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Sacrificing the Public's Health: Conspiracies and Trust in the Scientific Enterprise

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SACRIFICING THE PUBLIC'S HEALTH: CONSPIRACIES AND TRUST IN THE SCIENTIFIC ENTERPRISE

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Abstract

Conspiracy theory in common parlance evokes an image of anxious, misinformed purveyors of false information untethered from objective fact. However, sometimes the troublesome allegations or narratives are a conspiracy. Conspiracies may not constitute imaginary nefarious plans, but rather real paradigms that function as a mechanism to preserve power, obtain prestige, or produce financial gain. Focusing in the area of health law, this article describes how some conspiracies function as a critical alarm to the loss of trust in the scientific enterprise and the legitimacy of government power.

Despite making incredible advancements, medicine and public health also hold a distinguished history of elevating incorrect information as widely accepted fact. Physicians persecuted Dr. Ignaz Semmelweis for suggesting chlorine hand disinfection could decrease patient infections. For decades, physicians, public health professionals, and policymakers exalted eugenics as scientific and responsible public policy. In the 1900s, Bayer marketed Heroin as a non-addictive alternative to morphine. Such egregious lapses are not an anomaly, but rather continue through U.S. history. Powerful stakeholders blatantly and deliberately put the public in harm's way: public officials displayed callous disregard for the public's welfare when they denied dangerous levels of lead in the Flint, Michigan, water supply; Department of Defense sponsored research programs exercised shocking discretion secretly testing biological weapons on the American public; and in 2020, the Department of Justice alleged that dozens of pharmaceutical companies conspired to withhold life-saving medications from the American public by artificially inflating and fixing prices. This article asserts that democracy requires vigilant assessment of scientific policymaking to ensure the process is grounded in credible

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evidence, protects the vulnerable, promotes accountability, and furthers justice.

I. INTRODUCTION

Conspiracy theory in common parlance evokes an image of anxious, misinformed purveyors of false information untethered from objective fact. A variety of conspiracy theories pepper media headlines, such as: the airplane flying overhead is spraying toxic substances,[1] government officials are poisoning drinking water,[2] or pharmaceutical companies harm people by withholding lifesaving medication.[3] However, sometimes the troublesome allegations or narratives *are* a conspiracy. Conspiracies may not constitute imaginary nefarious plans, but rather real paradigms that function as a mechanism to preserve power, obtain prestige, or produce financial gain. Focusing in the area of health law, this article describes how some conspiracies provide a critical alarm to the loss of trust in the scientific enterprise and the legitimacy of government power.

Despite incredible advancements, medicine and public health also hold a distinguished history of elevating incorrect information as widely accepted fact. Physicians persecuted Dr. Ignaz Semmelweis for suggesting physician hand disinfection procedures could decrease patient infections. For decades, physicians, public health professionals, and policymakers exalted eugenics as scientifically correct and responsible public policy. In the 1900s, Bayer marketed Heroin as a new non-addictive alternative to morphine. Such egregious lapses are not an anomaly, but rather continue through U.S. history. Powerful stakeholders blatantly and deliberately put the public in harm's way: public officials displayed callous disregard for the public's welfare when they denied dangerous levels of lead in the Flint, Michigan water supply; Department of Defense sponsored research programs exercised shocking discretion secretly testing biological weapons on the

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[1] Preston Phillips, *Contrails or Chemtrails in Sky Over Valley?*, CBS ARIZ. FAM. (May 15, 2017), https://www.azfamily.com/archives/contrails-or-chemtrails-in-sky-over-valley/article_cdfc9223-4a48-5faf-94c5-cce174b614a1.html.

[2] Lakis Polycarpou, *Fluoridation of Water: Communist Conspiracy, Genuine Threat or Both?*, COLUM. CLIMATE SCH. (Dec. 23, 2010), https://news.climate.columbia.edu/2010/12/23/fluoridation-of-water-communist-conspiracy-genuine-threat-or-both/.

[3] Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016), https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=686e7335280c.

American public; and in 2020, the Department of Justice alleged that dozens of pharmaceutical companies conspired to withhold life-saving medications from the American public by artificially inflating and fixing prices.

In Section I, this article examines the meaning of conspiracy theory, the related concept of fake news, and how society should approach dissent and distrust of scientific policy. Weaving together the history of medicine and public health, this section describes the potential for perpetuating harm from stringently adhering to scientific dogma and blindly trusting medical expertise. Next, this article describes factual conspiracies in three sectors that resulted in significant harm to public in the areas of (1) public health, (2) scientific research, and (3) medicine. In Section II, this article explores when health officials in history harmed public health using the lever of the law for involuntary sterilization programs and more recently, failed to protect public health by exposing the public to toxic lead through the municipal water supply. Section III describes conspiracies in the area of conducting scientific research using human subjects and cases where investigators exposed participants to harmful substances such as biological weapons, radiation, lead, or withheld available treatment to further scientific knowledge. Next, Section IV provides an overview when conspiracies and alleged collusion caused harm in medicine by destroying competing providers and spiking medication prices. This article asserts that conspiracies and fake news can alert the public to investigate allegations of potential wrongdoing, abuse of authority, or criminal misdeeds. Democracy requires vigilant assessment of scientific policymaking to ensure the process is grounded in credible evidence, protects the vulnerable, promotes accountability, and furthers justice.

II. HOW TO APPROACH DISSENT AND DISTRUST IN SCIENCE

This section explores the meaning of conspiracy theory and defines the more recent concept of fake news. The manner in which society labels information and exerts control over the flow of information for public consumption holds powerful implications for democracy. In the second part of this section, the article provides examples in the history of science and medicine to demonstrate how stakeholders utilize specific terminology to elevate certain theories while suppressing dissent under the appearance of evidence-based infallible science.

A. Defining Conspiracy Theory and Fake News

1. Conspiracy Theories

Conspiracy theories in science such as those described – airplanes are spraying toxic substances, government officials are poisoning the drinking water, and pharmaceutical companies are withholding medication – reflect a belief that powerful stakeholders are acting in a coordinated manner that places the public in harm's way. Although some conspiracy theories appear unfounded, outlandish, or even silly, these examples reflect a range of categories: events that actually did occur, assessments and opinions that involve judgments, and imputing future harms based on past misconduct. Academics, psychologists, and political scientists provide varied definitions for what constitutes a conspiracy theory, such as secret plots by powerful and malevolent groups or a belief that secret cabals control world affairs.[4] Legal scholars Cass Sunstein and Adrian Vermeule define conspiracy theories as attributing extraordinary power to specific actors to plan, control, and maintain secrecy of their role.[5]

Sociologist Ted Goertzel refers to conspiracy theories as emotional reactions, unverified speculation, and rumors, asserting many conspiracy theories are "clearly absurd" but provide a target to blame for a specific predicament.[6] Goertzel posits people who are disempowered may hold conspiracy theories stemming from a belief that authorities don't care about people like them, which provides an external reason for unfortunate circumstances or adverse station in life.[7] These beliefs, according to legal scholars Mark Verstraete and Derek Bambauer, fuel group polarization, cynicism, and distrust.[8] Sunstein and Vermeule assert conspiracy theories reflect a type of paranoid cognition, where individuals distrust the motives of

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[4] Karen Douglas et al., *The Psychology of Conspiracy Theories*, 26(6) CURRENT DIRECTIONS PSYCH. SCI. 538 (2017); Ted Goertzel, *Belief in Conspiracy Theories*, 15(4) POL. PSYCH. 731 (1994); J. Eric Oliver & Thomas J. Wood, *Conspiracy Theories and the Paranoid Styles of Mass Opinion*, 58(4) AM. J. POL. SCI. 952 (2014); Kevin D. Hill, *Popular Delusions & the Law in the Age of the Internet – A review of Damian Thompson's Counterknowledge*, 35 OHIO N. UNIV. L. REV. 801 (2009).

[5] Cass Sunstein & Adrian Vermeule, *Symposium on Conspiracy Theories: Causes and Cures*, 17(2) J. POL. PHIL. 202, 207 (2009).

[6] Ted Goertzel, *Conspiracy Theories in Science*, 11(7) EUR. MOLECULAR BIOLOGY ORG. 493 (2010).

[7] Goertzel, *supra* note 6, at 493; Goertzel, *supra* note 4, at 739.

[8] Mark Verstraete & Derek E. Bambauer, *Ecosystem of Distrust*, 16 FIRST AMEND. L. REV. 129, 130 (2017).

those in positions of power, mistakenly attributing neutral actions with sinister motivations.[9] Philosopher Karl Popper asserts conspiracy theories overlook unintended consequences of political and social action, instead presuming the actors involved intended the specific outcomes.[10]

However, not all conspiracies may be driven by nefarious reasons designed to primarily harm the public. While some conspiracies may reflect "a secret plot by powerful conspirators," other conspiracies may fall within another definition, which encompasses circumstances where "a secret of great importance is being kept from the public."[11] Thus, conspiracies may include not only a specific action by powerful actors to achieve a certain goal, but also the silence that permits harmful actions against the public interest to occur. Importantly, this article asserts the motivations of actors in the conspiracy in multiple cases orient their focus toward promoting their own gain as opposed to actions specifically designed to harm the public interest. In this definition of conspiracy, stakeholders work in concert to maximize their self-interest while the public interest becomes an unfortunate, secondary casualty. This article posits that real conspiracies often function as paradigms to preserve power, obtain prestige, or produce financial gain.

2. Fake News

In current discourse, some stakeholders replace the terminology of conspiracy theory with the concept of fake news, a similar strategy to indicate the falsity of a particular claim and dissuade the public from believing the claim.[12] Legal scholars trace the rise of fake news as a product of how the internet democratized the information ecosystem, fueling a rapid spread of information more quickly between a greater number of people.[13] As more information floods online by individual users, organizations, and media, it becomes difficult to discern what constitutes truthful and trustworthy information. In the traditional analog system, media corporations served as

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[9] Sunstein & Vermeule, *supra* note 5, at 218.

[10] *Id.* at 208 (describing Karl Popper's definition of conspiracy theory).

[11] *Conspiracy Theory*, *MERRIAM WEBSTER DICTIONARY*, https://www.merriam-webster.com/dictionary/conspiracy%20theory.

[12] Verstraete & Bambauer, *supra* note 8, at 129; Anthony Gaughan, *Illiberal Democracy: The Toxic Mix of Fake News, Hyperpolarization, and Partisan Election Administration*, 12 DUKE J. CONST. L. & PUB. POL'Y 57 (2017); Clay Calvert & Austin Vining, *Filtering Fake News Through a Lens of Supreme Court Observations and Adages*, 16 FIRST AMEND. L. REV. 153 (2017); Kevin Hill, *Popular Delusions & the Law in the Age of Internet*, 35 OHIO N. UNIV. L. REV. 801 (2009).

[13] Verstraete & Bambauer, *supra* note 8, at 129; Gaughan, *supra* note 12, at 59.

gatekeepers for the creation and regulation of content that the public could access.[14] The rise of media consumption online exponentially increases the access and sharing of content that may contain partial truths, errors, or omissions.[15]

First Amendment scholars Clay Calvert and Austin Vining note that journalists, politicians, and the public overuse the concept of fake news to the point of rendering it meaningless.[16] Calvert and Vining assert fake news constitutes more than mistaken or incorrect information, but rather it is: (1) the conveyance of real news that (2) knowingly (3) includes a demonstrably false material assertion.[17] Under this definition, individual users passing along content does not meet the definition, but rather the material must suggest the conveyance of real news by a media organization by appearance and content.[18] The journalist or media organization must intentionally include false information, not simply communicate a mistaken belief or publish accidental errors.[19] This element requires deliberate fabrication, a failure of the media to vet evidence, or purposefully misleading the reader by omitting information to contextualize the story.[20] Finally, the journalist or media organization knowingly includes false information that can otherwise be proven incorrect with empirical evidence.[21] Notably, this definition focuses on facts, but would not classify opinions that counter the dominant narrative as fake news.[22]

3. Responding to Conspiracy Theories and Fake News

Both conspiracy theories and fake news can lead to discontent, loss of confidence in experts, distrust of certain scientific theories, and misgivings about statistics.[23] Trust encompasses confidence, reassurance, and reliance;

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[14] Verstraete & Bambauer, *supra* note 8, at 129; Gaughan, *supra* note 12, at 59.

