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Introduction To Regulating Innovation In Healthcare: Protecting The Public Or Stifling Progress?

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Abstract

Growing up seeing flames leaping and smoke billowing out of the smokestacks of steel mills along the river, children of southwestern Pennsylvania in the 1960s tended to develop one of two attitudes toward regulation in general.

KEYWORDS: flames, smokestacks, fumes

INTRODUCTION TO REGULATING INNOVATION IN HEALTHCARE: PROTECTING THE PUBLIC OR STIFLING PROGRESS?

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I. INTRODUCTION

Growing up seeing flames leaping and smoke billowing out of the smokestacks of steel mills along the river, children of southwestern Pennsylvania in the 1960s tended to develop one of two attitudes toward regulation in general. As the 1960s faded into the 1970s, it was regulation that rid the neighborhood of the rotten-egg stench of sulfurous fumes. It was regulation that cleared the air so that air quality index warnings receded into the past, enabling all citizens, including the elderly and young children, to go outside every day. Along with the clearer skies and non-toxic air, however, came the decline of the American steel industry. Certainly regulation was not the sole cause of that decline, and one also can attribute the decrease in pollution to the decline, but industry blamed increased environmental regulation in part for high production costs that led to foreign steel dominance. By 1983, unemployment had hit 13.9% in Allegheny County, home of Pittsburgh, the industrial center of the area.¹ Mills continued to close up and down the Monongahela River Valley over the next few years,² and it was easy for millworkers and their families to focus on the negatives of regulation, holding it responsible for at least part of their economic strife.

The tall, steep hill across the Monongahela River from the Clairton Works steel mill, however, demonstrates the benefits of regulation. During the 1960s and 1970s, no plant would grow on that hillside. Poisonous haze and particulates prevented any greenery from sprouting. Lacking vegetation anchoring the scant dirt covering its rocks, that hillside gave way periodically, and drivers had to detour around rockslide after rockslide closing the road below. Beginning with the onset of environmental regulation and continuing today, thanks to regulation, the hillside is covered in greenery holding the soil firmly in place. There are no more rockslides. The regulation some blamed at least in part for their misfortune was that

1. Bill Toland, *In desperate 1983, there was nowhere for Pittsburgh's economy to go but up*, PGH. POST-GAZETTE (Dec. 23, 2012, 10:00 AM), <http://www.post-gazette.com/business/businessnews/2012/12/23/In-desperate-1983-there-was-nowhere-for-Pittsburgh-s-economy-to-go-but-up/stories/201212230258>.

2. *Id.*

hillside's savior. Those enjoying clear skies and breathing cleaner air also were thankful for that greenery, the sight of which still pre-disposes some to look favorably upon regulation of business in general.

II. REGULATION OF THE FREE MARKET GUIDED BY ETHICS

This symposium issue of the *Nova Law Review* addresses regulation of the healthcare industry, not the environment; but that hillside outside of Clairton, Pennsylvania, symbolizes the recurring “regulation versus free market” debate in this country. Steel and associated heavy industries dominated southwestern Pennsylvania beginning in the late 1870s; by the 1940s, operating virtually free of environmental regulation, they had filled the sky with smoky haze, rendering Pittsburgh as dark as midnight in late morning.³ Skies began to clear after smoke control began in that city in 1946, but battles continued over regulatory expansion throughout the region.⁴ The memory of that hillside as it existed in the 1960s illustrates the effect of the free market, only recently regulated, on that particular patch of Earth. In contrast, its condition today, after increasing state and federal regulation, illustrates the benefits of regulation. Such an illustration can shape overall attitudes toward regulation regardless of the subject being regulated.

Titled *Regulating Innovation in Healthcare: Protecting the Public or Stifling Progress?*, the articles to follow comment on various aspects of the politically sensitive topic of healthcare regulation. Politicians and policymakers generally range from those favoring intense regulation, such as that with which “Americans had a love affair” from the 1880s to the late 1970s, to those advocating the “Age of Deregulation,” marked by some as beginning around 1978.⁵ The range of opinions is just as broad in healthcare, as the 2016 presidential campaign and the debates characterizing the beginning of the Trump Administration illustrate.⁶

3. See STEFAN LORANT, PITTSBURGH: THE STORY OF AN AMERICAN CITY 376 (2d ed. 1975) (illustrating downtown Pittsburgh with all lights on at 11 a.m. in 1945). Lorant describes Pittsburgh as “the hearth of the nation” beginning in the late 1800s. *Id.* at 177, 324 (picturing a “bleak scene” at 3:00 PM).

