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ANNALS OF HEALTH LAW
Advance Directive

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

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW AND LIFE SCIENCES
Advance Directive

Editors' Note

The *Annals of Health Law and Life Sciences* is proud to present the first issue of the thirty-third volume of our online, student-written publication, *Advance Directive*. This Issue's articles focus on innovative healthcare technologies and techniques.

The *Fall 2023 Advance Directive* Issue will highlight and explore a broad array of novel and innovative techniques across the United States healthcare landscape. Our Student Authors have also proposed adjustments to the current implementation, legal guidance, and regulatory landscape of these new technologies and techniques.

This Issue argues for an expansion in the enforcement of antitrust for healthcare transactions, as well as data breaches by digital healthcare companies. Additionally, this Issue discusses and recommends solutions to the disparities seen by women and same-sex couples within the fields of clinical trials and artificial reproductive technology, such as in-vitro fertilization. Furthermore, the Issue highlights new healthcare technologies and explains how increasing their use can advance positive healthcare outcomes. Lastly, the Issue explores and proposes amendments to the current regulatory landscape for PFAS "forever chemicals" and allergen labeling for food.

We would like to thank Kathryn Van Sistine, our Annals Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our Annals Editorial Board Members: Divya Das, Manuel (Manny) Franco, Grace Connelly, Jenna Miller, and Farisa Khan. The members of Annals deserve recognition for their hard work, dedication, and well-thought-out articles. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professors Nadia Sawicki and Kristin Finn, for their guidance and support.

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

Sincerely,

Bennett Murphy
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Antitrust Enforcement Using Merger Guidelines Aimed at Healthcare Transactions: A Short-Term Band-Aid for a Chronic Disease

Johannes Alvarez-Rivero

I. THE ENIGMA OF MERGER AND ACQUISITION ENFORCEMENT BY REGULATORY AGENCIES WITHIN THE HEALTHCARE SECTOR

The United States (U.S.) spends more on healthcare than any other nation in the world.[1] Over 4 trillion dollars, or $12,914 per person, was spent on healthcare in 2021, making it one of the largest marketplaces in the U.S.[2] Some of the largest corporations in the American economy have grown through their participation in the healthcare market.[3] In 2021, corporate healthcare merger and acquisition (M&A) transactions exceeded a total value of nearly 300 billion dollars domestically, making healthcare the third most valuable market for M&A deals in the U.S.[4] Due to the popularity of M&A deals in the healthcare sector, corporate executives and legal counsel counsels are required to consider antitrust regulations before executing letters of intent to follow through with a corporate transaction.[5]

Economists have argued that increased M&A activity in healthcare will improve the speed of research and development (R&D) for new drugs and lower costs, a sentiment that has played a significant part in the limited scope

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[1] *Historical*, CTRS. FOR MEDICARE & MEDICAID SERVS. (CMS) (Sept. 6, 2023), https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.
[2] *Id.*
[3] Katie Jennings, *Forbes Global 2000: The World's Largest Healthcare Companies in 2022*, FORBES (May 12, 2022, 6:15 PM), https://www.forbes.com/sites/katiejennings/2022/05/12/forbes-global-2000-the-worlds-largest-healthcare-companies-in-2022/?sh=314449223f78.
[4] Michael Deyong & Gregory Pryor, *Sector Overview: Strong M&A Activity Pervades Nearly Every Sector*, JDSUPRA (Feb. 18, 2022), https://www.jdsupra.com/legalnews/sector-overview-strong-m-a-activity-3444766/.
[5] *See Antitrust in Health Care M&A: Five Key Considerations to Guide Competitive Behavior*, HALL RENDER (July 28, 2020), https://www.hallrender.com/2020/07/28/antitrust-in-health-care-ma-five-key-considerations-to-guide-competitive-behavior/.

of antitrust laws in healthcare.[6] However, President Biden's appointment of Lina Khan as Chair of the Federal Trade Commission (FTC) suggested that new antitrust legislation might be a priority for the administration. This conclusion can be inferred by the additional 70 million dollars in budget the FTC has requested for the 2024 fiscal year to tackle healthcare mergers.[7] In theme, the FTC brought suit against numerous large transactions in the healthcare sector in 2022.[8] These challenges have been brought both when companies in the same or similar industries combine, otherwise known as horizontal integration, and when companies of different supply chain functions have merged, otherwise known as vertical integration.[9] Courts have generally looked favorably upon challenges against horizontal integration; however, they were not persuaded by the FTC's antitrust theories regarding vertical integration.[10] This is primarily because FTC challenges of M&A activity are motivated by showings of change in market share, which provides a shortcut in meeting a Section 7 antitrust claim.[11] It is easier to

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[6] Gordon M. Phillips & Alexei Zhdanov, *R&D and the Incentives from Merger and Acquisition Activity*, 26 THE REV. OF FIN. STUD. 34, 35 (2013); Jeffrey Bartel, *Healthcare Merger and Acquisition Trends and Outlook for 2023*, FORBES (Feb. 8, 2023), https://www.forbes.com/sites/forbesfinancecouncil/2023/02/08/healthcare-merger-and-acquisition-trends-and-outlook-for-2023/?sh=72e88c181d5c.

[7] Alan Condon, *FTC Wants $70M Budget Increase to Tackle Healthcare Challenges*, BECKER'S HOSP. CFO REP. (March 23, 2023, 9:11 AM), https://www.beckershospitalreview.com/finance/ftc-wants-70m-budget-increase-to-tackle-healthcare-challenges.html.

[8] Harris Meyer, *Biden's FTC Has Blocked 4 Hospital Mergers and Is Poised to Thwart More Consolidation Attempts*, KFF HEALTH NEWS (July 18, 2022), https://kffhealthnews.org/news/article/biden-ftc-block-hospital-mergers-antitrust/.

[9] Surbhi S, *Difference Between Horizontal and Vertical Integration*, KEY DIFFERENCES (July 27, 2021), https://keydifferences.com/difference-between-horizontal-and-vertical-integration.html.

[10] Devon Minnick, et al., *Top Ten Issues in Health Law 2023*, AM. HEALTH LAW ASS'N (AHLA) (Jan. 1, 2023), https://www.americanhealthlaw.org/content-library/connections-magazine/article/a615bfea-660e-49cd-bf60-5a36e9a83750/top-ten-issues-in-health-law-2023.

[11] J. Mark Gidley, et al., *U.S. Antitrust Agencies Propose Sweeping Changes to Merger Guidelines – 5 Key Things You Need to Know*, WHITE & CASE (July 20, 2023),

show an immediate substantial change in market share when the government is analyzing horizontal integration versus vertical integration, as vertical integration involves M&A activity lower on the supply chain rather than transactions involving directly competing corporations.[12]

On July 19, 2023, the FTC and Department of Justice (DOJ) released new draft merger guidelines outlining how M&A activity, including vertical integration, can weaken competition.[13] These new guidelines specifically mentioned healthcare in their discussion of regulating oligopolistic markets, and most provisions of the new guidelines alluded to the agency's critical perspective of M&A in the healthcare sector.[14] This article argues that the legal arguments provided by the newly released guidelines are far from what courts have been willing to accept when reviewing challenges against vertical mergers in the healthcare industry, and the real solution lies with a change to legislation.[15]

First, this article will examine recent judicial decisions arising out of FTC and DOJ enforcement of M&A activity in the healthcare sector. Next, this article will inspect the recent merger guidelines released by the FTC and DOJ and question its effectiveness. Finally, this article will explain how courts will only be able to follow the government's reasoning for challenging

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https://www.whitecase.com/insight-alert/us-antitrust-agencies-propose-sweeping-changes-merger-guidelines-5-key-things-you.

[12] *See Merger Guidelines*, U.S. DEP'T OF JUST. & THE FED. TRADE COMM'N (July 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf.

[13] Press Release, *FTC and DOJ Seek Comment on Draft Merger Guidelines*, FED. TRADE COMM'N (July 19, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-doj-seek-comment-draft-merger-guidelines.

[14] *Merger Guidelines*, U.S. DEP'T OF JUST. & THE FED. TRADE COMM'N (July 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf.

[15] John B. Dubrow, *Assessing the state of affairs in FTC/DOJ merger enforcement*, REUTERS (July 10, 2021, 11:00 AM), https://www.reuters.com/legal/transactional/assessing-state-affairs-ftcdoj-merger-enforcement-2023-07-10/.

vertical healthcare acquisitions if legislation is updated in conjunction with the newly released guidelines.[16]

II. THE UPTICK OF FTC ANTITRUST ENFORCEMENT IN THE HEALTHCARE SECTOR

Historically, the anti-competitive effects of horizontal mergers have been well documented.[17] For horizontal integration, specifically in the healthcare sector, extensive research has been conducted, which shows a clear trend of rising prices.[18] While some economists suggest that elevated prices should increase the number of possible new competitors in the market, there has been no evidence of this activity occurring.[19] Generally, recent FTC enforcement against horizontal integration in the healthcare sector has been successful.[20] The FTC managed to score victories against RWJBarnabas Health's acquisition of St. Peter's Healthcare System and HVA Healthcare's acquisition of Steward Health Care System.[21] The FTC's theories against horizontal mergers using Section 7 of the Clayton Act stem from the idea that further consolidation of a healthcare market will lead to raised prices and diminished patient quality of care.[22]

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[16] Bill Baer, *Improving Antitrust Law in America*, BROOKINGS (October 1, 2020), https://www.brookings.edu/articles/improving-antitrust-law-in-america/.
[17] Maryam Fathollahi, et al., *Anticompetitive Effects of Horizontal Acquisitions: The Impact of Within-Industry Product Similarity*, 144 J. OF FIN. ECON. 645 (June 22, 2021).
[18] Stefan Rao Kostas, *Hospital Mergers: The Symptoms of Anticompetitive Consolidation & A Routine Checkup on the Horizontal Merger Guidelines*, 31 U. MIA BUS. L. REV. 1, 3 (2023).
[19] Meyer, *supra* note 8.
[20] Minnick, *supra* note 10.
[21] *Id.*
[22] Hoag Levins, *Hospital Consolidation Continues to Boost Costs, Narrow Access, and Impact Care Quality*, Univ. of Penn, LEONARD DAVIS INSTITUTE OF HEALTH ECON. (Jan. 19, 2023), https://ldi.upenn.edu/our-work/research-updates/hospital-consolidation-continues-to-boost-costs-narrow-access-and-impact-care-quality/.

The Clayton Act encompasses a range of provisions but is primarily recognized for its Section 7 language, which prohibits mergers and acquisitions that could "substantially lessen competition or tend to create a monopoly."[23] This is the same antitrust statute that the FTC and DOJ utilize in their efforts to address vertical integration, though this application has not been nearly as successful.[24] Notably, the DOJ attempted to block UnitedHealth Group's proposed acquisition of Change Healthcare, only for a Judge to deny the request for the injunction.[25] In citing the 2001 case, *F.T.C. v. H.J. Heinz Co.*, the court quickly established the legal standard to show a negative effect of competition in the enforcement of a horizontal merger under Section 7 of the Clayton Act. [26] Presenting market-share statistics triggers "a presumption that the merger will substantially lessen competition."[27] When describing how that legal standard might change when analyzing a Section 7 challenge against a vertical merger, the court cited *United States v. AT&T Inc.*, explaining that for a vertical merger, there is no short-cut way to establish anti-competitive effects because "vertical mergers produce no immediate change in the relevant market share."[28] Accordingly, the government meets its prima facie burden in vertical merger cases by making a "fact-specific showing" that the proposed merger is likely to be anti-competitive.[29]

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[23] 15 U.S.C § 18 (1914).
[24] Minnick, *supra* note 10.
[25] United States v. UnitedHealth Grp. Inc., 630 F. Supp. 3d 118, 155 (D.D.C. 2022).
[26] *Id.* at 130; F.T.C. v. H.J. Heinz Co., 246 F.3d 708, 715 (D.C. Cir. 2001) ("In challenging a horizontal merger—that is, a merger between direct competitors—the government can establish its prima facie case simply by showing that the "merger would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market.").
[27] Heinz, 246 F.3d at 715.
[28] *Id.*
[29] *Id.*

Courts justify the use of the same legal standard for both types of transactions, specifically in the healthcare industry, for two significant reasons: 1) the statutory text only points to a showing that the transaction will substantially lessen competition, and 2) previous and largely outdated economic theories have detailed the potential benefits of vertical integration in the healthcare industry.[30] In regard to the latter, the economic theory behind this belief is relatively easy to follow: if a vertical transaction results in once-spread independent physicians being organized into one hospital system, then economies of scale will create greater efficiencies, and therefore, patients will get better quality of care through coordination.[31] However, recent studies from the Harvard Kennedy School point to quite the opposite effect.[32] Specifically, these studies show that after analyzing over two million patient visits, it "found that physicians significantly alter their care process after they vertically integrate," resulting "in [a] substantial increase in patients' post-procedure complications."[33] Additionally, because vertical integration leads to a monopoly in downstream products that were once independent, prices increase due to the corporation's control of the market, and consumers lack competitive alternatives.[34]

The Clayton Act is specific to the first point: mergers and acquisitions are prohibited if the effect may substantially lessen competition or tend to create

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[30] 15 U.S.C § 18; DEBORAH HAAS-WILSON, MANAGED CARE & MONOPOLY POWER: THE ANTITRUST CHALLENGE 161, (2003).
[31] Robert O'Neill, *Study Finds Vertical Integration in Medicine is Leading to Higher Costs and Worse Health Outcomes*, HARVARD KENNEDY SCH. (March 2, 2023), https://www.hks.harvard.edu/faculty-research/policy-topics/health/study-finds-vertical-integration-medicine-leading-higher.
[32] *Id.*
[33] *Id.*
[34] Xenia Shih Bion, *Is Vertical Integration Bad for Health Care Consumers?*, CAL. HEALTH CARE FOUND. (June 21, 2019), https://www.chcf.org/blog/is-vertical-integration-bad-consumers/.

a monopoly.[35] This statement's clarity has faded in the modern healthcare market, primarily because it is much easier to establish an effect on competition with horizontal rather than vertical mergers.[36] This is due to vertical integration being viral in highly consolidated oligopolistic markets, so parties to the oligopoly can control the price downstream of the supply chain.[37] This is illustrated by the Pharmacy Benefit Manager (PBM) submarket within the healthcare sector.

Due to an extensive series of vertical mergers, the national PBM market has become immensely consolidated, with three vertically integrated companies now controlling access to more than 80% of all prescriptions filled in the United States.[38] Subsequently, the PBM market can be described as a highly consolidated oligopoly, with CVS Health (Caremark), Cigna (Evernorth/Express Scripts), and UnitedHealth (OptumRx) using vertical acquisitions to control the market down the supply chain.[39] In trying to aid this dying market, the government would have to show an acquisition would substantially lessen competition under the Section 7 framework, and it is easy to see how a horizontal merger between the parties to the oligopoly would meet this definition. For example, if CVS acquired Cigna, CVS would have almost 60% of the PBM market share, compared to a 33% market share before the acquisition, showing an immense change in the spread of

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[35] 15 U.S.C. §18.
[36] Matthew Lane, *Antitrust in 60 Seconds: Vertical vs Horizontal Mergers*, Disruptive Competition Project (Nov. 19, 2018), https://www.project-disco.org/competition/111918-antitrust-60-seconds-vertical-vs-horizontal-mergers/.
[37] Letter from the National Community Pharmacists Association to Lisa Khan and Jonathan Kanter (Sept. 5, 2023), https://ncpa.org/sites/default/files/2022-02/letter-kahn-kanter-ugh-change-hc.pdf.
[38] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, DRUG CHANNELS (April 5, 2022), https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html?m=1.
[39] *Id.*

competition in the market.[40] However, if CVS were to conduct a vertical acquisition of a company providing products lower down the value chain, the overall market share of the PBM industry would only slightly change, if at all. Due to the market's significant consolidation and anti-competitive nature, it is exceedingly difficult to show an immediate lessening of competition with a vertical merger.[41] Courts are meant to review whether competition will be substantially lessened directly due to the merger, signaling a short-term analysis.[42] CVS's vertical integration may not show immediate short-term effects on competition within the PBM market, but over time and through continued vertical acquisitions, market share will slowly show significant change.[43] There is a clear disconnect between the expected analysis of mergers under Section 7 of the Clayton Act and the anticompetitive effects of vertical integration.

III. FTC GUIDELINES FAIL TO CONSIDER THE JUDICIAL EFFECTIVENESS OF MERGER GUIDELINES

Courts often fail to understand agency challenges of vertical integration in the healthcare sector under Section 7 of the Clayton Act, which led the FTC and DOJ to propose a new set of merger guidelines.[44] These guidelines attempted to warn corporations of the type of acquisition activity that would trigger their enforcement and provide further explanation to try and convince courts of its theory that vertical integration can lead to long-term anti-

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[40] *Id.*
[41] Sam Heather, *Unlocking Antitrust: Evaluating Vertical Mergers*, U.S. CHAMBER OF COM. (Jan. 25, 2021), https://www.uschamber.com/regulations/unlocking-antitrust-evaluating-vertical-mergers.
[42] *Id.*
[43] Steven C. Salop and Daniel P. Culley, *Potential Competitive Effects of Vertical Mergers: A How-To Guide for Practitioners*, 1392 GEO. L. CTR.: FAC. PUBL'NS & OTHER WORKS, 9 (2014).
[44] Press Release, *supra* note 13.

competitive effects.[45] Specifically, Merger Guideline 6 offered additional guidance on vertical mergers creating market structures that foreclose competition, stating that if the foreclosure share is above 50%, that factor alone is a sufficient basis to conclude that the effect of the merger may be to substantially lessen competition.[46] Additionally, Merger Guideline 7 focuses on how oligopolistic parties such as CVS in the PBM market should not use mergers to entrench or extend its dominant position, stating that the effect of entrenching or extending an already dominant position "may be substantially to lessen competition" or it "may be…to tend to create a monopoly" in violation of Section 7 of the Clayton Act.[47] These guidelines can provide more context for courts to understand why the government brought a suit against a vertical merger in a consolidated industry. However, as seen in *UnitedHealth* and surrounding cases in the healthcare sector, courts are still not convinced as the statutory language of the Clayton Act still sits far away from these theories.[48] Due to the immense separation between the statutory language and the FTC's new guidelines specifically targeting vertical mergers in the healthcare sector, there is a significant disconnect between our legislative and judicial branches regarding this subject of antitrust law. Therefore, the answer to providing the courts with the resources to create a legal standard surrounding how to measure the effects of vertical integration is to enact significant changes to the Clayton Act, something that occurs very infrequently despite the immense growth of the U.S. economy in modern history.[49]

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[45] Merger Guidelines, *supra* note 14.
[46] *Id.*
[47] *Id.*
[48] Dubrow, *supra* note 15.
[49] Fiona M. Scott Morton, *Is Antitrust Law Keeping Up?*, YALE INSIGHTS (July 12, 2013), https://insights.som.yale.edu/insights/is-antitrust-law-keeping-up.

IV. Proposal to Amend Section 7 of The Clayton Act to Account for Vertical Integration Challenges in Already Competitively Compromised Market Structure

To protect competition within the healthcare sector and patients from a decrease in the quality of medical care, a change in legislation is necessary. Most challenges to M&A activity in the healthcare sector consistently utilize Section 7 of the Clayton Act, and therefore, the legislation changes should amend rather than erase the current provisions.[50] The current framework of Section 7 includes a variety of provisions that are all based on corporate mergers and acquisitions being prohibited if "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[51] As discussed previously, this language worked well for antitrust enforcement of horizontal mergers in the healthcare sector.[52] Therefore, removing this language in exchange for a substitute that accounts for vertical merger enforcement would likely be a mistake. Such a substantial change would erase decades of legal precedent and economic analysis, which have proven the harmful effects of horizontal integration in the healthcare sector.[53] Recent research developments indicate that vertical integration provides similar price hike effects and lowers patient care quality, which illustrates that it would be best to add a new provision to Section 7.[54] These new provisions

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[50] Holly Vedova, et al., *Avoiding Antitrust Pitfalls During Pre-Merger Negotiations and Due Diligence,* Fed. Trade Comm'n (March 20, 2018), https://www.ftc.gov/enforcement/competition-matters/2018/03/avoiding-antitrust-pitfalls-during-pre-merger-negotiations-and-due-diligence.

[51] 15 U.S.C. §18.

[52] Minnick, *supra* note 10.

[53] *See generally* Raechel N. Warren, *What About the Patient? The Effects of Mergers and Acquisitions in the Hospital Industry on Patient Care*, 3 Seattle Univ. Undergraduate Rsch. J. 10 (2019).

[54] Princess Sutherland, *Healthcare Industry – The Rise of Vertical Integration*, Tom Spencer (Feb. 3, 2019), https://www.spencertom.com/2019/02/03/healthcare-industry-the-rise-of-vertical-

should mirror the "substantially lessen" statutory structure but should instruct the court to incur a different examination of merger consequences:

> Proposed Amendment. No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to *create a market structure that forecloses competition, such as an oligopoly, or entrenches an already established dominant market position in an anti-competitive market structure.*
>
> > No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition, of such stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially to *create a market structure than forecloses competition, such as an oligopoly, or entrenches an already established dominant market position in an anti-competitive market structure.*

By adding a provision looking to prohibit mergers that create market structures that foreclose competition, such as an oligopoly, the statutory language will reflect the spirit of antitrust laws. This amendment seeks to combat antitrust issues in their inception in the modern American economy, even when analyzing vertical integrations that may not in themselves immediately substantially affect competition.[55] The current language, which only names monopoly as the primary market structure violating Section 7, was included due to the dominance of monopolistic parties in the early 1900s,

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integration/#:~:text=Four%20disadvantages%20may%20include%20high,vertically%20integrated%20system%20is%20expensive.

[55] Merger Guidelines, *supra* note 14.

prior to the enactment of the Clayton Act.[56] The use of that language has led to a decrease in the prevalence of monopolies in the U.S. economy.[57] When the current language was enacted, oligopolistic market structures were not yet prevalent and, therefore, were not on the radar of antitrust regulators. This is very different than the modern age, where oligopolistic market structures are extremely prevalent, as seen in the pharmacy benefit management (PBM) industry of the healthcare sector.[58] With the addition of the term "oligopoly" in the statutory text of Section 7, the statute will provide the representation necessary for courts to truly understand the legislature's intent to stop the formation of both oligopolies and monopolies.

Additionally, by adding the provision that prohibits M&A activity that entrenches already dominant market positions, the FTC can adequately bring enforcement challenges against vertical integration transactions that support market structures where an oligopoly already exists, like the PBM market in the healthcare sector.[59] Adding provisions that move away from a short-term anti-competitive analysis and instead focus on long-term market structures

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[56] *Gilded Age Robber Barons*, STUDENTS OF HISTORY, https://www.studentsofhistory.com/gilded-age-robber-barons (last visited Oct. 18, 2023).
[57] *See* Fred Ashton, *Are Monopolies Really a Growing Feature of the U.S. Economy*, AM. ACTION F. (May 16, 2022), https://www.americanactionforum.org/research/are-monopolies-really-a-growing-feature-of-the-u-s-economy/.
[58] Smith Brain Trust, *America Has an Oligopoly Problem*, UNIV. OF MD. ROBERT H. SMITH SCH. OF BUS. (July 6, 2021), https://www.rhsmith.umd.edu/research/america-has-oligopoly-problem; Am. Pharmacists Ass'n, *Break Up PBM Oligopolies, APhA Tells FTC*, CISION PR NEWSWIRE (Sept. 15, 2021), https://www.prnewswire.com/news-releases/break-up-pbm-oligopolies-apha-tells-ftc-301378073.html#:~:text=Knoer%20told%20the%20FTC%20that,%2C%20anticompetitive%20conduct%2C%20he%20said; *see generally* Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates About Pharmacy Benefit Managers*, BROOKINGS (Sept. 7, 2023), https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/.
[59] National Community Pharmacists Association, *supra* note 37.

can prevent oligopolistic market structures within the healthcare sector and limit the growth of their market dominance.

V. An Example of Enforcement Against Hypothetical Vertical Integration Using the Proposed Amendments

A hypothetical situation within the healthcare sector allows for a test of the effectiveness of this amendment when it pertains specifically to vertical integration. Hemodialysis, a treatment to filter waste and water from your blood due to kidney failure, is a subsector of the healthcare industry that affects hundreds of thousands of people nationwide.[60] The hemodialysis market is a perfect example of another oligopoly rising within the healthcare umbrella, with 84% of the industry market share made up of two parties, Fresenius Medical Care and DaVita, translating to 366,000 patients out of a total of 433,000 patients in 2016.[61] If DaVita were to try to complete a horizontal acquisition of Fresenius, it would almost immediately be challenged and likely blocked by the FTC.[62] This is because Section 7 of the Clayton Act is aimed at a "substantially lessen competition" framework, and the only other party posing a competitive challenge to DaVita would effectively be eliminated. Compare this to if DaVita were to conduct a vertical acquisition, acquiring a large player of industry down the supply chain; the result would likely be the opposite. It may not increase their market share in hemodialysis, but it would increase the company's overall market power by adding market share in a downstream market. Additionally, no party within the hemodialysis market would be removed to create a

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[60] *See Hemodialysis*, Mayo Clinic (Aug. 5, 2023), https://www.mayoclinic.org/tests-procedures/hemodialysis/about/pac-20384824.
[61] Susan Eymann, *Fresenius and DaVita Capture 84% of U.S. Hemodialysis Market*, Transonic (Aug. 24, 2016), https://blog.transonic.com/hemodialysis/fresenius-and-davita-hemodialysis-market.
[62] *Id.*

monopoly, as represented in Section 7 statutory language. This type of merger left to close would beckon even further rising prices for hemodialysis.[63]

Now, change the enforcement analysis of this transaction under this article's proposed amendment to Section 7. The second part of the proposed amendment would likely provide a convincing argument to a court, as the acquisition would be entrenching the already dominant position of DaVita in an anti-competitive market structure, in this case, the oligopoly of the hemodialysis market. The entrenchment is being done by DaVita through purchasing corporate players down the supply chain, thereby preventing the remaining 16% of market share players from utilizing its services. As it pertains to vertical integration, proving oligopolistic entrenchment in line with the proposed statutory test would allow for the government to have a much better chance of proving harm caused by the transaction.

The inclusion of this amendment into the statutory text will shine a light on the need for legislative change and allow the FTC and DOJ to utilize the text in the enforcement of M&A activity, resulting in continued interpretation from judges and economic deliberation. The resulting judicial interpretation will allow for an adequate legal standard to develop when courts look to measure vertical integration based on its context-specific analysis rather than utilizing the same legal standard developed for horizontal integration.

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[63] Carrie Arnold & Larry C. Price, *Kidney Dialysis Is a Booming Business – Is It Also a Rigged One?*, SCIENTIFIC AM. (Dec. 14, 2020), https://www.scientificamerican.com/article/kidney-dialysis-is-a-booming-business-is-it-also-a-rigged-one1/.

VI. CONCLUSION

With the recently invigorated leadership of antitrust regulatory agencies, many have questioned whether this is finally the time for vertical integration to be haltered. This article shows that these agencies have been unable to convince courts of recent economic theories regarding the competitive downfalls of vertical integration in the healthcare sector and that this result will repeat itself in future challenges irrespective of the agency's new merger guidelines due to the judiciary's dependence on the textual language of federal antitrust statutes. Therefore, a much deeper-rooted legal change must occur to accommodate for this discrepancy, aimed directly at the language of Section 7 of the Clayton Act.