[15] Verstraete & Bambauer, *supra* note 8, at 129; Gaughan, *supra* note 12, at 59.

[16] Calvert & Vining, *supra* note 12, at 156.

[17] *Id.* at 158.

[18] *Id.* at 156-58 (Calvert and Vining provide the example that an individual user retweeting information would not meet the definition of fake news because it does not encompass falsehoods or items that are not posted by journalists).

[19] *Id.* at 160.

[20] *Id*; Anna Gonzalez & David Schulz, *Helping Truth With Its Boots: Accreditation as an Antidote to Fake News*, 127 YALE L. J. F. 315, 316 (2017-2018).

[21] Calvert & Vining, *supra* note 12, at 158-60.

[22] *Id.* at 160.

[23] Verstraete & Bambauer, *supra* note 8, at 139, 143-44.

without trust in the experts, statistics, or integrity of the scientific process, some members of the public express uncertainty, concerns, and lingering doubt.[24] Some scholars characterize disaffection as "fear of science," wherein conspiracy theorists leverage distorted propositions to discredit what constitutes the real or true scientific evidence.[25] Sunstein and Vermeule assert the process of disseminating false information constitutes a risky threat because it aims to undercut legitimate scientific policy.[26]

The immense concern relating to conspiracies and fake news has led some scholars to assert that the process of providing counterinformation cannot sufficiently suppress potential damage of incorrect theories.[27] Solutions to suppress conspiracy theories and fake news include driving the purveyors of false information from the public sphere, elevating third parties to an active gatekeeping role that certifies or censors certain information, or attempting to disband and discredit organizations that disseminate false information.[28]

4. Controlling Information and Democracy

These propositions to limit and suppress ideas and content pose grave risks to the very foundation of democracy. Legal scholar Steven Gey eloquently describes the fundamental importance of the freedom to speak and share information as indispensable to the discovery and spread of political truth.[29] Rather than attempting to identify and limit false information, stakeholders can instead focus on promoting the flow of truthful information

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[24] Steven Pearson & Lisa Raeke, *Patients' Trust in Physicians: Many Theories, Few Measures, and Little Data*, 15 J. GEN. INTERNAL MED. 509-13 (2000).

[25] Goertzel, *supra* note 6, at 493.

[26] *Id.* (discussing fear of science and discrediting science); Sunstein & Vermeule, *supra* note 5, at 226 (describing when conspiracy theories constitute "se rious risks").

[27] *See* Sunstein & Vermeule, *supra* note 5, at 221-22.

[28] *Id.* at 218-19 (discussing counterspeech, third party information verification, and the concept of cognitive infiltration); Gonzalez & Schulz, *supra* note 20, at 318-19 (describing social media fact checking, algorithms to demote "low quality conte nt,"), 325 (discussing news accreditation as a means to certify the accountability, v eracity, and accuracy of news content).

[29] Steven G. Gey, *The First Amendment and the Dissemination of Socially Worthless Untruths*, 36 FLA. ST. L. REV. 1, 7 (2008).

to create a marketplace of ideas.[30] Restrictions could unwittingly (or purposefully) suppress true arguments and obstruct rational discourse.[31]

Professors Lance deHaven-Smith and Matthew Witt note that dismissing what appears to be false information poses four distinct problems.[32] First, the label of false information may encompass an overly broad definition and creates difficulties determining what meets the criteria.[33] Second, labeling and dismissing information overlooks the fact that some claims that appeared outlandish at first blush turned out to be true.[34] Third, suppression of information blocks inquiry into the claim or specific allegations.[35] Finally, some claims involve serious matters such as scientific fraud, political misconduct, or criminal allegations, which affect the public interest.[36]

The Founding Fathers discussed at great length the ability of political power to serve as a corrupting influence and the duty of the public to engage in civil dialogue and deliberation during the policymaking process.[37] The Founding Fathers recognized the potential for dominant political factions to pursue their own agenda rather than serving the interests of the public.[38] As deHaven-Smith and Witt assert, the Founding Fathers articulated a belief that conspiracies against the public's liberty and interest were almost inevitable as a means of preserving power.[39] Ensuring access to transparent, objective, and thorough information serves a crucial role in the pursuit of determining what constitutes truth.[40]

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[30] *Id.*; *see also* Calvert & Vining, *supra* note 12, at 172; Gonzalez & Schulz, *supra* note 20, at 317.

[31] Christoph Bezemek, *The Epistemic Neutrality of the "Marketplace of Ideas": Milton, Mill, Brandeis and Holmes on Falsehood and Freedom of Speech*, 14 FIRST AMEND. L. REV. 159, 166-67 (2015).

[32] Lance deHaven-Smith & Matthew Witt, *Conspiracy Theory Reconsidered: Responding to Mass Suspicion of Political Criminality in High Office*, 45(3) ADMIN. & SOC'Y 267, 269 (2012).

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] Gey, *supra* note 29, at 20; deHaven-Smith & Witt, *supra* note 32, at 269-70.

[38] Gey, *supra* note 29, at 20.

[39] deHaven-Smith & Witt, *supra* note 32, at 269-70.

[40] *Id.*

Even in the field of science, certain facts are not self-interpreting but value laden.[41] In the context of the scientific method, what appears to be objective evidence-based research reflects certain interests and judgments, such as how to frame the scientific question, what question the study asks, how to assign weight to variables and outcomes, and what factors to observe (or not observe), and how to interpret the significance of findings.[42] Unintentional bias may include experiments that align with the investigator's belief system, which can reinforce the prevailing scientific theory.[43] In other instances, clinical trials and scientific publications may include deliberate manipulation of data, suppression of adverse findings, or selective publication.[44] Assessing the reliability and veracity of information requires transparency of evidence, open civic dialogue, and deliberation to discern the merit behind particular claims.[45]

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[41] Trisha Greenhalgh et al., *Moral Entrepreneurship, the Power-Knowledge Nexus and the Cochrane "Crisis,"* 25 J. EVALUATION CLINICAL PRAC. 717, 720 (2019) (discussing value judgments in framing the scientific question); Joachim Sturmberg, *Evidence-Based Medicine – Not a Panacea for the Problems of a Complex Adaptive World*, 25 J. EVALUATION CLINICAL PRAC. 706, 707 (2019) (discussing how each hypothesis, observation, and analysis can be designed to align with one's belief system); John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2(8) PLOS MED. 696 (2005) (asserting that some claimed research findings reflect the prevailing scientific consensus).

[42] Trisha Greenhalgh et al., *Moral Entrepreneurship, the Power-Knowledge Nexus and the Cochrane "Crisis,"* 25 J. EVALUATION CLINICAL PRAC. 717, 720 (2019) (discussing value judgments in framing the scientific question); Joachim Sturmberg, *Evidence-Based Medicine – Not a Panacea for the Problems of a Complex Adaptive World*, 25 J. EVALUATION CLINICAL PRAC. 706, 707 (2019) (discussing how each hypothesis, observation, and analysis can be designed to align with one's belief system); John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2(8) PLOS MED. 696 (2005) (asserting that some claimed research findings reflect the prevailing scientific consensus).

[43] Sturmberg, *supra* note 41; Ioannidis, *supra* note 41.

[44] Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 SYRACUSE L. REV. 439, 442-46 (2019) (describing fraud occurring in testing and drug marketing, clinical trial bias, and publication bias); Catherine D. DeAngelis & Phil B. Fontanarosa, *Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence*, 299(15) J. AM. MED. ASSOC. 1833 (2008); Deanna Minasi, *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 317-22 (2017) (discussing pharmaceutical manufacturers and physicians who engage in ghostwriting to promote fraudulent, incomplete, or misleading data on pharmaceutical drugs and biologics).

[45] deHaven-Smith & Witt, *supra* note 32, at 289; Gey, *supra* note 29, at 8.

Gey warns of the dangers of government control of the public's ideological perceptions.[46] Similar concerns should also apply to close government entanglement where the government requests that third parties control and limit the flow of information into the public sphere.[47] In these cases, the dominant narrative of what constitutes the "truth" would reflect the majority viewpoint and could be used as a mechanism to cloak self-interested actions.[48] Indeed, attaching the label of conspiracy theory or fake news provides a strategy to disparage reasonable suspicion as irrational paranoia and attempts to pathologize dissent.[49] This casts aspersion on those who express doubt and harbor concerns about misuse of power, which weakens popular vigilance that would ordinarily guard against genuine threats in scientific and political institutions.[50] Gey asserts that democracy must eschew any government authority to control or manipulate the public's ideological predispositions: this would permit the government to manufacture consent, control public opinion, and serve its own interests.[51]

In the 1940s, psychologist Edward Bernays developed the concept of engineering consent, wherein stakeholders manipulate public opinion, deliberately plan, and exert influence on the public to achieve a specific outcome by using stories, social movements, and campaigns.[52] Capitalizing on core psychology concepts of mass opinion and consensus, Bernays advocated for democratic leaders to "play their part" by engineering consent toward socially constructive values and goals.[53] Policymakers would work with media to *create* news.[54] The most effective campaigns, according to

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[46] Gey, *supra* note 29, at 7.

[47] Shannon Bond, *Facebook, Twitter, Google CEOs Testify Before Congress: 4 Things To Know*, NAT'L PUB. RADIO (March 21, 2021), https://www.npr.org/2021/03/25/980510388/facebook-twitter-google-ceos-testify-before-congress-4-things-to-know.

[48] Gey, *supra* note 29, at 7.

[49] Michael T. Wood, *Some Dare Call it Conspiracy: Labeling Something a Conspiracy Theory Does Not Reduce Belief in It*, 37(5) POL. PSYCH. 695 (2016); deHaven-Smith & Witt, *supra* note 32, at 268.

[50] deHaven-Smith & Witt, *supra* note 32, at 268, 279; Bezemek, *supra* note 31, at 166-167; Wood, *supra* note 49, at 695-96.

[51] Gey, *supra* note 29, at 7-9.

[52] Edward L. Bernays, *The Engineering of Consent*, 250(1) ANNALS AM. ACAD. POL. & SOC. SCI. 113 (1947). The public relations industry implemented many of Bernays' ideas into principles for marketing, advertising, and promotion.

[53] *Id.* at 114.

[54] *Id.* at 119 ("[N]ewsworthy events, involving people, usually do not happen by accident. They are planned deliberately to accomplish a purpose, to influence our ideas and actions.").

Bernays, entailed a well-formulated plan and mass acceptance, where the idea becomes "part and parcel of the people themselves."[55] Throughout history for specific issues, powerful stakeholders and public officials determine what constitutes the optimal version of truth in science and utilize hidden propaganda to covertly and effectively lead the public to not only accept a certain proposition, but believe they arrived at this opinion based on their own logic and reasoning. At its most effective, psychologists Thomas Gilovich and Lee Ross note that the public will even defend certain opinions as not only empirically correct, but the morally correct idea.[56] In science, mass acceptance of a particular idea combined with suppression of dissent has the ability to produce devastating consequences.

B. Harmful History in Science, Medicine, and Public Health

The fields of science, medicine, and public health produced immense achievements, such as improving sanitation, plumbing, and clean drinking water to reduce infectious disease, discovering penicillin, and developing effective anesthesia for surgical procedures.[57] Despite incredible advancements, this field also repeatedly elevated incorrect and harmful information as scientific fact. This raises the question of who determines what constitutes factual scientific information. The stories from history below reveal techniques and key phrases that stakeholders in power utilize to attach legitimacy to the reigning theory and demonstrate the consequences if society permits risky – or even wrong – ideas to flourish unchallenged.

1. Dr. Ignaz Semmelweis: That's Outrageous, and Not Supported by the Data. Do Not Be Misled.

In 1847, Dr. Ignaz Semmelweis, a Hungarian obstetrician, discovered the cause of puerperal or childbed fever, the leading cause of

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[55] *Id.* at 120.

[56] *Id.*; *see also* THOMAS GILOVICH & LEE ROSS, THE WISEST ONE IN THE ROOM (2015) (discussing the concept of moral entrepreneurs and how people adopt a belief system that elevates their belief as not only empirically correct, but morally correct); HOWARD S. BECKER, OUTSIDERS: STUDIES IN THE SOCIOLOGY OF DEVIANCE (1963) (discussing the concept of moral entrepreneurs who believe they have a mission to reform what they perceive as an ill or moral wrong in society).

