LOYOLA
UNIVERSITY CHICAGO
SCHOOL of LAW

Volume 34 | Issue 1
WINTER 2025

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

Annals OF Health Law

ADVANCE DIRECTIVE

The Student Health Policy and Law Review of
LOYOLA UNIVERSITY CHICAGO SCHOOL of LAW

ANNALS OF HEALTH LAW
Advance Directive

THE STUDENT HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

Beazley Institute for Health Law and Policy

VOLUME 34, STUDENT ISSUE 1 WINTER 2025

CONTENTS

ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The Annals of Health Law and Life Sciences is proud to present the first issue of the thirty-fourth volume of our online, student-written publication, *Advance Directive*. This *Fall 2024 Advance Directive* issue focuses on trending topics at the intersection of healthcare innovation and regulation.

The *Fall 2024 Advance Directive* issue explores a wide variety of topics within the current healthcare framework of the United States regarding various healthcare innovations and the regulation of these innovations. Our student authors have also proposed adjustments to the current implementation, legal guidance, and regulatory landscape of healthcare innovations.

This issue will examine topics ranging from the role of private equity investments in healthcare to discussions around impactful Supreme Court decisions in the healthcare landscape. The articles in this issue analyze longstanding problems plaguing the United States healthcare industry, including cost, regulatory, and accessibility obstacles. The range of topics specifically covered includes the implications of artificial intelligence within healthcare, regulatory hurdles regarding women's reproductive rights as well as other healthcare supplements, and rising healthcare costs across a variety of individualized health fields. This wide range of topics exemplifies the diverse legal challenges and systemic barriers confronting healthcare in the United States today.

The Annals of Health Law members deserve special recognition for their hard work and dedication to the well-thought-out articles included in this issue. We would like to thank Megan Baumgardner, our *Annals* Editor-in-Chief, for her constant leadership and support. We would also like to thank and acknowledge our *Annals* Executive Board Members, Alessandra Barbuto, Kayla Bradley, Payton Moore, Rae-Ali Raymond, and Maya Smith, for all their hard work. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Charlotte Tschider, and Kristin Finn, for all their guidance.

We hope you enjoy this issue of *Advance Directive*.

Sincerely,

Sarah Knoll
Advance Directive Executive Editor
Annals of Health Law
Loyola University Chicago School of Law

Johannes Alvarez-Rivero
Advance Directive Executive Editor
Annals of Health Law
Loyola University Chicago School of Law

Opill: Solutions for Advancing Reproductive Health Care in Illinois

Neha Alety

I. INTRODUCTION TO OPILL

Opill is the first daily oral contraceptive approved by the Food and Drug Administration ("FDA") for use in the United States without a prescription.[1] Opill is a progesterone-only form of birth control that uses progesterone to prevent the ovaries from releasing an egg every month, block sperm from reaching an egg, and change the uterine lining to keep a fertilized egg from implanting.[2] Opill is supposedly a more safe and effective option than other nonprescription contraceptive options already out on the market.[3] Opill costs $19.99 for a one month supply, which includes 28 pills–three month and six month supplies are also available for purchase.[4] It can be purchased on Opill's website, at pharmacies such as Walgreens and CVS, at major retailers such as Target and Walmart, and even on Amazon.[5] In order to be approved, Opill manufacturers had to show that Opill could be safely taken and understood by consumers with just the information on the label in order to make it accessible without physician guidance.[6] This article will aim to address the current state of reproductive health in the United States and how Opill fills the gaps in contraceptive care, while also recognizing its limitations. Further, this article will focus on the specific state of Illinois and propose policy changes to increase access and affordability.

First, this article will discuss contraceptive deserts and the effects of the recent Supreme Court reversal of *Roe v. Wade* on access to contraceptive

---

[1] *FDA Approves First Nonprescription Daily Oral Contraceptive*, U.S. FOOD & DRUG ADMIN. (July 13, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive.
[2] Candice Mazon & Amy Desrochers DiVasta, *Opill: Is This New Birth Control Pill Right for You?*, HARVARD HEALTH PUBLISHING (Nov. 8, 2023), https://www.health.harvard.edu/blog/opill-is-this-new-birth-control-pill-right- for-you-202311082989.
[3] *FDA Approves First Nonprescription Daily Oral Contraceptive*, *supra* note 1.
[4] OPILL (2024), https://opill.com/.
[5] *Id.*
[6] *FDA Approves First Nonprescription Daily Oral Contraceptive, supra* note 1.

services. Next, the article will discuss how Opill affects low-income, vulnerable populations and their ability to receive contraceptive care. Finally, the article will propose solutions address the issues of affordability and accessibility with the adoption of Opill.

II. CONTRACEPTIVE DESERTS AND ROE V. WADE

In 2022, the Supreme Court overturned *Roe v. Wade*, removing the constitutional right to an abortion and allowing for individual states to enforce their own abortion regulations.[7] In 2020, there were more than 930,000 women who legally had an abortion performed.[8] Of the abortions performed, ninety percent of them were unintended or unwanted pregnancies.[9] Of those unintended pregnancies, seventy percent were due to not using a form of contraceptives.[10] To obtain an abortion post-*Dobbs*, women in states with more restrictive abortion policies are likely to travel out of the state for abortion procedures, which is disproportionately harder for individuals of color due to limited financial resources or other barriers such as transportation.[11] According to the Kaiser Family Foundation, sixty-six percent of women who receive abortions are people of color.[12]

Given this decision by the Supreme Court, there is increased importance on access to contraceptive services. Contraceptives play a vital role in

---

[7] Nina Totenberg and Sarah McCammon, *Supreme Court Overturns Roe v. Wade, Ending Constitutional Right to Abortion,* NPR (June 24, 2022, 10:43 AM), https://www.npr.org/2022/06/24/1102305878/supreme-court-abortion- roe-v-wade-decision-overturn.

[8] Jeff Diamant et al., *What the Data Says About Abortion in the U.S.*, PEW RSCH. CTR. (March 25, 2024), https://www.pewresearch.org/short-reads/2024/03/25/what-the-data-says-about-abortion-in-the-us/.

[9] John Cleland, *The complex relationship between contraception and abortion*, 62 BEST PRAC. & RSCH. CLINICAL OBSTETRICS & GYNAECOLOGY 90 (2020).

[10] *Id.*

[11] *Id.*

[12] *Reported Legal Abortions by Race of Women Who Obtained Abortion by The State of Occurrence*, KFF (2021). https://www.kff.org/womens-health-policy/state-indicator/abortions-by- race/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

reducing the number of unwanted pregnancies by approximately ninety percent and the need for abortions by 4.5 million people.[13] There are currently over 66 million individuals of reproductive age living in the United States, with about 19 million of them lacking access to publicly funded contraceptive services.[14] These areas are known as "contraceptive deserts" which, for the purpose of this article, will be defined as areas where the number of health centers that offer the full range of contraceptive methods is not enough to meet the needs of the number of people eligible for publicly funded contraception.[15]

The *Dobbs* decision disproportionately impacts individuals who are residing in these contraceptive deserts and already experience increase barriers to accessing reproductive health resources. Many women residing in these contraceptive deserts are low-income, women of color that mainly reside in rural areas.[16] These individuals disproportionately face barriers to accessing a clinic that offers the full range of contraceptive methods such as transportation, lack of insurance coverage, affordability of services, ability to take time off work, and more.[17] According to HRSA, the full range of contraceptives encompasses those currently listed in the FDA's Birth Control Guide, which include IUDs, contraception injections, oral contraceptives, prosgestin only oral contraceptives, the patch, vaginal contraceptives, and male condoms.[18] Specifically, data shows that black women are three times

---

[13] Norman A. Ginsberg & Lee P. Shulman, *Life Without Roe v Wade*, 6 CONTRACEPTION AND REPROD. MED. 5 (2021).
[14] *Contraceptive Deserts*, POWER TO DECIDE (2024), https://powertodecide.org/what-we-do/contraceptive-deserts.
[15] Sarah M. Axelson et al., *Reproductive Well-Being: A Framework for Expanding Contraceptive Access,* 112 AM. J. OF PUB. HEALTH 504, 504 (2022).
[16] Candis Watts Smith et. al., *Contraception Deserts: The Effects of Title X Rule Changes on Access to Reproductive Health Care Resources*, 18 POLITICS & GENDER 672, 684 (2022).
[17] *Id.* at 683.
[18] *Women's Preventative Services Guidelines,* Health Resources and Services Administration (2024), https://www.hrsa.gov/womens-guidelines.

more likely to die due to pregnancy complications in comparison to their white counterparts, emphasizing the need for increased contraceptive services.[19] The *Dobbs* ruling exacerbates barriers that marginalized populations such as people of color, those residing in rural communities, and low-income individuals face when accessing safe and affordable reproductive healthcare.

III. Reproductive Health Policy in Illinois

In Illinois, over 780,000 women in need live in contraceptive deserts and, of that number, approximately 79,000 of them live in counties without a single health center that provides the full range of contraceptive methods.[20] Illinois has several regulations and programs in place in order to make contraceptives and other family planning resources more readily available.[21] To address the affordability of contraceptives and other family planning resources for low-income individuals, Medicaid in Illinois provides comprehensive coverage for all FDA approved contraceptive services including coverage for prescribing birth control, over-the-counter contraceptives, and long-acting reversible contraceptives such as IUDs and implants.[22] For those who otherwise do not qualify for Medicaid, the HFS Family Planning Program provides essential reproductive health services for those aged fifteen (15) to forty-four (44) to prevent unintended pregnancies and to educate members of the community on the choices available to them.[23] Eligible participants, who typically fall at income levels at or below 213% of the federal poverty level, can access these services through community health

---

[19] *Working Together to Reduce Black Maternal Mortality,* U.S. Ctr. for Disease Control & Prevention (April 8, 2024), https://www.cdc.gov/womens-health/features/maternal-mortality.html.
[20] *Contraceptive Access in Illinois*, *supra* note 14.
[21] *Id.*
[22] *Illinois Healthcare Portal: Women*, Ill. Dep't of Healthcare & Fam. Services, https://hfs.illinois.gov/medicalclients/health/woman.html (last visited, Nov. 11, 2024).
[23] *HFS Family Planning Program*, Ill. Dep't of Healthcare & Fam. Services, https://hfs.illinois.gov/medicalclients/familyplanning.html (last visited, Nov. 11, 2024).

centers and family planning clinics.[24] Illinois also provides coverage of reproductive health services for those who are waiting for their Medicaid eligibility to be determined.[25] The Illinois Family Planning Presumptive Eligibility program ("FPPE") allows participants to receive immediate coverage for contraception.[26] However, in order to participate, interested participants must go to a provider who will decide whether they are eligible for the program and fill out the required paperwork.[27] Once approved, the coverage begins on the day the provider completes the submission and lasts till the end of the month or until a final decision is made on Medicaid coverage.[28]

In addition to initiatives that address affordability, Illinois has programs that address accessibility of family planning services. The Illinois Contraceptive Access Now ("ICAN") program seeks to address how contraceptive care is delivered, covered, and accessed in order to make contraception and other reproductive health services more accessible to the populations residing in contraceptive deserts.[29] ICAN focuses on increasing awareness and availability of a wide range of contraceptive methods, including long-acting reversible contraceptives.[30] The program focuses on healthcare providers by providing them training and resources to enhance service delivery and making sure that patients receive comprehensive counseling and care.[31] Furthermore, the program engages with community organizations to raise awareness about available contraceptive methods and

---

[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *What is ICAN?*, ICAN, https://ican4all.org/about-us/ (last visited, Nov. 11, 2024).
[30] *Id.*
[31] *Id.*

services, targeting populations that may face exacerbated barriers to access, such as low-income individuals or those who reside in contraceptive deserts.[32] Additionally, ICAN works to ensure that clinics and health care centers have sufficient supply of contraceptives, making it easier for individuals to obtain free or low-cost options without financial strain.[33]

IV. THE ADOPTION OF OPILL IN ILLINOIS

In the wake of the *Dobbs* decision, the purpose of Opill is to make contraception more accessible.[34] While this eliminates barriers for many low-income individuals residing in contraceptive deserts by allowing them to receive contraception without needing to first go to a physician's office for a prescription and then finding a pharmacy that will provide them with the contraception, accessibility largely depends on availability and affordability, specifically insurance coverage.[35]

In anticipation of Opill, the Illinois Department of Healthcare and Family Services released a provider notice stating that Opill will be covered for women eighteen (18) and older without a prescription, covering both the fee-for-service program and managed care organizations.[36] Fee-for-service is a payment model where health care providers and clinics are reimbursed based on the number of services that they provide.[37] Under a fee-for-service health care model, physicians are reimbursed for the volume and quantity of services provided which can lead to uneven care between patients and excessive services and out-of-pocked costs.[38] Managed care organizations

---

[32] *Id.*
[33] *Id.*
[34] *FDA Approves First Nonprescription Daily Oral Contraceptive*, *supra* note 1.
[35] Michelle Long et al., *Over-the-Counter Oral Contraceptive Pills*, KFF (Sep. 27, 2024), https://www.kff.org/affordable-care-act/issue-brief/over-the-counter-oral-contraceptive-pills.
[36] Kelly Cunningham, *Provider Notice Issued 12/18/2023*, ILL. DEP'T OF HEALTHCARE & FAM. SERVICES (Dec 18, 2023), https://hfs.illinois.gov/medicalproviders/notices/notice.prn231218a.html.
[37] Neeloufar Fakourfar et al., *Fee-for-service*, AM. PHARMACISTS ASS'N (Sep. 2, 2021), https://www.pharmacist.com/Practice/Practice-Resources/Learn-the-Lingo/fee-for-service.
[38] *Id.*

include health maintenance organizations ("HMOs"), preferred provider organizations ("PPOs"), and point of service organizations ("POS"). The purpose of these plans are to limit costs but provide high quality health care to patients.[39] HMOs have lower monthly premiums but require patients to see in-network providers, costing less but offering less flexibility.[40] PPOs have higher costs but give patients the option to see any doctor that they would like.[41] To see an out-of-network provider, patients have to pay higher costs and may have to get referrals from a primary care physician to see specialists.[42] Lastly, POS plans are a combination of both HMOs and PPOs.[43]

In Illinois specifically, there are three managed care programs that fall within Illinois Medicaid: HealthChoice Illinois ("HCI"), YouthCare, and the Medicare Medicaid Alignment Initiative ("MMAI").[44] Following the approval of Opill by the FDA, healthcare providers and clinics in Illinois have begun offering Opill to their patients, emphasizing its ease of use and effectiveness. Furthermore, insurance coverage for all FDA-approved contraceptives is mandated under state law, requiring private health insurers to provide coverage for all FDA-approved contraceptives without cost-sharing.[45] This potentially allows for those with insurance to access Opill without out-of-pocket expenses, making it more affordable and accessible. Additionally, public health campaigns such as the ICAN initiative are heavily

---

[39] *What is Managed Care?,* CIGNA HEALTHCARE (2023), https://www.cigna.com/knowledge-center/what-is-managed-care.
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Illinois's Managed Care Programs,* HFS ILL. DEP'T OF HEALTHCARE & FAM. SERVS., https://hfs.illinois.gov/medicalclients/managedcare.html (last visited Oct. 24, 2024).
[45] *Reproductive Health Care Services, Including Abortion and Contraceptives*, ILL. DEP'T OF INS., https://idoi.illinois.gov/consumers/reproductive-health-care-services.html (last visited Oct. 24, 2024).

promoting Opill, as a safe to use estrogen-free daily contraceptive.[46] They have focused their efforts on educating both providers and patients about the benefits of Opill, particularly its suitability for individuals who may prefer non-estrogen options and how to access Opill through online retailers or their local supermarket and pharmacy.[47] Despite having another, more accessible option of contraception, contraceptive counseling can provide patients with the basic information that they need to make informed decisions about the type of contraception that fits their lifestyle and how to safely take their chosen method.[48] Additionally, though Opill is available online, without the need for a prescription, primary care physicians and other clinicians act as sources of information. Thus, having educated and knowledgable health care providers is important for provided high-quality contraceptive care and improving access to contraception.[49] Especially for oral contraception that need to be taken on a regular basis, inadequate knowledge of risks, benefits, side effects, effectiveness, and correct use can impact the consistency with which patients take their medication.[50] On the other hand, educating providers helps compliment patient education because having knowledgable providers leads to more favorable attitutes towards contraception amongst younger, more nervous populations and allows Opill to be marketed towards those who may not know about more modern contraceptive methods.[51]

V. LIMITATIONS WITH OPILL ADOPTION

---

[46] Sasha-Ann Simmons, *FDA Approves Over the Counter Birth Control*, ICAN (July 13, 2023), https://ican4all.org/kai-tao-speaks-with-wbez-about-new-fda-ruling/.
[47] *Id.*
[48] Karen Pazol et al., *Impact of Contraceptive Education on Contraceptive Knowledge and Decision Making: A Systematic Review*, 49 AM. J. OF PREVENTIVE MED. 46 (2015).
[49] *Id.*
[50] *Id.* at 53.
[51] Sidikiba Sidbé et al., *Knowledge, attitudes, and practices of health providers regarding access to and use of contraceptive methods among adolescents and youth in urban Guinea,* FRONTIERS IN PUB. HEALTH (2022), 1.

As previously discussed, over-the-counter and non-prescription required contraceptives are positive methods to decreasing access barriers for those residing in contraceptive deserts and low-income individuals. However, there are several limitations with contraceptives such as Opill.

Firstly, there is concern with the safety of allowing individuals, specifically those who may not be educated about family planning or reproductive health options, to take over-the-counter medication. There is concern with allowing customers to freely purchase a non-estrogen contraceptive without first consulting with a physician or pharmacist because it is during these visits that the medical provider is able to counsel patients on the best possible contraception choice for them and provide other screenings and family planning services that they might not otherwise receive.[52] These appointments can be crucial, especially with the variety in types of birth control that may have different effects on the body depending on the patient's medical history.[53]

Additionally, in order for birth control to be effective, it needs to continue to be taken on a regular basis. For those who are low-income or who may not reside in areas where major retailers or pharmacies are readily available, continued usage of Opill may be challenging. One may argue that Opill gets rid of this barrier by allowing for delivery of the contraceptive via their storefront or on Amazon. However, low-income individuals and those residing in rural areas may not have access to internet services or stable housing for them to have the contraception delivered to them on a monthly basis. Furthermore, while there commercial pharmacies such as CVS and

---

[52] Sneha Barot, *Moving Oral Contraceptives to Over-the-Counter Status: Policy Versus Politics,* 18 GUTTMACHER POL'Y REV. 85, 87 (2015).
[53] Mayo Clinic Staff, *Birth Control Options: Things to Consider*, MAYO CLINIC (Feb. 16, 2022), https://www.mayoclinic.org/healthy-lifestyle/birth-control/in-depth/birth-control-options/art-20045571.

Walgreens are stocking OPill, there may be hesitancy from independent pharmacies to stock the new form of birth control. Here, independent pharmacies are defined as pharmacies having fewer than four locations and commercial pharmacies are defined as those having more than four locations and possibly being located in a department store such as Target or Walmart.[54]

Prior studies show that independent pharmacies were less likely to stock other forms of contraception such as emergency contraception and female contraception.[55] Rural, lower-income areas are more likely to have less pharmacies than urban areas, and of these pharmacies, they are more likely to be independent pharmacies rather than franchise pharmacies.[56] A study surverying 500 pharmacies showed that independent pharmacies were less likely to have OPill available for purchase and were likely to sell it for a higher purchase price.[57] Furthermore, if not in stock at the pharmacy, independent pharmacies advised patients to go to a larger retail pharmacy and were less likely to order the contraceptive for pick up.[58] While the option to order it online directly from the OPill website is available, this limits the methods of accessibility that those residing in pharmacy deserts or more low-income, rural areas have to purchase OPill and other contraception.

VI. Policy Solutions to Increase Access to OPill in Contraceptive Deserts in Illinois

Though Illinois has comprehensive policies in place to make sure those with public and private insurance are able to access contraceptive care such as Opill, there is no system in place to ensure that supermarkets and pharmacies in Illinois supply Opill. Additionally, Illinois Medicaid and private insurance covers Opill without cost sharing, however, there are many

---

[54] Brandon G. Wagner et al., *Retail Availability of Over-the-Counter Birth Control Pills at Texas Pharmacies: Results from a Mystery Caller Study,* 139 Contraception 1, 1–2 (2024).
[55] *Id.* at 3.
[56] Noelle Kwan, *The Impact of Pharmacy Deserts,* 49 U.S. Pharmacist 32 (2024).
[57] Wagner et al., *supra* note 54, at 4.
[58] Wagner et al., *supra* note 54, at 4.

individuals who reside in contraceptive deserts that are uninsured or underinsured. In 2022, there were 815,100 uninsured individuals residing in Illinois.[59]

Opill costs approximately $20 for a 28-day supply; however, studies show that individuals taking over-the-counter contraceptives such as Opill would be willing to pay $1 to $10 per month for their supply.[60] Opill significantly reduces barriers to access by allowing for purchase in supermarkets, however, the cost is still an issue. One potential policy solution is for the Illinois Department of Health to coordinate a bulk purchasing initiative so that local supermarkets and gas stations can sell the pill at a lower price for those who are uninsured or underinsured. Bulk purchasing allows for these smaller, local supermarkets to buy contraceptive supplies at a lower cost per unit, significantly reducing the price of contraception for patients, making it more accessible. In response, these lower costs can make it easier for insurance companies and public health programs to cover contraceptive methods, ensuring that patients face minimal out-of-pocket expenses. Additionally, the bulk purchasing initiative can lead to a more consistent availability of contraceptives, reducing the risk of shortages that might prevent some patients from accessing Opill in the store. These lower prices would also encourage more consistent use. Many patients may not be able to consistently pay $20 a month for their oral contraception. However, lower prices would encourage low-income, more vulnerable patients to routinely take their contraception and purchase Opill on a regular basis.

---

[59] *Health Care in Illinois*, KFF (2024), https://www.kff.org/statedata/election-state-fact-sheets/illinois/.

[60] *3 Charts: The Cost and Coverage of Opill – the First FDA-approved Over-the-Counter Daily Oral Contraceptive Pill in the United States*, KFF (Mar. 5, 2024), https://www.kff.org/health-costs/press-release/three-charts-the-cost- and-coverage-of-opill-the-first-fda-approved-over-the-counter-daily-oral-contraceptive-pill-in-the-united-states/.

Specifically, bulk purchasing can help level the playing field by ensuring that low-income populations have the same access to contraceptive methods as higher-income individuals do. Bulk purchases and lower costs play a crucial role in enhancing access to contraception, improving health outcomes, and supporting public health initiatives. Furthermore, this would assist independent pharmacies in providing Opill to their clients. As mentioned above, Opill adoption is limited because even though there are more independent pharmacies in low-income areas, they are less likely to provide contraceptive methods. Independent pharmacies have less resources than franchise pharmacies making it difficult to maintain a routine stock of medications and provide services to patients.[61] This kind of purchasing initiative would make it easier for those independent pharmacies with limited resources to provide over-the-counter contraceptives by saving them money and resources when purchasing Opill. Additionally, it would create an easier way for them to maintain their stock of Opill so patients can continue their contraceptive regimine.

Additionally, those residing in contraceptive deserts may have limited access to reproductive health education and may not even be aware that Opill is available for purchase at their local supermarket or even online without a prescription. The Illinois Department of Health should partner with community organizations and community health providers such as ICAN to conduct outreach and perhaps even mobile clinics that can go out into the community. These mobile clinics can provide information and education regarding Opill's use and methods that it can be easily accessed tailored to those specifically residing in that community. While Opill helps to reduce barriers to accessing contraception by making their product deliverable to the home and available in the supermarket, there may be some individuals who are either unhoused or lack the transportation to go to the supermarket.

---

[61] Kwan, *supra* note 56.

By moving to different locations, mobile clinics can meet patients where they are and patients can access services closer to home, making it easier for them to obtain contraception. In the aftermath of *Roe v. Wade*, it may make patients more comfortable to purchase contraception in a space that is familiar to them due stigma of going to the store to purchase contraception. Furthermore, by providing services in a non-traditional setting, mobile clinics can help normalize discussions about contraception and reproductive health, reducing stigma and encouraging more people to seek reproductive health services. Mobile clinics can also provide a more private and less intimidating environment to discuss and obtain contraceptive options. Additionally, mobile clinics usually provide a range of services, including education about contraception, counseling, STI testing, which all be done in one visit, promoting a more holistic approach to health care that encourages patients to get the multiple services that they might need. Not only can these mobile clinics improve patient education and access to resources, but community organization workers can also educate pharmacists in retail pharmacies, department stores, and independent pharmacies on the benefits and risks of providing Opill to their customers to make the adoption of Opill more safe.

VII. OPILL BEGINS TO BRIDGE THE GAP IN CONTRACEPTIVE ACCESS BUT STILL NEEDS IMPROVEMENT

Opill is a groundbreaking solution to the gap in access to contraceptive services, especially for those in contraceptive deserts who face additional barriers to accessing reproductive health care. Opill allows for the purchase of a contraceptive without the need for a prescription from a physician first or being able to purchase contraception from the comfort of your home without the stigma of going to purchase contraception. However, in order to

expand the scope of its impact, initiatives must be implemented regarding cost and education for those who are low-income and residing in rural areas such as partnerships with community organizations and clinics and working with local markets and gas stations to encourage lowering the cost of a supply for those who are unable to pay twenty dollars a month for their contraceptives. Making contraception more affordable empowers individuals to make informed choices about their reproductive health. In a time where several states are restricting access to abortion and other family planning services, with the support of state initiatives, Opill has the potential to push reproductive health forward.

Regulating the Neural Frontier: Why Brain-Computer Interfaces (BCIs) Require a New Regulatory Model

Mehak Dureja

I. THE NEW FRONTIER: HOW BCIS ARE MERGING BRAINS WITH TECHNOLOGY

Imagine a future where computers and brains are fully linked, with information flowing both ways.[1] Brain-Computer Interface ("BCI") makes this connection possible by collecting, processing, and translating an individual's neurodata.[2] The data contains brain signals, which convert into commands to control external devices, like a robotic limb, or influence brain activity and behavior.[3] BCIs connect through wearable devices, like caps with conductors, or implantable devices surgically attached to brain tissue.[4]

BCI applications offer significant health benefits, such as restoring movement for paralyzed patients and enabling communication for stroke victims.[5] However, their ability to manipulate brain signals raises serious concerns about controlling individuals' actions and creating faulty and biased outcomes.[6] This article explores BCI applications, current United States regulations, risks for consumers, and proposes creating an independent agency to address regulatory challenges.

II. CURRENT LANDSCAPE OF BCI REGULATION

---

[1] Paul R. Wolpe, *Ethical and Social Challenges of Brain-Computer Interfaces*, 9 AM. MED. ASS'N J. OF ETHICS 128, 129 (2007).
[2] Mia Yin, *Privacy Risks in Brain-Computer Interfaces and Recommendations,* DATA SCI. W231, BEHIND THE DATA: HUM. & VALUES (Mar. 16, 2022), https://blogs.ischool.berkeley.edu/w231/2022/03/16/privacy-risks-in-brain-computer-interfaces-and-recommendations/.
[3] *Id.*
[4] U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-106118, SCIENCE & TECH SPOTLIGHT: BRAIN-COMPUTER INTERFACES (2022).
[5] Brooke Becher & Matthew Urwin, *Brain-Computer Interfaces (BCI) Explained*, BUILT IN (July 24, 2024), https://builtin.com/hardware/brain-computer-interface-bci.
[6] Manar Alohaly, *The Brain Computer Interface Market Is Growing - But What Are the Risks?*, WORLD ECON. F.: CYBERSECURITY (June 14, 2024), https://www.weforum.org/agenda/2024/06/the-brain-computer-interface-market-is-growing-but-what-are-the-risks/.

As BCIs evolve, they are expanding beyond medicine.[7] Enhancement BCIs, which augment cognitive functions like learning, memory, and emotion recognition, also serve non-medical purposes such as monitoring cognitive fatigue and entertainment.[8]

The Federal Trade Commission ("FTC") and United States Food and Drug Administration ("FDA") currently regulate BCI technology.[9] The FTC evaluates non-health-related devices for "unfair or deceptive practices", such as data protection.[10] The Health Insurance Portability and Accountability Act ("HIPAA") protects health information within the healthcare system.[11] However, a significant amount of consumer data collected through wearable devices, apps, and websites falls outside HIPAA's coverage, creating a privacy gap.[12] The FTC addresses this by applying the FTC Act to both HIPAA-covered entities and non-HIPAA entities.[13] Additionally, the FTC's Health Breach Notification Rule applies to some companies handling personal health records ("PHRs") that are not covered by HIPAA.[14] This rule mandates that companies notify consumers if a security breach exposes their health information without consent, especially when the data is not protected

---

[7] *Id.*
[8] Dorkina Myrick, *Cognitive Utopia or Dystopia? Brain-Computer Interface Enhancement and the Technological Singularity*, OXFORD POL. REV., no. 12, Mar. 2024, at 21.
[9] Henry Fisher, *The Challenges of Regulating Brain-Machine Interfaces*, THE REGUL. REV.: HEALTH (Nov. 24, 2022), https://www.theregreview.org/2022/11/24/fisher-the-challenges-of-regulating-brain-machine-interfaces/.
[10] *Id.*
[11] U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* (Sep. 10, 2024), https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html.
[12] Müge Fazlioglu, *Filling the Void? The 2023 State Privacy Laws and Consumer Health Data*, IAPP: NEWS (Mar. 28, 2023), https://iapp.org/news/a/filling-the-void-the-2023-state-privacy-laws-and-consumer-health-data#.
[13] *Collecting, Using, or Sharing Consumer Health Information? Look to HIPAA, the FTC Act, and the Health Breach Notification Rule*, FED. TRADE COMM'N.: BUS. GUIDANCE RES., https://www.ftc.gov/business-guidance/resources/collecting-using-or-sharing-consumer-health-information-look-hipaa-ftc-act-health-breach (Aug. 2024).
[14] *Id.*

by security technologies approved by the Department of Health and Human Services.[15]

The FDA reviews devices with health claims for safety and effectiveness.[16] It considers four factors when approving implantable devices: the materials, design and functionality, potential risks, and the implantation procedure.[17] In May 2021, the FDA issued guidance for BCIs titled "Implanted Brain-Computer Interface ("BCI") Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations.", which emphasized that obtaining an Investigational Device Exemption ("IDE") is a key step in the product development process.[18] Once an IDE is secured, the device can be tested on real patients in the United States.[19] The guidance outlines nine key areas to obtain an IDE: describing the device, managing risks to ensure patient safety, detailing software development, addressing potential misuse, assessing biological harm, ensuring electromagnetic safety, performing bench testing to confirm system performance, conducting non-clinical animal testing, and designing clinical trials.[20] After market introduction, the FDA's Adverse Event Reporting System ("FAERS") database collects and reports on adverse events, medication errors, and product quality complaints to support safety surveillance.[21] Safety surveillance refers to continuously monitoring the

---

[15] *Id.*
[16] Fisher, *supra* note 9.
[17] Charles E. Binkley, *Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?*, 23 AM. MED. ASS'N J. OF ETHICS 745, 746 (Sep. 2021).
[18] Jonathan Casey, *Neurotech Regulations: Why the Recent FDA Leapfrog Guidance on Medical BCIs Matters To You — Part 1 of 2*, MEDIUM: NEUROTECHX CONTENT LAB (Mar. 27, 2022), https://medium.com/neurotechx/neurotech-regulations-why-the-recent-fda-leapfrog-guidance-on-medical-bcis-matters-to-you-part-1-451f409b6b75.
[19] *Id.*
[20] *Id.*
[21] U.S. FOOD & DRUG ADMIN., *Understanding CDER's Postmarket Safety Surveillance Programs and Public Data* (Apr. 3, 2024), https://www.fda.gov/drugs/cder-conversations/understanding-cders-postmarket-safety-surveillance-programs-and-public-data.

safety of medical products after they are released to the market and quickly identifying and addressing any potential risks or adverse reactions.[22]

III. FDA AND FTC MODELS: STRUGGLING TO STAY ON PAR WITH INNOVATION

The United States is one of the few developed countries without a national data protection agency, leaving data privacy regulation fragmented across state and federal entities, primarily the FTC.[23] Some argue that the FTC's limited authority to penalize first-time offenders, coupled with the rapid evolution of BCI technology, underscores the urgent need for stronger privacy regulations.[24] Under the Health Breach Notification Rule, the FTC mandates that companies handling personal health records notify both users and the FTC in the event of a breach.[25] While this ensures individuals are informed and can take protective actions, failure to comply results in penalties.[26] However, the FTC has not always enforced this rule effectively.[27] Flo Health, Inc., a menstrual cycle tracking app, shared users' personal health information without consent.[28] Despite urging companies to comply with the rule, the FTC has never taken enforcement action.[29] This inefficacy is troubling, especially when considering the sensitive nature of neural data—information about thoughts, emotions, and mental states.[30]

---

[22] *See generally id.* ("CDER health care professionals with special expertise in drug safety carefully monitor the FAERS database and, together with medical and scientific experts from multiples disciplines, determine whether they represent adverse drug reactions.").
[23] ELEC. PRIV. INFO. CTR., *What the FTC Could Be Doing (But Isn't) To Protect Privacy*, at 1 (June 2021), https://epic.org/wp-content/uploads/2021/10/EPIC-FTC-Unused-Authorities-Report-June2021.pdf.
[24] *Id.* at 2.
[25] *Id.* at 16.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Mariana Meneses, *The Most Intimate Data: Accessing Another Human's Thoughts*, THE QUANTUM REC. (Feb. 29, 2024), https://thequantumrecord.com/science-news/intimate-data-accessing-another-humans-thoughts/.

Additionally, while the FDA has a detailed process, its authority over BCIs is limited to medical products.[31] This raises concerns about the agency's ability to regulate non-medical uses of BCIs, a problem highlighted in the case of *The Judge Rotenberg Educational Center, Inc. v. FDA*.[32] In this case, the U.S. Court of Appeals for the District of Columbia Circuit overturned an FDA ban on wearable devices that delivered painful electric shocks to treat self-harming behaviors.[33] The court ruled that the FDA overstepped by interfering with medical practice.[34] This decision is concerning because it opens the door for BCI devices to gain FDA approval for narrow uses, like treating physical disabilities, and then be applied more broadly, such as for behavior modification, without proper risk and benefit evaluation.[35] As BCI technology advances, particularly in cognitive enhancements, the regulatory challenges have exceeded the capabilities of the FDA and FTC, requiring more comprehensive solutions.

IV. THE RISK OF UNREGULATED BCIS

It is problematic that devices approved for medical use may later be repurposed for applications beyond the FDA's oversight.[36] Cultural and social differences blur the line between enhancement and treatment, complicating definitions of what is "healthy" or "enhanced."[37] For instance, while Adderall treats attention deficit hyperactivity disorder therapeutically, some use it non-medically for enhancement, creating unfair advantages.[38]

---

[31] *See generally* Lucille N. Tournas & Walter G. Johnson, *Ambiguities in Neurotech Regulation*, 39 ISSUES IN SCI. & TECH. 48, 48-49 (2023) (discussing the implications of FDA authority limited to medical devices in relation to BCI technology).
[32] J. Rotenberg Educ. Ctr., Inc. v. U.S. FDA, 453 U.S. App. D.C. 93, 93 (2021).
[33] Tournas, *supra* note 31, at 48.
[34] *Id.*
[35] *Id.* at 49.
[36] Tournas, *supra* note 31, at 49.
[37] Marietjie Botes, *Brain Computer Interfaces and Human Rights: Brave New Rights for a Brave New World*, ASS'N. FOR COMPUTING MACHINERY 1154, 1159 (June 20, 2022).
[38] *Id.*

Without clear regulations distinguishing therapeutic BCIs from enhancement BCIs, FDA policies risk exacerbating social inequality.[39] This regulatory gap widens the divide between those who can afford enhancements and those who cannot, further altering societal norms and deepening inequalities.[40]

BCIs can also undermine personal autonomy.[41] Enhancement BCIs may manipulate brain signals in ways that cause individuals to lose control.[42] For medical BCIs, individuals with conditions like dementia or Alzheimer's often experience shifting preferences, raising the question of whether BCIs should follow earlier preferences or adapt to their current state.[43] The lack of regulation complicates the use of new BCIs, potentially violating an individual's right to choose the best treatment. If BCIs continue to be regulated under the FDA's current model, personal autonomy will remain at risk, as the FDA struggles to regulate its use, with even less authority over enhancement BCIs.

Moreover, BCIs are vulnerable to mishaps, such as hacking, which could lead to the theft and misuse of neural data for extortion.[44] The lack of clear regulations poses serious risks to individuals' "brain rights."[45] "Brain rights" refer to the legal protections over one's neural data, encompassing the right to mental privacy, personal autonomy, and protection from interference with

---

[39] Nathi Magubane, *Challenges and Advances in Brain-Computer Interfaces*, PENN TODAY: SCI. & TECH. (June 28, 2023), https://penntoday.upenn.edu/news/challenges-and-advances-brain-computer-interfaces.
[40] *See* Botes, *supra* note 37, at 1159.
[41] *Id.* at 1154.
[42] *Id.*
[43] *Id.* at 1158.
[44] Alexandre Gonfalonieri, *What Brain-Computer Interfaces Could Mean for the Future of Work*, HARV. BUS. REV.: TECH. & ANALYTICS (Oct. 6, 2020), https://hbr.org/2020/10/what-brain-computer-interfaces-could-mean-for-the-future-of-work.
[45] Eva V. Mühlenen et al., *Regulating the Future: Navigating Ethical and Legal Pathways in Brain-Computer Interface Technology*, SIDLEY: INSIGHTS (Apr. 4, 2024), https://www.sidley.com/en/insights/publications/2024/04/regulating-the-future-navigating-ethical-and-legal-pathways-in-brain-computer-interface-technology.

brain activity.[46] One example of how this is being handled is Chile's approach, where, in 2021, they amended their Constitution to protect these rights, becoming the first country to pass legislation ensuring mental privacy and preventing brain data from being bought, sold, trafficked, or manipulated.[47] In the United States, Colorado and Minnesota have emphasized privacy and cybersecurity through legislation, but differing state laws create enforcement challenges and compliance issues for businesses.[48] Chile's reform and shifting United States individual state laws underscore the critical need to protect neural data, as current FTC regulations fall short. Failing to adopt a new regulatory model could threaten individuals' neuroprivacy.

Creating an agency involves four steps: designing its structure, delegating authority, setting procedural controls, and securing funding.[49] When delegating authority, Congress must provide an "intelligible principle."[50] An intelligible principle is a clear guideline or standard provided by Congress that an agency must follow when implementing laws, ensuring that the delegation of authority is not overly broad or unchecked.[51] Congress should establish an independent agency, named the Brain-Computer Interface and Neural Data Protection Agency ("BCINDPA"), to oversee research, development, approval, and regulation of neural data.[52] In a May 2023 congressional hearing, lawmakers discussed creating an independent agency

---

[46] Lorena Guzmán H., *Chile: Pioneering the Protection of Neurorights*, UNESCO (last updated Oct. 13, 2023), https://courier.unesco.org/en/articles/chile-pioneering-protection-neurorights.
[47] *Id.*
[48] Jennifer Dickey, *Navigating the Legal and Ethical Landscape of Brain-Computer Interfaces: Insights from Colorado and Minnesota*, IAPP: NEWS (June 11, 2024), https://iapp.org/news/a/navigating-the-legal-and-ethical-landscape-of-brain-computer-interfaces-insights-from-colorado-and-minnesota.
[49] Todd Garvey & Daniel J. Sheffner, CONG. RSCH. SERV., R45442, CONGRESS'S AUTHORITY TO INFLUENCE AND CONTROL EXECUTIVE BRANCH AGENCIES 1 (Dec. 19, 2018).
[50] *Id.* at 9-10.
[51] *Id.* at 10.
[52] Binkley, *supra* note 17, at 747.

to regulate artificial intelligence.[53] Sam Altman, CEO of OpenAI, suggested that this agency could issue and revoke licenses to ensure safety standards are met.[54] A professor proposed the agency would also conduct pre- and post-reviews for ongoing monitoring.[55] A similar model should apply to BCIs, giving the agency authority to grant and revoke licenses for both medical and enhancement BCIs based on ethical and safety standards. Congress will decide how the agency is led, who fills its positions, the qualifications for appointees, whether it operates independently or within an existing department, and the conditions for removing leaders.[56] These decisions shape the level of presidential control over the agency.[57]

The American Medical Association ("AMA") Journal of Ethics has raised concerns about bioethics groups appointed by the President becoming overly politicized.[58] They stress the need for a separate governing body for BCIs with humanistic aims, which prioritizes society's well-being over political interests.[59] To be effective, a BCI agency should be led by a commission, with the President appointing the leader and the Senate confirming the appointment under fixed-term, "for-cause" removal protection.[60] This structure would enhance the agency's independence and limit the President's ability to remove leaders over policy disagreements.[61] A fixed term would hold leaders accountable by requiring reappointment or replacement, ensuring they fulfill their duties with humanitarian aims, free from political

---

[53] Benjamin Cote et al., *Congress Contemplates Creating a New Federal AI Regulatory Agency*, PILLSBURY (May 26, 2023), https://www.pillsburylaw.com/en/news-and-insights/congress-federal-ai-regulatory-agency.html.
[54] *Id.*
[55] *Id.*
[56] Garvey & Sheffner, *supra* note 49, at 3.
[57] *Id.*
[58] Binkley, *supra* note 17, at 747.
[59] *Id.*
[60] Garvey & Sheffner, *supra* note 49, at 6.
[61] *Id.*

influence—especially given the risks BCIs pose to personal autonomy and privacy.[62]

The FDA model provides a strong foundation for developing a comprehensive certification and testing process, therefore, a joint oversight of BCI approval would be effective. The new agency would be responsible for approving enhancement BCIs, ensuring they demonstrate safety and that their benefits outweigh potential harms, similar to the FDA's model for medical devices.[63] The agency should oversee pre-market testing and post-market surveillance of enhancement BCIs. Currently, the FDA classifies medical devices into three categories based on their risk and regulatory requirements: Class I devices are low risk and subject to general controls, Class II devices are moderate risk and require special controls and premarket notification, and Class III devices are high risk, typically requiring premarket approval based on clinical evidence to ensure safety and effectiveness.[64] Devices are evaluated for classification based on their intended use, risk level, and the potential for harm, with higher-risk devices subjected to stricter regulatory controls.[65] Additionally, there should be collaboration with the FDA, especially for post-market surveillance.[66] FAERS should be used to monitor all approved devices and assess any adverse events missed during the approval process.[67] However, the new agency should retain the authority to perform risk analysis and determine appropriate actions for BCI devices.

---

[62] Binkley, *supra* note 17, at 748.
[63] *Id.* at 746.
[64] U.S. FOOD & DRUG ADMIN., *Classify Your Medical Device* (Feb. 7, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.
[65] *Id.*
[66] *See generally* U.S. FOOD & DRUG ADMIN., *Postmarketing Surveillance Programs* (Apr. 2, 2020), https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs ("The FDA Adverse Event Reporting System (FAERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products.").
[67] *Id.*

The Federal Advisory Committee Act ("FACA") of 1972 enables federal agencies to sponsor advisory committees, promoting public input.[68] Advisory committees hold public meetings and provide access to committee records, fostering transparency.[69] For example, NASA's Earth Science Advisory Committee enhances public understanding of the earth system to predict climate changes and respond to natural hazards.[70] Similarly, advisory committees for BCIs would improve transparency regarding device use, ethical implications, and neural data protection. A specialized subcommittee should evaluate all BCI devices, focusing on legal and ethical considerations before market release. This subcommittee should include mental health professionals, healthcare providers, legal scholars, bioethicists, and other relevant experts to ensure a thorough ethical review. Mental health professionals offer critical insight into the psychological impact of BCIs, healthcare providers ensure medical safety and patient well-being, legal scholars shape the regulatory and legal frameworks, and bioethicists analyze the ethical complexities of emerging technologies. Together, their collective knowledge ensures a thorough, balanced review that considers both the benefits and risks to individuals and society.

The United States Privacy Act of 1974 governs how federal agencies handle personal information, while the HIPAA Security Rule establishes standards to protect health data managed by covered entities.[71] Adding neural data protections to both laws would extend oversight to federal

---

[68] U.S. GEN. SERVICES ADMIN., *The Federal Advisory Committee Act Brochure*, https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/the-federal-advisory-committee-act-brochure (last updated Aug. 21, 2024).
[69] *Id.*
[70] NAT'L AERONAUTICS & SPACE ADMIN., *Earth Science Advisory Committee*, https://science.nasa.gov/researchers/nac/science-advisory-committees/esac/ (Sept. 2024).
[71] U.S. OFF. OF SPECIAL COUNS., *The Privacy Act of 1974*, https://osc.gov/Pages/Privacy-Act.aspx; *see also* U.S. DEP'T OF HEALTH & HUM. SERVICES, *Summary of the HIPAA Privacy Rule* (Oct. 19, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

agencies and HIPAA-covered entities, but it would still leave a regulatory gap for private companies and startups developing BCI technology. Given the current political climate, it is unlikely that the United States will amend its Constitution to protect "neural rights" in time to keep pace with BCI development, unlike Chile. Therefore, creating a dedicated BCI agency with authority over neural data protection would be the most effective solution.