The current antitrust legislation is no longer as effective in the current economy as it was in the Clayton Act's inception due to the decaying instances of monopolies. The proposed legislative amendment turns focus to examining whether an oligopoly is being substantiated through chronic vertical integration, a trend seen throughout some of the most powerful industries in the American economy in the modern era. If this amendment is not made, federal regulators will not be able to control the growing instances of vertical integration in the healthcare industry. This has significant personal consequences on consumers, such as rising healthcare prices and a decline in practitioner care standards. It is up to the newly revitalized FTC and DOJ to continue its challenges to vertical integration and the court's responsibility to develop the judicial interpretation needed to give the amendment legal support.

Regulating Embryo Cryopreservation Storage: Mitigating Litigation of Negligently Lost or Damaged Frozen Embryos

Megan Baumgardner

I. INTRODUCING THE CURRENT LANDSCAPE OF CRYOPRESERVATION REGULATIONS

Frozen embryos are a relatively new innovation out of assisted reproductive technology and remain highly unregulated.[1] Currently, there exists a substantial lack of regulation governing the use of assisted reproductive technology (ART), particularly embryo cryopreservation.[2] In 2019, New Jersey became the first state to pass regulatory laws governing the proper licensing of embryo storage facilities.[3] This came a year after a malfunction at an embryo storage facility that resulted in a catastrophic loss and a multi-million dollar class action suit.[4] This article will expand on the current legal status of cryopreserved embryos and advocate for increased regulations in order to mitigate similar negligence suits in the future.

This article proposes regulations to preemptively mitigate torts actions involving the loss or damage of frozen embryos. Rather than postulating as to the best method for remedying these losses, the proposed regulations will work to minimize claims entirely, by mandating that embryo storage facilities, and all employees who handle embryos at any stage of

[1] Priscilla Melantonio et al., *Delivering Embryos Following 10 Years of Cryopreservation, Using Unpaired Freeze/Thaw Techniques: A Case Report*, 25 NAT'L LIBR. OF MED. 644-46 (2021).
[2] Isabella Goza, *Note: The ART of Calculating Damages for Negligence*, 52 U. MEM. L. REV. 495, 498 (2021) ("With a lack of cohesive procedural rules, ART matters remain ongoing topics of dispute in need of resolution.")
[3] N.J. Stat. Ann. § 26:2A-25 (West).
[4] Bergman v. Coastal Fertility Med. Ctr., 2018 Cal. Super. LEXIS 48506.

cryopreservation and storage, are properly trained and licensed.[5] A system of regulations would reduce the potential loss, saving facilities millions in payouts and saving patients and hopeful parents from the heartbreaking loss of potential for a biological child.

II. AN OVERVIEW OF EMBRYO CRYOPRESERVATION AND RESULTING NEGLIGENCE SUITS

Embryo cryopreservation is a relatively new branch of ART, with the first successful frozen embryo transfer taking place in 1984.[6] Since then, embryo cryopreservation has become an effective means of fertility treatment and family planning.[7] The procedure involves the retrieval of eggs from a female who has undergone a period of hormone treatment, which are then frozen unfertilized, or fertilized with sperm, to create an embryo.[8] Embryos are typically frozen through one of two methods, either "vitrification (flash freezing)" or "slow programmable freezing."[9] By freezing the embryos, reproductive endocrinologists can pause all "biological activity" for an indefinite period.[10]

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[5] *Training and Education*, MINITUBE.COM, https://www.minitube.com/catalog/en/minitube/training-and-education/ (Last visited, Sept. 16, 2023).
[6] Priscilla Melantonio et al., *supra* note 1, at 644.
[7] National Perinatal Epidemiology and Statistics Unit, *IVF Success Rates Have Improved in the Last Decade Especially in Older Women: Report*, UNSW SYDNEy (Sept. 19, 2021), https://npesu.unsw.edu.au/news/ivf-success-rates-have-improved-last-decade-especially-older-women-report ("The biggest improvements happened in live birth rates in frozen embryo transfers v fresh transfers. There has been a 50% increase over the last decade in the live birth rate per frozen embryo transfer from 20% in 2010 to 30% in 2019. Over the same period the live birth following fresh transfers has increased from 24% to 25%").
[8] Seema Mohapatra, *Using Egg Freezing to Extend the Biological Clock: Fertility Insurance or False Hope?*, 8 HARV. L. & POL'Y REV. 381, 385-88 (2014) (discussing the financial costs of egg freezing and the process through which eggs are retrieved and stored).
[9] *What is embryo freezing?*, WOMEN & INFANTS FERTILITY CTR., https://fertility.womenandinfants.org/treatment/fertility-preservation/embryo-freezing (last visited Aug. 31, 2023).
[10] *Id.*

The freezing of embryos is a very precise and delicate science.[11] The cells are extremely fragile and must be handled delicately and if any damage is detected.[12] Physicians will consider the embryo unusable.[13] The sensitive nature of the process, and high risk of failure, leaves it vulnerable to litigation. There are several recent cases that illustrate common legal claims that arise out of negligent handling of frozen embryos.

In the case of *Bergman v. Coastal Fertility Med. Ctr.*, a storage facility was sued after laboratory technicians negligently destroyed the plaintiffs' frozen embryos during a transfer.[14] It was presumed that "the embryos may have become 'stuck' to the inside of the straw, resulting in them having 'dried out' prior to the actual thawing.[15] Plaintiffs' retained expert is of the opinion that defendants failed to properly load, seal or store the embryos …"[16] The Plaintiffs brought this suit under multiple counts, including one for negligence and another for conversion of property.[17] The conversion claim failed under a motion for summary judgment, as the court held the Plaintiffs were unable to present evidence that the Defendants had intent to deprive them of the embryos.[18] The negligence claim, however, survived the motion

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[11] *Id.*
[12] *Id.*
[13] Wong v. Stillwater Insurance Company, 92 Cal. App. 5th 1297, 1307 (Cal. App. 2023) ("The science behind IVF is precise, including what we know about vitrification. We don't know the consequences of embryos that could have partially thawed. We don't 'wing it' or guess that something is 'close enough.' There was—and is—no way to know about the resulting consequences to cells themselves. While it would be possible to look at thawed zygotes and observe the outer structure of cells to observe apparent integrity, even if the cell walls were to appear sound, there is no way to know whether the cells, once implanted, begin to divide. Nor is there a way to test sufficiently for any resulting damage to genes within any of these cells. I advised the Wongs that they should consider these embryos to have been irreversibly compromised, no longer viable, and lost").
[14] Bergman v. Coastal Fertility Med. Ctr., 2018 Cal. Super. LEXIS 48506.
[15] *Id.* at 3.
[16] *Id.*
[17] *Id.* at 6-7.
[18] *Id.* at 10.

as there was a triable issue of fact regarding whether the defendants "followed basic protocol."[19]

Another case, *Wong v. Stillwater Ins. Co.*, was brought by Plaintiffs after the catastrophic destruction of their frozen embryos after one of the storage tanks leaked liquid nitrogen and thawed several embryos.[20] In this instance, the plaintiffs were unable to recover damages for the loss of their embryos.[21] Because they brought suit under an insurance policy, which the court held did not cover "a loss of embryos resulting from a cryogenic tank failure," the plaintiffs were unable to recover damages.[22] Given that the tank had merely prematurely thawed the embryos the court determined they were not actually destroyed because there was no real way to determine if the embryos had undergone "an actual physical change."[23] Unfortunately, despite the uncertainty surrounding the physical state of the embryos after the tank failure, the reality is that the plaintiffs lost the opportunity to use the embryos. Medical standards in ART strongly disapprove of using any embryos that were not properly stored and thawed because of the uncertain repercussions.[24]

As recent cases show, it can be extremely difficult for plaintiffs to recover damages for negligently damaged or lost embryos. This is in large part due

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[19] *Id.* at 7 (holding that expert testimony was necessary to the determination of reasonableness of the defendant's conduct. Medical personnel are held to standards in line with their field and in order to assess whether the laboratory technicians properly handled the embryos trial needed to include the testimony from knowledgeable experts).
[20] Wong v. Stillwater Insurance Company, 92 Cal. App. 5th 1297, (Cal. App. 2023).
[21] *Id.* at 1326.
[22] *Id.*
[23] *Id.* at 1310-11 ("As to the no 'physical loss' issue, Stillwater's reply argued that Dr. Eyvazzadeh's declaration established what Stillwater had contended from the outset, that the Wongs could not meet their burden of proving a 'physical loss' because Dr. Eyvazzadeh herself admitted there is 'no way to know' whether the Wongs' embryos had undergone an actual physical change").
[24] Wong v. Stillwater Insurance Company, 92 Cal. App. 5th 1297 (Cal. App. 2023); *see also* Lisa A. Rinehart, *Storage, Transport, and Disposition of Gametes and Embryos: Legal Issues and Practical Considerations*, 115 FERTILITY & STERILITY 274, 274 (2021) (discussing the risks associated with thawing embryos and the best practices for clinics from a legal perspective).

to two issues, the first being the uncertainty surrounding how to classify embryos in a tort action, and the second being the lack of regulations enforcing best practices. With these two uncertainties, jurisdictions handle these negligence suits very differently. An important part of proposing regulations is doing so at the federal level to encourage uniformity across the states.

III. LEGAL CONCERNS SURROUNDING FROZEN EMBRYOS

With embryo cryopreservation being a relatively new technology that continues to experience growth and development each year, scholars in the legal field are still grappling with how to regulate frozen embryos.[25] ART is primarily regulated at the state level and there is great discrepancy in how states have chosen what legal status frozen embryos hold.[26] States that have addressed legal concerns surrounding embryos have primarily viewed the issue through the lens of estate planning.[27] Legal uncertainty about how to define ownership of embryos or who should receive rights to an embryo after a divorce have been the topic of much literature.[28] There is also a great deal of discussion concerning how to legally classify embryos in general. The two most common legal classifications granted to frozen embryos are as either persons or property.[29]

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[25] Bill E. Davidoff, *Frozen Embryos: A Need for Thawing in the Legislative Process*, 47 SMU L. REV. 131, 138-48 (1993) (discussing the theories behind settling on a definitive legal status for frozen embryos).
[26] Anna El-Zein, *Embry-Uh-Oh: An Alternative Approach to Frozen Embryo Disputes*, 82 MO. L. REV. 881, 883-99 (2017) (discussing the legal background of the interests for classifying frozen embryos in a certain manner and how state courts approach the issue).
[27] *Id.* at 890.
[28] *Id.* at 885-86.
[29] Caroline A. Harman, *Defining the Third Way - The Special-Request Legal Status of Frozen Embryos*, 26 GEO. MASON L. REV. 515, 521-48 (2018) (discussing three different means for legally classifying frozen embryos and the repercussions of each).

A. Argument for Embryos Classified as Persons

Embryos are genetically unique, able to respond to their environment, and hold a potential for birth.[30] Embryos' ability to develop into human tissue and human life sets them apart from any common belonging.[31] In 2018, only two states, Louisiana and New Mexico, granted personhood status to embryos.[32] In doing so, these states have allowed for a much higher liability for healthcare providers than states that view embryos as property.[33] Plaintiffs in cases of negligently lost or damaged embryos would subsequently be able to bring claims of wrongful death against defendant storage facilities or clinics.[34]

Choosing to grant a personhood status to a frozen embryo is an unpopular and highly consequential method of legal classification.[35] Especially after the *Dobbs* decision, revoking constitutional protections to the right to abortion access, there has been increased concern about the possible ramifications of classifying embryos as persons.[36] There is a high chance that some embryos will be left unused, as the process of embryo cryopreservation often requires several embryos to be created to bolster the chances of conception and only those with the highest chance of viability are implanted.[37] If classified as a person, there is concern that state laws may consider discarded embryos as a banned medical procedure under stricter

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[30] Davidoff, *supra* note 25, at 137 (discussing the theories behind settling on a definitive legal status for frozen embryos).
[31] *Id.* at 138.
[32] Harman, *supra* note 29, at 527 (discussing three different means for legally classifying frozen embryos, the repercussions of each, and the two states that treat a frozen human embryo as "human").
[33] *Id.*
[34] *Id.* at 528.
[35] *Id.* at 527.
[36] Gerard Letterie & Dov Fox, *Legal Personhood and Frozen Embryos: Implications for Fertility Patients and Providers in Post-Roe America*, 10 J. OF L. & THE BIOSCIENCES, 1-13 (2023) (discussing the implications of defining frozen embryos as persons in a post-*Dobbs* decision world).
[37] WOMEN & INFANTS FERTILITY CTR., *supra*, note 9.

abortion regulations.[38] Additionally, in the realm of tort litigation, this classification opens the door to possibilities for prospective parents who may have had embryos lost, damaged, or negligently destroyed to bring claims of wrongful death against ART facilities.[39]

B. Argument for Embryos Classified as Property

The other most common legal classification granted to frozen embryos is the designation of being property.[40] In the case *York v. Jones*, a couple brought suit to transfer embryos from one clinic to another, prompting the court to determine that the couple's embryos were in fact their property because "embryos were more like property than life."[41] Classifying a frozen embryo as property allows for contracts regarding the storage and use of the embryo without raising issues of property rights over a human body.[42] Additionally, in states where courts have determined that embryos may be considered property rather than persons, there is a higher potential for recovery in a torts action for the negligent loss or destruction of frozen embryos.[43]

However, concerns are raised under this theory about the extent to which recovery may be possible.[44] Because frozen embryos held at storage facilities are commonly under contract between the progenitors and the facilities, there is the possibility that progenitors signed away the potential for recovering

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[38] Letterie & Fox, *supra* note 36, at 5.
[39] *Id.* at 6.
[40] Molly O'Brien, *An Intersection of Ethics and Law: The Frozen Embryo Dilemma and the Chilling Choice Between Life and Death*, 32 WHITTIER L. REV. 171, 177-81 (2010) (discussing embryo status as either life or human tissue and the implications of considering embryos to be designated as property, life, or tissue with the potential for human life).
[41] *Id.* at 179.
[42] Harman, *supra* note 29, at 529 ("Because the embryos are solely the property of the progenitors, not deserving of any 'special respect' or 'human' component, they may also be contracted for without raising any Dred Scott concerns or arguments related to the sale of body parts and tissue").
[43] *Id.* at 534-35.
[44] *Id.*

certain damages.[45] Under contracts with facilities, progenitors may be restricted to recovering only the actual cost of the IVF procedures, which fails to adequately consider the full injury of loss or damage.[46] For many, frozen embryos are a final chance for a biological child and the emotional damage that occurs when this chance is taken away cannot be fairly compensated under a property framework.[47]

IV. PROPOSED REGULATIONS OF STORED CRYOPRESERVED EMBRYOS

A great deal of the current literature regarding the legal complexities presented by embryo cryopreservation technology focuses on the legal classification and possible tort remedies.[48] Considering recent major class actions discussed previously, this is a valid reaction. However, this article seeks to shift the focus of discussion to possible preemptive measures. The heated debate concerning how to remedy the loss or destruction of lost embryos is not one which will be solved with ease. There is great emotion in each case of frozen embryo loss and, considering the ramifications of each method of classification, it is unlikely state jurisdictions will settle on a best practice. It may then be more effective to turn to potential regulations for the storage facilities with the aim of reducing the negligent handling of frozen embryos.

There are few implemented regulations of frozen embryos in the United States. It has been postured that the reluctance to introduce regulations traces back to the innate family and moral values brought into question when considering best practices for assisted reproduction.[49] This creates a great deal of tension and reluctance to address potential legal

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[45] *Id.* at 535.
[46] *Id.*
[47] *Id.*; *see also* Frisina v. Women & Infants Hosp. of Rhode Island, No. CIV. A. 95-4037, 2002 WL 1288784, at 10 (R.I. Super. Ct. May 30, 2002).
[48] Harman, *supra* note 29.
[49] Dov Fox, *Essay: Reproductive Negligence*, 117 COLUM. L. REV. 149, 163-68 (2017).

concerns.[50] Additionally, there is the fact that the "multibillion-dollar fertility industry in America mounts powerful lobbying forces against occasional calls for regulation."[51] What has occurred, is an ineffective scheme of internal guidelines that are hardly enforced and result in catastrophic negligence, such as the storage facility malfunction in *Bergman,* or the mishandling of frozen embryos in *Ivinson v. New England Cryogenic Inc*.[52] This has led to publications, such as The New York Times, designating the industry of assisted reproduction as a form of "buyer-beware" scheme.[53]

Despite the hurdles to passing regulations of ART, New Jersey managed to become the first state to do so in 2019 and, in March of 2023, these regulations were expanded, in part, to include requirements for embryo storage facility licensure.[54] Section 26:2A-25, entitled "Licensure for embryo storage facility," of the New Jersey statute implements three requirements for embryo storage facilities.[55] First, subsection (a) prohibits any person from "conduct[ing], maintain[ing], or operat[ing] an embryo storage facility" unless they receive a license from the state's Department of Health.[56] Additional facility locations also require independent licenses and

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[50] *Id.*

[51] *Id.* at 164 (discussing possible explanations for the "regulatory vacuum" surrounding fertility treatment).

[52] *Id.*; *see also* Pat Murphy, *Would-be Mom Sues Cryogenic Storage Center Over Lost Eggs*, MASS. LAWYERS WEEKLY (June 14, 2023), https://masslawyersweekly.com/2023/06/14/would-be-mom-sues-cryogenic-storage-center-over-lost-eggs/; *see also* Bergman v. Coastal Fertility Med. Ctr., 2018 Cal. Super. LEXIS 48506.

[53] Tamar Lewin*, Sperm Banks Accused of Losing Samples and Lying About Donors*, N.Y. TIMES (July 21, 2016)*,* http://www.nytimes.com/2016/07/22/us/sperm-banks-accused-of-losing-samples-and-lying-about-donors.html (discussing the "laissez-faire" system of assisted reproductive technologies and the ramifications of not providing a stricter regulatory scheme for such delicate medical matters).

[54] N.J. Stat. Ann. § 26:2A-25 (West).

[55] *Id.*

[56] *Id.* ("No person shall conduct, maintain, or operate an embryo storage facility in this State unless licensed by

any change in ownership requires a notification to the department "within 14 calendar days and reapplication for licensure."[57] Second, the statute prohibits embryo storage facilities from employing individuals who "demonstrate good character, competency, and integrity."[58] Last, the statute requires that the facilities incorporate a standard system of keeping records and reports in accordance with the "Health Insurance Portability and Accountability Act of 1996."[59]

The New Jersey statute establishes a solid foundation for potential federal regulations.[60] However, the statute should be expanded as it fails to address key issues. This article proposes that an expanded version of the New Jersey statute should be implemented on a national level. Working as a preventative measure, federal regulations regarding embryo storage facilities would seek to lessen the chances of negligent loss or destruction of frozen embryos. In addition to the licensure requirements provided by the New Jersey statute, it is necessary to implement a training requirement for proper handling and storage techniques for every facility and to establish a nationwide standard for the classification of embryos. Because it is not uncommon for embryos to be stored at facilities in different states than where the progenitors, and potential plaintiffs, live, it is necessary for a nationwide standard to be implemented. With the current lack of regulation, the location

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the department pursuant to the provisions of this act. A separate license shall be required for each embryo storage facility location. The license shall be posted and displayed at all times in a prominent location within the facility. No license issued pursuant to this act shall be transferable. A change in the ownership of the facility shall require notification to the department within 14 calendar days and reapplication for licensure")

[57] *Id.*

[58] *Id.*

[59] *Id.*; *see also Health Insurance Portability and Accountability Act of 1996*, CTR. FOR DISEASE CONTROL (CDC) (June 27, 2022), https://www.cdc.gov/phlp/publications/topic/hipaa.html (last visited Sept. 19, 2023).

[60] N.J. Stat. Ann. § 26:2A-25 (West).

in which a plaintiff's embryos are frozen can drastically alter how they may attempt to recover damages.[61]

The proposed regulations would cover any embryo that has been frozen in a facility for the purposes of ART. This would allow for researchers and developers to continue to have an ability to conduct studies and craft innovations in the field without the extra hurdle of abiding by additional guidelines apart from those existing to regulate scientific research. These regulations would include similar language to the New Jersey statute and, additionally, include training requirements and an introduction of a set standard for legal classification of embryos. The federal regulation shall include the following language:

(a) No person shall conduct, maintain, or operate an embryo storage facility in the United States without attaining a license to do so by the Department of Health. "A separate license shall be required for each embryo storage facility location."[62] Licenses are to be prominently displayed within facilities, are not transferable, and any change in ownership requires a reapplication for renewed licensure. [63]

(b) No individual may be permitted to work in an embryo storage facility in the United States in a role requiring them to handle embryos or the technology storing embryos without undergoing training and receiving certification of completion.

(c) Facilities shall require progenitors to sign a statement agreeing that the embryos shall be treated as property.

(d) In the event the mishandling of embryos or failure of storage technology results in the loss or destruction of an embryo, subsequent litigation shall view embryos as a loss of property.

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[61] Harman, *supra* note 29.
[62] N.J. Stat. Ann. § 26:2A-25 (West).
[63] *Id.*

The proposed federal regulation would be a baseline for states; however, states would have the discretion to introduce stricter regulations than the proposed federal regulations. Currently, several federal agencies control various aspects of ART laws.[64] The Centers for Disease Control (CDC), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) have each been responsible for the enforcement of safety throughout ART procedures.[65] The above proposed legislation would likely be most successful if backed by CMS, who already spearheaded the Clinical Laboratory Act.[66] This Act focuses on diagnostic testing in clinical laboratories; however, it provides a good structure to expand components to embryo facilities.[67] Failure to comply with such laws will result in facilities losing their licensing and being barred from regaining certification for at least one year.[68]

Shortly after the introduction of the proposed legislation, a training program would need to be designed and implemented. Ideally, this would be done by a panel of medical experts in the field of ART who understand proper techniques and handling procedures to ensure the best chance of embryo survival. For similar past legislation, the American Board of Obstetrics and Gynecology (ABOG) has developed standards for training and a maintenance of certification program.[69] Additional provisions detailing the timeline of implementation and requirements for receipt of licensure would follow with input from trained professionals in the field to ensure the practicality of the regulations.

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[64] *Oversight of Assisted Reproductive Technology,* AM. SOC'Y FOR REPRODUCTIVE MED., https://www.asrm.org/advocacy-and-policy/media-and-public-affairs/oversite-of-art/ (last visited Oct. 15, 2023).
[65] *Id.* at 3.
[66] *Id.* at 6-7.
[67] *Id.* at 6 (requiring ART diagnostic testing laboratories to be registered and certified).
[68] Clinical Laboratory Improvement Amendments 42 U.S.C. § 263a(i) (1988).
[69] American Board of Obstetrics & Gynecology, https://www.abog.org/maintenance-of-certification/eligibility-requirements/specialty-requirements (last visited Oct. 15, 2023).

The proposed regulations are just a step in the right direction for the field of embryo cryopreservation. For an area of medicine that has been left relatively untouched by legislation, it will take numerous proposals to encapsulate all the current legal issues. The largest setback to these regulations seems to come from the field itself.[70] Legislatures may be reluctant to speak out on this topic because the moral and social values associated may not necessarily run cleanly along party lines.[71] There is also significant pressure from lobbyists representing the fertility industry that push strongly against regulations.[72]

V. MITIGATING CLAIMS OF NEGLIGENTLY LOST AND DESTROYED EMBRYOS WITH THE PROPOSED LEGISLATION

Implementing regulations defining and enforcing set training and licensing for embryo storage facilities has the possibility to mitigate litigation brought by negligently lost or damaged cryopreserved embryos.[73] The current absence of federal regulations has left progenitors vulnerable to reproductive negligence.[74] In a study analyzing ten years-worth of claims of embryo loss and destruction, it found that the failure to regulate cryopreservation tanks and communication systems between patients and facilities were the root cause of a majority of the cases brought.[75] Though there would likely be pushback from state legislators and lobbyists representing the ART industry, the benefits of uniform nationwide regulations would be worth the fight. For hesitant legislators, it is key to emphasize the bipartisan nature of the proposed regulations. Infertility is a

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[70] Fox, *supra* note 49.
[71] *Id.* at 163-64.
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] Gerard Letterie & Dov Fox, *Lawsuit Frequency and Claims Basis Over Lost, Damaged, and Destroyed Frozen Embryos Over a 10-year Period*, 2 F. S. REP. 78-82 (2020).

common problem and protecting frozen embryos from potential negligent loss or destruction would provide a sense of security to hopeful prospective parents.

The real challenge is handling the lobbyists in the industry.[76] As explained, the industry currently enjoys unregulated freedom and would have to endure some cost to implement proper training and licensing.[77] However, when these relatively minor costs are compared to the millions of dollars saved from preventing lawsuits it is easy to see the benefit.

VI. CONCLUSION

By implementing the proposed regulations, the goal is to mitigate claims over negligently lost or destroyed embryos. With stricter guidelines regulating how embryo storage facilities should be run and what certifications and trainings would be necessary for employees working in embryo facilities, there would be fewer incidents of negligently lost and destroyed embryos. This would take the pressure off the legal field from pinning embryos into a legal classification as there would, hopefully, be fewer cases arising in which damages would hinge on that delicate legal definition. As ART continues to develop and evolve, it is important for the law not to fall behind. Taking preemptive steps to reduce harms to patients in such a vulnerable position is just a first step in ensuring the ART industry is using best practices.

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[76] Fox, *supra* note 49.
[77] *Id.*

The FDA and the Fem-Tech Revolution: A Feminist Healthcare Perspective

Gilma Bernal

I. INTRODUCTION TO AGENCY ROLES IN REGULATORY SCIENCE

In recent years, it has become apparent that there are significant sex differences in the implementation, safety, and efficacy of regulated products.[1] In the age of regulatory science, administrative agencies play a key role in regulating major industry manufacturers and pharmaceutical corporations, industry innovators who produce highly sophisticated and innovative products in the feminist technology health care space.[2] One such agency is the U.S. Food and Drug Administration ("FDA"), which ensures the safety and efficacy of drugs and medical devices. Despite the host of existing regulations by the FDA, one area that remains insufficiently regulated is the representation of women in clinical studies. At the time of this writing, the FDA does not require who must be a part of clinical trials.[3] It is undisputed that the lack of women in clinical research results in disproportionate and harmful impacts on women's health.[4] In 2019, an FDA report stated that

[1] *Understanding Sex Differences at FDA*, https://www.fda.gov/science-research/womens-health-research/understanding-sex-differences-fda (last visited Oct. 18, 2023); *see also* Genevieve Grabman et al., *FDA Regulation Must Uphold Women's Health*, 77 FOOD & DRUG L. J. (2022) (noting that women metabolize drugs differently, have different hormones, differing fat to muscle ratios, and different body size).

[2] Emma Kemble et al., *The Dawn of the FemTech Revolution*, https://www.mckinsey.com/industries/healthcare/our-insights/the-dawn-of-the-femtech-revolution (last visited Oct. 18, 2023); *see generally Focus Areas of Regulatory Science,* https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-areas-regulatory-science-introduction (last visited Nov. 9, 2023) (defining regulatory science as the science of developing new tools, standards, and approaches to assess the safety and efficacy of FDA-regulated products).

[3] *Gender Studies in Product Development: Historical Overview*, https://www.fda.gov/science-research/womens-health-research/gender-studies-product-development-historical-overview (last visited Oct. 18, 2023).