[57] *Ten Great Public Health Achievements - United States, 2001 - 2010*, MORBIDITY & MORTALITY WKLY. REP. 619-23 (May 2011), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm; Dan Childs & Susan Kansagra, *10 Health Advances That Changed the World*, ABC NEWS (Sept. 20, 2007), https://abcnews.go.com/Health/TenWays/story?id=3605442&page=1.

maternal mortality during that era. [58] At the time, physicians believed that childbed fever was caused by miasma, or invisible noxious smelling particles and decaying matter that lingered in the air.[59] In the clinic where Semmelweis worked, the maternal mortality rate was three times that of locations where midwives delivered infants.[60] Semmelweis observed medical students as they transitioned from performing autopsies to assisting mothers in labor, and began to formulate a hypothesis that there was a causative agent in the cadavers that medical students were transferring on their hands to the laboring mothers that caused infection and death.[61] After witnessing another physician prick his finger during an autopsy procedure, subsequently develop an infection, and die, Semmelweis hypothesized that "cadaveric particles" adhered to physician hands and instruments.[62] While physicians washed their hands and instruments, Semmelweis asserted simple handwashing was insufficient to remove the cadaveric particles and implemented a protocol to use chlorine disinfection.[63]

Creating and implementing a new policy for chlorine disinfection produced dramatic results. When Semmelweis first implemented the policy in 1847, the maternal mortality rate dropped precipitously from 15.4% to 1.8%.[64] Semmelweis began collecting data, and refined his theory to include early exposition of germ theory; living people, too, with a disease or infection could transfer disease to another person through the mucous membranes or the person's vascular system.[65] While collecting data and developing his theory, Semmelweis wrote letters to other prominent physicians alerting them to his findings.[66] Semmelweis published his theory, shared his data, wrote editorials, and presented his findings at medical society conferences in Vienna.[67]

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[58] Nicholas Kadar, *Rediscovering Ignaz Phillip Semmelweis (1818-1865)*, 220(1) AM. J. OBSTETRICS & GYNECOLOGY 26 (2019); *see also* Vipin K. Gupta et al., *Semmelweis Reflex: An Age Old Prejudice*, 136 WORLD NEUROSURGERY e119 (2020); Antonei Csoka, *Innovation in Medicine: Ignaz the Reviled and Egas the Regaled*, 19 MED. HEALTH CARE & PHIL. 163 (2016).

[59] Kadar, *supra* note 58, at 28-29.

[60] *Id.* at 26.

[61] *Id.* at 30.

[62] *Id.* at 28-29.

[63] *Id.* at 30.

[64] *Id.* at 31.

[65] Kadar, *supra* note 58, at 31.

[66] *Id.* at 32.

[67] *Id.* at 32-34.

Despite this landmark discovery, many in the medical profession ridiculed and dismissed Semmelweis. He suffered career setbacks, received staunch criticism at medical conferences from physicians who insisted *the data supported miasma* as the cause of childbed fever, and faced opposition at the University of Pest when attempting to implement the chlorine disinfection protocol.[68] In 1856, Semmelweis continued to publish the ongoing improvements from instituting chlorine disinfection, demonstrating even lower rates of maternal mortality at 0.39%.[69] In an editorial accompanying Semmelweis's article, the editor sharply warned readers, "*We thought this theory of chlorine disinfection had died out long ago*: the *experience and statistical evidence*…protest against the opinions expressed in this article: it would be well that our *readers should not allow themselves to be misled by this theory*."[70]

The medical profession not only dismissed and scorned Semmelweis for introducing a new theory, but asserted *their* actions were grounded in scientific fact, data, and levied the charge that Semmelweis's proposition ran contrary to the available evidence. Semmelweis's theory appeared simplistic, challenged the dominant paradigm, and importantly, highlighted attention to physician iatrogenesis – when physicians cause harm.[71] As physician and health law scholar Nicholas Kadar summarizes, medicine has a "dark history of opposing new ideas and those who propose them."[72] Refining this observation, medicine shuns ideas that challenge the status quo by identifying how the reigning standard of care contributes to patient harm. To accept such observations, physicians would be acknowledging their own role in causing infection and patient death. History provides the lesson that challenging established scientific norms – particularly when the established belief may cause harm – stirs controversy and vehement opposition.

Facing ongoing criticism and professional setbacks, Semmelweis suffered from deep depression and was committed involuntarily to an asylum. Shortly after admission, attendants beat him and he tragically – ironically – died from infection.[73] Fifteen years after Semmelweis's death,

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[68] *Id.* at 29 (discussing Semmelweis's career setbacks), 33-34 (discussing the Medical Society of Vienna Conference and physician opposition).

[69] *Id.* at 34.

[70] *Id.*

[71] Kadar, *supra* note 58, at 27, 34; Gupta, *supra* note 58, at e120; Csoka, *supra* note 58, at 163-65, 167.

[72] Kadar, *supra* note 58, at 27; Csoka, *supra* note 58, at 167.

[73] Kadar, *supra* note 58, at 34-35.

the paradigm shifted, and more scientists began to accept germ theory as subsequently described by Louis Pasteur.[74]

2. Dr. Egas Moniz: This Intervention is Groundbreaking and Promising

In stark contrast to the story of Semmelweis, the medical community embraced Portuguese neurologist Dr. Egas Moniz who worked with neurosurgeons to pioneer leucotomy (and the similar procedure called prefrontal lobotomy) for psychiatry patients.[75] At the time, therapeutic techniques available to treat patients in psychiatry were limited and dismal. Options included straightjackets to restrain movement, shock therapy, and techniques to modify the patient's physical state to induce psychiatric changes, such as malaria therapy or injecting doses of insulin to trigger a diabetic coma.[76] After observing the bilateral removal of frontal lobes in chimpanzees resulted in more cooperation, less frustration, and greater willingness to approach tasks, Moniz began studying psychosurgery in animal models.[77] Moniz quickly hypothesized that similar results should follow in humans. He believed that certain circuits in the brain become fixed in a pattern of dysfunction resulting in symptoms of mental illness such as delusions, obsession, and anxiety.[78] Severing the connection between these circuits and the rest of the brain, Moniz theorized, would eliminate abnormal thinking and behavior in patients with severe mental illness.[79]

In 1936, Moniz first presented his findings from twenty case studies at the Paris Society of Medicine.[80] Initially, Moniz introduced leucotomy for only the most severe cases of mental illness and published qualitative accounts of patients pre- and post-surgery, reporting marked improvement in patient behavior and emotional state in the *American Journal of Psychiatry*.[81] Moniz asserted: "*the facts speak for themselves*," "*the patients were well-*

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[74] *Id.* at 27, 34; Gupta, *supra* note 58, at e120.

[75] Csoka, *supra* note 58; Louis-Marie Terrier et al., *Brain Lobotomy: A Historical and Moral Dilemma With No Alternative?* 132 WORLD NEUROSURGERY 211 (2019); Ann Jane Tierney, *Egas Moniz and the Origins of Psychosurgery: A Review Commemorating the 50th Anniversary of Moniz's Nobel Prize*, 9(1) J. HIST. NEUROSCIENCES 22 (2000).

[76] Terrier, *supra* note 75, at 212.

[77] Tierney, *supra* note 75, at 27.

[78] *Id.*

[79] *Id.*

[80] Terrier, *supra* note 75, at 212.

[81] Tierney, *supra* note 75, at 31.

studied and well followed" and "*recoveries have been maintained*."[82] Moniz characterized prefrontal leucotomy as a "*simple operation*," proclaimed that "it is *always safe*," and a *highly effective* surgical tool to treat patients with mental illness.[83]

Despite initial use in only the most severe cases of mental illness, Moniz began expanding indications covering multiple additional symptoms including epilepsy, anxiety, and depression.[84] Print media advertisements and the medical community began to portray psychosurgery as a much broader therapeutic strategy. One advertisement of the time featured a pretty blonde woman with a wide smile, proclaiming leucotomy would provide her "a new personality and fresh outlook on life."[85] Physicians in the field of psychosurgery declared the *results were "truly amazing*," produced significant improvement in patient mood and behavior, and advocated performing surgeries sooner rather than later, asserting this would provide a preventive measure against patients' mental illness deteriorating or patients developing chronic psychosis.[86]

Despite proclamations of "well studied" patients and summarily dismissing potential risks, the medical community overlooked the disconnect between promises for a groundbreaking surgical technique and gaps in supporting data. Published findings followed patients for days or weeks and provided the physicians' qualitative assessments of patient progress based on subjective perception.[87] Study findings did not provide control groups and downplayed or omitted the negative changes to patients' personality, emotion, and behavior.[88]

By 1937, Moniz had written a monograph on the topic of leucotomy, a book, and thirteen articles spanning six different countries.[89] Internationally known and professionally well-respected, Moniz was awarded the Nobel Prize in 1949 for his discovery.[90] Swift adoption, promises for groundbreaking outcomes invoking key phrases ("always safe," "highly effective," "patients were well studied") and dismissing criticism enabled

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[82] *Id.*
[83] *Id.*
[84] *Id.* at 29, 32.
[85] Terrier, *supra* note 75, at 217.
[86] Tierney, *supra* note 75, at 32.
[87] *Id.* at 31.
[88] *Id*.
[89] *Id.*
[90] Terrier, *supra* note 75, at 211.

physicians' use of leucotomy to flourish. By 1951, physicians lobotomized 20,000 Americans.[91]

Reforming the theory that psychosurgery provided a safe and highly effective option for patients came slowly. In 1949, the *New England Journal of Medicine* published a critique of lobotomy, asserting that rather than "curing" patients, the procedure induced new emotional and behavioral harm.[92] In response, some physicians attempted to refine and modify their technique, but the criticism did not reduce medicine's favor for psychosurgery. In the mid-1950s and 1960s, the rise of antipsychotic drugs sparked a new approach to treating mental illness, and psychosurgery eventually fell out of favor; it had been replaced by a new, more promising technique.[93] However, psychosurgery did not disappear; physicians still perform it as a method to treat intractable mental illness, modifying the name and assuring patients current techniques are more refined and advanced.[94]

Swedish health sciences professor Kenneth Ogren uncovered the seminal role of the media in shaping public opinion and acceptance of psychosurgery. One news article in 1937 described: "A new surgical technique, known as 'psychosurgery' which, it is claimed, cuts away sick parts of the human personality, and transforms wild animals into gentle creatures in the course of a few hours."[95] Physician Walter Freeman, who worked with Moniz to pioneer the technique, capitalized on partnering with the media to run human interest stories, editorials, and contrasting descriptions of suffering and benefit from psychosurgery.[96] Ogren notes that the media serves as a powerful force for arbitrating what constitutes scientific "facts" while establishing the boundaries of legitimate and desirable science policy. In this instance, media represented leucotomy and lobotomy as miraculous discoveries that cured patients and restored neurological functioning rather than a barbaric destructive intervention.[97]

The rise of psychosurgery and praise for Moniz reflected medicine's honor and cachet, wherein a respected profession offered a new technique for

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[91] Tierney, *supra* note 75, at 33.

[92] *Id*.

[93] *Id.* at 34.

[94] Jimmy C. Yang, *Lesion Analysis for Cingulotomy and Limbic Leucotomy: Comparison and Correlation with Clinical Outcomes*, 120(1) J. NEUROSURGERY 152 (2014).

[95] Kenneth Ogren, *Portrayals of Lobotomy in American and Swedish Media*, 206 PROGRESS BRAIN RSCH. 201, 203-04 (2013).

[96] *Id.*

[97] *Id.* at 214.

suffering patients.[98] Labeling the procedure as safe and effective in medical journals diverted attention away from closer assessments, such as examining the metrics for determining what constitutes patient improvement, accounting for serious risks, and worrisome mortality rates.[99] This brutal technique permanently destroyed critical neurological function, inducing irreversible changes in affect and personality.[100] Both patients and physicians accepted inflated promises and hollow data based on faith and the belief that modern medicine would provide the answer to alleviate patient suffering.