4. See *id.* at 381, 390 (noting that, despite the passage of a city ordinance in 1941, World War II postponed its operation until 1946 and explaining that state legislation to expand smoke control beyond the city first was introduced in 1947).

5. See Stephen G. Wood et al., *Regulations Deregulation and Re-Regulation: An American Perspective*, 1987 B.Y.U. L. REV. 381, 381–384 (1987).

6. See Andrew Gavil, *Trump's Simplistic Attack on Regulation is Misguided and Self-Defeating* FORBES (Mar. 8, 2017 9:41 AM), <https://www.forbes.com/sites/washingtonbytes/2017/03/08/trumps-simplistic-attack-on-regulation-is-misguided-and-self-defeating/#6f074dbf3e54>.

The authors in this symposium issue presented their ideas at Nova Southeastern University's Shepard Broad College of Law in the autumn of 2016, marking the 50th anniversary of Henry K. Beecher's "bombshell" of an article in *The New England Journal of Medicine* with the unassuming title *Ethics and Clinical Research*.⁷ In that article, Beecher documented 22 examples of "unethical or questionably ethical [medical research] studies."⁸ At the time Beecher wrote the piece, only 21 years after the Nuremberg trials,⁹ it was tempting to conclude that only Nazi physicians—not Americans—required regulation to guard against unethical behavior in medical research. Beecher's findings, in many readers' eyes, revealed otherwise. He himself, while not wishing to point a finger at particular researchers, explained:

Evidence is at hand that many of the patients in the examples to follow never had the risk [of research protocols] satisfactorily explained to them, and it seems obvious that further hundreds have not known that they were the subjects of an experience although grave consequences have been suffered as a direct result of experiences described here. There is a belief prevalent in some sophisticated circles that attention to these matters would "block progress." But, according to Pope Pius XII, ". . . science is not the highest value to which all other orders of values . . . should be subordinated."¹⁰

Beecher himself did not favor regulation. To him, the solution to the problem presented by unethical conduct of medical research rested primarily not on informed consent—the requirement of which is a form of regulation—but on a "more reliable safeguard provided by the presence of an intelligent, informed, conscientious, compassionate, responsible investigator."¹¹ After all, in medicine, the opposite of regulation is not purely the free market, as it is in the steel industry. Rather, the opposite of regulation in medicine is the free market guided by professionalism and ethics of a sort that does not dominate in the steel industry—or any other heavy industry for that matter.¹²

7. See generally Henry K. Beecher, *Ethics and Clinical Research*, 274 N. ENG. J. MED. 367 (1966); see also David S. Jones et al., "Ethics and Clinical Research" the 50th Anniversary of Beecher's Bombshell, 374 N. ENG. J. MED. 2393 (2016).

8. Beecher, *supra* note 7, at 368.

9. See Jones at 2293–2294 (describing the Nuremberg Code's appearance after World War II and noting that "[n]any U.S. scientists believed that the Code . . . did not apply to them").

10. Beecher, *supra* note 7, at 367 (footnote omitted).

11. *Id.* at 372.

12. See PETER J. HAMMER ET AL., UNCERTAIN TIMES: KENNETH ARROW AND THE CHANGING ECONOMICS OF HEALTHCARE 1–36 (2003) (*reprinting* Kenneth J. Arrow,

As bioethicist Robert Veatch writes, Beecher did not believe the researchers conducting the studies he described were consciously pursuing their self-interest and ignoring their ethical obligations. Rather, “for Beecher, the problem [was] well-meaning but thoughtless investigators who fail[ed] to grasp what they [were] doing,” and “consciousness-raising” was the solution.¹³

In contrast, Beecher’s former student, physician and bioethicist Jay Katz, operated under the conviction “that well-designed legal procedures could regulate (though not totally supplant) professional standards, which [Katz] found insufficient in themselves as a check on unethical practices.”¹⁴ As Veatch explains, “[b]y 1973, it was becoming more and more obvious that professional self-regulation was inadequate” in medical research.¹⁵ A whistleblower had revealed details of the Tuskegee Syphilis Study, through which the United States Public Health Service, under the guise of treatment, had studied untreated syphilis among poor, African-American men in Macon, Georgia, for the past forty years.¹⁶ In hearings thereafter, which led eventually to creation of the institutional review board (IRB) system of governmental regulation of research, Beecher testified that he favored “a massive professional education effort” instead.¹⁷ Nevertheless, as bioethicist Alexander Morgan Capron notes, “there is no question that [both] Beecher and Katz played pivotal roles in closing the post Nuremberg [ethical] lacuna that had become glaringly apparent by 1972.”¹⁸ Although Beecher favored reliance on ethics to govern the “free market” of medical research and Katz believed in research regulation, the development of such regulation in the United States stemmed at least partially from Katz’s “admiration for [Beecher’s] courage—Beecher’s willingness to risk his privileged position by lifting the veil that shielded the activities of his biomedical peers from public view.”¹⁹ For that reason, even research regulation advocates admire

Uncertainty and the Welfare Economics of Medical Care, 53 AM. ECON. REV. 941 (1963) and thereafter addressing the economics of modern healthcare issues).