[4] Grabman, *supra* note 1, at 3 (describing the historical failures of the FDA in the 1960s during which women receiving false negative results for pap-smears resulted in women discovering their cervical cancers when it was too late to treat).

women represented sixty-seven percent of people harmed by device-related injuries or deaths.[5]

While the FDA rolled out initiatives in the Office of Women's Health ("OWH") and the Center for Devices and Radiological Health ("CDRH"), it is clear these regulatory efforts have not done enough to mitigate the consequences of underrepresentation.[6] The FDA must engage in a multi-faceted approach to ensure proper representation of women in clinical trials. This article will analyze the efforts made by the FDA to prioritize women's health both in the OWH and CDRH. Further, this article will propose additional recommendations to the FDA for improved regulation of medical devices.

II. Overview: Past and Current Initiatives by the FDA for Inclusion of Women

The FDA regulates the manufacturing standards of drug quality and consistency and determines whether the drug can be marketed for sale and receive approval to go on the market.[7] The drug must be shown to be safe and effective and for a specific purpose to obtain FDA approval.[8] Through the CDRH, the FDA also regulates the manufacturing of medical devices by requiring manufacturers to establish registration, list their devices with the FDA, and undergo an approval process through one of three pathways to market approval.[9] From 1977 to 1993, the FDA explicitly recommended

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[5] Susan P. Phillips et al., *Medical Devices, Invisible Women, Harmful Consequences*, Int J Environ Res Pub. Health (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9657442/.
[6] Office of Women's Health, https://www.fda.gov/about-fda/office-commissioner/office-womens-health (last visited Sept. 22, 2023).
[7] Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-399 (1972) (expanding the FDA's authority to regulate biological drugs).
[8] Amal Mir, *What's Wrong with Having a Lot of Patents*?, 32 Annals of Health L. Advance Directive 1, 161 (2022).
[9] *Overview of Device Regulation*, U.S. Food & Drug Admin. (FDA) https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation (last visited Oct. 18, 2023).

women of childbearing ages be excluded from clinical trials due to fears of effects on potential fetuses.[10] Thus, drugs and devices approved between these years were approved without a clear understanding of how they impacted women.[11] Through a practice known as grandfathering, devices approved prior to 1976 were not required to establish safety and efficacy on the market.[12] Grandfathered products then became predicates for other devices that were approved through an abbreviated approval process by establishing substantial equivalence.[13] Worse still, many of the devices that have been "grandfathered" into market approval by the FDA are targeted towards women.[14]

As development of medicine and devices advanced, women began to demand representation in clinical trials.[15] In 1994, the FDA established the OWH, for the purpose of improving the understanding of women's health in the development of new drugs and devices.[16] Critics of OWH find that there are still many loopholes through which medical devices continue to remain on the market, including passive reporting systems that rely on manufacturers self-reporting medical device issues.[17] Importantly, OWH has listed out factors through its initiatives that it will consider when issuing research grants, including "factors affecting the toxicity or the safety, efficacy (or

[10] *Gender Studies in Product Development: Historical Overview*, *supra* note 3.
[11] *Id.*
[12] Madris Kinard et al., *Is the FDA Failing Women?,* 23 AMA J. OF ETHICS 750, 753 (Sept. 2021), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-08/vwpt2-peer-2109_0.pdf.
[13] Institute of Medicine, *Medical Device and the Public's Health: the FDA 510K Clearance Process at 35 Years*, INST. OF MED., 86 (2011).
[14] Phillips et al., *supra* note 5.
[15] *History of Women's Participation in Clinical Research*, NAT'L. INST. OF HEALTH, https://orwh.od.nih.gov/toolkit/recruitment/history (last visited Sept. 19, 2023).
[16] Grabman, *supra* note 1, at 4.
[17] *Id.* at 7.

effectiveness), and security of FDA-regulated products used by women."[18]

However, the problem with the OWH grant requirements is obvious—it only applies to research that is funded by OWH. Thus, many of the regulations and initiatives set forth by the OWH are not applicable to privately funded clinical trials. It is important to note that there are more privately funded clinicals trials that are sponsored by large pharmaceutical corporations than publicly funded clinical trials.[19] The distinction between a publicly funded versus privately funded clinical trial is an important one, as it determines the requirements that apply to a clinical trial. The FDA failed to properly regulate private clinical trials, creating a gap in regulation which has detrimental—and even fatal—consequences to women.[20]

As recently as 2016, the CDRH office within the FDA issued a proposed strategic plan which outlines three main priorities identified by the office to increase women-specific device efforts and close the "gap areas," including: "sex- and gender-specific analysis and reporting" and an "integrated approach for current and emerging issues related to health of women."[21] However, the critical issue with this strategic plan is that it does not have any binding authority because it is a plan meant to outline the CDRH's initiatives and does not mandate action from manufacturers. While the NIH and the

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[18] *Women's Health Research Roadmap: A Strategy for Science and Innovation to Improve the Health of Women*, OFF. OF WOMEN'S HEALTH (2015), https://www.fda.gov/media/97501/download?attachment (funding research for issues affecting women throughout their lifespan including endocrine and metabolic disorders, cardiovascular disease, breast cancer, sexually transmitted infections, and issues related to pregnancy).

[19] Stephan Ehrhardt et al., *Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919115/ (noting that NIH-funded research has decreased).

[20] Grabman, *supra* note 1, at 3.

[21] Terri Cornelison, *FDA Releases CDRH Health of Women Strategic Plan to Better Inform Medical Device Research and Regulation for All Women*, (Jan. 18, 2022), https://www.fda.gov/news-events/press-announcements/fda-releases-cdrh-health-women-strategic-plan-better-inform-medical-device-research-and-regulation (last visited Sept. 22, 2023).

FDA have rolled out significant initiatives in the name of women's health, these initiatives have done little to mitigate the harmful effects of women underrepresentation. Women continue to suffer from greater risk of adverse side effects from medications because sex differences in adverse drug reactions are not well understood.[22] Further, there is a lack of understanding on how sex differences in "hormones, anatomy, inflammatory responses, and physical function impact safety and efficacy."[23]

III. Looking Forward: Recommendations for FDA Regarding 510 (k) and Representation of Women in Clinical Research

It is important for the FDA to not lose sight of the modern medical device marketplace, particularly when considering how to regulate medical devices. Many medical devices today are geared towards women in what is known colloquially as the "dawn of the feminist technology revolution."[24] However, it is important to question whether it is in the best interests of women to continue developing medical devices without robust safeguards and proper regulatory oversight, just for the sake of innovation and profit. Without the proper regulations in place, the strides in medical device technology can prove to be harmful or even fatal, as it was for many women in the past who relied on medical devices that were not properly regulated.[25] As an administrative agency, the FDA is recognized as an expert in the field of regulatory science.[26] In the statute that confers the FDA with power to oversee medical device approvals, Congress set the standards of authorization for approval as safety and efficacy but made no express

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[22] Elizabeth Pratt, *We Don't Have Enough Women in Clinical Trials — Why That's a Problem*, HEALTHLINE (Oct. 25, 2020), https://www.healthline.com/health-news/we-dont-have-enough-women-in-clinical-trials-why-thats-a-problem (last visited Sept. 22, 2023).
[23] Phillips et al., *supra* note 5.
[24] Emma Kemble et al., *supra* note 2.
[25] Grabman, *supra* note 1, at 1.
[26] Wendy E Wagner, *A Place for Agency Expertise: Reconciling Agency Expertise With Presidential Power*, 115 COLUMBIA L. REV. at 1, 13. (2015).

definition of safety and efficacy.[27] The FDA has authorization to promulgate their own regulations on safety and efficacy.[28] Thus, the FDA can bolster its standards for safety and efficacy to better regulate the medical device industry. The recommendations for the FDA to better regulate the market of women's medical devices are based on the administrative law doctrines as follows.

First, the FDA must recognize the need for research standards that account for sex-differences. Without this recognition, industry leaders will not follow suit. The FDA must exercise the full extent of their authority under the Administrative Procedures Act ("APA") and promulgate clinical evidentiary standards to require representation of women, particularly for devices that are to be marketed towards women.[29] Under a rulemaking framework, as authorized by the APA, the FDA may issue a proposed rule that requires manufacturers to represent women in clinical studies. It is important that the FDA codify a requirement for female test subject representation in pre-clinical testing and increased representation of women in human studies, as these are two key areas where sex-differences are overlooked in research.[30] Further, the FDA must address the issue of substantial equivalence of predicate devices, which were never approved for safety and efficacy.[31] Currently, the 510(k) clearance is by far the most common pathway to approval. The 510(k) clearance process allows manufacturers to establish

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[27] 21 U.S.C. 9 (a) §355 (1972).
[28] *Federal Administrative Law Research Guide*, DUKE UNIV. SCHOOL OF L., https://law.duke.edu/lib/research-guides/federal-administrative-law/ (last visited Oct. 18, 2023).
[29] 5 U.S.C §553 (2023) (noting that rulemaking procedures require notice and comment in the Federal Register).
[30] Barbara E. Bierer et al., *Advancing the inclusion of underrepresented women in clinical research*, 3 CELL REP. MED. 4 (2022); *see generally* Urtė Fultinavičiūtė, *Sex and Science: Underrepresentation of Women in Early-Stage Clinical Trials*, CLINICAL TRIALS ARENA (Oct. 17, 2022), https://www.clinicaltrialsarena.com/features/underrepresentation-women-early-stage-clinical-trials/?cf-view (last visited Oct. 20, 2023).
[31] Danielle Kirsh, https://www.massdevice.com/exploring-fda-approval-pathways-for-medical-devices/ (last visited Nov. 9, 2023).

safety and efficacy by demonstrating "substantial equivalence" to a device that is already on the market.[32] It is likely that any proposed rule regarding 510(k) would be supported by organizations like the Institute of Medicine ("IOM"), which has previously issued criticisms of the abbreviated 510(k) approval process.[33] A proposed rule in the Federal Register would be as follows:

"The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to make explicit clinical studies for manufacturing devices must include female test subjects in pre-clinical and clinical trials for any medical devices intended for use in women. In conjunction with this amendment, FDA is proposing a policy under which the 510(k) process is no longer available for the evaluation of safety and effectiveness when substantial equivalence is established to a predicate device that was never tested for safety and efficacy in women and 'that the 510(k)-clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions."[34] Thus, the forementioned proposal is a truer representation of what the 510(k) clearance process ought to be, as an approval method that is limited to certain narrow exceptions.[35]

If the FDA were to implement such a rule, it is conceivable that medical device manufacturers could bring an action against the FDA. Still, if new clinical evidentiary standards are contested, the FDA could overcome

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[32] The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k (last visited Nov. 9, 2023).

[33] Thomas Sullivan, *Institute of Medicine Report Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, POLICY & MED. (May 6, 2018), https://www.policymed.com/2011/07/institute-of-medicine-report-medical-devices-and-the-publics-health-the-fda-510k-clearance-process-a.html (last visited Oct. 18, 2023).

[34] *Id.*

[35] *Id.* (explaining that the legislative and regulatory history of the 510(k) process as it was designed in 1976 was to provide only a determination of the substantial equivalence of a new device to an already marketed (predicate) device)

challenges against evidentiary standards for marketing approval because of the deference that administrative agencies are afforded in judicial review.[36] In *Skidmore v. Swift & Co.*, the Court held that administrative agencies may get a level of deference where an agency's position may be seen as persuasive authority if the agency has established sound reasoning for promulgating a rule.[37] Under a *Chevron v. NRDC* standard, the Court leans towards deference for the agency when the congressional statute has not spoken to the issue at question in the statute.[38] Under a *Chevron* deference framework, the FDA would likely receive deference because there is nothing in the statute that speaks directly to how the FDA should determine safety and efficacy standards, nor how to establish evidentiary guidance.[39] Thus, based on precedential administrative law cases, the FDA would receive deference in such a challenge or litigation. The *Chevron* deference is, however, facing challenges in the Supreme Court.[40] Thus, to acknowledge these shortcomings the FDA can rely on other precedents as listed below.

Many caution against agency overstepping, citing concerns that the agency is exercising powers exceeding its authority as granted by Congress.[41] However, a rule preventing the 510(k) process for medical devices intended for the use of women would not constitute regulatory over-stepping by the FDA because the FDA would not be exceeding its statutorily granted scope. Instead, the FDA would be exercising its discretionary authority granted within the Medical Device Amendments of 1976, which grants the FDA

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[36] James Kunhardt et al., *Judicial deference and the future of regulation*, https://www.brookings.edu/articles/judicial-deference-and-the-future-of-regulation/ (last visited Sept. 22, 2023).
[37] Skidmore v. Swift & Co., 323 U.S. 134, 139 (U.S. 1944).
[38] Chevron v. Natural Resources Defense Council, Inc., 467 U.S. 837, 846 (1984).
[39] 21 U.S.C. 9 (a) §355 (1972).
[40] Andrew Chung et al., *Federal agency powers in the crosshairs at the US Supreme Court*, REUTERS (July 5, 2023), https://www.reuters.com/legal/federal-agency-powers-crosshairs-us-supreme-court-2023-07-04/ (last visited Oct. 23, 2023).
[41] *Id.*

authority to determine substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with Section 510(k) of the Act.[42]

A well-known principle that supports the FDA's authority here is found in *SEC v. Chenery Corp.,* where the court recognized that agencies could address issues and create new standards.[43] In *Chenery*, the court reasoned that some problems cannot be reasonably foreseen at the time of an agency first interprets a statutory provision and will only arise after the agency's interpretation of it.[44] The *Chenery* court acknowledged that until an agency accumulates adequate experience to ascertain the suitable criteria and observe practical implications of a regulation, an agency may need to create additional regulations, so long as the agency exercising its powers were those upon which its action can be sustained.[45] The *Chenery* court held that the Securities and Exchange Commission ("SEC") has been given broad authority to determine what is detrimental to the public interest or to the interests of investors or consumers.[46] The court reasoned that as long as the SEC's decision was based on substantial evidence and was consistent with the SEC's statutory authority, the decision was to be upheld.[47]

Similar to the rule at issue in *Chenery*, the new proposed rule is based on substantial evidence. Research has indicated a lack of sex-based differences in testing and development of medical devices has negative impacts in women. Substantial evidence in furtherance of the FDA's support for removing the 510(k) pathway for predicate devices is found in studies, where, for instance, approximately 97% of recalls are for devices cleared through

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[42] *PMA Approvals* (2021), https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals, (last visited Oct. 18, 2023).
[43] SEC v. Chenery Corp., 332 U.S. 194 (U.S. 1947).
[44] *Id.* at 202.
[45] *Id.* at 209.
[46] *Id.* at 208.
[47] *Id.* at 207.

the 510(k) pathway.[48] Ultimately, removing the 510(k) processes for medical devices intended for use in women would not violate the FDA's authority, because the FDA was granted broad authority to determine "safety and efficacy" standards for market approval. Thus, the proposed rule is consistent with its statutory authority as granted by Congress.

Another mechanism that the FDA may use to better regulate devices is the use of mandatory recalls. Recalls are organized by class, with Class I recalls being the most severe, and defined as "risk is deemed unreasonable of when there is a reasonable probability that the use of or exposure to a voluntary product will cause serious adverse health consequences or death."[49] Because recalls are voluntary by the manufacturer, many harmful devices have remained in the market despite being harmful or fatal towards women.[50] A famous example of this was shown in the film *The Bleeding Edge*, where the FDA allowed a harmful transcervical contraceptive to remain on the market for 16 years, until the manufacturer voluntarily recalled it.[51] Importantly, while FDA has the authority to issue a request for a recall in urgent situations, it openly admits to rarely exercising this power.[52] It is therefore necessary for the FDA to create a clear standardized procedure by which they are to invoke requests for recalls in a timely and effective manner to avoid a repeat of what occurred in the *Bleeding Edge*.

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[48] Maryam Mooghali et al., *Characterization of US FDA Class I Recalls from 2018 to 2022 for Moderate- and High-Risk Medical Devices: A Cross-Sectional Study*, 16 MED. DEVICES (AUCKL) 111-122 (2023).
[49] Recalls, Corrections and Removals (Devices), https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices (last visited Sept. 22, 2023).
[50] *Id.*
[51] Kinard et al., *supra* note 12, at 8.
[52] Recalls, Corrections and Removals (Devices), *supra* note 49.

IV. CONCLUSION

Historically, women were intentionally excluded from clinical trials. In the years since, the FDA passed initiatives in an attempt to increase the representation of women in clinical trials. While well-intentioned, the efforts of the FDA are limited. Even after the FDA established the OWH and CDRH, women remain underrepresented in clinical trials. Importantly, commonly utilized yet dated practices such as the 510(k) pathway to approval have created loopholes allowing medical devices to establish substantial equivalency to predicate devices, some of which were never tested for medical safety and efficacy. Not only does this create harmful and devastating effects for women, but it also impedes the scientific understanding of sex-differences. Through the APA, the FDA has the power to create stronger binding rules to ensure that women are included in clinical research. By relying on administrative agency doctrines, statutory authority, and precedential case law, the FDA can promulgate binding rules for manufacturers of devices to increase the representation of women in clinical trials. The role of the FDA becomes even more important in light of the feminist technology revolution, in which many manufacturers are creating medical devices marketed directly towards women.

The Federal Trade Commission's Proposed Health Breach Notification Rule Amendment and the Loophole in Authorization

Kayla Bradley

I. INTRODUCTION

The digital health landscape has rapidly expanded in recent years to provide solutions to barriers in healthcare, such as "high costs and inadequate insurance coverage, limited options and long wait times, and logistical challenges [such as] reliable transportation" in areas such as mental healthcare and women's health.[1]

The Federal Trade Commission (FTC) announced the Health Breach Notification Rule (HBNR) in 2009 to "regulate how and when companies contact customers and the FTC in the event of a security breach," with enforcement beginning February 22, 2010.[2] The HBNR applies to non-Health Insurance Portability and Accountability Act (HIPAA) entities that handle personal health records (PHR).[3] In 2021, the FTC released a policy statement to clarify the scope of the HBNR followed by a proposed

[1] Leah R. Fowler et al., *Uncertain Terms,* 97 NOTRE DAME L. REV. 1, 14 (2021); *See generally* Kathleen Rowan et al., *Access and Cost Barriers to Mental Health Care, by Insurance Status, 1999–2010*, 32 HEALTH AFFS. 1723, 1728–17729 (2013).
[2] Kewa Jiang, *Mental Health Mobile Apps and the Need to Update Federal Regulations to Protect Users*, 28 MICH. TECH. L. REV. 421, 435–36 (2022); Press Release, Fed. Trade Comm'n, FTC Issues Final Breach Notification Rule for Electronic Health Information (Aug. 17, 2009), https://www.ftc.gov/news-events/news/press-releases/2009/08/ftc-issues-final-breach-notification-rule-electronic-health-information (announcing the final rule for the Health Breach Notification Rule to be published in the Federal Register); 16 C.F.R. §318.
[3] Proposed Rule Changes to Health Breach Notification Rule, 88 Fed. Reg. 37,819 (June 9, 2023) (to be codified at 16 C.F.R. §318) (defining PHR identifiable health information as "individually identifiable health information" pursuant to 42 U.S.C. §1320(d)(6) which "is provided by or on behalf of the individual" and "identifies the individual or … there is a reasonable basis to believe that the information can be used to identify the individual"); Health Breach Notification Rule (HBNR); FTC Health Breach Notification Rule, 16 C.F.R. §318.2(f) (2009) (defining a PHR related entity as "an entity, other than a HIPAA-covered entity" that offers Web-based products or services and deals with personal health records).

amendment to the HBNR in 2023.[4] The proposed amendment clarifies and expands the scope of the HBNR to encourage enforcement and compliance.[5]

It is important to understand the intent of the original HBNR, the FTC's 2021 Policy Statement, and the proposed changes to the original HBNR in the 2023 proposed rule amendment. Further, there are strengths and weaknesses to the changes in the proposed amendment. The use of authorization within the HBNR significantly weakens the consumer protection that it intends to provide. The FTC should strongly consider including a definition for "authorization" within the proposed HBNR amendment. Defining "authorization" within the HBNR can address and minimize concerns about an entity's ability to unilaterally amend what is authorized by a consumer when they agree to the entity's terms of use and privacy policies.

II. THE FTC'S HEALTH BREACH NOTIFICATION RULE

The FTC created the Health Breach Notification Rule to "help ensure that entities who are not covered by [HIPAA] . . . face accountability when consumers' sensitive health information is compromised," requiring notice when a breach to the consumer's PHR occurs.[6] In September 2021, the FTC issued a policy statement to "clarify the scope of the Rule, and place entities on notice of their ongoing obligation[s]" to report if a breach occurs because

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[4] Fed. Trade Comm'n, *Statement of the Commission: On Breaches by Health Apps and Other Connected Devices* (Sept. 15, 2021); Proposed Rule Changes to Health Breach Notification Rule, 88 Fed. Reg. 37,819 (proposed June 9, 2023) (to be codified at 16 C.F.R. 318).

[5] Proposed Rule Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,819.

[6] Fed. Trade Comm'n, *supra* note 4; Health Breach Notification Rule (HBNR), 16 C.F.R. §318.3(a)(1) (2009) ("Notify each individual… whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such breach of security…"); Fed. Trade Comm'n*,* Complying with FTC's Health Breach Notification Rule (Jan. 2022), https://www.ftc.gov/business-guidance/resources/complying-ftcs-health-breach-notification-rule-0 (using the U.S. Department of Health and Human Services' definition of "unsecured information," which applies to "any information that is not encrypted or destroyed").

"many appear to misunderstand its requirements."[7] Additionally, the FTC also defined a "breach of security" to include unauthorized access to PHR, as well as "cybersecurity intrusions" or "nefarious behavior."[8] At the time of the 2021 Policy Statement, the "FTC [had] never enforced the rule," however the 2021 Policy Statement indicated that "[the FTC intended] to bring actions to enforce the Rule consistent with [the] Policy Statement."[9] In 2023, the FTC pursued action under the HBNR for the first time against GoodRX and has since pursued action against Premom under allegations that each company had failed to notify users when unauthorized disclosure of their personally identifiable health information occurred.[10]

In June 2023, the FTC published a notice of proposed rulemaking in the Federal Registrar to "allow [the HBNR] to keep up with marketplace trends and respond to developments in technology."[11] The proposed changes include clarifying the scope of the Rule, clarifying when a "[PHR] [draws]

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[7] Fed. Trade Comm'n, *supra* note 4.
[8] *Id.*
[9] *Id.*
[10] *See generally* Press Release, Fed. Trade Comm'n, FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule (May 18, 2023), *https*://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-proposes-amendments-strengthen-modernize-health-breach-notification-rule; Press Release, Fed. Trade Comm'n, Ovulation Tracking App Premom Will be Barred from Sharing Health Data for Advertising Under Proposed FTC Order (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ovulation-tracking-app-premom-will-be-barred-sharing-health-data-advertising-under-proposed-ftc (discussing FTC's action towards Premom when Premom disclosed consumers' health data to third parties, deceived consumers' about their data sharing practices and violated HBNR); Press Release, Fed. Trade Comm'n, FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising (Feb. 1, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising (discussing FTC's HBNR enforcement which required GoodRX to pay a civil penalty of $1.5 million for violating the rule).
[11] Press Release, Fed. Trade Comm'n, FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule (May 18, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-proposes-amendments-strengthen-modernize-health-breach-notification-rule; Jiang, *supra* note 2 at 421.

information from multiple sources" in context of the rule, and implementing new notification requirements.[12]

The proposed rule provides an expansive definition for "Health care services" or "supplies," furthering the HBNR's original intention of regulating entities handling PHR that are outside the reach of HIPAA.[13] Under the proposed amendment,

> [h]ealth care services or supplies. . . [encompass] . . . any online service . . . or internet-connected device . . . to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.[14]

This addition clarifies that the HBNR "applies generally to online services . . . [and] . . . covers online services related . . . to medical issues . . . but also wellness issues."[15] This definition strengthens and broadens the HBNR's reach, as it explicitly applies to services or products handling PHR related to both medical and wellness issues.[16] This specification allows the HBNR to apply to more entities that handle PHR in the course of addressing wellness issues, but are outside of HIPAA's narrow scope as a medical privacy rule.[17]

Next, the proposed HBNR would widen the current definition of PHR by specifying that the "technical capacity to draw information from multiple sources" satisfies the statutory definition for PHR.[18] The addition of the definition for the "technical capacity to draw information" places the focus on the technology's capabilities, rather than how many sources it may or may

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[12] Proposed Rule Changes to Health Breach Notification Rule, 88 Fed. Reg. 37,819 (proposed June 9, 2023) (to be codified at 16 C.F.R. 318).
[13] Health Breach Notification Rule, *Purpose and scope,* 16 C.F.R. §318.1 (2009).
[14] Proposed Rule Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,823.
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,826.

not draw from.[19] Under the proposed language, an app or wearable is "a personal health record if it can draw *any* information from multiple sources, even if it only draws *health* information from one source," whereas the current language simply states that information "can be drawn from multiple sources."[20] Thus, the consumer's decision whether to utilize information gathering abilities does not affect a product's designation as a PHR and allows the HBNR to apply more uniformly based on the technology's abilities.[21] This change considers only the technology's capabilities and not the individual choice in utilizing a device or app so as not to restrict the definition of PHR under the HBNR. The two proposed changes attempt to narrow the gap created between HIPAA's narrow scope and the increase in applications and internet-based products and services that handle PHR.[22]

Third, by expanding the content of notice required in cases of a breach, the proposed HBNR promotes transparency and accountability.[23] Notice would then be required to include information about the security breach regarding "the potential harm that may result from the breach, [contact information for] . . . any third parties that acquired unsecured PHR identifiable health information, [and] a description of the types of unsecured PHR . . . involved."[24] The FTC would also require the entity who suffered the breach to provide information about the entity's own efforts "to protect affected individuals."[25] The FTC seeks to require a minimum of two listed methods for affected individuals to contact the entity about the breach.[26] Additionally, the FTC proposes that email be a qualified method of notice,

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[19] *Id.*
[20] *Id.*, 16 C.F.R. §318.2(d).
[21] Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,826.
[22] Kim Theodos & Scott Sittig, *Health Information Privacy Laws in the Digital Age: HIPAA Doesn't Apply*, 18 PERSP. HEALTH INFO. MGMT., 1, 5 (2021).
[23] Fed. Trade Comm'n, *supra* note 4; Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,828.
[24] Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,828.
[25] *Id.*
[26] *Id.*

replacing the current requirement of written notice.[27] The proposed rule furthers consumer-friendly policy by requiring entities to briefly explain the potential harm to the consumer from the breach, specify what information was accessed, and what the entity is doing to protect affected individuals.[28] These requirements place more responsibility on entities by requiring affirmative steps to inform affected customers in the case of a breach. This change, in turn, could increase transparency and accessibility of information.

Finally, the FTC proposes in the amended rule that "a third party service provider is not . . . a PHR related entity when it access[es] unsecured PHR identifiable health information [when]. . . providing services" and argues this change would incentivize entities to select third-party services responsibly.[29] The amended rule does not extend oversight to third party services that may access PHR "in the course of providing services," which loosens regulatory oversight to companies that handle any consumer PHR simply because they are third parties.[30] In the event a third-party service experiences a breach, they would inform the entity they were serving, who would then notify the impacted customers.[31] The policy rationale is overly optimistic and places the responsibility of determining whether data has been treated responsibly by third party providers on the entities employing them, rather than the FTC's authority as a regulatory agency.

