be true.).
breast cancer genetics, and if these ideas are treated as any other traditionally patented products, the public "marketplace of ideas" will be burdened by patent regulations.99

Because the significance of the test results of BRCA genetic tests are often unclear and meaningless, the results lack an objective quality—even though other physicians who actually interpret these results have the ability to perform further testing.100 When a patient or a physician receives a test result of "variants of unknown significance," it can be confusing because there is no way to acquire a definite answer whether the patient can surely be at a higher risk of developing cancer.101 Especially in the realm of medicine and health, the providers of beneficial services should act with the patients' best interests in mind.

Progress in the natural sciences is not remotely confined to findings made in the laboratory. Insights into the mysteries of nature are born of hypothesis and speculation. The more so is this true in the pursuit of understanding in the groping endeavors...the concern of which is man and society...[I]f understanding be an essential need of society—inquiries into these problems [by those in their respective occupations], speculations about them, stimulation in others of reflection upon them, must be left as unfettered as possible. Political power must abstain from intrusion into this activity of freedom [that is a special concern of the First Amendment].102

By allowing Myriad Genetics to hold the power and wealth of vital information to sick patients, the quality of health care inevitably suffers. The complaint of Association for Molecular Pathology points to the fact that "[f]or at least some portions of the life of the [BRCA genes], Myriad did not perform certain tests that were known to reveal additional mutations that

99. See Farber, supra note 83, at 5 (noting that society can benefit from a wide array of ideas in order to conceptualize and confirm true ideas by disproving false, or bad, ones).

100. See generally Cho et al., supra note 60 (finding that genetic laboratory directors felt that gene patents delayed or inhibited research, especially regarding genetic testing they had already been performing before the issuance of a gene patent). While there exists an experimental use exemption for infringement liability, it has been interpreted to have no significant effect on the patent system and researchers’ rights. See American Innovation at Risk, supra note 8, at 16 (noting that "it seems perverse to subject scientific research to the risk of infringement liability, ... [but] legislative action is now [needed] to restore the proper balance between the private rights of patent holders and the public interest in advancing technology.").


increased the risk of breast and/or ovarian cancer." 103 Myriad’s patent over the BRCA genes, therefore, does not coincide with the constitutional purposes behind the Patent Act and merely has the effect of prohibiting others in the medical and scientific fields from disseminating useful knowledge and ideas. 104 Contrary to what proponents of patents on genes may argue about negative impacts of duplicative research, multiple teams of researchers can actually scrutinize the same problems in order to efficiently reach and validate a particular result. 105 In fact, it is likely that when multiple individuals research the same subject matter—BRCA genes and the significance of their mutations—the “marketplace of ideas” can be filled with new implications and conclusions arising from the initial discovery. 106

2. Chilling Effects Doctrine and the Public’s Right to Know

Today, doctors are viewed as individuals who are part of a prestigious team and work together by sharing insights and intellectual honesty, in order to inform each other and their patients. 107 However, because Myriad does not share the information that is personally held in its large database of BRCA1 and BRCA2 data, researchers are “chilled from engaging in research on other genes,” despite the fact that it is well-known that the BRCA genes “interact with other genes in ways that are not yet fully understood.” 108 Up until this point in time, there have only been two lawsuits involving Myriad and its BRCA patents, but neither proceeded far enough to reach a substantive ruling. 109 Consequently, “none of the fears” and potential harm caused by gene patents have materialized, despite the fact that many would agree that declaring private ownership of a human gene is morally inappropriate. 110 One lawsuit for infringement involved the University of Pennsylvania, which had been providing commercial genetic testing for the BRCA1 gene, but decided to cease testing in order to avoid litigation. 111 This demonstrates the

103. Complaint, supra note 2, at 26.
104. See Brenner v. Manson, 383 U.S. 519, 536 (1966) (Congress did not intend for a patent to be “a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”) (emphasis added).
105. Katopis, supra note 54, at 390.
106. See id. (“The benefits of the parallel research strategy include, increased returns corresponding to the number of alternatives; [as well as] a higher rate of ‘learning’. . . .”) (citing Eisenberg, supra note 97, at 1065).
107. Id. at 388.
108. Complaint, supra note 2, at 28.
110. Id. at 352.
111. Id. at 347.
"chilling effect of gene patents" and the negative impact on access to healthcare and genetic testing.\textsuperscript{112}