The agency would enforce rules on neural data, including clear consent requirements for data collection, bans on selling data without explicit user permission, and mandatory encryption to protect privacy. Like the FTC, it would have authority to investigate and penalize companies for data misuse or breaches.[72] Similar to the Colorado Privacy Act ("CPA"), it would set specific informed consent guidelines tailored to medical and enhancement BCIs, ensuring that users understand how their data is collected, stored, and used.[73] The agency could also develop special protections for vulnerable populations, such as requiring Alzheimer's patients to create treatment plans specifying how their neural data will be used as their condition progresses. This approach ensures individuals retain full control over their neural data and the freedom to decide how it is used in their treatment, preserving personal autonomy.

A memorandum of understanding ("MoU") outlines the intent of participating organizations to collaborate toward a shared goal.[74] It specifies the agreement's terms and conditions and provides a broad overview of the operations required to achieve the objectives.[75] Because the FDA and FTC

---

[72] Fisher, *supra* note 9.
[73] Frances Green et al., *Who's Reading Your Mind? Exploring the Intersection of Neural Data and Privacy Protections*, LAW.COM: N.Y. L.J. (May 22, 2024, 10:00 AM), https://www.law.com/newyorklawjournal/2024/05/22/whos-reading-your-mind-exploring-the-intersection-of-neural-data-and-privacy-protections/.
[74] CTRS. FOR MEDICAID & MEDICARE SERVICES INFO. SEC. & PRIV. GRP., *CMS Memorandum of Understanding*, https://security.cms.gov/learn/cms-memorandum-understanding-mou.
[75] *Id.*

would have overlapping roles with the BCI agency, an MoU should clarify responsibilities to prevent gridlock.[76] The BCI agency would regulate non-medical applications, neural data privacy, and ethical use, while the FDA would oversee BCIs as medical devices, including clinical trials and post-market surveillance. In cases where a BCI serves both medical and enhancement purposes, the FDA would lead on medical aspects, and the BCI agency would take the lead on enhancement-related issues. The MoU would also align penalties for privacy, safety, and consumer protection violations with the FTC. For neural data protection, the BCI agency would lead, but in consumer rights cases, it would collaborate with the FTC, which would take the lead in investigations.

In terms of the "intelligible principle," Congress would provide a directive that limits the agency's discretion but allows flexibility to function effectively.[77] The agency's primary purpose would be to ensure BCIs are developed, commercialized, and used to protect public health and safety, while safeguarding privacy and upholding ethical standards. Its role is to further balance regulation and innovation, using clear, evidence-based standards to prevent unnecessary restrictions. This ensures technological growth while protecting individual rights and public safety.

V. REDEFINING REGULATION TOWARDS A SAFER FUTURE

Creating an independent agency for BCIs would centralize neural data regulation, addressing gaps left by the FDA and FTC. It would enforce stricter standards for informed consent and encryption, reducing data breaches and legal penalties for companies. An advisory committee under FACA would build public trust by enhancing awareness of neural data and its uses through open meetings and accessible records.[78] Allowing public

[76] *Id.*
[77] Garvey & Sheffner, *supra* note 49, at 9-10.
[78] U.S. GEN. SERVICES ADMIN., *supra* note 68.

input on BCI proposals ensures the agency remains accountable and leads with humanistic aims, as emphasized by the AMA.[79] A dedicated ethical review advisory committee with diverse perspectives would contemplate both safety and ethical concerns. Mental health professionals could assess the risks of behavior-modification BCIs, preventing misuse as seen in *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, while the new agency would also have the authority to monitor and take action, unlike the FDA in that case.[80] This approach ensures that the social impacts of BCIs, including access and inequality, are considered from the start. In the case of enhancement BCIs, regulating societal impacts is critical to avoid widening the wealth gap, especially amid global inequality.[81] Experts with knowledge of humanitarian and societal issues would ensure that only necessary and beneficial BCIs reach the market.

Critics may argue that establishing a new agency and coordinating with the FDA and FTC would be resource-intensive, and that the FDA and FTC are sufficient. This was also the argument made regarding AI regulation.[82] However, AI and BCI technologies present fundamentally different risks. AI's primary concerns lie within decision-making, automation, and data analysis, which the FTC is better equipped to manage, particularly because AI is more about processing information without directly altering an individual's biological or psychological state.[83] The risks are largely about

---

[79] Binkley, *supra* note 17, at 748.
[80] Tournas, *supra* note 31, at 48.
[81] *See generally* Andrew Stanley, *Global Inequalities*, INT'L MONETARY FUND: FIN. & DEV. MAG., Mar. 2022, at 50-51 (discussing the current state of inequality in the world).
[82] Mark MacCarthy, *Congress Should Regulate Artificial Intelligence*, Tech. Pol'y Press (Oct. 6, 2023), https://www.techpolicy.press/congress-should-regulate-artificial-intelligence/.
[83] *See generally* Anthony E. DiResta & Zachary E. Sherman, *The FTC is Regulating AI: A Comprehensive Analysis*, HOLLAND & KNIGHT (July 25, 2023), https://www.hklaw.com/en/insights/publications/2023/07/the-ftc-is-regulating-ai-a-comprehensive-analysis (discussing the FTC's authority to regulate AI under existing legal principles, focusing on deceptive practices, consumer protection, and competition within the evolving AI landscape).

fairness, transparency, and ensuring that AI technologies do not perpetuate biases or harm individuals indirectly.[84] In contrast, BCIs interact directly with the brain, manipulating neural data, which raises profound ethical, privacy, and safety concerns that cannot be fully addressed by existing agencies.[85] The cost of creating the agency is outweighed by the long-term benefits of protecting consumer neural data, safeguarding personal autonomy, and preventing exploitation. Some may also worry that the agency could face political pressure due to the presidential appointments, but fixed-term appointments and "for-cause" removal protections limit political influence.[86] Advisory committees from academia, the medical field, and civil society would further safeguard the agency from politicization, while public input and oversight would ensure transparency.[87] There may also be concern regarding international regulation; varying global frameworks could pose compliance challenges for BCI companies.[88] Alternatively, the United States could lead by setting a regulatory standard that promotes international cooperation. A dedicated agency could serve as a model for ethical BCI use and neural data protection, fostering global harmonization. As BCI technology becomes more widespread, countries will need to establish stringent ethical standards, and the United States setting ethical standards would help streamline global regulatory processes.

An independent agency for BCIs is superior because it provides specialized oversight for the unique ethical and legal challenges of neural data. Unlike the FDA and FTC, which have broader mandates, this agency would focus solely on BCIs, ensuring stronger privacy protections, preventing data misuse, and addressing social impacts like inequality.

---

[84] *Id.*
[85] ELEC. PRIV. INFO. CTR., *supra* note 23; *see also* Binkley, *supra* note 17, at 746.
[86] Garvey & Sheffner, *supra* note 49, at 6.
[87] U.S. GEN. SERVICES ADMIN., *supra* note 68.
[88] Dickey, *supra* note 48.

Centralizing regulation under one authority promotes efficiency, while fixed-term appointments and diverse advisory committees guard against political interference. Ultimately, it offers more targeted and consistent regulation than the fragmented approach of existing agencies.

VI. CONCLUSION

This article argues that the FDA and FTC models inadequately regulate BCI technology. Devices approved for medical use can be repurposed for non-medical enhancements, leading to social inequality and potential violations of personal autonomy. Moreover, the FTC's current data privacy regulations fall short in addressing the unique challenges posed by BCIs, leaving significant gaps in the protection of individuals' neural data and privacy rights.

To address this, Congress should establish an independent agency for BCI regulation, modeled on existing frameworks but focused on ethical, legal, and safety standards unique to BCIs. This agency would oversee all BCIs, protect neural data, and include advisory committees to build public trust and accountability. While critics argue that establishing a new agency for may strain resources and create bureaucratic complexity, the unique risks associated with neural data privacy and ethical concerns necessitate specialized oversight that existing agencies cannot adequately provide. An MoU would streamline responsibilities between the BCI agency, FDA, and FTC, facilitating efficient collaboration and reducing regulatory overlap. By creating clear regulations, the United States can set a global benchmark for ethical BCI use and neural data privacy.

Machine Versus Man: The Potential Liability Issues of Introducing AI to Oncology

Owen Fink

I. INTRODUCTION TO THE STATE OF ARTIFICIAL INTELLIGENCE LIABILITY WITHIN U.S. HEALTHCARE

Artificial intelligence ("AI") is a highly controversial and widely applicable emergent technology, with incredible potential to cause both good and harm.[1] Within the healthcare field, the most impactful application of AI is its ability to accurately detect and diagnose cancer, rivaling or even outperforming trained physicians.[2] However, "no comprehensive federal laws or regulations" currently exists within the United States, "specifically to regulate AI"; accordingly, healthcare providers and courts are left to fend for themselves on determining where liability lies in healthcare cases regarding AI use.[3] Though the learned intermediary doctrine would suggest that liability should rest with the healthcare provider and not the AI developer, scholarship suggests that AI use within healthcare may never get off the ground if this becomes the standard.[4] Given AI's ability to outperform professionals in both accuracy and speed, and the necessity of early detection

---

[1] James Somers, *The Pastry A.I. That Learned to Fight Cancer*, THE NEW YORKER, Mar. 18, 2021, https://www.newyorker.com/tech/annals-of-technology/the-pastry-ai-that-learned-to-fight-cancer.

[2] Hanna Ziady, *Google's AI System Can Beat Doctors at Detecting Breast Cancer*, CNN (Jan. 2, 2020), https://www.cnn.com/2020/01/02/tech/google-health-breast-cancer/index.html [https://perma.cc/8HDA-QFAY].

[3] White & Case, *AI Watch: Global Regul. Tracker – United States*, WHITE & CASE (May 13, 2024) https://www.whitecase.com/insight-our-thinking/ai-watch-global-regulatory-tracker-united-states

[4] Elise N. McQuain, *The Learned Intermediary Doctrine: An Update*, FROST BROWN TODD (Dec. 19, 2018), https://frostbrowntodd.com/the-learned-intermediary-doctrine-an-update/ (stating that "manufacturer[s] of prescription medications or medical decives [have] a duty to advise the prescribing medical professional" of the use and risks of a product, as opposed to "a duty to advise the patient or the public."); Mark Geistfeld, *Does Tort Law Stifle Innovative Med. Treatments?*, JOTWELL (June 2, 2015) (reviewing Anna B. Laakmann, *When Should Physicians Be Liable for Innovation?*, 36 CARDOZO L. REV. 913 (2015)), http://torts.jotwell.com/does-tort-law-stifle-innovativemedical-treatments/); A. Michael Froomkin et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Mach. Learning*, 61 ARIZ. L. REV. 33, 56 (2019). *See generally* Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285 (2008) (arguing that judicial and legal reliance on custom "chills innovation and distorts its path.").

in cancer treatment, resolving this issue is imperative to improving cancer treatment.[5]

First, this article will address the significance of greater liability for healthcare providers and practitioners. Next, this article will discuss why regulatory groundwork on AI is needed from a practical perspective. Finally, this article will propose a solution for resolving the dispute between healthcare needs and the absence of legislation in the form of regulation requiring patient decision aids.

II. INTRODUCING AI TO THE STANDARD OF CARE

Traditionally, healthcare providers are liable for malpractice when they violate the standard of care.[6] The National Cancer Institute defines the standard of care in its Dictionary of Cancer Terms as "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by health care professionals."[7] Though AI is currently not part of the standard of care, "once [machine learning] diagnostics are statistically superior to humans, it will only be a short while before legal systems…treat machine diagnosis as the 'standard of care.'"[8] Fully replacing human physicians with machine diagnoses, however, carries unique problems. With no human to check its output, it is possible an AI may never learn about the existence of a better option.[9] For example, if an AI has only been trained to recommend a certain drug, it will never think about the possibility that radiation may be a more effective treatment option.[10] On the other hand, AI fully out of the picture is also likely not an option. In many cases, there may simply not be enough physicians to keep up with patient

---

[5] Elizabeth Svboda, *Deep Learning Delivers Early Detection*, 587 NATURE S20 (2020).
[6] Froomkin et. al, *supra* note 4, at 51.
[7] NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-of-care (last visited Sept. 22, 2024).
[8] Froomkin et. al, *supra* note 4, at 50.
[9] *Id.* at 77.
[10] *Id.*

demand without some form of assistance.[11] Thus, it is likely that the standard of care in the future will trend more towards AI plus human physician, even if AI has a demonstrably higher success rate.[12]

However, introducing AI to the mix will almost certainly increase provider liability. Without a current comprehensive federal law regulating the use and development of AI, there is no way to consistently determine whether physician use of AI meets the standard of care. Accordingly, *any* use of AI will fall outside the standard of care, even though current AI algorithms can be as much as nineteen percent more accurate or greater than human physicians in diagnosing certain cancers.[13] Thus, even though a physician making an AI-assisted diagnosis may be doing what is best for her patient (potentially even saving their life via early cancer detection), she may be liable for malpractice.

III. THE LACK OF A NATIONAL STANDARD

There is currently no comprehensive federal law regulating the use or development of AI within the United States.[14] Within healthcare specifically, there is, at best, a voluntary commitment to the "safe, secure, and trustworthy use and purchase…of AI in healthcare."[15] Without legislation or regulations directing AI use in health care to help guide and protect physicians from liability, it is likely that the technology will fail to be implemented, even as AI-assisted treatment surpasses current treatment options for diseases like

---

[11] *See* Svboda, *supra* note 5, at S21.
[12] Froomkin et. al*, supra* note 4, at 49.
[13] Yun Liu et al., *Detecting Cancer Metastases on Gigapixel Pathology Images*, ARXIV:1703.02442 [CS] (Mar. 8, 2017), http://arxiv.org/abs/1703.02442 (comparing human accuracy rate of 73.2% to AI accuracy rate of 92.4%).
[14] White & Case, *supra* note 3.
[15] Lael Brainard et. al, *Delivering on the Promise of AI to Improve Health Outcomes*, THE WHITE HOUSE (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/blog/2023/12/14/delivering-on-the-promise-of-ai-to-improve-health-outcomes/

cancer.[16] Considering that AI can already detect certain types of cancer a year or more before human radiologists, and that early detection remains an imperative tool in the fight against cancer, this would be an unacceptable outcome.[17]

Additional problems stem from the complexity of AI, demonstrating why federal guidance is needed to clarify the area. There are two main categories of AI: predictive and generative.[18] Predictive AI is fed training data in order to "predict" an outcome in a novel situation, whereas generative AI "creates novel outputs that were not explicitly in the training data."[19] A predictive AI algorithm would be the type of system to diagnose cancer from scans, whereas a generative AI algorithm could conceivably look at a patient's health record and produce a recommended treatment plan.[20] This article will only discuss the potential liability issues of predictive AI, as there is not yet enough data on the use of generative AI in oncology.

IV. The Impact of Liability Issues

The struggle within healthcare between the use of innovative technologies and procedures versus potential medical malpractice liability has been documented for years.[21] A lack of legislation or regulation on a new technology can discourage innovation and encourage "defensive medicine," resulting in rising costs across the board: the costs of rising liability insurance premiums are passed on to patients, who then receive more when a medical malpractice suit succeeds, which in turn leads to an increase in liability insurance premiums again.[22] Failing to regulate AI within cancer detection

---

[16] Liu et. al, *supra* note 13.
[17] Svboda, *supra* note 5, at S20.
[18] Likhitha Kolla & Ravi Parikh, *Uses and limitations of artificial intel. for oncology,* 130 Cancer 12, 2101-2107, https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.35307.
[19] *Id.* at 2101.
[20] *Id.*
[21] Geistfeld, *supra* note 4.
[22] Richard G. Roberts, *Understanding the Physician Liability Insurance Crisis*, 9 Fam. Pract. Mgmt. 9 (2002), 47-51, https://www.aafp.org/pubs/fpm/issues/2002/1000/p47.html.

will increase the liability for its use, consequently discouraging medical providers from using the most effective treatment method. Without the most effective treatment method, patients are likely to receive delayed diagnoses, thus affecting the quality of their care. A later diagnosis can easily result in even higher costs for a cancer patient by causing them to receive more treatment for longer when the average cost of treatment is already around $150,000.[23] The government also suffers when cancer treatment is drawn out. According to the National Cancer Institute, the national cost for cancer care was estimated at $190.2 billion in 2015, rising to $208.9 billion in 2020.[24] Though regulating AI in oncology would not necessarily cut down on treatment costs, reducing physicians' inclination to practice defensive medicine could incentivize them to utilize AI scans and cancer screening earlier, thus detecting cancer earlier and saving money on less invasive, less experimental treatments only available at the early stages of cancer.

A lack of legislation or regulation in the area also makes it difficult for providers to know whether they are truly assuming liability by using AI. The learned intermediary doctrine states that a "manufacturer of prescription medications or medical devices has a duty to advise the prescribing medical professional of the proper use and potential risks of its products, rather than a duty to advise the patient or the public," on the theory that the prescribing professional will then be able to discern whether the medication or device is suitable for a patient's treatment.[25] However, even if the physician that rendered treatment in a medical malpractice suit was properly informed by the company, patients may still have product-liability claims against the

---

[23] Peter Moore, *The High Cost of Cancer Treatment*, AARP (June 1, 2018), https://www.aarp.org/money/credit-loans-debt/info-2018/the-high-cost-of-cancer-treatment.html.
[24] NAT'L CANCER INST., *Financial Burden of Cancer Care*, https://progressreport.cancer.gov/after/economic_burden (last visited Sept. 22, 2024).
[25] McQuain, *supra* note 4.

company that originally developed the AI.[26] This can cause confusion for providers, who may merely refuse to use AI for simplicity's sake, but would be remiss to do so when AI is more accurate at identifying cancer diagnoses.[27]

Pushing the burden of AI liability onto healthcare providers through the learned intermediary doctrine would also increase costs for the provider, which would likely then be passed onto the patient, thus further increasing the cost of care for cancer patients. Though training an AI program may not be as expensive as employing a human physician full-time, it is unlikely that AI will ever fully replace human physicians.[28] As one article notes, "unless [machine learning ("ML")] replaces all or part of some other cost—the human doctor being the natural target—ML is just one more cost, whether small, medium, or large."[29] Thus, requiring healthcare providers to bear the burden of malpractice liability for using AI in cancer detection and treatment would have the combined effect of increasing costs while lowering the quality of patient care.

Pushing liability for AI's mistakes onto physicians using AI programs can also ignore the fact that the responsibility for an error may not actually lay with the physicians. One problem with predictive AI is that they must be trained on massive amounts of data.[30] However, "[u]nderreporting, underrepresentation, and heterogeneity in image acquisition can skew the data used to train an AI algorithm."[31] Furthermore, "[m]any published AI algorithms are trained on publicly available image data sets that are biased."[32]

---

[26] Froomkin et. al, *supra* note 4, at 66.
[27] Liu, *supra* note 13.
[28] Ted A James, *How Artificial Intel. is Disrupting Med. and What it Means for Physicians*, HARV. MED. SCH. (Apr. 13, 2023), https://postgraduateeducation.hms.harvard.edu/trends-medicine/how-artificial-intelligence-disrupting-medicine-what-means-physicians (describing how holistic patient care includes the human aspects of empathy, compassion, critical thinking, and complex decision-making).
[29] Froomkin et. al, *supra* note 4, at 65.
[30] *Id.* at 74.
[31] Kolla & Parikh, *supra* note 18, at 2102.
[32] *Id.*

For example, AI may have a harder time accurately diagnosing a patient with a different skin color than the images in the data set on which the program was trained. The argument could certainly be made that the physician utilizing this AI is equally liable for failing to act as a "check" on the program, but when human diagnosis rates for cancers are lower than that of AI, this argument is unpersuasive. Additionally, the sheer number of images that predictive AI models must be trained on frequently renders their decision-making processes inexplicable to outside observers. As AI models learn and develop mechanisms to efficiently synthesize so much data, they tend to format their models in a way that is indecipherable to human observers.[33] These models are often incomprehensible even to those in the field working directly with predictive AI. Given this, it is manifestly unreasonable to expect physicans to act as a check on AI were it to become the standard of care.

V. PROPOSED REGULATION FOR AI PATIENT DECISION AIDS

The obvious solution to the problem at hand is simply to remove as much liability from physicians as possible for using AI in cancer detection and treatment. Although this sounds idealistic, the implementation is more feasible than it sounds: require informed consent through legislation implementing patient decision aids ("PDAs") before AI is used for treating patients. Patient decision aids, already required in some instances by the Center for Medicare and Medicaid Services ("CMS"), are physical or digital materials (like pamphlets, leaflets, or videos) that help physicians provide patients with background information on a treatment, drug, or technology without having to explain the process themselves, thus ensuring a patient's

[33] *Id.*

consent is truly informed.[34] These PDAs can help bridge the gap between physician fear of tort liability and the learned intermediary doctrine, which would place liability on healthcare providers for new technology use. By implementing PDAs, patients would be able to understand the risks and benefits of AI and make the choice for themselves whether to receive AI-assisted treatment or traditional human-only treatment.

Because CMS is an administrative agency, no draft legislation would be needed to implement this PDA requirement for cancer treatment using AI. Instead, CMS would make a national coverage determination ("NCD"), the process by which CMS decides which medical devices and drugs it will cover, to determine whether AI-assisted cancer treatment without the use of a PDA beforehand to obtain informed consent would be covered by Medicare and Medicaid.[35] The NCD process begins when CMS formally accepts an NCD request and informs the public through posting a tracking sheet on its coverage webpage; CMS also customarily invites public comment on the matter, though it is not required to do so.[36] "Public comment" means that any member of the public, from individuals to large corporations, may submit feedback on a proposed rule, permit, or other comment.[37]

CMS is then required to consider these comments when promulgating the final version of its proposed rule.[38] Six months after posting the tracking sheet, a proposed NCD must be published with a statutorily-required thirty day period for public comment. This six-month period is extended to nine months if an NCD analysis includes an "external technology assessment or

---

[34] THE OTTAWA HOSP., *Patient Decision Aids Research Group*, https://decisionaid.ohri.ca (last visited Sept. 22, 2024).
[35] CTR. FOR MEDICARE AND MEDICAID SERVICES, *National Coverage Determination Process & Timeline*, https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coverage/national-coverage-determination-process-timeline (last visited Sept. 22, 2024).
[36] *Id.*
[37] Administrative Procedure Act §1, 5 U.S.C. §553(c).
[38] *Id.*

Medicare Evidence Development and Coverage Advisory Committee meeting," which would likely be the case here since the proposed NCD would deal with AI.[39] Finally, a final decision must be published within sixty days of the close of the public comment period, and is effective as soon as it is posted to the CMS coverage website.[40]

This proposed solution of requiring PDAs and informed consent is highly comparable to the "medical judgment rule" postulated by Dr. Anna Laakmann, where physicians would be shielded from liability for poor patient outcomes when the physician:

> "(1) considers generalized data and customary practices in order to assess their relative efficacy for the individual patient in light of her particular health needs and preferences; and (2) reaches a collaborative decision with the patient, based on the sharing of all material information, that an innovative departure from custom is warranted for the health condition in question."[41]

Currently, the use of AI within oncology would certainly be an innovative departure from custom, as no comprehensive federal legislation on AI exists to truly regulate the technology.[42] However, AI is becoming increasingly prevalent, and it is likely that the use of AI within health care will be neither innovative nor a departure from custom in the near future.

---

[39] CTR. FOR MEDICARE AND MEDICAID SERVICES, *supra* note 35.
[40] *Id.*
[41] Geistfeld, *supra* note 4. Dr. Laakmann's "medical judgment rule" stems from the business judgment rule in corporate law, a rule deferring to the discretion of directors in business decisions on the basis that "the law should protect corporate fiduciaries from hindsight bias because managers must make risky decisions with uncertain outcomes." Anna Laakmann, *When Should Physicians Be Liable for Innovation?*, 36 CARDOZO L. REV. 913, 960-61 (Aug, 2018).
[42] White & Case, *supra* note 3.

VI. Benefits and Drawbacks of Reducing Physician Liability and Increasing AI Usage in Health Care

Implementing this solution would be easier than it appears. The National Cancer Institute states that the median age of a cancer diagnosis is sixty-six years.[43] Coincidentally, Medicare eligibility frequently begins at age sixty-five.[44] Were the Center for Medicare and Medicaid Services to promulgate a new regulation requiring the use of AI in cancer treatment to be preceded by mandatory PDAs, the agency could almost entirely sidestep the bureaucratic process in which legislation and regulation so frequently becomes tied up. This regulation would not directly affect cancer patients under sixty-five years of age, but requiring AI PDAs for the treatment of those over sixty-five almost certainly ensures that healthcare providers who treat cancer patients will have them in the office to distribute should a cancer patient of any age arrive.

The most obvious critique with this plan is that it seems to suggest that simply handing a patient a pamphlet would relieve a provider of all liability for the use of AI in that patient's treatment. However, the same concern could be levied against current PDAs, yet providers can still be sued for malpractice. In the state of Washington, the burden of proof simply shifts to the patient once it has been proven that the provider used a PDA in treatment.[45] Furthermore, the National Practitioner Data Bank reports over 11,000 instances of Medical Malpractice Payment Reports from 2023 alone.[46] Taken together, these two sources show that patients suffering from

---

[43] Nat'l Cancer Inst., *Age and Cancer Risk*, https://www.cancer.gov/about-cancer/causes-prevention/risk/age (last visited Sept. 22, 2024).
[44] U.S. Dep't. of Health and Hum. Services, *Who's eligible for Medicare?*, https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html (last visited Sept. 22, 2024).
[45] Rev. Code. Wash. § 7.70.060.
[46] Map of NPDB Reports, https://www.npdb.hrsa.gov/analysistool/ (search "Report Type: Medical Malpractice Payment Report").

malpractice are hardly rendered helpless simply by the use of PDAs within modern treatment plans.

Nevertheless, although it may seem obvious that the average physician would agree that obtaining informed consent is important when utilizing new technology, it is still important to enact this solution for the numerous benefits that implementing AI in oncology would bring to healthcare providers' offices. First and foremost, AI has been shown to cut down on physician workloads. One study estimated that AI software could potentially cut radiologist workloads by 30% in reading mammography scans.[47] Lower workloads, in turn, can help reduce physician burnout and increase time spent with patients.[48] AI utilization in oncological care can also help reduce the necessity and frequency of invasive treatments.[49]

Additionally, AI can analyze CT scans in all three dimensions at once, rather than only looking at a sequence of 2D slides like human physicians.[50] This process helps to improve the AI's accuracy for future scans, as well as providing information on features that are not part of the main tumor.[51] Furthermore, AI programs can diagnose tumors around one to three millimeters in size, which are difficult to spot for human radiologists.[52] Because AI programs are trained on thousands of images, they can become so adept at certain tasks that they outperform human specialists.[53] Finally, AI programs can also make predictions about cancer reoccurrence, thus allowing physicians to carefully monitor certain cancer patients more closely than they otherwise might.[54]

---

[47] Kolla & Parikh, *supra* note 18, at 2103.
[48] *Id.*; Brainard et. al, *supra* note 15.
[49] Kolla & Parikh, *supra* note 18, at 2103.
[50] Svboda, *supra* note 5, at S21.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

Several drawbacks to AI development would suggest implementation of AI in cancer detection is still a number of years off. A primary issue is the fact that AI must continually be trained and retrained to stay relevant and accurate; however, this costs both time and money, and carries the risk of messing up the AI's data set if bad new data is introduced into the good old data.[55] Even if no bad data is introduced, an AI may still need to be entirely retrained. Imagine, for example, if an AI had a low-resolution scanner replaced with a high-resolution one: "Human beings who could recognize tumors on the old photos might have little or no difficulty recognizing the same tumors on the new, sharper images…Unfortunately, ML systems do not work like that. To an ML system, *the new, higher-resolution image is a completely new thing*…[emphasis added]."[56]

Additionally, if AI programs become so relevant that they entirely displace medical specialists, it is possible there may be no new human-created data on which to train and retrain AI models.[57] Accordingly, what was once an accurate, effective, and more efficient version of a physician may quickly degrade over time, as patient needs change and the machine fails to adapt. The more complicated the AI, the more confusing as well: when humans are unable to understand the logic under which the AI operates, they will be unable to verify the integrity of a given analysis, and thus will not be able to accurately determine when an AI makes a mistake.[58] Without confident and capable personnel to check AI models, it is frighteningly possible that this technology could someday lower the standard of care rather than raise it.

Furthermore, AI mistakes in cancer detection may not emerge until years down the road.[59] Even if the AI is eventually presented with the correct information, being corrected years down the road may be too late to reverse

---

[55] Froomkin et. al, *supra* note 4, at 72.
[56] *Id.* at 74.
[57] *Id.* at 73.
[58] *Id.* at 80.
[59] *Id.* at 78.

the corrupted data.[60] AI also has no idea of the concept of a "mistake" – it must be taught what is correct and incorrect by human supervisors.[61]

Given all these drawbacks, it may be tempting to argue that it would be easier to not introduce AI into oncology rather than create new AI-based PDAs. However, this would be a massive misstep. As the potential upsides documented above show, AI is highly likely to become part of the healthcare sphere. Indeed, it is even reasonable to expect that it will eventually become the standard of care, if perhaps only in oncology. When a new technology has such potent implications for the field, it would be negligent to not properly prepare for its eventual introduction. Additionally, research already shows that almost 50 percent of all medical treatments are "preference-sensitive,"[62] meaning that the treatments "involve significant tradeoffs affecting the patient's quality and/or length of life," and will thus require significant discussion between a patient and their provider.[63] This alone should justify the use of PDAs for every treatment plan involving AI. If AI is such a black box that not even those extensively trained on it can fully understand it, then patients should be given as much information as possible before deciding on a treatment with their provider so that responsibility and liability for the decision to use or withhold AI in a patient's treatment are exceedingly clear.

VII. CONCLUSION

---

[60] *Id.*
[61] *Id.*
[62] Marie-Anne Durand et. al, *Can shared decision-making reduce medical malpractice litigation? A systematic review*, 15 BMC Health Services 1, 2 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4409730/pdf/12913_2015_Article_823.pdf
[63] John E. Wennberg, *Preference-Sensitive Care: A Dartmouth Atlas Project Topic Brief*, 1, (Ctr. for the Evaluative Clinical Services, 2007, https://www.ncbi.nlm.nih.gov/books/NBK586631/pdf/Bookshelf_NBK586631.pdf.

With the advent of AI, oncology is poised for an almost-total revolution; indeed, machine might soon replace man. This article shows, however, it is imperative that concerns over physician liability be addressed first. Though legislation on AI is pending in numerous states, and several federal agencies have claimed authority over AI, no law exists to enforce and regulate compliance with federal AI obligations. With no federal guidance and ever-rising malpractice liability costs, physicians have no incentive to utilize and engage with AI without the assurance they will be protected. The lack of a federal standard means agencies and states must step up and fill the gap so they do not fall behind. CMS is uniquely poised to provide this assurance through PDA regulation clarifying physician liability standards.

Without proper safeguards in place to ensure physicians can utilize AI technology for cancer detection and treatment, it is unlikely that patients will receive the best care they deserve. When the "best care" includes cancer detection years before conventional methods more accurate than specialists, potentially lower costs for less treatment, and less invasive treatment overall, it is unthinkable to let this technology fade away.

Challenging Gender-Affirming Care Bans: The Impact on Trans Youth and the Fight for Equal Protection

Samantha Galinson

I. RISE OF ANTI-TRANSGENDER LEGISLATION: IMPACT ON YOUTH MENTAL HEALTH

Since 2020, many states have gone to great lengths to prevent transgender adolescents from accessing care through restrictive legislation.[1] In 2024 alone, there have been over 535 newly introduced anti-trans bills.[2] On top of the alarming amount of new laws, twenty-five states across the country have already adopted legislation and policies that ban or harshly limit gender affirming care for minors.[3] In fact, this is the fifth year of unprecedented growth in restrictive legislation which followed an enormous surge in 2023.[4]

So, why have state governments decided to restrict transgender healthcare? They claim it is in the best interest of children; however, the data says otherwise. When trans youth are unable to express themselves in a manner that is aligned with their gender, their mental health suffers dramatically. There are reports that "52% of trans and nonbinary youth seriously considered suicide in [2023], and one in five attempted suicides."[5]

---

[1] Erica Browning, Elana Redfield et al., *Prohibiting Gender-Affirming Medical Care for Youth*, UCLA SCH. L. WILLIAMS. INST., 17 (March 2023), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Youth-Health-Bans-Mar-2023.pdf ("Since 2020, 36 states have attempted to restrict access to gender-affirming care—primarily through legislative action.").

[2] Amy Novotney, *"The Young People Feel It": A Look at the Mental Health Impact of Transgender Legislation*, AM. PSYCH. ASS'N (June 3, 2024), https://www.apa.org/topics/lgbtq/mental-health-anti-transgender-legislation ("The American Civil Liberties Union is currently tracking 535 anti-LGBTQ bills in the United States.").

[3] Novotney, *supra* note 2, ("Across the United States, 25 states have adopted laws or policies that ban or severely limit gender-affirming care for minors, and several others are eyeing the possibility.").

[4] *2024 Anti-Trans Bills Tracker*, TRANS LEGIS. TRACKER, https://translegislation.com/ (last visited Nov. 10, 2024) ("2024 is the fifth consecutive record-breaking year for total bills considered. This follows the unprecedented surge in 2023, which tripled the record set the year before.").

[5] *Fact Sheet: Evidence Based Healthcare for Transgender People and Youth*, GLAAD (Jan. 12, 2024), https://glaad.org/factsheet-evidence-based-healthcare-transgender-people-and-youth/ (reporting statistics about mental health for transgender and non-binary youth).

Currently, medical best practice for adolescents who identify as transgender is gender affirming care.[6] The affirming care ranges from using correct pronouns and allowing authentic gender expression to access to puberty blockers.[7]

The sweeping restrictions on access to gender affirming care for trans youth has instilled fear in the trans community, with data indicating that 85 percent of transgender and non-binary youth reported that the debates about state laws restricting the rights of transgender people has negatively impacted their mental health.[8] In *"Prohibition of Gender-Affirming Care as a Form of Child Maltreatment: Reframing the Discussion,"* the authors state that:

> [T]hese legislative efforts operate under the guise of protecting children. In reality, they punish caregivers and physicians when they choose to support children. They deny children access to routine health care that has been shown to decrease dramatically high rates of suicide and depression for TGD [transgender and gender diverse] youth. They fuel discriminatory rhetoric, which negatively impacts the mental health of TGD children and imperils their safety."[9]

These bans on gender affirming care, the mental health crisis plaguing trans-communities, and the rise in conservative judges in the federal circuit courts are cause for concern.[10]

---

[6] *Id.*
[7] *Id.*
[8] Oriana Gonzalez, *Poll: Most LGBTQ Kids' Mental Health Negatively Impacted by Anti-Trans Legislation*, AXIOS (Jan. 10, 2022), https://www.axios.com/2022/01/10/mental-health-lgbtq-youth-anti-trans-bills ("Seven in 10 LGBTQ youth said they regularly follow news related to the issues that impact the trans community, and as a result: . . . the impact is even greater among trans and non-binary youth: 85% of those polled – four in five of this group – said their mental health had been negatively affected.").
[9] Emily Georges et al., *Prohibition of Gender- Affirming Care as a Form of Child Maltreatment: Reframing the Discussion,* PEDIATRICS PERSPS., Jan. 2024,at 1, 1, https://publications.aap.org/pediatrics/article/153/1/e2023064292/196236/Prohibition-of-Gender-Affirming-Care-as-a-Form-of.
[10] *See*, *e.g.*, *Transgender Youth More Often Diagnosed with Mental Health Conditions*, DEP'T RSCH. & EVALUATION, S. CAl., https://www.kp-scalresearch.org/transgender-youth-more-often-diagnosed-with-mental-health-conditions/ (last visited December 3,2024) ("We

This article focuses on how to provide care for trans youth, with a particular focus on how courts should handle challenges to puberty blocker bans, and restrictions on transgender care. Recently, the 11th Circuit Court of Appeals made a landmark decision regarding a gender affirming care ban in Alabama.[11] The decision ruled staunchly against Fourteenth Amendment challenges both on equal protection and due process grounds.[12] This article concludes with solutions outside the court system and thoughts for the future.

II. MEDICAL CONSENSUS ON GENDER-AFFIRMING CARE: UNDERSTANDING PUBERTY BLOCKERS AND THEIR IMPORTANCE FOR TRANSGENDER YOUTH

To fully appreciate the severity of the restrictive bans, it is important to understand the scope and standard of care that has been long accepted by the medical community. Typically, people who identify as transgender receive a diagnosis of gender dysphoria.[13] The World Professional Association for

---

looked at mental health in transgender and gender-nonconforming youth retrospectively between 2006 and 2014 and found that these youths had 3 to 13 times the mental health conditions of their cisgender counterparts"); *See also* David Fonseca, *21 More Conservative Judges Confirmed to the Federal Appellate Courts*, AMER. CTR. L. & JUST. (July 17, 2019), https://aclj.org/constitution/21-more-conservative-judges-confirmed-to-the-federal-appellate-courts ("This year we have seen a record number of constitutionally minded judges confirmed. . . . There have been two stellar [conservative] Supreme Court Justices (Justice Neil Gorsuch and Justice Brett Kavanaugh), 42 Circuit Court of Appeals judges, and 83 district court judges confirmed so far under President Trump.").

[11] *See generally* Eknes-Tucker v. Governor, of the State of Alabama, 80 F.4th 1205 (11th Cir. 2023) (analyzing the constitutionality of a state law banning gender affirming care in the state of Alabama).

[12] *See also* Eknes-Tucker, 80 F.4th at (holding the district court erred by applying the intermediate scrutiny standard to plaintiffs' claim… The district court erred by entering a preliminary injunction enjoining Alabama from enforcing § 4(a)(1)-(3); [2]-The district court also erred by applying the intermediate scrutiny standard to plaintiffs' claim that Ala. Code § 26-26-4(a)(1)-(3) violated the equal protection clause).

[13] *See Gender Dysphoria*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/22634-gender-dysphoria (last visited Nov. 6, 2024) ("Gender dysphoria describes a sense of unease regarding the mismatch between assigned gender and gender identity. This feeling affects many — but not all — transgender

Transgender Health ("WPATH") defines gender dysphoria as the "discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth."[14] Common symptoms of gender dysphoria include a difference between gender identity and genitals, a strong desire to be rid of genitals, and longing to be treated as the other gender or a strong belief of having typical feelings of another gender.[15]

Youth experiencing gender dysphoria turn to puberty blockers to relieve symptoms. The common drug used to delay puberty for transgender minors is called gonadotropin-releasing hormone ("GnRH").[16] The ability to delay the puberty process allows transgender adolescents time to discover their gender identity.[17] Along with giving adolescents more time, puberty blockers have the potential to relieve symptoms of depression and anxiety, decrease the need for future gender-affirming surgeries, and decrease thoughts and actions of self-harm.[18]

For a doctor to administer puberty blockers to an adolescent patient, the WPATH recommends that the doctor ensure the adolescent meets the following minimum criteria:

---

people before they begin living as their authentic selves (transition and gender expression).").

[14] WORLD PRO. ASS'N FOR TRANSGENDER HEALTH, STANDARDS OF CARE FOR THE HEALTH OF TRANSSEXUAL, TRANSGENDER, AND GENDER NONCONFORMING PEOPLE 5 (7th version 2022). https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf [Hereinafter "WPATH"].

[15] *See id.* at 12.

[16] Mayo Clinic Staff, *Puberty Blockers for Transgender and Gender-Diverse Youth*, MAYO CLINIC (June 14, 2023), https://www.mayoclinic.org/diseases-conditions/gender-dysphoria/in-depth/pubertal-blockers/art-20459075 ("Puberty blockers can be used to delay the changes of puberty in transgender and gender-diverse youth who have started puberty. The medicines most often used for this purpose are called gonadotropin-releasing hormone (GnRH) analogues.").

[17] *Id.* ("GnRH analogues don't cause permanent physical changes. Instead, they pause puberty. That offers a chance to explore gender identity.").

[18] *Id.*

> . . . 1) The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); 2) Gender dysphoria emerged or worsened with the onset of puberty; 3) Any co-existing psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; [and] 4) The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.[19]

The previous paragraphs highlight the accepted medical practices and positive outcomes from puberty blockers. However, authors of puberty blocker bans heavily rely on the argument that GnRH will result in irreversible physical changes once a child stops treatment.[20] WPATH stated that the use of puberty blockers is a reversible medical intervention.[21] Also, it is relatively uncommon for people who have transitioned to want to transition back to their sex assigned at birth.[22] Thus, the legislator's argument that the medication causes irreversible physical changes holds little weight as a majority of the community receiving puberty blockers as adolescents go through with their transition once they are adults.

It is also important to note that requiring transgender people to wait until adulthood to access GnRH can make their transition more difficult than

---

[19] WPATH, *supra* note 14, at 19.
[20] *See*, *e.g.*, Eknes-Tucker, F.80 4th at 1212 ("This unproven, poorly studied series of interventions results in numerous harmful effects for minors, as well as risks of effects simply unknown due to the new and experimental nature of these interventions.").
[21] WPATH, *supra* note 14, at 18-19.
[22] *See* Associated Press, *How Common is Transgender Treatment Regret, Detransitioning*?, VOICE OF AMERICA, (Mar. 7, 2023), https://www.voanews.com/a/how-common-is-transgender-treatment-regret-detransitioning-/6993101.html ("Some studies suggest that rates of regret have declined over the years as patient selection and treatment methods have improved. In a review of 27 studies involving almost 8,000 teens and adults who had transgender surgeries, mostly in Europe, the U.S and Canada, 1% on average expressed regret. For some, regret was temporary, but a small number went on to have detransitioning or reversal surgeries, the 2021 review said.").

starting their process before puberty.[23] If a person decides that they want to have gender affirming surgery, the procedures tend to be less invasive, expensive, and difficult for doctors to administer when the person previously used puberty blockers.[24]

There has been some work to overturn gender affirming care bans where parents represent their transgender children. The following section lays out the structure of Alabama's Vulnerable Child Compassion and Protection Act and addresses legislators' arguments when creating the statute.

III. TRANSGENDER MINORS CHALLENGE TO ALABAMA'S GENDER-AFFIRMING CARE BAN

In the precedent setting case, *Eknes-Tucker v. Governor of Alabama*, the 11th Circuit considered provision 4(a)(1)-(3) of the Vulnerable Child Compassion and Protection Act, which stated that… "no person shall engage in or cause the prescription or administration of puberty blocking medicine or cross sex hormone treatment to a minor."[25] The statute made it a crime in Alabama for doctors to administer certain types of treatment that addresses discordance between minors' biological sex and sense of gender.[26]

The Act is problematic as not only are there repercussions for doctors who administer gender affirming care to minors, but minors and parents of minors

---

[23] *See* Katherine T. Litaker, *Growing Pains: An Arkansas Case Study on Adolescent Autonomy and Access to Puberty Blockers for Gender-Affirming Care*, 30 WM. & MARY J. RACE, GENDER, & SOC. JUST. 357, 364 (2024) ("Additionally, waiting on sex reassignment until adulthood can make transitioning far more difficult than starting the process prior to puberty. Developing secondary sex characteristics - Adam's apple, hips, and breasts - can become permanent if not managed from the early stages.").
[24] *See id.*
[25] Eknes-Tucker, 80 F.4th at 1210.
[26] *Id.*

are at a loss when it comes to what to do next when these bans go into place.[27] Alabama argued that a "wait and see" approach for transgender minors would be the best route for treatment.[28] The experts brought in on behalf of the Alabama legislature insisted that psychiatric counseling was enough to treat gender dysphoria.[29] However, the wait and see approach is not one that is supported by U.S. trans scholars and activists. One such activist, Katherine Litaker, argues that psychotherapy is not enough, even though it can reduce distress related to gender dysphoria.[30] Litaker argues that only physical interventions like puberty blockers give trans youth enough time to deeply understand their gender identity. [31] She posits that the "stress of forcing minors . . . to undergo puberty instead of allowing them to take puberty blockers leads to significant stress that puts the minors at high risk of violence, suicide, and substance abuse."[32] Still, the Alabama legislature

---

[27] *See*, *e.g.*, Stacy Weiner, *States are Banning Gender-Affirming Care for Minors. What Does that Mean for Patients and Providers?*, ASS'N AMER. MED. COLL.: NEWS (Feb. 20, 2024), https://www.aamc.org/news/states-are-banning-gender-affirming-care-minors-what-does-mean-patients-and-providers (explaining how a single family was affected by gender affirming care bans, parents and child crying when doctors explained how they can no longer provide care).

[28] Eknes-Tucker, 80 F.4th at 1211 ("As a result, taking a wait-and-see approach to children who reveal signs of gender nonconformity results in a large majority of those children resolving to an identity congruent with their sex by late adolescence.").

[29] *See Id.* at 1217 ("Alabama, for its part, first tendered Dr. James Cantor. Dr. Cantor is a clinical psychologist and neuroscientist who was called as an expert on psychology, human sexuality, research methodology, and the state of research on gender dysphoria. In his opinion, gender dysphoria can be treated with a "watchful waiting approach" whereby decisions about medical interventions are withheld, but therapy is continued, until more information becomes available.").

[30] Litaker, *supra* note 23, at 362 ("Additionally, many falsely believe that psychotherapy is sufficient to cure gender dysphoria. While counseling and supportive therapy "may help reduce distress related to gender dysphoria" it does not "get at the heart of the problem - the development of unwanted permanent secondary sex characteristics." Psychotherapy can be helpful, "but only physical interventions like puberty-suppressing hormonal treatment can allow individuals to `buy time' to think about their gender identity.").

[31] *Id.* ("Psychotherapy can be helpful, "but only physical interventions like puberty-suppressing hormonal treatment can allow individuals to 'buy time' to think about their gender identity."").

[32] *Id.* at 363.

maintains that these medical interventions are not safe, and children are better off without access.[33] Besides relying on safety arguments, Alabama fought against Fourteenth Amendment protections; these arguments and the 11th Circuit decisions are addressed in the following section.