The proposed changes serve to clarify the scope and requirements of the HBNR; however, the proposed changes provide companies handling PHR wide latitude in determining what authorized access or disclosure is through their control of their privacy policies and terms of service agreements.[32]

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[27] *Id.*
[28] *Id.*
[29] *Id.* at 37,825 (providing examples of third-party service providers "such as attribution and analytics…and technologies providing healthcare services and supplies")
[30] *Id.*
[31] *Id.*
[32] Fed. Trade Comm'n, *supra* note 4, at 1; Fowler, *supra* note 1, at 22.

Authorization is not defined within the original or proposed HBNR.[33] Authorization is typically determined by the entity's privacy policy or terms of service agreement, which may generally be unilaterally amended by the entity themselves after the consumer has agreed to it.[34] Thus, the consumer may be effectively agreeing to any future policy changes the entity makes in how the consumer's PHR data is accessed or disseminated, creating a loophole weakening the transparency and assurance the HBNR seeks to provide consumers.[35]

III. FTC ACTION INVOLVING HBNR AND AUTHORIZATION

The FTC has brought actions related to consumer authorization in how consumer PHR was handled under HBNR and deceptive practice violations.[36] In 2023, the FTC brought enforcement actions against GoodRx and Easy Healthcare under the HBNR on the basis that the companies violated their *own* privacy policies when sharing customer information with unauthorized third parties and failing to notify the affected customers and FTC.[37] However, if the companies had simply changed their privacy policies to authorize such disclosure of PHR, before sharing PHR with third parties (such as Google), the HBNR would not have been triggered because such use would have been authorized.[38] The FTC has

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[33] *See* 16 C.F.R. §318; Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,829.
[34] Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37830; Fowler, *supra* note 1, at 26.
[35] Fowler, *supra* note 1, at 42.
[36] *See* Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,821.
[37] Press Release, Fed. Trade Comm'n, FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising (Feb. 1, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising; Health Breach Notification Rule, 88 Fed. Reg. at 37,821.
[38] Proposed Changes to Health Breach Notification Rule, 88 Fed. Reg. at 37,821; Press Release, Fed. Trade Comm'n, FTC Finalizes Order with Flo Health, a Fertility-Tracking App that Shared Sensitive Health Data with Facebook, Google, and Others (June 22, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/06/ftc-finalizes-order-flo-health-fertility-tracking-app-shared-sensitive-health-data-facebook-google (discussing the settlement reached between Flo Health and the FTC when Flo Health shared consumers'

also pursued action concerning authorization violation without involving the HBNR, demonstrating the FTC's overarching interest in ensuring companies are held accountable to promises they make to consumers related to how consumer information is used.[39]

Previously, authorization violation triggered FTC action against Flo for deceptive practices, rather than a HBNR violation, because Flo had violated their own terms of service when sharing customers' information with companies such as Facebook and Google.[40] Had Flo amended their terms of service to authorize sharing users' data with third parties for marketing and data analytics, before actually sharing users' data, Flo would not have violated their terms of service because their terms would then have authorized such use.[41] Even though the action against Flo did not involve the HBNR, the deceptive practice involved in Flo is similar to the issue of authorization or unauthorized information access that would then require an entity to notify relevant parties under the HBNR.[42]

IV. AUTHORIZATION WITHIN THE HEALTH BREACH NOTIFICATION RULE

The premise behind requiring notice to consumers of unauthorized dissemination or access to their PHR is simple; companies cannot break privacy promises they make to their consumers. [43] The idea may appear to encourage consumers to take more responsibility in investigating the privacy

private health data); Press Release, Fed. Trade Comm'n, FTC to Ban BetterHelp from Revealing Consumers' Data, Including Sensitive Mental Health Information, to Facebook and Other Targeted Advertising (Mar. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/03/ftc-ban-betterhelp-revealing-consumers-data-including-sensitive-mental-health-information-facebook (requiring BetterHelp to pay $7.8 million for deceiving consumers when they promised to keep consumer's personal data private and banning BetterHelp from sharing consumers' health data).

[39] *See generally* Fed. Trade Comm'n, *supra* note 4.

[40] Fed. Trade Comm'n, *supra* note 11; Fowler, *supra* note 1, at 3.

[41] Fed. Trade Comm'n, *supra* note 11; Fowler, *supra* note 1, at 4.

[42] Fowler, *supra* note 1, at 4.

[43] *Id.* at 3.

policies of products and services with access to their health information. However, a consumer's efforts to perform such due diligence may be in vain when companies routinely reserve the right to unilaterally amend their privacy policies and terms of service.[44]

The policy behind the doctrine of unconscionability may lend support to implementing a definition for "authorization" within the context of the HBNR because it considers the bargaining power between two parties at the time of contract formation when determining whether to invalidate a contract term.[45] Privacy policies and terms of use agreements typically resemble adhesion contracts, and are generally treated as enforceable contracts.[46] Typically, terms of service agreements are considered contracts, however privacy policies are not always considered contracts and may be considered "quasi-contractual statements."[47]

Unilateral amendment clauses may be considered unconscionable in adhesion contracts, such as a terms of use agreements, because they "[transform] an ordinary contract of adhesion into a contract that [gives the company] the largely unfettered power to control the terms of its relationship."[48] Some jurisdictions only require procedural unconscionability, however some require both procedural and substantive unconscionability.[49] In jurisdictions requiring substantive unconscionability,

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[44] *Id.* at 42.
[45] *Id.* at 32.
[46] *Id.* at 31; Charlotte A. Tschider, *Meaningful Choice: A History of Consent and Alternatives to the Consent Myth*, 22 N.C. J. OF L. AND TECH. 617, 635 (2021) ("Contracts of adhesion, by definition, involve unequal bargaining power, often between a sophisticated business and consumers or some product or service."); Charlotte A. Tschider, *The Consent Myth: Improving Choice for Patients of the Future*, 96 WASH. UNIV. L. REV. 1505, 1520 (2019).
[47] Fowler, *supra* note 1, at 31; James Fallows Tierney, *Contract Design in the Shadow of Regulation*, 98 NEB. L. REV. 874, 889 (2020) ("Privacy policies are quasi-contractual statements that disclose how a firm will collect and use information").
[48] Fowler *supra* note 1, at 32; Merkin v. Vonage Am. Inc., No. 13-CV-08026, 2014 WL 457942, at *7 (C.D. Cal. Feb. 3, 2014), *rev'd*, No. 14-55397, 2016 WL 775620 (9th Cir. Feb. 29, 2016), *opinion withdrawn and rev'g trial court* 639 F.App'x 481 (9th Cir. 2016).
[49] Fowler, *supra* note 1, at 33.

substantive unconscionability presents a hard hurdle to clear in court.[50] *Tompkins v. 23andMe, Inc.* held that "courts routinely enforce such terms in form contracts" and did not find the arbitration clause involved to be unconscionable against claims of "unfair business practices . . . and misrepresentations about . . . 23andMe's services."[51] Unconscionability may not be the exact mechanism to protect consumers' health data, however the policy behind the doctrine is relevant due to the difference in bargaining power with terms of use agreements and privacy policies, as they determine what is and is not authorized information access in context of the HBNR.[52]

Additionally, when a consumer is faced with the decision whether to agree to a company's privacy policy and/or terms of use agreement, the consumer typically does not have an opportunity to opt out of specific provisions.[53] Creating an "all or nothing" approach further reduces the consumer's bargaining power when entering these agreements.[54] Entities have broad control over their terms of service and privacy policies through unilateral amendment and bundling a variety of data use authorizations within an agreement or policy, leaving consumers with very little bargaining power when deciding whether to agree to the entity's policies.[55]

The FTC should propose a definition for "authorization" within the HBNR, which could help mitigate the bargaining and power difference between a consumer and the entity handling their PHR. Defining "authorization" within the HBNR would continue to clarify the rule's scope. Setting criteria or specific standards for what constitutes "authorization" can help to better

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[50] Fowler, *supra* note 1, at 33; Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1021 (9th Cir. 2016).
[51] Fowler *supra* note 1, at 31.
[52] *Id.* at 34.
[53] *Id.* at 26.
[54] Fowler, *supra* note 1, at 26; Charlotte A. Tschider, *The Consent Myth: Improving Choice for Patients of the Future*, 96 WASH. UNIV. L. REV. 1505, 1528–29 (2019).
[55] Bar Fargon Mizrahi, *Risky Fine Print: A Novel Typology of Ethical Risks in Mobile App User Agreements*, 66 VILL. L. REV. 483, 501 (2021).

inform consumers of how their information may be used by an entity. When creating a definition for "authorization" under the HBNR, the FTC could use the procedure outlined in their 2009 Decision and Order against Sears to define what constitutes a consumer's initial authorization and agreement.[56] The FTC's Decision and Order required Sears to

> (1) Clearly and prominently, and prior to the display of, and ***on a separate*** screen from, any final …"privacy policy" [or] "terms of use" page,…disclose: (1) all types of data that will be monitor[ed], record[ed], or transmit[ted]…how the data may be used, and…whether the data may be used by a third party…[and] [o]btain express consent…[for] the collection of data…"

by requiring the customer to "click a button or link that was not pre-selected as the default."[57]

Additionally, the scope of "authorization" should prohibit entities from construing a consumer's continued use of a product or service as implied consent to a unilateral alteration to the entity's terms of service and privacy policies regarding PHR use.[58] Removing implied consent through continued use would remove an entity's ability to unilaterally amend their policies to alter or expand authorized use of PHR without any notice to the consumer. The method of notice to consumers in the case of changes to terms of service or privacy policies that were previously agreed to could be substantially similar or identical to the procedure for the original authorization the consumer granted. This would require entities to obtain reauthorization from the consumer for the entity to then use or share the consumer's PHR in a way differing from the original authorization given by the consumer. Removing continued use as assent to altered terms would

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[56] Decision and Order, Sears Holdings Mgmt. Corp., FTC Docket No. C-4262, 2009 WL 1639520 (June 4, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/09/090604searsdo.pdf.
[57] *Id.*; Susan E. Gindin, *Nobody Reads Your Privacy Policy or Online Contract? Lessons Learned and Questions Raised by the FTC's Action Against Sears*, 8 NW. J. TECH. & INTELL. PROP. 1, 18 (2009).
[58] Fowler, *supra* note 1, at 25.

allow the HBNR to substantially narrow the loophole created through unilateral contract amendment. Removing assent through continued use would ensure that consumers have a minimum notice to the terms they are agreeing to related to PHR access and use, as well as an opportunity to grant or deny authorization to the terms.

Defining "authorization" and requiring reauthorization if an entity alters their terms of use or privacy policy in relation to how PHR is handled could provide a compromise to the concerns that unilateral contract amendment presents by creating a minimum requirement of notice to maintain authorization from the consumer. Under this sort of rule, if a consumer is unable to reauthorize the amended privacy policy or user agreement, then any new provisions expanding authorized access may be considered unauthorized access under an amended HBNR. Reauthorization would hold the application of any new provisions until the consumer agrees to the new policy through the process required under the definition. This would then protect the consumer's interest as an informed consumer because it would maintain their PHR information under a standard that provides a minimum of notice to the consumer.

V. CONCLUSION

The FTC's HBNR serves to help address a gap in consumer data protection in the wake of a rapidly expanding digital health sector that may not be regulated by HIPAA.[59] The FTC's proposed amendment to the HBNR clarifies and expands what types of entities are required to notify consumers if their consumer's PHR has been breached, while including

[59] Fed. Trade Comm'n, *supra* note 4; Health Breach Notification Rule (HBNR), 16 C.F.R. §318.3(a)(1) (2009); Fed. Trade Comm'n, Complying with FTC's Health Breach Notification Rule (Jan. 2022), https://www.ftc.gov/business-guidance/resources/complying-ftcs-health-breach-notification-rule-0.

unauthorized access within the definition of a breach.[60] However, the HBNR's utilization of authorization to determine when a breach occurs provides a large loophole for entities to utilize their broad authority to amend their privacy policies and terms of agreements after users have agreed to them, without a minimum requirement to notify those users of the alterations. This loophole weakens the consumer protection that the HBNR seeks to offer consumer PHR. The FTC could narrow this loophole by defining what constitutes a consumer's authorization and what is required to maintain that consumer's authorization, should a company decide to alter privacy policies or terms of agreement after agreement. The FTC's intent to update the HBNR to keep up with current developments and practices in protecting consumer's PHR would be reinforced well by the addition of a definition for "authorization" in their upcoming HBNR amendment.

[60] Fed. Trade Comm'n, Statement of the Commission: On Breaches by Health Apps and Other Connected Devices (Sept. 15, 2021).

Organoids: Limitations for Replacing Animal Testing at the Pre-Clinical Stage

Brent Harding

I. INTRODUCTION

The journey of a pharmaceutical company's drug candidate toward U.S. Food and Drug Administration ("FDA") approval is a difficult, expensive, and time-intensive process. Currently, the success rate of moving drug candidates from pre-clinical stage to final approval is approximately 0.1 percent.[1] Addressing the many factors contributing to this inefficiency, Congress aimed to enhance the drug approval process by permitting innovative technologies to substitute animal testing in the pre-clinical stage.[2] This legislative shift resulted in increased utilization and comprehension of organoids, miniature 3D cell models resembling organs, in biology and disease research.[3] However, these alternative technologies have not yet replaced animal testing at the pre-clinical stage.[4]

This article begins by discussing the regulatory and technological background of replacing animal testing during the pre-clinical stage. Next, it investigates the enhanced capabilities of organoids as a viable replacement in the pre-clinical stage. Then, the discussion shifts to an analysis of the current dynamics of organoid and animal models within ongoing clinical

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[1] *See* Attila A. Seyhan, *Lost in Translation: The Valley of Death across Preclinical and Clinical Divide – Identification of Problems and Overcoming Obstacles*, 4 TRANSLATIONAL MED. COMM'N 18 (2019), https://transmedcomms.biomedcentral.com/articles/10.1186/s41231-019-0050-7 (stating that 80 to 90% of research projects fail before human testing, that 1,000 drugs are developed and failed for each drug that gains FDA approval, and that almost 50% of all experimental drugs fail in Phase III trials).

[2] FDA Modernization Act 2.0, 21 U.S.C. § 355 (2022).

[3] *See* Laleh Shariati, et al., *Organoid technology: Current standing and future perspective*, 39 STEM CELLS 1625, 1627 (Dec. 2021), (displaying exponential growth in Pubmed entries for organoids from 2000 to 2019).

[4] *See* Vidya Mahalmani, et al., *Do alternatives to animal experimentation replace preclinical research?*, 55(2) INDIAN J. OF PHARMACOLOGY, Mar.-Apr. 2023, 71, 73 (stating that till date, animal testing is still being performed in the preclinical phases, and does not support the substitution of alternative methods).

trials. The current dynamics suggest the need for a sunset provision to enforce the transition to alternative models. Finally, the article centers on government funding, emphasizing the need for increased financial support to establish sole reliance on organoids.

On December 29, 2022, President Biden signed into law the FDA Modernization Act 2.0 ("Act"), with the purpose of "allow[ing] for alternative to animal testing for purposes of drug and biological product application."[5] To accomplish this, the new law effectively reverses portions of the Federal Food, Drug, and Cosmetics Act of 1938, which mandated animal testing for every new drug in development.[6] While not requiring pre-clinical tests to terminate their use of animal testing, the Act provides alternative testing models in line with FDA compliance that can qualify for approval.[7] Under the new legislation, a "nonclinical test" is a test conducted "in vitro, in silico, or in chemico, or a nonhuman in vivo that occurs before or during the clinical trial phase."[8] As a result of these updates, there has been a new focus on organoids and their application for replacing animal testing in the non-clinical stage.

Organoids are "cells with stem cell potential that are incubated under 3D culture systems to aggregate by adhesion, self-organize, and differentiate into 3D cell masses with the corresponding organ tissue morphology."[9] They have the unique capacity to self-renew and self-organize, contain various cell types, perform specific functions, and form spatial structures similar to in vivo organs.[10] As a result of the FDA's recent removal of required animal-

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[5] FDA Modernization Act 2.0, S. 5002, 117th Cong. (as passed by Senate, Sept. 29, 2022).
[6] Jason J. Han, *FDA Modernization Act 2.0 allows for alternatives to animal testing*, 47 ARTIFICIAL ORGANS 449 (2023), https://onlinelibrary.wiley.com/doi/10.1111/aor.14503.
[7] *See* 21 U.S.C. §355(z)(1)–(5) (listing all non-clinical tests, including cell-based assays, organ chips and microphysiological systems, computer modeling, other nonhuman or human-based test methods, and animal tests).
[8] *Id.*
[9] Siqi Yang et al., *Organoids: The current status and biomedical applications*, 4 MEDCOMM e274 (2023), https://onlinelibrary.wiley.com/doi/10.1002/mco2.274.
[10] *Id.*

trials and the promising results organoids have displayed, there has been a recent surge in organoid research and testing.[11] However, until there are increases in funding and certainty in organoid testing, clinical trials persist in relying on animal testing and enhancing organoid capabilities without a current impetus for complete replacement.

II. THE FDA MODERNIZATION ACT 2.0 AIMED TO ADDRESS ETHICAL, COST, AND EFFICIENCY CONCERNS RELATED TO ANIMAL TESTING IN THE PRE-CLINICAL TESTING PHASE.

Congress passed the FDA Modernization Act 2.0 with unanimous consent and without amendments.[12] The Act removes the requirement to use animal studies as part of the process to obtain a license for a biological product that is biosimilar or interchangeable with another biological product.[13] Specifically, the Act replaces Section 505 of the Federal Food, Drug, and Cosmetic Act's reference to animal testing with "nonclinical tests," which includes cell-based assays, organ chips and microphysiological systems, computer modeling, other nonhuman or human biology-based test methods, and animal tests.[14] The FDA, however, still requires toxicity tests on one rodent species and one nonrodent species.[15]

This legislative change is indicative of the FDA's efforts to keep up with recent technological advances and respond to certain ethical concerns in

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[11] *See* Uduak Thomas, *After Mod 2.0, What Can Be Done to Boost Adoption of Alternatives to Animal Models?*, GENEDGE (Sept. 21, 2023), https://www.genengnews.com/gen-edge/after-mod-2-0-what-can-be-done-to-boost-adoption-of-alternatives-to-animal-models/ (stating that a biotechnology company Emulate experienced a 40% increase in total revenue, 90% increase in instrument sales, and 45% increase of new customers in 8 months since the Act passed); *see* Shariati, *supra* note 3 (displaying exponential growth in Pubmed entries for organoids from 2000 to 2019).

[12] Eli Y. Adashi, Daniel P. O'Mahony & I. Glenn Cohen, *The FDA Modernization Act 2.0: Drug Testing in Animals Is Rendered Optional*, 136 AM. J. MEDICINE 853 (2023), https://linkinghub.elsevier.com/retrieve/pii/S0002934323002541.

[13] *Id.*

[14] *Id.*

[15] *Id.*

animal testing. Primarily, there is a significant "translational failure" between animals and humans, where development results from animal models have a low success rate for human application.[16] Furthermore, animal testing is extremely costly. For example, rodent testing for cancer therapeutics costs an estimated $2 to $4 million in drug development.[17] Global costs for animal testing in 2018 were estimated at $7.4 billion for drug discovery, $11.2 billion for preclinical development and safety, and $2.3 for laboratory testing.[18] Lastly, the Act responds to many ethical concerns, as humane organizations praise the FDA for sparing millions of animals' lives over time.[19] The Act effectively addressed scientific limitations in animal models for drug development and testing, while simultaneously responding to humane concerns raised against animal testing.

III. ORGANOIDS HAVE CAPABILITIES TO MODEL HUMAN ORGANS & EFFICIENTLY PROVIDE NEEDED DISEASE AND TREATMENT INFORMATION

Organoids are artificially grown, three-dimensional biomasses that can be modeled after a variety of human organs.[20] Recent scientific advances have provided organoids the ability to display direct correlations with their respective organs, including "morphological features, functional activities,

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[16] Cathalijn H. C. Leenaars et al., *Animal to human translation: A systematic scoping review of reported concordance rates*, 17 J. TRANSLATIONAL MED. 223 (2019), https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-019-1976-2.
[17] Gail A. Van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials*, 4 JACC: BASIC TO TRANSLATIONAL SCI. 845 (2019), https://linkinghub.elsevier.com/retrieve/pii/S2452302X1930316X.
[18] *Id.*
[19] *See Modernize Testing*, ANIMAL WELLNESS ACTION, https://animalwellnessaction.org/modernize-testing (last visited Nov. 11, 2023) (stating positively that the Act, with proper oversight from Congress and the animal welfare community, will spare millions of animals over time); *see Victory! President Signs Groundbreaking FDA Modernization Act 2.0*, PETA, https://www.peta.org/action/action-alerts/victory-congress-passes-groundbreaking-fda-modernization-act-2-0/ (last updated Dec. 27, 2022) (posting praise for the Act's transition to superior, non-animal testing methods, instead of requiring "deadly and scientifically bogus animal tests").
[20] Yang, *supra* note 9.

and personalized responses to specific pathogens."[21] Derived from stem cells, organoids can serve as new ex vivo models and are critical to understanding a variety of illnesses, including infectious diseases, cancer, and defective genes, by providing practical knowledge from preclinical studies.[22] Consequently, organoid technology and research has provided "better options for studying cell development, tissue maintenance, and pathogenesis of the hepatobiliary system under physiological or pathological conditions closely resembling natural conditions."[23]

Organoids provide unique advantages because they: (1) are human-derived and reprise human physiological characteristics; (2) are quick, relatively easy to establish, and highly efficient; (3) have stability in all aspects during large-scale genomic screening or drug screening; and (4) are highly individualized.[24] Furthermore, a study supported by Johns Hopkins University School of Medicine found broad patient support for the derivation and use of organoids in enhancing understanding of human development, diseases, and drug development.[25] Interestingly, the sense of personal connection to the organoids did not correspond with the desire for control over their use.[26]

Organoids have already played a key role in drug development and in understanding diseases and disease prevention. In one study, methylene blue in 3-D mini-brain organoids inhibited viral replication of cells relevant to

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[21] Zahra Heydari et al., *Organoids: A novel modality in disease modeling*, 4 BIODES MFR. 689 (2021).
[22] *Id.*
[23] Yang, *supra* note 9.
[24] *Id.*
[25] Juli Bollinger et al., *Patients' perspectives on the derivation and use of organoids*, 16 STEM CELL REP. 1874 (2021), https://linkinghub.elsevier.com/retrieve/pii/S2213671121003295.
[26] *Id.*

Zika virus and protect against the Zika virus infection.[27] Similarly, liver islet organoids provided greater understanding of islet biochemical or biophysical mechanisms and developmental defects that result in congenital diabetes.[28] The ability to model islet function resolved a previous lack of authentic disease models, which has hampered studies on diabetes and diabetes treatment.[29] Lastly, human liver organoids have modelled HBV infection in vitro and provided a viable platform for anti-viral drug screening and drug-induced toxicity.[30] This modelling is crucial because, other than humans, chimpanzees are the only natural hosts to HBV, and testing on chimpanzees has been banned in the USA since 2011.[31] Other cell lines that replicate HBV have been unsuitable for breaking down the molecular steps in the tumor-derived gene expression.[32]

While organoids provide numerous benefits in the biomedical space, there are still some pivotal limitations to relying on its sole use, including availability, cost, standardization, and garnering support. There are many laboratory-based limitations and hurdles organoid technology must overcome.[33] First, there are a limited number of laboratories capable of performing organoid cultures due to the timely activation of morphogenetic signaling pathways and the high price of growth factors that requires.[34] Furthermore, current organoid technology does not reflect the complexity of

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[27] Zhong Li et al., *Methylene blue is a potent and broad-spectrum inhibitor against Zika virus* in vitro *and* in vivo, 9 EMERGING MICROBES & INFECTIONS 2404 (2020), https://www.tandfonline.com/doi/full/10.1080/22221751.2020.1838954.
[28] Xiaofei Zhang et al., *Islet organoid as a promising model for diabetes*, 13 PROTEIN CELL 239 (2022), https://academic.oup.com/proteincell/article/13/4/239/6746941.
[29] *Id.*
[30] Elisa De Crignis et al., *Application of human liver organoids as a patient-derived primary model for HBV infection and related hepatocellular carcinoma*, 10 eLIFE e60747 (2021), https://elifesciences.org/articles/60747.
[31] Ulrike Protzer, *The bumpy road to animal models for HBV infection*, 14 NATURE REV. GASTROENTEROLOGY & HEPATOLOGY 327 (2017), https://www.nature.com/articles/nrgastro.2017.44.
[32] *Id.*
[33] Yang, *supra* note 9.
[34] *Id.*

cell-cell interactions of native tissue, largely due to limited cellular development and low cell maturity.[35] Lastly, the extracellular matrix, which supports the 3D organoid structure and development, may have inconsistent biochemical properties that hampers with transfection and drug screening.[36] These biological and laboratory errors must be addressed to encourage greater organoid dependence and reliance for the future.

Administrative limitations including validation methods, ethical concerns, and general acceptance also hinder the biomedical community from utilizing organoids solely in the pre-clinical stage. There are a series of obstacles concerning human cell-based 3D models, like "the lack of robust validation methods, appropriate standards, absence of large-scale production protocols, funding, regulatory rules for stem cell us and organoid commercialization, and ethical issues."[37] Additionally, a key hurdle remains in convincing and motivating the medical community into large-scale use of advanced 3D culture technologies.[38] Short-term goals that encourage better research and accessibility for substituting animal-based disease models with human-cell-based 3D in vitro models can offer a solution.[39]

Although the cost of developing organoids remains high, their use in the preclinical stage could save pharmaceutical and biomedical companies money in the long term. Under the FDA's previous regulations, animal testing generated long delays and high costs when developing a drug.[40] Organoids, however, provide disease- and human-specific information, while

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[35] *Id.*
[36] *Id.*
[37] Chrianjay Mukhopadhyay & Manash K. Paul, *Organoid-based 3D in vitro microphysiological systems as alternatives to animal experimentation for preclinical and clinical research*, 97 ARCHIVES TOXICOLOGY 1429 (2023), https://link.springer.com/10.1007/s00204-023-03466-8.
[38] *Id.*
[39] *Id.*
[40] *E.g.*, Van Norman, *supra* note 17 (estimating the cost of rodent testing for cancer therapeutics ranges from $2 to $4 million).

avoiding the costs and wait of animal testing.[41] Organoids can help reduce the 90 percent failure rate in drug discovery and development, particularly by targeting the lack of clinical efficacy that contributes around forty to fifty percent of these failures.[42] Recent discoveries have improved the reproducibility of cortical, nephron, hepatic, and lung organoids while reducing original costs by eighty to ninety-five percent.[43] Therefore, organoid technology is rapidly advancing, leading towards greater efficacy and cost-saving techniques. Greater affordability of organoids and their increased efficiency in the pre-clinical phase will lead to greater long-term savings for drug developers and researchers.