The chilling effect doctrine, as a basis for protecting First Amendment rights, understands that when the expression of viewpoints and freedom to engage in certain activities is limited because of indirect government regulation, a chilling effect occurs because of the abridgment of First Amendment freedoms.\textsuperscript{113} Myriad, as the exclusive holder of the rights to the BRCA genes, charges approximately $3000 for a genetic test, and charges high amounts for licensing fees.\textsuperscript{114} However, even if these licensing practices are available, the high prices and fees have led researchers to shut down labs and halt research efforts.\textsuperscript{115} Lab shut-downs result in the chilling effect of not being able "to gain access to the latest information [and] can result in a discovery . . . not being made at all."\textsuperscript{116} Plaintiff Arupa Ganguly is an Associate Professor in the Department of Genetics at the Hospital of the University of Pennsylvania whose field of study involved clinical practice relating to breast cancer, but she was forced to discontinue her research because of a cease-and-desist letter from defendant Myriad.\textsuperscript{117} "If [Myriad's patents] are invalidated now, she would seriously consider resuming clinical practice that is now prohibited."\textsuperscript{118} First Amendment rights, and the chilling effect doctrine, are implicated through the exercise of patent rights held by Myriad because it affects those who have put time and effort and devoted their lives to studying breast cancer and related genetic disorders.

When there is a lack of competition in diagnostic testing, such as the current situation of BRCA genetic testing, different viewpoints and avenues for testing are chilled, as many providers have been prevented from providing genetic testing for breast cancer.\textsuperscript{119} Because Myriad has the ability to refuse to offer certain diagnostic testing, there is a reduction in possible accumulated knowledge. The chilling effects do not only harm certain individuals wishing to assemble together in order to acquire, share, and reap the benefits of their knowledge and viewpoints, but also harms society and the general public—especially in the world of health care—because "[t]he great-

\textsuperscript{112} Id.
\textsuperscript{113} DANIEL J. SOLOVE, UNDERSTANDING PRIVACY 178 (2008).
\textsuperscript{114} Complaint, supra note 2, at 27; Horn, supra note 34, at 275.
\textsuperscript{115} Horn, supra note 34, at 275.
\textsuperscript{116} Id.
\textsuperscript{117} Complaint, supra note 2, at 6.
\textsuperscript{118} Id.
\textsuperscript{119} See Plaintiff Statements, supra note 11 (statement of Stephen T. Warren, Ph.D.) ("Even if an improvement in testing methodology is available, another laboratory is prohibited by the exclusive license from implementing the testing refinement.").
est benefit DNA patents bring is the promise and potential of curing, treating, diagnosing, and eliminating medical conditions that afflict all."\footnote{120}

When patents on DNA have the effect of privatizing biomedical research, they chill upstream and downstream research.\footnote{121} Where clinical laboratory directors and genetic physicians would otherwise have the right to freely practice their own trade, patents on DNA force them to deal and license with the private patent holders.\footnote{122} Therefore, the monopoly of the BRCA genes held by Myriad preempts any alternative avenues for communicating related expression and viewpoints regarding breast cancer and genetic disorders, effectually chilling, undermining, and blocking the public's right to benefit from better medical care for hereditary forms of breast cancer.\footnote{123} "As it currently stands, because of exclusive gene testing patents, no single laboratory in the United States could offer full genome sequencing for clinical purposes."\footnote{124} Therefore, by raising First Amendment challenges to the patents held by Myriad, the plaintiffs in Association for Molecular Pathology have the ability to prove that the BRCA gene patents hamper the progress of useful arts and sciences on new legal bases that voice concern for the chilling effects of restricting the bounds of practicing medicine and silencing new research.\footnote{125} "'What they have really patented, . . . is knowledge.'"\footnote{126}

\begin{footnotes}
\footnote{121.} See Horn, supra note 34, at 264 ("[P]atents limit the availability and raise the cost of the therapeutic and diagnostic end products because the patents are owned too far upstream in the research and development process.").
\footnote{122.} See Cho et al., supra note 60, at 3 (finding a significant number of respondents reported that they had decided to stop performing genetic tests for clinical purposes because of patents or licenses).
\footnote{123.} See Hearing: Stifling or Stimulating, supra note 12, at 6 (statement of Marc Grodman) ("[W]hen an exclusive license is granted, research on finding new genes that will enhance the clinical significance of the original discovery is brought to a halt. . . . In the area of genetic testing, exclusivity is a formula for mediocrity.").
\footnote{124.} Plaintiff Statements, supra note 11 (statement of Stephen T. Warren) (emphasis omitted). Allowing a broad patent claim "amounts to granting a patent on the practice of medicine." Ohara, supra note 48, at 147.
\footnote{125.} Broad medical diagnostic patents "could have a chilling effect on free speech in terms of communicating good medical advice or the practice of medicine." Ohara, supra note 48, at 165 & n.248.
\footnote{126.} Schwartz, supra note 13 (quoting statement of Christopher Hansen, Senior National Staff Counsel, American Civil Liberties Union). "Gene patents implicate the First Amendment because the very thought that there is a relationship between specific genetic mutations and diseases has been patented and because scientific inquiry is limited." LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 5. The monopoly that is created by granting ex-
B. Fourteenth Amendment, Fundamental Rights, Privacy, and Informed Consent