IV. 11TH CIRCUIT COURT DENIAL OF DUE PROCESS AND EQUAL PROTECTION ARGUMENTS

In *Eknes-Tucker v. Governor of Alabama*, the 11th Circuit Court of Appeals ("Court of Appeals" or "Appellate Court") held that parents do not have a constitutional right to treat their children with transitioning medications that are subject to medically accepted standards, and that rational basis review should be applied in cases involving this issue.[34]

The Appellate Court addressed the parents of transgender youth and transgender minor's substantive due process argument, first by outlining the precedent of the right of parents to treat their children with medication.[35] The Court of Appeals found that, generally, such a right was not rooted in the United States's history and tradition – particularly not for children.[36] Further, the Court of Appeals noted that there have been transgender or otherwise gender nonconforming people throughout history, but the use of medicine to

---

[33] *Id.*

[34] Eknes-Tucker,80 F.4th at 1210 ("The plaintiffs have not presented any authority that supports the existence of a constitutional right to "treat [one's] children with transitioning medications subject to medically accepted standards. Nor have they shown that section 4(a)(1)-(3) classifies on the basis of sex or any other protected characteristic. Accordingly, section 4(a)(1)-(3) is subject only to rational basis review.").

[35] *Id.* at 1221-24 (discussing the Due Process Clause and the liberties recognized under substantive due process such as the fundamental right to marry, establish a home, and bring up children).

[36] *Id.* at 1225-26 (noting that the district court reached its decision "without performing any analysis of whether that specific right is deeply rooted in our nation's history and tradition. That was error. Neither the record nor any binding authority establishes that the "right to treat [one's] children with transitioning medications subject to medically accepted standards" is a fundamental right protected by the Constitution." (citations omitted)).

treat gender dysphoria was not available until the 20th Century.[37] Finally, it rejected the argument made in *Troxel v. Granville*, which held that there is a broader fundamental right to make decisions concerning care, custody and control of one's children.[38] Instead, the Appellate Court supported its opinion citing the 6th Circuit decision in *L.W. v. Skrmetti*, which narrowed *Troxel*'s holding and found that parents "have a substantive due process right 'to make decisions concerning the care, custody, and control of their children" but that "[n]o Supreme Court case extends it to a general right to receive new medical or experimental drug treatments."[39] Furthermore, the Appellate Court posited the common thread that states may limit the authority of parents where "it appears that parental decisions will jeopardize the health or safety of the child or have a potential for significant social burdens."[40] The Appellate Court found no substantive due process rights awarded under the applied rational basis review of the statute.[41]

After the 11th Circuit shot down a substantive due process argument, the plaintiffs, the parents and minors, argued under the Equal Protection's Clause that the government discriminated on the basis of sex and the statute must

---

[37] *Id.* at 1220-21 ("Although there are records of transgender or otherwise gender nonconforming individuals from various points in history, the earliest recorded, uses of puberty blocking medication and cross-sex hormone treatment for purposes of treating the discordance between an individual's biological sex and sense of gender identity did not occur until well into the twentieth century."). *See* Pierce, 268 U.S. at 534-35;Troxel, 530 U.S.at 66. That was error.")

[38] *See id*.; Troxel v. Granville, 530 U.S. 57, 66 (2000).

[39] *Eknes-Tucker*, 80 F. 4th at 1224.

[40] *Id.* ("Moreover, all of the cases dealing with the fundamental parental right reflect the common thread that states properly may limit the authority of parents where "it appears that parental decisions will jeopardize the health or safety of the child or have a potential for significant social burdens.").

[41] *Id.* ("Plaintiffs have not shown it to be likely that the Due Process Clause of the Constitution guarantees a fundamental "right to treat [one's] children with transitioning medications subject to medically accepted standards. . . . Because the Due Process Clause does not guarantee the described right, state regulation of the use of puberty blockers and cross-sex hormone treatment for minors would be subject only to rational basis review and thus afforded "a 'strong presumption of validity.'").

therefore be analyzed under intermediate scrutiny.[42] The plaintiffs asserted that the Vulnerable Children's Act classifies individuals on the basis of sex by using sex-based terms and by classifying on the basis of gender nonconformity.[43] Alabama insisted that the Act classified who could receive puberty blockers based on age and procedure, not sex or gender nonconformity.[44] The state maintained that the Act should instead be subject to rational basis review, and the Appellate Court agreed.[45]

The Appellate Court's statutory interpretation found that the language of the statute did not apply the hierarchy that is typically laid out in sex discrimination statutes treating men and women differently.[46] It explained that the Act applied to all minors seeking puberty blockers.[47] Therefore, the Act did not discriminate between males or females seeking certain types of treatments.[48] Plus, the Appellate Court found the statute only referred to sex because of the medical procedures it regulates, not for any discriminatory purpose.[49]

The outcome in *Eknes-Tucker* sets problematic precedent for transgender youth. The next portion of this article recommends how appellate courts

---

[42] *Id.* at 1227.
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.* at 1228-29.
[47] *See id.* at 1228 (""Of course, section 4(a)(1)-(3) discusses sex insofar as it generally addresses treatment for discordance between biological sex and gender identity, and insofar as it identifies the applicable cross-sex hormone(s) for each sex—estrogen for males and testosterone and other androgens for females.").
[48] *Id.* ("We nonetheless believe the statute does not discriminate based on sex for two reasons. First, the statute does not establish an unequal regime for males and females.").
[49] *Id.* ("Second, the statute refers to sex only because the medical procedures that it regulates—puberty blockers and cross-sex hormones as a treatment for gender dysphoria—are themselves sex-based. or that reason, it is difficult to imagine how a state might regulate the use of puberty blockers and cross-sex hormones for the relevant purposes in specific terms without referencing sex in some way. Thus, we do not find the direct sex-classification argument to be persuasive.").

should analyze similar bans with heightened scrutiny, instead of the 11th Circuit's rational basis test.

V. COURTS SHOULD ANALYZE PUBERTY BLOCKER BANS WITH HEIGHTENED SCRUTINY

There are different types of review that courts use when analyzing statutory classifications: rational-basis, intermediate scrutiny, and strict scrutiny.[50] Rational basis review is the most deferential to states, and typically a statute will pass rational basis review if it addresses a legitimate state interest and is rationally connected to that interest.[51] Whereas intermediate scrutiny, which arguably should be applied by the 11th Circuit when analyzing transgender health care bans, must show an "exceedingly persuasive justification" or "important government interest" for classifying individuals based on sex and must demonstrate that the classification is "substantially related" to achieving that interest.[52] The substantive due process right of parents to treat their children with experimental medication was less persuasive to the court especially because it denied a history of medical intervention to treat gender dysphoria. However, an equal protection argument that highlights sex discrimination has been successful in other jurisdictions and is an argument that the 11th Circuit should have accepted in *Eknes-Tucker*.

---

[50] *See id.*
[51] *See id.* at 1220 ("Conversely, laws that do not burden the exercise of a fundamental right (and do not discriminate against a suspect class under the Equal Protection Clause) are subject to rational basis review and need only "be rationally related to a legitimate governmental interest." . . . Although not "toothless," rational basis review is "highly deferential to government action.").
[52] *Id.* at 1234-35.

In contrast to the 11th Circuit, the 8th Circuit Court of Appeals applied the heightened scrutiny standard of review to a similar statutory regime put into place in Arkansas. In *Brandt v. Rutledge*, the 8th Circuit Court of Appeals analyzed an Arkansas statute that criminalized the distribution of puberty blockers for transgender minors and banned surgical procedures for gender affirming care.[53] The 8th Circuit reasoned that the law discriminated on the basis of sex because males could receive a testosterone treatment, while females could not receive the same treatment.[54]

Additionally, in other cases where transgender people have been discriminated against, they have been classified as a quasi-suspect class and heightened scrutiny was applied when evaluating classifications in statutes.[55] In equal protection challenges raised in school restroom access challenges, several federal appellate courts concluded that laws prohibiting transgender individuals from access consistent with their gender identity amount to sex-based classifications subject to intermediate scrutiny.[56]

There is precedent set in the 2020 Supreme Court case, *Bostock v. Clayton*, which held that discrimination against transgender people in the workplace was sex discrimination under Title VII.[57] The same logic can be applied when assessing puberty blocker bans: the bans discriminate based on sex when they deny minors assigned one sex at birth access to certain medical procedures for gender-affirming purposes, but allow those same procedures

---

[53] *Id.* at 1232.
[54] Eknes-Tucker, 80 F.4th at 1232.
[55] *See*, *e.g.*, Whitaker v. Kenosha Unified School District, 858 F. 3d 1034, 1050-51 (7th Cir. 2017).
[56] *See*, *e.g.*, *id.* ("Here, the School District's policy cannot be stated without referencing sex, as the School District decides which bathroom a student may use based upon the sex listed on the student's birth certificate. This policy is inherently based upon a sex-classification and heightened review applies.").
[57] *Outlawing Trans Youth: State Legislatures and the Battle Over Gender Affirming Healthcare for Minors*, 134 HARV. L. REV. 2163, 2180 (Apr. 2021).

to be performed on minors for non-gender-affirming purposes.[58] The plaintiffs could have and should have used *Bostock*'s interpretation to analyze the statute. Perhaps if the information had been presented this way, the Court of Appeals would recognize the parallels between the discrimination.

The federal system has had mixed interpretations of how to analyze transgender classifications and it has proven challenging for plaintiffs to win. However, state courts are still an option, and plaintiffs have found success in that arena. The following section discusses state constitution protections of health care.

VI. STATE CONSTITUTIONAL CHALLENGES TO BANS: HEALTHCARE FREEDOM PROVISIONS

There has been success in challenging anti-LGBT legislation in the state court system.[59] State constitutions tend to enshrine more rights to individuals than the United States Constitution.[60] While there have been steps to restrict privacy protections and access to healthcare at the federal level after the

---

[58] *See id.* ("Although Bostock's holding formally reached only Title VII, Justice Alito's dissent and several courts of appeals recognized that its analysis applies just as clearly to equal protection claims.").

[59] *See*, *e.g.*, *Transgender Healthcare Shield Laws*, MOVEMENT ADVANCEMENT PROJECT: EQUALITY MAPS (Oct.18, 2024) https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws ("[A] growing number of states are taking action to protect access to this medically necessary health care. These "shield" or "refuge" laws can vary from one state to the next, but their primary goal is to protect transgender people, their families, and their medical providers against these ongoing attacks and to protect access to transgender-related health care. For example, if a person travels from a state where transgender healthcare is banned and receives that care in another state, a "shield" law can protect the recipient and/or provider of that healthcare against civil or criminal charges from the state where healthcare is banned.").

[60] *See* Caroline Sullivan, *The Power of State Constitutions*, DEMOCRACY DOCKET (July 26, 2022) https://www.democracydocket.com/analysis/the-power-of-state-constitutions/ ("Every state has its own constitution. These documents often grant rights beyond the federal Constitution.").

Dobbs decision, states offer broader rights in their constitutions. Thus, state courts have been a battleground where trans-activists have found success, [61] particularly when litigating healthcare bans through the state constitution's "healthcare freedom" provisions.[62]

After the Affordable Care Act in the early 2010s, many states with a large GOP presence put healthcare freedom provisions in their state constitutions.[63] For example, Ohio's health care freedom provision states that no law or rule can "compel anyone to participate in a health care system," "prohibit the purchase or sale of health care or health care insurance," or "impose a fine or penalty for that purchase."[64] Under the Ohio statute, healthcare is defined as "any care, treatment, service, or procedure to maintain, diagnose, or treat an individual's physical or mental condition or physical or mental health."[65]

The possible interpretations of such provisions allow for plaintiffs to craft creative arguments. One argument is that forbidding physicians from

---

[61] *See* Quinn Yeargain, *Challenging Anti-Trans Legislation Under State Constitutions*, STATE COURT REPORT, (July 11, 2023), https://statecourtreport.org/our-work/analysis-opinion/challenging-anti-trans-legislation-under-state-constitutions ("Not only is there an unequivocally stronger textual argument for LGBTQ+ rights under state constitutions, but in many states, the state judiciaries may be friendlier, too.").

[62] *See id.* ("Third, a handful of states contain what are colloquially known as "healthcare freedom" amendments. These provisions were adopted in several conservative states in the years immediately following the passage of the Affordable Care Act, designed to protect individual rights to healthcare "from undue governmental infringement. In the abortion rights context, litigants in Ohio and Wyoming have relied on these provisions to challenge their states' abortion bans.").

[63] *Id.*

[64] Julia Livingston, *Abortion and Trans Rights Advocates Turn to Unlikely Tool in State Constitutions*, STATE COURT REPORT, (May 14, 2024), https://statecourtreport.org/our-work/analysis-opinion/abortion-and-trans-rights-advocates-turn-unlikely-tool-state ("Ohio's provision provides that no law or rule can "compel anyone to participate in a health care system," "prohibit the purchase or sale of health care or health care insurance," or "impose a fine or penalty for that purchase." "Health care" is defined as "any care, treatment, service, or procedure to maintain, diagnose, or treat an individual's physical or mental condition or physical or mental health.").

[65] *Id.*

administering gender affirming care and hormone therapy is essentially forbidding the purchase of health care.[66] These arguments have been persuasive to state court justices and could be another avenue for states within the 11th Circuit to undo restrictions on gender affirming care. Alabama's healthcare freedom provision could be a viable solution to reverse the restrictions.[67]

If a state's constitution does not protect access to gender affirming care, we need medical authorities to step in and stop the spread of misinformation that creates these bans in the first place. The next section emphasizes the need to combat misinformation and expand protections.

VII. COMBATING MISINFORMATION AND EXPANDING PROTECTIONS: THE ROLE OF MEDICAL AUTHORITIES AND FEDERAL REGULATIONS IN ADVANCING TRANSGENDER HEALTH CARE RIGHTS

Education on gender affirming care and hormone therapy could potentially mitigate the creation of more statutes like the one addressed *Eknes-Tucker*. Education would debunk consistent false information laid out by legislators as to why transgender children need to be protected from gender affirming care.[68] The American Academy of Pediatrics ("AAP") and

---

[66] *Id.*

[67] *See* Quinn Yeargain, *The Right to "Health Care Freedom" in State Constitutions*, 93 UMKC L. REV. 2 (forthcoming 2024-2025) ("voters also had the opportunity to add a right to "health care freedom" to their state constitutions. Some state constitutions speak broadly, though without many specifics, about public health, but these provisions have had relatively narrow effects. In contrast, the rights contained in these health care freedom provisions were seemingly narrow, with most protecting the ability to pay for health care services and a prohibition on compelled participation in any "health care system." Voters in Alabama, Arizona, Ohio, Oklahoma, and Wyoming ratified these amendments.").

[68] *See* Anne Alstott, et al., *Demons and Imps: Misinformation and Religious Pseudoscience in State Anti-Transgender Laws*, 35 YALE J.L. & FEMINISM 223, 275 (2024) ("There is a potential role for private actors, including medical organizations, to adopt systematic review processes that can publicly call out the use of falsehoods in legal action.").

the American Medical Association ("AMA") have already filed some amicus briefs and "publicly call[ed] out scientific claims made in defense of healthcare bans."[69] Also, independent physicians and researchers have published materials identifying the misuse of science in health care bans.[70] However, the National Institutes of Science and Medicine ("NIH"), one of the most persuasive medical academic authorities, has not leveraged its power to weigh in on anti-trans laws.[71] The NIH should put forth amicus briefs and information about the dangers of transgender healthcare bans. There is a need for influential leaders in the medical community to intervene. If it is not already being heavily researched, the NIH should specifically provide ample information on puberty blockers since this tends to be the gender-affirming care that the state bans target. Proponents of the bans have dominated the conversation about gender affirming care.[72] There is a need for counter opinions in the public sphere. It must be well funded, filled with medical expert testimony, and transgender youth stories. If this happens, the discourse could lead to changes in policy.

In addition to norm setting agencies speaking out, administrative agencies have stepped in to try to limit transgender healthcare bans. In May 2024, the Health and Human Services Office for Civil Rights ("HHS" "OCR") and the Centers for Medicare & Medicaid ("CMS") published final regulations for

---

[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *See* Alejandra Caraballo & Heron Greenesmith, *The Narrative of Trans Rights is Being Shaped by Right-Wing Media*, TEEN VOGUE (Mar. 17, 2022), https://www.teenvogue.com/story/trans-people-right-wing-media ("The anti-trans movement has been amplified largely by the right-wing media machine, which effectively galvanized the Christian right and other movements obsessed with gender essentialism. Fearmongering, one-sided reportage about transgender people has proliferated without much pushback or sustained criticism from the left.").

implementing 1557 of the Affordable Care Act.[73] The final rule prohibits categorical coverage exclusions or limitations for health services related to gender transitions and other gender-affirming care.[74] However, there is an ongoing discussion about how prohibiting a ban does not guarantee access to gender affirming care under all circumstances.[75]

Covered entities under the Affordable Care Act cannot:

> [D]eny or limit services based on gender identity or sex assigned at birth, adopt any policy of treating individuals differently on the basis of sex, including to the extent it prevents an individual from engaging in a health program or activity consistent with the individual's gender identity, or deny or limit services sought for gender transition or other gender-affirming care based on sex assigned at birth or gender identity.[76]

This provision is an enormous stride for trans activists because it outlaws bans on both gender-affirming care itself and gender-affirming procedures.[77] However, it is still uncertain how this new final rule will interact with statutes like the one in place in Alabama.[78] The HHS's OCR argues that these discriminatory state statutes are preempted by the ACA, which came into law in 2010, and these new bans came into place in 2022.[79] It is likely we will see litigation or counter-action to HHS's final rule in the near future.

VIII. IMPACT AND LEGAL FUTURE OF GENDER AFFIRMING CARE

---

[73] Alden Bianchi, *The Impact of the ACA 1557 Final Regulations on Gender-Affirming Care*, NATIONAL L. REV. (May 30, 2024), https://natlawreview.com/article/impact-aca-1557-final-regulations-gender-affirming-care, (explaining the impact of the new HHS final rule, summarizing impacts on gender affirming care bans).
[74] *Id.*
[75] *See id.* ("But prohibiting categorical coverage exclusions is not the same thing as requiring covered entities to provide access to gender-affirming care under all circumstances.").
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *Id.*

In conclusion, the narrow ruling in the 11th Circuit will have a massive impact on the transgender population across the south. Adolescents who are struggling with gender dysphoria will no longer be able to access gender affirming healthcare that is monitored by a medical professional.[80] This does not mean that they will not try to seek care, but rather they will access riskier care without proper instruction.[81] However, as noted, there have been strides in the state court system and through administrative agencies to ensure protections to transgender minors seeking gender affirming care. As for the future, the constitutionality of gender affirming care bans is on the Supreme Court docket for the 2024-25 term.[82] The courts will continue to grapple with this issue.

[80] *See* Litaker, *supra* note 23, at 363-64. ("Without safe and legal access to puberty blockers, minors won't stop seeking treatment, they will just turn elsewhere. Minors will try to initiate transition on their own without supervision or assistance by physicians. This may lead to the child attempting to "obtain medication [from] the illegal market," exposing themselves to the dangers of unsupervised drugs.").

[81] *Id.*

[82] Amy Howe, *Supreme Court Takes Up Challenge to Ban on Gender-Affirming Care*, SCOTUSBLOG (June 24, 2024, 10:03 AM), https://www.scotusblog.com/2024/06/supreme-court-takes-up-challenge-to-ban-on-gender-affirming-care/.

What's In This? The Need for Stricter Punishments and Incentives for Compliance in the Dietary Supplement Listing Act

Aariz Gawandi

I. THE CONSEQUENCES OF DANGEROUS DIETARY SUPPLEMENTS AND THE LEGISLATION AIMED TO HELP REGULATE THEM

The dietary supplement industry in America is a powerful machine that generates significant economic value, and its products are a regular staple in the lives of many Americans.[1] In 2023 alone, around seventy-four percent of American adults reported taking dietary supplements, with fifty-five percent of those surveyed describing themselves as taking supplements regularly.[2] The widespread use of dietary supplements has resulted in a 158.6 billion dollar industry in the U.S. alone.[3] While the massive amount of supplement usage may suggest that these are safe products that many Americans believe benefit them, that is not always the case. In early 2024, the Food and Drug Administration ("FDA") issued multiple warnings regarding the supplement known as "Neptune's Fix."[4] The supplement was marketed to the public as providing "happiness in a bottle."[5] More specifically, the product claimed to provide a remedy for treating anxiety,

[1] Press Release, Council for Responsible Nutrition, Three-quarters of Americans Take Dietary Supplements; Most Users Agree They are Essential to Maintaining Health, CRN Consumer Survey Finds (Oct. 5, 2023) (on file with author), https://www.crnusa.org/newsroom/three-quarters-americans-take-dietary-supplements-most-users-agree-they-are-essential.
[2] *Id.*
[3] Press Release, Council for Responsible Nutrition, CRN Report: Dietary Supplement Companies Pump More Than $158 Billion into U.S. Economy, Up 23% from 2016 (Jan. 23, 2024) (on file with author), https://www.crnusa.org/newsroom/crn-report-dietary-supplement-companies-pump-more-158-billion-us-economy-23-2016.
[4] Kate Gibson, *Neptune's Fix products recalled nationwide due to serious health risks*, CBS News (Jan. 30, 2024, 11:42 AM), https://www.cbsnews.com/news/fda-neptunes-fix-tianeptine-product-recall-gas-station-heroin/.
[5] *Id.*

pain, et cetera.[6] However, these products contained tianeptine, a drug not approved by the FDA, that carries serious risks such as coma and death.[7] After health officials in New Jersey traced several cases of tianeptine poisonings to Neptune's Fix specifically, the manufacturer behind the product issued a recall.[8]

With the significant risks that can be posed by supplements, the importance of regulation in the supplement industry is clear. A bill recently proposed by U.S. Senator Dick Durbin, the Dietary Supplement Listing Act of 2024 ("DSLA"), seeks to increase transparency from supplement manufacturers with the FDA and consumers.[9] The proposed legislation in its current form has two main components.[10] First, supplement manufacturers would be required to submit certain information to the FDA about their products, most importantly a full list of the ingredients in each supplement, as well as their claims of what those ingredients supposedly do for a disease or a health-related condition.[11] Secondly, the bill, if enacted, would establish a publicly available online database containing the information each supplement is required to provide.[12] While the bill in its current proposed form would provide an increase in transparency and regulation, there are still necessary additions to the bill to maximize compliance from supplement

---

[6] FOOD AND DRUG ADMIN., FDA warns consumers not to purchase or use Neptune's Fix or any tianeptine product due to serious risks (Nov. 21, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-neptunes-fix-or-any-tianeptine-product-due-serious-risks.

[7] Gibson, *supra* note 4.

[8] *Id.*

[9] Dietary Supplement Listing Act of 2024, S. 4827, 118th Cong. (2024).

[10] *Id.*

[11] *Id.* ("A list of all ingredients in each such dietary supplement required under sections 101.4 and 101.36, title 21, Code of Federal Regulations (or any successor regulations), to appear on the label of a dietary supplement, including … (i) characterizes the relationship of any ingredient to a disease or a health-related condition and is described in section 4403(r)(1)(B)").

[12] *Id.* ("The Secretary shall make such information maintained in the electronic database publicly searchable, including by dietary supplement product listing number, and by any field of information or combination of fields of information provided under subsection (b)(1)").

manufacturers and reduce the risk of dangerous products. This paper will argue for the addition of two provisions to the DSLA: first, the adoption of stricter punishments for manufacturers who refuse to comply with its provisions, along with appropriate, literature-backed enforcement mechanisms; second, voluntary compliance and an increase in supplement quality will be encouraged by providing incentives for companies who invest in research and development to improve product efficacy. These incentives would mainly be in the form of tax credits, with an increased percentage for supplement manufacturers who create new products with demonstrable health benefits. The implementation of these two provisions in the DSLA will encourage maximizing compliance from supplement manufacturers, who hold a lot of power in the health of everyday Americans.

II. THE RISE OF THE AMERICAN SUPPLEMENT INDUSTRY

To understand why additional provisions are necessary to the DSLA, it is important to understand how the supplement industry enjoys loose regulation by the FDA.[13] Before the 1990's, the FDA had wide discretion in regulating dietary supplements, and each individual supplement on the market could be regulated as a food item, a drug, or both by the agency.[14] If a supplement made drug-like claims, meaning they purported to be effective treatments for illness or promoted improved physiology, they would go through a strict drug

[13] Kathy Talkington, *Stronger Federal Oversight of Dietary Supplements Will Protect Consumers From Unsafe Products*, PEW (Jan. 26, 2023), https://www.pewtrusts.org/en/research-and-analysis/articles/2023/01/26/stronger-federal-oversight-of-dietary-supplements-will-protect-consumers-from-unsafe-products. ("The truth is that although the Food and Drug Administration oversees supplements, it does not review or test their safety before they are sold…Since 1994, when the law governing FDA oversight of dietary supplements was last updated, the industry has grown 20-fold and has shown no signs of stopping").

[14] Alessa Thomas, *Making Sense of Supplements: Suggestions for Improving the Regulation of Dietary Supplements in the United States*, 2010 MICH. ST. L. REV. 203, 207 (2010).

approval process before being allowed to sell in the market.[15] In short, supplements that were being regulated as drugs needed to show that they were safe *and* effective at what they were claiming to do.[16] However, this regulatory framework started to change in 1990, catalyzed by the passage of the Nutrition Labeling and Education Act ("NLEA").[17] The NLEA expanded the FDA's regulatory power, and any health claims made by supplement products had to undergo a review under established scientific standards for these claims.[18]

The passage of the NLEA was alarming to supplement manufacturers and members of the public.[19] Supplement manufacturers felt their products were being over-regulated by the FDA, and industry leaders launched a grassroots campaign to convince the public, millions of whom used supplements, against expanded FDA regulation.[20] Public pressure and industry lobbying led to Congress passing the Dietary Supplement Health and Education Act ("DSHEA"), which placed supplements under a separate safety standard.[21] Under the DSHEA, dietary supplements are not regulated in the same category as drugs or food additives and do not need to undergo pre-market approval.[22] After the passage of this bill, supplement manufacturers were no longer required to undergo a scientific review of their products unless they contained ingredients not marketed before in the US.[23] With the DSHEA,

---

[15] *Id.* at 207-08.
[16] *Id.* at 208.
[17] *Id.* at 210.
[18] *Id.* at 210.
[19] *Id.* at 211.
[20] *Id*. at 212-13.
[21] Theodora McCormick, *DSHEA – 20 Years Later – The Good, The Bad And The Ugly*, CORP. COUNS. BUS. J. (May 21, 2014), https://ccbjournal.com/articles/dshea---20-years-later---good-bad-and-ugly.
[22] CONG. RSCH. SERV., Dietary Supplement Health and Education Act of 1994, 4 (Oct. 22, 2020), https://cdn.centerforinquiry.org/wp-content/uploads/sites/33/2020/10/22170817/crs_dshea_1994.pdf. ("The Act allows the ingredients in a supplement to be excluded from regulation as a food additive or drug, which both require premarket approval").
[23] McCormick, *supra* note 21.

supplements no longer had to show that they were effective along with being safe to the FDA, and the Act provided a presumption of safety for these products.[24] Furthermore, if the FDA is concerned about a supplement being unsafe, they have the burden of proof in showing that a product has a "significant or unreasonable risk of illness or injury."[25] With the passage of one Act, the FDA went from being able to widely regulate dietary supplements to having a very limited amount of regulatory power.[26]

The supplement industry today, enjoying the loose system of regulation by the FDA, boasts new innovations in its products, most notably the ingredients and blends. A prime example of this is the marketing of nootropic supplements.[27] Nootropics, often referred to as "smart drugs," are a group of ingredients that can be found in dietary supplements that purport to enhance memory and cognitive function.[28] Nootropic ingredients can range from synthetic compounds to plant extracts, but a commonality between these ingredients in general is that the long-term effects are relatively unknown.[29] Despite this, nootropic supplements are being marketed to the public as "smart drugs" even though, as previously discussed, supplements containing these ingredients do not have to undergo any scientific scrutiny to support their claims.[30] Manufacturers are even going so far as to offer "personalized" supplement blends that use genomic data or individual results of lifestyle questionnaires to sell their products to hopeful

---

[24] Thomas, *supra* note 14, at 214.
[25] INST. OF MED. & NAT'L RSCH. COUNCIL, Comm. on the Framework for Evaluating the Safety of Dietary Supplements, *Dietary Supplements: A Framework for Evaluating Safety* 2 (2005).
[26] Thomas, *supra*, note 14, at 215 ("DSHEA does not adequately provide the FDA with the tools it needs to ensure consumer safety").
[27] Matěj Malík & Pavel Tlustoš, *Nootropics as Cognitive Enhancers: Types, Dosage and Side Effects of Smart Drugs*, 14 NUTRIENTS 3367, 1 (2022).
[28] *Id.*
[29] *Id.*
[30] McCormick, *supra* note 21.

Americans.[31] However, researchers and nutritionists are skeptical of the reliability of these claims.[32] The leniency in current supplement regulation by the FDA plays a role in manufacturers making these types of promises to consumers. It is crucial for the DSLA to have provisions in place that significantly bolster its ability to regulate and ensure compliance from supplement manufacturers and minimize the risks of supplement innovation gone wrong.

III. THE DSLA MUST SET STRICTER PUNISHMENT STANDARDS FOR MANUFACTURERS WHO DO NOT COMPLY WITH ITS PROVISIONS

As the DSLA is currently written, no provision explicitly states punishment for supplement manufacturers who do not comply.[33] Instead, the Act seeks to add an amendment to a section of a separate statute, the Federal Food, Drug, and Cosmetic Act ("FDCA").[34] The DSLA would amend section 403 of the FDCA, which defines under what circumstances food items can be deemed as misbranded.[35] Specifically:

> (z) If it is a dietary supplement for which a responsible person or the United States agent of such a person is required under section 403D to file a listing, file a change to an existing listing, or provide additional information to the Secretary, and such person or agent has failed to comply with any such requirements under section 403D with respect to such dietary supplement"

---

[31] Shawna Williams, *Personalized Nutrition Companies' Claims Overhyped: Scientists*, THESCIENTIST (Aug. 21, 2019), https://www.the-scientist.com/personalized-nutrition-companies-claims-overhyped--scientists-66321.
[32] *Id.* ("Take the BCMO1 alleles used by PureGenomics to suggest a possible need for vitamin A supplements. "As far as I can see, there is not enough information out there in the moment to support such a claim," writes Georg Lietz, a nutrition researcher at Newcastle University").
[33] S. 4827, 118th Cong. (2024).
[34] *Id.*
[35] *Id.*

This provision would be added to the end of Section 403 of the FDCA.[36] In essence, if a supplement manufacturer fails to provide the required information as mandated by the DSLA, their product would be categorized as misbranded and face the consequences of such.[37] As it stands, if a manufacturer produces a supplement that is labeled as misbranded, there is a fine of $1,000 and/or a maximum of one year of imprisonment.[38] If there is a repeat offense, or if it was shown that the manufacturer had the intent to defraud or mislead, there is a $10,000 fine and/or a maximum of three years of imprisonment.[39] In summary, the DSLA itself does not list out a penalty for noncompliance and instead amends a section of a separate statute, the FDCA, which can then result in a punishment for not complying with the DSLA through the FDCA.[40]

With the amount of money that supplement manufacturers make, a fine of $1,000 and a possibility of a year of imprisonment is not enough to maximize compliance and public safety. In fact, there are few documented instances of imprisonment being imposed for FDCA violations as a whole, let alone for misbranding.[41] Statistically, criminal prosecutions under the FDCA arise from only a tiny fraction of FDA inspections, less than one percent.[42] Technical violations in particular almost never lead to criminal charges.[43] With the minimal fine imposed for violations and the unlikelihood of criminal charges filed against their executives, supplement manufacturers

---

[36] *Id.*
[37] *Id.*
[38] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 333.
[39] *Id.*
[40] S. 4827, 118th Cong. (2024).; 21 U.S.C. §§ 331.
[41] CONG. RSCH. SERV., Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues, 17 (Feb. 9, 2018), https://crsreports.congress.gov/product/pdf/R/R43609 ("Criminal prosecutions under the FD&C Act are rare, with one commentator finding that "only a miniscule fraction of 1 per cent of the [FDA's] inspections will result in criminal prosecution").
[42] *Id.*
[43] *Id.*

have very little to fear from the FDCA, therefore they have little incentive to comply with the DSLA in its current state. Instead of adding an amendment to the FDCA, the DSLA should directly state penalties for noncompliance, and these penalties should be more severe than what the current version of the bill proposes. In exact words, it should have a provision that states:

> (6) PENALTIES FOR NONCOMPLIANCE –
>
> (a) Penalties for First Offense -
> Any dietary supplement manufacturer that fails to comply with the provisions of this Act shall be subject to a civil penalty of $250,000, imposed by the Secretary, and/or one year of imprisonment
> (b) Accruing Civil Penalties for Ongoing Noncompliance -
> In the event a dietary supplement manufacturer remains noncompliant with the provisions of the act for more than 14 days after receiving a notice of violation, additional civil penalties shall be enforced. The non-compliant manufacturer shall be fined $10,000 per day for each day noncompliance continues past the 14-day notice period until the violation is rectified, as determined by the Secretary.
> (c) Penalties for Repeat Offenders –
> In the event where a dietary supplement manufacturer commits a repeat violation of the Act involving a separate product, said manufacturer will be barred from selling or distributing said product for a period of one year.

If faced with the possibility of a substantial fine, such as $250,000 for a first-time offense, along with an increased frequency of penalties through the daily civil fine, compliance would theoretically increase from supplement manufacturers. Manufacturers would not want to forfeit a large sum of money due to noncompliance, and this would in turn increase the FDA's reputation for imposing strict punishments on those who do not comply with federal regulations, further increasing the probability of compliance. These penalties should be in place regardless of whether the manufacturer had an intention to defraud or mislead. Public safety is at issue, and potential harm from a supplement doesn't change depending on the intentionality of a non-compliant manufacturer. In addition, if penalties were only enforced when manufacturers were shown to have intentionally violated the Act, that would undermine its effectiveness, as manufacturers could simply claim ignorance

as a defense. This would, in essence, place a burden of proof on the FDA to prove intentionality, leading to drawn-out legal battles instead of straightforward enforcement and quick action to remedy any violation. This type of strict liability enforcement is already used in forms of regulatory legislation that can affect supplement manufacturers, such as the FDCA.[44] The DSLA should also adopt such an approach to incentivize manufacturers to comply with it to the best of their ability.

Although these penalties appear harsh on the surface, research has shown strict penalties like these are more likely to increase compliance than lighter ones.[45] In a dissertation written by Vid Adrison, who examined the effects of penalty severity on regulatory compliance, he argues that significant effects from penalties come when those penalties have an increased frequency and severity.[46] The dissertation looked at data from multiple government agencies that contained records of compliance with the Clean Water Act ("CWA") from a broad range of major entities, both public and private.[47] After their analysis, the researchers concluded that although penalties do ultimately reduce noncompliance with regulations, penalty increases that are only slight do not lead to a significant reduction in the likelihood of violations.[48]

There are multiple justifications for having more significant and frequent penalties according to the results of Adrison's research.[49] One is that there is a deterrence effect strict penalties will impose.[50] In the data sample used

---

[44] 21 U.S.C. §§ 331. (This section stating prohibited acts under the FDCA begins with "The following acts and the causing thereof are prohibited" and does not make any reference to intentionality).
[45] Vid Adrison, Estimating the Effect of Penalties on Regulatory Compliance, 36 (Jan. 13, 2008) (Ph.D. dissertation, Georgia State University) (ScholarWorks).
[46] *Id.*
[47] *Id.* at 22.
[48] *Id.* at 36.
[49] *Id.*
[50] *Id.*

by Adrison, the entities penalized were only somewhat less likely to violate the CWA afterward, and the overall impact on compliance was relatively minor.[51] The researchers linked these findings to penalties not being consistently enforced on violators, and when they were, they were usually a small fine.[52] Adrison argues that stricter and more frequent penalties are necessary from regulators to increase compliance from an entity as a whole.[53] When applying this argument to the DSLA, imposing harsher penalties and enforcing them on non-compliant manufacturers would theoretically increase overall compliance with the Act from the supplement industry. If one manufacturer sees another receive harsh penalties, this would incentivize compliance as a method of preventing the same outcome from happening to them.

Secondly, imposing stricter and more frequent penalties will increase the reputation of the regulatory body, according to Adrison.[54] His dissertation also examined the effect of regulator reputation on compliance, as measured by multiple metrics including the average penalty imposed by the regulator, and the use of enforcement actions without monetary fines.[55] The results show that a higher regulator reputation does improve compliance, and this contributes to Adrison recommending stricter penalties as a way of increasing this.[56] Applying this theory to the DSLA, severe penalties for noncompliance would signal to supplement manufacturers that a regulator, such as the FDA, would be more likely to impose these punishments. This, in turn, makes manufacturers more likely to comply with the DSLA to avoid said penalties.

---

[51] *Id.* at xi.
[52] *Id.* at 31.
[53] *Id.* at 36.
[54] *Id.*
[55] *Id.* at 23.
[56] *Id.* at 35-36.

In summary, the DSLA should directly state in its text that the punishment for noncompliance with the Act is $250,000 along with a possibility of one year of imprisonment for a first-time offense. Additionally, the Act should also state that there will be a civil fine of $10,000 daily until the requirements of the Act are complied with. For a repeat offense, the Act should state that noncomplying supplement manufacturers will be barred from selling that product for a period of up to one year. Implementing a provision surrounding the proposed punishment in the Act's text can significantly increase compliance from supplement manufacturers, resulting in increased transparency between them, the FDA, and consumers of supplements.[57]

IV. THE DSLA SHOULD INCLUDE A PROVISION THAT INCENTIVIZES SUPPLEMENT MANUFACTURERS TO INVEST IN RESEARCH AND DEVELOPMENT TO IMPROVE PRODUCT EFFICACY

In addition to the DSLA not directly including a provision surrounding punishment for noncompliance, there are also no provisions encouraging voluntary compliance through incentives. A second provision that should be added to the DSLA is an amendment to the Internal Revenue Code, particularly regarding the Research & Development ("R&D") tax credit.[58] The Internal Revenue Service ("IRS") currently allows for organizations that are engaged in research as part of their organizational model and fit certain criteria to claim an R&D tax credit.[59] This is located in §41 of the U.S. Tax Code, and it allows companies with "qualified research expenses" to claim a twenty percent tax credit for the excess of these expenses over the calculated

[57] *Id.* at 36 (alluding to Adrison's theory that frequent and significant penalties can increase compliance from entities).
[58] Credit for Increasing Research Activities, I.R.C. § 41.
[59] *Id.*

base amount.[60] To qualify, taxable entities need to participate in research and experimentation that aims to discover new information, is technological, used to create or improve products, and follows an experimental process.[61] Research into the practical effects of the R&D tax shows that the quality of business operations generally increases among entities that receive them.[62]

In one analysis, the impact of R&D tax credits was analyzed on growth potential for businesses.[63] The researchers of the analysis point out that a contributory factor for an increase in growth potential is that R&D tax credits can lower the cost of capital as well as the cost of research.[64] This in turn allows more investment in innovation, which can then lead to increased growth for an entity.[65] The potential for increased growth through these tax credits could be enticing for supplement manufacturers as it could allow them to sell more of their products while increasing their scientific backing. The amendment proposed by this paper would require supplement manufacturers to comply with the DSLA to be eligible for the R&D tax credit. Furthermore, if a manufacturer creates a supplement product that results in demonstratable health benefits, then the tax credit they can receive would increase from twenty to twenty-five percent. What this means in practice is that if a supplement manufacturer creates a new product, they can have that supplement undergo clinical testing from an independent laboratory. Those results can then be submitted for peer review, and if it is found that the

---

[60] *Id.* ("(1) 20 percent of the excess (if any) of (A) the qualified research expenses for the taxable year, over (B) the base amount").
[61] *Id.* (Section (d)).
[62] Catherine Fazio, Jorge Guzman & Scott Stern, *The Impact of State-Level R&D Tax Credits on the Quantity and Quality of Entrepreneurship* 4 (Nat'l Bureau of Econ. Rsch., Working Paper No. 26099, 2019), https://www.nber.org/papers/w26099.
[63] *Id.* at 1 (While there is a strong empirical base linking the R&D tax credit to increased R&D expenditures and innovation, prior work has not provided causal evidence that this policy effects the rate of formation and growth potential of new businesses. This paper combines data from the US Startup Cartography Project with the Panel Database on Incentives and Taxes to implement a difference-in-differences estimate of the impact of the R&D tax credit on the quantity and quality-adjusted quantity of entrepreneurship").
[64] *Id.* at 24.
[65] *Id.*

product significantly improves the health outcome it claims to affect, then the manufacturer is eligible for the increased tax credit. The credit would apply to the qualified research expenses, as defined by the IRC, involved in developing this specific drug. The added provision to the DSLA should state:

> (7) Research & Development Tax Credit for Dietary Supplement Manufacturers – Section 41 of the Internal Revenue Code (26 U.S.C. § 41) is amended by adding at the end of the following:
> (i) Compliance with the Dietary Supplement Listing Act -
> If a dietary supplement manufacturer wishes to claim the Research & Development tax credit under this section, they are only eligible to do so through compliance with the provisions of the Dietary Supplement Listing Act. Compliance shall be determined by the Secretary of the Department of Health and Human Services."
> (j) Increased Credit for Supplements with Demonstrable Health Benefits –
> If a dietary supplement product developed by a manufacturer results in demonstrable health benefits, as determined by the Secretary of Health and Human Services, the credit percentage for qualified research expenses related to the development of said product shall increase from 20 percent to 25 percent. Demonstratable health benefits shall be defined as significant improvements in health outcomes, verified by independent clinical studies, as approved by the Secretary.

Adding this proposed amendment to IRC §41 will achieve two effects. First, mandating compliance with the DSLA to be eligible for R&D tax credits would increase transparency between manufacturers, the FDA, and consumers leading to an overall increase in supplement regulation. Second, by offering an increased tax credit of twenty-five percent if a new supplement product results in an independently verified demonstratable health benefit, this spurs manufacturers to conduct higher quality research and put forth products that improve consumer health instead of harming it or having no effect.

Furthermore, the addition of this amendment would help remedy a possible criticism of the overall proposal suggested in this paper. One possible critique of this proposal is that it is more reactive than proactive,

since a significant portion relates to stricter penalties for noncompliance instead of, for example, altering the approval process for supplements to be sold. While this is a valid concern, the suggested provisions are aimed to strike a balance between not just enforcing accountability in the supplement industry but fostering innovation in it as well to create a safer product market. The stricter punishments are meant to serve as an immediate form of deterrence against noncompliance, while the increased R&D tax credit provision contributes to proactive improvements in supplement quality. Manufacturers would be incentivized to voluntarily invest in higher standards for their products through research. Over time, this makes the DSLA more effective by encouraging manufacturers themselves to prioritize complying with the Act to get the increased R&D tax credit. This, in turn, would likely lessen the overall enforcement burden on the FDA more than a change in the product approval process would. Ultimately, the addition of the proposed provision to the DSLA would foster innovation among supplement manufacturers and make their products not just safer, but more effective for consumers.

V. CONCLUSION

The dietary supplement industry in the United States is a powerful force that used to be strictly regulated by the federal government, but now enjoys the full extent of loose regulation.[66] This creates real-world consequences, including supplements such as Neptune's Fix causing severe harm to consumers.[67] In addition, supplement manufacturers are making more advanced claims about their products, such as the "smart drug" branding of Nootropics, as well as genetically personalized supplements.[68] The Dietary Supplement Listing Act aims to enact necessary regulation to this industry,

[66] Thomas, *supra*, note 14, at 215.
[67] FDA, *supra*, note 6.
[68] Williams, *supra* note 31.

and the core of the bill makes great strides in doing this through increasing transparency.[69] However, the DSLA needs to be modified in order to maximize the effectiveness of the regulation that it intends. The addition of a provision that imposes stricter financial punishments for noncompliance, with a possibility of being barred from selling a product if there are repeat infractions would help achieve this goal. This addition would increase the likelihood of compliance from the current version of the proposed Act. Furthermore, the DSLA should add a provision that amends IRC §41, mandating compliance with the DSLA in order to obtain R&D tax credits, along with increasing the credit percentage for creating products with demonstratable health benefits. Through the addition of these two provisions, the DSLA will go a long way in protecting consumer safety throughout the country and minimize further harm from the supplement industry.

[69] S. 4827, 118th Cong. (2024).