IV. CURRENT CLINICAL TRIALS SUGGEST STRONG RELIANCE ON ORGANOIDS WITH FINAL VALIDATION FROM ANIMAL TESTING

There are currently no FDA regulations and guidelines specific to organoids. Organoids are regulated under human cells, tissues, and cellular or tissue-based products (HCT/Ps) and are subject to the same clinical-trials as any other drug or medical device. Furthermore, because the technology is so new, there are no industry standards or protocols regarding their use.[44]

Despite this, there are currently 180 clinical studies testing or using organoids listed with the National Institutes of Health ("NIH").[45] NIH funds nine studies, various industries fund fourteen studies, and a combination of individuals, universities, and organizations fund 173 studies.[46] Many of these

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[41] Mukhopadhyay & Paul, *supra* note 37.
[42] Duxin Sun et al., *Why 90% of clinical drug development fails and how to improve it?*, 12 ACTA PHARM. SINICA B 3049 (2022), https://linkinghub.elsevier.com/retrieve/pii/S2211383522000521.
[43] Xiao-Shan Zhang et al., *Highly reproducible and cost-effective one-pot organoid differentiation using a novel platform based on PF-127 triggered spheroid assembly*, 15 BIOFABRICATION 045014 (2023), https://iopscience.iop.org/article/10.1088/1758-5090/acee21.
[44] Mukhopadhyay & Paul, *supra* note 37.
[45] ClinicalTrials.gov, NAT'L LIB. OF MED., https://clinicaltrials.gov/search?term=organoid&limit=100&page=1&viewType=Table (last visited Sep. 22, 2023).
[46] *Id.*

trials are international, with only thirty-seven occurring in the United States.[47] To date, there are no FDA-approved drugs that rely solely on organoid models in the preclinical state.

However, some existing drugs relied heavily on organoid models, with the aid of animal models for final testing. The drugs Texacaftor, Ivacaftor, and Exavaftor are novel drugs that target the primary molecular defect of cystic fibrosis.[48] Patient-derived intestinal organoids had been critical for disease modeling, drug screening, and personalized medicine, and demonstrated high-throughput potential to predict drug efficacy in individuals with cystic fibrosis.[49] Another example is IONIS-HTTRX, the first therapy in clinical development designed to target the underlying cause of Huntington's Disease.[50] *In vitro* brain organoids from Huntington patients' fibroblasts enabled the neurodevelopmental studies of the disease and aided in drug screening.[51] Later studies then tested these findings in animal models which led to the clinical drug trial for IONIS-HTTRX.[52] Although these and other drug trials relied on organoids for precision and efficacy testing, organoid use still had not reached a point of replacing animal testing in the pre-clinical stage.

These clinical trials suggest that the pre-clinical process relies heavily on organoids models, encompassing assessments of efficacy, safety, disease testing, and predictions of tissue response, with researchers primarily

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[47] *Id.*
[48] Jessica Conti, Claudio Sorio & Paola Melotti, *Organoid Technology and Its Role for Theratyping Applications in Cystic Fibrosis*, 10 CHILD. 4 (2022), https://www.mdpi.com/2227-9067/10/1/4.
[49] *Id.*
[50] *Breaking News: Update on the Status of the IONIS-HTTRX Program and its Future*, HUNTINGTON'S DISEASE SOC'Y OF AM. (2023) https://hdsa.org/news/breaking-news-update-on-the-status-of-the-ionis-httrx-program-and-its-future/.
[51] Jenny Sassone, Elsa Papadimitriou & Dimitra Thomaidou, *Regenerative Approaches in Huntington's Disease: From Mechanistic Insights to Therapeutic Protocols*, 12 FRONTIERS NEUROSCIENCE. 800 (2018), https://www.frontiersin.org/article/10.3389/fnins.2018.00800/full.
[52] *Id.*

employing animal testing for final validation. There are many benefits to this approach including the minimization of animal testing, greater usage and comfort with organoid models, and providing time for labs to further develop organoid capabilities. Over time, it is possible that this approach can independently address many of the difficulties of implementing organoids as the sole model for pre-clinical testing. However, because animal testing is not banned under the FDA Modernization Act 2.0 and the use of animal testing for final validation has been successful, the necessary momentum to solely rely on organoids may be lacking.

To avoid permanent reliance on animal testing, the FDA should revise the Act to incorporate a sunset provision, explicitly prohibiting the use of animal testing by a specified future date. A modelled amendment is as follows:

> Amendment to the FDA Modernization Act 2.0
>
> §1: Purpose
>
> This amendment aims to enforce the phasing out of animal testing in drug development and promoting the adoption of alternative methods.
>
> §2: Sunset Provision
>
> By January 1, 2040, the Food and Drug Administration (FDA) shall prohibit the use of animal testing in all drug development phases as part of the approval process. A transition period will precede the ban, emphasizing the adoption and refinement of alternative methods, such as organoid models.
>
> §3: Reporting and Flexibility
>
> Starting in 2030, the FDA shall submit annual reports on the progress towards eliminating animal testing. Temporary waivers may be granted under exceptional circumstances with scientific justification, as determined by the Commissioner.

As a result, biomedical research can continue to gain assurance with organoid and alternative testing models while continuing to ensure the elimination of animal testing for drug development.

V. GREATER GOVERNMENT FUNDING AND GRANTS ARE NECESSARY TO BOLSTER SUPPORT FOR ORGANOIDS TO FULLY REPLACE ANIMAL TESTING IN THE PRE-CLINICAL STAGE.

The FDA Modernization Act 2.0 is a progressive break away from animal testing and aims to invoke greater reliance and use of other technological models, such as organoids. However, organoid development is costly, and there are notable challenges that must be addressed to broaden widespread application.[53] In response to this challenge, the FDA's budget delegated $5 million to implement a New Alternative Methods Program to incentivize the adoption of new alternative methods for regulatory use that can "replace, reduce, and refine animal testing."[54] This funding will provide real momentum for the development of alternative models.

Because the FDA issued this funding for fiscal year 2023, its effects remain unclear. However, the FDA should not be the sole financer for innovation of alternative models. Other government entities, such as the National Institutes of Health, the Centers of Disease Control and Prevention, and the National Science Foundation, should develop programs and designated funding for alternatives to animal testing. In 2023, the NIH designated $3,050,739,547 to Biomedical Research and Research Training project grants.[55] Future project grants should be used to promote organoid development by providing necessary lab equipment and resources, encourage stable and consistent organoid use, as well as incentivize new capabilities for research. Funding from multiple public actors will additionally foster acceptance of organoid models within the biomedical community.

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[53] Yang, *supra* note 9.
[54] FDA, *Justification of Estimates for Appropriations Committees*, DEPT. OF HEALTH & HUMAN SERVS. (HHS) (2023).
[55] *Biomedical Research and Research Training*, TRACKING ACCOUNTABILITY IN GOV'T GRANTS SYS., https://taggs.hhs.gov/Detail/CFDADetail?arg_CFDA_NUM=93859 (last visited Nov. 10, 2023).

Furthermore, private industries have begun using organoids to provide personalized medicine and a platform for drug development. HUB Organoids provides a fast and cost-effective screening platform on a panel of patient-derived cancer organoids.[56] Their labs developed protocols for a range of organs and disease types to allow the development of living biobanks of patient-derived organoids that are stable in long-term culture.[57] As a private company, HUB Organoids describes the FDA Modernization Act 2.0 as a "revolutionary moment for modern medicine," and embodies the private sector's inclination towards greater utilization of this technology.[58] As pharmaceutical companies realize the long term cost saving of organoid models, private industry will be a significant driver and funding source for developing these models.

Furthermore, encouraging the private sector to utilize organoids can take a multi-faceted approach. First, financial incentives, such as research grants and tax credits serve as powerful motivators. Next, establishing collaborative frameworks between private industries, research organizations, and academic institutes can aid resource-sharing and knowledge exchange that unify efforts of organoid developments. Lastly, educational and training programs will enhance proficiency and understanding in the private sector, ensuring industry professionals remain up-to-date on the latest developments and methodologies. In tandem with the public sector, private industries can play a pivotal role in advancing organoid development and standardizing its use.

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[56] Hub Organoids, https://www.huborganoids.nl/pdo-screen-2/?hsCtaTracking=d9e36bce-f2ec-4a38-ade5-da317dc900a6%7C80c0140a-c4d9-4e03-88e0-298fa7f8c09c (last visited Sept. 27, 2023).
[57] *Id.*
[58] Hub Organoids, *The FDA Modernization Act 2.0: A patient-centric paradigm shift in drug development*, HUB'S BLOG (Jan. 6, 2023), https://blog.huborganoids.nl/patient-centric-drug-development-with-organoids.

VI. CONCLUSION

The FDA Modernization Act dramatically shifted the drug development space by removing the requirement for animal testing and allowing for greater opportunities of organoid and in vitro cell models. Organoids, given their remarkable ability to mimic tissue functionality and response to treatments, are at the forefront of non-animal pre-clinical testing. As seen in the development of drugs and numerous clinical trials, organoids are a promising new wave for treatment and testing. Public and private funders recognize organoid potential, as both the FDA and private industry are rapidly investing in organoids to replace animal testing in drug development.

However, until organoid models increase in accuracy, have greater standardization, and are more affordable, they will not fully replace animal models in the pre-clinical stage. Notably, the FDA Modernization Act 2.0 does not require pre-clinical tests to step away from animal testing but gives parties the option to test using other technologies. Furthermore, organoids are still costly and lack the standard techniques and protocols that decades of animal testing have created. Lastly, the tandem of both organoid and animal testing has been successful as a compromise between utilizing organoid models while shortening the use of animal testing.

To address these hurdles, the FDA should enact a sunset provision to ban the use of animal testing in the pre-clinical stage. In the interim, organoids can drive the pre-clinical process with final validation from animal models to strengthen and encourage routine-use of organoids in the clinical stage. Additionally, more funding from multiple actors can address many of the technological inhibitions as well as foster greater acceptance of organoids among the biomedical community. With these efforts, organoids may fully replace animal testing and provide a more-accurate, less-costly medium for drug development and research.

Tumor Treating Fields Technology: Grant Fund Creation to Alter Standard of Care for Glioblastoma Treatment

Sarah Knoll

I. INTRODUCTION TO TTFIELDS THERAPY

Tumor Treating Fields ("TTFields") are a form of innovative cancer therapy traditionally used on glioblastoma ("GBM") patients by targeting cells using an electric field approach.[1] As glioblastoma is commonly an extremely aggressive and deadly form of cancer, current treatments, while useful, only produce a five-year survival rate of less than ten percent.[2] TTFields are unique in their ability to inhibit tumor growth in a noninvasive manner.[3] This technology was originally approved for patients aged twenty-two or older by the United States Food and Drug Administration ("FDA") in 2011, making it a viable treatment option for over a decade after proving its efficacy in clinical trials.[4] This article will aim to discuss the current application of TTFields, with a detailed analysis of how they have been effectively utilized thus far. Further, this article will propose the implementation of a research and development grant focused on TTFields therapy to spread awareness in hopes of bringing the treatment into the standard of care for GBM.

First, this article will discuss the current role of TTFields and how they have been implemented as a cancer treatment option. Next, the article will discuss the FDA approval process and how TTFields have already

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[1] *See* Cornelia Wenger et al., *A Review on Tumor-Treating Fields (TTFields): Clinical Implications Inferred From Computational Modeling,* PUBMED 195, 195-96 (2018) (noting that these electric fields are administered to patients at a low-density, intermediate frequency mechanism where the tumor is localized).
[2] Xiaopeng Guo et al., *Tumor Treating Fields in Glioblastomas: Past, Present, and Future*, CANCERS, 2022, at 2.
[3] Wenger et al., *supra* note 1.
[4] Guo et al., *supra* note 2, at 8.

undergone this step which should allow for more widespread usage. Finally, the article will analyze the standard of care for cancer treatment and how TTFields can be added with the help of a research and development grant to spread awareness about the treatment.

II. ROLE OF TTFIELDS AND OTHER CANCER TREATMENTS

Broadly, Tumor Treating Fields use electric fields at varying intermediate frequencies in order to disrupt cell division and target cancer cells.[5] In terms of current glioblastoma treatment, the common courses of action include radiotherapy and chemotherapy, and often can call for surgical resection if necessary.[6] While these forms of treatment are aggressive when targeting the cancerous cells, there are a large number of side effects, and likeliness of reoccurrence is high.[7] Until TTFields were established, there was no set form of radiation or treatment that was able to target specific cells.[8] TTFields target cancer cells via electric fields that emit short pulses which can induce irreversible changes to cell membranes and cause cell death.[9] By targeting proliferating cells only, TTFields are able to disrupt the cell cycle in cancerous cells, causing more significant damage to them than they would to regularly functioning cells.[10] Clinical trials have found that TTFields

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[5] *Id.* at 2.
[6] *See* Chaochao Zhang et al., *The Value of Tumor Treating Fields in Glioblastoma,* 63 J. KOREAN NEUROSURGEON SOC'Y. 681, 681-82 (2020) (explaining TTFields research in recent years and how this application could guide the future of the treatment); *see also Surgery for Glioblastoma Multiform,* WEILL CORNELL MED. BRAIN & SPINE CTR. (defining surgical resection of the brain as a procedure known as a craniotomy which removes a portion of the skull and ideally as much tumor as possible).
[7] *Id.* at 682.
[8] *Id.*
[9] Jacquelyn Zimmerman et al., *Targeted treatment of cancer with radiofrequency electromagnetic fields amplitude-modulated at tumor-specific frequencies,* CHINESE J. OF CANCER 573, 574 (2013).
[10] *See* Eunbi Ye, et al., *Effect of duty cycles of tumor-treating fields on glioblastoma cells and normal brain organoids,* INT'L J. OF ONCOLOGY. Dec. 2022, at 1 (showing that TTFields not

therapy is successful in prolonging survival of GBM patients while also significantly improving quality of life.[11] In one study, the overall survival rate of patients treated with TTFields eighteen hours a day was nearly double the control group.[12] Additionally, the worst noted side effect of the TTFields therapy was contact dermatitis, essentially a skin rash, which could be easily treated by using a steroid cream. [13]

Currently, one oncology company, Novocure, carries Optune, the name brand for TTFields Therapy.[14] Optune is a wearable, adhesive head mask for glioblastoma patients that includes a carrier bag, portable batteries, cables, chargers, and a power supply.[15] Even with several individual parts, the Optune device is very portable, weighing just over two pounds.[16] The two main components of the device consist of an electric field generator and a series of insulated transducers.[17] The insulated electrode is then applied to the human body, generally on the head of glioblastoma patients, and the electric fields are subsequently released.[18] One of the important advantages of the electric field therapy is that it is approved and recommended for both newly diagnosed and recurrent GBM.[19]

When TTFields were approved by the FDA, in both 2011 and 2015, the medical device fell under Class III of FDA approval, premarket approval ("PMA").[20] A Class III device is one that is able to "support or sustain human

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only received FDA approval at a quick rate, but also showed great treatment improvements in comparison to chemotherapy alone).

[11] Zhang et al., *supra* note 6, at 684.

[12] *Id.*

[13] *Id.*

[14] *See* Guo et al., *supra* note 2, at 8.

[15] *Id.*

[16] *Id.*

[17] Zhang et al., *supra* note 6, at 682 (explaining TTFields research in recent years and how this application could guide the future of the treatment).

[18] *Id.*

[19] *Id.*

[20] *Premarket Approval (PMA),* U.S. FOOD & DRUG ADMIN. (Sep. 18, 2023), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100034S013.

life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury".[21] Premarket approval is the strictest pathway used for device application by the FDA because FDA approval must be granted to the applicant before the device can be marketed.[22] When it was approved in 2015, the FDA specified that TTFields were to be considered an alternative medical therapy for glioblastoma, but could only be used after surgical and radiation therapy options were exhausted.[23] These more traditional approaches have been well-developed and used consistently since the early to mid-nineties, however they still pose significant risks and side effects.[24]

Despite TTFields seeming success for GBM patients and approval by the FDA, there are still barriers to accessing this type of therapy when undergoing cancer treatment. Currently, TTFields are not considered the standard of care for glioblastoma treatment or for any other form of cancer.[25] However, there is no set standard of care for progressive and recurrent forms of glioblastoma.[26] As standard of care is generally defined by state legislatures and administrative agencies, it is viewed typically as a continuum with which a doctor's care is expected to fall within.[27] For glioblastoma patients who are suffering from malignant brain tumors, standard of care can play a crucial role in receiving effective and alleviating treatment, especially to meet the national standard.[28] As standard of care represents an array of

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[21] Premarket Approval (PMA), U.S. FOOD & DRUG ADMIN. (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.
[22] *Id.*
[23] U.S. FOOD & DRUG ADMIN., *supra* note 20.
[24] Presidential Address, *A history of cancer and its treatment*, 91 ULSTER MED. J., 124, 125-26 (2021).
[25] Catarina Fernandes et al., *Current Standards of Care in Glioblastoma Therapy*, NAT'L LIBR. OF MED. (Sep. 27, 2017), https://www.ncbi.nlm.nih.gov/books/NBK469998/.
[26] *Id.*
[27] Donna Vanderpool, *The Standard of Care,* 18 NAT'L LIBR. OF MED. 50, 51 (2021).
[28] *Id.* at 51.

treatment options for patients, expanding those options to include TTFields therapy could be a beneficial tool for GBM patients.[29] To introduce this type of treatment into the standard of care, it is important to spread awareness of the success and effectiveness of the therapy, while also recognizing the current shortcomings of standard GBM treatment.

III. CURRENT TREATMENT PROBLEMS AND LACK OF AWARENESS REGARDING TREATMENT AVENUES

Issues surrounding current glioblastoma treatment generally arise due to a lack of cell death and the cell migration that occurs during the traditional chemotherapy approach.[30] The usual course of treatment used on GBM patients is unable to consistently kill tumor cells, meaning that some cells inevitably survive.[31] These remaining cells can become resistant to further treatment, rendering the therapeutic outcome even more bleak for suffering patients.[32] Additionally, cells have a great capacity for migration.[33] This results in the cells forming tumors in areas far away from the original malignancy, which is a dangerous outcome.[34] The overall lack in the current system of glioblastoma treatment reinforces the ongoing issue that lack of research poses. Innovative options for treatment are essential to cancer patients and their well-being. Currently, new options cannot become more widespread if there continues to be little knowledge on what viable options exist.

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[29] *Id.*
[30] *See* Joao Cruz et al., *Obstacles to Glioblastoma Treatment Two Decades after Temozolomide*, CANCERS (Jul. 2022).
[31] *Id.* at 1.
[32] *Id.*
[33] *Id.*
[34] *Id.*

Further, cancer, like many other chronic illnesses, faces scrutiny for the standard of care that is generally delivered.[35] Chemotherapy poses yet another problem; it can be fatally toxic to the liver and the kidneys, as these organs are metabolizing and excreting the chemotherapy agents.[36] If the doses for individual patients are not closely monitored, the buildup of toxins can lead to organ failure and, ultimately, death.[37] Further problems with chemotherapy include an increased risk of infections due to immunosuppression and affecting non-cancerous cells, such as those in the GI tract, bone marrow, and within hair follicles.[38] Long-term effects can also include infertility and infusion reactions.[39] Additionally, the side effects of chemotherapy are nearly impossible to predict on an individualized basis. Generally, chemotherapy poses significant risks to patients which places emphasis on the need for a new route of treatment, especially in aggressive cancers like glioblastoma.[40]

IV. Research and Development Grant Fund to Allow for Widespread Implementation of TTFields Therapy in Glioblastoma Patients

To introduce TTFields into the world of cancer treatment options, the applicable standard of care must be addressed. By adding TTFields to the standard of care, patients and physicians would be able to choose therapeutic TTFields as an alternative route of treatment. As GBM patients often succumb to their disease within the first year of diagnosis, expanding

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[35] John Marshall, *The Standard of Care in Oncology is Unacceptable,* CANCERNETWORK, (Jun. 1, 2006), https://www.cancernetwork.com/view/standard-care-oncology-unacceptable.
[36] Amjad et al., *Cancer Chemotherapy,* NAT'L LIBR. OF MED., (Feb. 27, 2013), https://www.ncbi.nlm.nih.gov/books/NBK564367/.
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*

treatment options is essential to changing their quality of life as well as potentially altering the prognosis of the cancer's toll itself.[41] Due to the cancer's aggressive nature, quality of life is a large component of glioblastoma patients' care, which cannot be overlooked. Oftentimes, this short life expectancy causes patients to choose the path of least debilitating treatment, meaning chemotherapy is not necessarily a viable option.[42] In most clinical trials thus far, TTFields were used as a form of therapy alongside Trimetazidine ("TMZ").[43] TMZ is commonly used to treat various forms of recently diagnosed or recurring brain cancer, glioblastoma included.[44] Bringing this treatment option into the standard of care requires more knowledge to be obtained on the topic, which starts in the medical field itself.[45]

Doctors are at the forefront of practical knowledge and experience within the standards of care for various diseases.[46] An important component to the utilization of treatments under the standard of care stems from physician discretion and clinical judgement.[47] To help bring TTFields into the standard of care, the creation of a research and development grant to spread information about the safety and efficacy of the specific treatment could be beneficial. The grant would have to undergo the approval process

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[41] Mehta et al., *Critical Review of the Addition of Tumor Treating Fields (TTFields) to the Existing Standard of Care for Newly Diagnosed Glioblastoma Patients,* 111 SCIENCEDIRECT 60, 61 (2017).
[42] *Id.*
[43] *Id.*
[44] *Drugs and Supplements- Temozolomide (Oral Route),* MAYO CLINIC (Aug. 1, 2023), https://www.mayoclinic.org/drugs-supplements/temozolomide-oral-route/side-effects/drg-20066228?p=1.
[45] *See* Neda Laiteerapong and Elbert Huang, *The Pace of Change in Medical Practice and Health Policy: Collision or Coexistence?,* J. GEN INTERN MED. at 848 (2015) (emphasizing how, in recent years, physicians have fought to stay up to date with medical standards of practice while there is an ever-evolving shift to more individualized care for patients).
[46] Vanderpool, *supra* note 27.
[47] *Id.*

from the government, oftentimes via grant-providing agencies. Further, the grant money would need to be approved by Congress in order to be used.

The goal of the fund would be to educate doctors in a more direct manner about the success of TTFields therapy. One way in which this could be achieved through the grant would be to have a designated portion that focused on an education program for doctors. Although doctors play an integral role in all patient treatment, oncologists focusing on cancer patients form an ongoing and ever-present relationship. Cancer treatment is oftentimes long and arduous, meaning doctors play a very advanced role in suggesting and discussing treatment options, as well as being a listening ear for all their patients' needs. Thus, new treatment options will come into practice if doctors have more knowledge of them and how they can help treat certain patients. The research and development grant fund would be one of the first steps in allowing doctors to bring this innovative therapy into daily treatment.

The U.S. government consistently supports many scientific research and development programs to spread awareness on a variety of topics and help the general public take note of their worth.[48] The grant would help to funnel money into the research and development of TTFields, which would assist in spreading awareness within the oncology field about the new treatment option and, in turn, allow it to become a part of the standard of care. Specifically, the grant would allow more research and testing to be performed surrounding the implementation of TTFields therapy. The grant would also create more open discussions about the workings of TTFields, their application, and how they might be most effectively used in treating glioblastoma.

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[48] John Sargent Jr., *Federal Research and Development Funding: FY2024*, 1 (2023).

Understanding the importance and usefulness behind this type of innovative therapy could help doctors to become familiar with TTFields and have incentive to implement the therapy into treatment for GBM patients. Where research currently is with TTFields, the next important step is related to exposure. Additionally, at this point in time, TTFields would benefit most from being more well known. The field of cancer treatment is ever evolving and complex, meaning that these new treatments require time in order to work their way into the trusting eyes of long-time doctors. Implementation will therefore require that the treatment is well thought-out, tested, and fulfills the goals needed to treat patients suffering from glioblastoma.

Alongside funding for the grant, the FDA approval process can also help spread awareness regarding the benefits of TTFields therapy. A research and development grant can kickstart the support of vital discoveries made during clinical trials that can translate into realistic treatment options for dying patients, and the FDA approval process can also help spread awareness that will help patients during their GBM treatment process.[49] For a drug to be passed under the premarket approval standard, the FDA must determine that it is safe and effective if used under the conditions prescribed.[50] As Tumor Treating Fields have already been approved by the FDA, this endorsement should translate into trust for doctors and the general population about the use of the therapy.[51] Further, this means that the treatment could potentially reach beyond Glioblastoma patients and treat other forms of cancer as well.[52] More widespread application of the treatment would assist

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[49] *Biomedical Research Funding,* ENDOCRINE SOC'Y (Mar. 15, 2023), https://www.endocrine.org/advocacy/position-statements/biomedical- research- funding.
[50] Center for Drug Evaluation and Research, *Benefit-Risk Assessment for New Drug and Biological Products,* U.S. FOOD & DRUG ADMIN (Sep. 2021), https://www.fda.gov/media/152544/download.
[51] Zhang et al., *supra* note 6.
[52] Ignace Vergote et al., *Tumor Treating Fields (TTFields) Therapy Concomitant with Taxanes for Cancer Treatment,* Cancers, Feb. 2023 at 1 (discussing how TTFields have

in building trust for the therapy in the medical industry and increase overall exposure to assist with implementation. TTFields noninvasive nature also allows them to be a more mellow form of treatment when it comes to cancer care, which can be further developed through the research and development grant.[53] When weighing the severity of glioblastoma, and TTFields ability to treat this cancer in a desirable way, the FDA's approval can help guide opponents of the therapy to recognize the benefits versus the risks of the treatment.

Thus, by funding a research and development grant for TTFields research, the nature of the treatment as currently applied would change. The general population, and most importantly, doctors, would become further aware of the benefits of the therapy, considering the research that would come out of funding the grant. The outcome of the funding would ideally allow doctors to become more accustomed to and immersed in the realm of TTFields therapy, which would allow the treatment to become a standard treatment option for patients. The therapy would naturally become a more trusted route of care, via exposure to those within the medical field as more results surrounding the therapy are discovered. By allowing doctors to gain deeper insight on the current beneficial procedures of TTFields therapy, a starting point for adding this treatment into the standard of care would form. What TTFields are currently missing is the fact that they are underdeveloped and unrecognizable to a large portion of the population.[54] However, studies have shown that there is a shift in that paradigm that supports the promise of

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allowed a variety of cancers to be treated effectively during clinical trials, including pancreatic and ovarian cancer cells).

[53] Guo et al., *supra* note 2, at 2.

[54] *See* Wolfgang Wick, *TTFields: where does all the skepticism come from?,* 18 NEURO-ONCOLOGY 303, 303-04 (2016) (analyzing the troublesome aspects of TTFields by running a current study on antiangiogenic or targeted therapy styles that may not have induced their intended outcome).

TTFields as an innovated targeted therapy.[55] Supporting funding for research on this type of treatment would meet the overarching goal of spreading awareness and bringing the therapy into a place where it could become more effectively utilized under the standard of care.