3. History of Opioids: This Miracle Drug Provides a Remarkable Remedy

In the mid-1800s, physicians often prescribed morphine for pain, to relieve intestinal distress, and induce sleep.[101] Physicians hailed morphine as a "miracle drug" for its effective pain management properties.[102] Chemists extracted morphine from opium, a substance found in the poppy plant. Morphine, however, is ten times more powerful than naturally occurring opium.[103] Recreational abuse and physician reports of patient dependence began to reveal the adverse effects and risks of morphine.[104]

In 1897, chemists at Bayer worked toward developing a newer and more promising iteration: Heroin.[105] Bayer began marketing Heroin as a

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[98] Csoka, *supra* note 58, at 163, 165.

[99] Ogren, *supra* note 95, at 215 (citing mortality rates at 10-16%).

[100] Harry Allison & Sarah Allison, *Personality Changes Following Transorbital Lobotomy*, 42(2) J. ABNORMAL SOC. PSYCH. 19 (1954); *see also* Tony Leys, *Barbaric Practice 'Took the Life Out of Him*,' DES MOINES REG. (Jan. 5, 2014), https://www.usatoday.com/story/news/nation/2014/01/05/barbaric-practice-took-the-life-out-of-him/4319835/.

[101] Carmen Drahl, *Five Things to Know About Heroin's Curious Chemistry History*, FORBES (June 12, 2017), https://www.forbes.com/sites/carmendrahl/2017/06/12/five-things-heroins-curious-chemistry-history/?sh=3846e2f0157c; *History, Opium Poppy*, DRUG ENF'T ADMIN. MUSEUM, https://www.deamuseum.org/ccp/opium/history.html.

[102] DRUG ENF'T ADMIN. MUSEUM, *supra* note 101.

[103] *Id.*

[104] *Id.*; *see also* Morphine Drug Fact Sheet, DRUG ENF'T ADMIN. (April 2020), https://www.dea.gov/sites/default/files/2020-06/Morphine-2020.pdf.

[105] Drahl, *supra* note 101; *see also* Haider J. Warraich, *What an 1890s Opioid Epidemic Can Teach Us About Ending Addiction Today*, STAT NEWS (Feb. 11, 2020), https://www.statnews.com/2020/02/11/1890s-opioid-epidemic-teach-us-about-addiction-today/;
Jim Edwards, *Yes, Bayer Promoted Heroin for Children-*

replacement to morphine, calling it a treatment for addiction and a "remarkable remedy."[106] In addition to addiction treatment, Bayer marketed Heroin as an effective cough suppressant for patients suffering from tuberculosis and pneumonia.[107] Print advertisements appealing to parents informed readers Heroin worked as an effective cough suppressant for children, too, and would effectively alleviate children's bronchitis symptoms.[108]

During this time, some products such as cough syrups and even infant teething syrup contained unlabeled opioids. In 1912, multiple infants died from ingesting Mrs. Winslow's Soothing Syrup for Teething and Colicky Babies, which was laced with morphine.[109] In response to accidental ingestion and growing concerns of addiction, Congress passed several laws to regulate opioids such as the 1912 Sherley Amendment, prohibiting false therapeutic claims on medicines, and the Harrison Narcotic Tax Act of 1914, which set forth prescription recordkeeping requirements and allowable limits for dispensing narcotics.[110]

Today, the Controlled Substances Act classifies heroin as a Schedule I controlled drug, defined as a drug with no currently accepted medical use and a high potential for abuse.[111] Short-term effects of heroin and other opioids including morphine include nausea and vomiting, itching, impairment, and loss of consciousness.[112] Long-term use can lead to dependence, cardiac infections, mental disorders, pneumonia, and kidney and liver disease.[113] The public would likely presume that more stringent federal

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Here Are the Ads That Prove It, BUS. INSIDER (Nov. 17, 2011), https://www.businessinsider.com/yes-bayer-promoted-heroin-for-children-here-are-the-ads-that-prove-it-2011-11.

[106] Drahl, *supra* note 101; *see also* Warraich, *supra* note 105; Edwards, *supra* note 105.

[107] Drahl, *supra* note 101; *see also* Warraich, *supra* note 105; Edwards, *supra* note 105.

[108] Edwards, *supra* note 105.

[109] *Milestones in U.S. Food and Drug History Law*, FOOD & DRUG ADMIN. https://www.fda.gov/media/109482/download#:~:text=1912%20Congress%20enacts%20the%20Sherley,a%20standard%20difficult%20to%20prove.

[110] *Id.*

[111] *Drug Scheduling*, DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/drug-scheduling.

[112] *Heroin Drug Facts*, NAT'L. INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/drugfacts/heroin; *Opioids*, NAT'L. INST. ON DRUG ABUSE, https://www.drugabuse.gov/drug-topics/opioids.

[113] *Id.*

regulations and oversight provide barriers from exposing patients to risky and unproven medications. Indeed, federal regulations set forth exacting requirements for manufacturers to demonstrate clinical trial evidence for safety and efficacy. Yet this raises the question: by what metrics are we measuring safety and efficacy, how much weight – and trust – do we afford manufacturers' specific claims, and what margin of risk is acceptable?

Approximately one hundred years after Bayer introduced Heroin as a pain reliever and addiction treatment, Purdue Pharma introduced a new and better drug with promises of the same.[114] A singular editorial in the *New England Journal of Medicine* promised oxycodone provided the answer for a non-hypnotic and non-addictive pain reliever.[115] Torrents of patients developed opioid dependency from legitimately prescribed oxycodone.[116] Clinical guidelines and federal drug policy modified the traditional label of opioid addiction from illicit heroin to include iatrogenic opioid dependency, sweeping all people under a new label of Opioid Use Disorder.[117] Federal policymakers and medical journals assured patients that effective medication existed to treat patients with Opioid Use Disorder, and began aggressively promoting access to Medication Assisted Treatment (replacement opioids) as the first line therapy for all patients with Opioid Use Disorder.[118] To be sure, opioid medications serve critical functions in medicine as pain relievers. However, I've described in other research that designating another replacement opioid as standard for all patients' treatment ignores the history of ineffective reliance on revolving medications, overlooks critical metrics declaring Medication Assisted Treatment as successful, and suppresses significant risks to patients.[119] As physician Haider Warraich observes, reliance on pharmaceutical drugs is not an accident; rather, it arises from a culture deliberately crafted by the pharmaceutical industry.[120]

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[114] Warraich, *supra* note 105.

[115] *Id.*

[116] ANNA LEMBKE, DRUG DEALER, MD: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP (2016).

[117] *Id.*

[118] *See* Katherine Drabiak, *Expanding Medication Assisted Treatment is Not the Answer: Flaws in the Substance Abuse Treatment Paradigm*, 21(1) J. HEALTH CARE L. 1 (2019).

[119] *Id.*

[120] Warraich, *supra* note 105.

4. Eugenics: Eugenics is a science. It is a fact, and the experts agree.

In 1883, Francis Galton coined the term eugenics and began studying the theory that success and failure in life originated from genetic inheritance.[121] Geneticists of the era studied individual traits and asserted that certain behaviors and conditions such as "feeblemindedness, epilepsy, drunkenness, criminality, and insanity" had strong hereditary influences.[122] From 1850 to 1890, states built prisons, hospitals, asylums, and colonies for people with mental illness, developmental disabilities, and criminals. The undesirable and unfit population also included foreign immigrants, people of low socioeconomic status, and racial minorities.[123] Prominent Harvard educated scientist Charles Davenport served as the director of the Eugenics Record Office, an organization funded by the Carnegie and Rockefeller Foundations that advocated for research, education, and legal reform to promote the concept of eugenics.[124] Davenport asserted that "3-4% of the population is a fearful drag on our civilization…shall we not rather take the steps that scientific study dictates as necessary to dry up the spring that feeds the torrent of defective and degenerate protoplasm?"[125] Davenport and others such as Margaret Sanger promoted the concept of negative eugenics, which entailed preventing undesirable children from being born through contraception or sterilization.[126]

Importantly, eugenics constituted mainstream highly respected scientific policy and well-known scientists such as Francis Crick, Linus Pauling, and Konrad Lorenz embraced its tenets.[127] Eugenics featured prominently in medical school curriculum, professional society meetings such as the American Association for the Study and Prevention of Infant

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[121] PHILIP REILLY, EUGENICS, ETHICS, STERILIZATION LAWS, ENCYC. ETHICAL, LEGAL, & POL'Y ISSUES BIOTECHNOLOGY (Thomas Murray & Maxwell Mehlman eds. 2000).

[122] EDWARD LARSON, SEX, RACE AND SCIENCE: EUGENICS IN THE DEEP SOUTH 148 (1995).

[123] *Id.* at 103-04 (discussing foreign immigrants), 154 (discussing socioeconomic status), 155 (discussing race).

[124] Paul A. Lombardo, *Taking Eugenics Seriously, Three Generations of??? are Enough?*, 30 FLA. ST. UNIV. L. REV. 191, 204 (2003).

[125] *Id.*

[126] Larson, *supra* note 122, at 104; EDWIN BLACK, WAR AGAINST THE WEAK: EUGENICS AND AMERICA'S CAMPAIGN TO CREATE A MASTER RACE 131 (2003).

[127] Lombardo, *supra* note 124, at 209.

Mortality, and medical journals.[128] Dr. Harvey Jordan, Dean and faculty member at the University of Virginia School of Medicine, asserted eugenics should be included in medical school curriculum.[129] The U.S. Public Health Service (USPHS) endorsed and supported eugenics, performed eugenic examinations, and issued marriage certificates based on genetic suitability.[130] Dr. W.C. Rucker, the Assistant Surgeon General of the USPHS stated bluntly: "*Eugenics is a science. It is a fact*, not a fad."[131] Indeed, scientists at the time emphasized eugenics constituted true science, specifically distinguishing it from pseudoscience such as phrenology to bolster its credibility.[132] Scientists and progressive social thinkers believed it was their duty to educate the public on the true scientific facts, defined as the need for eugenic public health and social policies.[133]

Physicians categorized practicing eugenics within the definition of preventive medicine: to eliminate "physical, mental, and moral sickness and weakness" before it occurred.[134] Social philanthropy was both costly and could not save future generations from "vice, imbecility, and suffering."[135] By framing eugenics as humane and progressive, law professor and historian Paul Lombardo observes that this characterization promoted hope; eugenics would enable physicians to prevent suffering and alleviate harm.[136]

Scientists, physicians, public health officials, and policymakers promoted eugenics as scientific fact for decades, from the 1890s through the 1970s. Fervent advocacy for eugenics fell from favor during the 1940s, when the Third Reich in Germany adopted key scientific tenets as evidence for its national euthanasia policy.[137] In the U.S., dozens of state laws facilitated

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[128] Larson, *supra* note 122, at 49-50; Lombardo, *supra* note 124, at 208, 213-14.

[129] Lombardo, *supra* note 124, at 213-14.

[130] *Id.* at 210.

[131] *Id.*

[132] *Id.* at 208.

[133] Larson, *supra* note 122, at 104.

[134] Lombardo, *supra* note 124, at 204.

[135] Black, *supra* note 126, at 130 (describing Margaret Sanger's assertion that philanthropy was too costly for society as compared to contraception and sterilization); Lombardo, *supra* note 123, at 208, 211 (discussing eugenics as preventive medicine).

[136] Lombardo, *supra* note 124, at 208; Larson, *supra* note 122, at 112.

[137] Black, *supra* note 126, at 249. Scientists adopted the tenets of eugenics that advocated for sterilization and modified the means to include euthanasia according to the premise that society was acting in self-defense against crime and social harms. Euthanasia, asserted scientists, would not only protect the public but was economical, humane, and could be painlessly performed.

eugenics' mission by enacting laws permitting involuntary sterilization of certain types of "undesirable" people. The theory of eugenics exerted powerful influence over public health policy, and Lombardo estimates that physicians in the U.S. sterilized more than 60,000 Americans over seven decades.[138]

5. Learning from History

Each of these stories highlights specific techniques and phrases that stakeholders in power utilize to designate the parameters and focus of legitimate science. In the case of Semmelweis, physicians asserted evidence, experience, and statistics to support the miasma theory of disease. Scientists and policymakers during the time of eugenics adopted similar appeals: asserting eugenics constituted "true science" rather than pseudoscience, "a fact," and appealed to expert agreement. Establishing consensus among scientists in both the case of Semmelweis and eugenics affords dominance and power to the reigning theory. Proponents of the dominant theory may also warn professionals and the public against being misled by dissent or disagreement in the field. Instead, scientists and physicians have a duty to educate the public and promote the *true* scientific principles. Oriented toward helping the public, medicine and public health may elevate novel interventions based on faith and promises, such as in the case of Heroin and leucotomy. Each of these examples appeals to the deepest forces driving science and medicine: how do we understand disease and suffering? How can we best use science to alleviate illness and promote health? Yet, these cases illustrate that insulating dominant scientific policy from debate would permit risky and devastatingly harmful ideas to flourish. Science has a duty to examine dissent, acknowledge criticism, and engage in a process that reviews the best available evidence to assess competing claims.