The Future of Human Genome Editing Implementation Technology Post *LePage*

Eva Goldblat

I. INTRODUCING HOW THE CIRCUMSTANCES SURROUNDING ALABAMA'S *LEPAGE* CASE AND HUMAN GENOME EDITING ARE INTERWOVEN

Imagine a world where fatal genetic mutations could quite literally be edited out of existence, where inheritable diseases are extracted from DNA thanks to groundbreaking scientific advancements. Recently imposed legal roadblocks, however, threaten this favorable dream from becoming reality. In recent decades, genetic engineering has made incredible advancements towards disease prevention and treatment for the improvement of an individual's health and the overall betterment of society.[1] In the realm of human genome editing, the CRISPR-Cas9 system possesses leading technology with its ability to alter the DNA of an organism to achieve a desired outcome on a molecular level.[2] The system allows for more direct intervention in the genome by targeting mutated DNA, removing the affected material by way of deletion, and inserting a non-affected genetic strand via replacement.[3]

This article proposes a reevaluation of the evidence and analysis used by the Alabama Supreme Court in order to determine their ruling in *LePage v. Center for Reproductive Medicine, P.C.* which classified embryos as unborn children. The proposed new analysis will leave laws defining unborn children as they stand, leaving the modern issue of in vitro versus in vivo to be promulgated by current legislative and adjudicatory bodies. Doing so will open the door for the creation and implementation of new laws and regulations specifically meant to tackle potential problems that arise from

[1] Mara Almeida and Robert Ranisch, *Beyond Safety: Mapping the Ethical Debate on Heritable Genome Editing Interventions*, 9 HUMANIT. & SOC. SCI. COMM. 1, 2 (2022).
[2] S. Soni, *Recent Developments in the Regulation of Heritable Human Genome Editing*, J. BIOETHICAL INQUIRY, 21, 15-18 (2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11052803/.
[3] Almeida & Ranisch, *supra* at 1.

developing technological innovations in the healthcare sphere. Taking a more logical approach to the evidence used by the Alabama Supreme Court will result in a ruling that would not hinder the future implementation of healthcare services and technologies, such as the CRISPR-Cas9 human genome editing system, which specifically focus on embryonic and in vitro services.[4]

II. A LOOK INTO THE INNER WORKINGS OF THE CRISPR-CAS9 SYSTEM AND THE ALABAMA SUPREME COURT'S RULING ON EMBRYO CLASSIFICATION

One of the most influential and promising technologies of today's modern world goes by the name "Clustered Regularly Interspaced Short Palindromic Repeats-Associated Protein 9."[5] This system unveiled the possibility to minimize, or even completely eradicate, fatal diseases, many of which are inheritable by way of correcting errors within the genome.[6] Upon infiltration, bacteria in the human body naturally acquire assorted fragments of the viruses' DNA and then implements that information into its own DNA in order to create what is known as CRISPR arrays.[7] These arrays are akin to a memory bank for bacteria, thus, in the instance the same or very similar type of virus is to attack again, the bacteria will produce RNA segments from the arrays that will then attach to an area of the viruses' DNA.[8] A Cas9 enzyme

---

[4] Melody Redman et al., *What is CRISPR/Cas9?*, 101 Archives of Disease in Childhood Educ. Prac. Edition 213, 214-15 (2016).
[5] Russell Franco D'Souza et al., *A Scoping Review on the Ethical Issues in the Use of CRISPR-Cas9 in the Creation of Human Disease Models*, J. of Clinical and Diagnostic Rsch., 17, 1-8 (2023), https://www.jcdr.net/articles/PDF/18809/68275_CE%5BRa1%5D_F(SHU)_QC(AK_RDW_SHU)_PF1(RI_OM)_PFA(RI_OM)_PN(KM).pdf.
[6] Redman et al., *supra* note 4, at 213.
[7] U.S. NAT'L LIBRARY OF MED., *What are genome editing and CRISPR-Cas9?*, MedlinePlus, https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/ (last visited October 17, 2024).
[8] *Id.*

will ultimately cut the DNA apart, resulting in what we commonly understand to be the body's naturally occurring and intelligent defense mechanism of the dismantling of viruses.[9] Similarly, researchers have reconfigured this defense system in order to edit DNA whereby:

> [t]hey create a small piece of RNA with a short "guide" sequence that attaches (binds) to a specific target sequence in a cell's DNA, much like the RNA segments bacteria produce from the CRISPR array. This guide RNA also attaches to the Cas9 enzyme. When introduced into cells, the guide RNA recognizes the intended DNA sequence, and the Cas9 enzyme cuts the DNA at the targeted location, mirroring the process in bacteria.[10]

At this point, researchers can go in and perform any of the necessary adjustments, such as deletion and replacement of the mutated material with a healthy DNA sequence.[11] The utilization of the CRISPR-Cas9 system gives in vitro embryos a fighting chance at a life unencumbered with the quality of life-depleting consequences that result from inheritable diseases such as breast cancer, Huntington's disease, and Tay-Sachs.[12] In addition to the elimination of mutated DNA by way of deletion and replacement with a non-affected sequence in the embryo, this technology ultimately opens yet another door.[13] By way of CRISPR-Cas9, those who carry inheritable genetic mutations can have the ability to bear fully genetic children of their own, without the fear of passing these life-altering conditions not only to their children, but to their subsequent generations as well.[14]

Pivoting now to the Supreme Court of Alabama, where the justices on the bench were met with the question of whether an in vitro, or an extrauterine embryo, falls under the definition of an unborn child under Alabama's 1872

---

[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] NAT'L ACADEMIES OF SCI.'S, ENG'G, AND MED., Human Genome Editing: Science, Ethics, and Governance, 113-14 (Rona Briere & Helaine Resnick eds., 2017).
[13] *Id.*
[14] *Id.*

Wrongful Death of a Minor Act.[15] This case arises from plaintiffs seeking to collect damages from a fertility clinic who provides in vitro fertilization (IVF) treatments.[16] At this facility, embryos of patients were artificially gestated to the equivalence of only a "few days of age," and then were placed inside of a cryogenic nursery which facilitated in the longevity of the embryos and maintained their "few days of age" status by being stored at subzero temperatures.[17] The plaintiff's embryos were destroyed due to an accident caused by the actions of a third-party.[18] The plaintiffs then filed suit against the fertility clinic on claims of negligence and wrongful-death.[19] According to this Court, the language of the Act was ambiguous enough that upon an analysis of its meaning, unborn children who are located outside of a biological uterus at the time they are killed or destroyed are included under the definition of unborn child, as there is no unwritten exception that would eliminate them otherwise.[20] The justices further explained that "nothing about the act narrows that definition to unborn children who are physically 'in utero.'"[21] The Court ruled in favor of the plaintiffs and held that plaintiffs were entitled to seek punitive damages for the death of their embryos at the cryogenic nursery as, on its face, the Act applies to all unborn children regardless of their physical location.[22]

III. PROBLEM: DOES THE TRUE MEANING OF THE ACT LAY BETWEEN THE LINES?

The Wrongful Death of a Minor Act, first enacted in 1872, "allows the parents of a deceased child to bring a claim seeking punitive damages

---

[15] LePage v. Ctr. for Reprod. Med., P.C., 2024 WL 656591 (Ala. Sup. Ct. 2024).
[16] *Id.*
[17] *Id.* at 2-3.
[18] *Id.*
[19] *Id.* at 4.
[20] *Id.* at 1.
[21] *Id.* at 13.
[22] *Id.* at 1.

'[w]hen the death of a minor child is caused by the wrongful act, omission, or negligence of any person,' provided that they do so within six months of the child's passing."[23] Though the Act does not provide an exact definition for the term "child" or "minor child," the Supreme Court of Alabama had previously held in cases *Mack v. Carmack, 79 So. 3d 597 (Ala. 2011)* and *Hamilton v. Scott, 97 So. 3d 728 (Ala. 2012)* that children who have not yet been born are included under the terminology.[24] It is also true that at the time of the Act's creation the leading dictionary definition of "the word 'child' was as 'the immediate progeny of parents' and indicated that this term encompassed children in the womb."[25] The problem arises with the Alabama Supreme Court stating that, "Nothing about the Act narrows that definition to unborn children are physically 'in utero.' Instead, the Act provides a cause of action for the death of any 'minor child,' without exception or limitation."[26] But, Courts are also required to give the words within the statute which they are interpreting their "natural, ordinary, commonly understood meaning" unless there is clear indication a different meaning is meant to be applied.[27]

It is not appropriate when interpreting the language of a 150-year-old law to mold its language in the attempt to make it speak to today's modern problems when that is not plausible. It is like trying to compare apples and oranges. The theme at the root is the same, embryos, but the questions presented are worlds apart. The 1872 act was written in an era where medical science, alongside societal understanding of reproduction, were vastly different. The world back then existed without concepts of in vitro fertilization or extrauterine viability. Attempting to stretch its definitions to

[23] *Id.* at 9.
[24] *Id.* at 9-10.
[25] *Id.* at 10-11.
[26] *Id.* at 13.
[27] *Id.* at 11.

encompass 21st-century technologies, imposes unintended consequences that could not have been foreseen by the lawmakers of that period. It is interesting that the Court is relying on the ambiguity of the language of this Act from 1872 as the reasoning behind their holding. In 1872 there was no such thing as extrauterine children, and they were not being created and developed in in vitro settings. In fact, the technology creating viable extrauterine children, commonly seen in IVF treatments, only came about in 1978, a little over 100 years after the creation of this Act.[28] Therefore, how could the language of the Act possibly narrow the definition any further to boldly state that unborn children are those who are physically in utero. It is impossible to have exclusionary language of an idea, extrauterine children, considering the concept did not yet exist. The commonly understood meaning of unborn children in the year 1872 were those that were found within a biological woman's womb. That conclusion is based on the sheer fact that the science and technology did not exist that would allow people to yield extrauterine children. Retroactively applying modern interpretations risks distorting the statute's original meaning and purpose. Laws crafted without anticipating today's scientific advancements may struggle to address complex issues like IVF and genetic editing in a manner that is both effective and equitable.

While modern 21st Century technologies, such as CRISPR-Cas9, potentially hold the key to the elimination of inheritable diseases, the legal risks surrounding the *LePage* decision could seriously limit its application in the United States. If embryos, especially in vitro embryos, are considered to be "children," then any clinical researcher, scientist or provider who uses genome-editing tools such as CRISPR-Cas9 could be opening themselves up

[28] Jeff Wang and Mark V. Sauer, *In Vitro Fertilization (IVF): A Review of 3 Decades of Clinical Innovation and Technological Advancement*, 2 THERAPEUTICS CLINICAL RISK MGMT. 355, 355 (2006).

to wrongful-death lawsuits. This legal fallacy creates a significant challenge for the future implementation and utilization of genome editing treatments that ultimately aid in the prevention of inhibiting and potentially fatal inheritable diseases.

The Supreme Court of Alabama, by its flawed and extreme interpretation of the Act, is taking on a role eerily similar to one that is legislative. This is beyond its scope as a judicial branch of government. As a judiciary, the Court is simply meant to interpret the laws, not create, change, or expand their meaning. It is clear that the Court here extended its role far beyond that which is appropriate by molding the language of a 19th Century legal concept to fit its agenda concerning 21st Century medical advancements. Therefore, the Supreme Court of Alabama's interpretation of the Wrongful Death of a Minor Act of 1872 is wrong.

IV. THE IMPACT OF THE ALABAMA SUPREME COURT'S QUESTIONABLE JUDICIAL INTERPRETATION AND ITS LIMITING HOLDING ON IN VITRO EMBRYONIC SERVICES

It is undeniable that the holding of the Alabama Supreme Court in this case will have a significant negative impact on the use of Assisted Reproductive Technologies (ART) going forward, while also increasing the likelihood of stalling future implementation of human genome editing technologies like CRISPR-Cas9. Such an expansion of personhood law contributes to the limitation for people to choose when and how they want to grow their families, and restricts their reproductive healthcare options.[29] Judges who extend the interpretation of laws to its extremes are placing an

[29] Sabrina Talukder, *How the Alabama IVF Ruling is Connected to Upcoming Supreme Court Cases on Abortion*, CTR. FOR AM. PROGRESS (Mar. 11, 2024), https://www.americanprogress.org/article/how-the-alabama-ivf-ruling-is-connected-to-upcoming-supreme-court-cases-on-abortion/.

emphasis on the importance of their personal and political beliefs ahead of the rights of American citizens' option to utilize the best and safest health treatments and technologies.[30] Immediately this leads to a largely unwelcome shift in public policy outcomes.[31] With the threat of civil suit looming over the heads of clinics and their providers, the healthcare sphere will see a dramatic decrease in functioning ART clinics, and in providers who choose to offer these services.[32] This lends truth to the maxim that where scarcity is found, an increase in cost of service follows.[33] This all circles back to a lack of equity for those in society who cannot naturally have biological children of their own. As a result of the Court's decision, those who would normally have the opportunity to use ART to aid in family planning will face a difficult time finding these services and simultaneously suffer a significant increase in the cost of such services.[34]

The legal field faces its own unique challenges when confronted with the analysis used to determine the outcome of this case. The flawed logic used by the Alabama Court to explain how it interpreted the Act's meaning clearly illustrates the judges' blatant ignorance of duty and requirement to analyze words within a statute in their ordinary and commonly understood meaning.[35] With a proper understanding of history and existing scientific technologies of the time, it is easy to come to the realization that including the term "extrauterine embryos" to fall under the definition of an unborn child would not be realistic. The idea of an in vitro child was not yet conceptualized at

---

[30] *Id.*
[31] *LePage*, 2024 WL 656591 at 17.
[32] *Id.*
[33] *Id.*
[34] Susan Crockin and Francesca Nardi, *Alabama Supreme Court Rules Frozen Embryos are "Unbrn Children" and Admonishes IVF'S "Wild West" Treatment*, AM. SOC'Y REPROD. MED., https://www.asrm.org/news-and-events/asrm-news/legally-speaking/frozen-embryo-destruction-and--potential-travel-restrictions-for-surrogacy-arrangements2/ (last visited Sept. 18, 2024) (explaining the impact the Alabama Supreme Court's ruling has on the future of IVF clinics, including a cessation of treatment and limiting services).
[35] LePage, 2024 WL 656591 at 11.

that time.[36] Hence that particular terminology could not have existed under the commonly understood meaning of "unborn child." The Court's analysis conveniently glossed over the glaring absence of in vitro technologies at the time, and yet claimed embryos located outside of the womb were qualified to be labeled under personhood status under the Act.[37] The Court's interpretation of the Act, which shows a clear disregard for historical accuracy, and thus deviating from its judicial duty, constitutes an abuse of its power and misuse of judicial authority. By stretching the law's language to align with their ideological preferences, the Court has compromised the integrity of its rulings. When a Court wrongfully wields its judicial authority, an erosion of public trust in the integrity of its judiciary is a consequence that is likely to follow.

V. PROPOSED REGULATIONS FOR PROPER ANALYSIS AND INTERPRETATION OF THE ACT

As of this moment, the Alabama Supreme Court's ruling is as it stands. However, if this treatment were to get challenged again, the Court should reanalyze its definition of who or what actually qualifies for personhood status under the definition of "child" or "unborn child." This court should have analyzed the Wrongful Death of a Minor Act through an Originalist lens. An Originalist would interpret the law as it was meant to be understood at the time of its adoption.[38] The Act states that civil action may be brought by parents '[w]hen the death of a minor child is caused by the wrongful act, omission, or negligence of any person,' provided that they do so within six

[36] *See generally* Wang and Sauer, *supra* note 28 (discussing the timeframe and introduction of in vitro technologies).
[37] *Id.* at 10-11.
[38] Steven G. Calabresi, *On Originalism in Constitutional Interpretation*, NAT'L CONST. CTR., https://constitutioncenter.org/the-constitution/white-papers/on-originalism-in-constitutional-interpretation (last visited Sept. 20, 2024).

months of the child's passing."[39] The Court should have read the language of the Act, specifically in reference to the term "minor child," as it was presented and meant to be understood given the era of its creation. Referring, once more, to the leading dictionary definition of that era which classified a "child" as the immediate progeny of parents including an indication that the term also encompassed children in the womb."[40] Instead the Court intentionally labeled the language and terminology found within the statute as "ambiguous" in order to promote the Court's political ideology and fit its narrative.[41] From an Originalist perspective one would never interpret laws with the mindset that the meaning of the words within are flexible and whose interpretation is subject to evolution alongside societal changes.[42] The Court teetered onto duties devoted to the legislature by expanding the language of the Act to include embryos located outside the womb, and in doing so superseded the approach any Originalist would take, which is solely interpreting the words of the statute.

At the time this law was enacted by the legislature in 1872, embryos outside of the womb did not exist, the science was simply not there.[43] Thus the term "minor child" could not include unborn children, or embryos, that exist in vitro. The likely historical purpose of the Act was to provide parents the ability to seek punitive damages and address the loss of a child, which in the 19th-century would have either been a viable fetus or a child born alive. Considering IVF technologies were not yet invented when the Act was implemented, it is implausible to extend the statute's meaning to cover embryos that are in vitro. In fact, extending the statute's meaning is problematic in of itself as it extends the Act's purpose far beyond its original

---

[39] LePage, 2024 WL 656591 at 9.
[40] *Id.* at 10-11.
[41] *See* Talukder, *supra* note 29.
[42] *See* Calabresi, *supra* note 38.
[43] *See generally* Wang and Sauer, *supra* note 28 (discussing the creation and implementation of in vitro sciences beginning in the 1970s and beyond).

intent. By analyzing the Act from an Originalist lens, the Court would have reached the exact opposite result from its holding and would have instead ruled correctly that embryos physically not present in utero do not qualify as an unborn child under the statute. Concluding that an action, therefore, actually cannot be brought for the wrongful death of extrauterine embryos under the 1872 Wrongful Death of a Minor Act.

VI. POSITIVE IMPLICATIONS OF INTERPRETING THE WRONGFUL DEATH OF A MINOR ACT THROUGH AN ORIGINALIST LENS

An Originalist interpretation of the Act, which excludes extrauterine children from the definition of unborn child, would have significant positive implications for the advancement of Assisted Reproductive Technologies and human genome editing systems like CRISPR-Cas9. By aligning with the original intent of the law, this interpretation would create a far more favorable legal environment for these technologies.

Firstly, such an interpretation would provide greater reassurance around legal certainty for healthcare providers working in the field of reproductive technology. The assurance that a civil suit for a claim of wrongful death could not be brought upon them would encourage investment, further innovation, development of new procedures, and treatments, and of course, implementation. Alleviating the concerns about potential legal liabilities ultimately fosters a more conducive atmosphere for embryo research and clinical applications. With the potential for fewer legal risks, researchers and clinics can likely attract investors and resources to better fund and enhance trials. The more rigorous and long-term studies are, the more reliable the data on efficacy and safety, and the quicker these treatments can be developed, approved, and turned out to the public. With the potential for

fewer legal risks, providers can re-center their work and priorities around who matters most, patients and their safety.

Secondly, an Originalist interpretation would lead to more equitable access to reproductive technologies. By removing the uncertainty surrounding the legal status of in vitro embryos, it would be easier to develop and implement regulations that ensure these technologies are available to all who need or desire them. Access to such technologies particularly affects those who are looking for assistance in family planning, whether that be due to the inability to naturally conceive biological children, or due to an unavoidable risk of passing on potentially fatal inheritable diseases to the next generation. Reducing or even eliminating inheritable genetic diseases is one of the many abilities of the CRISPR-Cas9 system. Providing prospective parents the opportunity to mitigate the risk of passing on genetic mutations to their children, opens the door to realistically lessen the burden of family planning and alleviate future human suffering that occurs from these diseases.[44] The utilization of such technology will overall aid in the betterment of human life by facilitating longevity and quality of persons who would have otherwise been encumbered by such life-altering inheritable diseases including breast cancer, Cystic Fibrosis, and Huntington's Disease.[45]

Finally, an Originalist interpretation could open the door for more informed discourse about reproductive technologies. Considering how relatively new ART and human genome editing technologies are, cohesive

---

[44] NAT'L ACADEMIES OF SCI.'S, ENG'G, AND MED., *supra* note 12 (discussing how some avenues for not passing down genetic diseases to future generations includes not having genetically related children at all, and rather adopting, or using donated embryos, eggs, or sperm. On the other hand, heritable genome editing yields a path for individuals who do wish to have a genetic connection to their child who is free from the risk of mutation).
[45] *See* D'Souza et al., *supra* note 5, at 5-6 (discussing how the CRISPR-Cas9 system can alter genes to help us better understand genetic illnesses and how to treat them, explaining how the system can alter mutated genetic sequences to lower mortality rates that occur due to genetic disease).

legislation has yet to be understood and adopted when it comes to the regulation of embryos.[46] By clarifying, or at least developing a better understanding for the legal and ethical issues involved, thoughtful discussions about the benefits, risks, and societal implications of these advancements is far more likely. Eventually, a more informed and favorable legal framework would help to ensure that reproductive technologies are developed and used in a beneficial and responsible manner.

VII. CONCLUSION

The Alabama Supreme Court's ruling in *LePage v. Center for Reproductive Medicine, P.C.* creates far-reaching consequences for the future of human genome editing and Assisted Reproductive Technologies. By misinterpreting the Wrongful Death of a Minor Act, the Court has created a legal precedent that could hinder advancements in these fields. Attempting to retrofit such outdated legislation, ultimately undermines the legal clarity that is needed for consistent application. A more accurate analysis grounded in historical relevance would have recognized that the Act was limited in its inability to address what were then nonexistent reproductive technologies. To address these issues, it is imperative to develop new laws and regulations tailored to the unique complexities posed by these cutting-edge technologies. Modern statutes that are designed to account for today's reproductive and genetic technologies would ensure that ethical, medical, and legal standards progress together. The result presents a structure that aligns with the modern world. That, though, is a power delegated to the legislature and not the courts. After all, there is no answer to be found hidden in the meaning of

[46] David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY & STERILITY 932, 932-934 (2002) (discussing how ART is primarily regulated by individual states and federally regulated by only a few administrative agencies who oversee the projects).

centuries old statutes. By doing so, we can strike a balance between protecting the rights of individuals while simultaneously embracing scientific innovation in healthcare.

Beyond the Pill: Revitalizing Patent Term Extensions to Foster Medical Device Innovation

Dasha Ignatova

I. AN INTRODUCTION INTO THE CRITICAL ROLE OF PATENTS IN MEDICAL DEVICE INNOVATION

Medical devices are critical to modern healthcare, ranging from simple instruments like syringes to complex technologies such as pacemakers and MRI machines.[1] Their development and commercialization depend heavily on patent protections, which grant inventors exclusive rights over their inventions.[2] However, the process of obtaining patents and securing regulatory approval for these devices can lead to overlapping timelines that shorten the effective life of the patent.[3] The regulatory approval process, particularly through the Federal Drug Administration ("FDA"), can introduce significant delays, which often leave medical device patents with reduced market exclusivity.[4]

This article explores the intersection between patent law and FDA regulatory pathways, focusing on the barriers faced by medical device manufacturers in obtaining Patent Term Extensions ("PTEs"). First, it provides an overview of the patent application and FDA approval processes, detailing how each can influence a medical device's patent life. Next, it highlights the challenges that medical device companies face when seeking PTEs, emphasizing the complexity and unpredictability of regulatory timelines compared to those for pharmaceuticals.

---

[1] Asad Abbas, *Revolutionizing Patient Care: The Role of Medical Devices in Modern Medicine*, DEP'T OF A.I. (Feb. 2024), https://www.researchgate.net/publication/378298396_Revolutionizing_Patient_Care_The_Role_of_Medical_Devices_in_Modern_Medicine.
[2] C. Benson Kuo & Frances Richmond, *Use of Patent Term Extensions to Restore Regulatory Time for Medical Devices in the United States*, 21 EXPERT REV. OF MED. DEVICES 527, 527 (2024).
[3] Erika Lietzan et al., *The Case of The Missing Device Patents, Or: Why Device Patents Matter*, 33 FORDHAM INTELL. PROP., MEDIA & ENTER. L. J. 407, 418–419 (2023).
[4] *Id.*

Since June 2024, the average extension period for medical devices is 987 days, compared to the 1,063 days for pharmaceuticals.[5] Data suggests not only a significant gap in the average extension periods granted, but also in PTE utilization when comparing the pharmaceutical and medical device industries, with the latter pursuing extensions far less frequently.[6] This disparity is particularly stark given that medical devices, especially high-risk Class III devices, undergo lengthy and uncertain regulatory processes that often mirror the time-consuming pathways of drug approvals.[7] Despite these challenges, the current PTE framework is not optimized to support the unique nature of medical devices, which often require multiple patents to cover various aspects of a single product.

The article then presents several potential solutions to encourage greater use of PTEs in the medical device sector. These include extending the PTE application window for Class III devices and introducing a rolling application process to accommodate regulatory delays. It also discusses recalculating the regulatory review period to include pre-submission consultations and other FDA-related interactions. Additionally, strategies to raise awareness of the PTE process among smaller companies and individual inventors are explored, as these innovators are often the backbone of medical device innovation but may lack the resources or knowledge to fully leverage PTEs.

By adapting the PTE framework to better suit the realities of medical device development, the industry could see an increase in both innovation and market competitiveness. The proposed reforms aim to create a more flexible and equitable system that reflects the diverse nature of medical devices, fostering an environment where inventors are better protected, and lifesaving technologies can reach patients more effectively.

---

[5] Kuo & Richmond, *supra* note 2, at 528.
[6] *Id.* at 527.
[7] *Id.* at 530.

II. AN OVERVIEW OF THE INTERPLAY BETWEEN PATENT LAW AND FDA REGULATORY APPROVAL

In the complex landscape where patent law intersects with FDA regulatory processes, medical devices occupy a unique and often challenging position.[8] Patents provide an exclusive right to an inventor's claimed invention for a term of approximately twenty (20) years from the date the application is filed with the United States Patent and Trademark Office (USPTO).[9] While 35 U.S.C § 154 provides that patents are granted for a period of twenty (20) years because there are no rights to the patent until it is granted, in reality, the evaluation process may last a few years, reducing the average term that a patent is actually enforceable, to seventeen (17) years .[10] Patents likewise cover a wide range of inventions including medical devices, pharmaceutical drugs, health care information technology, medical and surgical methods, and others.[11] Once patent protection is granted, it aids economic development by promoting innovation and competition.[12]

Many companies and inventors who seek patent protection on products like medical devices and pharmaceuticals must also meet strict regulatory guidelines in ensuring safety and efficacy prior to marketing.[13] As a result,

---

[8] Xirui Zhang et al., *The Interplay Between the FDA Regulatory Process for Medical Devices and Patent Law – Considerations for 510(k) Submission*, FINNEGAN (Aug. 4, 2020), https://www.finnegan.com/en/insights/blogs/ip-health-blog/the-interplay-between-the-fda-regulatory-process-for-medical-devices-and-patent-law-considerations-for-510k-submission.html.

[9] *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (2014), https://www.uspto.gov/sites/default/files/inventors/edu-inf/BasicPatentGuide.pdf.

[10] *See* 35 U.S.C. § 154(a)(2). (For most of the 20th century, a patent lasted for 17 years from issuance). *E.g.*, 35 U.S.C. § 154 (amending 35 U.S.C. § 154(a)(2) (1995)). That was changed with the enactment of the Uruguay Rounds Agreement Act (URAA), PUB. L. NO. 103–465, § 532, 108 STAT. 4809 (1995).

[11] Denise L. Mayfield, *Medical Patents and How New Instruments or Medications Might Be Patented*, 113 MO. MED. 456, 458 (2016).

[12] Chandra N. Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry*, 2 J. ADV. PHARM. TECH. RES. 88, 88 (2011).

[13] Elisabetta Bianchini & Christopher C. Mayer, *Medical Device Regulation: Should We Care About It?*, 28 ARTERY RES. 55, 55–56 (2022).

countries like the United States take stringent measures in regulating their products by registering them with the FDA.[14]

The FDA categorizes medical devices into classes based on risk: Class I, II and III.[15] Class I and II devices only require approval of a 510(k)application for marketing, while Class III devices require a Premarket approval application (PMA).[16] The traditional 510(k) pathway requires demonstration that the device to be marketed is "as safe and effective, that is, substantially equivalent, to a legally marketed device" (i.e. predicate device).[17] This list of predicates includes devices legally marketed before 1976, when the Medical Device Amendments Act (MDA) gave authority to the FDA to regulate the industry.[18] Unlike the 510(k) pathway, the PMA route does not rely on a predicate device, "but rather requires entirely new validation of the safety and effectiveness," making the process longer and more expensive.[19] Not only is this route long, but it can also be more nuanced from the pharmaceutical industry.[20]

Because of the different and often flexible forms that clinical trials take on, medical devices differ from pharmaceuticals and thus make it difficult for regulators to articulate general rules or guidelines for clinical trials.[21] For example, while in new drug studies where three phases of randomized

---

[14] 21 C.F.R. § 807 (2024) (defining procedures for device establishments and premarket notifications).
[15] *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (Last visited Sept. 18, 2024).
[16] *Id*.
[17] Mateo Aboy et al., *Beyond the 510(k): The Regulation of Novel Moderate-Risk Medical Devices, Intellectual Property Considerations, and Innovation Incentives in the FDA's De Novo Pathway*, 7 NPJ DIGITAL MED. 1, 1 (2024).
[18] *Id*.; *See generally* Medical Device Amendments Act of 1976, PUB. L. NO. 94–295, 90 STAT. 539 (1976).
[19] Maheen Nadeem & Arnold-Peter C. Weiss, *Medical Product Development Part 2: Patent and FDA Issues*, 46 J. HAND. SURG. AM. 918, 921 (2021).
[20] Ariel D. Stern, *Innovation Under Regulatory Uncertainty: Evidence From Medical Technology*, 145 J. PUBLIC ECON. 181, 189 (2018).
[21] *Id.*

controlled trials are normal procedure, device trials vary from "controlled investigations, partially controlled investigations, objective trials without matched controls," and other conditions.[22] Similarly, while drugs are almost always delivered in conventional ways (orally, injected, inhaled, or topically administered), delivery methods of high-risk medical devices are often novel processes unlike those found in prior device clinical trials.[23] As a result, medical device regulatory approval can differ substantially from pharmaceutical pathways, making the regulatory process for devices far more uncertain than that of drugs.[24]

Because of the uncertainty with regulatory approval timelines and unexpected delays, the Patent Term Extension ("PTE") provision of the Hatch-Waxman Act[25] sought to extend the patent terms of products requiring regulatory approval prior to entering the market.[26] Specifically, the current PTE provision, codified in 35 U.S.C. § 156, allows certain patent holders to extend their patent terms based on the time spent in regulatory review.[27] Thus, the PTE attempts to provide guidance to the delicate balance between encouraging patent protection and ensuring safety and efficacy of medical devices.

III. UNDERUTILIZATION IN THE MEDICAL DEVICE INDUSTRY

[22] *Id.*
[23] *Id.* at 190.
[24] *Id.*
[25] Drug Price Competition and Patent Term Restoration Act, PUB. L. NO. 98–417, 98 Stat. 1585 (1984).
[26] Lori M. Brandes & Tarja H. Naukkarinen, *Patent Term Extension*, STERNE KESSLER, GOLDSTEIN & FOX (Jul. 7, 2020), https://www.sternekessler.com/news-insights/publications/patent-term-extension/.
[27] 35 U.S.C. § 156(g)(3)(B)(i) (2006 & Supp. V. 2011).

Through April 2012, of the 617 patents extended under § 156, only 47 were for medical devices, compared to 570 for pharmaceuticals.[28] While it is unsurprising that Class III devices, with their lengthy development timelines, are the most appropriate candidates for patent extensions, the PTE process remains underutilized for medical devices.[29] This low utilization may be attributed to two factors: the restriction that only one patent can be extended per regulatory review period per product, and the differing regulatory pathways between drugs and medical devices.[30] These limitations highlight the need for a critical examination of the PTE system and its effectiveness in fostering innovation within the medical device sector.

IV. CONSEQUENCES OF PATENT EXTENSION BARRIERS IN THE MEDICAL DEVICE SECTOR

"Between 2009 and 2014, there was a 170% increase worldwide in medical device patents granted in the United States."[31] Yet, even with this increase in medical device patentability, there remains low utilization of PTEs.[32] Under 35 U.S.C. § 156, a patent owner can only request extension of one patent for the same regulatory review period for any product.[33] If multiple patents have different regulatory review periods, the inventor is restricted to extending protection on only one of those patents.[34] More specifically, the decision to extend a particular patent depends on factors including "the ability of the patent to withstand a challenge based on validity or unenforceability, the expiration date of the patent, and the difficulty a

---

[28] Suneel Arora et al., *The Interplay between FDA and Patent Law: Infusing Organizational Knowledge for Medical Device Companies*, 39 WILLIAM MITCHELL L. REV. 1175, 1202–03 (2013).
[29] Kuo & Richmond, *supra* note 2, at 530.
[30] *Id.*; *see also* 35 U.S.C. § 156(c)(4).
[31] Mayfield, *supra* note 11, at 460.
[32] Kuo & Richmond, *supra* note 2, at 532.
[33] Brandes & Naukkarinen, *supra* note 26.
[34] 37 C.F.R. § 1.78.

competitor would have in avoiding the patent, i.e., the scope and ability to design around the patent claims."[35]

Since the enactment of 35 U.S.C. § 156 (patent term extension), the FDA has approved approximately 1,152 premarket approval applications (PMAs) for new medical devices, yet a mere 13% (149) of those were followed with requests for PTE.[36] Contrastingly, nearly all pharmaceutical applicants likewise eligible for extension, pursue this benefit.[37] Although the reasons for this stark contrast are not entirely clear, the most compelling explanation lies in the differences between the regulatory frameworks for drugs and medical devices.[38] Professor Stuart Graham, in a 2008 survey of more than 1,000 US-based startup companies primarily including medical device and biotechnology companies, found that 76% of the surveyed medical device startup companies held patents, and that on average, held at least fifteen (15) patents.[39] It is clear that companies are actively seeking patent protection, so the issue is not a lack of patents but rather a gap in pursuing patent term extensions.

In addressing some of the statistics that surround this issue, attorneys of the Fordham IP, Media, and Entertainment Law Journal conducted a variety of analyses that highlighted the lengths of regulatory periods between drugs and devices.[40] They found that for the one-hundred-and-two (102) approved medical devices in the dataset, clinical testing averaged 1,624 days (4.45 years), with a total regulatory review period averaging about 2,296 days (6.29

---

[35] Erik K. Steffe & Gaby L. Longsworth, *Patent Term Extension Considerations For Regulated Products*, STERNE KESSLER, GOLDSTEIN & FOX (Mar. 18, 2016), https://www.sternekessler.com/news-insights/publications/patent-term-extension-considerations-regulated-products/.
[36] Lietzan, *supra* note 3, at 412.
[37] *Id*.
[38] *Id*.
[39] Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKLEY TECH. L.J. 1255, 1277 (2009).
[40] Lietzan, *supra* note 3, at 414.

years).[41] In a different study, Dr. Josh Makower examined the impact of the current regulatory environment on medical device innovation, noting that in a survey of medical device companies in 2010, 100 of those companies indicated that their products took an average of 54 months (4.5 years) to work with the FDA from first initiating conversations to being approved to market the device.[42]

In contrast, the new drug approval pathway under the FDA is much more straightforward and more easily understood. While both drugs and medical devices require proof of safety and effectiveness supported by clinical trials,[43] drug applications generally follow a more consistent regulatory framework, with fewer variables influencing the process. This is because although new drugs go through a similar premarket research and development program as devices, drugs typically adhere to standard administration methods – such as ingestion, injection or topical application – resulting in less variation compared to the diverse nature of medical devices.[44] Consequently, drug approval timelines often face fewer hurdles and complexities compared to those encountered by medical devices.

Devices, due to their greater variability in function and length of clinical trials, contrast with the drug approval pathway primarily in three ways. First, device categories can vary much greater than drugs, leading to regulatory pathways that mirror that variance.[45] Because of the extreme "diversity" of products attempting to meet the "medical device" definition – ranging from

---

[41] *Id.* at 434, 436. Using USPTO's Public Patent Application Information Retrieval (PAIR) system, attorneys determined the outcome of the PTE for each medical device, identifying 110 grants of PTEs between September 28, 1984, and December 21, 2020. These 110 grants of PTEs covered a range of 102 devices, which became the focal points of the study.
[42] *See* Josh Makower, FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES (Nov. 2010), https://www.medtecheurope.org/wp-content/uploads/2015/09/01112010_FDA-impact-on-US-medical-technology-innovation_Backgrounder.pdf.
[43] Lietzan, *supra* note 3, at 449.
[44] *Id*.
[45] *Id*.

a medical staple to a heart valve – policymakers avoided a single, simplified device approval process that mirrors drug approval.[46] Second, devices are primarily sorted by what they do from a clinical perspective, not what they are.[47] As such, the classification of devices and finding predicates to meet the equivalence requirements becomes a gruesome process that drug products do not similarly share.[48] Third, medical device innovators may not be entirely aware of the PTE process, nor desire to incur the extra costs of filing a PTE application.[49]

V. STRATEGIES FOR PATENT TERM EXTENSIONS

The regulatory framework for medical devices is expansive and constantly evolving to improve safety, efficiency, and innovation.[50] As such, proposing to alter the framework for how medical devices come to market is a feat left to the agencies and policymakers.[51] Nevertheless, improvements can be made in ways that better address the needs of the medical device industry. For medical devices, regulation is not a "one size fits all" approach, and the Patent Term Extension (PTE) framework should similarly be adaptable to reflect the diverse nature of these products.

One possible solution is to allow medical devices more flexibility in applying for PTEs, especially when regulatory delays affect the approval

---

[46] *Id*. at 451.
[47] *Id*. at 449.
[48] *Id*. at 457–58; *See* FDA, THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Jul. 28, 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[49] Lietzan, *supra* note 3, at 449.
[50] Fiona Maini, *The Regulatory Evolution in Medical Device Development*, MED. DEVICE & DIAGNOSTICS (Jan. 4, 2021), https://www.medidata.com/en/life-science-resources/medidata-blog/the-regulatory-evolution-in-medical-device-development/.
[51] Adam Thierer & Michael Wilt, *The Need for FDA Reform: Four Models*, GEORGE MASON UNIV. (Sept. 14, 2016), https://www.mercatus.org/research/policy-briefs/need-fda-reform-four-models.

timeline. Currently, the PTE process allows for 60 days from the date a product receives permission for commercial marketing or use from the FDA, to file a PTE application.[52] For medical devices, especially those with complex regulatory pathways, this window may be insufficient. Two ways in which medical devices may increase interest in applying for PTEs is to 1) extend the application window to 120 days for Class III medical devices that require Premarket Approval (PMA) and/or 2) implement a "rolling application" process that allows device manufacturers to initiate the PTE application earlier in the regulatory process, with the ability to update and finalize within sixty (60) days of approval. This could be done by amending 37 CFR § 1.720, the regulation that currently sets out the 60-day limit.[53] These changes would provide more time for smaller companies and individual inventors to navigate the PTE process without compromising the intent of the statute.

Likewise, the current extension period statute 35 U.S.C. § 156(c) operates as a reduction clause, deducting time from the regulatory review period for various reasons (c)(1) to (3).[54] This period of extension is determined by the mathematical equation: PTE = RRP – PGRRP – DD – ½(TP-PGTP).[55] Currently, the RRP (regulatory review period) is calculated by the regulatory

---

[52] Brandes & Naukkarinen, *supra* note 26.
[53] 37 C.F.R. § 1.720.
[54] 35 U.S.C. § 156(c). The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that"… "(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period" … "(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining…" and "if the period remaining in the term of a patent after the date of the approval… exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years."
[55] N. Nicole Stakleff & Kyle A. Dolinsky, *Not So Simple Math: Calculating the Regulatory Review Period for Patent Term Extension*, TROUTMAN PEPPER (May 18, 2017), https://www.troutman.com/insights/not-so-simple-math-calculating-the-regulatory-review-period-for-patent-term-extension.html.

agency which is broken into the testing phase and approval phase of the device.[56] While this process attempts to capture the relevant time periods under regulatory review, it may leave unaccounted days spent consulting, responding, and clarifying with the regulatory agency.

To address this gap and provide devices with a more encompassing PTE period prior to any reductions under 35 U.S.C. § 156(c), the RRP calculation could include the addition of variables reflecting days spent in pre-submission consultations with the FDA or time spent addressing FDA requests for additional clarification. Since conversations between the FDA and medical device companies can take multiple days, if not weeks, this could provide PTE applicants the advantage of a longer RRP calculation before any reductions are applied. These changes would more accurately reflect the true regulatory burden on device manufacturers and potentially increase the available extension period.

Similarly, a possible solution to addressing the disparities in PTEs between devices and drugs is to enhance both awareness and transparency in the application process, particularly for smaller companies that hold device patents. "Conventional wisdom holds that break-through medical device innovation stems mainly from individual inventors and small (start-up) companies."[57] However, these smaller entities may not otherwise have the experience, structured framework, or comprehensive knowledge to effectively pursue patent extensions.

One way to address this knowledge gap is by creating tailored educational programs and resources specifically designed for smaller medical device companies and individual inventors. This could involve a strategic

---

[56] *Id.* The testing phase is calculated from when the investigational device exemption (IDE) was submitted for a device, to the filing date of the new drug application (NDA). The approval phase is calculated from the filing date of the NDA to its approval date.
[57] Lietzan, *supra* note 3, at 445.; *see also* Brenda M. Simon, *Patents, Information, and Innovation*, 85 BROOK. L. REV. 726, 733 (2020) ("Truly groundbreaking medical devices often originate with small companies.").

partnership between the USPTO and the FDA to develop a series of accessible webinars, in-person workshops, and comprehensive written guides. These resources would break down the complex PTE application process into manageable parts, explaining key eligibility criteria and highlighting the potential benefits of obtaining an extension. Step-by-step guidance could take the form of flowcharts and diagrams, annotated checklists, timelines with milestones, and expert Q&A sessions. These resources would assist smaller medical device companies to proactively seek out and manage PTE opportunities, reducing their reliance on external consultants and strengthening their capacity for long-term intellectual property strategy planning.

VI. MEASURING THE IMPACT

In proposing a more flexible application window for PTEs, extending the window to one-hundred-and-twenty (120) days for Class III devices and implementing a rolling application process could result in better quality applications. With more time to prepare comprehensive applications, this may reduce the workload on the USPTO and lead to faster PTE approval timelines. Likewise, the rolling application process may allow companies to better integrate PTE strategies and planning into their overall product development management, leading to more effective market exclusivity periods.

Presently, the calculation for the regulatory review period of the patent term extension does not take into account important preparatory phases, such as pre-submission consultations or the time spent addressing FDA questions and requests. Including these periods in the regulatory review calculation could provide a more accurate representation of the resources and time invested by medical device companies, especially for those developing novel or complex devices. Such an adjustment could also encourage earlier and

more frequent collaboration with the FDA, promoting a more transparent and streamlined regulatory and PTE review process.

Finally, by providing information about PTE eligibility earlier in the FDA approval process, more companies, especially smaller ones and individual inventors, could integrate patent extension strategies into their product development plans at an earlier stage. This could lead to more strategic patent filing and prosecution practices, with companies potentially filing certain key patents later in the development process to maximize the effective life of patent protection. With a greater understanding of how regulatory pathways affect patent terms, companies might shift their development focus towards more innovative, higher-risk devices that could qualify for longer regulatory review periods and thus longer PTEs.

While these proposed solutions could enhance the PTE framework for medical devices, some criticisms may arise. Extending the PTE application window to 120 days and introducing a rolling submission process could increase administrative complexity and prolong uncertainty for both regulators and stakeholders. Critics may argue that this could slow down the overall approval and extension process, counteracting any intended efficiency gains. Additionally, including pre-submission consultation time in the regulatory review period could be seen as inflating the extension period unfairly, as these discussions often occur early in product development and may not always constitute formal regulatory delays. Some may also point out that such measures could unintentionally benefit larger companies with more resources, potentially exacerbating inequalities rather than leveling the playing field for smaller inventors.

However, the potential benefits of these proposed changes may ultimately outweigh these criticisms. By granting medical device companies, especially smaller entities, more flexibility and support, these measures could

encourage innovation and foster a more equitable environment for patent protection.

VII. THE TAKEAWAYS

In conclusion, the stark disparity in Patent Term Extension (PTE) utilization between pharmaceuticals and medical devices underscores a need for reform in the current system. The unique challenges faced by the medical device industry, including complex regulatory pathways and diverse product categories, have led to an underutilization of PTEs, potentially stifling innovation in this crucial healthcare sector. The proposed solutions, including extending application windows, adjusting regulatory review period calculations, and implementing guidance, offer a pathway to a more equitable and effective PTE system for medical devices. These changes could significantly impact the industry by encouraging innovation, providing better protection for inventors, and ultimately fostering the development of lifesaving and life-improving technologies.

The Fallacy of Caps on Non-Economic Damages in Medical Malpractice Litigation

Michael Menendez

I. THE CURRENT REALITY OF MEDICAL MALPRACTICE LITIGATION

Doctors work in an inherently dangerous, risk-heavy field. Unfortunately, for those injured persons who rely on doctors to save their lives, doctors are also human. This means, simply, that doctors make mistakes. These mistakes are of particular consequence when they lead to the death or serious bodily harm of a patient. Whether one agrees or disagrees with the advent of malpractice and Tort law in the realm of medicine, it is the current accepted avenue for injured plaintiffs to be compensated for what can never be replaced: the life of a loved one. These aforementioned truths however, all revolve around statutory and case law limits placed on medical malpractice litigation.

This article will aim to prove that limits on medical malpractice litigation such as, caps on non-economic damages, are not a solution to the issue of steep medical malpractice premiums and will attempt to provide an alternate solution. First, this article will examine current statutory language that enforces these limits as well as the sources they stemmed from. Next, it will show judicial decisions that have both supported and combatted these limits. Lastly, it will introduce a solution to these issues that includes a combination of already enacted legislation and models from around the country.