13. Robert M. Veatch, *Henry Beecher’s Contributions to the Ethics of Clinical Research*, 59 PERSPS. IN BIOL. & MED. 3, 9 (2016).

14. Alexander Morgan Capron, *Henry Knowles Beecher, Jay Katz, and the Transformation of Research With Human Beings*, 59 PERSPS. IN BIOL. & MED. 55, 67 (2016).

15. Veatch, *supra* note 13, at 15.

16. Capron, *supra* note 14, at 68. See also JAMES H. JONES, *BAD BLOOD: THE STORY OF THE TUSKEGEE SYPHILIS STUDY* (rev. ed. 1993) (for more about the Tuskegee Syphilis Study).

17. Veatch, *supra* note 13, at 16 (quoting Beecher as saying, “I think it is a little too soon for this to be frozen into law.”).

18. Capron, *supra* note 14, at 75.

19. *Id.*

and honor Beecher to this day, and it seemed fitting to hold a symposium in his honor on the 50th anniversary of the article by which most know him.

III. HEALTHCARE REGULATION BEYOND MEDICAL RESEARCH

The topics of innovation and the role that its regulation plays raise questions in many areas of healthcare, not just clinical research. This symposium addresses important aspects of healthcare innovation dealing with delivery, payment, data collection, and technology. In organizing the symposium at NSU, we brought together experts from across the country in academia, government, and private practice to address the challenges in the transformation of healthcare. The result was an explicitly interprofessional event, during which the legal, medical, public health, and patient communities learned from each other. These articles provide insight on both sides of the question of whether regulating innovation is helping or hurting the future of healthcare.

Jackson Williams, the Director of Government Affairs for Dialysis Patient Citizens, addresses the need for innovation in healthcare business models. He argues that a business model change could be a solution to the current problem of high costs and low quality of healthcare in the United States. Specifically, Williams “argues that insurance regulators [could] catalyze cost containment efforts by encouraging, or mandating, insurers to act vigorously as agents of consumers in obtaining low prices from providers.”²⁰ He also notes that insurance regulators could police provider misconduct in healthcare markets, providing extra protection for patients.²¹ Williams discusses how an insurance commissioner’s regulatory authority could solve the collective action problem by apportioning costs and thereby incentivizing provider cooperation.²² Williams’ innovative proposal could alleviate the skyrocketing cost-sharing obligations that currently exist in the majority of employer-sponsored health insurance plans.

Another equally important area of innovation is digital health information technology. As the healthcare industry has shifted from paper to digital, new legal issues have arisen with how to keep patients and their privacy interests protected. Cason Schmit, Research Assistant Professor of Public Health at Texas A&M University, introduces a research project undertaken by the Centers for Disease Control to examine the regulatory framework of state statutes dealing with health information technology. The

20. Jackson Williams, *The Persistence of Opportunistic Business Models in Healthcare and a Stronger Role for Insurance Regulators in Containing Healthcare Costs*, 41 NOVA L. REV. 313, 314 (2017).

21. *Id.*

22. *Id.*

research reveals that there are literally thousands of state laws addressing digital health information in healthcare. Schmit notes that as technology has continued to outpace legislation at an exponential rate, the states have stepped up to create a patchwork of laws to try and keep up. Schmit argues that this complicated patchwork of state laws could be impeding advancements in health information technology because it is difficult to discern the applicable laws, and, therefore, businesses that want to avoid exposure to liability may steer clear of innovation for this reason. Schmit notes, however, that some laws are helpful in enabling entities to engage in new and innovative health information technology. In these instances, instead of regulation becoming a barrier to innovation, the regulations actually encourage and enable innovation. Schmit highlights how the law has been both a benefit and a burden to innovation in healthcare.