"Imagine if one of your family members was making a decision about surgery to remove her breasts [or ovaries] after a gene test result placed her at high risk for breast [or ovarian] cancer and there was no place to get an independent test done to confirm the results . . . ."127 This is the disturbing situation of many patients looking for some insight into their own personal diseases or those of family members. The rapid pace at which scientific and genetic technology are advancing foreshadows the continuing concerns over "genetic privacy, informed consent, and the ownership and custodianship of patient data . . . ."128 When a person is denied the information that might be readily available concerning his or her own health, the exclusion has an effect of taking away a person’s constitutional right to control over his or her own life and liberty.

The Fourteenth Amendment states that a person shall not be deprived of "life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."129 The Supreme Court has recognized that individual rights and liberty interests encompassing individual sovereignty, bodily integrity, and informed consent are vital in order to protect and guarantee the most important decisions a person will make in her lifetime.130 The freedom over one’s own body and health has been characterized as being pivotal to the liberties encompassed in the Fourteenth Amendment.131 Modern constitutional analysis, in addition, encompasses certain "zones of privacy, which were evident and sustained under law since before the nation’s founding."132

In the world of therapeutic and non-therapeutic medical experimentation, a patient has the fundamental right to be informed through disclosure of the benefits and risks of medical procedures—including complete and accurate information containing a full description of a patient’s condition—to

132. Id.
maintain autonomy over his or her body. In the case of Myriad Genetics and its patents to the BRCA genes, breast cancer victims and those whose family members have succumbed to the disease have been excluded from information regarding personal information and the use of personal data. When people are excluded from participating in how their personal data contained in their genes can be used, there is an effectual feeling of uncertainty. The lack of ability to maintain knowledge of one’s own bodily and genetic information can make a person powerless. In the realm of possibilities genetic information can reveal, the patent on the BRCA genes prevents the discovery of new personal facts about a person that result from the aggregation of information taken from the original, isolated gene. Information contained in a person’s genes is vital to understanding how the body functions and reacts. Therefore, in order to make intelligent and informed decisions about one’s body, one must have the most accessible and accurate information. The women who are denied testing because they are unable to afford Myriad’s exorbitant diagnostic fees are therefore denied their fundamental rights to make informed decisions regarding choices over their body and health.

1. Reproductive Liberty and Gender Discrimination

Reproductive liberty is a certain autonomy encompassed in privacy over certain intimate decisions. By focusing on the general realm of reproductive health and freedom, discrimination and subordination of women can be found because the patents restrict a woman’s freedom to choose to reproduce at her will. Because reproductive liberty is a non-express fundamental constitutional right, some scholars believe it falls under a penumbra of rights under a right of privacy. However, “even if privacy is taken to mean [reproductive] autonomy, that kind of freedom of decision making presupposes that the one exercising it has control over the . . . act or its effects.” Breast cancer and ovarian cancer are diseases that mainly affect women, who as a

134. See Complaint, supra note 2, at 2, 18.
135. SOLOVE, supra note 113, at 134–35.
136. Id.
137. See Complaint, supra note 2, at 2, 18.
138. See id. at 2, 16.
139. Id. at 2–3.
142. Id.; see, e.g., Roe, 410 U.S. at 152–53.
143. BOUMIL ET AL., supra note 141, at 19–20.
class, are unequally burdened by Myriad's patents. "Because of this, reproductive liberty must be found in the Equal Protection Clause of the Fourteenth Amendment."

Because of the patent over the BRCA genes, the collaboration of some of the nation's most experienced people in the world of cancer and genetics are missing, and these women are suffering as a result. Therefore, a woman who is denied the completely informed decisional authority to remove her ovaries is inevitably denied her fundamental right to choose freely whether or not to have a child. One of the plaintiffs in Association for Molecular Pathology, Lisbeth Ceriani, submitted a blood sample, as recommended by her oncologist, in order to determine if she should undergo surgery in order to reduce her risk for ovarian cancer.

However, she was notified that Myriad would not process the sample. Even though her insurance has informed her that it would cover the BRCA genetic test, Myriad will not accept [her] coverage. Ms. Ceriani is unable to pay the full cost out-of-pocket and, to date, has not been tested. Without the genetic test results, she cannot determine the best medical course for herself. If the patents are invalidated, Ceriani is ready, willing, and able to utilize [other] additional resources for testing and research.