II. THE ACTUAL RELATIONSHIP BETWEEN CAPS ON NON-ECONOMIC DAMAGES AND RISING INSURANCE PREMIUMS

Limits on medical malpractice litigation can be found all over the country is various forms and degrees.[1] Perhaps the most common of these limits are

[1] Frank A. Perrecone, *The Fleecing of Seriously Injured Medical Malpractice Victims in Illinois*, 26 N. ILL. U. L. REV. 527, 528 (2006).

caps on non-economic damages in medical malpractice litigation.[2] This a popular type of statutory limit among states aiming to reduce medical malpractice premiums among its healthcare system.[3] In its most basic sense, caps on non-economic damages are limits on what a plaintiff can recover in a medical malpractice suit that does not include medical expenses, loss of income, care-taking expenses and other purely economic damages.[4] Non-economic damages can include, but are not limited to, compensation for human loss, loss of quality of life, pain and suffering, disability, disfigurement, and the loss of love and happiness on the behalf of the family of a deceased plaintiff.[5] While not particularly common, some judgments for these non-economic damages can range into the millions.[6] Pushed by insurance companies, the purported purpose of these caps is to limit the financial blow a large judgement can inflict on an insurance company, which, in turn, seemingly forces malpractice premiums to increase to compensate for the loss.[7]

The flaw in these attempts, however, is the stark evidence that these caps do nothing to reduce these premiums.[8] In fact, Florida, Nevada, Michigan, West Virginia, and Ohio, five states with some of the highest medical malpractice premiums, all have some form of damages caps.[9] Additionally, in states where studies show that medical malpractice payouts have decreased, there are still strong pushes for additional limits on non-economic damages.[10] These specific types of limits on plaintiffs' capacity to recover

---

[2] *Id*.
[3] *Id.* at 529.
[4] *Id.* at 528.
[5] *Id.*
[6] *National Practitioner Data Bank*, *NPDB Data Analysis Tool*, (Sept. 18, 2024), https://npdb.hrsa.gov/analysistool/.
[7] Perrecone, 26 N. ILL. U. L. REV. at 528
[8] *Id.*
[9] Patrick A. Salvi, *Why Medical Malpractice Caps are Wrong*, 26 N. ILL. U. L. REV. 553, 554 (2006).
[10] *Id.*

are not only ineffectual attempts at lowering medical malpractice premiums, but they also fail to avoid substantial premium increases.[11] This is evidenced by insurers in states like Texas and Florida, requesting rate increases as high as sixty percent in some areas, soon after legislation instituting damage caps were passed.[12] A study from an independent insurance rating agency, Weiss Ratings, Inc, also showed that, in actuality, damage caps were more likely to increase medical malpractice insurance rates, rather than decrease.[13] The study detailed the trend that, over a decade, premiums rose only 35.9 percent in states without caps, versus 48.2 percent in states with caps.[14] This statistic coupled with the fact that medium claim payouts were higher in states without damage caps is indicative that other factors are responsible for the raising of premium rates.[15]

III. Effects of Caps on Non-Economic Damages on Plaintiffs

Now that it has been established that caps on non-economic damages do not succeed in their supposed goal, and perhaps even exacerbate the issue of rising premium rates, the negative effects of these caps on plaintiffs become relevant. When reviewing previously discussed evidence of states seeking inordinate premium rate increases after the institution of damage caps, it is also important to acknowledge that these rate increases consequentially reduced the quality and access of care to patients.[16] To look at one state in particular, the already limited health care coverage in Florida was further denied to over one million uninsured people.[17] The reason for this was the

---

[11] *Id.* at 555.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] Paul Branch, *The Unintended Consequences of Florida Medical Liability Legislation*, Patient Safety Network (Sept. 18, 2024), https://psnet.ahrq.gov/perspective/unintended-consequences-florida-medical-liability-legislation.
[17] *Id.*

rising rates forced many healthcare providers to spend an exorbitant amount solely on these premiums, putting further strain on an already overburdened healthcare system and, consequentially, taking services away from those in need.[18]

Additionally, while many proponents of damage caps argue the economic benefits, a fallacy that has already been analyzed and continually disproven, capping recovery is also contradictory to the system of justice that our country currently utilizes. This is evident in the plethora of state Supreme Courts that have found caps on non-economic damages to be unconstitutional including, but not limited to, Alabama, Illinois, Kansas, Florida, New Hampshire, Oregon, and Oklahoma.[19] These constitutional challenges come in a variety of forms as well.[20] One of the more successful state constitutional arguments made is that damage caps limit plaintiffs' access to courts.[21] Through state constitutional provisions, a large majority of states guarantee their citizens access to the court system in the form of civil lawsuits.[22] Some state Supreme Courts have interpreted damage caps to be in violation of these provisions.[23]

In reviewing these challenges, several courts in states like Texas and Florida considered if there was an adequate substitute remedy provided and how effective the damage cap was in achieving its purported goal of lowering insurance premiums.[24] State courts that have stricken down statutes providing damage caps tend to rely on both of these considerations and have

---

[18] *Id.*
[19] CTR. FOR JUST. & DEMOCRACY AT NEW YORK L. SCH., *Caps on Damages and Who's Hurt Most*, (Sept. 18, 2024), https://centerjd.org/content/backgrounder-caps-damages-and-who%E2%80%99s-hurt-most.
[20] *Id.*
[21] Carly N. Kelly & Michelle M. Mello, *Are Medical Malpractice Damages Caps Constitutional? An Overview of State Litigation*, 33 J. L. MED. ETHICS 515, 518 (Sept. 14, 2024).
[22] *Id.*
[23] *Id.*
[24] *Id.* at 519.

found that neither are satisfied, specifically calling into question the speculative date that damages lower premium rates.[25] In *Lucas v. United States*, the Texas Supreme Court even went so far as to say that damage caps "imposed impermissible burdens on the severely injured," showing support for the argument that plaintiffs' access to courts would be further restricted as lawyers are much less likely to take a costly medical malpractice case that would not result in a fair payoff for both the client and attorney alike.[26] Another example of this harm is shown by Robert Baker, a prominent California insurance defense attorney, who argued that "there are entire categories of cases that have been eliminated," in his address to Congress.[27]

The harsh truth is that these supposed beneficiary limits do nothing but harm the plaintiff and show the creeping greed and influential lobbying power of large insurance companies attempting to increase their profit without regard for the patients who depend on the healthcare they cover.

IV. CURRENT EFFECTIVE ALTERNATIVES TO CAPS ON NON-ECONOMIC DAMAGES

One current, yet imperfect, model that contains some helpful material on how to address this issue is the Michigan Model.[28] The main influential facet of the Michigan Model actually does not involve enacted limits on medical malpractice litigation.[29] Instead, it looks to how hospitals and healthcare providers can lower their insurance premiums on their end.[30] The focus of this model emphasizes the pre-suit process and how proactivity on the part of the healthcare provider, when approached with these situations, can benefit

---

[25] *Id.*
[26] *Id.*
[27] CTR. FOR JUST. & DEMOCRACY AT NEW YORK L. SCH., *Caps on Damages and Who's Hurt Most*, (Sept. 18, 2024).
[28] *The Michigan Model: Medical Malpractice and Patient Safety at Michigan Medicine*, UNIV. OF MICH. HEALTH, https://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs (last visited Feb. 8, 2025).
[29] *Id.*
[30] *Id.*

both parties.[31] Through use of this model, the University of Michigan Health System reported substantial drops in legal costs and a leveling of malpractice premiums despite increased clinical business.[32] Implementing practices such as the one described above, a solution to supposed rising malpractice premiums presents itself without adverse effects on plaintiffs seeking to recover for the harms done unto them. This is only one of many parts of tort reform within the medical field that can be favorable for both sides, while not limiting the justice that many plaintiffs deserve.

Another alternative to caps on non-economic damages that has proved effective at reducing the increase of medical malpractice premiums is a statute enacted in California named Proposition 103.[33] In the midst of a crisis where premiums rose 190 percent in just over a decade, Proposition 103 refunded millions in past overcharges to physicians, froze premiums, rolled back insurance rates up to twenty percent, and, perhaps, most importantly, required stringent government oversight of rate increases.[34] This government oversight also permitted challenges to proposed rate increases by consumers and turned the position of insurance commissioner into that of an elected official.[35] These changes made by the legislation reduced insurance companies' power to dictate insurance premium rates and allowed for a more regulated practice of insurance premium fluctuations. The impact of this sweeping change was almost immediate as premiums decreased by twenty point two percent in a three-year period, stabilizing, contrary to national trends, and healthcare providers were refunded roughly $135,000,000 by insurers.[36] Overall, Proposition 103 shows the potential benefits strict

---

[31] *Id.*
[32] *Id.*
[33] 1988 Cal. Legis. Serv. Prop. 103 (West) (codified at CAL. INS. CODE §1861.01)
[34] The Found. for Taxpayer & Consumer Rts., *How Insurance Reform Lowered Doctors' Medical Malpractice Rates in California and How Malpractice Caps Failed*, 1, 9 (2003), https://consumerwatchdog.org/resources/1008.pdf.
[35] *Id.* at 2.
[36] *Id.* at 1.

government regulation has on insurance premiums when insurance companies are not allowed free reign to pursue solely profit, rather than what is in the best interest of those whose healthcare they cover.

One last instance of a successful tort reform model with beneficial effects on those affected by rising insurance premiums are the Wisconsin Healthcare Liability Insurance Plan ("WHLIP") and the Patients Compensation Fund, originating in the same state.[37] The fund is meant to act like an excess insurer and is primarily financed through an annual fee placed on all healthcare providers in the state.[38] The fund, coupled with the WHILP, which requires that doctors who carry primary insurance with limits of $1,000,000, pay any damage award that exceeds the $1,000,000 of the required primary coverage.[39] In essence, WHILP acts similarly to a private insurance company and provides malpractice insurance for any healthcare provider who is unable to acquire said insurance on the open market, the only difference being that it acts with unlimited exposure, unlike private insurers who routinely operate with a policy limit.[40]

Additionally, the Fund comes with the added benefits of its non-profit status, which means its assessments do not depend on the projected profit of a company, and by only having four assessment classifications, it allows for a more even distribution of the cost of insuring these risks.[41] This even distribution is achieved by reducing the cost to high-risk areas of healthcare through the slight increase in cost to lower-risk areas.[42] These high-risk areas include people with preexsisting high-cost medical conditions that might be considered "uninsurable" by private insurance companies as the coverage

---

[37] Injured Patients and Families Compensation Fund, WIS. STAT. § 655.27 (2005).
[38] WIS. ACAD. OF TRIAL L., *Tilting the Scales of Justice Against Injured Patients and their Families* (2005).
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *Id.*

would be too costly to insure.[43] Overall, these two pieces of legislation in conjunction with one another provide for a fair valuation of medical malpractice insurance that does not have to rely on the private interests of a corporation seeking profit.[44] In fact, the success of these two pieces of legislation in the stabilizing of insurance premium rates was used by the Wisconsin Supreme Court in *Ferdon v. Wisconsin Patients Compensation Fund* as a reasoning to their ruling of caps on non-economic damages being unconstitutional in the state of Wisconsin.[45] The benefits stemming from these legislative acts indicate the potential success of stringent government oversight in the realm of medical malpractice insurance and its effectiveness at stabilizing and lowering insurance premiums.

V. A SOLUTION TO LOWERING MEDICAL MALPRACTICE INSURANCE PREMIUMS

At its heart, the solution to rising medical malpractice premiums presents itself in three main avenues. These avenues include forcing proactivity in litigation on behalf of the healthcare provider, placing governmental restrictions on how insurance companies may operate in relation to medical malpractice insurance and the regulation of their premiums' fluctuations, and eliminates caps on non-economic damages and plaintiffs' capacity to fairly recover. The enaction of this solution would come at the state level through introduction of legislation that would: (1) prohibit or repeal already enforced caps on non-economic damages, (2) institute restrictions on insurance companies forcing them to show actual justification for changes in insurance premiums rates, and (3) implement government-run liability insurance plans

---

[43] THE COMMONWEALTH FUND, *Essential Facts About Health Reform Alternatives: High-Risk Pools*, (2017), https://www.commonwealthfund.org/publications/explainer/2017/mar/essential-facts-about-health-reform-alternatives-high-risk-pools.

[44] *Id.*

[45] Perrecone, *The Fleecing of Seriously Injured Medical Malpractice Victims in Illinois*, at 547.

that may act as excess insurers. This solution would require a bipartisan joint effort as state constitutional amendments regularly require support from voters of both major parties.

The first of this three-part solution is fairly simple. It has been repeatedly proven that capping a plaintiff's recovery on non-economic damages does nothing to lower, and perhaps even raises, medical malpractice insurance premiums.[46] Being that these caps are solely harmful, it is clear that the first step to this solution would be the immediate enaction of legislation that prohibits the placement of caps on non-economic damages in medical malpractice litigation. The enaction can also come in multiple forms as some jurisdictions have found caps on non-economic damages to be unconstitutional according to their respective state constitutions. This means that perhaps a more effective implementation to this solution can be found in an amendment to a state's constitution, rather than a seemingly simpler statutory enaction.

While the passing of a state constitutional amendments are often difficult, as many states either require a successful majority or super majority vote from the populous, this would ensure fair representation by voters on this issue in the best inerests of equity and justice.[47] The enaction of this amendment would force stabilization in the contentious nature of this subject. The enshrinment of this plan in state constitutions would make these solutions difficult to contend as once an state constitutional amendment is passed, a state's supreme sourt cannot pass down a decision that goes contrary to a State's constitution. The only way to reverse these amendments would be the United States Supreme Court passing down a decision that

---

[46] Salvi, *Why Medical Malpractice Caps are Wrong*, at 554.
[47] STATE COURT REPORT, *Constitutional Amendment Processes in the 50 States*, (2023), https://statecourtreport.org/our-work/analysis-opinion/constitutional-amendment-processes-50-states.

states that the amendment is in conflict with the United States Constitution.[48] The passing of such an amendment to a state's constitution would also likely take a bipartisan effort. Because passing a state constitutional amendment is no easy feat, the popular vote must likely see a joint effort by both parties in passing an amendment that only serves to aid the populous in their seeking of justice and fair and affordable healthcare. Lastly, as some states already have variations or parts of this amendment already signed into law, a slightly differing amendment may be necessary to esure that all parts of the solution are effective in aiding that state achieve the above goals.

An amendment that would accomplish the above goals would look as follows:

Proposed Amendment.

(a) No state or municipal legislation shall enact a statute enforcing a maximum judgement or "cap" on damages in medical malpractice litigation.
    a. Any already enacted statute shall be repealed.

(b) Stirct government oversight will require any rise in the rates of insurance premiums by private insurance companies to be accompanied by a full and detailed economic report, showing for good cause, that a rise in rates is required and reasonbale in order to stabilize the losses suffered by extreme circumstances.
    a. The state legislation shall appoint their own chosen economic experts in order to determine that the raise is justified and reasonable.
    b. Furhter government oversight would allow for challenges to proposed rate increases by consumers.
    c. Additionally, the position of insurance commissioner shall be that of an elected official.

(c) A state-run liability insurance plan operating as liability insurance for healthcare providers in medical malpractice litigation shall be created to act as an excess insurer in conjunction with a fund supporting this plan.
    a. The plan will require healthcare providers to carry primary insurance with limits of $1,000,000 and will pay any damage

[48] U.S. SUP. CT., *The Court and Constitutional Interpretation*, (2024), https://www.supremecourt.gov/about/constitutional.aspx.

award that exceed the $1,000,000 of the required primary converage.

i. Unlike private insurers, the fund will operate with unlimited esposure and no policy limit.

The next part of an effective solution to this issue draws inspiration from several states that placed the power of regulation of these insurance companies and their ability to raise insurance premiums in the hands of state governments and essentially, the people. As evidenced previously, insurance companies regulate their medical malpractice premium rates while keeping in mind their profits and investments. This often leads to excessive premium rate rises pushed by faulty reasoning or motives that are not prioritizing the health of the people they inevitably impact. Overall, further government regulation that hinders insurance companies' ability to raise premium rates on a whim is necessary keep these premium rates level, insurance affordable for all eligible healthcare providers, and consequentially affordable healthcare for all.

This regulation would mainly come in the form of aforementioned mandatory reports that would require insurance companies to show good cause and the reasonableness of a proposed hike in insurance premium rates. Additionally, the proposed amendment would change, or create, the position of insurance commissioner to that of an elected official. These two changes, along with allowed challenges to proposed rate increases by consumers, would prove to be an effective use of government regulation that would halt the unreasonably high insurance rate increases that currently plague many markets. The above amendment solidifies these changes in a state's constitution so that the outside influence of insurance companies that currently set these unchallenged rates and abvocate for these harmful damage caps cannot negatively impact this solution.

Another important facet in this proposed solution is the creation of government-run liability insurance plans that may act as an excess insurer

and may even include a fund to support this. This fund would be financed through fees placed on healthcare providers. While this may seem counterintuitive, as the purpose of this is to lower medical malpractice premium rate and consequentially lower insurance costs for healthcare providers, even distribution of the costs of insuring these risks would still provide for an affordable and efficient method of excess insurance. Additionally, while this may receive initial pushback, the savings in avoiding exorbitant insurance premium rate costs, will outweigh and support the costs of the fees placed on the healthcare providers. Overall, this system would save the healthcare provider from these fees and allow for more widespread availability and acces to general healthcare. Implementation of this plan and fund would be statutory and entail complete government oversight that would stem mainly from the newly elected position of the insurance commissioner's office. A liability plan and fund acting as an excess insurer would be instrumental in ensuring every eligible healthcare provider can afford insurance and therefore, keep their healthcare costs affordable. This would not render insurance companies useless, rather it would only act as a supplement.

Perhaps the most important facet of this solution, is all three parts working cohesively and in conjunction with one another. The first being the unconstitutionality of damage caps. This is the beginning of the three step solution and perhaps even the most important. Without damage caps, plaintiffs' means of achieving justice for their loss can no longer be hindered, and the solution to rising malpractice premiums can begin to unfold. The next part, further government oversight on insurance companies' ability to raise premium rates, will only allow reasonable rises in rates, as well as only for good cause. This will mainly aim to solve the issue of rising insurance premiums that are falsely predicated on certain topics, such as the lack of a damage cap in that state. Since the relationship of a lack of a damage cap

and rising rates has continually been disproven, strict government oversight is needed in order to halt this deceitful behavior. Additionally, giving consumers a voice in the decisions of premium rates, as the proposed solution allows for, provides for another hurdle for insurance companies to overcome when trivially raising premium rates. Lastly, the proposed state-run liability plan and fund will allow for those who may not be able to get insurance on the open market, to be fairly covered and provide for more accessible healthcare overall. All three of these points must work cohesively to provide a complete and effective solution.

VI. Conclusion

Recent healthcare insurance crises have been largely met with caps on non-economic damages. This, however, has largely been proven to be ineffective at lowering medical malpractice insurance premiums. A solution to this issue would require several effective aspects working in conjunction to combat this complex, repetitive issue. Of the proposed facets of the overall solution, perhaps the most important aspect is the conjunction of all three parts working together. While each component has its own added benefits and may alleviate some pressures created by the issue, only the enaction of the complete proposed solution presents a favorable result.

Imposing a Duty to Recontact Regarding Genomic Information in Illinois

Jack Nelson

I. INTRODUCTION

The study of the human genome and its application to medicine is not a new concept, however, the initiative to use genomics as a means of precision medicine has been a cutting-edge development.[1] The government's push to use genomics through the "Precision Medicine Initiative" has created an exciting opportunity for genomic exploration and innovation.[2] However, with the increased use of genomic medicine comes an increased instance of genomic liability.[3] This liability stems from the negligent use of genetic testing and, more generally, the application of genetic medicine.[4] Specifically, genomic malpractice refers to malpractice liability against physicians and other healthcare professionals, such as genetic counselors, for their negligent use and/or implementation of genomic information.[5]

As the development of genomic science, medicine, and innovation rises, so does the incidence of genomic malpractice. The growth of genomic malpractice can impose a double-edged sword on the field of genomics by positively enforcing practice standards of providers and independent facilities. However, the freshness of genomics and limited precedent and statutory framework of genomic malpractice can create uncertainty in the field, which may inhibit willingness to innovate or willingness to insure.[6]

---

[1] Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 NEW ENG. J.MED. 793 (2015).
[2] *Id.*
[3] John Carroll, *Genetic Testing: Counselors Desperately Needed*, 6(2) BIOTECHNOLOGY HEALTHCARE, 14, 21 (2009) (discussing the rise of genetic testing and the need for more genetic healthcare professionals, as well as the increased liabilities that are caused by more genetic testing).
[4] *Id.*
[5] M.J. Howlett, Denise Avard & B.M. Knoppers, *Physicians and Genetic Malpractice*, 21 MED. & L. 661, 667 (2002).
[6] Gary E. Marchant & Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide or Gentle Ripple?*, 73 FOOD & DRUG L.J. 1 (2018).

This article will use case law, secondary sources, and professional guidelines to outline a framework of genomic malpractice and support the argument that Illinois should implement a duty to recontact patients regarding new genetic information. This article will provide a concise understanding of what professionals and other entities can be responsible for regarding genomic malpractice, how far professionals' and entities' duties extend in terms of genomic malpractice liability, what they may be liable for, and the benefits and risks associated with implementing liability on genomic science and medicine. First, this article will lay a framework for the emergence of genomic malpractice to serve as a starting point for discussion. Next, this article will evaluate relevant case law within several causes of action under which claims of genomic malpractice arise. Finally, this article will examine what genomic malpractice looks like in Illinois, compare the genomic malpractice framework to the case law that has been discussed, and incorporate Professional Guidelines in the genomic space to provide recommendations for modifications to the genomic malpractice framework in Illinois.

II. EMERGENCE OF CAUSES OF ACTION IN GENOMIC MALPRACTICE

While the use of genetics and the true beginning of understanding the human genome dates back to pre-World War II, innovation in precision medicine using the human genome strongly correlates with the commencement of the Human Genome Project in 2003.[7] Despite the rapid innovation following the Human Genome Project, the use of precision medicine has been slower than expected, in part due to a lack of formal

[7] Eric D. Green et al., *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204, 204–05 (2011) (defining the Human Genome Project as a large-scale international research effort attempting to map the entire human genome).

training for physicians not specialized in genetics and the lack of strong clinical guidelines for practitioners to utilize.[8]

With the increased use of genetic tests and study of genetics in general, liability for genomic malpractice arises out of five types of errors: failure to diagnose a genetic disorder, failure to appropriately interpret results of genetic testing, failure to offer genetic testing despite indications of its use being appropriate, failure to return the results of genetic tests, and failure to properly treat patients with genetic disorders/ diseases.[9] Comparatively, the errors that claims arise from in general medical malpractice are errors of omission, where actions are not taken, and errors of commission, where the wrong act is taken.[10] The majority of genomic malpractice cases that are brought fall into the failure to diagnose, interpret, and offer categories, all of which are knowledge-based errors.[11] An example of failure to diagnose is failure to diagnose Phenylketonuria (PKU), a genetic disease, in an infant before brain damage occurs.[12] An example of failure to interpret is failing to interpret the results of a quad screen in pregnancy, which helps to recognize a higher risk of Down syndrome.[13] Finally, an example of failure to offer is the provider failing to offer genetic testing despite knowing the high risk of genetic disorders related to maternal age, strong family history, or high-risk ethnicity for certain genetic diseases.[14]

Several novel claims arise to subvert the legislative restrictions surrounding traditional medical malpractice claims in the context of

---

[8] U. Amstutz & B.C. Carleton, *Pharmacogenetic Testing: Time for Clinical Practice Guidelines*, 89 CLINICAL.
[9] Marchant, *supra* note 6, at 7.
[10] Thomas L. Rodziewicz et al., *National Library of Medicine*, MEDICAL ERROR REDUCTION AND PREVENTION (May 2, 2023), https://www.ncbi.nlm.nih.gov/books/NBK499956/.
[11] Marchant, *supra* note 6.
[12] *Id.* at 18.
[13] *Id.*
[14] *Id.* at 19.

genetics.[15] The first of these causes of action is wrongful birth/wrongful life, where plaintiffs claim that health care provider's negligence when informing them of genetic risks associated with creating a child or deciding to have an abortion caused them to have a child with genetic disorders, they otherwise would not have chosen to have.[16] Another common claim brought by plaintiffs is a claim for lack of informed consent, claiming that genetic testing should have been recommended and failure to do so is a lack of proper informed consent.[17] Other claims include intentional and negligent infliction of emotional distress,[18] a provider's duty to a patient's family to disclose genetic information,[19] and the statute of limitations for genomic malpractice claims.[20] Finally, there is a broad cause of action of unique genomic malpractice claims that do not fall under the aforementioned causes of action yet exist in the legal system today.[21]

III. UNIQUE CASE LAW IN GENOMIC MALPRACTICE

A. Wrongful Birth/Wrongful Life

Case law within the tort of wrongful life/wrongful birth began to emerge in the 1980s and 1990s and, since then, has diverged into its own genomic malpractice claim on a state-by-state basis, where some states allow the claim and others do not recognize it.[22] For a wrongful life claim, parents must argue, but for the negligent action of the provider, they would have aborted the fetus due to its genetic disorder.[23] These claims would not be recognized in states where abortion is not legal since the parents could not have aborted

---

[15] *Id.* at 9.
[16] *Id.*
[17] Munro v. Regents of Univ. of Cal., 263 Cal. Rptr. 878, 885, 988 (1989).
[18] *Id.*
[19] Kristin E. Schleiter, *A Physician's Duty to Warn Third Parties of Hereditary Risk*, 11 AM. MED. ASS 'N J. ETHICS 697, 697–99 (2009).
[20] Marchant, *supra* note 6, at 26.
[21] *Id.* at 29.
[22] *Id.* at 20.
[23] Provenzano v. Integrated Genetics, 66 F.Supp. 2d 588 (D.N.J. 1999).

the fetus regardless.[24] One key component to the claim that often causes plaintiffs to be unsuccessful in their claim is the need to assert that if they were informed of all the genetic information for the child, they would have elected for abortion.

This issue is highlighted in *Thornhill*, where the plaintiff claimed that had the defendant properly identified that their child would be born with Down syndrome, they would have chosen to have an abortion.[25] In this case, the defendant physician administered an alpha-fetoprotein test, which helps to screen for Down syndrome, and mistakenly interpreted the result that the plaintiff's child would not have Down syndrome.[26] By the time the mistake was corrected, it was too late for the plaintiff to electively terminate the pregnancy.[27] The Defendant testified, saying that in the course of their dealings, the Plaintiff had stated that even if the child had a genetic disorder, they would not abort the fetus.[28] The court accepted the Defendant's statement and held that a plaintiff must show through evidence that, but for a defendant's negligence, they would have aborted the fetus in order to have a successful wrongful birth claim.[29] In wrongful birth claims, one must be in a state where abortion is legal for it to be a recognizable claim, and the plaintiff must prove that had they had all the information regarding genetic testing, they would have aborted the fetus.[30] This places a large emotional burden on the plaintiffs to say that the child they currently have, but for the defendant's negligence, they would have aborted the fetus.

---

[24] Wood v. Univ. of Utah Med. Ctr., 67 P.3d 436, 445 (Utah 2002).
[25] Thornhill v. Midwest Physician Ctr., 787 N.E.2d 247 (Ill. App. Ct. 2003).
[26] *Id.* at 252.
[27] *Id.*
[28] *Id.* at 254.
[29] *Id.*
[30] Marchant, *supra* note 6, at 23.

B. Duty to a Patient's Family

One large ethical and moral question that is explored in case law is whether a physician has a duty to the family of a patient to warn the patient of the genetically transferable nature of the condition for which they are treating the patient.[31] A principal case that addresses this question is *Pate*, where the daughter of a patient brought suit against the patient's treating physician for medullary thyroid carcinoma, a genetically inheritable condition, claiming that the physician had a duty to warn her of the risk of inheriting that condition.[32] The court held that Section 766.102, Florida Statutes (1989) requires a reasonably prudent healthcare provider to warn a patient of the genetically transferable nature of the condition for which the physician is treating.[33] Further, the court held that it is obvious the duty to warn extends to the patient since there is privity, but also, the lack of privity between the physician and the family of the patient does not foreclose liability.[34] The court concludes that physicians do not have a duty to seek out family members and warn them, as that would place an undue burden upon the physician; however, the physician does have a duty to warn the patient of the risk of transferring the condition with the intention that the patient will disclose the risk to their family.[35]

Another important case that examines a provider's duty to a patient's family is *Safer*, where the Plaintiff's father had a physician-patient relationship with the Defendant while the Defendant was treating the father for retroperitoneal cancer, a genetically transferable disease.[36] The Plaintiff developed the same type of cancer as her father and claimed that the

---

[31] MAXWELL J. MEHLMAN ET AL., GENETICS: ETHICS, LAW AND POLICY 124 (West 5th ed. 2020).
[32] Pate v. Threlkel*,* 661 So. 2d 278 (Fla. 1995).
[33] *Id.* at 282.
[34] *Id.*
[35] *Id.*
[36] MAXWELL J. MEHLMAN ET AL., GENETICS: ETHICS, LAW AND POLICY 124 (West 5th ed. 2020); Safer v. Pack, 677 A.2d 1188, 1191 (N.J. Super. Ct. App. Div. 1996).

Defendant failed to warn her of the risk to her health.[37] The court, in this case, did not precisely decide to whom the duty of disclosure extends; rather, the court held that it is required "that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit."[38] The *Safer* court acknowledges the decision in *Pate* and asserts that, while not in all circumstances, the physician must warn family members of patients with inheritable conditions for which they are treating are satisfied by simply telling the patient with the expectation they will inform their family members.[39] This decision broadens the duty of treating physicians in the way they disclose information and also creates a heavy reliance on evidence and testimony to establish whether treating physicians took reasonable steps to ensure that the information reached those likely to be affected.[40]

In response to this decision, New Jersey enacted N.J. STAT. ANN. § 10:5-47 (2013), where they limited the physician's duty and ability to disclose genetic information except in very specific circumstances.[41] In Illinois, similar safeguards regarding a physician's duty to disclose genetic information to family members of patients have been codified. The Illinois Genetic Information Privacy Act excludes providers from being required to disclose any genetic information to anyone except as authorized by the patient or to law enforcement for investigative purposes.[42] Generally, as highlighted in the difference between the *Pate* and *Safer* cases and subsequent state legislation, courts have held that there is such a duty to warn

---

[37] Safer, 677 A.2d at 1191.
[38] *Id.*
[39] *Id.* at 1192.
[40] *Id.*
[41] N.J. Stat. Ann. § 10:5-47 (West).
[42] 410 ILCS 513/15.

patients, but these courts are inconsistent as to how far that duty reaches persons beyond the patient.[43] The real-world implications of this inconsistency place genetic providers in a state of uncertainty as far as the determination as to what the hard and fast rules have to how far their duty to disclose genetic information really extends.[44]

IV. CURRENT STATUS OF GENOMIC MALPRACTICE IN ILLINOIS

As previously mentioned, states must allow abortion to have a recognizable wrongful birth/wrongful life claim.[45] Illinois, being a state that recognizes a woman's right to abortion, does allow the claim for wrongful birth, and a key case in Illinois' wrongful birth precedent is *Clark v. Children's Memorial Hospital*.[46] In *Clark*, the claim alleged the defendant negligently failed to inform plaintiffs of test results revealing that their son suffered from Angelman Syndrome due to a genetic mutation and that they would have had an abortion had they been informed of the risks of having a child with that syndrome.[47] The court held that the parents were entitled to recover damages only up to the child's age of majority, and following reaching that age, the child would have to bring their own suit.[48] The court overturned the decision in *Siemieniec v. Lutheran General Hospital* that recognized wrongful life claims, reasoning that, though the child is burdened, they have suffered no legal wrong as to be able to recover damages.[49] These changes within wrongful life claims and genomic malpractice as a whole can be viewed positively as reducing the legal burden on genomic providers and slowing the ever-present legal floodgate of malpractice liability. These modifications can also be viewed as a negative towards patient protection by

---

[43] Marchant, *supra* note 6, at 25.
[44] *Id.*
[45] Wood v. Univ. of Utah Med. Ctr., 67 P.3d 436, 445 (Utah 2002).
[46] Clark v. Children's Mem'l Hosp., 2011 IL 108656, 258.
[47] *Id.* at 259.
[48] *Id.* at 268.
[49] *Id.* at 273.

reducing the number of claims that can be brought and limiting the damages that can be afforded despite ongoing costs past the age of majority.

Illinois has also taken steps to protect both genomic providers and patients by codifying the Genomic Information Privacy Act. The Illinois statute states that no provider shall be compelled to share the results of any genetic testing except in very specific circumstances and further specifies, "This paragraph does not create a duty or obligation under which a health care provider must notify the subject's spouse or legal guardian of the test results, and no such duty or obligation shall be implied."[50] Section 30-1 of the Illinois Genomic Malpractice Act clearly excuses providers of any duty to inform families of their patients and also establishes that good faith on the part of the physicians is presumed.[51] Beyond protections to providers, the Illinois Genetic Information Privacy Act also affords protections to patients by prohibiting results of genetic testing from being shared with employers or prospective insurers to protect them from discrimination based on genetic condition.[52] The statute prohibits the nonconsensual disclosing of genetic information in all situations except as legally required by law enforcement's need for the use of the information.[53]

This shows a concerted effort on behalf of the Illinois legislature to protect patient interest against discrimination based on genetic information and provides a cause of action for patients whose information was wrongly disclosed and discriminated against because of that. However, this protection does not afford more latitude within genomic malpractice for patients to bring

---

[50] 410 ILCS 513/30-1 ("This paragraph does not create a duty or obligation under which a health care provider must notify the subject's spouse or legal guardian of the test results, and no such duty or obligation shall be implied").
[51] *Id.*
[52] 410 ILCS 513/15.
[53] *Id.*

claims of lack of informed consent or other genomic malpractice-related claims. Cases like *Clark* and Section 30-1 of the Illinois Genetic Information Privacy Act have narrowed the ability for patients to bring claims arising from genomic malpractice.

The dichotomy within the Illinois Genetic Information Privacy Act and the shifting case law within Illinois highlight the difficult ethical and legal concerns within genomic malpractice. Comparing Illinois to other states' case law, it is evident that there is a general difficulty when looking to balance physician protection with patient's interest. As shown in *Safer*, New Jersey courts found it to be appropriate to compel a duty on a genetic provider to warn a patient's family of genetic diseases, but following that decision, the state legislature felt that there should be no duty.[54] Expounding beyond the legal framework of genomic malpractice, professional institutions also recognize the difficulty of weighing patient interests with understanding the burden being placed on the provider. In a Professional Guideline provided by the American Society of Human Genetics ("ASHG"), the author addresses the responsibility to recontact research participants after reinterpretation of genomic results.[55] Here, the ASHG analyzes the ethical and legal implications for a duty to recontact and ultimately states that there should be a duty for providers to reconnect, and that duty must be weighed against the burdens to perform that duty, such as time, cost, and technological limitations.[56] These conclusions highlight the same struggle that Illinois legislature and other state legislatures face when it comes to genomic malpractice and its statutory framework.

---

[54] Safer v. Pack, 677 A.2d 1188, 1191 (N.J. Super. Ct. App. Div. 1996); N.J. Stat. Ann. § 10:5-47 (West).
[55] Yvonne Bombard, *ASHG Position Statement*, THE RESPONSIBILITY TO RECONTACT RESEARCH PARTICIPANTS AFTER REINTERPRETATION OF GENETIC AND GENOMIC RESEARCH RESULTS, https://www.cell.com/ajhg/fulltext/S0002-9297(19)30070-9 (last updated Apr. 4, 2019).
[56] *Id.*

V. IMPLEMENTING A DUTY TO RECONTACT PATIENTS WITHIN ILLINOIS

As mentioned in the previous paragraph, there is a great burden on the Illinois legislature to protect patient interests as well as balance the amount of burdensome liability there is on genetic providers. Within the Illinois Genetic Information Privacy Act, no language imposes a duty for genetic providers to recontact current or former patients to provide them with information regarding a new discovery within their genetic information.[57] Genetic testing is unique to other medical tests that are often repeated and followed up upon due to the nature of the test; however, genetic tests are typically completed and interpreted only once.[58] While the DNA makeup of the patient remains static, the implications of the information within their genetic sequence are ever-changing and therefore demands a need for patient recontact.[59] This new information can profoundly impact a patient's health and choices surrounding their way of life.[60] The importance and impact of this new data should create a legal duty for genomic clinicians to provide patients with invaluable information that will impact their health decisions.

A provider's duty to recontact is generally restricted to those situations where the provider has already rendered a service.[61] Existing medical malpractice principles that require a duty to recontact are abandonment, where the physician performs a procedure or service that requires subsequent

---

[57] 410 ILCS 513.
[58] *See* Yvonne Stevens et al., *Physicians' Duty to Recontact and Update Genetic Advice*, 14 PERSONALIZED MED. (2017) ("What is unique about genetic sequencing is that unlike most medical tests that can, and should, be repeated over time to assess the changing status of the patient, whole-exome sequencing or whole-genome sequencing of a patient's genotype only needs to be conducted once").
[59] *Id.*
[60] *Id.*
[61] *Id.*

follow-up, and a failure to perform such follow-up results in abandonment.[62] Another classic duty to recontact arises from the principle of requiring physicians to inform patients that a current treatment they are using has newly discovered negative health effects.[63] Despite these general malpractice principles, there remains no general duty to recontact existing or past patients with new medical information unrelated to current treatment.[64] While this standard is arguably most practical for medicine in general, in the world of genetics, the positive health impact of sharing new genetic discoveries with past patients far outweighs the burden imposed on providers.[65] Implementing a duty to recontact patients is no small feat, but the benefits to public health and safety outweigh the communication burden implemented on genetic providers.

Illinois legislature should add language to Section 35 of the Genetic Information Privacy Act that says, "genomic providers have a legal duty to recontact past and current patients regarding important, verified changes in the understanding of their genetic information." Further, genomic providers would need to be explicitly defined within the Act as an expansion of the definition of healthcare providers that is given in the Act. New genomic information must have a definitive potential impact on the health of the patient in order to require that it be shared with the patient. The duty being codified into the Illinois Statute creates clear guidance for providers' legal obligations compared to allowing this issue to become case law. This clarity is essential for the fair and effective implementation of this modification to

---

[62] Barbra E. Calfee, *What You Don't Know Will Hurt You: Physicians' Duty to Warn Patients about Newly Discovered Dangers in Previously Initiated Treatment*, 31 CLEV. ST. L. REV. 649, 649-77 (1982) (discussing the definition of patient abandonment and the liability imposed on physicians).
[63] Martin Letendre & Beatrice Godard, *Expanding the Physician's Duty of Care: A Duty to Recontact*, 23 MED. & L. 531,531-39 (2004) (discussing liability that has been imposed on physicians for failing to update about new health risk with current treatment for patients).
[64] Stevens, *supra* note 58, at 3.
[65] *Id.* at 4.

the duty of genomic malpractice.[66] Illinois legislature can further clarify this modified duty by relying on the current definition of a physician-patient relationship and tailoring it to meet the unique needs of genomics. In Illinois, courts have held that a physician-patient relationship is formed when the patient seeks care from the physician and the physician accepts that patient.[67] U.S. courts have held that the physician-patient relationship is terminated by "(1) the mutual consent of the parties, (2) the physician's withdrawal after reasonable notice, (3) the dismissal of the physician by the patient, or (4) the cessation of the necessity that gave rise to the relationship."[68] The ongoing nature of genetic development would help to justify Illinois lawmakers to say there was not sufficient cessation that gave rise to the physician-patient relationship, and therefore, we can require that genomic providers have a duty to recontact patients regarding new genetic information.[69]

A. The Positive Impact of a Duty to Recontact on Patients

There is little doubt that modifying the Illinois Genetic Information Privacy Act is predominantly beneficial to patients compared to providers. This duty imposed solely on providers still allows patients to recontact their providers, yet ensures that patients, who may not know when to recontact or what information to recontact regarding, are informed on new and important

---

[66] *See* Gary Marchant et al., *Personalized Medicine and Genetic Malpractice*, 15 GENET MED. 921, 921-22 (2013) (discussing how the shifts and decisions are expanding the liability risks for physicians with respect to genetic testing, such as the duty to disclose to patient's relatives or to recontact patients).

[67] *See, e.g.,* Lenahan v. University of Chicago, 348 Ill. App. 3d 155, 163, 283 Ill. Dec. 790, 808 N.E.2d 1078 (2004) (where a physician's duty is limited to those situations in which a direct physician-patient relationship exists or there is a special relationship such as when a physician is asked by another physician to provide a service to a patient, conduct laboratory tests, or review test results).

[68] Norman v. Lehman*,* 347 S.W.3d 611, 614 (Mo. Ct. App. 2011).

[69] Stevens, *supra* 58, at 5.

genetic information.[70] Importantly, establishing this duty to recontact allows patients to make medical decisions when variants of unknown significance (VUS) within a patient's genetic code become understood and their impact on the patients' health is fully grasped.[71] Patients would not only be able to identify relevant medical issues that need to be addressed but also understand the future of their health to be able to take prophylactic measures to prevent the need for treatment.[72] Genetic data is so complex that the interpretation of data can change daily.[73] Patients should not lose out on this available benefit because the Illinois legislature has failed to implement a duty to recontact.

B. Changes in Practice for Genomic Clinicians/ Providers

A modification to the Illinois Genomic Information Privacy Act enacting a duty for genomic providers to recontact patients creates a burden on those providers. Critics of this modification will say that a legal duty to recontact is unattainable given technological, resource, and organizational constraints.[74] Another criticism that imposing the duty to recontact may create is that it opens providers up to yet another means of liability. However, it is reasonable to expect that, in the very near future, health technologies will improve, and with the improvement, the burden of recontact will be reduced.[75] Health information systems will develop to automatically trigger the reinterpretation of genetic information upon the discovery of new and relevant clinical information because genetic providers and laboratories are economically incentivized to conduct reinterpretation in the most automated

---

[70] Shane Doheny, *Recontacting in Medical Genetics: The Implications of a Broadening Knowledge Base*, 141 HUM. GENET. 1045, 1045-51 (2022).
[71] Paul Appelbaum et. al., *Is There a Duty to Reinterpret Genetic Data? The Ethical Dimensions*, 22 GENET. MED. 633, 633-39 (2020).
[72] *Id.* at 635.
[73] Doheny, *supra* note 70, at 1048.
[74] *Id.* at 1049.
[75] Mitchell Ploem et. al., *A Duty to Recontact in the Context of Genetics: Futuristic or Realistic?*, 25 EUR. J. OF HEALTH L. 537, 553 (2018).

and efficient manner, mitigating costs.[76] Once this reinterpretation is begun, health information systems can then automatically recontact patients who may be impacted by this new information and provide clinical recommendations.[77] This automation and reinterpretation that is on the horizon will drastically reduce the burden on genomic providers to recontact past and current patients.

Beyond the inevitable progression of health system technologies, there is already an existing wealth of recommendations for executing recontacting that will act as a framework for implementing this duty in Illinois. Creating this duty to recontact in Illinois would require that genomic providers (1) store patient data, (2) initiate reinterpretation of data when understanding genetic information changes, (3) reinterpret the stored genetic data, and (4) recontact the patient.[78] The Public and Professional Policy Committee of the European Society of Human Genetics (ESHG) developed a list of twelve recommendations for genetic providers to carry out effective, ethical, and legal recontact with patients regarding genetic information.[79] These twelve recommendations provide insight into data storage and sharing amongst genetic providers as well as identifying ways the duty of recontacting can be placed on patients and genetic laboratories.[80] These guidelines and others like them help to address the criticisms that a duty of recontacting creates and help genetic providers address the logistical and ethical concerns surrounding recontacting.[81] Genomic providers can also create narrowly tailored consent

---

[76] Appelbaum, *supra* note 71, at 635.
[77] *Id.*
[78] *Id.* at 635-36 (describing the four elements needed to implement a duty to recontact).
[79] Daniele Carrieri et. al., *Recontacting Patients in Clinical Genetics Services: Recommendations of the European Society of Human Genetics*, 27 EUR. J. OF HUM. GENETICS, 169, 179-80 (2019).
[80] *Id.*
[81] Bombard, *supra* note 55 (discussing the ASHG's position and recommendations for recontact).

forms that clearly define the physician-patient relationship and their duty to recontact, as well as explain the logistics surrounding recontact to serve as protection for liability.[82] The progression of health information systems, in conjunction with the wealth of informational frameworks, will allow genomic providers to fulfill their duty of beneficence and nonmaleficence to their patients while reducing the logistic burden and minimizing legal liability.

VI. CONCLUSION

The rapid nature of expansion, new discovery, and new genetic practice calls lawmakers to reexamine the rules and duties that govern genomic providers. Modifying the Illinois Genetic Information Privacy Act to impose a duty to recontact patients regarding new and relevant genetic information provides greater patient autonomy. This update to the Act also fulfills the ethical duties of genomic providers of beneficence and nonmaleficence. Through ever-evolving health information systems and framework guidelines, genomic providers can overcome the logistical barriers to recontact and avoid liability for genomic malpractice. By assuming and fulfilling this proposed duty, genomic providers will enable patients to make informed medical decisions.

---

[82] *See* Stevens, *supra* note 58 ("It would be prudent for any physician providing genetic advice to ask the patient if they wish to be recontacted if pertinent new information becomes available, and to only recontact and update if the patient provides such consent.").