While there are numerous benefits to be gained from the shift from paper to digital, there are also new vulnerabilities associated with the data that did not exist before this transition. This cycle of innovation and legal catch-up is not uncommon in the law. Since its inception, the organization now known as the Food and Drug Administration (“FDA”) has been charged with protecting a vulnerable public from the manufacturers and sellers of medical products. Initially, its purview was over products characterized as drugs, but as medical devices became more sophisticated, and consequently more dangerous, the FDA’s scope expanded to cover them as well.²³ Despite its best efforts, however, the FDA and the regulations that govern it have always lagged behind the pace of technological advances, resulting in a cycle of inaction, tragedy, and reaction.²⁴

Innovation in health information technology mirrors the last century of innovation in medical devices in that they both outpace the advancements in law. They both also carry with them risks to a vulnerable public in different ways. As advancements in health information technology bring benefits to healthcare, they bring the potential for damage – not only physical injury, as with medical devices, but also damage to financial and privacy interests. Paul R. DeMuro, Associate Professor of Pharmacy at NSU, examines the cybersecurity risks inherent in health information technology. Specifically, DeMuro’s article discusses ransomware, a virus cybercriminals use to bring patient care to a halt while they hold patients’ health information captive. Ransomware has the potential to destroy privacy and prevent appropriate care from being delivered to patients because computer systems

23. 1 JAMES T. O’REILLY & KATHERINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 12:9 (4th ed. 2016).

24. *See id.* at § 12:7.

are frozen until the ransom is paid to the cybercriminal.²⁵ As innovation creates new technology, existing security measures and regulations have proven insufficient to protect against the vulnerabilities. DeMuro analyzes the existing legal framework governing digital health information in the healthcare industry and argues that negotiation theory should be applied to the ransomware context to shed light on whether healthcare organizations should be permitted to engage in ransom negotiations with cybercriminals.

As discussed above, this same tension between innovation and regulation arises with the societal desire for advancement in medical devices. Whether it is an improved implantable cardioverter defibrillator or an insulin pump, most would agree that innovation in medical devices benefits the public. However, as technology has increased with medical devices, so has the ability to capture sensitive patient information through vulnerabilities in the hardware or software. As Chris Kersbergen, Assistant Professor at Keiser University, discusses in his article, it is easy hack into such devices.²⁶ Kersbergen examines a recent draft FDA guidance on cybersecurity for manufacturers of wirelessly connected, implanted medical devices.²⁷ He discusses why it is so easy to hack into such devices and critiques three aspects of the draft guidance, suggesting that the FDA should include patient privacy within the concept of patient safety when regulating in this area.²⁸ Kersbergen argues for additional FDA regulation that focuses heavily on the financial and other “identity” implications of hacking into medical devices as a way to obtain patient data.²⁹

Not only is there a risk that patient health information can be exploited for financial gain, but the patient’s physical safety also could be jeopardized by these various vulnerabilities. Michael Woods’s article focuses on the physical safety aspect of cybersecurity of the same devices. Woods is not as concerned about financial identity theft or patient data; he is mainly concerned about patient physical safety and about terrorists who could hack into medical devices to physically hurt patients. He does not focus on any one agency or any one regulation or guidance document; part of his point is that too many agencies are responsible for monitoring

25. Paul R. DeMuro, *Keeping Internet Pirates at Bay: Ransomware Negotiation in the Healthcare Industry*, 41 NOVA L. REV. 349, 352–53 (2017).

26. Christopher Kersbergen, *Patient Safety Should Include Patient Privacy: The Shortcomings of the FDA’s Recent Draft Guidance Regarding Cybersecurity of Medical Devices*, 41 NOVA. L. REV. 397, 397 (2017).

27. *Id.* at 417–18.

28. *Id.* at 412–14.

29. *Id.* at 401.

cybersecurity of such devices, in various ways.³⁰ Similar to Schmit's highlighting of the complicated patchwork of regulations, Woods seeks clarification among the various government agencies regulating in this area. This is an area characterized by duplication of laws and overlap of authority, creating problems in effective enforcement of the law. When the potential for serious harm is so high, Woods argues, there should be a unified approach to regulation among agencies.³¹ Without a unified, proactive approach to these regulations, the United States could be facing another cycle of inaction, tragedy, and reaction.

The transformation of healthcare is certain. If and how regulation will respond to this transformation will have a profound personal impact on us all. This symposium explores the highly political question of how much involvement the law should have in the innovation of healthcare. We hope it adds to the discourse and exposes areas where changes in the law can help shape the healthcare industry.

30. Michael Woods, *Cardiac Defibrillators Need to Have a Bulletproof Vest: The National Security Risk Posed by the Lack of Cybersecurity in Implantable Medical Devices*, 41 NOVA L. REV. 419, 437–39 (2017).

31. *Id.* at 440–42.