For a woman who is deciding to remove her ovaries, it is essentially a decision to terminate her ability to give birth to a child. Something that the Supreme Court has also recognized as part of substantive due process is a fundamental right to be free from governmental interference affecting a person's decision whether or not to terminate—or in this case, prevent—a pregnancy. The possibility of unnecessarily preventing someone from having children brings back thoughts of Social Darwinism and the theory of eugenics, which has been held to be morally unacceptable and inhumane. When a woman is not informed to a sufficient degree to make a completely voluntary decision to make herself infertile, but a more knowledgeable physician and genetic counselor is able to make such a recommendation for her, the

144. See Complaint, supra note 2, at 26, 29; BOUMIL ET AL., supra note 141, at 20.
145. BOUMIL ET AL., supra note 141, at 20.
146. Complaint, supra note 2, at 2, 18–19.
147. See id. at 2.
148. Id. at 10.
149. Id.
151. See BOUMIL ET AL., supra note 141, at 57.
right to procreate is no longer a fundamental choice to uphold the existence and survival of one’s familial line. 152

2. Family Rights

In the doctor-patient relationship, there are many issues regarding disclosure to family members regarding knowledge of a certain genetic condition. 153 The genetic information of patients wishing to access BRCA testing may not only reveal information regarding their own personal risks of developing cancer, but also may answer questions about relatives who have died of breast or ovarian cancer. 154 Currently, Myriad only offers genetic testing on blood samples and has not developed any other methods of testing through human tissue. 155 If the family members have passed away due to breast or ovarian cancer, the only available specimen available for testing is human tissue from a previously removed cancerous tumor because the blood is no longer available. 156 Therefore, family members wishing to have Myriad perform genetic testing are denied from doing so, despite the fact that other laboratories in the country are able to do so. 157 The family, as a collective unit, has a common public interest and private right to claiming the information in question. 158

3. Equal Protection as a Basis for Discriminatory Genetic Testing Quality

In 2005, approximately 1,433 BRCA1/BRCA2 genetic tests resulted in genetic variations of unknown significance. 159 Unfortunately, the problematic test results provided by Myriad disproportionately affect African Americans, Hispanics, and Asian women, who have been less likely to volunteer in research studies to add information to genetic databases. 160 "[T]here are mul-

152. See id. at 20.
154. See id. at 210. "E[ven if family members are not actually tested, in order to verify a diagnosis clinical practice normally entails obtaining information about family members in successive generations leading to the creation of a family pedigree." Id.
155. Hearing: Stifling or Stimulating, supra note 12, at 4 (statement of Dr. Wendy Chung).
156. Id.
157. See id.
159. Hearing: Stifling or Stimulating, supra note 12, at 3 (statement of Dr. Wendy Chung).
160. Id.
multiple links among race, gender, and genetics, . . . [but] genetic differences, too, are typically regarded as biological and ‘real,’ justifying differences in treatment, with too little attention to the social choices involved.”  

Under Susan M. Wolf’s approach to an antidiscrimination approach, the lack of knowledge of genetic information of minority populations results because “a norm exists . . . that all should be treated in conformance.” The Myriad genetic testing:

counsels that people of color should be treated like whites . . . . It bifurcates the world into those who nonproblematically fit the norm . . . and those who are problematically different . . . . In genetic terms, this means bifurcating the world into those with nonproblematically “normal” genotypes and those with problematically “abnormal” ones.

Because no person has the same exact genetic makeup, it is important to have a genetic database containing variants in a wide range of ethnicities, in order to analyze and conserve the information to compare and correlate these variants. The Myriad gene patents, however, result in disproportionate medical exclusion of minorities. Because Myriad faces no competition in the market, “there is no incentive for them to improve the quality of data interpretation . . . .”

IV. Conclusion: Case Implications and Suggestions for Future Approaches

The outcome of Association for Molecular Pathology is still indefinite. “The rock was tossed into the biotech pond on March 29, 2010, when