Regulating Maternal Mortality in the United States: The Committee on Energy and Commerce's Proposed Bill

Sara Noronha

I. THE MATERNAL MORTALITY CRISIS IN THE UNITED STATES

A maternal death is defined as "the death of a pregnant woman, not caused by accident, but by a cause related to the pregnancy or its control."[1] A maternal death can also be a death of a woman within forty-two days of the termination of the pregnancy, again related to the pregnancy or its control rather than mishap.[2] These deaths are most often preventable or treatable.[3] The World Health Organization explains that even if the woman had a health complication before her pregnancy, due to poor care management, these issues can worsen.[4] These complications make up three-fourths of all maternal deaths in the world.[5] The World Health Organization detailed that in 2020, almost 800 women died from causes related to pregnancy and childbirth.[6] These preventable causes have led the Organization to realize that in 2020, every two minutes a woman died from a maternal death.[7] Geographically, maternal death trends higher in low and middle-income countries in 2020.[8] In fact, 95 percent of maternal deaths happen in these countries, and, according to the World Health Organization, many of these deaths could have been prevented.[9]

Despite being regarded as one of the wealthiest countries in the world, the United States of America currently has one of the highest maternal mortality

---

[1] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2022*, NAT'L CTR. FOR HEALTH STAT. 1 (May 2024), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.htm.
[2] *Id.*
[3] WORLD HEALTH ORGANIZATION, *Maternal Mortality* (Apr. 26, 2024), https://www.who.int/news-room/fact-sheets/detail/maternal-mortality.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.* (finding that in low income countries the maternal mortality rate was 430 per 100,000 compared to a rate of 13 per 100,000 in high income countries).
[9] *Id.*

rates.[10] In 2018, the US held a ratio of maternal morbidity more than two times higher than other countries regarded for wealth.[11] This rate places the country in a maternal health crisis.[12] When computing rates of maternal mortality, studies often look to how many maternal deaths occurred per 100,000 births.[13] Maternal mortality rates are much higher in minority populations than rates of white women.[14] Compared to the rate for white women, which is 13.7 deaths per 100,000 births, black, American Indian and Alaska Native ("AIAN") women experience death related to pregnancy at a rate of over two to three times higher.[15] The rates of maternal deaths related to pregnancy for black and AIAN women is 41.4 and 26.2 per 100,000 live births.[16] The heightened risk of maternal death for women in minority populations puts them at top risk within the health crisis the country is currently in.

The COVID-19 pandemic had an impact on maternal mortality in the United States, especially in minority groups.[17] In 2021, after the pandemic had introduced itself, the country experienced a thirty-seven percent increase

---

[10] Statements and Releases, The White House, The White House Blueprint for Addressing the Maternal Health Crisis: Two Years of Progress (Jul. 10, 2024), https://www.whitehouse.gov/briefing-room/statements-releases/2024/07/10/the-white-house-blueprint-for-addressing-the-maternal-health-crisis-two-years-of-progress/ (President Biden and Vice President Harris have deemed the United States of America to have such a high rate of maternal mortality rates to place the country in an official maternal health crisis as there is urgent need to improve maternal health in the country).

[11] Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, COMMONWEALTH FUND (Nov. 18, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries.

[12] *The White House Blueprint for Addressing the Maternal Health Crisis: Two Years of Progress* [hereinafter *The White House Blueprint*], *supra* note 3.

[13] HOYERT, *supra* note 1, at 1.

[14] Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF 1, 1-2 (Nov. 01, 2022).

[15] *Id.* at 1.

[16] *Id.*

[17] Kathleen Rice Simpson, *Effect of the COVID-19 Pandemic on Maternal Health in the United* States, 48(2) MCN AM. J. MATERNAL CHILD NURSING 61 (Feb. 24, 2023).

of maternal deaths from 2020.[18] During the COVID-19 pandemic, black women experienced "widened" rates of maternal death.[19] For non-hispanic black women, in 2021, every 68.9 women in 100,000 experienced maternal death, as opposed to 44.0 in 2019.[20] While rates for Hispanic women were lower, maternal deaths still increased from 12.6 in 2019 to 27.5 out of 100,000 in 2021.[21] Comparing these rates to white women, maternal death rates in 2019 were 17.9 and in 2021, they saw a rate of 26.1.[22] Across the country, maternal death rates suffered the negative effects of the COVID-19 pandemic, but minority groups were hit the hardest.[23]

II. INTRODUCTION TO H.R. 3838 – PREVENTING MATERNAL DEATHS REAUTHORIZATION ACT OF 2023

In efforts to lower the rates of maternal mortality and increase access to safe and sustainable health for mothers, the Committee on Energy and Commerce has introduced the Preventing Maternal Deaths Reauthorization Act of 2023.[24] This Act not only aims to decrease disparities in outcomes for pregnant women, but it seeks to identify solutions to increase the quality in outcomes.[25] The Preventing Maternal Deaths Reauthorization Act of 2023 ("PMDRA") amends Section 317K of Title III of the Public Health Service Act.[26] Section 317K of Title III of the Public Health Service Act discusses safe motherhood and establishes a 'Federal initiative' to back maternal mortality review committees.[27] The PMDRA seeks to amend Section 317K

---

[18] *Id.*
[19] Latoya Hill, *supra* note 14, at 2.
[20] Kathleen Rice Simpson, *supra* note 17.
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] Preventing Maternal Deaths Reauthorization Act of 2023, H.R.3838, 118th Cong. (2024).
[25] *Id.*
[26] *Id.*
[27] Public Health Services Act, H.R.2365, 118th Cong. §317K (2024).

through language change and practice implementations within two subsections.[28]

Before understanding the changes and implementations this Act is proposing, it is important to understand the verbiage that is used throughout the text. Section 2 of the PMDRA discusses changes to the language of the maternal mortality review committee's subsection of the Public Health Service Act.[29] The Centers for Disease Control and Prevention has defined maternal morality review committees as "multidisciplinary groups that convene at the state or local level to comprehensively review deaths that occur during or within one year of the end of pregnancy."[30] These groups utilize logic models which connect goals the group is trying to achieve with resources and activities to ensure for quality outcomes and health system improvements.[31] The model looks to process factors such as inputs, activities, and outputs, to obtain successful and quality outcomes; the outcomes can be short, intermediate, or long.[32] Maternal mortality review committees are essential in the cycle of maternal health, as they make recommendations and implement improvements aiding a change in the maternal health crisis.[33]

The PMDRA amends the Public Health Service Act's section on maternal mortality review committees by both editing the terms it uses, such as adding specific medical titles when discussing specialties, and inserting the implementation of improving reports and records that discuss the cause-of-

---

[28] Preventing Maternal Deaths Reauthorization Act of 2023, H.R. 3838, 118th Cong. (2024), https://www.congress.gov/bill/118th-congress/house-bill/3838/text.
[29] *Id.*
[30] CTR. FOR DISEASE CONTROL, *About Maternal Mortality Review Committees*, Maternal Mortality Prevention (2024).
[31] *Id.*
[32] Photography/Illustration of Maternal Mortality Review Committee Logic Model in Maternal Mortality Review Information App.
[33] *Id.*

death for pregnant women post-mortem.[34] This is an important change to this section as it allows for obstetricians and gynecologists to be at the forefront of review committee membership.[35] Having these two specialties specifically included in the text of this Act will allow for those with clinic expertise and the most relevant education and training to identify and recommend solutions to help decrease maternal mortality rates. The Act also proposes pregnancy related death surveillance with death certifiers in attempt to appropriately improve death records for pregnant women as it relates to their cause of death.[36] This is an important and worthy amendment, as it would allow for these review committees to more accurately and appropriately identify the cause of death for maternal deaths by learning from previous deaths[37] and recommend improvements based on the correct issues.

The second big change that the PMDRA proposes is to add a subsection proposing increased federal support through consultation and conversation.[38] This addition that the Act proposes is a positive request as it seeks out, at a minimum, an annual collaboration and consultation for the Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention.[39] This mandatory meeting would allow for a consistent review, looking to hospitals and other expertise groups, of practices that provide successful and unsuccessful outcomes and allow for early issue identification.[40]

---

[34] *Preventing Maternal Deaths Reauthorization Act of 2023, H.R.3838*, *supra* note 24.
[35] *Id.* at 2.; *Public Health Service Act,* supra note 27.
[36] *Preventing Maternal Deaths Reauthorization Act of 2023, H.R.3838*, *supra* note 24.
[37] Centers for Disease Control, *Maternal Death Surveillance and Response*, Global Reproductive Health (2024), https://www.cdc.gov/global-reproductive-health/php/maternal-death-surveillance-response/index.html.
[38] *Preventing Maternal Deaths Reauthorization Act of 2023, H.R.3838*, *supra* note 24.
[39] *Id.*
[40] *Id.*; Siwen Wang, et al., Maternal Mortality in the United States: Trends and Opportunities for Prevention, 74 ANNU. REV. MED. 199, 200-204 (2023).

The Preventing Maternal Deaths Reauthorization Act of 2023, H.R.3838, has made progress in the process to becoming law, but is still in the early stages.[41] On March 5, 2024, the House of Representatives passed the bill in a vote of 382-12.[42] Once passed into Senate, the bill has been read twice and currently sits on the Senate Legislative Calendar.[43] If passed by Senate, the President will review and either approve and sign, or veto the bill; if signed, the proposed bill will become law.[44] There is a high chance that this bill will be passed through the Senate and receive the President's signature to be turned into law. The Biden-Harris administration has focused a lot of attention on the Maternal Health Crisis.[45] In fact, the administration has even made extensions to postpartum Medicaid coverage for up to a full year after birth, allowing for increased health care to pregnant women.[46] These efforts show the American people the urgency in change that is needed surrounding maternal health and give motive to passing the bill into law.

Along with the motive for change, this bill proposes a cost increase to practices aimed towards decreased maternal morbidity.[47] The PMDRA would require a $244 million expense from 2024-2028 to allow for the changes and implementations to be enacted successfully.[48] Realistically, this is an easily achievable amount for a necessary change this country seeks, one

---

[41] H.R.3838 - Preventing Maternal Deaths Reauthorization Act of 2023, Passed House Summary (2023-2024), https://www.congress.gov/bill/118th-congress/house-bill/3838.
[42] *Id*.
[43] H.R.3838 - Preventing Maternal Deaths Reauthorization Act of 2023, Bill History - Congressional Record References (2023-2024), https://www.congress.gov/bill/118th-congress/house-bill/3838/all-actions?overview=closed&s=3&r=12#tabs
[44] THE LEGISLATIVE BRANCH, https://www.whitehouse.gov/about-the-white-house/our-government/the-legislative-branch/ (last visited Sep. 22, 2024).
[45] *The White House Blueprint*, *supra* note 12.
[46] *Id.*
[47] Senate Committee on Health, Education, Labor, and Pensions, Cost Estimate, Congressional Budget Office (2024).
[48] *Id.*

in which both parties can agree on.[49] For these reasons, the Preventing Maternal Deaths Reauthorization Act of 2023 will most likely be passed by Senate, approved and signed by the President, and introduced into law, evoking a necessary and effective change the country desperately needs.

III. WHERE IS ACCESS TO HEALTHCARE LACKING?

The Preventing Maternal Deaths Reauthorization Act of 2023 is a well-designed bill that currently sits in Senate, as it calls for language edits and practice implementations. However, the goal for the amendments is to decrease maternal mortality rates in the country while increasing access to health and positive outcomes regarding maternal health. There is more that can be done to achieve these goals. The introduction of automated scheduling would be of great benefit for this bill. It would not only allow for greater access to health for pregnant women and women postpartum, but it would additionally help diminish the racial disparities that surround maternal healthcare and be a major addition to the proposal.

Right now, more than ever, there is a big need for an increase in access to healthcare for pregnant and women postpartum. A study done by the March of Dimes, a non-profit organization aimed at reducing and ending maternal death and health risks, concluded that the number of birthing hospitals in the country has decreased significantly, creating more barriers for maternal health access.[50] Because of the lack of facilities for women to see healthcare, maternity care decreased in several counties, some even classifying as

---

[49] Javier M. Rodriguez, *Political Ideology Direction of Policy Agendas and Maternal Mortality Outcomes in the U.S., 1915-2007*, 28 MATERNAL CHILD HEALTH J. 865 (2024).
[50] *New March of Dimes Research Shows Access to Maternity Care Worsening for Millions of Women in the U.S*, MARCH OF DIMES (Aug. 01, 2023), https://www.marchofdimes.org/about/news/new-march-dimes-research-shows-access-to-maternity-care-worsening-millions-women-us.; *About Us*, MARCH OF DIMES, https://www.marchofdimes.org/about-us.

'maternity care deserts'.[51] While in a health crisis for maternal care, a decrease in accessible hospitals fights any progress for positive change. What this country needs is a positive system that will allow for increased access to quality care that women in their pregnancy and postpartum can access, regardless of their race, ethnicity, or socioeconomic status.

One way access to healthcare can be increased is through the use of automated scheduling. Automated scheduling is a software managed process that uses artificial intelligence to create optimal scheduling.[52] The point of this process is to remove human existence within scheduling appointments while making the process seamless and more accessible.[53] There are many difficulties that can affect a patient's satisfaction and overall visit tied to appointment management, such as long wait times and scheduling conflicts.[54] Advantages of this automated system include less room for human error regarding scheduling, which, in turn, also reduces costs and wait times.[55] This process allows for easier updates, corrections, and management regarding appointments.[56]

This system is beneficial for burdened groups, as it allows for convenience and increased access.[57] Racial and socioeconomic disparities are heavily influential among maternal mortality rates, with race and ethnicity having the highest rates.[58] In fact, black women experience maternal morbidity at a rate

---

[51] *Id.*
[52] Ashley Grant, *Automated Scheduling: What is it, and How Does it Work?*, 1, 2, Tagg (2022), https://www.taggg.com/blog/what-is-automated-scheduling.
[53] *Id.*
[54] Khaled F. Alrasheedi et al., *The Association Between Wait Times and Patient Satisfaction: Findings From Primary Health Centers in the Kingdom of Saudi Arabia*, NAT'L. LIBR. MED. (Jul. 7, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6614942/.
[55] Ashley Grant, *supra* note 52, at 2-4.
[56] *Id.* at 5.
[57] Elizabeth Howell, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, NAT'L. LIBR. MED. (Jun. 1, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/.
[58] Siwen Wang, *supra* note 40, at 200-204

three times higher than rates of white women.[59] Limits to healthcare create the gap in quality care for women of color within the country, which could be reduced with structure change surrounding maternal health.[60] With structure change through automated scheduling, these disparity groups can access scheduling with fewer errors, find optimal times for appointments more efficiently, and access healthcare providers quicker.[61]

IV. PROPOSAL TO IMPLEMENT AUTOMATED SCHEDULING INTO ACT TO FILL THE GAPS OF ACCESS TO HEALTHCARE

The Preventing Maternal Deaths Reauthorization Act of 2023 seeks to make changes to the Public Health Service Act's sections on maternal health, but needs to also include a change that will improve access to healthcare for pregnant women and women postpartum. In a press release on June 7, 2023, United States Representative Diana DeGette discussed maternal morbidity and stated that this bill, if made law, will "add critical resources" to provide women with the healthcare they need for sustainable lives.[62] While it is true that it adds critical resources, it also lacks an essential task of improving accessibility to women seeking healthcare during and after their pregnancy. Representative DeGette stated that this legislation is not only for the health of the women during their pregnancy, but it is aimed at seeking increased quality for women during childbirth and the period after birth as well.[63] By including a need for automated scheduling into the amendments of this bill,

---

[59] CTR. FOR DISEASE CONTROL, *Working Together to Reduce Black Maternal Mortality, Women's Health* (2024), https://www.cdc.gov/womens-health/features/maternal-mortality.html.
[60] *Maternal Mortality in the United States: Trends and Opportunities for Prevention*, [Hereinafter *Maternal Mortality in the United States*] *supra* note 60.
[61] Ashley Grant, *supra* note 52, at 5.
[62] Press Release, Michael C. Burgess, M.D., Burgess, DeGette Introduce Legislation to Address Maternal Health Disparities and Prevent Maternal Deaths (June 7, 2023), https://burgess.house.gov/news/documentsingle.aspx?DocumentID=403759.
[63] *Id.*

the PMDRA would be able to hit all the essential elements that it needs to see successful outcomes. The United States, currently in a Maternal Health Crisis, needs legislation that will focus on equitable access to exceptional health care for women,[64] especially women who are within minority groups experiencing limited access to high-quality services.

Within the text of the PMDRA, there should be an additional point within the requested subsection to include a proposal for the inclusion of automated scheduling. This piece of proposed legislation requests a subsection titled 'Best Practices Relating to the Prevention of Maternal Mortality' under a section titled "SEC. 2. SAFE MOTHERHOOD".[65] Within this new subsection is where the dissemination to hospitals and the frequency of conversations of best practices is addressed.[66] The current proposal subsection reads as follows:[67]

> (b) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY. – Section 317K of the Public Health Service Act (42 U.S.C. 247b—12) is amended –
>
> (1) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively; and
>
> (2) by inserting after subsection (d) the following:
>
> "(e) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY. –"
>
> "(1) IN GENERAL. – The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, in consultation with the Administrator of the Health Resources and Services Administration, disseminate to hospitals, State professional society groups, and perinatal quality collaboratives, best practices on how to prevent maternal mortality

---

[64] GLOBAL PROGRESS AND PROJECTIONS FOR MATERNAL MORTALITY, https://www.gatesfoundation.org/goalkeepers/report/2022-report/progress-indicators/maternal-mortality/ (last visited Sep. 22, 2024).
[65] Preventing Maternal Deaths Reauthorization Act of 2023, H.R. 3838, 118th Cong. (2024).
[66] *Id.*
[67] *Id.*

> and morbidity that consider and reflect best practices identified through other relevant Federal maternal health programs."
>
> "(2) FREQUENCY. -- The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall disseminate the best practices referred to in paragraph (1) not less than once per fiscal year."

Within this subsection, there should be a point to call for an increase in the use of automated scheduling. Here, it should be stated that as applicable and available, automated scheduling is implemented into local systems and utilized as frequently as obtainable. This addition to the proposal would read as follows:

> (b) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY. – Section 317K of the Public Health Service Act (42 U.S.C. 247b—12) is amended –
>
> (1) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively; and
>
> (2) by inserting after subsection (d) the following:
>
> "(e) IF AVAILABLE, UTILIZING AUTOMATED SCHEDULING"
>
> "(1) Where technology allows, employing automated scheduling to enhance the efficiency and accessibility of prenatal care throughout the course of the pregnancy to ensure timely consultations and interventions as well as continuous care within transition to primary care services."

As this is a practice that health systems would need to implement, this proposal fits under the section discussing practices to prevent maternal mortality within the bill. A study conducted by the JAMA Network Open showed that through automated scheduling, there was an increase as significant as nineteen percent for patient visits with women after childbirth.[68] This study also discusses the accessibility this automated system gives women as they transition from prenatal care to primary care and the

[68] Mark Clapp et al., *Postpartum Primary Care Engagement Using Default Scheduling and Tailored Messaging*, JAMA Network 1, 1 (2024).

support that they receive through this highly technological way of setting up visits.[69] By adding the need for this system through section 2 in the PMDRA, women will be able to have a way for more accessible healthcare written in legislation.

The impact of having this accessibility written into legislation will go beyond the ease of setting up appointments, as it will also allow for maternal mortality rates to decrease. In JAMA's study on postpartum primary care, it was concluded that using default scheduling resulted in women after their pregnancy receiving screening tests that they needed from their primary care physician.[70] The only negative this could potentially create is the need for increased funding for hospitals and healthcare entities to fund the technology needed to make this change. However, the positives of implementing automated scheduling outweigh the financial cost. The conclusion of this JAMA trial was that there is a need for improving the ease of patient care for women postpartum and that implementing automated scheduling is a "low-resource, high-impact" avenue to achieve that goal.[71] Women of color, especially black women, in this country experience higher rates both of mortality and morbidity linked to the socioeconomic disparities they are faced with.[72] Since these women specifically experience higher pregnancy related mortality than white women, low cost and low resource, but high impact systems that make health care accessible is crucial.[73] Low resource and high-impact is critical for access to quality healthcare, which is why this big positive is more signficiant than the potential need for more funds.

---

[69] *Id.*
[70] *Id* at 1-5.
[71] *Id* at 9.
[72] Elizabeth Howell, *supra* note 57.
[73] *Id.*

This change would bolster the bill and allow it to pass through Senate swiftly and be put into the hands of the President for signing. As this country faces a Maternal Health Crisis, there is a desperate need to meet the inequalities and address the issues that are causing the United States to have a significantly high maternal mortality rate.[74] The Biden-Harris administration has made it known that efforts are underway to decrease this rate, but there is room for more work to be done.[75] Right now, the bill has been read twice by the Senate and is awaiting approval to be sent to the President.[76] With this addition, it will easily be passed and turned into law. Vice President Kamala Harris has repeatedly addressed the need for awareness of maternal health and has even enacted that December 07 be named 'White House Day of Action' on maternal health.[77] Especially with the addition of automated scheduling, this bill will likely be passed into law, as it improves the country's access to healthcare and helps decrease maternal morbidity rates. This public need for change, tied along with the addition of promoting access to healthcare, will move the Preventing Maternal Deaths Reauthorization Act of 2023 into law.

V. CONCLUSION

With the introduction and proposal of the Preventing Maternal Deaths Reauthorization Act of 2023, the Committee on Energy and Commerce is taking a step for change regarding maternal health.[78] This Act calling for

---

[74] *Burgess, DeGette Introduce Legislation to Address Maternal Health Disparities and Prevent Maternal Deaths* [Hereinafter *Burgess*] *supra* note 74; *The White House Blueprint*, *supra* note 12.
[75] *The White House Blueprint*, *supra* note 12.
[76] Preventing Maternal Deaths Reauthorization Act of 2023, H.R. 3838, 118th Cong. (2024).
[77] Statements and Releases, THE WHITE HOUSE, *Remarks by Vice President Harris at the Maternal Day of Action Summit* (Dec. 07, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/remarks-by-vice-president-harris-at-the-maternal-day-of-action-summit/.
[78] Preventing Maternal Deaths Reauthorization Act of 2023, H.R. 3838, 118th Cong. (2024).

changes and implementations that will promote more inclusiveness, specificity and an annual review, which will call for consistent issue spotting, will be influential to decrease maternal mortality rates. While this bill is sophisticated and, if turned into law, will provide great effects, with an addition for implementing automated scheduling, it would be more comprehensive. With healthcare made more readily accessible through automated scheduling, there would be an increase in regular screening and testing. Congressman Michael C. Burgess, M.D., Representative of Texas, is sponsoring this bill, as he is aiming to preserve maternal health and decrease maternal mortality rates. This country is facing a crisis, and with changes such as these ones, including the implementation of automated scheduling, Congressman Burgess's goals can be achieved.[79]

[79] *Burgess*, *supra* note 74.

Printing Life: Suggested Guidelines for 3D Printed Organs

Matthew Padilla

I. 3D PRINTED ORGANS IN A MODERN MEDICAL MARKET

The recent commercial availability of three-dimensional ("3D") printing technology has allowed for biological applications of the technology within food manufacturing, medical equipment, and synthetic organs.[1] Medical doctors all over the world are currently innovating ways to use 3D printed medical devices instead of regularly manufactured medical devices as they discover novel ways to use the technology for their patients.[2] Medical device manufacturers have also been inspired by this technology and are gearing up for mass production of synthetic and bio-organic devices using 3D printing technology.[3] While widespread adoption of synthetic human organs is still many years away, the regulatory guidelines that new medical technologies have received in the past is indicative of how 3D printed organs might be classified.[4] Most medical experts predict that 3D printed organs may be classified as medical devices.[5]

---

[1] Kat de Naoum, *3D Printing in Medicine and Healthcare*, XOMETRY (Aug. 27, 2024), https://www.xometry.com/resources/3d-printing/3d-printing-in-medicine-and-healthcare/ (discussing various medical applications of 3D printed medical technology).
[2] Marissa Fessenden, *3-D printed windpipe gives infant breath of life*, NATURE (May 28, 2013), https://www.nature.com/articles/nature.2013.13085.
[3] Deepa, *3D-Printed Medical Devices Industry Analysis and Companies Report (2023 – 2032)*, TOWARDS HEALTHCARE (May 2024), https://www.towardshealthcare.com/insights/3d-printed-medical-devices-market; *3D Bioprinting Market Grows At Rate Of 21% Supported By Rising Funding For Research As Per The Business Research Company's 3D Bioprinting Global Market Report 2021***,** GLOBE NEWS WIRE (Oct. 14, 2021 11:30 est), https://www.globenewswire.com/news-release/2021/10/14/2314512/0/en/3D-Bioprinting-Market-Grows-At-Rate-Of-21-Supported-By-Rising-Funding-For-Research-As-Per-The-Business-Research-Company-s-3D-Bioprinting-Global-Market-Report-2021.html.
[4] FDA, *Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP)* (2024), https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp.
[5] Jamil Ammar, *The 'Medical Mile' Gearing toward 3D-Bespoke Healthcare a Comparison of United States and European Union Patent Regimes*, 52 GONZ. L. REV. 279, 322-23 (2017) (discussing how 3D printed organs might be classified).

Since the United States Food and Drug Administration ("FDA") routinely oversees newly developed medical devices, it follows they would become the federal agency that oversees the introduction of 3D printed organs.[6] While the FDA has done an adequate job in regulating medical devices and ensuring manufacturers comply with their strict standards of quality, those standards should not be enough for living organ tissue and are currently not for naturally donated organs.[7] The Organ Procurement & Transplantation Network ("OPTN") is currently the federal agency that oversees organ donations and distributions and should be involved in the future regulation of synthetic organs.[8] However, even with their strict oversight, medical facilities routinely have to discard donated organs to meet the agencies' standards, potentially robbing a patient at a chance at life.[9] Medical devices, while helpful to prolong lives, are rarely made to the same complexity as a healthy human organ, and are held to an uncomfortably low standard for a person requiring a life risking organ transplant.[10]

---

[6] Jasper L. Tran, *The Law and 3D Printing,* 31 J. MARSHALL J. COMPUTER & INFO. L. 505**;** *supra* note 4.
[7] Elizabeth Kelly, *FDA Regulation of 3D-Printed Organs and Associated Ethical Challenges*, 166 U. PA. L. REV. 515 (2018).
[8] OPTN, History & NOTA (2024) (The OPTN is authorized by NOTA and is designated with contract by the HHS), CMS, Transplant (2024) (CMS acknowledges compliance with OPTN standards when reviewing organ transplantation compliance).
[9] Casey Ross, *Hospitals are throwing out organs and denying transplants to meet federal* standards, PBS NEWS (August 13, 2016, 9:52 AM), https://www.pbs.org/newshour/health/hospitals-throwing-organs-denying-transplants-meet-federal-standards.
[10] OPTN, *How organ allocation works*, https://optn.transplant.hrsa.gov/patients/about-transplantation/how-organ-allocation-works/ (last visited August 30, 2024); *Donor Selection Criteria,* UC DAVIS HEALTH, https://health.ucdavis.edu/transplant/livingkidneydonation/donor-selection-criteria.html (last visited August 30, 2024); Julian R. Jones, *Biomaterials, Artificial Organs, and Tissue Engineering*, SCI. DIRECT (2005) https://www.sciencedirect.com/science/article/abs/pii/B9781855737372500146; Kelly, *supra* note 7 (expands on specific FDA standards that could be considered problematic for synthethic organ transplants).

As no laws or regulations currently exist regarding 3D printed organs, when they become viable, a law should be made classifying them as a riskier type of medical device than what is currently allowed by the FDA and requiring bioprinted organs to be clinically tested before being made available for surgical use.[11] When the time comes for bioprinted organs to be comparable in function to human organs, regulation should be conducted alongside the OPTN, a contracted entity of the U.S. Department of Health & Human Services ("HHS").[12] This proposed law would not only ensure an adherence to higher standards, but also protect manufacturers from liability if the organs are properly created within the suggested guidelines.[13]

II. CURRENT MEDICAL PRINTING REGULATIONS AND ORGAN DONATION GUIDELINES

The applications of 3D printing for mass medical manufacturing are great for market prices, but create regulatory issues for health law and federal agencies.[14] The technology is predicted to be able to use cellular material to print entire organs and living tissue for use in transplants.[15] As with any medical technology, medical experts are eager to discuss what kind of route it will take in legal regulation and how one might come to profit from how it is regulated.[16]

---

[11] Katherine A. Smith, "*Transplanting" Organ Donors with Printers: The Legal and Ethical Implications of Manufacturing Organs*, 49 AKRON L. REV. 739, 766-67 (2016); FDA, Overview of Device Regulation (2024); Kelly, *supra* note 7.
[12] OPTN, About (2024), *supra* note 8.
[13] Tran, *supra* note 6.
[14] Deepa, *supra* note 3.
[15] *Id.*
[16] Shelly Simana, *Reflections on Bioprinting Law: How Should 3D-Bioprinted Organs Be Classified, and What Does It Mean to Treat Them as "Property"?*, STAN. L. BLOG (September 12, 2022), https://law.stanford.edu/2022/09/12/reflections-on-bioprinting-law-how-should-3d-bioprinted-organs-be-classified-and-what-does-it-mean-to-treat-them-as-property/.

Historically, medical device guidelines and their manufacturing are overseen by the FDA.[17] The FDA classifies medical devices on a three-Class scale and imposes guidelines depending on the level of risk associated with the use of the medical device in humans.[18] A Class I medical device is designated as low to no risk in its use, a Class II medical device represents a moderate risk in their use, while a Class III medical device is deemed high risk/experimental and are allowed only with the highest clinical scrutiny and premarket approval.[19] Alternatively, organic organ implantation and distribution is regulated by the OPTN,[20] and they not only oversee organ transplants in every state, they also also provide guidelines to hospitals to determine who qualifies to get the organs and how they should be used or not used.[21] Over time, donated organs have become scarcer, leading to extensive transplant lists, higher costs, and an implied emergence of discrimination in determining eligibility for implantation, although discrimination is currently hard to prove.[22] The problem with bioprinted organs will lie in whether the regulatory language will classify them as a device or an organ.[23]

III. REGULATORY UNCERTAINTY

[17] FDA, *supra* note 4.
[18] Amanda K. Sarata, *FDA Regulation of Medical Devices*, R47374 1, 1-3 (2023), https://crsreports.congress.gov/product/pdf/R/R47374.
[19] *Id.*
[20] OPTN, *supra* note 10.
[21] *Donor Selection Criteria,* UC DAVIS HEALTH, https://health.ucdavis.edu/transplant/livingkidneydonation/donor-selection-criteria.html (last visited August 30, 2024).
[22] Sara Reardon, *Push is on for states to ban organ transplant discrimination*, NBC NEWS (March 10, 2021, 2:30 AM CST), https://www.nbcnews.com/health/health-news/push-states-ban-organ-transplant-discrimination-n1259662; Ross, *supra* note 9.
[23] Tesh W. Dagne, *Governance of 3-D Printing Applications in Health: Between Regulated and Unregulated Innovation***,** 21 COLUM. SCI. & TECH. L. REV. 281 (2020).

At present, experts do not agree where 3D printed organs will end up in the legal landscape.[24] Most scholars suspect that 3D printed organs will be classified as medical devices owing to the use of synthetic material in manufacturing the organs.[25] Others have written that the FDA's current classifications for medical devices are out of scope for bioprinted organs and might open patent law issues as well philosophical concerns.[26] Additionally, classification of printed organs by the FDA, while synthetic, opens the door for discussion of an inevitable market for printed organ selling.[27] Elizabeth Kelly of the *University of Pennsylvania Law Review* cites the National Organ Transplant Act of 1984 ("NOTA") as a hurdle for an open organ market as the Act essentially makes selling organs a federal crime.[28] Furthermore, the language the OPTN uses only covers the current legal definition of human organs, and thus far do not have reason to change the language behind what constitutes a human organ, making any present regulation of bioprinted organs under the OPTN unclear.[29] With the introduction of manufactured tissue into the transplantation scene, a revision of the language behind both NOTA's and the OPTN's definition of "human organ" is necessary.[30]

IV. WILL THE FDA REGULATE?

The fears medical scholars pose are understandable, as this new medical device will essentially replace a vital human organ and is intended to keep a

---

[24] *Id.*; Kelly, *supra* note 7.
[25] Michael H. Park, *For a New Heart, Just Click Print: The Effect on Medical and Products Liability from 3D Printed Organs*, 2015 U. ILL. J.L. TECH. & POL'Y 187, 198 (2015).
[26] *Will Bioprinted Organs Be Regulated by the FDA Like Medical Devices?,* https://penrod.co/will-bioprinted-organs-be-regulated-by-the-fda-like-medical-devices/.
[27] Kelly, *supra* note 7.
[28] *Id.*; National Organ Transplant Act, S. 2048, 98th Cong. (1983).
[29] Linda Foit, *The Tin Man Needs a Heart: A Proposed Framework for the Regulation of Bioprinted Organs*, 90 FORDHAM L. REV. 2347, 2376 (2022).
[30] *Id.* at 2365 (The HHS is authorized by NOTA to expand the regulatory definition of a human organ).

person indefinitely alive.[31] Without strict regulation and clinical testing, any lack of scrutiny can allow for hardware defects and leave a person vulnerable to a crudely manufactured heart, lung, or kidney.[32] Cases like *Riegel v. Medtronic, Inc.* can be indicative of how medical devices can be preempted from litigation if they followed the correct FDA guidelines to gain entry into the medical marketplace.[33] However, this preemption could eventually create an opening for frivolous malpractice litigation due to the estimated ten percent failure rate of vital organ transplants, especially major ones, as patients begin to seek unclear avenues of legal action in vain.[34] If bioprinted organs are classified under the current medical device standards under the FDA, there is also a possibility the percentage of failed transplants may rise. Transplants would become a gamble for patients, not only hoping that their body accepts the organ, but that the entity that made the organ followed the approved manufacturing guidelines. Suddenly, a synthetic organ supplier cutting a corner in manufacturing could become a life-ending mistake for the patient seeking a necessary organ transplant and ultimately lose the device approval by the FDA.

At present, medical devices that are FDA approved are not tested individually.[35] They are manufactured in bulk and the FDA simply trusts the manufacturing process once it has been approved.[36] Currently, there are over

---

[31] Tim Lewis, *Could 3D printing solve the organ transplant shortage?*, THE GUARDIAN (July 30, 2017 3:30 EDT), https://www.theguardian.com/technology/2017/jul/30/will-3d-printing-solve-the-organ-transplant-shortage.
[32] Brooke Becher, *3D-Printed Organs: Are We Close?*, builtin (Aug. 28, 2024), https://builtin.com/articles/3d-printed-organs.
[33] *Riegel v. Medtronic, Inc*., 552 U.S. 312, 319 (2008).
[34] *Outcome Measures for Organ Transplantation*, UC SAN DIEGO HEALTH, https://health.ucsd.edu/care/transplant-programs/quality/ (last visited Sept. 19, 2024) (vital organs include heart, kidney, lung, and liver).
[35] FDA, Overview of Device Regulation (2024).
[36] *Id.* (While devices are generally trusted once the FDA approves them, the agency still regularly inspects their facilities for compliance with regulatory language).

two million defective medical devices reported to the FDA each year that have resulted in a device related death or injury.[37] With the introduction of organic medical devices that essentially replace a vital organ, this number has a chance to go up exponentially, increasing the chance of liability. Without a proper definition or preemption amendment to include manufactured bio tissue, it is highly likely that medical malpractice suits will increase. This hike will most likely be attributed to both the estimated ten percent failure of natural organs reported by some medical centers and the large number of defective medical devices reported to the FDA each year.[38] Likewise, development of the technology could lead to a legal/regulatory issue in the future if bioprinted organs become virtually indistinguishable to regular human organs in how they function.[39] This could create potential legal avenues for patients seeking action against an organ printer and for manufacturers seeking protection from liability while also creating further affordability issues for a patient seeking an already expensive and legally risky synthetic organ.[40]

V. NEW FDA CLASSIFICATION AND INTERDEPARTMENTAL COOPERATION

Solutions proposed by legal scholars call for stricter scrutiny of 3D bioprinted products as the technology develops.[41] One example of this is

---

[37] FDA, MDR Data Files (2024), https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files.
[38] *Id.*; *Outcome Measures for Organ Transplantation*, *supra* note 34.
[39] Lindsay Brownell, *3D-printed blood vessels bring artificial organs closer to reality*, WYSS INST. (Aug. 7, 2024), https://wyss.harvard.edu/news/3d-printed-blood-vessels-bring-artificial-organs-closer-to-reality/ ("This vascular architecture closely mimics that of naturally occurring blood vessels and represents significant progress toward being able to manufacture implantable human organs.").
[40] Kristen Rogers, *When we'll be able to 3D-print organs and who will be able to afford them*, CNN HEALTH (Mar. 10, 2023, 10:40 AM), https://www.cnn.com/2022/06/10/health/3d-printed-organs-bioprinting-life-itself-wellness-scn/index.html.
[41] Foit, *supra* note 29.

illustrated in an article by Linda Foit in the *Fordham Law Review*, who called for entirely new offices within the FDA itself to oversee the manufacturing and distribution of synthetic organs, a "Center for Bioprinted Organs."[42] Others speculate that classification under the current standards of the FDA would pair well with the current state of 3D bioprinting technology as it emerges due to their competence in handling other higher risk medical devices such as the artificial heart.[43] A solution to bioprinting regulation does not require sweeping industry reform or even new government offices to oversee the technology. The bodies that govern medical technologies and organ procurement already work, but they could benefit from the addition of specific language that includes synthetic organs to eliminate any regulatory confusion surrounding classification when it becomes feasible. Nonetheless, while FDA guidelines are effective in classifying most medical devices, for an emerging technology such as bioprinted organs, the present controls in place for a highly dangerous medical device would not be effective.

Current Class III protections require premarket approval and general controls for its classified medical devices.[44] General controls simply mean an adherence to "basic provisions (authorities) of the May 28, 1976 Medical Device Amendments (hereafter referred to as the Amendments) to the Federal Food, Drug and Cosmetic Act, that provide the FDA with the means of regulating devices to ensure their safety and effectiveness."[45] Premarket approval ("PMA"), itself, is a lengthy, rigorous process which may require annual reporting to maintain PMA.[46] Once the FDA approves the device under Class III, the manufacturer cannot deviate from the approved process

---

[42] *Id*.
[43] Dagne, *supra* note 23.
[44] FDA, Classify Your Medical Device (2020); FDA, Premarket Approval (2019).
[45] FDA, General Controls for Medical Devices (2023).
[46] FDA, Annual Reports for Approved Premarket Approval Applications (PMA) (2019); FDA, *supra* note 44.

or they risk having to supplement their already lengthy PMA along with annual reporting, which adds extra safety costs.[47] While rigorous to meet, this standard is currently not enough for the introduction of untested manufactured organs into the medical marketplace.

Over time, the standards for FDA market approval have become simpler to satisfy and most regulatory decisions for innovative devices are made only after the device has been introduced into the market using post approval data collection to maintain approval, a move that has been backed by Congress.[48] Following the Humanitarian Device Exemption Act of 1990, Congress has increasingly expanded exemptions to premarket review.[49] Congress created such an exemption in 1997 which "created a streamlined "de novo" pathway for novel devices thought to not be high-risk, and directed FDA to require the "least burdensome" means of satisfying regulatory standards."[50] This approach was later reinforced in 2016 by the 21st Century Cures Act, which encouraged post-approval data collection to circumvent some premarket approval requirements.[51] This Act also created a Breakthrough Devices Program under the FDA meant to allow moderate risk medical devices leniency in the name of scientific innovation.[52] Meaning, under the current laws, risky medical devices classified to be innovative by the FDA have a broader range to fail and suppliers are only encouraged to fix issues after a reported failure to keep de novo approval of their product.

---

[47] FDA, Modifications to Devices Subject to Premarket Approval (PMA) (2008) - The PMA Supplement Decision-Making Process; *Id.*
[48] Darrow et al., *Changing FDA Approval Standards: Ethical Implications for Patient Consent*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8029608/pdf/11606_2021_Article_6762.
[49] *Id.*; FDA, Humanitarian Device Exemption (2022).
[50] Darrow, *supra* note 48.
[51] *Id.*; FDA, 21st Century Cures Act (2020).
[52] FDA, Breakthrough Devices Program (2024); FDA, *supra* note 51.

Simpler standards are a dangerous implication for a medical device meant to replace entire organ systems in a patient. Due to the potential danger in synthetic organs being able to meet simpler standards, those organs should be classified no lower than Class III and the following changes to the laws should be made: First, the FDA should create a Class IV risk medical device guideline and classify synthetic organs as such. Second, the regulatory language around the legal term "organ" should be changed by the HHS to better reflect the modern technology developing. Third, the FDA should collaborate with the OPTN in the distribution of 3D printed organs.

Full disclosure of medical risk and a temporary waiving of a right of action is essential to protect patients' rights and the feasibility of synthetic organs as legitimate medical device. Accordingly, the FDA should classify them as a higher risk medical device – a Class IV medical device. This new classification would have the special controls of Class II, an added addition to Class I general controls, that adheres to any amendments to the definition of the word 'organ' and the premarket approval condition of Class III.[53] This premarket approval will have new added protections (special controls) of testing the device before transplantation into a human host and a committee that analyzes deaths/injuries surrounding synthetic organ use.[54] Should the organ pass initial protections, but later fail in injury analysis, the patient would be allowed to pursue litigation against the responsible party.[55]

In the spirit of developing the technology, the FDA should initially oversee synthetic organ implantation. A patient opting in to use this kind of device would be told the risks associated with experimental medical technology by

---

[53] FDA, Class II Special Controls Documents (2022) (special controls carry the same general controls outlined by the FDA but require addressing a specific risk before market approval); FDA, *supra* note 44.

[54] *Id.*

[55] *Defective Medical Device: Do You Have a Case?*, https://www.spencelawyers.com/firm-news/defective-medical-device-do-you-have-a-case (Aug. 23, 2023).

a doctor and have it implanted as a form of clinical trial.[56] Likewise a Class IV medical device would be barred from eligibility as a Breakthrough Device under the FDA, which would also bar the device from being able to apply for de novo approval.[57] Allowing for de novo preapproval under Class IV would give initial manufacturers room to fail without fearing loss of FDA approval, a leniency patients seeking new synthetic organs to replace their old ones would hardly consent to.

When bioprinted organs eventually become medically comparable to naturally donated organs, regulation of the devices should be overseen by the OPTN. To prevent initial regulatory confusion, the language used by the OPTN, HRSA, and the HHS to define organ should be expanded to include 3D printed organs. This can be accomplished by amending the language in NOTA's Section 301 and the OPTN's Section 121.13 to include synthetic organs similarly to how the HHS amended the definition in 2013 to include modern treatments that help replace natural organs.[58] Currently the regulatory language of the OPTN reads ""Human organ," as covered by section 301 of the National Organ Transplant Act, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow and other hematopoietic stem/progenitor cells without regard to the method of their collection, cornea, eye, bone skin, and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract."[59] This amendment would add the following language

---

[56] Marston & Bugin, *FDA Promotes Clinical Trial Innovation*, FDA (May 20, 2024), https://www.fda.gov/news-events/fda-voices/fda-promotes-clinical-trial-innovation; Katherine A. Smith, "*Transplanting" Organ Donors with Printers: The Legal and Ethical Implications of Manufacturing Organs*, 49 AKRON L. REV. 739, 766-67 (2016).
[57] FDA, *supra* note 52.
[58] Organ Procurement and Transplantation Network, 78 Fed. Reg. 40,033 (July 3, 2013) (to be codified 42 C.F.R. pt. 121); Foit, *supra* note 29.
[59] Change to the Definition of "Human Organ" Under Section 301 of the National Organ Transplant Act of 1984**,** 78 Fed. Reg. 60,810 (Oct. 2, 2013) (to be codified at 42 C.F.R. pt. 121).

"Any medical device that could be classified as a synthetic organ, without regard to manufacturing process, will be overseen by the FDA until medically indistinguishable from a naturally procured organ. When that occurs, regulation will happen interdepartmentally between the OPTN and FDA." Changing the necessary language would coincide with an ongoing interdepartmental working relationship between the FDA and OPTN.

The FDA will oversee manufacturing while the OPTN will oversee distribution and testing. The OPTN already has guidelines and databanks in place for where human organs should go and how they should be distributed to hospitals.[60] Additionally, the agency already has guidelines for how hospitals should manage and request organs.[61] As the FDA is a large department, it is assumed that regulation of such a huge technology along with individual testing of every printed organ will significantly affect how many resources it can dedicate to a singular technology.[62] Currently, the FDA is funded both by tax dollars and user fees, however, with the implementation of individually tested medical devices, the agency's already dwindling funds and manpower might grow thinner, further limiting their intervention in other important areas such as drugs and food.[63] If supervision of synthetic organs distribution is eventually given to the OPTN, printed organs can be given the regulatory attention required to be truly effective in the marketplace.

VI. FUTURE IMPACT OF BIOPRINTING ORGANS

---

[60] OPTN, Guidance (last visited Oct. 11, 2024).
[61] *Id.*
[62] Hernandez & White, *The FDA's weak drug manufacturing oversight is a potentially deadly problem*, THE CONVERSATION (June 23, 2021), https://theconversation.com/the-fdas-weak-drug-manufacturing-oversight-is-a-potentially-deadly-problem-162898; Mary Clare Jalonick, *Report Finds FDA Is 'Stretched Thin'*, MANUFACTURING.NET (June 8, 2010), https://www.manufacturing.net/operations/news/13074474/report-finds-fda-is-stretched-thin.
[63] C. Michael White, *Why is the FDA Funded in Part by the Companies It Regulates?*, UCONN TODAY (May 21, 2021), https://today.uconn.edu/2021/05/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-2/.

The use of existing and new FDA resources in the regulation of 3D printed organs would make adding a stricter Class IV classification financially viable and allow the organs to be classified speedily.[64] Currently, it only takes about a year or so for a Class III medical device to be approved, with the timeline getting only slightly longer as the agency has tweaked premarket approval and has more to regulate.[65] Along with an increased budget, a new Class with only one initial technology to oversee would most likely make this process occur faster. While synthetic organs are overseen by the FDA, the technology can be allowed to flourish without being bogged down by frivolous litigation. Because there will be an opt-in only approach, patients would be required to sign a temporary waiver of rights to be transplanted with one of these Class IV medical devices, then have similar litigation options to Class III medical devices once the technology ceases to be overly experimental. Additionally, organ transplant lists should vacate and open slots for those who might need or want a naturally donated organ and have time to wait. Those who otherwise would not be able to wait would have a viable means to attempt to save their lives and/or improve their quality of life.