V. UPDATES TO THE CURRENT TTFIELDS DEVICE WILL PROMOTE OVERALL USAGE

Although there are a plethora of advantages to TTFields, the practical application is a prevalent concern.[56] Namely, there is an unbalanced distribution of devices, with only two-fifths of centers worldwide having the ability to distribute the devices.[57] The limited accessibility of TTFields is something that could be a barrier to its ability to be an efficient mode of GBM treatment.[58]

Additionally, there are concerns related to the practicability of the device, especially for older patients.[59] The device must be carried around, charged, and administered properly, which also requires a patient to have a shaved head.[60] Patients undergoing chemotherapy are generally told to expect hair loss, but this is presumably less of a concern when other, more therapeutic treatments are introduced. The Optune device requiring a patient to undergo complete hair loss could be a small deterrent factor in its use. The device is also recommended to be worn for eighteen hours of the day, which can be a difficult threshold to meet.[61] Thus far, Optune has seen a decrease in compliance once patients are out of the hospital, simply because of the nature

[55] *Id.* at 304.
[56] Guo et al., *supra* note 2, at 7.
[57] *Id.* at 8.
[58] *Id.* at 10.
[59] Zhang et al., *supra* note 6, at 686.
[60] *Id.*
[61] Mehta et al., *supra* note 41.

of the device and its application.[62] This result means that patients may struggle to use the device on their own, or that its use is unable to blend effectively with their day-to-day life outside of the hospital.[63]

An even broader concern relates to the position that Tumor Treating Fields simply have not proven themselves to be effective enough to become more widespread practice.[64] There is the lingering concern that there could be large subsets of people who would not respond to TTFields therapy at all, which puts into question if the therapy really belongs under the title of standard of care.[65] Outside of concerns about the compatibility of the device itself, the steep price of Optune is also impractical for certain populations of patients, specifically those who may not have commercial insurance.[66]

While TTFields do face a variety of obstacles surrounding a more widespread application, standard of care is not meant to force patients down a specific path. As standard of care is flexible in the options it provides by using a spectrum approach, patients and doctors are able to make decisions that allow the best course of treatment on an individualized basis.[67] Tumor Treating Fields have proved themselves to be safe, effective, and an important treatment option for a variety of patients thus far in ongoing clinical trials.[68] Additionally, cost concerns have been mitigated a bit more in recent years as the evolving technology has provided discount options.[69] Bringing awareness to this type of treatment would simply allow patients to have greater latitude in choosing a path that is best suited to their specific needs. The new addition would not take away from any other current

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[62] Guo et al., *supra* note 2.
[63] *Id.* at 13.
[64] *Id.* at 17.
[65] *Id.*
[66] *Id.* at 13.
[67] Vanderpool, *supra* note 27.
[68] Guo et al., *supra* note 2, at 2.
[69] *Id.*

practices and would simply expand the net of options faced by patients fighting one of the most aggressive and lethal tumors of the central nervous system.[70]

Alongside recent developments that have mitigated some concerns with TTFields therapy, the proposed grant could also help to combat current issues. The grant money could help assist in the development of an even lighter weight device that could become more cost effective and less restrictive for suffering patients. These developments would help patients who may have trouble using the device as often as they should to maximize effective treatment and also allow the device to reach as many patients as possible.

VI. TTFIELDS SHOULD BE AN UP-AND-COMING ADDITION TO STANDARD OF CARE FOR GLIOBLASTOMA PATIENTS

Overall, the addition of TTFields therapy into the standard of care would allow patients the ability to explore options with regard to cancer treatment. Creating a grant fund to increase research and development on the treatment would help to convince the health care community as a whole about the importance of the treatment option. Additionally, this approach helps to give researchers more time to work through TTFields as a treatment option, while also allowing the therapy to become more widespread and well known in general. While there are certain practical concerns to the general use of the Optune device itself, TTFields approval by the FDA and overall clinical achievements allow it to be a serious contender for innovative cancer care. Standard of care is one of the many necessary components to proper patient

[70] Ivana Jovcevska, *Genetic secrets of long-term glioblastoma survivors,* 19 BOSN J BASIC MED SCI. 116, 119 (2019).

treatment, and the cancer field overall would benefit from the expansion to TTFields therapy for glioblastoma treatment.

Conceiving Equality: Eliminating Sex Discrimination from Fertility Insurance Mandates

Logan March

I. INTRODUCTION

In 1923, the Supreme Court declared that the rights "to marry, establish a home and bring up children" are "essential to the orderly pursuit of happiness by free men" and constitutionally guaranteed to all Americans through the Due Process Clause.[1] However, this constitutional guarantee was not given to *all* Americans until 2015, when Supreme Court in *Obergefell v. Hodges* finally granted the right of marriage to lesbian, gay, bisexual transgender, queer, and otherwise non-cis-gender heterosexual ("LGBTQ+") couples.[2] Over the next five years, over 290,000 same-sex couples married and established homes.[3] However, lingering inequities in access to sexual and reproductive healthcare prevent same-sex couples from enjoying the attached right to bring up children. One of these inequities is driven by the high cost of *in vitro* fertilization (IVF), the most popular method of artificial reproductive technology (ART) same-sex couples utilize to have children.[4] Same-sex couples in the United States can face disproportionately higher financial costs for fertility treatments as compared to equivalent opposite-sex couples, based solely on their sex, sexuality, and state of residency.[5]

Fortunately, there is a growing movement recognizing this inequity and push for change. In the last year, sixteen states, the District of Columbia, and

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[1] Meyer v. Nebraska, 262 U.S. 390, 399. Since *Meyer*, the Supreme Court has also identified a constitutional right to marriage in the Equal Protection Clause and in the 14th Amendment's right to privacy; Zablocki v. Redhail, 434 U.S. 374, 381-386 (1978).
[2] *See* Obergefell v. Hodges, 576 U.S. 644 (2015).
[3] Christy Mallory & Brad Sears, *The Economic Impact of Marriage Equality Five Years After* Obergefell v. Hodges, UCLS SCH. OF L. 3 (May 2020).
[4] *See Assisted Reproductive Technologies*, SOC'Y FOR ASSISTED REPRODUCTIVE TECH., https://www.sart.org/patients/a-patients-guide-to-assisted-reproductive-technology/general-information/assisted-reproductive-technologies/ (last visited Oc. 20, 2023) ("Approximately 99 percent of ART cycles performed are IVF-ET").
[5] *See* Amy Klein, *I.V.F. is Expensive. Here's How to Bring Down the Cost*, N.Y. TIMES (April 18, 2020) https://www.nytimes.com/article/ivf-treatment-costs-guide.html.

United States members of Congress have introduced legislation designed to grant fertility insurance coverage to same sex couples.[6] United States Congresswoman Rosa DeLauro summarized the need for expanded legislation when she stated, "When people do not have insurance coverage for infertility treatment and care, they are forced to make the impossible choice between essentials like food, clothing, and housing, or paying out of pocket for the chance to have a child."[7]

Expanding insurance legislation around IVF is long overdue, and the recent successful state laws can serve as a model to further expand coverage in other states and at the federal level. This article will first discuss the high financial burden same-sex couples face when seeking to have biological children. Through a comparison of existing state statutes, this article will then describe the existing coverage landscape and summarize key features of state legislation and their impact on LGBTQ+ couples. Finally, this article will offer three methods to fix discriminatory statutes and secure the right of parenthood for same-sex couples.

II. THE ART COST INEQUALITY FOR SAME-SEX PARENTS

In the United States, more than 20 million Americans identify as LGBTQ+,[8] and almost one third of this population are raising children.[9] The majority of same-sex couples having children today choose to have

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[6] Tim Henderson, *Fertility health coverage is still hard to come by in many states*, COLO. NEWSLINE (July 29, 2023), https://coloradonewsline.com/2023/07/29/fertility-health-coverage-is-still-hard-to-come-by-in-many-states/.
[7] Corey Booker*, DeLauro Re-Introduce Bill to Increase Access to Infertility Treatment*, CORY BOOKER S. (Jul. 16, 2021), https://www.booker.senate.gov/news/press/booker-delauro-re-introduce-bill-to-increase-access-to-infertility-treatment.
[8] *We Are Here: Understanding The Size of the LGBTQ+ Community*, THE HUM. RTS. CAMPAIGN FOUND. 2 (2021), https://hrc-prod-requests.s3-us-west-2.amazonaws.com/We-Are-Here-120821.pdf.
[9] The Williams Institute, *LGBT Demographic Data Interactive*, UCLA SCHOOL OF L. (January 2019), https://williamsinstitute.law.ucla.edu/visualization/lgbt-stats/?topic=LGBT#about-the-data.

biological children over alternatives like adoption,[10] but without insurance coverage, these parents face significant financial barriers.[11] Most couples choose to have biological children through IVF, a medical procedure where mature egg cells are removed from a woman, fertilized with sperm outside the body, and inserted into the uterus of a woman where the fertilized embryo matures and develops into a fetus.[12] The cost of IVF ranges from $12,000 to $17,000 per cycle (implantation procedure) without medication.[13] With medication, costs can rise to $30,000 per cycle,[14] and with a success rate of only 40.9%, more than half of couples will have to undergo more than one round of IVF before a successful birth.[15] In addition, these figures do not include the cost of a donor egg (which can be between $14,000 and $47,000),[16] surrogacy (between $125,000 and $175,000),[17] and delivery (up to $3,500 with insurance, or $24,000 without).[18] Added together, these costs

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[10] Laquitta Walker & Danielle Taylor, *Same-Sex Couple Households: 2019 American Community Survey Briefs*, U.S. CENSUS BUREAU 6 (Feb. 2021) (explaining the survey finding that 51.6% of married same-sex couples and 44% of unmarried same-sex couples were found to be raising only biological children and 17.1% of married and 5.9% of unmarried same-sex couples were raising only adopted children. Less than 10% in both categories were raising more than one type of child).

[11] *See Insurance Coverage by State*, RESOLVE: THE NAT'L INFERTILITY ASS'N, https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/insurance-coverage-by-state/ (last viewed Sept. 22, 2023) (documenting the current landscape of U.S. infertility insurance coverage).

[12] *In vitro fertilization*, ENCYC. BRITANNICA, https://www.britannica.com/science/in-vitro-fertilization (last visited Oct. 20, 2023); *supra* note 4.

[13] Amy Klein, *I.V.F. is Expensive. Here's How to Bring Down the Cost*, N.Y. TIMES (April 18, 2020), https://www.nytimes.com/article/ivf-treatment-costs-guide.html.

[14] Marissa Conrad & James Grifo, *How Much Does IVF Cost?*, FORBES (Aug. 14, 2023), https://www.forbes.com/health/womens-health/how-much-does-ivf-cost/.

[15] *See* Centers for Disease Control and Prevention, *2020 Assisted Reproductive Technology Fertility Clinic and National Summary Report*, U.S. DEPT. OF HEALTH & HUMAN SERVS. (2022), https://www.cdc.gov/art/reports/2020/pdf/Report-ART-Fertility-Clinic-National-Summary-H.pdf (explaining noncumulative ART success rates for transfers among patients using eggs or embryos from a donor or donated embryos).

[16] Klein, *Supra* note 13.

[17] Amanda Mushro, *How much does surrogacy cost?*, TODAY (July 26, 2022), https://www.today.com/parents/parents/surrogacy-costs-rcna40050#.

[18] Chris Gilligan, *Research Finds the Cost of Childbirth Varies Widely*, U.S. NEWS (May 12, 2023), https://www.usnews.com/news/best-states/articles/2023-05-12/new-reports-find-the-cost-of-childbirth-varies-by-state.

are nearly insurmountable when the average United States household income is $74,580.[19] It is therefore not surprising that a recent survey by the United States Census Bureau found that same-sex married couples have children about half as frequently as opposite-sex married couples.[20]

III. COVERAGE LANDSCAPE

In the United States, insurance coverage is regulated at the state level, which means different states have different laws requiring different levels of coverage.[21] Currently most states have no coverage requirement for IVF services.[22] This means that in the 29 states without coverage mandates, some plans *may* cover the service, but no plan *must* provide coverage. In the twenty-one other states, private insurance carriers are required to provide some level of ART coverage, but the way the statutes define terms like "infertility," "covered individuals," and "services" creates glaring inequalities.[23]

Consider the following hypothetical. Jack and Sally are a straight cis-gender couple, happily married, living in Texas. Their neighbors are Jim and Sam, a cis-gender male gay couple who are also happily married. All four are infertile but want to have a child. Both couples have health insurance under the same insurance policy. Jack and Sally consult with their in-network healthcare provider and undergo three rounds of IVF, all of which are

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[19] Gloria Guzman & Melissa Kollar, *Income in the United States: 2022*, U.S. CENSUS BUREAU 1 (Sept. 2023).
[20] Walker & Taylor, *supra* note 10.
[21] Office of Health Policy, The Regulation of the Individual Health Insurance Market, U.S. DEPT. OF HEALTH & HUMAN SERVS. 2 (2008), https://aspe.hhs.gov/sites/default/files/private/pdf/75786/report.pdf.
[22] *See Insurance Coverage by State*, RESOLVE: THE NAT'L INFERTILITY ASS'N, https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/insurance-coverage-by-state/ (last viewed Sept. 22, 2023) (documenting current landscape of U.S. infertility insurance coverage).
[23] Devin Dwyer & Patty See, *LGBTQ Couples Push for 'Fertility Equality' in Family-Building Benefits,* ABC NEWS (June 27, 2023), https://abcnews.go.com/US/lgbtq-couples-push-fertility-equality-family-building-benefits/story?id=100243800.

covered by their insurance. Jim and Sam hear about the good news and go to the same in-network healthcare provider. They undergo three rounds of IVF with a surrogate and are overjoyed when they have their first child. However, unlike Jack and Sally, Jim and Sam were charged $40,000 for the three rounds of IVF. Insurance coverage was denied merely based on their sex and sexuality alone. How could this be?

First, a bit of history. When defining "infertility," insurance carriers and legislators modeled the definition after the American Society of Reproductive Medicine (ASRM) and World Health Organization (WHO), which characterized infertility as "a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse."[24] This definition is problematic for two reasons. First, an opposite-sex relationship is required for an individual to be deemed "infertile" under this definition. Does this mean same-sex female couples have to undergo 12 months of unsuccessful ART to "prove" infertility and gain coverage? Unfortunately, the answer has historically been yes.[25] Second, when applied in the insurance context, the definition excludes all same-sex male couples from ever qualifying for coverage because cisgender males can never "achieve pregnancy." Even though neither member of a gay couple could ever become pregnant, they do not meet the definition of infertility, which is characterized as a "disease."[26] Moreover, even if both men are infertile, they cannot qualify under the

[24] *Infertility*, WORLD HEALTH ORG., https://www.who.int/health-topics/infertility#tab=tab_1 (last visited Oct. 20, 2023).
[25] *See* Brendan Pierson, *Aetna LGBT+ discrimination suit expands to employer plans*, REUTERS (Nov. 4, 2021), https://www.reuters.com/legal/transactional/aetna-lgbt-discrimination-suit-expands-employer-plans-2021-11-04/. (describing three lesbian couples' lawsuit after insurance company refuses coverage for multiple unsuccessful ART procedures).
[26] Pierson, *supra* note 24.

definition without having "regular unprotected sexual intercourse" with a woman. Obviously, this is a big problem.

To their credit, in 2023 the ASRM updated their definition of infertility to include those who need "donor gametes or donor embryos in order to achieve a successful pregnancy either as an individual or with a partner" and expressly forbid denial of services under this definition on the basis of sex or sexual orientation.[27] This newly-adopted language could push insurance companies and state legislators to revise their own definition of infertility, but on its own, it has no force of law. It is merely representative of a growing recognition of the discriminatory effect of the historic definition.

So far at least, insurance companies continue to rely on the traditional definition of "infertility." UnitedHealth Group ("UHG") is the largest private health insurance carrier by market share[28] and under UHG's healthcare coverage policy terms, infertility is defined as "a disease… of the reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery" that is "defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination."[29] Aetna, another major national health insurance provider, tried to change their healthcare policy terms to be include a more inclusive definition of infertility, but to little effect.[30] Aetna's revised policy still requires "1 year of egg-sperm

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[27] *Definition of infertility: a committee opinion*, AM. SOC'Y OF REPRODUCTIVE MED. (2023), https://www.asrm.org/globalassets/_asrm/practice-guidance/practice-guidelines/pdf/definition-of-infertility.pdf.

[28] Mark Rosanes, *Top 10 Health Insurance Companies in the US*, INS. BUS. AM. (Aug. 23, 2021), https://www.insurancebusinessmag.com/us/news/healthcare/top-10-health-insurance-companies-in-the-us-212292.aspx.

[29] *See Infertility Diagnosis, Treatment and Fertility Preservation*, UNITED HEALTHCARE, (Sept. 9, 2023), https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/infertility-diagnosis-treatment.pdf.

[30] *Compare* Aetna, *Infertility Policy*, http://www.aetna.com/cpb/medical/data/300_399/0327.html (last visited April 29, 2022) ("A member is considered infertile if he or she is unable to conceive or produce conception after

contact" without pregnancy to be deemed infertile.[31] As a result of this language, same-sex female couples must undergo one year of ART before qualifying for coverage, and same-sex male couples are completely barred from coverage and would need to pay out of pocket for 12 rounds of ART with a surrogate.

On the public insurance side, there is virtually no mandatory fertility insurance coverage. Medicare is typically only available to those who are over the age of 65, so coverage for infertility services under the Medicare program is understandably limited. As of November 2021, there were over 92 million individuals enrolled in Medicaid,[32] but so far, only New York, Illinois, and D.C. provide fertility coverage through Medicaid.[33] In New York and Illinois, coverage is limited to the preservation of sperm or egg when an individual undergoes treatment likely render them infertile, making it an emergency solution and not a family-creation plan.[34] In Washington, D.C., where lawmakers recently passed the Expanding Access to Fertility Treatment Amendment Act of 2023 (Act), individuals on both public and

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1 year of frequent, unprotected heterosexual sexual intercourse, or 6 months of frequent, unprotected heterosexual sexual intercourse if the female partner is 35 years of age or older. Alternately, a woman without a male partner may be considered infertile if she is unable to conceive or produce conception after at least 12 cycles of donor insemination (6 cycles for women 35 years of age or older)") *with* Aetna, *Infertility Policy*, http://www.aetna.com/cpb/medical/data/300_399/0327.html (last visit April 29, 2022), ("This definition applies to all individuals regardless of sexual orientation or the presence/availability of a reproductive partner. Infertility may also be established by the demonstration of a disease of the reproductive tract such that timed egg-sperm contact would be ineffective.")

[31] *Id.*

[32] *June 2023 Medicaid & CHIP Enrollment Data Highlights*, CTRS. FOR MEDICAID & MEDICAID SERVS. (June 2023), https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html [https://perma.cc/RC58-FB7F].

[33] Time Henderson, *Few States Extend Fertility Treatment Coverage to Medicaid Recipients*, OHIO CAPITAL J. (Aug. 15, 2023), https://ohiocapitaljournal.com/2023/08/15/few-states-extend-fertility-treatment-coverage-to-medicaid-recipients/.

[34] *Id.*

private insurance are entitled to broad IVF coverage.[35] The Act granted coverage to individuals including those in a "status characterized by… [a] person's inability to reproduce without medical intervention either as a single individual or with their partner…."[36] This is a novel way to expand coverage to same sex-couples and to those on public insurance plans, and the first substantive expansion of IVF coverage under Medicaid. Due to the small size of D.C., it may not be a viable plan for larger states as it would add significant cost to the already expensive Medicaid program, but it is an exciting development nonetheless.

Let's now return to the two couples in the hypothetical. In Texas,[37] Arkansas,[38] and Hawaii,[39] IVF is only covered when the patient (the woman who will carry the baby) is implanted with an embryo made from her oocyte (egg cell) and her husband's sperm.[40] Coverage is required **only** between a cisgendered man and a cisgendered woman who are married to each other. These three states make up the most restrictive and LGBTQ+-exclusive group of insurance mandates. Insurers are allowed to deny coverage to unmarried couples and married same-sex couples. In short, denial of coverage can be based on gender or sexuality alone. In the hypothetical, both couples were identical in every way except sex and sexuality. Under existing legislation in these three states, insurance companies are allowed to grant the straight couple's claims and deny the gay couple's.

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[35] D.C. Council Bill 250034, 25th Council (2023).
[36] *Id.*
[37] Tex. Ins. Code § 1366.003 (Apr. 1, 2005).
[38] Ark. Admin. Code R. § 054.00.1-5 (2017) ("The patient and spouse must have a history of unexplained infertility of at least 2 years in duration, or (ii) the infertility must be associated with one or more of the following: endometriosis, exposure in utero to DES, blockage of or removal of one or both fallopian tubes not a result of voluntary sterilization, or abnormal male factors…").
[39] Haw. Rev. Stat. § 431:10A-116.5 (2013).
[40] *See supra* note 22 ("The coverage [of IVF] is required only if… the fertilization or attempted fertilization of the patient's oocytes is made only with the sperm of the patient's spouse…").

In a second grouping of states, coverage is more ambiguous. In Connecticut, Delaware, Massachusetts, Ohio, and Rhode Island, infertility is characterized as a disease, following the traditional ASRM definition, so coverage is available only where "medically necessary."[41] This, too, bars most same-sex couples, who have a structural (not a medical) bar to reproduction. In Montana and New Hampshire, the statutes require providers to cover "infertility services," but the statutes do not define "infertility," leaving it up to the providers.[42] In West Virginia, a similar statute requires infertility coverage without defining it.[43]

In the third group, insurers in California and Louisiana are required to offer fertility treatments, but not required to offer IVF. [44] This benefits same-sex female couples, who have other ART options like intrauterine insemination (IUI) available, but bars coverage for same-sex male couples.

In recent years, a final grouping made up of three states and the District of Columbia recognized the discriminatory nature of these statutes and amended their laws to grant LGBTQ+ couples the right to IVF by amending their statutory definition of "infertility."[45] In 2015, Maryland exempted same-sex couples from the two-year infertility demonstration requirement, as well as other provisions that made it impossible for same-sex couples to access IVF coverage.[46] In February 2021, under a directive from Governor Cuomo, New York expanded its laws "to provide immediate coverage of

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[41] Conn. Health Ins. Code § 38a-509 (Jan. 1, 2018); Del. Code Ann. tit. 18, § 3556(i)(1) (2018); 211 Code of Mass. Reg. § 37(3) (2010); Ohio Rev. Code §§ 1751.01; 1751.02 (2021); R.I. Gen. L. § 27-18-30 (2007).
[42] *Supra* note 11.
[43] W. Va. Code § 33-25(A)(2).
[44] Cal. Health & Safety Code § 1374.55 (2011); Cal Ins. Code § 10119.6 (2014); La. Rev. Stat. § 22:1036 (2001).
[45] Aimee Cho, *DC law expands IVF insurance coverage. Here's how it works*, NBC (Sept. 13, 2023), https://www.nbcwashington.com/news/local/dc-law-expands-ivf-insurance-coverage-heres-how-it-works/3422802/.
[46] Ma. S.B. 416 (2015).

diagnostic and treatment services, including prescription drugs, for the diagnosis and treatment of infertility ('basic infertility treatments') for individuals who are unable to conceive due to their sexual orientation or gender identity."[47] Finally, in July 2021, Governor Pritzker of Illinois signed HB3709 which removed the provision stating that "infertility" meant the inability to sustain a pregnancy after 12 months of unprotected intercourse and prevented discrimination in coverage.[48] Each of these models offer important ideas that we can use when crafting a more effective policy measure.

IV. SOLUTIONS

A. The Legislative Option

The right to a biological child is central to the dignity and autonomy granted to every individual in the United States. Existing state infertility insurance mandates demonstrate the belief that those who are unable to carry a child to term because of infertility still deserve the opportunity to have a biological child. The trend in recent years has moved toward granting IVF coverage generally, and, importantly, toward granting IVF coverage for same-sex couples. In some of the most restrictive states, attempts by legislators to revise the statutes to make them more equitable have been unsuccessful. [49] Recent state legislation offers different, imperfect, approaches that together offer a strong path forward.

Of course, the best option is for a federal expansion of coverage that would require insurance carriers, both private and public, to provide IVF coverage to all who are "infertile" under a new, expanded definition of

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[47] Lisette Johnson, *Ins. Circular Letter No. 3*, N.Y. ST. DEPT. OF FIN SERV. (Feb 23, 2021) https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2021_03.
[48] Ill. H.B. 3709, 102nd Gen. Assembly (July 7, 2021).
[49] *See e.g.*, S.B. 993, 32nd Leg. Reg. Sess. (Haw. 2023) and H.B. 664, 29th Leg., Reg. Sess. (Haw. 2017).

infertility. The existing state statutes typically lie in the state's insurance code,[50] but since there is no federal insurance code, there are several ways Congress could enact the legislation. Most likely, the statute would be an amendment to the Public Health Services Act[51] and the Social Security Act,[52] which contain the core United States laws dealing with private and public health insurance and include the series of amendments made under the Affordable Care Act.[53] The statute, modeled after the recently adopted D.C. statute, should read:

> *Beginning January 1, 2025, an individual health plan, group health plan, health insurer, and a health insurer offering health insurance coverage through Medicaid and other state- and federally-funded health insurance programs shall provide coverage for the diagnosis and treatment of infertility, including* in vitro *fertilization.*

In the definitions portion of the statute, there should be a new definition of "infertility" that expands coverage to same-sex couples:

> Current Common Definition
>
> *Infertility is disease historically defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/ his partner.*
>
> Recommended Definition
>
> *For the purposes of this statute, "infertility" shall be understood to mean a person's inability to achieve a successful pregnancy due a demonstrated medical condition, a person's sexual orientation or gender, or a non-voluntary impairment of a person's capacity to reproduce either as an individual or with others.*

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[50] *See e.g. supra* note 37.
[51] Public Health Services Act, Pub. L. 78-410 (1944).
[52] Social Security Act, Pub. L. 74–271, 49 Stat. 620 (1935).
[53] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).

This definition, adopted from the ASRM's existing definition,[54] is preferable because it removes language that limits coverage to heterosexual couples and opens coverage up to other couples, without being overly broad, lengthy, or confusing. By removing the word "disease" at the start of the definition, the new definition changes the very initial understanding of the term, which naturally colors the rest of the definition. Infertility does not have to be associated with any kind of disease, and this is the message the proposed language seeks to convey. By removing the "after 12 months or more of regular, unprotected sexual intercourse" requirement, the model pulls from the revised Maryland statute and removes the requirement that couples "prove" infertility, which is impossible for same-sex male couples and expensive for same-sex female couples. Same-sex couples are therefore exempted automatically from the requirement of regular, or at least monthly, intercourse, which is now an implicit condition within "inability to achieve a successful pregnancy" language and only applies to opposite-sex couples, without a specific time requirement. The "proof" language was discriminatory because heterosexual couples do not need to provide any documentation or evidence to demonstrate 12 months of regular, unprotected sexual intercourse, they merely need to tell the doctor it happened. Thus, removing the requirement does nothing to weaken the statute because it applies to opposite-sex couples, and does not create a greater burden for straight couples.

By adding a second condition for inability to conceive, the "inability to achieve a successful pregnancy due to… sexual orientation or gender," modeled after the Illinois revised statute, the definition explicitly includes same-sex couples who are functionally or structurally infertile as a couple because of their sexual orientation. While tying this category to gender and

[54] *See* World Health Organization, *supra* note 24.

sexuality instead of calling it "functional infertility" may limit the ability of some people to qualify for coverage, it omits other groups of people, like those who had voluntary vasectomies. This statute is designed to allow those who are unable to conceive merely because of the way they were born or because of natural causes; it is not designed to reimburse medical expenses for those who had elective surgeries and *chose* to become infertile as a result.

Lastly, the final portion of the proposed definition, "or a non-voluntary impairment of a person's capacity to reproduce either as an individual or with others," will account for those who are rendered infertile by non-voluntary medical procedures, illness, genetics, etc. There is a strong sentiment that those who have chosen to become infertile should not be granted insurance coverage for a procedure that would not have otherwise been medically necessary. Gender affirmation surgery, while considered voluntary by some, would not bar someone from IVF coverage because transgender people are explicitly protected by the "sexual orientation or gender" portion of the proposed statute. To make this clear, DHHS should issue guidance on the statute that conveys its intention to include transgender individuals in coverage.