III. WHEN CONSPIRACIES IN PUBLIC HEALTH CAUSE HARM

In many cases, public health officials, government officials, and policymakers act in furtherance of the public's best interest to promote public health and safety. However, powerful stakeholders may incorporate science in a manner that harms the public health or abdicates the role of safeguarding public health. This section continues the description of eugenics as a historical public health policy that enjoyed broad scientific acceptance. Using

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[138] Lombardo, *supra* note 124, at 202; *see also* Reilly, *supra* note 121; Larson, *supra* note 122.

the case of *Buck v. Bell*, this section explores how collusion among powerful stakeholders can use the law to reify and justify harmful public health policy. Next, this section describes an example when government officials relinquished their duty to protect public health by permitting water contamination in Flint, Michigan. The alleged conspiracy relating to water contamination illustrates the drive to preserve power and maximize individual interest through hidden agreement at the expense of protecting public health.

A. Public Health History: Eugenics Enshrined in Law

In addition to widespread scientific support for eugenics, physicians and prominent scientists worked with legislators to pass state laws that would facilitate the process of involuntary sterilization. Eugenics policies functioned to further both the power and prestige of science by demonstrating how to leverage science to engineer social good and protect the public from perceived harm. In 1907, Indiana was the first state to pass a law that designated a procedure for determining the appropriateness and means of involuntary sterilization.[139] Over the next several decades, over thirty states enacted laws describing processes for involuntary sterilization.[140]

In 1927, the U.S. Supreme Court upheld Virginia's involuntary sterilization law in *Buck v. Bell*. Carrie Buck, a seventeen-year-old girl provided the test case for Virginia's involuntary sterilization law.[141] Justice Holmes' recitation of the facts portrays Buck as the prime candidate for sterilization based on Virginia law. The state committed Buck involuntarily to the Virginia Colony for the Epileptic and Feeble Minded, alleging she met the criteria for both "feeblemindedness" and moral delinquency because she had a child out of wedlock.[142] Moreover, Buck was a second generation of persons that the state classified as an "imbecile" or "feebleminded." Buck's mother Emma was already a resident of the Colony, and officials at the Colony said that Buck and her mother shared the hereditary traits of "feeblemindedness" and sexual promiscuity.[143]

Virginia law stated: "the health of the patient and the welfare of society may be promoted in certain cases by the sterilization of mental

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[139] Reilly, *supra* note 121.

[140] *Id.*; Larson, *supra* note 122.

[141] Buck v. Bell, 274 U.S. 200 (1927).

[142] *Id*.

[143] Paul Lombardo, *Three Generations: No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 31, 53 (1985).

defectives."[144] The law set forth specific procedures to provide evidence and certify that the patient met the criteria to order sterilization, and the patient had the opportunity to object. Carrie Buck challenged the order for salpingectomy, asserting insufficient due process.

The Court upheld Virginia's law permitting involuntary sterilization through vasectomy or salpingectomy, stating the procedure was "without serious pain or substantial danger to life" and provided significant public benefit.[145] Incorporating accepted science of the era, the Court stated that certain undesirable traits such as crime, moral delinquency, and low intellect are hereditary.[146] According to Justice Holmes, discharging certain types of people such as the "feebleminded" or criminals from colonies and prisons would create a menace to society.[147] Justice Holmes reasoned that if this population was incapable of procreating, the state could release them without worry of propagating undesirable and dangerous genetic traits to their offspring in a manner that would harm others.[148] The law would permit sterilizing Buck and other persons "without detriment to her general health" while simultaneously promoting public good.[149]

Part of the Court's reasoning relied on the concept of police power, and the state's ability to enact laws to promote the health, safety, and welfare of society. In this instance, the Court erroneously affirmed the state's power to order a forced invasive medical procedure, justifying it would benefit the greater good.[150] The Court framed the action as benevolent preventive public health policy: "Instead of waiting to execute" them or let them starve, the action "prevent[s] those who are manifestly unfit from continuing their kind."[151] Finally, the Court held there was "no doubt" that Buck was permitted due process, because the law set forth a procedure for the state to hear evidence, appoint a guardian to represent the patient, and an opportunity

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[144] Buck v. Bell, 274 U.S. at 205.

[145] *Id*.

[146] *Id.*

[147] *Id.*

[148] *Id.*

[149] *Id.* at 207.

[150] *But see* Katherine Drabiak, *Disentangling Dicta: Prince v. Massachusetts, Police Power and Childhood Vaccine Policy*, 29 (1) ANNALS HEALTH L. & LIFE SCI.'S 173, 183-85 (2020) (discussing the evolution of substantive due process, police power to mandate medical interventions, and informed consent in medical decision-making).

[151] Buck v. Bell, 274 U.S. 200, 207-08 (1927).

to object.[152] Media described the holding as sane, beneficial, and progressive – the decision applied scientific knowledge to simultaneously provide beneficial medical interventions with no perceived harm to the patient at great benefit to society.[153]

Buck v. Bell represents a dark stain of egregious error and injustice in the history of the Supreme Court. With thorough investigation, Lombardo discovered pertinent omissions from the historical story of Carrie Buck. Lombardo provides compelling evidence of private collusion between health professionals, attorneys, and the State involved in Carrie Buck's case, characterizing the trial as a "sham."[154] Lombardo documents lack of evidence of Buck's "low intelligence," pointing out she was a "very good" student according to school records and members of her church choir.[155] Moreover, the state's evidence for Buck's low morals hinged upon portraying Buck as promiscuous for having an out-of-wedlock-child. However, when Buck's mother was committed to the Virginia Colony, Buck was sent to live with the Dobbs' family under foster care.[156] During her stay with the Dobbs' family, the Dobbs' son sexually assaulted Buck, which resulted in pregnancy and birth of her daughter Vivian.[157] To avoid suffering a marred reputation, the Dobbs family moved to institutionalize Buck. Following Buck's involuntary commitment and order for sterilization, Lombardo uncovered collusion not only between health officials and witnesses, but between the physician issuing the sterilization order and Buck's own attorney.[158]

Buck v. Bell demonstrates not only how scientists and policymakers can leverage dominant scientific theory as socially beneficial and correct, but how this conviction can manifest as strident justification for eroding liberty through coercive means. Secret collusion to ignore inconvenient opposing facts in public health policy has the potential to fervently propel unjust and misguided applications of science.

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[152] *Id.*

[153] *See* Paul Lombardo, *Three Generations: No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 31 (1985).

[154] Lombardo, *supra* note 143, at 56; Lombardo, *supra* note 124, at 216-17.

[155] Lombardo, *supra* note 143, at 52-53.

[156] *Id.* at 53-55.

[157] *Id.* at 54.

[158] *Id.*

B. Contemporary Public Health: Water Contamination in Flint, Michigan

1. Background Facts

This case of Flint, Michigan, water contamination involves allegedly intentional decisions by public health officials, local government officials, and state government officials that led to passive poisoning of residents through the municipal water supply.[159] Thousands of residents in Flint, Michigan, consumed, bathed in, and used water they believed was safe but instead was tainted.[160] Water testing revealed the presence of lead far above permitted regulatory levels, microbial contaminants that led to outbreaks of disease such as Shigellosis and Legionnaires disease, and regulatory violations arising from too much disinfectant byproduct called total trihalomethanes.[161] This resulted in numerous cases of lead poisoning, permanent injury, and death.[162]

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[159] *Flint Water Crisis Fast Facts*, CNN (Jan. 14, 2021), https://www.cnn.com/2016/03/04/us/flint-water-crisis-fast-facts/index.html; Laura Carravallah et al., *Lessons for Physicians from Flint's Water Crisis*, 19(10) AMA J. ETHICS 1001-10, 1001 (2017) (citing administrative failures, alleged cover-ups, and conflicts of interest among government officials); David Bellinger, *Lead Contamination in Flint – an Abject Failure*, 374 NEW ENGLAND J. MED. 11-1-1103 (2016).

[160] *See* ANNA CLARK, THE POISONED CITY (2018); MONA HANNA-ATTISHA, WHAT THE EYES DON'T SEE (2018).

[161] *Flint Water Crisis Fast Facts*, *supra* note 159; Sara Ganim, *Michigan Officials Charged in Flint Legionnaire's Outbreak*, CNN (June 14, 2017), https://www.cnn.com/2017/06/14/health/flint-water-crisis-legionnaires-manslaughter-charges/index.html; Ron Fonger, *City Warns of Potential Health Risks After Flint Water Tests Revealed Too Much Disinfection Byproduct*, M LIVE NEWS (Jan. 3, 2015), https://www.mlive.com/news/flint/2015/01/flint_water_has_high_disinfect.html.

[162] *Flint Water Crisis Fast Facts*, *supra* note 159; Ganim, *supra* note 161; Fonger, *supra* note 161; Clark, *supra* note 160; Hanna-Attisha, *supra* note 160; Mona Hanna-Attisha et al., *Elevated Blood Lead Levels in Children Association with Drinking Water*, 106(2) AM. J. PUB. HEALTH 283-90 (2016); *see also* Erica Green, *Flint's Children Suffer in Class After Years of Drinking the Lead-Poisoned Water*, N.Y. TIMES (Nov. 6, 2019), https://www.nytimes.com/2019/11/06/us/politics/flint-michigan-schools.html.

2. Water Quality Standards in Federal Law

The United Nations classifies access to water as a basic human right, and it is essential for the survival of all life forms.[163] Clean water is integral to public health for drinking, bathing, sanitation, and plumbing uses. Water constitutes a non-substitutable resource and supports human biological, economic, and social life.[164] In the U.S., the law treats access to water under the framework of a negative right.[165] Thus, the public has a right to be free from certain unwanted contaminants that might be present in the water.[166] But this does not encompass a positive right to water in the law, which means there is no absolute right to receive water, for example from a municipal water supply.

Federal law sets forth specific standards for drinking water and limits on contaminants in the Safe Water Drinking Act (SWDA).[167] In 1974, Congress passed the SWDA as a measure to protect public health by regulating the drinking water supply.[168] The SWDA authorizes the Environmental Protection Agency (EPA) to establish minimum standards to protect tap water and sets limits for both naturally occurring and man-made contaminants.[169] SWDA defines contaminants broadly to include physical, chemical, biological, or radiological substances or matter in water besides water molecules.[170] This would include substances such as sediment, pesticides, metals including lead and copper, bacteria and parasites, or radioactive compounds such as uranium.[171] The National Primary Water Drinking Regulations set enforceable maximum levels for contaminants, require mitigation to remove the contaminants exceeding a particular level,

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[163] Bruce Jennings & Leslie Lyons Duncan, *Water Safety and Lead Regulation: Physicians' Community Health Responsibilities*, 19(10) AMA J. ETHICS 1027-35, 1027 (2017); Nadia Gaber, *Mobilizing Health Metrics for the Human Right to Water in Flint and Detroit, Michigan*, 21(10) HEALTH & HUM. RTS. J. 179-89 (2019).

[164] Jennings & Leslie Duncan, *supra* note 163; Gaber, *supra* note 163.

[165] Gaber, *supra* note 163, at 181-82.

[166] *Id.*

[167] 42 U.S.C. § 300f et seq. (1974).

[168] *Overview of the Safe Water Drinking Act*, ENV'T PROT. AGENCY, https://www.epa.gov/sdwa/overview-safe-drinking-water-act#:~:text=SDWA%20authorizes%20the%20United%20States,be%20found%20in%20drinking%20water; *Summary of the Safe Water Drinking Act*, ENV'T PROT. AGENCY, https://www.epa.gov/laws-regulations/summary-safe-drinking-water-act.

[169] *Id.*

[170] *Types of Drinking Water Contaminants*, ENV'T PROT. AGENCY, https://www.epa.gov/ccl/types-drinking-water-contaminants.