This solution will also have a broader impact on how organs are procured. Human organs are presently procured through the HRSA's OPTN agency.[66] The introduction of these organs can eliminate two problems plaguing organ procurement: organ black markets and lack of a legal open market. Black

---

[64] FDA, FDA Seeks $7.2 Billion to Enhance Food Safety and Nutrition, Advance Medical Product Safety, and Strengthen Public Health (2024), https://www.fda.gov/news-events/press-announcements/fda-seeks-72-billion-enhance-food-safety-and-nutrition-advance-medical-product-safety-and-strengthen (refering to money for these proposed guidelines which would come from this $7.2 billion should the FDA be granted the sum).
[65] FDA, PMA Approvals (2024), https://www.fda.gov/medical-devices/device-approvals-and-clearances/pma-approvals (stating that the length of time is inferred as preamendment requirements took long longer than a year but added supplements prolong approval and redoing notices takes significant time).
[66] OPTN, *supra* note 8; Organ Donation Legislation and Policy (2021), https://www.organdonor.gov/about-us/legislation-policy.

markets for human organ selling have seen an inferred increase in trend in the past couple of years.[67] Human transplant organs have only gotten rarer with time, and as that scarcity increases so does the demand for them.[68] A major reason Congress passed NOTA in 1984 was to directly address a shortage in organs used for transplantation.[69] Currently, organ supply still does not meet demand, and regulatory guidelines have only gotten tighter because they have become such a precious resource.[70] If the FDA is allowed to regulate the manufacturing of 3D printed organs, supply will begin to meet demand. Synthetic organs will eventually enter the medical market and be sold to hospitals in bulk as with any other medical device, effectively erasing the need for a black market for human organs. The market will face some adaptation time and printed organs might be very expensive at first, but as more medical manufacturers begin printing, they could become less expensive. Notably, there are also significant negative ethical implications of selling organs in a legal market and that might lead to extensive regulatory issues, but there is already bioprinted tissue on the market that can be used as a precursor guideline.[71] Significantly, NOTA's Section 301 is also the section that criminalizes the selling of human organs with a fine of up to $50,000 and five years in prison.[72] However, as mentioned previously, the HHS has the power to change the definition in Section 301 and most likely

---

[67] *Organ Trafficking: The Unseen Form of Human Trafficking*, ACAMS TODAY (June 26, 2018), https://www.acamstoday.org/organ-trafficking-the-unseen-form-of-human-trafficking/.
[68] *Id.*
[69] Foit, *supra* note 29.
[70] Ross, *supra* note 9.
[71] Rhiannon Williams, *3D printing human tissue and organs to 'spark ethics debate'*, THE TELEGRAPH (Jan. 29, 2014, 10:41 AM), https://www.telegraph.co.uk/technology/news/10604035/3D-printing-human-tissue-and-organs-to-spark-ethics-debate.html; Smith, *supra* note 56.
[72] Change to the Definition of "Human Organ" Under Section 301 of the National Organ Transplant Act of 1984, *supra* note 59.

will should an ethically viable manufacturing process arise that allows entities to sell organ like devices be introduced by the FDA.[73]

While the technology is regulated by the FDA, it can be allowed to flourish and gain commercial viability but can potentially create another problem. The market could become oversaturated by substantial equivalents through the 510(k) approval process, allowing for a chance at a lower FDA classification and loss in quality.[74] To curtail this loss in quality, testing and distribution should eventually be overseen by the OPTN as this solution outlines.[75] While the agency has been scrutinized in the past for how it handles organs and its growing strict guidelines, this is because of the rarity of donated human organs.[76] At present, organs are only tested for transferable diseases and compatibility before they are transplanted into a patient.[77] Healthy organs from a healthy donor are expected to work, the problem comes in the body rejecting the organs.[78] Implementing organ testing within the OPTN may allow manufactures to not worry about being sued for a faulty synthetic organ, and ease the mind of patients. This change could erase market liability and instead allow it to flourish with synthetic organs that are expected to meet the standard of both FDA regulations and OPTN regulations, as well as stay in compliance with NOTA.

VII. CONCLUSION

---

[73] *Id.*
[74] FDA, Premarket Notification 510(k) (2024).
[75] Carolyn Barber, *3D-printed organs may soon be a reality. 'Looking ahead, we'll not need donor hearts'*, FORTUNE WELL (Feb. 15, 2023, 5:00 PM), https://fortune.com/well/2023/02/15/3d-printed-organs-may-soon-be-a-reality/; Rogers, *supra* note 40.
[76] Ross, *supra* note 9.
[77] CDC, Transplant Safety (2024).
[78] Becher, *supra* note 32.

The technology of 3D printed organs should be allowed to develop without manufacturers worrying about superfluous litigation due to regulatory mismanagement. While the FDA is seemingly going to be the federal agency that oversees the initial development, distribution, and marketability of 3D printed organs, this does not mean that they should be the only agency involved nor should they be expected to regulate this technology on their own forever. As synthetic and human organs become more and more indistinguishable from each other, the OPTN should be utilized to test, regulate, and distribute organs to patients as they have been doing so for decades. This leaves the FDA with the familiar task of overseeing manufacturing, allowing the agency some breathing room without stretching itself too thin in resources.

Eventually, a legal synthetic organ market overseen by both the FDA and the OPTN should be allowed by NOTA in the medical marketplace to allow further scientific progress into the technology, disable human organ black markets, and create viable financial return for both manufacturers and patients. While this new technology's classification is complicated, the current structures in place are almost satisfactory to oversee the development of organ printing technology and only minor amendments to the current regulatory language are necessary to ensure this miracle technology is overseen by the right people as it comes into the medical device market.

Reverse Payment Settlements Applied to Biosimilars: A Proposed New Standard and Greater Anti-Trust Enforcement Mechanisms

Christina Ramesh

I. INTRODUCING BIOSIMILARS IN THE CONTEXT OF REVERSE PAYMENT SETTLEMENTS

Biologics have been prevalent over the past few decades, establishing themselves as a multifaceted treatment option.[1] More recently, biologics have been used to treat cancer through immunotherapeutic drugs, which have accounted for one-third of all new medicine approvals.[2] As patents for biologic drugs have expired over the past decade, a new class of drugs, biosimilars, has emerged.[3] Biosimilars provide an affordable alternative for patient-consumers, yet legal barriers persist, particularly due to the high costs of settling infringement suits in a manner that delays market entry for biosimilars.[4] This practice is known as reverse payment settlements.[5]

This article will discuss how the *Federal Trade Commission v. Actavis* ("Actavis") holding and subsequent legal authorities on reverse payment settlements have affected the delay of biosimilars into the market. Subsequently, this article will explore the differences between generics and biosimilars supporting the assertion that they should be treated differently in

---

[1] U.S. Food & Drug Admin., *Biosimilar Basics for Patients* (Aug. 1, 2024), https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients.
[2] David L Carl et al., *Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland*, 12 JAMA NETWORK OPEN 1, 2 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9719051/.
[3] U.S. Food & Drug Admin., *supra* note 1.
[4] *Id.*; Damien Geradin & Douglas Ginsburg, et al., *Reverse Payment Patent Settlements in the European Union and the United States*, GEO. MASON U. L. & ECON. RESEARCH PAPER SERIES, 1, 2 https://www.law.gmu.edu/assets/files/publications/working_papers/LS1522.pdf (last visited Nov. 10, 2024).
[5] *Id.*

the anti-trust landscape of reverse payment settlements.[6] Further, this article will advocate for a different standard for settlement agreements between biologic and biosimilar companies and further contemplate additional regulatory oversight such as requiring companies to file an economic impact analysis with the Federal Trade Commission ("FTC"), Department of Justice ("DOJ"), and Patent Trial and Appeal Board ("PTAB").

II. AN OVERVIEW OF THE LEGAL LANDSCAPE OF REVERSE PAYMENT SETTLEMENTS

Biosimilar drugs are marketed at a lower cost compared to its reference biologic drug, effectively providing patients greater access to life saving medicine.[7] A recent study concluded that the relative prices of biosimilars were fifty-five percent to nine-hundred percent lower than the reference biologic.[8] This is largely due to biosimilars spurring market competition, meaning patients are provided treatment options at reduced costs.[9] With biosimilars marketed at a reduced cost, insurance companies are more likely to cover these types of drugs.[10] Insurance coverage is the gateway for access to biosimilars for many patients, as it may be the only way that some patients can afford them.[11]

The rate at which biosimilars enter the market is significantly lower than their approval rate.[12] The first biosimilar approved by the Food and Drug

---

[6] *See Infra* section II, *Actavis* settled the question of whether reverse payment settlements inherently violated anti-trust laws, to which the court responded that they do not. Lower courts must use Actavis' factor test to determine whether reverse payment settlements violate anti-trust laws.

[7] David L Carl et al., *supra* note 2, at 5.

[8] *Id.*

[9] *Id.* at 8.

[10] U.S. Food & Drug Admin., *supra* note 1.

[11] U.S. Food & Drug Admin., 9 Things to Know About Biosimilars and Interchangeable Biosimilars, https://www.fda.gov/drugs/things-know-about/9-things-know-about-biosimilars-and-interchangeable-biosimilars.

[12] David L Carl et al., *supra* note 2, at 7.

Administration (FDA) and to enter the United States market was in 2015.[13] Since then, fifty-nine other biosimilars have been approved, yet only forty-one biosimilars have launched into the United States market.[14] Subsequently, to combat delayed market entry, Congress created the regulatory approval pathway for biosimilars established via the Biologics Competition and Innovations Act of 2009.[15] The Act provides an abbreviated approval process for market entry of biosimilars by creating five requirements.[16] First, a biologic must be biosimilar to a reference product and the reference product must be a biologic that was previously FDA approved.[17] This creates the standard that biosimilars have no meaningful difference in terms of safety, efficacy, or purity with the biologic reference product.[18]

Although this abbreviated pathway effectively reduces the time for biosimilar entry into the market and saves patients money, reverse payment settlements can counteract this progress.[19] Reverse payment settlements, in the context of biologic and biosimilar infringement lawsuits, encompasses a biologic company paying a large settlement agreement to the biosimilar company in return for the biosimilar company delaying their drug from market entry.[20] The payment transferred from the biologic company to the

---

[13] Lisa A. Raedler, *Zarxio: First Biosimilar Approved in the United States*, 9 AM. HEALTH DRUG BENEFITS 150 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5013845/#R4.
[14] U.S. FOOD & DRUG ADMIN., *Biosimilar Product Information* (Aug. 6, 2024), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information; https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-sep24.pdf.
[15] Biologics Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001, 124 Stat. 119, 804-35 (2010).
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] David L Carl et al., *supra* note 2, at 7.
[20] Damien Geradin & Douglas Ginsburg, et al., *Reverse Payment Patent Settlements in the European Union and the United States*, GEO. MASON U. L. & ECON. RESEARCH PAPER SERIES, 1, 2, https://www.law.gmu.edu/assets/files/publications/working_papers/LS1522.pdf (last visited Nov. 10, 2024).

biosimilar company can be actual costs, which are typically identified as court costs and fees, or can be a value transferred, such as allowing a biosimilar company to sell their drug in a market other than the US.[21]

The landmark Supreme Court case, *Actavis*, established a framework for identifying when reverse payment settlements are anti-competitive or lack anti-competitive concerns.[22] In *Actavis*, the Court held that the FTC may find that these reverse payment patent settlements violate Federal Anti-Trust laws, but that it is not presumed to do so and as such may be reviewed under a "rule by reason" analysis.[23] The Court laid out certain factors that lower courts may use to assess whether a reverse settlement payment violates anti-trust laws.[24] These factors include: the settlement's size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification outside paying to delay market entry.[25]

Reverse settlement agreements were largely going undetected because of the inability for enforcement personnel to attain access to the settlement agreements.[26] In response, Congress and federal agencies have created mechanisms to attain access to certain settlement agreements to help understand whether the payment or transfer or value is anti-competitive.[27] The Patient Right to Know Act ("PRKA") is a congressional directive

---

[21] Traci Aoki, *The Problem of Reverse Payments in the Pharmaceutical Industry Following Actavis*, 67 HASTINGS L. J. 259, 277 (2015), https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=1041&context=hastings_law_journal.

[22] FTC v. Actavis, Inc., 570 U.S. 136, 152 (2013).

[23] *Id.*

[24] *Id*.

[25] *Id.*

[26] FEDERAL TRADE COMMISSION, *MMA Reports: No Tricks or Treats-Just Facts*, (Oct. 27, 2020), https://www.ftc.gov/enforcement/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts.

[27] FEDERAL TRADE COMMISSION, *Patient Right to Know Drug Prices Act,* https://www.ftc.gov/legal-library/browse/statutes/patient-right-know-drug-prices-act (last visited Sept. 9, 2024).

requiring certain agreements involving biosimilar and biological drugs to be filed with the antitrust agencies, the FTC and the DOJ.[28] Additionally, the United States Patent and Trademark Office ("USPTO") recently filed a notice of proposed rulemaking that would expand the requirement of filing settlement agreements with the USPTO to settlement agreements that not only occurred after the trial proceedings, but also that occurred prior to the trial proceedings termination.[29]

III. THE MISCONCEPTION OF TREATING BIOSIMILARS AND GENERICS SIMILARLY IN THE CONTEXT OF REVERSE PAYMENT SETTLEMENTS

Actavis is widely known to apply to reverse payment settlements of lawsuits between a drug manufacturer and a generic manufacturer. But whether *Actavis* extends to reverse payment settlements of lawsuits between biologic manufacturers and biosimilar manufacturers was not directly addressed by the Court.[30] Thus, this prompts the question of whether *Actavis* applies to reverse payment settlements of lawsuits between biologic manufacturers and biosimilar manufacturers.[31] This is supported by the lack of attention by the *Actavis* court to address reference product versus biosimilar lawsuits.[32] This lack of attention could be because the first biosimilar that entered the United States market was in 2015, two years after

---

[28] *Id.*

[29] Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 77 (to be codified at 37 C.F.R. pt. 42).

[30] FTC v. Actavis, Inc., 570 U.S. 136, 152 (2013); Laura Karas, Rachel Sachs & Gerald Anderson, *Legal Obstacles to Biosimilar Market Entry,* BOS. CONG. PUB. HEALTH REV. (2021), https://bcphr.org/28-article-laura/.

[31] Laura Karas, Rachel Sachs & Gerald Anderson, *Legal Obstacles to Biosimilar Market Entry,* BOS. CONG. PUB. HEALTH REV. (2021), https://bcphr.org/28-article-laura/.

[32] *See generally* FTC v. Actavis, Inc., 570 U.S. 136 (2013).

the *Actavis* case was decided.[33] Although the holding of the *Actavis* case is "reverse payment settlements in patent infringement litigation can sometimes violate the antitrust laws," the Court could not have considered biosimilars in its decision.[34] Regardless, lower courts have applied the *Actavis* "rule by reason" analysis to reverse payment settlements in biologic versus biosimilar infringement suits.[35]

The "rule by reason" framework should not apply to reference product versus biosimilar lawsuits for a variety of reasons. Patent thicketing, a process by which a pharmaceutical company can file multiple patents over a single drug which often overlap which each other, is more prevalent over biologics than small molecule drugs.[36] With a vast number of primary and overlapping patents over a biologic, there is a greater difficulty for biosimilar drug companies to contest patents that are improperly listed.[37] Additionally, the statutory exclusivity period for a biosimilar is twelve years, compared to five years for a single molecular drug.[38] This period will prevent companies from attempting to create a biosimilar from having earlier access to the data needed to establish a biosimilar to being "highly similar" to the biologic.[39] Thus, pharmaceutical companies that create biosimilars are already disincentivized to produce cost reducing versions of biologic drugs.

---

[33] Raedler, *supra* note 13.
[34] *See generally* FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[35] O'MELVENY & MYERS LLP, *Reverse-Payment Claims Fail at the Second Circuit in Latest Case to Assess Pleading Standards Under FTC v. Actavis* (May 22, 2024), https://www.omm.com/insights/alerts-publications/reverse-payment-claims-fail-at-the-second-circuit-in-latest-case-to-assess-pleading-standards-under-ftc-v-actavis/.
[36] Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93 (2020).
[37] *Id.*
[38] THE PEW CHARITABLE TRUSTS, *Policy Proposal: Reducing the Exclusivity Period for Biologic Products* (Sept. 8, 2017), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/09/policy-proposal-reducing-the-exclusivity-period-for-biological-products.
[39] *Id.*

Additionally, a study from 2021 showed that the effects of biosimilar competition is greater than the effects of generic competition.[40] When biosimilars were first admitted into the United States market, the lack of price competition with other biosimilars limited its ability to have significant price cuts.[41] It was only after several years that biosimilars reached a higher average price cut.[42] On average, generic drugs are eighty-five percent cheaper than their brand name counterparts, while biosimilar drugs are thirty percent cheaper than their biologic equivalents.[43] Though generic drugs are marketed at a significantly lower cost than their brand name, the price cut yields a lower cost savings compared to biosimilars.[44] A thirty percent price reduction for a biologic yields about $665 in savings.[45]

Though the congressional mandate of pharmaceutical companies filing certain agreements with the FTC, DOJ, and USPTO, has helped reduce anti-competitive reverse payment agreements, there remain issues with the burden of proof being placed on the plaintiff.[46] A recent decision before the Commission portrays this problem. In 2023, the FTC issued a complaint against Amgen Inc., but it was dismissed on summary judgment.[47] The Commission reasoned that since the approval process for biosimilars is more

---

[40] LEONARD D. SCHAEFFER CTR. FOR HEALTH POL'Y & ECON., *Biosimilars Competition Helps Patients More Than Generic Competition* (Oct. 8, 2021), https://healthpolicy.usc.edu/article/biosimilars-competition-helps-patients-more-than-generic-competition/.
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] FEDERAL TRADE COMMISSION, *FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (Dec. 3, 2020), https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent-settlements-generic-competitors.
[47] *Id.*

complex and that negotiation between the biologic company and biosimilar company is lengthy, the FTC had to show that the agreement would harm consumers in a substantial way.[48] The Commission in this case presumed a higher burden on the FTC, yet the FTC's enforcement authority has generally remained the same since the past decade.

IV. THE UNIQUE EFFECTS OF REVERSE PAYMENT SETTLEMENTS ON BIOSIMILAR MARKET ENTRY

The anti-competitive lens in the *Actavis* case provides a limited perspective on the issue of reverse payment settlements for biologic and biosimilar infringement suits. It effectively minimizes the immense impact these agreements have on patient consumers by perpetuating the unfortunate cycle that certain medication in the United States are outside the economic reach of many patients.[49] Biologics cost around $100,000 annually and either insurance coverage is limited or the premium and deductibles are raised to costs that are unattainable for patients to pay.[50] Hence why these out-of-pocket costs are causing patients to be reluctant to seek out the medicine they need, further delaying the use of preventative medicine.[51]

This issue becomes more relevant when acknowledging that several biosimilars are expected to enter the market in a few years with the potential for being delayed by anti-competitive reverse payment settlements.[52] This is illustrated by the controversy surrounding the drug Humira and its associated

---

[48] *Id.*
[49] Victor L. Van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation*, HEALTH AFF'S (Aug. 2021), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02484.
[50] *Id*.
[51] *Id*.
[52] IQVIA INST., *Biosimilars in the United States 2023-2027* (Jan. 31, 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

patents that expired.[53] AbbVie, the producer of Humira, entered into a settlement agreement with Amgen, Sandoz, and Bioepis, large biotech companies that created biosimilars of the Humira drug.[54] This agreement was contingent on these biotech companies delaying the entry of their biosimilars in the United States in return for them to sell these biosimilars in the European Union market instead.[55] The Northern District Court of Illinois held that this settlement agreement did not constitute a reverse payment settlement agreement violating anti-trust laws; rather, the Court characterized the payment as an "early entry," meaning that the drug was admittedly delayed but was allowed to enter the market earlier than the exclusivity period ends.[56] Yet, without this settlement agreement, the biosimilars created by Amgen, Sandoz, and Bioepis would have entered the United States market five years prior to when they did, if the underlying patents were invalid.[57]

The Supreme Court's holding in *Actavis* creates a disadvantage for the market entry of biosimilars involved with reverse patent settlements.[58] Biosimilars are more expensive than generic drugs and a court applying the "rule by reason" framework may have to find that a higher settlement payment constitutes a reverse patent settlement that violates anti-trust laws.[59]

---

[53] *In Re: Humira Antitrust Litigation*, Memorandum Opinion and Order, No. 19 CV 1873 (N.D. Ill. June 8, 2020), https://images.law.com/contrib/content/uploads/documents/398/55864/In-re-Humira-antitrust-litigation.Shah-order.pdf.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] Michele B. Kaufman, *First Biosimilar to Adalimumab (Humira) Enters the U.S. Market After Years of Legal Battles*, AM. COLL. RHEUMATOLOGY (Mar. 2023), https://www.the-rheumatologist.org/article/first-biosimilar-to-adalimumab-enters-the-u-s-market-after-years-of-legal-battles/.
[58] *See generally* FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[59] Kirke M. Hasson, *Biosimilars Enter the Courts: How Will Patent Infringement Settlements Be Tested For Validity Under Antitrust Laws*, PILLSBURY WINTHROP SHAW PITTMAN LLP (Dec. 2016), https://www.pillsburylaw.com/a/web/109239/109239.pdf.

By requiring a higher payment, a smaller reverse settlement payment with the potential intent to delay a biosimilar into the market will go unnoticed.[60] Additionally, because courts characterize early delay as merely an opportunity cost, the potential true intention behind it as a transfer of value for delay will go unnoticed.[61]

V. PROPOSED STANDARD FOR BIOSIMILAR SUITS AND THE NEED FOR HEIGHTENED ANTI-TRUST ENFORCEMENT MECHANISMS

A separate standard for analyzing whether a reverse payment settlement for a biologic and biosimilar infringement lawsuit constitutes a violation of anti-trust laws is warranted. The standard that should be implemented is one that directly answers whether the effect of the settlement agreement hinders competition rather than focusing on whether the pharmaceutical brand company intended to delay the biosimilar drug.[62] If the effect of the settlement agreement hinders competition, then the next step in the analysis should be whether there are alternative less restrictive settlement agreement options available for the parties.[63]

The Federal Trade Commission Act ("FTC Act") authorizes the FTC to prohibit unfair business practices that restrict competition.[64] Section 6(g) of the FTC Act includes a rulemaking provision which empowers the FTC to

---

[60] *Id.*
[61] Bret M. Dickey & Daniel L. Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. COMPETITION L. & ECON. 615, 618 (Aug. 2012), https://www.law.berkeley.edu/wp-content/uploads/2015/04/Dickey-Rubinfeld-Would-the-Per-Se-Treatment-of-Reverse-Payment-Settlements-Inhibit-Generic-Drug-Investment-2012.pdf.
[62] *Id.*
[63] *See* JONES DAY, *FTC Notches Win in Fifth Circuit Reverse Payment Patent Settlement Case* (Apr. 30, 2021), https://www.jonesday.com/en/insights/2021/04/ftc-notches-win-in-fifth-circuit-reverse-payment-case. (commission utilized a factor test to support their holding including that there must not be less restrictive ways to achieve those benefits of the settlement agreement executed).
[64] Federal Trade Commission Act, 15 U.S.C. §§ 41-68.

"make rules and regulations for the purpose of carrying out the provisions of the subchapter".[65] This broad rulemaking authority allows the FTC to define unfair or deceptive practices.[66] Additionally, under Section 18, the Commission is authorized to prescribe "rules which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce" within the meaning of Section 5(a)(1) of the Act.[67] The FTC has passed rules pursuant to this authorization in areas such as misleading gas labels and requiring octane rating to be included on gas pumps.[68] With both of these authorities, the FTC should issue a notice of proposed rulemaking defining reverse payments among biologic and biosimilar infringement suits that have anti-competitive affects to be an unfair and deceptive practice. This new standard would be contingent on whether the biologic and biosimilar companies can reach a similar agreement in ways that do not affect competition.

Subsequently, the FTC should use its full enforcement authority to determine whether a settlement agreement between a biologic and biosimilar company has anti-competitive effects.[69] The PRKA expanded the mandatory reporting of settlement agreements to include those between biologic and biosimilar companies.[70] The amendment defines the subject matter of the agreements that are within the scope of the mandatory reporting and also includes a provision that requires these companies to file additional

---

[65] *Id*.
[66] *Id.*
[67] *Id.*
[68] National Petroleum Refiners Ass'n v. FTC, 482 F.2d 672 (D.C. Cir. 1973).
[69] *See* Victor L. Van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation*, HEALTH AFF'S (Aug. 2021), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02484. (calling for stronger anti-trust enforcement mechanisms).
[70] Patient Right to Know Drug Prices Act, 42 U.S.C. § 2729 (2018).

agreements that are contingent or related to the original agreement.[71] Subsequently, the statute includes an agency rulemaking section that authorizes the FTC and the Attorney General to define terms used in the subtitle, exempt classes of person or agreements from the requirements of the subtitle, and prescribe other rules as may be necessary and appropriate to carry out the purposes of the subtitle.[72]

The purpose of the subtitle is not explicitly stated in the statute but Congress included a summary of the amended statute which can be used to discern congressional intent.[73] The summary states, "the bill also amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to apply certain antitrust filing requirements for generic drug applicants to biosimilar biological product applicants."[74] Thus, it can be inferred that the amendment was to curb anti-trust practices involving settlement agreements specifically within the confines of filing these settlement agreements. Additionally, Congress' requirement for "other agreements" is also an indicator that other documents are needed for the FTC and DOJ to discern if a settlement agreement is anti-competitive.[75] This broad purpose falls within the FTC's ability to promulgate a rule requiring the filing of an economic impact analysis, which the FTC should do.

The USPTO originally required that settlement agreements executed after a trial proceeding has initiated should be filed with the USPTO.[76] Recently, the USPTO published a Notice of Proposed Rulemaking that would expand

---

[71] *Id.*
[72] *Id.*
[73] *See* 115th Congress. *S.2554 - An act to ensure that health insurance issuers and group health plans do not prohibit pharmacy providers from providing certain information to enrollees*, Summary, https://www.congress.gov/bill/115th-congress/senate-bill/2554.
[74] *Id.*
[75] Patient Right to Know Drug Prices Act, 42 U.S.C. § 2729 (2018).
[76] Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 77 (to be codified at 37 C.F.R. pt. 42).

the required filing of settlement agreements to ones executed prior to a trial proceeding even beginning.[77] These settlement agreements may be shared with the FTC and DOJ for investigation purposes.[78] Accordingly, these pre-institution settlement agreements will help the FTC and DOJ in their investigative efforts but not without gaps.[79] Since these agreements are prior to the proceeding, parties will not have engaged in the discovery process, thus these anti-trust agencies may not have the full context needed to provide a thorough analysis and make the determination to request the companies to cease their settlement or pursue litigation.[80] To provide the FTC and DOJ with the full context that they need to assess if the settlement agreement has anti-competitive effects, the USPTO should include in their proposal a requirement for companies to also file additional agreements or documents that are contingent on the decision they made to settle the patent infringement suit just as seen in the PRKA.[81] As such, one of the required documents should be an economic impact analysis.

VI. EARLIER ACCESS TO BIOSIMILAR MEDICATION UNDER THE PROPOSED REGULATION

Applying a "rule by reason" analysis for biologic and biosimilar reverse payment settlements will allow courts to continue to justify the payments as opportunity costs, which under *Actavis*, are not inherently anti-competitive and rather fall under normal settlement practices.[82] Thus, biosimilar drugs will be delayed and patients will not be able to access lifesaving medicine at

---

[77] *Id.*
[78] *Id.*
[79] LAW360, *FTC Focus: What Access to Patent Settlements Would Mean* (Sept. 5, 2024), https://www.proskauer.com/pub/ftc-focus-what-access-to-patent-settlements-would-mean.
[80] *Id.*
[81] Patient Right to Know Drug Prices Act, 42 U.S.C. § 2729 (2018).
[82] Dickey & Rubinfeld, *supra* note 60.; FTC v. Actavis, Inc., 570 U.S. 136, 151-152 (2013).

a cost that they can afford, as seen with the drug Humira.[83] Comparatively, a standard that places greater emphasis on the effects of the reverse payment settlement will make it harder for biosimilars to be intentionally delayed into the market.[84] This pro-consumer standard tailored to biosimilars will enhance a patient's ability to choose the medicine they need at an affordable price.[85] Under this standard, if the FTC wants to file a suit against the brand name company and the biosimilar company, the only requirement it has to show the court is that the settlement agreement will delay market competition with biosimilars and that there are less restrictive alternative settlement options available to the parties. By requiring both, the FTC will strike a balance between protecting patients and protecting private company autonomy.

Countries and states are seeing the value in implementing laws that have some variation of per se violations to anti-trust laws.[86] The European Union has an approach that views reverse payment settlements as per object restrictions if the brand name company cannot explain any reason for the entry delay of generic or biosimilar other than a commercial interest not to engage in competition.[87] Additionally, California became the first state to make settlement agreements where the accused infringing applicant receives any value in exchange for delayed market entry presumptively anti-

---

[83] *In Re: Humira Antitrust Litigation*, *supra* note 53.
[84] Laura Karas, *Pharmaceutical "Pay-for-Delay" Reexamined: a Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L. J. 959, 969 (2020), https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=3896&context=hastings_law_journal.
[85] *Id.*
[86] Yi Yang, *Antitrust Review of Reverse Payment Agreements to Settle Patent Disputes: The Emerging Legal Landscape in Mainland China* (Nov. 27, 2023), https://www.cliffordchance.com/insights/resources/blogs/talking-tech/en/articles/2023/11/antitrust-review-of-reverse-payment-agreements-to-settle-patent-disputes.html.
[87] *Id.*

competitive.[88] Though a subsequent lawsuit to this California law held that California could only enforce this law for those settlement agreements negotiated, completed, or entered in California, the law has the effect of placing less financial burden on agencies for cases that are straightforward.[89] This is especially true in the context of biologic and biosimilar settlement agreements.

The FTC, DOJ, and USPTO should have access to an economic impact analysis conducted by the companies for them to have the necessary information to make a preliminary finding if the companies are engaging in anti-competitive practices. By having these documents early on, the FTC, DOJ, and USPTO can determine if they should use their limited resources to pursue litigation. Reasons such as the fact that, litigation is costly for the parties, courts typically favor settlement agreements, and litigation by a government agency places a cost burden on society, all favor the need for the FTC, DOJ, and USPTO to have access to an economic impact analysis prior to any antitrust proceeding.[90]

This proposal attempts to effectuate a fair balance between pharmaceutical companies and the FTC regarding the burden of proof for these anti-trust claim. The plaintiff carries the burden to show that the defendant's settlement agreement created harm to consumers, specifically that the

---

[88] Kevin Wallentine, *Shifting the Burden on Pay-For-Delay Challenges: Analyzing AB 824's Effects on Reverse Payment Settlements and Drug Costs*, 54 LOY. L.A. L. REV. 367, 369 (2020), https://digitalcommons.lmu.edu/cgi/viewcontent.cgi?article=3098&context=llr.

[89] Adam M. Acosta, Eric Grannon & Kathryn Jordan Mims, *Federal District Court Holds That California's Anti-Reverse Payment Law is Enforceable, But Only Against Settlements "Negotiated, Completed, or Entered" in California* (Mar. 1, 2020), https://www.whitecase.com/insight-alert/federal-district-court-holds-californias-anti-reverse-payment-law-enforceable-only.

[90] David M. Trubek et al., *The Costs of Ordinary Litigation*, 31 UCLA L. REV. 72 (1983), https://api.law.wisc.edu/repository-pdf/uwlaw-library-repository-omekav3/original/60102be8b498b4ce3ba9aab4ab7f14e4e810650e.pdf.

agreement directly resulted in higher prices for consumers or that it unjustifiably delayed market entry for the drug.[91] This burden generally favors defendants because of the complexity of biologic and biosimilar infringement suits.[92] This approach holds companies accountable to consider consumer patients when making decisions between themselves. It indirectly requires biologic and biosimilar companies to conduct an economic impact analysis before they decide to engage in reverse payment settlements, thereby minimizing the potential issue of pay-for-delay.

A conceivable response to this proposal is that it places too much of a burden for companies just for settling an agreement and may even deter settlement agreements. Yet, this proposal implements a few safeguards. The standard allows for companies to show that there are no least restrictive alternatives to the settlement agreement. Additionally, by engaging in informal notice and comment rulemaking in both stated proposed rules, companies will be able to voice their support or concerns with the proposal. This is a pathway for both the FTC and these companies affected to collaborate and find a balance between encouraging settlement agreements between companies but also protecting patient consumers.

VII. CONCLUSION

The *Actavis* holding should not apply to biosimilars because of the unique regulatory structure governing them. Additionally, when filing settlement agreements with the FTC, DOJ, and USPTO pre- or post-institution, there should be a requirement for such companies to also file an economic impact analysis that they have conducted to lessen the burden on enforcement agencies. Implementing this new framework will effectuate a balance between the need for stronger enforcement mechanisms for anti-trust

---

[91] Laura Karas, *supra* note 84, at 963.
[92] *Id.*

agencies and preserving the practice of settlement agreements. This will perpetuate the goal to increase market entry of biosimilars for patient consumers to access lifesaving and cost-effective medicine at an earlier time.

Long COVID, Longer Consequences: Strengthening State Authority Over Post-Pandemic Healthcare Consolidation

Gurujjal Roopra

I. INTRODUCTION

The rate of mergers and acquisitions in the health care industry has steadily increased since the COVID-19 pandemic, resulting in a decrease in market competition, higher healthcare costs, and worsened healthcare outcomes. Increased costs for consumers, gaps in access to care, and lower overall quality of care are often synonymous when consolidation within the healthcare industry is discussed. Federal and state agencies play complementary roles in mitigating the anticompetitive effects of healthcare transactions, with the federal government providing greater resources and general antitrust expertise and states providing more specialized knowledge of local market conditions. Since the pandemic, the Federal Trade Commission (FTC) has substantially increased their rate of antitrust enforcement, with 3,152 merger and acquisition proposals across industries during 2022.[1] States have also begun bolstering their enforcement authority in health care consolidation, with thirty-five states having developed statutory requirements for attorney general review on proposed health care transactions before approval.[2]

This article will examine how healthcare consolidation has become a major factor driving up costs for patients and families in the post-pandemic era. First, this article will discuss the effects of a COVID-19-induced consolidation on consumers and the pandemic's long-term impact on the healthcare market. Next, this article will examine the federal government's

[1] Mary Bennett & Rob Robinson, *FTC and DOJ Report on Merger Trends in 2023: A Year of Big Deals and Big Scrutiny,* JD SUPRA (Oct. 18, 2024), https://www.jdsupra.com/legalnews/ftc-and-doj-report-on-merger-trends-in-5919669/.
[2] Tara Oakman et al., *How States Can Advance Equity When Addressing Health Care Consolidation,* THE CENTURY FOUND. (Mar. 6, 2024), https://tcf.org/content/report/how-states-can-advance-equity-when-addressing-health-care-consolidation.

role in preventing anticompetitive consolidation, highlighting gaps in the Federal Trade Commission (FTC) and Department of Justice's (DOJ) 2023 Merger Guidelines and updated rules to the Hart-Scott-Rodino (HSR) Act. Then, this article discusses how state governments can address these gaps, focusing on Oregon HB 2362—one of the nation's most comprehensive healthcare market oversight statutes. Finally, this article proposes amendments to Oregon HB 2362 that incorporate clear limitations on scope of authority and establish robust oversight and review procedures, with the aim of establishing it as model legislation for other states.

II. COVID-19 AS A CATALYST FOR ACCELERATED CONSOLIDATION

The adverse financial impact of COVID-19 was felt by corporations economy wide.[3] Understandably, the United States healthcare industry was among the most impacted,[4] posing significant clinical, operational, and financial challenges for hospitals while exacerbating long-standing issues related to access to care.[5] Since 2020, the financial strain on healthcare providers, intensified by the COVID-19 pandemic, has heightened concerns that these pressures could accelerate consolidation trends within the industry.[6] Hospitals had to manage the complex, resource-heavy demands of treating COVID-19 patients, continue routine care for non-COVID patients,

---

[3] Jakub Hlávka & Adam Rose, *COVID-19's Total Cost to the U.S. Economy Will Reach $14 Trillion by End of 2023*, USC SCHAEFFER CTR. FOR HEALTH POL'Y AND ECON. (May 16, 2023), https://healthpolicy.usc.edu/article/covid-19s-total-cost-to-the-economy-in-us-will-reach-14-trillion-by-end-of-2023-new-research.

[4] *See id.* (detailing the economic toll of the COVID-19 pandemic on the United States economy, which reached $14 trillion by the end of 2023).

[5] Kate Li et al., *Early Financial Impact of the COVID-19 Pandemic on U.S. Hospitals,* 68 J. HEALTHCARE MGMT. 268, 269 (2023).

[6] Lovisa Gustafsson & David Blumenthal, *The Pandemic Will Fuel Consolidation in U.S. Health Care*, HARV. BUS. REV. (Mar. 9, 2021), https://hbr.org/2021/03/the-pandemic-will-fuel-consolidation-in-u-s-health-care ("Given the financial difficulty that many providers have suffered during the pandemic, this trend [concentration in the U.S. Health sector] is likely to continue, reducing competition and increasing prices.").

cope with staffing shortages, and navigate financial difficulties due to increased costs and reduced utilization of services.[7] Unsurprisingly, financial challenges induced by the pandemic were the "nail in the coffin" for many providers. In a survey of 230 physician-owned practices in July 2020, 26 percent indicated they were likely to partner with a larger healthcare entity due to COVID-19,[8] with 428 hospital mergers occurring in the midst of the pandemic.[9] Post-pandemic, economic pressures remain a key driver for M&A activity, with financial distress cited as a factor in almost 30 percent of the announced transactions in 2023.[10] Rising rates of underpayment for care provided, labor shortages, increased administrative and regulatory burdens, and the cost of new equipment and technology are a few of the issues that have "created an environment of financial uncertainty where many hospitals and health systems are operating with little to no margin."[11] When taken together, these persistent challenges have influenced increased rates of consolidation.[12]

---

[7] Li et al., *supra* note 5, at 269.
[8] Robert P. Kocher et al., *Overcoming the Market Dominance of Hospitals*, 325 J. AMA 929, 929 (2021).
[9] *See* generally Zachary Levinson et al., *Ten Things to Know About Consolidation in Health Care Provider Markets*, KFF (Apr. 19, 2024), https://www.kff.org/health-costs/issue-brief/ten-things-to-know-about-consolidation-in-health-care-provider-markets/ (noting that 428 hospital mergers were announced between 2018 to 2023).
[10] *See generally* Anu Singh, *Hospital and Health System M&A in Review: Financial Pressures Emerge as Key Driver in 2023,* KAUFMANHALL (Jan. 18, 2024), https://www.kaufmanhall.com/insights/research-report/2023-hospital-and-health-system-ma-review ("Those financial pressures emerged as a key M&A activity in 2023, with financial distress cited as a factor or otherwise evident in 28% of announced transactions, compared with 15% in 2022.").
[11] AM. HOSP. ASS'N, *America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities*, 1 (Apr. 2024), https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf (introducing issues creating an environment of financial uncertainty for hospitals and health systems during the COVID-19 pandemic).
[12] *See generally* AM. HOSP. ASS'N, FAST FACTS ON U.S. HOSPITALS, 2 (2024), https://www.aha.org/system/files/media/file/2024/01/fast-facts-on-us-hospitals-2024-20240112.pdf.

As rates of healthcare consolidation continue to rise, the increased market power of the largest healthcare systems decreases competition.[13] A large body of evidence highlights the real-world implications of increased consolidation and reduced competition in the healthcare market for consumers. Research consistently shows that "hospitals and doctors who face less competition charge higher prices to private payers, without accompanying gains in efficiency or quality."[14] Evidence indicates that 'when hospitals merge, they face less competition and, as a result, charge as much as 40 to 50 percent higher prices than if they had not merged or consolidated."[15] Furthermore, consolidation has not led to improved quality for patients.[16] The elimination of competition reduces incentives to improve quality of care, despite higher costs for patients.[17] ". . .[W]hen patients went to high-priced hospitals in concentrated markets, their spending went up by 52 percent but they did not get better outcomes."[18] Furthermore, "mergers also lead to decreased access to care for patients due to reductions in service lines that are less profitable or duplicative of services offered by the acquiring

---

[13] *See Health System Consolidation,* NAT'L CONF. OF STATE LEGIS., https://www.ncsl.org/health/health-system-consolidation (last updated Feb. 7, 2024).
[14] Michael F. Cannon, *Market Concentration in Health Care: Government Is the Problem, Not the Solution*, CATO, 1 (July 19, 2022), https://www.cato.org/sites/cato.org/files/2022-07/briefing-paper-139-updated.pdf.
[15] Arthur H. Gale, *Bigger but Not Better: Hospital Mergers Increase Costs and Do Not Improve Quality*, 112 J. MO. STATE MED. ASS'N 4, 4 (2015).
[16] *See* Martin Gaynor & Robert J. Town, *Policy Brief No. 9, the Impact of Hospital Consolidation - Update*, ROBERT WOOD JOHNSON FOUND., THE SYNTHESIS PROJECT, 4 (June 2021), https://www.researchgate.net/publication/283910115_The_Impact_of_Hospital_Consolidation_-_Update (graph listing studies demonstrating that an increase in competition increases quality of care).
[17] *See* Sara Sirota, *The Harms of Hospital Mergers and How to Stop Them*, AM. ECON. LIBR. PROJECT, 4-5 (Apr. 2023), https://www.economicliberties.us/wp-content/uploads/2023/04/Hospital_QuickTake-0421-002.pdf ("One economic article found that mergers between 2007 and 2011 among nearby hospitals resulted in prices rising by more than 6%, and prices at monopoly hospitals for patients with employer-sponsored insurance are 12% higher than those in markets with at least four competitors.").
[18] Mike Cummings, *A Yale Economist on Taming Rising Hospital Prices While Maintaining Quality*, YALE NEWS (Mar. 7, 2022), https://news.yale.edu/2022/03/07/yale-economist-taming-rising-hospital-prices-while-maintaining-quality.

entity."[19] Many healthcare systems often move to close services like intensive care, labor and delivery, and surgical care after acquiring smaller hospitals.[20] Despite the documented drawbacks of consolidation in healthcare, M&A activity is projected to rise in 2024 and beyond, further reducing market competition and increasing harm to patients nationwide.[21]

III. POST-PANDEMIC UPDATES TO THE FEDERAL MERGER GUIDELINES AND KEY RULES

In light of the danger posed by increased health care consolidation, federal agencies have demonstrated a refreshed commitment to prohibiting anticompetitive practices in the healthcare industry.[22] On December 18, 2023, the FTC and DOJ jointly issued the 2023 Merger Guidelines.[23] Notably, the updated guidelines broaden the agencies' ability to identify mergers that may substantially lessen competition or create a monopoly.[24] Additionally, the guidelines target areas the agencies previously lacked the

[19] Rachel M. Henke et al., *Access to Obstetric, Behavioral Health, and Surgical Inpatient Services After Hospital Mergers In Rural Areas*, 10 HEALTH AFF. 1627, 1627 (2021); *see also* Sirota, *supra* note 17 at 5 (highlighting shutdowns of departments and specialized care units as implications of health care acquisitions).
[20] Henke et al., *supra* note 19, at 1627.
[21] *See generally* Singh, *supra* note 10.
[22] *See generally* Press Release, Fed. Trade Comm'n, Statement of FTC Chairwoman Lina M. Khan on the FY2022 HSR Annual Report to Congress (Dec. 21, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/StatementofChairKhanJoinedbyComm%27rSlaughterandComm%27rBedoyareFY2022HSRAnnualReport.pdf (reporting that the FTC had its highest level of enforcement activity in over 20 years) [hereinafter Statement of Lina Khan].
[23] *See generally* U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines (2023), https://www.ftc.gov/system/files/ftc_gov/pdf/P234000-NEW-MERGER-GUIDELINES.pdf.
[24] *Id.* at 5-6.

authority to enforce[25], including vertical[26] and cross-market mergers.[27] On October 10, 2024, the FTC announced key changes to the premerger notification rules under the HSR Act, the statute mandating parties to report transactions exceeding a certain financial threshold to the FTC and DOJ.[28] The HSR updates require merging parties to provide "significantly more data and documents regarding the proposed transaction than they do currently, specifically for technology and life sciences companies and private equity groups."[29] Given that the final rule of the HSR Act has not been enacted, its impact on consolidation in health care markets is yet to be determined.[30]

While the 2023 Merger Guidelines and final HSR rule constitute a more aggressive approach to merger review, key gaps regarding federal oversight of consolidation in healthcare markets remain. First, given the volume of business documents required by the new HSR rule coupled with the lowered threshold of review in Merger Guidelines, it is unlikely the agencies will challenge every proposed merger that triggers the threshold and will focus

---

[25] *See generally* La. Children's Med. Ctr. v. Att'y Gen. of the U.S., No. 23-1890 (E.D. La. 2023) (noting that state Certificate of Public Advantage laws exempt hospital acquisitions from federal antitrust laws under the FTC's previous merger guidelines in September 2023).
[26] *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 23 at 16, 22, 23 (discussing the incorporation of vertical mergers as transactions in which the FTC has review and enforcement authority).
[27] *See id.* at 12 (discussing the incorporation of cross-market mergers as transactions in which the FTC has review and enforcement authority).
[28] *See generally* Scott Hulver & Zachary Levinson, *Understanding the Role of the FTC, DOJ, and States in Challenging Anticompetitive Practices of Hospitals and Other Health Care Providers*, KFF (Aug. 7, 2023), https://www.kff.org/health-costs/issue-brief/understanding-the-role-of-the-ftc-doj-and-states-in-challenging-anticompetitive-practices-of-hospitals-and-other-health-care-providers/ (discussing the role of the Hart Scott Rodino Act in mandating reporting requirements of transactions over a certain threshold); Press Release, Fed. Trade Comm'n, FTC Finalizes Changes to Premerger Notification Form (Oct. 10, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/10/ftc-finalizes-changes-premerger-notification-form.
[29] Harry T. Robins et al., *US Federal Trade Commission Issues Final Rules on HSR Pre-Merger Reporting*, MORGAN LEWIS (Oct. 14, 2024), https://www.morganlewis.com/pubs/2024/10/us-federal-trade-commission-issues-final-rules-on-hsr-pre-merger-reporting.
[30] Fed. Trade Comm'n, supra note 26 (noting that the effective date for the new HSR rule is early 2025).

their resources on the matters they are most likely to prevail on.[31] Additionally, neither the merger guidelines nor the updated HSR Rule were developed with healthcare-specific mergers in mind and lack metrics to assess factors like quality of care and access to services, with the guidelines broadly mentioning "non-price indicators . . . as relevant indicators in markets where price forms a relatively small or no part of the exchange of value."[32] Finally, while FTC and DOJ can impose conditions on anticompetitive mergers, as federal agencies, they may not fully address regional impacts, which is crucial in healthcare due to significant market variations across states.[33]

IV. THE IMPORTANCE OF STATE ENFORCEMENT AUTHORITIES SUCH AS OREGON HOUSE BILL 2362 AS A COMPLEMENT TO FEDERAL OVERSIGHT IN MANAGING CONSOLIDATION IN HEALTH CARE MARKETS

As challenges in federal enforcement continue, many states have expanded their oversight of transactions in the health care industry.[34] In 2021, Oregon passed House Bill 2362 (codified at Or. Rev. Stat. §§ 415.500 et seq.), one of the most robust healthcare merger review laws in the

---

[31] Carrie A. Hanger et al., *Predictions for What the 2023 Merger Guidelines Mean in the Health Care Industry*, THE NAT'L L. J. (Apr. 22, 2024), https://www.law.com/nationallawjournal/2024/04/22/predictions-for-what-the-2023-merger-guidelines-mean-in-the-health-care-industry/.