While this would ideally be a federal law, this proposed statute faces an almost insurmountable hurdle in the current Congress, and in many states. The recent decision in *Dobbs v. Jackson Women's Health* drastically changed long-standing legal precedent related to family, conception, and birth by overturning *Roe v. Wade*.[55] In the wake of this decision, states are adopting increasingly extreme abortion bans and there is some concern that IVF might come under fire.[56] If conservative legal thought continues on its current

[55] 142 S. Ct. 2228 (2022).
[56] Michelle Jokisch Polo*, Infertility Patients Fear Abortion Bans Could Affect Access to IVF Treatment*, NAT'L PUB. RADIO (July 21, 2022), https://www.npr.org/sections/health-shots/2022/07/21/1112127457/infertility-patients-fear-abortion-bans-could-affect-access-to-ivf-treatment.

trajectory, it is likely that the bans on abortion will soon encompass bans on discarding embryos created, but not used, during the IVF process. During IVF, multiple embryos are created to ensure the healthiest embryos are implanted to increase the already tenuous likelihood of success. Similarly, when a couple has a heritable genetic disorder, they often use IVF as a preventative measure by creating multiple embryos, conducting genetic testing to see which embryos do not have the genetic disease, and implanting only the "healthy" embryos. The rest are destroyed. By banning the discarding that happens during this practice, lawmakers would make the process far riskier and less likely to succeed. Similarly, a common procedure called Multiple Pregnancy Reduction is recommended when too many implanted embryos are viable, resulting in a high-risk multifetal pregnancy.[57] Health practitioners may recommend the procedure to terminate one or more fetuses during the first or early second trimester for the safety of the mother and the other children.[58] This, too, could raise problems in a post-*Roe* legislative landscape. Indeed, in Arkansas, Kansas, and West Virginia, state lawmakers have introduced bills seeking to criminalize the destruction of fertilized embryos.[59]

Thus, this will likely have to be a state-by-state adoption, so states that value making it easier for LGBTQ+ families to have children can look to the model statute proposed above as a legislative model. As some states adopt this legislation and others continue to make it more difficult for all couples to have children, family demographics may shift. Those who choose to stay

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[57] *Multifetal Pregnancy Reduction*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Sept. 2017), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/09/multifetal-pregnancy-reduction.
[58] *Id.*
[59] Kylie Cheung, *In Vitro Fertilization Is in Trouble As 3 States Try to Criminalize the Destruction of Embryos*, JEZEBEL (Feb 8, 2023), https://jezebel.com/in-vitro-fertilization-is-in-trouble-as-3-states-try-to-1850089683.

in the past will hopefully decide to reconsider their stance and start working toward equal and inclusive family practices.

B. The Litigation Option

At its core, this is a civil rights issue. Section 1557 of the Affordable Care Act (ACA) offers federal civil rights protections in the healthcare context.[60] It prohibits discrimination in health care based on race, color, national origin, sex, age, or disability.[61] In 2020, the Centers for Medicare & Medicaid Services (CMS), Office for Civil Rights (OCR), and DHHS issued a final rule interpreting section 1557's prohibition on sex discrimination to include a prohibition on sexual orientation and gender identity discrimination, giving OCR authority to investigate claims of discrimination based on sexual orientation in insurance coverage.[62] A couple like Jim and Sam in the hypothetical, who are denied insurance coverage of IVF solely on the basis of sexual orientation, could file an OCR complaint. Importantly, this would only be available in the first two categories of states, where coverage is either ambiguous or only available to married heterosexual couples. In the rest of the states, straight and gay couples alike will be denied coverage. The benefit of an OCR complaint is the potential for sweeping change, but the drawback is the length of time it takes for OCR to complete the investigation and make a determination, and the lack of control that individuals and lawmakers have over the investigation.

Section 1557 also creates a private right of action.[63] Similar to an OCR complaint, an individual or class who are denied coverage could file a sex

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[60] *Supra* note 53.
[61] *Id.*
[62] Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 119 (Aug. 18, 2020).
[63] *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 96 (May 18, 2016) ("In addition, we provided that based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such

discrimination complaint under Section 1557 of the ACA. The downside of this option is the expense of litigation and the limited likelihood of systemic change. There is no research on the number of couples who are denied coverage based on sexuality, and it is likely that many do not even attempt IVF until they can afford to pay out of pocket. Thus, there might not be many individuals who are able to join a class and force insurance companies to take notice.

C. The Administrative Law Option

A third option is for the Office of Personnel Management (OPM) to issue a carrier letter advising Federal Employee Health Benefits (FEHB) carriers to change their definition of infertility to expand coverage eligibility to LGBTQ+. Roughly 8 million federal employees receive health insurance through the FEHB program, which is run by OPM.[64] An estimated six percent of these employees identify as LBGTQ+.[65] In August of 2023, more than thirty members of congress wrote to urge OPM to outline plans to change the definition of "infertility" to grant eligibility to members of the LGBTQ+ community.[66] Carrier letters outline OPM's policy goals for the upcoming year, which are then negotiated for with each carrier. In a 2015 carrier letter, OPM asked carriers to provide or update their definition of infertility and provided, for "purposes of illustration," "selected excerpts from

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enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504… to recipients of Federal financial assistance.")

[64] Molly Weisner, *Lawmakers urge OPM to expand infertility benefits for same-sex couples*, FED. TIMES (Aug. 18, 2023), https://www.federaltimes.com/management/pay-benefits/2023/08/18/lawmakers-urge-opm-to-expand-infertility-benefits-for-same-sex-couples/.

[65] *Id.*

[66] Letter from Gerald E. Connolly et al., Members of Congress, to Kiran Ahuja, Dir. of Off. of Pers. Mgmt. (Aug. 17, 2023), https://connolly.house.gov/uploadedfiles/letter_to_opm_re_fehb_infertility_definition.pdf.

contemporary language."[67] Despite asking for an update that included homosexual relationships, two of the three excerpts defined infertility as the inability for a woman under 35 to conceive after 12 months.[68] The third recommendation, however, stated, "Procedure is covered if the couple has a relationship under which the FEHB Program recognizes each partner as a spouse of the other."[69] It is clear however that the 2015 letter was not strong enough. OPM should issue a new technical guidance recommending a definition change for "infertility" in line with the proposed definition described above and mandating that providers who cover ART must extend coverage to LGBTQ+ couples. This could be effective, but it would only apply to federal employees.

Additionally, the Department of Health and Human Services (DHHS) could issue a formal rule mandating insurance providers cover IVF. Like a federal statute, this would grant national coverage to those insured by private health plans. However, unlike a federal statue, DHHS would need statutory authorization to enact such a rule. The Patient Protection and Affordable Care Act (PPACA) requires insurance providers to cover ten "essential health benefits," defined in Section 1302(b) to include "maternity and newborn care" and "prescription drugs."[70] While it is traditionally up to the states to decide how to interpret coverage under these categories, DHHS can propose new rulemaking or interpret the way "maternity and newborn care" is defined to include ART or IVF in that category, or mandate coverage of IVF drugs, which represent roughly 35% of the cost, under the "prescription drugs"

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[67] Letter No. 2015-03 (c), Off. of Pers. Mgmt. 6-7 (Mar. 17, 2015), https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-03c.pdf.
[68] *Id.* at 7.
[69] *Id.*
[70] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302(b) (2010).

mandate.[71] Both options would increase equity and accessibility for millions of Americans, but for LGBTQ+ couples especially. However, the Supreme Court decisions in *FDA v. Brown & Williamson Tobacco Corp.* and more recently in *West Virginia v. Environmental Protection Agency* suggest an attempt to expand coverage through administrative rulemaking may fall short of the major questions doctrine, which requires "clear congressional authorization" for agency action that has such "economic and political magnitude."[72]

V. CONCLUSION

After years of fighting for equal rights, it is important for same-sex couples to finally be able to have biological children without paying the high cost of fertility treatments before the child is even born. Moreover, in states where same-sex couples are denied coverage on the basis of sex, lawmakers should immediately move to end this constitutional rights violation. Expanding the coverage through new legislation will allow queer couples from wider socioeconomic backgrounds to start families and raise children, making for a stronger and more diverse national community. Other methods, like litigation and administrative rulemaking, offer more tenuous, but still potentially successful options to make broad change. Same-sex couples should no longer be forced to incur medical bills that could easily exceed $100,000 for the right to have a child when opposite-sex couples are able to obtain health insurance coverage of the exact same services through the exact same insurance providers. The proposed legislative changes, litigation options, and administrative law changes outlined in this article are necessary

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[71] *See e.g.,* Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7236 (proposed Feb. 2, 2023) (to be codified at 26 CFR Part 54, 29 CFR Part 2590, and 45 CFR Parts 147 and 156) (proposing rule mandating coverage of contraceptives under preventative care portion of ACA); Conrad & Grifo, *supra* note 14.

[72] Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) and W. Virginia v. Env't Prot. Agency, 142 S. Ct. 2587, 2609 (2022).

to end sex discrimination against LGBTQ+ couples and finally grant same-sex couples the full parental rights afforded to opposite-sex couples.

Illinois' PFAS Regulations and the Need for a Better Response

Katie Najjar

I. AN INTRODUCTION TO PER- AND POLYFLUOROALKYL SUBSTANCES

Non-stick cookware, pizza boxes, umbrellas, nail polish, dental floss, rain jackets, firefighting foam, and cleaning products. What do these items have in common? These products are all designed to be grease, water, or stain resistant, and they all can contain perfluoroalkyl and polyfluoroalkyl substances (PFAS).[1] PFAS are a group of thousands of synthetic chemicals that have been commonly used in many consumer products since the 1940s.[2] PFAS are also commonly referred to as "forever chemicals" because they either do not break down, or they break down very slowly over time.[3] Out of the thousands of PFAS that exist, the two that have been most widely studied are perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), which, since the early 2000s, have been largely phased out in the United States.[4] However, despite growing concern regarding use of PFAS, PFOS and PFOA were replaced with other PFAS that can have harmful effects on human health.[5] Due to the continued widespread use of these "forever chemicals" in many industrial and consumer products, PFAS have contaminated our environment— including soil, drinking water, wildlife, dairy products, and have even affected humans.[6] This contamination is widespread — the U.S. Geological Survey estimated that at least forty-five

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[1] EPA, *Our Current Understanding of the Human Health and Environmental Risks of PFAS,* ENV'T PROT. AGENCY (EPA) (June 7, 2023), https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas; *Chemicals: Perfluoroalkyl and Polyfluoroalkyl (PFAS) Substances*, WIS. DEP'T OF HEALTH SERVS. (last revised Sep. 14, 2023), https://www.dhs.wisconsin.gov/chemical/pfas.htm.
[2] EPA, *supra* note 1.
[3] Carol F. Kwiatkowski et al., *Scientific Basis for Managing PFAS as a Chemical Class,* 7 ENV'T SCI. & TECH. LETTERS 532- 533 (2020), https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.0c00255.
[4] EPA, *supra* note 1.
[5] *Id.*
[6] *What are PFAS?*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY (last updated Nov. 1, 2022), https://www.atsdr.cdc.gov/pfas/health-effects/overview.html.

percent of the drinking water supply in the United States is contaminated with one or more types of PFAS.[7] A 2003 study found the presence of PFOS, PFOA, and other types of PFAS in 98% of people living in the United States.[8] In addition, one study led by researchers at the Johns Hopkins Bloomberg School of Public Health proved that in blood samples from nearly 300 umbilical cords, ninety-nine percent detected PFOS and one hundred percent detected PFOA in infants.[9] Although PFAS is a nationwide issue, there has been no coordinated nationwide response. This article will examine how Illinois is addressing the issue and recommendations the State should consider going forward.

II. FEDERAL INACTION

Currently, there are no federal regulations or standards regarding PFAS.[10] However, under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) is authorized to set legally enforceable regulations for drinking water.[11] In March 2023, the EPA announced a proposed drinking water regulation that would establish legally enforceable Maximum Contaminant Levels (MCLs) for six types of PFAS in drinking water,

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[7] *Tap Water Study Detects PFAS 'Forever Chemicals' Across the US*, U.S. GEOLOGICAL SURV. (July 5, 2023), https://www.usgs.gov/news/national-news-release/tap-water-study-detects-pfas-forever-chemicals-across-us.
[8] Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003-2004 and Comparisons with NHANES 1999-2000*, 115 ENV'T HEALTH PERSP. 11 (2007).
[9] *PFOA and PFOS Detected in Newborns*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Dec. 20, 2012), https://publichealth.jhu.edu/2007/goldman-pfoa-pfos.
[10] Blake Langenbach & Mark Wilson, *Per- and Polyfluoroalkyl Substances (PFAS): Significance and Considerations within the Regulatory Framework of the USA*, INT'L J. OF ENV'T RSCH. & PUB. HEALTH (Oct. 23, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8583519/.
[11] Safe Drinking Water Act, 42 U.S.C. §300f (1974).

including PFOA and PFOS.[12] The EPA expects the finalization of the proposed regulation by the end of 2023.[13]

III. FEDERAL INACTION LEAVES STATES ON THEIR OWN

Due to the current lack of federal regulation on PFAS, it is up to individual states to decide how to handle the issue of PFAS.[14] As of August 2023, the Environmental Working Group, an environmental nonprofit organization, mapped at least 3,186 PFAS contamination sites across all fifty states, showing the severity of the problem nationwide.[15] Unfortunately, there is a large discrepancy between the regulations set by each state. While many states have not yet taken action to set guidelines or regulations for PFAS in drinking water or other products, more states are beginning to take action.[16] Ten states already have adopted enforceable MCLs for PFAS in drinking water in their state.[17] Another twelve states, including Illinois, have banned the sale of PFAS-containing firefighting foam.[18] In addition, many states have also sought to hold polluters accountable.[19] In 2010, Minnesota was the first state to file a lawsuit against 3M, a manufacturer of PFAS.[20] The lawsuit alleged that 3M polluted groundwater and "knew or should have known" the dangers of PFAS to health and the environment.[21] Since then, Attorneys

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[12] EPA, *Proposed PFAS National Primary Drinking Water Regulation*, ENV'T PROT. AGENCY (EPA) https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas (last updated June 6, 2023).
[13] *Id.*
[14] *Id.*
[15] Environmental Working Group, *Mapping the PFAS contamination crisis: New data show 3,186 sites in 50 states, the District of Columbia and two territories,* EWG (Aug. 18, 2023), https://www.ewg.org/interactive-maps/pfas_contamination/.
[16] Safer States, *PFAS*, SAFER STATES, https://www.saferstates.org/toxic-chemicals/pfas.
[17] *Id.*
[18] *Id.*
[19] Safer States, *More than Half of US State Attorneys General Have Taken Action Against PFAS Manufacturers and Key Users*, (Aug. 24, 2023), https://www.saferstates.org/press-room/more-than-half-of-us-state-attorneys-general-have-taken-action-against-pfas-manufacturers-and-key-users/.
[20] Sharon Lerner, *3M Knew About the Dangers of PFOA and PFOS Decades Ago, Internal Documents Show*, THE INTERCEPT (July 31, 2018, 12:23 PM), https://theintercept.com/2018/07/31/3m-pfas-minnesota-pfoa-pfos/.
[21] *Id.*

General from twenty-five other states have filed suits against 3M and other chemical manufacturers over PFAS contamination.[22] In June 2023, 3M reached a $10.3 billion settlement over the contamination of many public water systems.[23] However, companies like 3M are now filing their own lawsuits against states, challenging state regulations on PFAS.[24] For example, after New Jersey announced a new set of PFAS regulations in 2020, 3M, along with a coalition of "publicly owned utilities, business, and trade and business associations" filed suit and released a press statement, in part discussing the high costs that such regulations would impose on businesses.[25] Even though the costs of these regulations may be high, the cost of removing PFAS from the public water supply is higher — one estimate says it could be as high as $400 billion.[26]

In Illinois, there has been some movement in recent years. In 2021, the Illinois EPA completed the sampling of all public water supplies in preparation to establish MCLs for certain PFAS.[27] In the same year, the Illinois EPA also proposed several amendments to 35 IAC 620, which established standards for groundwater quality and protocols for the protection of groundwater.[28] Proposed amendments include introducing groundwater quality standards for six hazardous types of PFAS.[29]

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[22] Safer States, *supra* note 16.
[23] John Flesher, *3M Reaches $10.3 Billion Settlement Over Contamination of Water Systems with 'Forever Chemicals'*, AP NEWS (June 22, 2023, 7:59 PM), https://apnews.com/article/pfas-forever-chemicals-3m-drinking-water-81775af23d6aeae63533796b1a1d2cdb.
[24] *Coalition Challenges New Jersey PFAS Regulatory Overreach*, 3M NEWS CTR. (Oct. 1, 2020), https://news.3m.com/Coalition-Challenges-New-Jersey-PFAS-Regulatory-Overreach.
[25] *Id.*
[26] Ry Rivard & Jordan Wolman, *'Forever Chemicals' Are Everywhere. The Battle Over Who Pays to Clean Them up is Just Getting Started*, POLITICO (Sep. 13, 2022, 4:30 AM), https://www.politico.com/news/2022/09/13/the-battle-over-who-pays-to-clean-up-chemicals-00056136.
[27] Ill. Env't Prot. Agency, *Per- and Polyfluoroalkyl Substances*, https://epa.illinois.gov/topics/water-quality/pfas.html#StateActions.
[28] *Id.*
[29] *Id.*

Additionally, effective January 1, 2022, the PFAS Reduction Act regulates the usage of PFAS-containing firefighting foam in order to help reduce PFAS exposure to firefighters, other persons, and the environment.[30] One action made Illinois stand out from other states in their efforts to reduce PFAS contamination. In June 2022, Illinois Governor JB Pritzker signed into a law an amendment to the IL Environmental Protection Act, which implemented a statewide prohibition on PFAS incineration as a means of disposal.[31] This amendment made Illinois the first and only state with a statewide prohibition on PFAS incineration.[32]

IV. PFAS ARE A PUBLIC HEALTH THREAT

PFAS contamination and exposure present threats to public health. Because of the widespread use of PFAS in many different industries and products, PFAS exposure is extremely common.[33] Repeated exposure can cause a range of adverse health effects, such as kidney or liver disease, certain cancers, and increased cholesterol levels.[34] Even though PFAS exposure affects nearly everyone, it does not affect everyone or every community equally.[35] Low-income and underrepresented communities that are located near industrial or military sites are more likely to encounter higher levels of PFAS exposure.[36] These groups of individuals frequently face adverse health outcomes from various and repeated exposures to hazardous chemicals due to proximity to major pollution sources.[37] People living in these communities

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[30] *Id.*
[31] Press Release, Gov. Pritzker Signs Legislation Aimed at Curbing Pollution and Reducing Harmful Emissions, Illinois.gov (June 8, 2022), https://www.illinois.gov/news/press-release.25014.html.
[32] *Id.*
[33] Race Creeden, *Advancing Health Equity Means Banning PFAS…ASAP*, 6 UNIV. OF MINN. SCH. OF PUB. HEALTH 1 (June 2023).
[34] *Id.*
[35] *Id.*
[36] Creeden, *supra* at 33.
[37] Joel D. Kaufman & Anjum Hajat, *Confronting Environmental Racism*, 129 ENV'T. HEALTH PERSP. (2021).

are frequently susceptible to health issues, but also commonly have a lack of access to adequate or affordable health care.[38]

Throughout Illinois, many communities are dealing with PFAS contamination. In Rockton, Illinois, residents living near a Chemtool factory had to be evacuated after a factory explosion in 2021 due to PFAS contamination from the firefighting foam used.[39] Testing of residents' drinking water showed levels of PFOA up to 130 parts per trillion in their drinking water, sixty-five times higher than the limit that has been proposed by the Illinois EPA.[40] In Cordova, Illinois, home to a 3M facility, a sampling of drinking water from nearby private wells found at least 19 types of PFAS, including PFOA at up to 25 parts per trillion and PFOS at up to 30 parts per trillion.[41] The EPA found that this widespread contamination constituted "an imminent and substantial endangerment under the federal Safe Drinking Water Act" and took action against 3M.[42] As part of the settlement agreement, 3M is required to sample nearby drinking water for both private wells and public water systems, and to offer cleanup to all nearby private well owners.[43] Across the state, many Illinois residents are being impacted by the harmful effects of PFAS exposures.

V. PROPOSAL

Very few states have taken any steps to reduce PFAS exposure and contamination, and the states that have taken steps have done so by implementing only one or two PFAS regulations or recommendations. But

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[38] Creeden, *supra* at 33.
[39] Michael Hawthorne, *Millions of Illinois Residents Get Their Drinking Water from Municipal and Private Wells Contaminated with Toxic Forever Chemicals*, CHICAGO TRIBUNE (June 25, 2023, 5:00 AM), https://www.chicagotribune.com/news/environment/ct-forever-chemicals-illinois-well-water-20230625-7yjoupnh3zdbfkhls6ln52ms3m-story.html.
[40] *Id.*
[41] Ill. Env't Prot. Agency, *3M Cordova*, (last updated Aug. 4, 2023) https://www.epa.gov/il/3m-cordova.
[42] *Id.*
[43] *Id.*

there are several states that have implemented a more comprehensive approach. For example, states like Illinois should follow the lead of other states like Michigan, New Jersey, and Connecticut, in order to protect the health of individuals.

First, PFAS is a widespread issue that requires a coordinated response. Illinois should establish a multi-agency response team similar to the Michigan PFAS Action Response Team (MPART).[44] Michigan's unique, multi-agency approach is "the most comprehensive approach of any state in the country," according to Steve Silver, former head of the Michigan PFAS Action and Response Team.[45] In 2017, then-Governor Rick Snyder issued an Executive Directive, directing various state agencies to develop MPART.[46] This team was created to investigate sources and locations of PFAS contamination and implement a strategy to protect drinking water and public health throughout the state.[47] In 2019, Governor Gretchen Whitmer issued an Executive Order that made MPART an "established, enduring body to address the threat of PFAS contamination in Michigan, protect public health, and ensure the safety of Michigan's land, air, and water."[48]

In addition to MPART, Michigan created several regulations aimed at reducing PFAS exposure and contamination, one regulation focusing on the protection of drinking water.[49] First, in 2020, the Michigan Department of Environment, Great Lakes, and Energy (EGLE) set individual MCLs for seven types of PFAS, which apply to approximately 2,700 public water sources in the state of Michigan.[50] However, 3M filed suit shortly after the MCLs rule went into effect, saying that the state had not properly calculated

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[44] Paula Gardner, *Michigan has More PFAS Sites Than Other States. There's a Reason.*, MLIVE (Aug. 26, 2019, 2:58 PM), https://www.mlive.com/news/2019/08/michigan-has-more-pfas-sites-than-other-states-theres-a-reason.html.
[45] *Id.*
[46] Michigan PFAS Action Response Team, Exec. Directive No. 2017-4 (Nov. 13, 2017).
[47] *Id.*
[48] Michigan PFAS Action Response Team, Exec. Order No. 2019-03 (Feb. 4, 2019).
[49] MPART, *Maximum Contaminant Levels (MCLs)*, https://www.michigan.gov/pfasresponse/drinking-water/mcl.
[50] *Id.*

or accounted for the costs of businesses to comply with the new rules.[51] The Court of Claims and the Court of Appeals sided with 3M, agreeing that the state had failed to follow proper procedures, but allowed the rule to stay in effect while the ruling is appealed to the Michigan Supreme Court.[52]

In Illinois, there are many state agencies that could be an important part of the team— like the Department of Agriculture, Environmental Protection Agency, Department of Human Services, Pollution Control Board, Department of Public Health, Department of Veteran Affairs, and more.[53] State universities could also be an important part of the team by contributing valuable research and other efforts. The EPA recently announced that the University of Illinois Urbana-Champaign (UIUC) and the University of Illinois Chicago (UIC) recently were selected to receive over two million dollars in grants to "develop and adopt practices that prevent pollution at the source."[54] UIUC has proposed a project to help "food service businesses" lessen their usage of PFAS-containing items. UIUC believes their project will "reduce harmful chemical exposures for food service employees and customers, reduce drinking water contamination and soil pollution and decrease the number of PFAS-containing products entering landfills or compost facilities".[55] UIC has proposed a project to help restaurants transition from using PFAS-containing food contact materials to PFAS-free

[51] Beth LeBlanc & Carol Thompson, *Appeals Court Sides with 3M in Invalidating Michigan PFAS rules*, THE DETROIT NEWS (Aug. 23, 2023, 9:55 PM), https://www.detroitnews.com/story/news/local/michigan/2023/08/23/pfas-forever-chemicals-michigan-drinking-water-rules-invalid-court-of-appeals-3m-chemical-company/70658343007/.
[52] *Id.*
[53] The Office of the Illinois Secretary of State, *Illinois Government Services*, ILSOS.GOV, https://www.ilsos.gov/services/illinks.html.
[54] News Release, *Biden-Harris Administration Selects Illinois Recipients to Receive Over $2 Million in Pollution Prevention Grants to Advance Environmental Justice*, ENV'T PROT. AGENCY (Oct. 12, 2023), https://www.epa.gov/newsreleases/biden-harris-administration-selects-illinois-recipients-receive-over-2-million.
[55] *Id.*

materials by creating an awareness campaign and offering incentives to restaurants that choose to participate in the program.[56]

New Jersey is another state that leads the nation regarding the efforts to reduce PFAS exposure and contamination and protect public health. New Jersey first took action back in 2006, conducting the first statewide studies of PFAS contamination in drinking water in the U.S.[57] In 2019, New Jersey became the first state to implement enforceable MCLs for PFOA and PFOS.[58] The New Jersey Department of Environmental Protection (NJDEP) set the MCL for PFOA at fourteen parts per trillion, which makes it the most stringent regulation in the U.S.[59] Illinois should set statewide MCLs for PFOA and PFOS, and should examine setting MCLs for other PFAS as well.