[171] *Id.*

set forth systems of testing water quality, and outline collection of water quality data to ensure compliance.[172] Regulatory standards balance potential risk of contaminants, technological feasibility, and cost effectiveness, each of which reflects a set of policy tradeoffs.[173]

In 1991, the EPA promulgated the Lead and Copper Rule, a regulation pertaining to the maximum allowable amounts of lead and copper in drinking water.[174] Lead and copper may enter drinking water through plumbing materials and fixtures, underground pipes and service lines that bring water into residential homes and buildings, and storage tank facilities.[175] The Lead and Copper Rule sets a maximum allowable limit for lead and copper.[176] It requires water systems serving more than 50,000 residents to implement corrosion control, actions designed to reduce the corrosivity of water to reduce the chance of water breaking down metals from pipes and carrying contaminants such as lead and copper into customer taps.[177] The Lead and Copper Rule also establishes a requirement for water systems to monitor drinking water emitted through customer taps, and requires water systems take corrective action if lead concentrations exceeded a set level.[178] Federal standards are enforceable through administrative orders, litigation, and fines.[179]

3. EPA and State Oversight

The EPA delegates oversight of federal water quality laws to states, which oversee compliance with federal law. In Michigan, the government body tasked with ensuring compliance with water standards is the Michigan Department of Environmental Quality (MDEQ).[180] MDEQ approves the permitting process to switch water supply from one source to another and sets forth requirements to make sure the water meets federal regulations once

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[172] *Understanding the Safe Water Drinking Act*, ENV'T PROT. AGENCY, https://www.epa.gov/sites/production/files/2015-04/documents/epa816f04030.pdf

[173] Jennings & Lyons Duncan, *supra* note 163, at 1028.

[174] 40 C.F.R. § 141.80 (2021).

[175] Jennings & Lyons Duncan, *supra* note 163, at 1027.

[176] 40 C.F.R. § 141.80 (2021).

[177] Jennings & Lyons Duncan, *supra* note 163, at 1029; Hanna-Attisha, *supra* note 160, at 283.

[178] *Lead and Copper Rule: Rule Summary*, ENV'T PROT. AGENCY, https://www.epa.gov/dwreginfo/lead-and-copper-rule.

[179] *Understanding the Safe Water Drinking Act*, *supra* note 172.

[180] Peter Jacobsen et al., *The Role of the Legal System in the Flint Water Crisis*, 98(2) MILBANK Q. 554-80 (2020).

the water is flowing. In April 2014, a state emergency manager ordered the city of Flint to switch the water supply from the Detroit water system to the Flint River.[181] The Michigan Governor's Task Force report concluded that MDEQ failed to comply with key provisions in federal law that led to, and exacerbated, the water contamination.[182] Public health law professor Peter Jacobsen and colleagues analyzed the omissions and errors, and found MDEQ did not require corrosion control or require necessary upgrades to the Flint Water Treatment plant prior to the water switch.[183] MDEQ did not require Department of Public Works to correct the Lead and Copper Rule violations once the water was flowing.[184] MDEQ also reported inaccurate and false information to the EPA by representing it did comply with the Lead and Copper Rule's requirements for corrosion control.[185] Finally, it did not cooperate with the Michigan state and county health departments that tried to investigate an outbreak of Legionnaire's disease.[186] Instead, MDEQ stated the outbreak came from a hospital where patients were staying, not the drinking water. Jacobsen and colleagues concluded that MDEQ's actions in implementing the laws contributed to the development, progression, and perpetuation of Flint's water crisis.[187]

4. Timeline of Events in Flint, Michigan

The timeline of events that unfolded in Flint, Michigan, illustrates the number of government officials and employees involved in supplying water to Flint residents that had knowledge of concerns relating to water quality, how key officials ignored warnings, suppressed public concerns, and denied any problems existed with the water quality.

In March 2012, the city of Flint announced it intended to switch the water supply from the Detroit water system to the Flint River as a cost saving measure.[188] Following this decision, a supervisor at MDEQ sent an email to his director discussing risks associated with switching the water supply, describing how switching would pose increased health risks such as microbial contaminants, risks of additional disinfection byproduct to control

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[181] *Id.* at 555.
[182] *Id.* 567-68.
[183] *Id.* at 566-68.
[184] *Id.* at 568.
[185] *Id.*
[186] Peter Jacobsen et al., *supra* note 180, at 568.
[187] *Id.* at 569.
[188] *Flint Water Crisis Fast Facts*, *supra* note 159.

microbial contamination, that the Flint Water Treatment plant would need additional upgrades prior to switching, and the switch would add additional regulatory requirements to comply with federal law.[189] On April 17, 2014, an employee at the City of Flint Water Treatment Plant informed MDEQ the water plant was not fit to begin operations.[190] He said, "I do not anticipate giving the ok to begin sending water. If water is distributed from the plant in the next couple of weeks it would be against my direction."[191] The next day, on April 18, 2014, the City of Flint issued a press release stating: "The tests are in, the water is good. And in an effort to *dispel myths*, we have conducted countless tests to *ensure the water is safe* for use."[192]

However, water quality tests suggested otherwise. In August 2014, the City of Flint announced water quality tests detected fecal coliform bacteria in the water supply in violation of the National Primary Drinking Water Regulations, issued a water boil advisory, and increased the amount of chlorine in the water.[193] One month later, Flint issued another water quality advisory informing residents of the presence of total coliform bacteria, and city officials informed residents the city would add additional chlorine.[194] In December 2014, water quality tests revealed the presence of total trihalomethanes, a disinfection byproduct from additional chlorine use, was above permissible limits.[195]

During this time, Michigan Governor Rick Snyder oversaw the water supply switch from the Detroit water system to the Flint River. According to discovery documents obtained during litigation against local and state officials, internal communications and emails from Gov. Snyder's staff informed him that the expedited timeframe for switching the water supply was "less than ideal" and "could lead to potential disasters down the road."[196] Advisors to then Gov. Snyder in Michigan warned him around October 2014: "It might come out that the composition exceeds regulatory standards," and

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[189] Fourth Amended and Consolidated Plaintiff's Complaint at 40, In Re Flint Water Cases, 969 F.3d 298 (6th Cir. 2020) (No. 5:16-cv-10444-JEL-MKM) [hereinafter Pl.'s Compl.].

[190] *Id.* at 46.

[191] *Id.*

[192] *Id.* at 47.

[193] *Flint Water Crisis Fast Facts*, *supra* note 160.

[194] *Id.*

[195] Miguel Del Toral, *Memorandum: High Levels of Lead in Flint, Michigan – Interim Report*, ENV'T PROT. AGENCY (June 24, 2015).

[196] In Re Flint Water Cases, 969 F.3d 298, 303 (6th Cir. 2020).

emails from his team stated the water issues are "downright scary."[197] Following receipt of these emails, former Gov. Snyder ordered water coolers into government buildings.[198]

Around this time, the local General Motors plant switched its water supply and discontinued using the Flint River in car manufacturing.[199] General Motors cited concerns that the water's corrosivity would ruin metal used during the automobile manufacturing process.[200]

Soon thereafter, residents started voicing concerns about the water, informing city officials in community forums that it was causing headaches, rashes, and sickness, especially in children.[201] Residents began toting jugs of discolored water to community forums.[202] One resident, a mother named LeAnne Walters contacted the EPA directly and the EPA conducted testing of lead levels in her home.[203] According to EPA testing, the tap water in Walters's home indicated the presence of iron, and the presence of lead ranging from 200-13, 200 ppb, far in excess of the EPA's limit of 15 ppb.[204] As a reference, the EPA classifies water containing lead above 5,000 ppb as hazardous waste.[205]

The EPA contacted MDEQ with its findings, but MDEQ asserted the lead levels originated from Walters's plumbing, not the source or service lines to her home.[206] The EPA conducted additional testing, inspected Walters's home faucets, and confirmed the lead did not originate from the plumbing in Walters's home but likely originated from service lines.[207] Walters also provided the EPA with medical testing of her children's blood lead levels documenting one child's blood lead levels had tripled since the water supply switch.[208] The EPA issued an interim report in June 2015,

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[197] *Id.*

[198] *Id.*

[199] *See* Clark, *supra* note 160, at 64-65.

[200] *Id.*

[201] *Flint Water Crisis Fast Facts*, *supra* note 159.

[202] *Id.*; *see generally* Clark *supra* note 160; Del Toral, *supra* note 195.

[203] *Flint Water Crisis Fast Facts*, *supra* note 159.

[204] Del Toral, *supra* note 195, at 2, 4. Del Toral's report noted that residents collected samples from the tap according to a specific procedure, which included pre-flushing the water, a method that would minimize the presence of lead that flows from the tap. Del Toral concluded: "actual lead levels at these homes may be much higher."

[205] *Flint Water Crisis Fast Facts*, *supra* note 159.

[206] Del Toral, *supra* note 195, at 3.

[207] *Id.*

[208] *Id.*

documenting a list of violations under the National Primary Drinking Water Regulations, noncompliance with the Lead and Copper Rule, results of testing from Walters's residence, and interim recommendations for legal compliance.[209]

Despite concerns of city residents and the EPA's interim report, Mayor Dayne Walling and representatives from MDEQ denied any problems existed with water quality. In July 2015, one month after the EPA's interim report, Mayor Walling appeared on television to publicly drink from a glass of water, communicating to residents that the water was safe.[210] An MDEQ employee provided an interview to Michigan Public Radio, similarly assuring the public the water was "safe" and anyone who is concerned should "relax."[211]

Two separate professionals began investigating the water and impact to the community, collected data, reported their findings, and spoke to the media.

First, Professor Marc Edwards, a civil and environmental engineer from Virginia Tech University, organized a research team to sample water throughout residential homes in Flint. Edwards and his team found 40% of residential homes had elevated lead levels above the permissible limit, shared the report with MDEQ, and allegedly spent months attempting to notify city and state officials.[212] Edwards subsequently announced the findings in a press conference.[213] In response, MDEQ brushed off Edwards' findings, stating he set out to prove a specific theory, and offering "dire public health advice based on some quick testing could be seen as fanning political flames irresponsibly."[214]

Second, pediatrician Dr. Mona Hanna-Attisha from Hurley Medical Center, began investigating claims of lead contamination by reviewing

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[209] *Id.* at 4-5.

[210] *Flint Water Crisis Fast Facts*, *supra* note 159; Pl.'s Compl., *supra* note 189, at 88.

[211] *Flint Water Crisis Fast Facts*, *supra* note 159; Pl.'s Compl., *supra* note 189, at 88.

[212] *Flint Water Crisis Fast Facts*, *supra* note 159; Pl.'s Compl., *supra* note 189, at 91-92.

[213] *Flint Water Crisis Fast Facts*, *supra* note 159; *see also Our Sampling of 252 Homes Demonstrates a High Lead in Water Risk: Flint Should Be Failing to Meet the EPA Lead and Copper Rule*, FLINT WATER STUDY (Sept. 8, 2015), http://flintwaterstudy.org/2015/09/our-sampling-of-252-homes-demonstrates-a-high-lead-in-water-risk-flint-should-be-failing-to-meet-the-epa-lead-and-copper-rule/.

[214] Pl.'s Compl., *supra* note 189, at 91-92.

children's blood lead levels from routine pediatric screenings and compared their blood lead levels prior to the water supply switch to lead levels following the switch.[215] Hanna-Attisha published her research in the *American Journal of Public Health*, finding that children's blood lead levels doubled after the water supply switch.[216] Officials at MDEQ responded by stating they re-examined the data and found no significant changes in blood lead levels outside the ordinary.[217] MDEQ officials suggested any changes originated from children ingesting lead from other sources and referred to Hanna-Attisha's report as inaccurate and "unfortunate."[218]

Approximately eighteen months after the initial water supply switch, the EPA issued its final report. The EPA described extensive water quality violations, including noncompliance with federal standards, and confirmed contamination from microbes, lead, and total trihalomethanes.[219] In January 2016, the state of Michigan declared an emergency.[220]

5. The Danger of Lead Exposure

Despite a minimum allowable level for contaminants such as lead, scientists and physicians note that there is no safe level of lead exposure for humans.[221] Lead is a potent neurotoxin that impacts biological and developmental processes.[222] Lead has the capacity to enter the blood-brain barrier and affect the central nervous system.[223] Scientists have linked lead exposure to anemia, kidney impairment, neurological illness including learning disabilities, impaired cognition, behavioral disorders, aggression, and death.[224]

In addition to water, lead is present in the environment from sources such as paint, contaminated dust, soil, and consumer products such as

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[215] Hanna-Attisha, *supra* note 160; Hanna-Attisha, *supra* note 162.