[32] U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 23, at 50.

[33] *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-94-220, HEALTH CARE: FEDERAL AND STATE ANTITRUST ACTIONS CONCERNING THE HEALTH CARE INDUSTRY (1994) (noting long-standing challenges in addressing the regional concerns of antitrust enforcement in healthcare).

[34] Ari Jonathan Markenson et al., *State Healthcare Transaction Review Laws: A New Landscape*, AM. BAR ASS'N (June 25, 2024), https://www.americanbar.org/groups/business law/resources/business-law-today/2024-june/state-healthcare-transaction-review-laws-a-new-landscape/ ("In recent years an increasing number of states have enacted legislation designed to review the impact of certain healthcare transactions on cost, quality, access, need, competition, and other related issues.").

country,[35] that requires healthcare entities to obtain approval from the Oregon Health Authority (OHA) before a "material change transaction."[36] The OHA implemented the Health Care Market Oversight (HCMO) program under Or. Admin. Code § 409-070-0000 et seq., which set forth the procedures for review and criteria to be used when assessing proposed healthcare mergers' impacts on cost, access, quality, and equity.[37] Oregon's law grants OHA authority to block transactions outright or to impose conditional approvals, extending beyond the oversight powers of many other programs, including the Massachusetts Health Policy Commission, which is often cited as a leading model for state merger review authority.[38]

Oregon's review process consists of two parts: a preliminary review, and if necessary, a comprehensive review.[39] After receiving notice,[40] the OHA conducts a preliminary review to determine the following criteria: whether the deal risks limiting affordable care access or offers benefits to control healthcare costs, expands access in underserved areas, or improves health outcomes.[41] During this stage, the OHA aggregates data from various state

---

[35] *See* Or. Rev. Stat. §§ 415.500-.900 (2022); *see also* Robin Davinson et al., *A Step Forward for Health Care Market Oversight: Oregon Health Authority's Health Care Market Oversight Program*, MILBANK MEMORIAL FUND, 3 (Mar. 2023), https://www.milbank.org/wp-content/uploads/2023/03/Oregon-HCMO-Program-Report_4.pdf ("Although the HCMO program is new and to date has completed only a few reviews, Oregon has established one of the strongest merger oversight programs in the country.").

[36] Or. Rev. Stat. §§ 415.500(6)(a) (2022) (defining material change transactions as mergers, acquisitions or affiliations of an entity with an average of $25 million or more in net patient revenue in each of the preceding three fiscal years with an entity with an average of $10 million or more in net patient revenue in each of the preceding three fiscal years).

[37] Or. Admin. R. 409-070-0000 et seq. (2022).

[38] *See* Robin Davinson et al., *supra* note 38, at 5 (detailing the Massachusetts Health Policy Commission (HPC) and how the Oregon legislature has built on the HPC experience by blocking transactions outright or imposing conditions to mitigate potential detrimental effects resulting from the consummated transaction. Through this expansion on the HPC, Oregon "seeks to better understand the situation on the ground and identify and address concerning consolidation trends.").

[39] Or. Rev. Stat. §§ 415.501(5)-(7)(a) (2022).

[40] Or. Rev. Stat. §§ 415.501(4) (2022) ("An entity shall submit to the authority a notice of a material change transaction…no less than 180 days before the date of the transaction...").

[41] Or. Rev. Stat. §§ 415.501(5) (2022); Or. Admin. R. 409-070-0055(2) (2022).

agencies and programs to supplement its review process.[42] OHA's cost impact assessment compares current and projected metrics for market concentration, consumer prices, and state spending,[43] while access evaluation examines changes in service availability and patient transportation times using hospital discharge data.[44] The HCMO program also assesses equity impacts by analyzing how the transaction affects care access and quality across demographic factors including race, ethnicity, language, and disability status.[45] Based on these analyses, the OHA will approve, conditionally approve, or recommend the transaction undergo comprehensive review.[46]

If a transaction's impact raises concerns around cost, access, equity, or quality in healthcare, a comprehensive review provides additional safeguards through a community-based review board that includes local stakeholders, consumer advocates, and healthcare experts.[47] OHA requests detailed datasets such as workforce data, insurance contracts, and patient reviews from the parties to assess impacts on access, equity, and quality.[48] This additional data enables OHA to conduct detailed antitrust analyses, using willingness-to-pay, merger simulation, and diversion analyses to assess potential efficiencies from the transaction.[49] Following the comprehensive review, OHA will approve transactions that demonstrate *at least* one of the

---

[42] OR. HEALTH AUTH., *Health Care Market Oversight Analytic Framework*, at 3 (Oct. 2022) https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/OHA-HCMO-Analytic-Framework-FINAL.pdf.
[43] *Id.* at 5.
[44] *Id.*
[45] *Id.* at 7.
[46] Or. Admin. R. 409-070-0055(2) (2022).
[47] Or. Rev. Stat. Ann. §415.501(7)(a); Or. Rev. Stat. Ann. §415.501(8); Or. Rev. Stat. Ann. §415.501(11)(a); Or. Health Auth., Criteria for Comprehensive Review of Material Change Transaction at 1 (Feb. 2022), https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/HCMO-Criteria-for-Comprehensive-Review.pdf.
[48] OR. HEALTH AUTH., *supra* note 42, at 5-6.
[49] *Id.*

following criteria: lower patient costs, expanded access in underserved areas, or enhanced health outcomes,[50] provided these benefits outweigh potential anticompetitive effects.[51] If OHA has specific concerns about a deal, it may impose conditions to mitigate identified risks,[52] such as requiring regular reporting on patient demographics, utilization of services, and numbers of providers or mandating participation in Medicare/Medicaid.[53]

Following approval, OHA must conduct post-transaction reviews of all transactions at one, two, and five years after completion, monitoring entities' adherence to conditions.[54] The OHA's investigative and enforcement authority extends to post-transaction monitoring, giving it the power to issue subpoenas, take depositions, and compel records to enforce compliance.[55] Additionally, every four years, OHA must complete a statewide study on healthcare consolidation to assess the overall impact of collective transactions on consumer costs and care quality.[56] Since its implementation in March 2022, the HCMO program has reviewed 35 transactions, with most receiving preliminary approval and only five requiring comprehensive review.[57]

On October 3, 2022, the Oregon Association of Hospitals and Health Systems (OAHHS) filed a lawsuit against the state and OHA, arguing that the law grants OHA "unprecedented authority to approve, deny, and dictate terms of a wide range of healthcare transactions," violating the 14th

---

[50] Or. Rev. Stat. Ann. §415.501(9)(A)–(B).
[51] Or. Rev. Stat. Ann. §415.501(9)(B)(b).
[52] Or. Admin. R. 409-070-0065.
[53] *See* Davinson et al., *supra* note 38, at 15 (listing potential conditions OHA could consider for future transactions that raise concerns).
[54] Or. Rev. Stat. Ann. §415.501(19).
[55] Or. Rev. Stat. Ann. §415.013.
[56] Or. Rev. Stat. Ann. §415.510.
[57] *HCMO Transactions and Reviews*, OR. HEALTH AUTH., https://www.oregon.gov/oha/HPA/HP/Pages/HCMO-transaction-notices-and-reviews.aspx (last visited Nov. 8, 2024).

Amendment and the Oregon Constitution.[58] The plaintiffs argued that the law lacks clear standards for evaluating transactions, improperly extends OHA's power, and causes unnecessary delays that hinder access to care.[59] While the federal court rejected claims of unconstitutional vagueness under the 14th Amendment due to factors like OHA's clarifying regulations and the availability of pre-enforcement review,[60] it declined to exercise supplemental jurisdiction over OAHHS's state nondelegation doctrine challenge.[61] On June 18, 2024, OAHHS filed a notice of appeal.[62] Although the appellate court's decision is uncertain, the nondelegation claim is crucial—if the court determines the Oregon legislature improperly delegated authority to OHA, other states may be reluctant to create similar healthcare market oversight programs for fear they cannot grant agencies enough authority to implement them.[63]

V. PROPOSAL TO AMEND OREGON'S PRE-MERGER NOTIFICATION STATUTE AND RELEVANT ADMINISTRATIVE RULES TO ENHANCE REVIEW CRITERIA AND ESTABLISH ROBUST ENFORCEMENT MECHANISMS

While the Health Care Market Oversight program represents an innovative approach to healthcare consolidation oversight, its effectiveness may be undermined by legal challenges to the Oregon Health Authority's broad

---

[58] Complaint at 2, Or. Ass'n of Hosp. & Health Sys. v. Or., No. 3:22-cv-1486-SI, 2024 U.S. Dist. LEXIS 88329 (D. Or. May 16, 2024).
[59] *Id.* at 2–3.
[60] Or. Ass'n of Hosp. & Health Sys. v. Or., No. 3:22-cv-1486-SI, 2024 U.S. Dist. LEXIS 88329, at 35 (D. Or. May 16, 2024) ("…OHA has issued detailed regulations and guidance clarifying the scope of the statute; and a regulated party may obtain even further clarification of the meaning or applicability of the statute through an administrative process.").
[61] *Id.* at 55.
[62] *Hospital Association of Oregon Appeals Court Decision in Health Care Market Oversight Program Case*, HOSP. ASSOC. OR. (June 18, 2024), https://oregonhospitals.org/publication/hospital-association-of-oregon-appeals-u-s-district-court-ruling/.
[63] Davinson et al., *supra* note 38, at 19.

discretionary power unless additional restrictions and oversight provisions are implemented. Amending both ORS §415.501 and OAR §409-070-0000 will create a comprehensive framework where the statute establishes constitutionally-sound boundaries and oversight mechanisms for OHA's authority, while the administrative rules provide the detailed procedures needed to implement these safeguards.

The current language of ORS §415.501 states its purpose as "to promote the public interest and to advance the goals set forth in ORS §414.018…"[64] and establishes the OHA's rulemaking authority in stating ". . . the Oregon Health Authority shall adopt by rule criteria . . . for the consideration of . . . material change transaction[s] and procedures for the[ir] review . . . ".[65] The law's lack of limits on OHA's enforcement authority and gaps in authority oversight and review processes makes it vulnerable to legal challenges.[66] The following additions would fortify the law against nondelegation challenges by implementing specific legislative parameters, while maintaining OHA's ability to effectively review healthcare transactions:

> ORS §415.501 **Procedures for review of material transactions; rules**.
> **(1)(b):** The authority granted to the Oregon Health Authority in subsection (2)
> of this section shall be exercised in accordance with the nondelegation principles
> found in Article I, §21; Article III, §1; and Article IV, §1(1) of the Oregon Constitution.
> **(2)(b):** This section establishes explicit boundaries and oversight mechanisms
> to ensure constitutional compliance while maintaining efficient program operations. The Oregon Health Authority may not: (1) Implement program changes that substantially alter the purpose, procedures, and scope set forth in this and subsequent subsections; (2) Impose conditions, requirements, and/or other obligations on any persons, parties, or agencies that exceed the scope of the authority delegated here within.

---

[64] Or. Rev. Stat. Ann. §415.501(1)
[65] Or. Rev. Stat. Ann. §415.501(2).
[66] Or. Rev. Stat. Ann. §415.501(1)-(2) (noting that the statute confers expansive enforcement authority on the OHA regarding material change transactions).

> **(25)(1):** The Authority shall be subject to at least one annual review by an Independent Review Board appointed by the Legislative Assembly and reviewed by the Oregon Health Policy Board pursuant to requirements outlined in OAR 409-070-0000.
>
> Or. Admin. Code § 409-070-0000 **Authority Oversight Provisions.**
> **(4)** Pursuant to ORS §415.501(25)(1)**,** the Authority will be subject to at least one Annual Review by an **Independent Oversight Board** ("the Board")**.**
>
> (a) The Board will be comprised of nine members: two healthcare providers; two public health experts; one economists; three patient advocates from the community; and one antitrust expert.
> (b) The Board will be appointed as follows: three appointments by the Oregon House of Representatives; three appointments by the Oregon Senate; three appointments by the Governor. The Oregon Health Policy Board will train the Board on the criteria and systems for the review process.
> (c) The Annual Review will include an analysis of: (i) Process Evaluation; (iii) Decision Consistency; (iv) Program Effectiveness; (v) Market Impacts; and (vi) Consumer Benefits.
> (d) Metrics for the Annual Review are as follows: (i) Process Evaluation, measured by: average timeline for decision making, compliance with statutory deadlines, rate of successful appeals or challenges; (ii) Decision Consistency, measured by: analysis of variance for similar mergers, documentation of reasoning for unique or unusual decisions; (iii) Program Effectiveness, measured by: administrative efficiency ratios, average Medicare costs per beneficiary trends; (iv) Market Impacts, measured by: changes in market concentration (as measured the by Herfindahl–Hirschman index), insurance premium cost trends as compared to regional benchmarks, provider participation rates; (v) Consumer benefits, measured by: out-of pocket costs trends, average wait times for services; access to care and specialty service metrics by geographic region.
> (e) Target goals for Annual Review metrics are to be determined by the Board; should additional metrics be implemented, the Board is required to notify the OHA of such addition at least 120 days in advance of a formal review proceeding.

By including the provisions above, the statute more clearly delineates the scope and purpose of the OHA's rulemaking and limits the Authority's oversight and enforcement power for merger reviews. This dual approach incorporated essential oversight on the OHA while preserving the HCMO

program's ability to respond swiftly to evolving health care markets. With these added provisions, ORS §415.501 provides a statutory model that allows the OHA to have autonomy in developing the HCMO program but also enforces systematic reviews to ensure accountability and systematic review processes.[67] Similarly, the additional subsections in OAR § 409-070-0000 create the procedures for the enhanced oversight provisions in ORS §415.501(25)(1), allowing for flexible amendments to the review criteria and metrics, board composition, and appointment processes should the proposed procedures need to change as market concentration and health care outcomes continue to evolve. Furthermore, there are strategic advantages to the metric alignment between the Review Board and the HCMO program.[68] First, the alignment of review processes and metrics shows a linear connection between the Authority and the appointed oversight committee. Another benefit is efficient and streamlined evaluation as the Review Board would use already established data collection systems and leverage existing infrastructure. Additionally, the use of similar criteria strengthens the OHA's compliance with Oregon's nondelegation principles. This is because alignment of review criteria and metrics creates a transparent evaluation framework and consistent review standards, making it easier for the public and the Oregon legislature to evaluate the impact of the HCMO program.

Despite the benefits of the proposed amendments, there are a variety of potential criticisms to the proposed provisions. First, challengers of ORS §415.501 may claim that it is unnecessarily complex due to multiple constitutional references in the statutory language. However, the multiple

---

[67] Davinson et al., *supra* note 38, at 21 ("An effective health care market oversight program must also find the appropriate thresholds for review – too narrow and the program will not catch potentially problematic transactions, but too broad and the program risks being overburdened and inefficient.").

[68] *See generally* OR. HEALTH AUTH., *supra* note 42, at 13 (noting that the community review boards convened for comprehensive reviews integrate seamlessly with the HCMO's equity impact analysis).

constitutional references in ORS §415.501(1)(b) strengthen, rather than weaken, the provision. As demonstrated in *Oregon Association of Hospitals & Health Systems* and other Oregon cases,[69] courts routinely analyze these constitutional provisions together when deciding nondelegation issues. By explicitly citing all relevant constitutional provisions, the statute aligns with this judicial approach and provides a comprehensive foundation for defining the OHA's authority limits. Another potential criticism may be that an annual review is insufficient to ensure adequate oversight over the OHA and HCMO program. However, the statutory language simply states that (1) annual review is the *minimum* and subjects the OHA to additional reviews as they are deemed necessary. The detailed review categories and metrics may be of issue to some, however Or. Admin. Code §409-070-0000(4)(e) builds in intentionally flexible framework which allows the criteria under which the OHA is reviewed to remain adaptable. Furthermore, the use of combined qualitative and quantitative measures ensures that the HCMO program's commitment to equity, in addition to consumer costs and state spending, is being assessed through comprehensive evaluation.

VI. CONCLUSION

COVID-19 continues to fuel rates of consolidation in the health care industry, leading to increased costs, reduced access to care, and diminished quality of services for patients nationwide. While federal antitrust agencies have responded with increased antitrust enforcement activity and updated

[69] *See generally* Or. Ass'n of Hosp. & Health Sys. v. Oregon, No. 3:22-cv-1486-SI, 2024 U.S. Dist. LEXIS 88329, at 55 (D. Or. May 16, 2024) ("… [B]ecause OAHHS asks this federal court to invalidate a state law solely on state constitutional grounds, considerations of comity strongly favor the conclusion that a federal court should decline jurisdiction."); *See generally* State v. Sargent, 449 P.2d 845, 847 (Or. 1969) ("It is sufficient for the purposes of this case to hold that the delegation in ORS 475.010(1) does not violate either the state or federal constitution.").

merger guidelines and Rules, the scope of impact for federal oversight does not address the full scope of challenges posed by consolidated health care markets, specifically when considering local and regional impacts. This article highlights the critical role states can play in establishing specific merger review criteria and implementation procedures to most efficiently defend against anticompetitive health care transactions on a local level. Oregon's pioneering Health Care Market Oversight program is among the strongest state-level programs in the country, but recent legal challenges have challenged its status as model legislation for other states to follow suit.

The sections proposed in this article strengthen the relevant statute and administrative rules, resulting in a comprehensive framework that addresses its legal issues by establishing clear limitations to the Oregon Health Authority's delegated powers while maintaining the Authority's necessary scope of power and regulatory flexibility. The dual approach addressing statutory authority and administrative procedures creates a framework that can be altered and adapted to a majority of different states. As rates of consolidation rise year after year, patients continue to suffer. Oregon's enhanced Health Care Market Oversight program can be used as a model for states who seek to protect their healthcare markets from anticompetitive practices through the advancement of healthcare equity, affordability, and access.

Private Equity's Influence in Navigating the Shift to Value Based Healthcare Models

Manya Shah

I. INTRODUCTION

As the healthcare landscape undergoes significant transformation, the shift from traditional fee-for-service models to value-based care (VBC) is becoming increasingly prominent.[1] The increasing involvement of private equity (PE) firms in healthcare is partly driven by providers seeking support in transitioning to value-based reimbursement models.[2] VBC emphasizes delivering high-quality healthcare services that improve patient outcomes while reducing costs, aligning provider incentives with the quality of care.[3] Between 2019 and 2021, PE investments in VBC companies quadrupled, accounting for 30 percent of all healthcare investments by 2021, up from just 6 percent in 2019.[4] This surge in invested capital reflects the diverse business models and risk profiles inherent in VBC, which appeals to a broad spectrum of PE firms.[5] The VBC sector is poised to grow into a $1 trillion market, driven by an increasing number of covered lives and improvements in provider efficiency and cost management.[6] By leveraging their resources and expertise, PE firms can assist providers looking to shift to VBC in scaling operations, adopting advanced technologies, and standardizing clinical practices, thus enhancing patient care.[7]

---

[1] Rebecca Springer, *Value-Based Care: An Investor's Guide*, PITCHBOOK, 1 (Apr. 26, 2023), https://files.pitchbook.com/website/files/pdf/Q2_2023_PitchBook_Analyst_Note_Value-Based_Care_An_Investors_Guide.pdf.
[2] Sandra Desautels et al., *Healthcare Private Equity: Managing Increased Regulatory Scrutiny*, GUIDEHOUSE. (Aug. 14, 2024), https://guidehouse.com/insights/healthcare/2024/healthcare-private-equity-regulatory-scrutiny.
[3] HUMANA, *Value-Based Care Report 2023*, at 1, https://provider.humana.com/value-based-care/value-based-care-report.
[4] Zahy Abou-Atme et al., *Investing in the New Era of Value-Based Care*, MCKINSEY & COMPANY (Dec. 16, 2022), https://www.mckinsey.com/industries/healthcare/our-insights/investing-in-the-new-era-of-value-based-care/.
[5] *Id.*
[6] *Id.* at 3.
[7] *Id.* at 10.

Historically, the fee-for-service (FFS) model has incentivized volume over value, often leading to unnecessary procedures and inflated costs.[8] In contrast, VBC models promote accountability for both cost and quality of outcomes, aligning the interests of payers, providers, and investors.[9] Financial performance in these models is directly tied to the quality of care delivered.[10] PE firms, driven by financial incentives, are well-positioned to encourage investments that promote better health outcomes and lower costs.[11] While the infusion of capital from PE can facilitate the implementation of innovative care models aimed at improving patient outcomes, there are concerns about whether financial motives may overshadow patient care, especially when healthcare organizations are under pressure to deliver returns.

This paper will explore the evolving relationship between PE and VBC and assess the current regulatory landscape to determine whether existing laws adequately address the challenges and opportunities posed by this dynamic. By analyzing critiques of PE's involvement in VBC, the paper will propose a three-step legislative framework inspired by recent initiatives like the Health Over Wealth Act, Massachusetts Bill S2871, and California Assembly Bill 3129. This framework aims to protect patient safety while promoting investment strategies that align financial incentives with improved health outcomes.

II. PRIVATE EQUITY AS A CATALYST FOR VALUE-BASED CARE IMPROVEMENT

---

[8] HUMANA, *supra* note 3.
[9] Abou-Atme et al., *supra* note 4.
[10] Brian W. Powers et al., *Private Equity and Health Care Delivery: Value-Based Payment as a Guardrail*, 326 JAMA, 907 (Aug. 11, 2021), https://jamanetwork.com/journals/jama/fullarticle/2783121.
[11] *Id.*

The integration of PE investments into the healthcare sector, particularly in the context of VBC, has generated considerable discourse surrounding its potential benefits. Despite concerns about PE ownership, these investments offer significant advantages when aligned with VBC goals. This section explores how PE can enhance operational efficiency, expand healthcare services, and ultimately improve patient outcomes.

One primary advantage of PE investments in healthcare is the substantial capital they can provide, which is essential for transitioning to VBC models.[12] The shift from FFS to VBC often necessitates considerable upfront investments in technology, data analytics, and care coordination infrastructure.[13] According to Bain & Co., 80 percent of primary care providers are interested in VBC adoption but cite technological and administrative constraints as barriers.[14] PE firms provide an alternative source of capital outside public ownership, allowing physicians to retain equity and financially benefit from future transactions.[15] Additionally, PE firms bring expertise in optimizing operations, streamlining processes, and implementing technology solutions.[16] The financial resources and expertise provided facilitates the transition to VBC, which many providers struggle to achieve independently.[17] This, in turn, allows providers to concentrate on patient care, alleviating operational burdens.[18]

---

[12] Springer, *supra* note 1, at 5.
[13] *Id.*
[14] *Global Healthcare Private Equity and M&A Report 2023*, BAIN & CO., 44, https://www.bain.com/globalassets/noindex/2023/bain_report_global_healthcare_private_equity_and_ma_2023.pdf.
[15] Jane M. Zhu and Daniel Polsky, *Private Equity and Physician Medical Practices — Navigating a Changing Ecosystem*, 384 NEW ENG. J. MED., 981, 981 (Mar. 13, 2021), https://www.nejm.org/doi/full/10.1056/NEJMp2032115.
[16] *Id.*
[17] Desautels et al., *supra* note 2.
[18] Kenneth Jonathan Yood & Shalyn Watkins, *Private Equity Healthcare Transactions Under Scrutiny*, HOLLAND & KNIGHT (Mar. 14, 2024), https://www.hklaw.com/en/insights/publications/2024/03/private-equity-healthcare-transactions-under-scrutiny.

The transition to VBC inherently shifts financial risk to healthcare providers, holding them accountable for patient outcomes and the total cost of care.[19] This shift in incentives can align PE's profit motives with VBC goals, emphasizing cost-effectiveness and quality improvement.[20] Under VBC models with capitated payments or shared savings arrangements, PE firms have a financial incentive to ensure their companies deliver high-quality care, reduce unnecessary utilization, and improve efficiency to maximize financial performance.[21] These financial risks encourage PE-backed healthcare businesses to manage care effectively, as mismanagement could lead to significant repercussions.[22]

A specific area where PE is active in VBC is through backing "enablers."[23] The "enabler" companies partner with existing physician groups or health systems to assist their transition towards VBC.[24] They provide a suite of services including population health software, care pathway guidance, outcomes measurement tools, and contracting support.[25] This helps providers engage in value-based contracts and share in savings, while the enabler assumes the downside risk.[26]

PE's focus on growth and market expansion facilitates the scaling of successful VBC models, broadening access to these approaches and extending their benefits to a wider patient population.[27]

---

[19] Springer, *supra* note 1.
[20] Abou-Atme et al., *supra* note 4.
[21] Powers et al., *supra* note 10, at 907.
[22] *Id.*
[23] Springer, *supra* note 1, at 7.
[24] *Id.*
[25] *Id.* at 7-8.
[26] *Id.* at 7.
[27] Powers et al., *supra* note 10, at 908.

III. THE DOUBLE-EDGED SWORD OF PRIVATE EQUITY IN VALUE-BASED CARE

While PE brings opportunities for innovation and operational efficiency in VBC, it also raises concerns about potential conflicts between profit motives and patient care. A key issue is the inherent tension between the short-term profit motives of PE firms and the long-term goals of VBC.[28] PE firms typically aim for substantial returns—often exceeding 20 percent—within three to seven years.[29] This pressure to generate quick financial returns may prompt PE-backed healthcare providers to prioritize affluent communities and profitable services, potentially avoiding patients with complex medical and social needs.[30] Such "cherry-picking" strategies target healthier, commercially insured patients who are perceived as less costly and more profitable.[31] This potential for patient selection would amplify existing health disparities and work against VBC objectives, which aim to improve care for vulnerable populations.[32]

Cost-cutting strategies common to PE firms also pose risks to the quality of care delivered in VBC settings. Practices like reducing staffing, lowering wages, and asset stripping can weaken healthcare providers' long-term financial stability and compromise patient care.[33] Additionally, PE's lack of transparency and the fragmented nature of healthcare data make it challenging to evaluate its true impact on VBC.[34] PE firms often operate

---

[28] Zhu, *supra* note 15, at 981-982.
[29] Yashaswini Singh et al., *Assc. of Private Equity Acquisition of Physician Practices with Changes in Health Care Spending and Utilization*, JAMA (Sept. 2, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2795946.
[30] Powers et al., *supra* note 10, at 908.
[31] Alex M. Azar II et al., *Reforming America's Healthcare System Through Choice and Competition*, U.S. DEP'T OF HEALTH & HUM. SERV'S, 88-89 (Dec. 3, 2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.
[32] *See generally supra* note 3.
[33] Christopher Cai, *Private Equity in Health Care: Prevalence, Impact, and Policy Options for California and the US*, CAL. HEALTH CARE FOUND. (May 7, 2024), https://www.chcf.org/wpcontent/uploads/2024/05/PrivateEquityPrevalenceImpactPolicy.pdf.
[34] Zhu, *supra* note 15, at 982.

under nondisclosure agreements and are not required to publicly disclose acquisitions or financial details.[35] This opacity, combined with the difficulty of accessing data from multiple insurers and payers with varying systems and reporting standards, creates obstacles to fully understanding PE's influence on healthcare costs, quality, and access.

IV. SOLUTION

The regulatory landscape surrounding PE investments in healthcare is continuously evolving, driven by significant growth in this sector and increased scrutiny from federal and state regulators. Between 2019 and 2023, PE firms engaged in approximately 3,300 deals worth around $47 billion, raising concerns about the potential prioritization of profits over patient care.[36] Critics argue that profit-driven motives of PE firms can lead to aggressive cost-cutting measures, negatively affecting healthcare quality.[37] Another concern is the lack of comprehensive federal oversight tailored specifically to PE investments in healthcare.[38] Existing corporate and securities laws do not adequately address the unique risks associated with these investments, allowing PE firms to operate with substantial autonomy that prioritizes profit over patient care.[39]

In response to these concerns, several legislative initiatives, including the Health Over Wealth Act (S. 4804), Massachusetts Bill S2871/H4653, and California Assembly Bill 3129, are paving the way for a more accountable

---

[35] *Id.*
[36] Desautels et al., *supra* note 2.
[37] Hannah-Alise Rogers & Alexander H. Pepper, *Private Equity Investments in Health Care: Selected Enforcement Issues*, CONG. RSCH. SERV., 1 (Aug. 8, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11215.
[38] Brian McCalmon, *Health Care Transactions Facing Increased Federal and State Regulatory Scrutiny*, NAT'L L. REV. (July 2, 2024), https://natlawreview.com/article/health-care-transactions-facing-increased-federal-and-state-regulatory-scrutiny.
[39] *Id.*

and patient-centered healthcare system. This proposal integrates these initiatives into a comprehensive three-step solution to optimize the benefits of PE investments while safeguarding patient outcomes through effective congressional legislation and federal implementation.

The first step would involve amending and implementing Section 3404 of the Health Over Wealth Act (S. 4804), introduced in the U.S. Senate on July 25, 2024.[40] This Act proposes a task force to monitor the influence of PE in healthcare, assessing how PE impacts cost, quality, and accessibility.[41] The task force, chaired by the Secretary of Health and Human Services (HHS), is tasked with evaluating healthcare mergers and acquisitions to prevent negative effects, such as rising costs, reduced care quality, and access barriers.[42] The composition of the task force would include healthcare providers, academic experts, consumer advocates, and labor unions, ensuring input from key stakeholders.[43] Additionally, the Federal Trade Commission (FTC) and Attorney General would serve as advisors, providing insight into antitrust law and public interest concerns.[44] Section 3404 also imposes a moratorium on PE acquisitions in healthcare.[45] This moratorium empowers the HHS Secretary to temporarily halt transactions, preventing PE firms from acquiring healthcare entities until a thorough analysis and recommendations are completed.[46] This provision reflects the Act's intention to protect patient care from profit-driven mergers, especially during the task force's review period.

---

[40] Health Over Wealth Act, 118th Cong. § 4804 (2024).
[41] Roger D. Strode, *Private Equity: Proposed Health over Wealth Act – What This Means for You*, FOLEY & LARDNER (Apr. 10, 2024), https://www.foley.com/insights/publications/2024/04/private-equity-proposed-health-over-wealth-act/.
[42] *Id.*
[43] Health Over Wealth Act, 118th Cong. § 4804 (2024).
[44] *Id.*
[45] *Id.* at § 3404.
[46] Strode, *supra* note 42.

However, the goal should not be to limit or eliminate such investments but rather to ensure that they prioritize patient outcomes. The language in Section 3404(c)(1) currently reads that the task force:

"Identify best practices and, for purposes of subsection (d), develop recommendations for limiting the role of private equity in health care, taking into account the implications on health outcomes and staff working conditions."[47]

The proposed amendment to change the language in Section 3404(c)(1) of the Health Over Wealth Act from "limiting" to "optimizing" reflects a more balanced understanding of private equity's role in healthcare. The amended text would read:

"Identify best practices and, for purposes of subsection (d), develop recommendations for optimizing the role of private equity in health care, taking into account the implications on health outcomes and staff working conditions."[48]

This shift is significant for several reasons, even with existing FTC oversight. First, changing from "limiting" to "optimizing" moves from a restrictive to a facilitative approach, signaling a balanced perspective that seeks to harness PE's potential benefits while mitigating risks. Second, an emphasis on value creation implies maximizing the positive impact of PE investments, including improvements in patient outcomes, care quality, and service access. Third, "optimizing" encourages innovation, prompting the exploration of new models that align financial incentives with patient care goals. Finally, this expanded oversight addresses FTC limitations, broadening the scope beyond antitrust issues to consider PE's overall impact on healthcare, including cost, quality, access, and equity.

---

[47] Health Over Wealth Act, *supra* note 43.
[48] *Id.*

Updating the language to "optimizing" shifts the focus from restricting PE's role to enhancing its positive contributions to healthcare. This approach fosters a collaborative relationship between PE and healthcare providers, allowing the task force to leverage PE's potential to improve healthcare delivery without compromising patient access or quality of care.[49]

The second step would involve establishing the "public interest standard" provision outlined in California Assembly Bill 3129, which was passed in the California legislature on August 31, 2024.[50] If enacted, this provision (Section 1190.20) would guide the Attorney General's evaluation process, ensuring that proposed transactions do not substantially lessen competition, create a risk of monopoly, or significantly impact the access and availability of healthcare services in the affected community.[51] Under Section 1190.20(b), the definition of "public interest" emphasizes protecting "competitive and accessible healthcare markets."[52] This ensures that the primary goal of healthcare transactions remains centered on serving the public rather than financial stakeholders even as private capital enters the healthcare market.[53] To determine whether a transaction meets the "public interest standard," the California Attorney General evaluates critical factors such as anticompetitive risks, potential impacts on access to services, and a comprehensive weighing of benefits versus risks.[54] Notably, the bill clarifies that transactions will not be presumed efficient by default, placing the burden of proof on the involved parties to demonstrate alignment with the public interest.[55]

---

[49] Desautels et al., *supra* note 2.
[50] Jennifer L. Romig et al., *California's AB 3129 Passes in California Legislature*, ROPES & GRAY (Sept. 5, 2024), https://www.ropesgray.com/en/insights/alerts/2024/09/californias-ab-3129-passes-in-california-legislature.
[51] A.B. 3129, 2023-2024 Reg. Sess. (Cal. 2024).
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*

The federal adoption of similar standards enables the HHS and the FTC to apply these criteria nationwide. Implementing the public interest standard federally would involve establishing national oversight where the task force from step one reviews significant healthcare transactions involving PE firms. Federal agencies would evaluate proposed transactions against the public interest standard using the same evaluation factors outlined in AB 3129, creating consistency in reviews and enhancing regulatory scrutiny. Moreover, federal legislation would require that the burden of proof rests with parties involved in transactions to demonstrate alignment with public interests, ensuring that the focus remains on patient welfare rather than profit motives.

This public interest standard aligns with Section 5 of the FTC Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce."[56] This broad provision encompasses all entities engaged in commerce, including banks, and empowers state attorneys general and private parties to bring lawsuits against unfair practices.[57] By establishing clear criteria for evaluating healthcare transactions, the public interest standard could enhance the FTC's ability to assess potential consumer harm resulting from these transactions, particularly in instances where access to care or service quality may be compromised.

Additionally, the public interest standard would interact with Section 7 of the Clayton Act, which prohibits mergers and acquisitions that may substantially lessen competition or create a monopoly.[58] By incorporating the public interest criteria into merger assessments, regulators could evaluate

---

[56] F.R.B., *Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices*, https://www.federalreserve.gov/boarddocs/supmanual/cch/200806/ftca.pdf.
[57] *Id.*
[58] AM. ANTITRUST INST., *Summary of Section 7 of the Clayton Act*, https://www.antitrustinstitute.org/wp-content/uploads/2018/09/Section-7.pdf.

whether proposed transactions lead to anticompetitive outcomes and their broader implications for public health. Given the lower standard of proof required under the Clayton Act, regulators could intervene early in potentially harmful mergers, aligning with the proactive focus of the public interest standard. Overall, integrating the public interest standard into federal oversight of healthcare transactions represents a critical step toward safeguarding competitive healthcare markets and ensuring they remain responsive to community needs amid the growing influence of private equity.

The third step proposes enacting congressional legislation that imposes strict penalties on PE firms that fail to meet reporting or compliance standards. This would be modeled after Massachusetts Bill S2871, passed by the Senate on July 18, 2024. This bill aims to extend oversight over investors and foster a more accountable healthcare system.[59]

The Massachusetts Bill empowers the Massachusetts Health Policy Commission (HPC) to enhance its review capabilities for healthcare transactions.[60] Key changes include broadening the Notice of Material Change (MCN) process to encompass significant investments by for-profit entities, particularly PE firms.[61] This expansion triggers reviews for various scenarios, including substantial asset sales, lease-back arrangements, and conversions from non-profit to for-profit status.[62] The HPC is then authorized to recommend modifications to transactions if their Cost and Market Impact Review (CMIR) indicates a potential for negative impacts on healthcare consumers.[63] While the HPC cannot outright approve or deny transactions, it can impose substantial penalties on provider organizations

---

[59] Jennifer L. Romig et al., *Massachusetts Expected to Pass Law with Broad Implications for Private Equity Health Care Investments*, ROPES & GRAY (July 26, 2024), https://www.ropesgray.com/en/insights/alerts/2024/07/massachusetts-expected-to-pass-law-with-broad-implications-for-private-equity-health-care.
[60] *Id.*
[61] *Id.*
[62] *Id.* at 3.
[63] *Id.*

that fail to submit required MCN filings, with fines of up to $25,000 per week for each week of delay in providing the necessary information.[64] Additionally, the bill grants the Attorney General the power to seek injunctions to block transactions deemed detrimental based on the CMIR, enhancing the state's enforcement capabilities.[65]

To effectively enforce stricter oversight and accountability for PE firms at the federal level, a comprehensive legislative framework like the Massachusetts Bill should be established on a national scale. In place of the Massachusetts HPC, the task force established in Step One within the HHS would oversee all significant healthcare transactions involving PE firms and ensure thorough reviews of mergers, acquisitions, and financial activities that impact patient care.[66] Agencies like HHS and the FTC would then impose significant penalties on firms that fail to adhere to regulations, mirroring the fines of up to $25,000 established in the Massachusetts law.[67] This alignment reinforces the importance of compliance and promotes a healthcare landscape that prioritizes patient welfare over profit motives.

Strengthened notification laws, like those proposed in the Massachusetts Bill, are essential for enhancing regulatory oversight and accountability of PE firms in healthcare. These laws facilitate early detection of potentially harmful transactions by providing regulators with advance notice, allowing them to identify issues before deals are finalized.[68] This proactive approach enables early intervention to prevent transactions that could harm competition, reduce access to care, or negatively impact quality.[69] Moreover,

---

[64] *Id.* at 4.
[65] *Id.* at 3.
[66] Romig et al., *supra* note 59.
[67] *Id.*
[68] Yood, *supra* note 18.
[69] David Blumenthal, *Private Equity's Role in Health Care*, THE COMMONWEALTH FUND (Nov. 17, 2023),

increased transparency through mandated reporting requirements compels PE firms to disclose critical information about their investments, improving understanding of the financial arrangements, ownership structures, and potential conflicts of interest associated with PE investments in healthcare.[70] While direct evidence linking notification laws to increased enforcement actions may be lacking, enhanced notification acts as a catalyst for scrutiny and investigations. By providing regulators with detailed information about proposed transactions, notification laws help identify red flags that warrant further examination.[71] Lastly, the potential for regulatory review and enforcement action triggered by mandatory notification can act as a deterrent to PE firms engaging in harmful practices, encouraging them to adopt responsible investment strategies and prioritize compliance with regulations.[72]

The proposed three-step solution emphasizes monitoring, accountability, and committing to patient-centered outcomes. Integrating the Health Over Wealth Act, the Massachusetts Bill, and the California Assembly Bill 3129 into a cohesive legislative strategy effectively addresses the challenges posed by PE in healthcare.

V. STRIKING A BALANCE BETWEEN INCENTIVES AND DISINCENTIVES IN VBC INVESTMENTS

The proposed legal reforms aimed at optimizing PE investments in healthcare have significant implications for the advancement of VBC models. By amending the Health Over Wealth Act and establishing a public interest standard, these reforms create a regulatory environment that

---

https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care.

[70] *Id.*

[71] Yood, *supra* note 18.

[72] Desautels et al., *supra* note 2.

accommodates PE involvement while ensuring alignment with the core principles of VBC—enhancing patient outcomes while controlling costs.[73]

Under these reforms, PE investments become integral to VBC by supporting healthcare innovations, such as data analytics and population health management. Such investments enhance patient outcomes and reduce healthcare costs, which, in turn, can improve the return on PE investments. A focus on sustainable, long-term growth could also attract more capital to healthcare initiatives, especially those prioritizing equitable access.

However, the public interest standard and pre-transaction review process may deter certain PE firms, especially those accustomed to less regulated environments. The need for detailed disclosures to regulatory bodies such as the FTC and state Attorney Generals could introduce significant compliance costs. PE firms that traditionally prioritize short-term returns may find the focus on long-term infrastructure and care improvements challenging, as these investments do not yield immediate financial returns.

Consider a firm, PE Healthcare Partners, intends to acquire a chain of dialysis clinics operating in a large metropolitan area, primarily serving low-income patients reliant on Medicaid. As part of the proposed reforms, the firm would need to submit a detailed notification to both the FTC and the state's Attorney General due to the size of the transaction and its potential impact on a vulnerable patient population. This would include information about the firm's investment strategy, proposed operational changes, financial projections demonstrating the transaction's viability without compromising patient care, and data analysis showing alignment with the public interest standard, particularly regarding access, quality, and affordability of care for Medicaid beneficiaries.

---

[73] HUMANA, *supra* note 3.

The FTC and the state Attorney General would conduct a thorough review, applying the "public interest" standard. Areas of focus would include assessing the potential for anticompetitive effects—specifically reduced competition in the dialysis market for Medicaid patients—and the impact on service access and quality. The review would also examine the financial viability and sustainability of the proposed business model, ensuring that safeguards are in place to prevent asset stripping that could harm the clinics' long-term viability. The task force established under the amended Health Over Wealth Act, which emphasizes "optimizing" rather than "limiting" PE in healthcare, would provide recommendations based on its review. These recommendations might include implementing quality monitoring programs to prevent operational changes from compromising patient care, aligning financial incentives for physicians and clinic administrators with patient outcomes and VBC principles. Another recommendation may require transparent reporting on financial performance, quality metrics, and patient access data.

Depending on the review findings, several outcomes are possible. The transaction might be approved with conditions to mitigate potential negative impacts on patients, such as maintaining specific staffing levels or guarantees regarding service availability in low-income areas. Alternatively, PE Healthcare Partners could be required to adjust their investment strategy or operational plans to better align with public interest goals. If the risks to patients and the public interest are deemed too significant, the transaction could be denied. Noncompliance with notification requirements, reporting standards, or imposed conditions could result in significant financial penalties, similar to those in Massachusetts Bill S2871.[74]

The proposed reforms benefit patients, especially vulnerable populations, by emphasizing access, quality, and affordability. The combination of

[74] Romig et al., *supra* note 59.

notification requirements, the public interest standard, and the optimization framework ensures a thorough review of PE transactions in healthcare. The focus on quality metrics and patient outcomes aligns with VBC principles, encouraging PE investments that enhance healthcare delivery rather than solely prioritizing profit. The potential for penalties incentivize compliance and promote transparency by requiring PE firms to provide detailed information about their investment plans and operations.

Ultimately, while the disincentives may pose challenges, the long-term benefits of participating in the VBC landscape, estimated to grow to be worth $1 trillion, present a compelling case for PE firms.[75] The healthcare industry is increasingly emphasizing patient-centered care, making VBC investments more attractive.[76] By positioning themselves to facilitate positive social impact, PE firms can enhance their reputations and appeal to a broader range of stakeholders, including patients, providers, and regulatory bodies.

VI. CONCLUSION

The evolving landscape of healthcare, marked by the increasing involvement of private equity firms, necessitates a careful balance between fostering investment and safeguarding patient care. The proposed legislative reforms aim to create a regulatory framework that prioritizes patient outcomes while allowing PE firms to play a constructive role in advancing value-based care models.

---

[75] Abou-Atme et al., *supra* note 4, at 2.
[76] *Id.*