162. Id. at 161.
163. Id. at 161–62.
164. See Hearing: See Stifling or Stimulating, supra note 12, at 3–4 (statement of Dr. Wendy Chung).
165. See id. at 3.
166. Id. at 4.
167. See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 369–70 (S.D.N.Y. 2009). Since completion of this paper in the summer of 2009, Defendants moved to dismiss, and Plaintiffs moved for summary judgment on August 26, 2009. Id. at 370. “Defendants’ motion to dismiss, and Plaintiffs’ motion for jurisdictional discovery were heard and marked fully submitted on September 30, 2009, and Plaintiffs’
Judge Robert W. Sweet issued a 156-page opinion holding that the purification of a natural product (in this case, human BRCA1 and BRCA2 genes), without more, could not transform it into patentable subject matter. In reaching the conclusion, Judge Sweet relied on Supreme Court precedent, and determined that the proper test to analyze the patents was "whether the invention had 'markedly different characteristics' from the natural product." The court ultimately invalidated the human gene claims by looking "at the isolated DNA for the BRCA1 and BRCA2 genes as claimed in the patents, and held that it was unpatentable as it was not markedly different from native DNA as it exists in the human body." With regards to Myriad's method claims, Judge Sweet sided with the plaintiffs and ruled that the patents were indefinite and "were directed to an unpatentable abstract mental process."

The case is surely to have an effect in the world of policy and law as it relates to the world of intellectual property and medicine. Because of the future wealth that awaits in the pharmaceutical and health care industries as a result of genetic discoveries, it is unlikely that a court would completely ban...
the patenting of genes, in general. However, in order to maximize the
benefits to the public, it is necessary that genetic testing is widely available
with the greatest possible quality. The case against the USPTO and Myriad
is rather a way to demonstrate the actual harms of broad patenting and licens-
ing schemes in such an unknown yet valuable realm of information and
sciences.

A recent case, Prometheus Laboratories, Inc. v. Mayo Collaborative
Services, held that a correlation between metabolite levels and toxic results
from metabolic activity in the human body were natural, unpatentable, phe-
nomena, that would have existed without human intervention. Certain
natural metabolites were not patentable on their own because the correlation
was a result from a natural body process. However, with Judge Sweet’s
new opinion, there might be hope that an appeals court may still hold that the
mutations on the BRCA genes—while believed to be environmentally caused
in an isolated, purified gene—are naturally correlated with a higher risk of
breast cancer, and are therefore not patentable. It will likely take years of
litigation to see whether Myriad’s patents will meet whatever standard the
Supreme Court devises in the future.

Perhaps the answer to gene patents might be to develop a patenting
scheme where there would still be incentive for intellectual efforts by ensur-
ing financial merit; but, instead of granting exclusive rights and licenses, the
patent would allow certain health-care providers access without infringe-
ment, or perhaps setting limits on licensing fees so that there would be de-
creased insurance barriers to patient access to quality healthcare. Further-

173. Because only some of Myriad’s claims were invalidated, while some remained un-
challenged. Ramage, supra note 168.
174. No. 04cv1200JAH(RBB), 2008 WL 878910, at *1 (S.D. Cal. Mar. 28, 2008), rev’d,
581 F.3d 1336 (Fed. Cir. 2009).
175. Id. at *6–9.
176. Id. at *7.
177. Susan Decker & Thom Weidlich, Myriad Loses Ruling over Breast Cancer-Gene
178. After completion of author’s own research, conclusions, and recommendations—as
stated in Part IV of this article—the Secretary’s Advisory Committee on Genetics, Health and
Society (SACGHS) for the Department of Health and Human Services (HHS) issued a revised
draft report, entitled Gene Patents and Licensing Practices and Their Impact on Patient
Access to Genetic Tests, which includes six recommendations that stress equal and uninhibited
access to the benefits of genetic testing and research for Plaintiffs like those affected by the
broad BRCA patents. See SECRETARY’S ADVISORY COMM. ON GENETICS, HEALTH, AND
SOCIETY, REVISED DRAFT REPORT ON GENE PATENTS AND LICENSING PRACTICES AND THEIR
IMPACT ON PATIENT ACCESS TO GENETIC TESTS 2 (Feb. 5, 2010), available at http://
more, if the same genetic test could be performed with better quality and knowledge by someone who has greater skills than that of Myriad, the government should not allow the public to suffer as a result. The personal right of those wishing to exercise their constitutional rights to access and share information and make informed decisions over their body should not be abridged simply because a court has read a patent too broadly.

pdf. The most controversial recommendation is “Recommendation 1: Support the Creation of Exemptions from Infringement Liability,” which suggests carving out statutory “exemption[s] from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes,” and “for those who use patent-protected genes in the pursuit of research.” Id. at 90. The other recommendations are as follows: “Recommendation 2: Promote Adherence to Norms Designed to Ensure Access”; “Recommendation 3: Enhance Transparency in Licensing”; “Recommendation 4: Establish an Advisory Body on the Health Impact of Gene Patenting and Licensing Practices”; “Recommendation 5: Provide Needed Expertise to USPTO”; and “Recommendation 6: Ensure Equal Access to Clinically Useful Genetic Tests.” Id. at 91–93.