[216] Hanna-Attisha, *supra* note 160; Hanna-Attisha, *supra* note 162.

[217] Pl.'s Compl., *supra* note 189, at 93-94.

[218] *Id.*

[219] *Final Report: High Lead Levels in Flint Michigan*, ENV'T PROT. AGENCY (Oct. 21, 2015), https://www.epa.gov/sites/production/files/2015-11/documents/transmittal_of_final_redacted_report_to_mdeq.pdf.

[220] *Flint Water Crisis Fast Facts*, *supra* note 159.

[221] Jennings & Lyons Duncan, *supra* note 163, at 1028.

[222] Simoni Triantafyllidou & Marc Edwards, *Lead (Pb) in Tap Water and Blood: Implications for Lead Exposure in the United States*, 42(13) CRITICAL REV.'S IN ENV'T SCI. & TECH. 1297, 1318-19 (2012).

[223] *Id.*

[224] *Id.*

synthetic turf, children's toys, and dietary supplements.[225] Certain populations face an increased risk of lead's effects. Fetuses, infants, and young children are particularly susceptible to lead exposure.[226] Infants and children may ingest more lead per body weight as compared to adults, and young children have greater hand to mouth activity, which increases their inadvertent ingestion of lead from soil, dust, or toys.[227] Infants are also vulnerable to lead exposure from ingesting formula made with contaminated tap water.[228] Exposure early in life increases risk of developmental impairment and neurobehavioral disorders in childhood and adulthood, affecting the child's lifetime trajectory for intelligence, behavior, and achievement. [229] Hanna-Attisha notes lead exposure is irreversible, life-altering, and costly.[230] Scientists assert that primary prevention is necessary to limit exposure and mitigate potential health risks.[231]

6. Litigation

These tragic and devastating incidents led to multiple lawsuits filed by residents of Flint alleging a variety of legal claims and injuries arising from the ongoing exposure to contaminated water.[232]

7. In Re Flint Water Cases

In Re Flint Water Cases was a class action lawsuit initiated by about 100,000 residents who alleged personal injury and property damage caused

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[225] Triantafyllidou & Edwards, *supra* note 222, at 1305; Hanna-Attisha, *supra* note 160, at 154-55 (discussing sources of lead), 195-97 (discussing compounded lead and environmental justice).

[226] Triantafyllidou & Edwards, *supra* note 222, at 1320.

[227] *Id.*

[228] *Id.*; *see also* Hanna-Attisha, *supra* note 160, at 250-57; Pl.'s Compl., *supra* note 189, at 88 (discussing an email obtained from discovery from Utilities Administrator of the City of Flint to MDEQ pointing to the problem of infants drinking formula with tap water and MDEQ's assurances that the water was safe).

[229] Jennings & Lyons Duncan, *supra* note 163, at 1028.

[230] Hanna-Attisha, *supra* note 162.

[231] *Id.*

[232] In Re Flint Water Cases, 969 F.3d 298, 303 (6th Cir. 2020); *see also* Guertin v. State, 912 F.3d 907, 921, 927-28 (6th Cir. 2019). In *Guertin v. State*, city residents brought a claim for violation of bodily integrity and substantive due process. Plaintiffs alleged the water contamination crisis was predictable and preventable and substantive due process encompasses protecting residents against deprivations by the state. Plaintiffs asserted that Defendants knowingly and intentionally introduced life-threatening substances into the water supply without residents' consent, while repeatedly announcing to the public the water was safe to drink.

by defendants' "deliberate, negligent, and reckless misconduct."[233] The complaint named extensive defendants, including officials that worked at MDEQ, the Flint Water Treatment Plant, and various government officials including Mayor Walling and Gov. Snyder.[234] Plaintiffs asserted that defendants caused a public health crisis by exposing them to contaminated water, exacerbated the crisis by concealing and misrepresenting its scope, and failed to take effective remedial action.[235] According to plaintiffs, these actions resulted in personal injuries such as health harms arising from lead poisoning, property damage to plumbing and homes from corrosive water, and emotional injuries.[236]

Plaintiffs raised several causes of action, alleging defendants violated residents' substantive due process rights. First, plaintiffs relied upon the created danger doctrine, which states that the public has a right to be protected from the dangers created by employees acting under color of law.[237] Here, plaintiffs maintained that the named officials and employees were acting in their official capacity when they made key decisions that fueled the water contamination and permitted it to continue. Second, plaintiffs asserted a claim that defendants' actions violated their right to bodily integrity and substantive due process, asserting that they have a right to be free from unwanted contaminants such as lead, disease causing microbes, and total trihalomethanes that exceed regulatory limits.[238] Finally, plaintiffs also alleged that defendants engaged in a conspiracy to violate plaintiffs' Constitutional rights.[239] Plaintiffs alleged that multiple state officials and employees conspired with other defendants to permit the contamination and subsequently conceal the risk of harm.[240]

Defendants provided a variety of responses, including mistaken interpretation of federal law, and several government officials including Gov. Snyder sought qualified immunity.[241] The Sixth Circuit Court of Appeals

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[233] Pl.'s Compl., *supra* note 189, at 1-5.

[234] *Id.* at 17-33.

[235] *Id.* at 1, 26

[236] *Id.* at 5, 104-05 (describing health risks of lead exposure), 107-08 (discussing Shigellosis and Legionnaires disease outbreaks), 108-11 (discussing property damages including costs of replacing pipes, damages appliances, and water damages to properties).

[237] *Id.* at 203-04.

[238] *Id.* at 167-68.

[239] Pl.'s Compl., *supra* note 189, at 5, 29-32.

[240] *Id*.

[241] *See* In Re Flint Water Cases*,* 969 F.3d 298, 303 (6th Cir. 2020).

denied multiple claims for qualified immunity, stating Gov. Snyder knew or should have known of the risks of water contamination, citing multiple emails from his staff and legal counsel documenting concerns with water quality issues.[242]

The parties reached a massive settlement of $641 million, which went toward establishing a healthcare fund for ongoing medical bills for damage caused by lead exposure.[243]

a. Criminal Allegations

As of the time of this writing, the Michigan State Attorney General also filed criminal charges against multiple defendants involved in the incident.[244] Some defendants settled criminal charges, some charges were dismissed, and some are still pending.[245] Notably, the Attorney General included charging high ranking officials such as former Gov. Rick Snyder and the Flint Public Works Director with criminal charges such as willful neglect of duty, alleging defendants knew what was occurring, knew the potential scope of risk and harm to the public, but failed to remediate the problem.[246]

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[242] *Id.*

[243] Associated Press, *Flint Joins $641 Million Deal to Settle Lawsuits Over Lead in Water*, PBS NEWS Dec. 22, 2020), https://www.pbs.org/newshour/nation/flint-joins-641-million-deal-to-settle-lawsuits-over-lead-in-water; Amelia Benavides-Colón & Beth LeBlanc, *Nearly 85,600 sign up for $641M Flint water settlement, but issues remain*, DETROIT NEWS (May 31, 2021), https://www.detroitnews.com/story/news/michigan/flint-water-crisis/2021/05/31/flint-water-crisis-litigation-settlement-court-filing/5284761001/.

[244] *Nine Indicted on Criminal Charges in Flint Water Crisis Investigation*, MICH. OFF. ATT'Y GEN., https://www.michigan.gov/som/0,4669,7-192-47796-549541--,00.html; Theresa Waldrop et al., *Ex-Michigan Gov. Rick Snyder Charged With Willful Neglect of Duty Related to Flint Water Crisis*, CNN (Jan. 13, 2021), https://www.cnn.com/2021/01/13/us/michigan-former-governor-snyder-flint-water-charges/index.html.

[245] *Nine Indicted on Criminal Charges in Flint Water Crisis Investigation, supra* note 244.

[246] In Re Flint Water Cases, 969 F.3d 298 (6th Cir. 2020).

b. Water Contamination and Alleged Cover-up Redux

Despite these shocking allegations, water contamination, an alleged cover-up, and officials minimizing the extent of the problem has occurred before.[247]

In 2002, Washington, D.C. also made headlines for lead contamination in the public water supply.[248] According to research by Professor Marc Edwards, who conducted testing at both Washington, D.C. and Flint, the incident at D.C. involved more lead poisoning and exposed even more people to contaminated water than Flint.[249] What did not make as many news headlines, however, was a Congressional investigation into the Centers for Disease Control and Prevention's (CDC) response.[250] Once news hit, the CDC published its findings in *Morbidity and Mortality Weekly Report*, stating it only found a small increase in blood lead levels, but testing homes demonstrated that none of the residents had blood lead levels above the threshold of concern.[251] The CDC coordinated distribution of water filters and public notices, conveying the message that the presence of lead was not worrisome.[252]

In 2010, the House of Representatives Committee on Science and Technology published a scathing report on the topic of water contamination

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[247] Alaina Fruge, *How the Washington DC Lead Crisis Foreshadowed Flint*, DETROIT TODAY (Aug. 18, 2019), https://wdet.org/posts/2019/07/18/88422-how-the-washington-dc-lead-crisis-foreshadowed-flint/; PREVENTING HARM – PROTECTING PUBLIC HEALTH: REFORMING CDC'S ENVIRONMENTAL PUBLIC HEALTH PRACTICES, HOUSE OF REPRESENTATIVES COMMITTEE ON SCIENCE AND TECHNOLOGY, 111th CONGRESS (2010), https://www.govinfo.gov/content/pkg/CHRG-111hhrg57173/pdf/CHRG-111hhrg57173.pdf;
see also Sacred Huff, *Overcoming Environmental Racism: A Lesson from the Votin g Rights Act of 1965*, 11 GEO. WASH. J. ENERGY & ENV'T L. 22 (2020) (discussing environmental risk arising from air, water, and soil contamination).

[248] Fruge, *supra* note 247; PREVENTING HARM – PROTECTING PUBLIC HEALTH, *supra* note 247.

[249] Fruge, *supra* note 247; Michael Andrei, *Failure to Learn from D.C. Water Crisis Led to Flint, Edwards Tells UB Audience*, UNIV. BUFFALO RSCH. NEWS (Oct. 20, 2016), http://www.buffalo.edu/ubnow/stories/2016/10/edwards-renew-lecture.html.

[250] PREVENTING HARM – PROTECTING PUBLIC HEALTH, *supra* note 247; *see also* Clark, *supra* note 160, at 105-07.

[251] *Blood Lead Levels in Residents on Homes with Elevated Lead in Tap Water – District of Columbia*, 2004, 53(12) MORBIDITY & MORTALITY WKLY. REP. 268-270 (April 2, 2004).

[252] Andrei, *supra* note 249.

and the CDC's response in D.C.[253] The report detailed allegations of CDC officials' forgery and data manipulation.[254] Congress's investigation uncovered how CDC officials excluded homes with the highest lead levels, and conducted blood lead level testing on people who were drinking bottled water, not tap water.[255] The hearing concluded that the CDC's response encompassed multiple systemic failures: it did not appropriately design public health studies, it failed to adequately validate public health data, and failed to sufficiently examine public health consequences.[256] According to the committee, this resulted in flawed, incomplete, or scientifically unsound conclusions.[257]

C. Lessons for Public Health

These examples provide significant lessons to take forward for how scientists, policymakers, and public health officials can cause harm with targeted policies or fail to protect the public interest through misrepresentations and suppressing evidence of wrongdoing.

The history of eugenics provides a reminder that broad acceptance among scientists declaring a proposition as scientific truth is not sufficient to discern the veracity of a specific claim. Consensus without dissent permits incorrect and harmful public health policy to flourish. Moreover, the law can incorrectly legitimize application of public health science in a manner that justifies sacrificing the liberty of individual rights in the name of protection and safety for the public good. The public should rightfully and stringently scrutinize policies that cloak demands to extract individual liberty or compromise Constitutional rights in exchange for enhancing public welfare.