Finally, Connecticut has taken recent action not only to help prevent PFAS contamination, but to begin cleanup efforts. Public Act No. 23-205, which went into effect on July 1, 2023, authorizes the sale of bonds to provide financing for many statewide projects.[60] This Act includes up to $3 million to Connecticut municipalities to test water for PFAS, remedial action for PFAS contamination, and buyback of PFAS-containing firefighting foam.[61] In addition, the Act also provides for up to $2.5 million for the identification, investigation, and remedial efforts to clean up "contaminated industrial sites in urban areas".[62]

Illinois also has several proposed bills that would help reduce the harmful effects of PFAS. The first, House Bill 1282, if passed, would add Illinois to a short list of states that ban the manufacture or sale of PFAS-containing

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[56] *Id.*
[57] State of New Jersey Department of Environmental Protection, *Per- and Polyfluoroalkyl Substances (PFAS) Research*, NJ DEP'T ENV'T PROT., https://dep.nj.gov/dsr/pfas/.
[58] State of New Jersey Department of Environmental Protection, *Affirming National Leadership Role, New Jersey Proposes Stringent Drinking Water Standards for PFOA and PFOS*, NJ DEP'T ENV'T PROT. (Apr. 1, 2019), https://www.nj.gov/dep/newsrel/2019/19_0021.htm.
[59] Livingston N.J., *PFOA & PFAS: Important Information About Drinking Water*, https://www.livingstonnj.org/1484/PFOA-PFAS-Important-Information-About-Dr.
[60] Conn. Acts No. 23-205 (2023).
[61] *Id.*
[62] *Id.*

cosmetic products.[63] In addition to passing this ban, Illinois should join the eight other states that are considering regulations regarding the use of PFAS and other toxic chemicals in menstrual products[64], and create a regulation prohibiting the sale or manufacture of these harmful menstrual products within the State. Next, SB 0088 would amend the Illinois Procurement Code to prohibit the sale or distribution of certain products that contain "intentionally added" PFAS chemicals after January 1, 2025.[65] This proposed bill would also require manufacturers of cookware that contain "intentionally added PFAS chemicals" to place a warning listing the presence of PFAS on the label.[66] Finally, HB 3128 would amend the PFAS Reduction Act to create a take-back program for fire departments that use PFAS-containing firefighting foam.[67]

Additionally, even though Illinois passed the nation's first PFAS incineration ban, critics say the bill carved out a large exception that still allows for a certain type of PFAS incineration.[68] Governor Pritzker initially vetoed the PFAS incineration ban before signing an amended bill that carved out an exception for thermal oxidation, allowing a hazardous plant in Sauget, Illinois, to continue its use of incineration.[69] This plant has caused concern for years. In 2020, Illinois Senators Duckworth and Durbin sent a letter to an EPA Administrator, urging him to test the air emissions around the Sauget plant.[70] Additionally, critics of the bill say that not enough of the thousands of PFAS chemicals that exist were listed, and that too many PFAS chemicals are still able to be incinerated in Illinois.[71] Illinois only restricted the

[63] H.B.1282, 103rd Gen. Assemb., Reg. Sess. (IL. 2023).
[64] Safer States, *supra* note 19.
[65] S.B. 0088, 103rd Gen. Assemb., Reg. Sess. (IL. 2023).
[66] *Id.*
[67] H.B.3128, 103rd Gen. Assemb., Reg. Sess. (IL. 2023).
[68] The Office of the Illinois Secretary of State, *supra* note 53.
[69] Juanpablo Ramirez-Franco, *PFAS Can Still be Incinerated in Illinois*, IPM NEWS (Jul. 13, 2022), https://ipmnewsroom.org/pfas-can-still-be-incinerated-in-illinois/.
[70] Letter from Senator Duckworth, Bustos, and Senator Durbin to Kurt Thiede.
[71] Ramirez-Franco, *supra* 69.

incineration of PFAS that are listed on the EPA's Toxics Release Inventory, which contains less than 200 total.[72] To protect public health, Illinois should revisit this bill and the exception made for thermal oxidation, and should consider expanding the list of PFAS chemicals that are banned from incineration.

VI. CONCLUSION

Widespread PFAS exposure and contamination present many threats to public health. With no current federal regulations, it is up to individual states to protect their residents. Illinois has taken several steps towards reducing PFAS exposure through various recommendations and regulations over the past several years, but those actions are not enough. Illinois should follow the lead of other states working to reduce PFAS exposure and implement cleanup efforts. The state would greatly benefit from implementing a coordinated, multi-agency response, passing regulations to protect consumers from harmful PFAS-containing products, and implementing a takeback program for PFAS-containing firefighting foam. Without a coordinated approach, this issue will continue to put lives in danger.

[72] *Id.*

Innovations in Food Allergen Labeling: Removing the Guesswork from Precautionary Allergen Labels

Laura Snell

I. INTRODUCTION TO FOOD ALLERGEN LABELING IN THE UNITED STATES

Current regulations surrounding precautionary food allergen labeling ("PAL") in the U.S. are insufficient to meet the needs of individuals that suffer from food allergies.[1] The Food and Drug Administration (FDA) has considered solutions for twenty years but has failed to take true steps to address the issue.[2] Throughout these decades, the number of food allergies in the United States has risen substantially.[3] A recent study by Food Allergy Research and Education (FARE) estimated that "one in every four – or [eighty-five] million Americans – avoid buying food products that contain the top nine allergens[,]" either because of their own allergy or the allergy of someone in their life.[4] In 2023, the World Health Organization (WHO) released its report "Risk Assessment of Food Allergens Part 3: Review and Establish Precautionary Labeling in Foods of the Priority Allergens" that provides recommendations for precautionary allergen labeling.[5] To improve the safety of those with food allergies, Congress should amend the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) to

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[1] Gwen Smith, *FARE Makes Case for Standardized Food Allergy 'May Contain' Label*, ALLERGIC LIVING (July 11, 2020), https://www.allergicliving.com/2020/07/11/fare-makes-case-for-standardized-food-allergy-may-contain-label/.

[2] Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), 21 U.S.C. §§ 201-210 (2004); Sarah Besnoff, *May Contain: Allergen Labeling Regulations*, 162 U. PA. L. REV. 1465, 1476 (2014); Smith, *supra* note 1.

[3] *Educators – Safe Classrooms for Kids with Allergies*, FOOD ALLERGY RSCH. & EDUC., https://www.foodallergy.org/living-food-allergies/information-you/educators (last visited Sept. 12, 2023) ("Food allergies among children increased by 50 percent between 1997 and 2011 … 1 in 13 children has food allergies, and nearly 40 percent of these children have already experienced a severe allergic reaction").

[4] *The Food Allergy Consumer Journey: Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success*, LIVING TEAL, 1, 2 & 4 (2020), https://www.foodallergy.org/sites/default/files/2020-07/FARE-Food-Allergy-Consumer-Journey-Study-July2020.pdf.

[5] *FAO & WHO, Risk Assessment of Food Allergens – Part 3: Review and Establish Precautionary Labelling in Foods of the Priority Allergens, Meeting Report*, 16 FOOD SAFETY & QUALITY SERIES NO. 16. ROME. iii, xii - xiv (2023), https://doi.org/10.4060/cc6081en.

include recommendations from the 2023 WHO report, such as a risk assessment with threshold values and language changes.[6]

First, it is important to examine issues caused by the current lack of precautionary allergen regulations and potential solutions. This article proposes changes to FALCPA, as well as delves into short-term and long-term considerations, including lessons from other countries who have implemented mandatory and voluntary PAL regulations. Further, it will explore implementation concerns involving manufacturing and customer confusion.

A. Room for Improvement: Food Allergen Labels in the United States

In the United States, food allergen labels are regulated under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).[7] When a regulated allergen is present in a prepackaged food, FALCPA requires an allergen alert, or "contains statement," which includes "the common or usual name of the major food allergen."[8] In contrast, FALCPA does not regulate precautionary allergen statements (PAL) that address potential "unintentional incorporation of a food allergen," giving manufacturers complete discretion in deciding whether to label for "cross-contact."[9] Regardless of a product's risk level, manufacturers can choose not to use PAL labels or include a PAL

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[6] *Id.* at 21-23; Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), *supra* note 2.

[7] Jonathan B. Roses, *Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Food Allergy Sufferers*, 66 FOOD DRUG L. J. 225, 225 (2011).

[8] *See* Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), *supra* note 2, at § 202-03 (stating that under FALCPA, the eight regulated allergens in the United States are milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans); *see generally* Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act of 2021), S. 578, 117th Cong. § 2 (2021) (stating that with the passage of the FASTER ACT in 2021 sesame was added as a major allergen).

[9] 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance policy Guide 6 (Draft May 2023); *Food Labels: Read It Before You Eat It!*, AM. ACAD. OF ALLERGY, ASTHMA & IMMUNOLOGY (Jan. 4, 2023), https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/food-labels.

label on every product they manufacture.[10] Due to the uncertainty surrounding PAL labels, the labels are often "misinterpreted … [and] increasingly ignored," which can have deadly consequences.[11]

In January of 2016, Bruce Kelly ("Kelly"), a 22-year old with a peanut allergy, died after consuming chocolate with a PAL label for peanut.[12] While Kelly was normally careful regarding his allergy, his family believes that after so many instances of consuming foods with PAL labels and not having a reaction, Kelly underestimated the risk.[13] Kelly's story is one that is all too common in the United States with a 2021 study emphasizing that individuals are more likely to purchase products with PAL statements when they have done so safely before.[14] However, twenty-seven percent of individuals surveyed reported "that they or a family member had experienced an allergic reaction from a product that contained a PAL statement."[15]

Despite the inadequacy of PAL labeling, individuals with food allergies have no choice but to rely on these labels to keep themselves safe.[16] Nevertheless, when the FDA issued a new Draft Compliance Policy Guide in May of 2023, PAL statements remained "voluntary" with no guidance on

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[10] Besnoff, *supra* note 2, at 1476.
[11] Smith, *supra* note 1; FAO & WHO, *supra* note 5, at 6; Mary Lynn Smith, *Allergic Reaction to Peanut Residue Kills 22-Year-Old Twin Cities Man*, STAR TRIBUNE (Minneapolis) (Jan. 22, 2016), https://www.startribune.com/peanut-allergy-kills-22-year-old-twin-cities-man/366152021/.
[12] Smith, *supra* note 11 ("[Kelly] had already eaten several chocolates from the same package with no adverse effects").
[13] *Id.*; *Parents of Allergy Victim Press for Broader Warnings*, CBS NEWS (Minneapolis) (Jan. 22, 2016), https://www.cbsnews.com/minnesota/news/ramsey-man-22-dies-of-reaction-to-peanuts/; *Man with Peanut Allergy Dies After Eating 'My Contain' Chocolate*, ALLERGIC LIVING, (Jan. 22, 2016), https://www.allergicliving.com/2016/01/22/man-with-peanut-allergy-dies-after-eating-may-contain-chocolate/.
[14] Ruchi Gupta et al., *Understanding Precautionary Allergen Labeling (PAL) Preferences Among Food Allergy Stakeholders*, 9 J. ALLERGY CLINICAL IMMUNOL PRACTICE 254, 259 (2021); *Parents of Allergy Victim Press for Broader Warnings*, *supra* note 13.
[15] *Id.* at 256.
[16] *Food Labels: Read It Before You Eat It!*, *supra* note 9.

language, simply reminding manufacturers that "allergen advisory statements are not a substitute for adherence to current good manufacturing practices."[17]

II. WHO FRAMEWORK FOR PAL LABELING IN THE UNITED STATES

In 2023, after several years of research, the WHO issued a report offering recommendations for the global challenges associated with PAL labels.[18] PAL statements would be reserved for instances where cross-contact is unavoidable at a level exceeding the preestablished threshold value for that allergen.[19] Given the understanding that achieving a risk level of zero is unattainable, the threshold value would be set at a low enough level that ninety-five percent of individuals with the allergy could ingest the product without a reaction, and the reaction in the remaining five percent would be mild.[20] A PAL statement would only be used when the manufacturers' risk assessment indicates unavoidable cross-contact and testing results in a value above the predetermined threshold level.[21] Regardless, all food labels would include a statement informing customers whether a risk assessment has been conducted.[22] In addition to the threshold recommendation, the WHO recommends changing the language of PAL labels to ensure that they are "clear, concise, truthful, and not misleading."[23]

There are several countries, including Australia and Japan, that have successfully instituted programs similar to the WHO's recommendations.[24]

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[17] Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance policy Guide, *supra* note 9, at 8.
[18] FAO & WHO, *supra* note 5, at 1, 22-23, 48; Reed Baker, *COMMENT: The Global Status of Food Allergen Labeling Laws*, 54 CAL. W. L. REV. 294, 316-323 (2018).
[19] FAO & WHO, *supra* note 5, at 22.
[20] *Id.* at 16, 22.
[21] *Id.* at xv.
[22] *Id.* at xiv, 23.
[23] *Id.* at 23.
[24] *Id.* at 21-23; Katrina J. Allen et al., *Precautionary Labelling of Foods for Allergen Content: Are We Ready for a Global Framework?*, WORLD ALLERGY ORG. J. 2014, at 8-10.

Since 2002, Japan has successfully implemented a "mandatory" allergen program that requires testing to confirm the presence of both "intentionally" and "unintentionally" present allergens.[25] In addition, Australia's Voluntary Incidental Trace Allergen Labeling program (VITAL) determines the need for precautionary labeling through a "risk assessment," which includes "reference doses."[26] The VITAL Online system has been adopted globally by manufacturers to assist in "risk assessment[,] … cross-contact thresholds[, and] labeling outcomes."[27]

III. PROPOSAL: REMOVING THE GUESSWORK FROM PAL LABELS IN THE UNITED STATES

Given the growth in the number of individuals with food allergies in the United States over the past several decades, the Food Allergen and Consumer Protection Act of 2004 is insufficient to protect these individuals from the significant risk of cross-contamination that exists.[28] To address these insufficiencies, Congress must amend FALCPA (21 U.S.C. §§ 203) to include precautionary allergen guidance, including: a risk assessment, with threshold testing when determined necessary, a "symbol" representing that an assessment has occurred, and a "single" PAL phrase in accordance with the WHO recommendations.[29] The regulatory language below should be added to FALCPA.

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[25] *See* Allen et al., *supra* note 24, at 8-9 & 11 (explaining Japan's establishment of a mandatory threshold allergen program is unique, since only four countries regulate PAL statements. In Japan, "the use of 'may contain' statements [are] strictly prohibited; a threshold of 10 microgram protein/g food weight (10 ppm) was established, above which mandatory labeling for the … allergens is required, irrespective of whether that allergen was intentionally present as an ingredient or due to cross contamination").
[26] *Id.* at 10; *see also* Simon Brooke Taylor et al., *The Allergen Bureau VITAL Program*, 101 AOAC INT'L 77, 78-79 (2018).
[27] Taylor et al., *supra* note 26, at 81.
[28] Smith, *supra* note 1; *Educators – Safe Classrooms for Kids with Allergies*, *supra* note 3.
[29] FAO & WHO, *supra* note 5, at 22-23, 46-48.

> (a) As of January 2033, all food sold and distributed in the United States shall undergo an allergen risk assessment, including quantitative threshold analysis, when necessary, to determine the presence of major food allergens, considering any risk of unintentional cross-contamination.[30]
> (b) Until January 2033 - If a voluntary risk assessment has been completed, those food products shall have a seal below the ingredient label that indicates that a risk assessment, including quantitative threshold analysis, when necessary, has been completed.[31]
> (c) As of January 2024, when a Precautionary Allergen Label is placed on a product, only a label that reads "cross-contaminated with X" will be permitted on the package.[32]

A. Short- and Long-term Considerations in Implementing PAL Regulations

Instituting legislation as described above in the United States is a significant undertaking.[33] Despite this, other countries have successfully implemented programs similar to what the WHO is recommending.[34] Japan and Australia offer important guidance to the United States in establishing PAL labeling regulations, including balancing expectations in both the short-term and long-term.[35]

Undeniably, Japan's "mandatory" allergen program is attractive due to how reliably allergic consumers are able to avoid their allergens.[36] In Japan, allergen labels are compulsory any time an allergen is present at a level greater than the threshold value regardless of "whether that allergen was

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[30] *Id.* at 22-23; Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance policy Guide, *supra* note 9, at 6 ("cross-contact is the unintentional incorporation of a food allergen into a food…").
[31] FAO & WHO, *supra* note 5, at 22-23, 46-48.
[32] *Id.* at 48.
[33] Wendy Mondello, *Food Allergy Experts Weigh In on: Global 'May Contain' Labels*, ALLERGIC LIVING (June 13, 2023), https://www.allergicliving.com/2023/06/13/food-allergy-experts-weigh-in-on-global-may-contain-labels.
[34] Allen et al., *supra* note 24, at 8-10.
[35] *Id.*
[36] Allen et al., *supra* note 24, at 8-9; Hiroshi Akiyama & Reiko Adachi, *Japanese Food Allergy – Labeling System and Comparison with the International Experience; Detection and Thresholds*, 9 FOOD SAFETY 101, 114 (2021).

intentionally present as an ingredient or due to cross-contamination."[37] However, under FALCPA, PAL is currently completely unregulated.[38] In addition, manufacturers have established policies under FALCPA for intentionally present allergens.[39] Given the current lack of regulations, a voluntary program such as Australia's VITAL would be more successful in the short-term in the United States.[40] In order to achieve success manufacturers must perceive the FALCPA amendment as attainable.[41] Attempting to mandate significant regulations quickly can lead to manufacturers cutting corners, which was witnessed with the addition of sesame as a major allergen under the FASTER Act.[42] This article proposes giving manufacturers ten years to bring their allergen programs in line with the amended FALCPA. Given the extensiveness of the change, it is essential that manufacturers are given the "flexibility to adapt to new methods of allergen detection and … new information relating to allergen thresholds."[43] Manufacturers would benefit from compliance, since allergic consumers are "loyal" to brands and willing to pay a higher price for a safe product.[44]

During the ten-year voluntary period, there are two steps that Congress can take to increase the safety of the food allergic consumer: making sure

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[37] Allen et al., *supra* note 24, at 9; Rene Crevel, *Quantitative Allergen Labeling*, 13 EUR. FOOD & FEED L. REV. 2, 8 (2018).
[38] *Food Labels: Read It Before You Eat It!*, *supra* note 9.
[39] Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), 21 U.S.C. §§ 201-210 (2004).
[40] *Food Labels: Read It Before You Eat It!*, *supra* note 9; Allen et al., *supra* note 24, at 10.
[41] *See* Jonel Aleccia, *New label law has unintended effect: Sesame in more foods*, AP NEWS (Dec. 21, 2022), https://apnews.com/article/sesame-allergies-label-b28f8eb3dc846f2a19d87b03440848f1 (discussing manufacturers adding allergens to their foods in response to the perceived rigidity of the FASTER Act's food-labeling requirements).
[42] *Id.*
[43] Allen et al., *supra* note 24, at 11.
[44] *The Food Allergy Consumer Journey*, *supra* note 4, at 6.

that consumers are aware of which products have undergone a risk assessment and only allowing a "single" PAL statement to be used.[45]

First, allergic consumers need to be able to determine which products have undergone a risk assessment and threshold testing in order to begin to make safer purchasing decisions.[46] Since the Japanese program is mandatory, all consumers immediately know that the item they are purchasing has been tested for regulated allergens.[47] In contrast, Australia's VITAL is voluntary, which means that "the allergic consumer cannot distinguish that this food product is likely to be safer than one that has no label but not subjected to VITAL."[48] In a survey cited by the WHO, individuals conveyed the need for a symbol "to remove ambiguity as to whether a product without PAL would be suitable … in the event the risk assessment was not made mandatory."[49] The WHO recommendation to include a symbol that an allergen risk assessment has been conducted would serve as a message to allergic consumers that a manufacturer has taken steps to ensure their safety.[50] While mandating threshold testing would take time to implement industry wide, in the short term, Congress could provide a standard label to manufacturers to signify that a risk assessment and any testing required has been completed.[51]

Second, Congress could immediately begin to alleviate confusion by requiring "a single" PAL phrase.[52] The WHO, while not advocating for a particular phrase, recommends "a single, clear and concise phrase," which would send a straightforward message and prevent consumers from

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[45] FAO & WHO, *supra* note 5, at 22-23, 48-9; *Food Labels: Read It Before You Eat It!*, *supra* note 9.
[46] Allen et al., *supra* note 24, at 10; Mondello, *supra* note 33.
[47] Allen et al., *supra* note 24, at 8-9; Akiyama, *supra* note 36, at 114.
[48] Allen et al., *supra* note 24, at 10.
[49] FAO & WHO, *supra* note 5, at 48.
[50] *Id.* at 23, 46-8.
[51] *Id.*
[52] *Id.* at 48.

disregarding the PAL statement.[53] Despite varying opinions on the ideal phrase, the WHO advises against using "may contain," viewing it as "hazard-based" instead of "the risk-based outcome of the risk assessment."[54] Overall, it is not surprising that, "consumers preferred having clearer, more specific, and consistent labeling."[55] In addition, "a single option for PAL" received support from seventy-eight percent of US manufacturers asked.[56] When the single PAL phrase is combined with a label that indicates an allergen risk assessment has been completed, allergic customers will be better able to "understand the label and empower[ed]" to make safe choices.[57] Therefore, this proposal emphasizes that the "single" PAL statement should be "cross-contaminated with X."[58]

IV. Concerns Related to the Implementation of PAL Regulations

A. Manufacturing

There are many concerns present when discussing the implementation of these proposed PAL Regulations. The first being manufacturing, since U.S. manufacturers have a history of adding allergens to products that would otherwise not contain that allergen to avoid having to clean and control for that allergen.[59] When the FASTER Act was implemented manufacturers began to add sesame to their products in order to declare it on the allergen label, even arguing that they were unable to sanitize sufficiently.[60] Adding allergens is not new; in 2016 individuals with peanut allergies were distressed

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[53] *Id.*
[54] *Id.*
[55] Gupta, *supra* note 14, at 263.
[56] *Id.*
[57] FAO & WHO, *supra* note 5, at 46-47; *The Food Allergy Consumer Journey*, *supra* note 4, at 4.
[58] FAO & WHO, *supra* note 5, at 48.
[59] Aleccia, *supra* note 41.
[60] *Id.*; Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act of 2021), *supra* note 39, at § 2.

to learn that Kellogg had included peanut flour in several varieties of crackers "that were previously considered safe," so the company did not have to worry about cross-contact.[61] However, there is significant evidence that there are benefits to manufacturers who utilize quantitative risk based allergen assessments.[62]

A 2022 study conducted in the Netherlands interviewed quality control professionals who discussed the potential for cross-contamination as products change hands multiple times throughout the manufacturing process.[63] Given the varying levels of allergen knowledge across the industry, professionals "prefer[ed] a harmonized system and thresholds…."[64] Some workers expressed concern that the absence of a standardized allergen risk assessment plan would lead to an increase in errors when transferring allergen information into a new system at each facility.[65] Further, another study discussed that the formal regulation of PAL labels provides a framework for manufacturers to make decisions.[66] The study found that "science-based thresholds[,] … risk assessment[s,] and … a standardized message for PAL…. [would] reduce accidental allergic reactions in consumers … and reduce the enormous costs to food manufacturers."[67] Examining data from the Food and Drug Administration, there were "1471 [food allergen and gluten] recalls" in the United States between the years of

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[61] Dave Bloom, *Media Briefing: Kellogg's Intentionally Adding Allergens to Products*, SNACK SAFELY (May 3, 2016), https://snacksafely.com/2016/05/media-briefing-kelloggs-intentionally-adding-allergens-to-products/.
[62] Jupiter Yeung & Marie-Claude Robert, *Challenges and Path Forward on Mandatory Allergen Labeling and Voluntary Precautionary Allergen Labeling for a Global Company*, 101 J. OF AOAC INT'L 70, 75 (2018).
[63] Yvette F.M. Linders et al., *Precautionary Allergen Labels: Current Communication Problems and Potential for Future Improvements*, 147 FOOD CONTROL 1, 1-3 (May 2023)
[64] *Id.* at 6-8.
[65] *Id.* at 3.
[66] Yeung, *supra* note 62, at 73.
[67] *Id.* at 75.

2013 and 2019.[68] Of these recalls, "allergen cross-contact resulted in [twenty-one percent]."[69] In addition to cross-contamination concerns, seventy-six percent of food allergen recalls resulted from labeling issues.[70] Not only would the proposed regulatory amendment allow manufacturers to limit safety concerns for allergic consumers, but manufacturers would also be able to avoid the cost of recalling their products.[71]

B. Public Education Challenges and Limiting Confusion When Regulating PAL

The second major challenge when implementing these changes is public education.[72] PAL labels in the U.S. are not only "confus[ing]," but are often described as "unreliable and inconsistent," with some individuals going as far as calling them "meaningless."[73] Despite the severity of the issue, there is still concern that instituting a new threshold based PAL system would make explaining PAL statements significantly "more complex."[74] Changing the PAL regulations would require substantial effort from "advocacy groups[,]… the FDA, the medical community (…), and food manufacturers and retailers."[75] Even WHO emphasized the importance of education in implementing a program like this.[76]

While the education efforts would be substantial, "fifty-three percent" of individuals in FARE's "Food Allergy Consumer Journey Report" conveyed that "current labels are problematic and interfere with their daily lives."[77]

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[68] Girdhari M. Sharma et al., *Recalls Associated with Food Allergens and Gluten in FDA-Regulated Foods from Fiscal Years 2013 to 2019*, J. OF FOOD PROTECTION 1, 3 (March 2023).
[69] *Id.* at 7.
[70] *Id*. at 9.
[71] *Id.*; Yeung, *supra* note 62, at 75.
[72] Mondello, *supra* note 33.
[73] Mondello, *supra* note 33; Besnoff, *supra* note 2, at 1483.
[74] Mondello, *supra* note 33.
[75] *Id.*
[76] FAO & WHO, *supra* note 5, at 16, 26.
[77] *The Food Allergy Consumer Journey*, *supra* note 4, at 9; Mondello, *supra* note 33.

Without additional regulation, it is impossible for individuals to determine which products that display a PAL statement are most likely to contain the indicated allergen.[78] This lack of clarity can lead to dangerous misunderstandings, where individuals "who tolerate a product with PAL on one or more occasions … assume that the same product will *always* be tolerated by them in the future."[79] Unsurprisingly, a recent survey in the United States found that a significant number of individuals with food allergies answered basic questions regarding labeling incorrectly.[80] Consequently, due to this lack of "trust" and understanding, "up to [seventy] percent of allergic individuals (depending on the PAL statement) report consuming prepackaged food products with PAL at least some of the time."[81] Despite this, allergic reactions after consuming these products are not uncommon, which can have fatal consequences.[82] As previously discussed, twenty-two-year-old Bruce Kelly died after consuming chocolate with a PAL label for peanut that he believed was safe, since he had not had previous issues with PAL labels.[83]

V. CONCLUSION

"One in every four – or [eighty-five] million Americans – avoid buying food products that contain the top nine allergens…" either because of their own allergy or the allergy of someone in their life.[84] Despite the huge number of Americans affected by food allergies, the FDA has failed to regulate PAL,

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[78] Besnoff, *supra* note 2, at 1476.
[79] FAO & WHO, *supra* note 5, at 4.
[80] Gupta, *supra* note 14, at 259 ("28.8% of the respondents incorrectly believed that PAL is required by law, and 16.9% admitted that they did not know the answer. Moreover, over 37% of respondents answered incorrectly when asked if advisory labels were based on the amount of allergen present in the product").
[81] FAO & WHO, *supra* note 5, at 4-5; Crevel, *supra* note 37, at 3.
[82] Gupta, *supra* note 14, at 256; Smith, *supra* note 11.
[83] Smith, *supra* note 11; *Parents of Allergy Victim Press for Broader Warnings*, *supra* note 13; *Man with Peanut Allergy Dies After Eating 'My Contain' Chocolate*, *supra* note 13.
[84] *The Food Allergy Consumer Journey*, *supra* note 4, at 2-4.

which has had deadly consequences.[85] As a result, the time has come for Congress to amend the Food Allergen Labeling and Consumer Protection Act of 2004 in order to protect allergic consumers.[86] The United States' Food and Drug Administration needs to regulate precautionary allergen labels by implementing a risk assessment, with threshold values, and making changes to the language of the labels as described in the 2023 WHO recommendations to improve the safety of those with food allergies.[87]

[85] *Id.* at 4; Besnoff, *supra* note 2, at 1476; *Parents of Allergy Victim Press for Broader Warnings*, *supra* note 13.
[86] Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), *supra* note 2.; Mondello, *supra* note 33.
[87] FAO & WHO, *supra* note 5, at 22-23, 47-48.