The contemporary example of water contamination in both Flint and Washington, D.C. illustrates that unfathomable harm to the public can occur when multiple individuals charged with protecting the public health abdicate their duties. In Flint, residents who voiced concerns and questioned the water's status were met with hostility and derision. Officials downplayed potential risks, denied existence of the problem, and even maligned experts

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[253] PREVENTING HARM – PROTECTING PUBLIC HEALTH, *supra* note 247.
[254] *Id.* at 23.
[255] *Id.* at 41, 48.
[256] *Id.* at 5, 7, 11.
[257] *Id.* at 5, 50.

who spoke out.[258] The public should be skeptical of propagandistic assurances of safety and testing when officials present conclusions without clear evidence or that appear contrary to the evidence. Restoring and retaining public trust requires closely evaluating doubts, thoroughly investigating allegations, assessing compliance, and upholding principles of transparency and accountability.

IV. WHEN CONSPIRACIES IN SCIENTIFIC RESEARCH CAUSE HARM

Research involving human subjects is imperative for both science and medicine to understand the disease process, how certain diseases develop, why certain people develop disease and others do not, and to be able to test what treatments and therapies are effective. Despite the critical importance of research to further generalizable knowledge, several instances throughout history demonstrate cases when researchers elevated the plight for advancing science above the interests of people involved in the research.

First, this section will provide a description of research studies in history, including the well-known example of research observing the course of syphilis conducted by the U.S. Public Health Service at Tuskegee Institute. This section will also describe lesser-known examples where the Department of Defense used the American public as unwitting test subjects for biological weapons and the effects of nuclear radiation on the human body.

Second, this section will describe a more recent example in *Grimes v. Kennedy Krieger Institute*, where researchers withheld critical information about risks of lead exposure for children. These research protocols demonstrate how powerful stakeholders may conceal the true purpose of the study, the risks involved, or in some cases even the fact that they are conducting research in their quest to seek scientific prestige and power, exposing the participants to undue harm in the process.

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[258] Colleen Boufides et al., *Learning from the Flint Water Crisis: Restoring and Improving Public Health Practice, Accountability, and Trust*, 47 J.L., MED. & ETHICS 23-26, 24 (discussing accountability and downplaying harm), 25 (discussing strategies to restore public trust) (2019).

A. Research Ethics History: Observing the Public and Experimenting on the Public

1. U.S. Public Health Service Study of Syphilis at Tuskegee

a. Description of the Study

The U.S. Public Health Service (USPHS) Study of Syphilis at Tuskegee Institute is one of the most widely known examples of research ethics violations. The study occurred from 1932 until 1972, prior to the formal development of research ethics law in the U.S.[259] Despite lack of formal laws governing human subject research, academic publications and textbooks from the era documented foundational standards for conducting research, such as preventing harm and obtaining informed consent from participants.[260]

In 1929, the USPHS began conducting studies on the prevalence of syphilis in Macon County, Alabama, and discovered unusually high rates of untreated syphilis among black men.[261] U.S. Surgeon General H.S. Cumming wrote to the Director of the Tuskegee Institute, characterizing the high incidence of disease concentrated among the population as an "unparalleled opportunity for carrying on this piece of scientific research."[262] USPHS characterized the research as observational, or a "study in nature," and a means to observe the natural course of syphilis in men who were already infected.[263]

At the time, understanding the course of syphilis was in its infancy, and no effective treatments were available.[264] In one study during the 1920s, a scientist observed exposure to the syphilis spirochete bacteria appeared to affect people differently: 27.9% of untreated patients experienced spontaneous regression and displayed no disease symptoms, estimating 70%

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[259] Office for Human Research Protections*, Federal Policy for the Protection of Human Subjects*, U.S. DEP'T HEALTH & HUM. SERV.'S, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

[260] Allan Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8(6) HASTINGS CTR. REP. 21, 26 (1978).

[261] *Id.*; *see also* David Smolin, *The Tuskegee Syphilis Experiment, Social Change, and the Future of Bioethics*, 3 FAULKNER L. REV. 229, 229-30 (2012).

[262] Brandt, *supra* note 260, at 22.

[263] *Id.*

[264] Smolin, *supra* note 261, at 230.

of patients went through life without serious symptoms.[265] Early figures suggested that the other 30% of patients with untreated syphilis progressed to serious complications, such as cardiovascular disease, neurological decline, and death.[266] The treatments physicians offered during the time included mercury, and subsequently arsenic, both compounds which not only offer no medical value, but which the World Health Organization currently classifies as highly toxic to humans.[267]

USPHS sent Dr. Raymond Vonderlehr to begin recruiting men to participate in the study, informing them they had "bad blood," which was the vernacular for syphilis, and promised them free treatment.[268] Over time, the study included 400 men with syphilis and 200 uninfected men as controls.[269] Initially, researchers offered standard treatments, such as mercurial ointment and neoarsphenamine.[270] Throughout the study, researchers provided "spring tonic," aspirin, medical visits, transportation to appointments, and hot meals.[271] Notably, the protocol also included invasive interventions, such as drawing participants' blood and performing spinal punctures to sample spinal fluid.[272] To induce men to participate in painful spinal punctures, letters to subjects stated, "You will now be given your last chance for a final examination…this examination is a very special one…this is your last chance for a special free treatment."[273]

The protocol continued to examine subjects following their death, and USPHS promised participants that if they died during the study it would cover the family's burial expenses.[274] In addition to burial benefits,

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[265] Brandt, *supra* note 260, at 23.

[266] *Id.*; *see also Syphilis*, MAYO CLINIC https://www.mayoclinic.org/diseases-conditions/syphilis/symptoms-causes/syc-20351756.

[267] *Mercury and Health*, WORLD HEALTH ORG. (March 31, 2017), https://www.who.int/news-room/fact-sheets/detail/mercury-and-health; *Arsenic*, WORLD HEALTH ORG. (Feb. 15, 2018), https://www.who.int/news-room/fact-sheets/detail/arsenic#:~:text=Arsenic%20is%20highly%20toxic%20in,cause%20cancer%20and%20skin%20lesions.

[268] Brandt, *supra* note 260, at 24.

[269] *Id.* at 21.

[270] *Id.* at 24.

[271] *Id.* at 25.

[272] *Id.*

[273] *Id.* at 24.

[274] Allan Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8(6) HASTINGS CTR REP. 21, 25 (1978).; Smolin, *supra* note 261, at 232.

researchers discussed the utility of participants' bodies after their death.[275] Surgeon General Cumming explained autopsying the bodies would provide scientific insight to internal organ damage and confirm how syphilis progresses in the body.[276] However, written communication between physician researchers revealed conversations discussing the importance of maintaining secrecy of the project's new autopsy aim, noting that revealing this information would discourage participation.[277]

Despite the USPHS representing the research as an observational study, physician researchers intervened multiple times to prevent participants from receiving evolving treatment. In 1928, Alexander Fleming discovered the mold penicillin, an antibiotic that destroyed certain bacteria including syphilis spirochetes.[278] Physicians began treating patients with syphilis with penicillin in 1943.[279] Vonderlehr met with groups of local physicians, sent letters to local clinics, and warned the Alabama Health Department not to treat men who presented with syphilis but refer them back to the USPHS researchers.[280] When the Army drafted men from Macon County that were also participants in the study and indicated they should begin penicillin treatment, USPHS similarly requested that the military exclude the men from treatment.[281] Vonderlehr viewed the availability of treatment as a potential research obstacle, lamenting, "I hope the availability of antibiotics has not interfered too much with this project."[282] Indeed, if the protocol provided treatment this would disrupt the original study aim and undermine the potential gain of scientific knowledge.

In the 1960s, physician researchers met at the CDC to discuss whether they should modify the study to provide the available treatment of penicillin or whether to discontinue the study. One physician reasoned against intervening with penicillin, asserting "these people were at the point that therapy would no longer help them. They are getting better medical care

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[275] One physician researcher Dr. O.C. Wenger stated, "We have no further interest in these patients until they die." Brandt, *supra* note 260, at 24.

[276] *Id.* at 22.

[277] *Id.* at 25.

[278] Adriane Gelpi & Joseph Tucker, *A Cure at Last? Penicillin's Unintended Consequences on Syphilis Control*, 1944–1964, 91(1) SEXUALLY TRANSMITTED INFECTIONS 70 (2015); *Syphilis Treatment and Care*, CTR.'S DISEASE CONTROL & PREVENTION, https://www.cdc.gov/std/syphilis/treatment.htm.

[279] Brandt, *supra* note 260, at 25.

[280] *Id*.

[281] *Id.* at 25-26.

[282] *Id.* at 26.

than they would under any other circumstances."[283] The CDC meeting concluded that researchers should continue the study "along present lines."[284] One physician involved, Dr. John Cutler, justified the importance of continuing the study as leverage in the struggle against disease, gain scientific knowledge, and improve medical progress.[285] The USPHS research continued until the Health, Education, and Welfare Committee launched an investigation and published a report in 1973.[286]

b. Lessons from the USPHS Study of Syphilis at Tuskegee Institute

The Health, Education, and Welfare Report concluded the USPHS study "was ethically unjustified," lacked informed consent from participants, and was "scientifically unsound."[287] Historian Allan Brandt details numerous deficiencies in the protocol relating to informed consent.[288] Subjects participated based on therapeutic misconception, or the belief that they were receiving medical treatment.[289] However, as Brandt notes submitting voluntarily does not constitute informed consent, which was the minimal standard for conducting ethical research during the era.[290] Multiple components of the protocol relied on active deception and withholding key details: the purpose of the study, information about the disease, the purpose of spinal punctures, information about the availability of medication, and the aim to autopsy participants' bodies. Exclusion from treatment exemplifies the principle of elevating the perceived priority to gain scientific knowledge above individual welfare.

Despite egregious ethical violations, multiple physician researchers not only defended the study but received public praise and career accolades

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[283] *Id*.

[284] *Id.*

[285] Dr. John Cutler was involved in both the USPHS Study of Syphilis at Tuskegee and also research funded by the USPHS and National Institutes of Health to study sexually transmitted disease in Guatemala. In Guatemala, Cutler's protocol involved deliberately infecting participants with bacteria to induce sexually transmitted disease and monitoring the course of disease. Cutler received numerous career accolades, worked for the World Health Organization, received a promotion to Assistant Surgeon General in the USPHS, and the media referred to him as a "pioneer." *See* Smolin, *supra* note 261, at 232-33.

[286] Brandt, *supra* note 260, at 25-26.

[287] *Id.*

[288] *Id.* at 27.

[289] *Id.* at 24.

[290] *Id.* at 27.

for their contributions to science and medicine. Cutler, for example, viewed this research as progressive, scientific, and rational.[291] Legal scholar David Smolin posits that researchers justified their concerted deception because they focused on the promise of the research's end goal to promote the advancement of knowledge and enhance medical progress.[292] Elevating the notion that science constitutes the highest value permits a system that will accept secrecy and harm to individual people as an amoral or even necessary step in the pursuit of true progress. Importantly, this ideology entails a mindset shared by multiple scientists, which has led to a litany of research ethics violations in the name of beneficial science.[293]

2. Experimenting on the Public in the Name of National Security

While scientists justify some research as a contribution to generalizable knowledge and a way to further medical progress, other research conducted by the military and the U.S. Department of Defense (DOD) aims to protect national security. During the Cold War, the DOD partnered with scientists at universities, medical centers, and research institutions to focus their efforts on increasing knowledge and assessing vulnerabilities in the area of biological, chemical, and nuclear warfare. From 1949 to 1974, these experiments involved hundreds of separate projects, throughout hundreds of cities across the U.S., and involved at least half a million civilians.[294] Despite the importance of both advancing knowledge and protecting national security, scientists shrouded these projects in secrecy, extending in some cases to the very fact that the experiments occurred. In 1994, Congress conducted an investigation detailing de-classified secret

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[291] Smolin, *supra* note 261, at 233-35.

[292] *Id.*

[293] *Id.* at 236-38.

[294] Cold War Era Human Subjects Experiments, Hearing Before the Legislation and National Security Subcommittee, 103RD CONGRESS (Sept. 28, 1994), https://archive.org/details/coldwarerahumans00unit at 6-7, 10-11, 21-22, 70-71, 133; *See also* JUDITH MILLER, GERMS: BIOLOGICAL WEAPONS AND AMERICA'S SECRET WAR (2002); Stephen Kinzer, *The Secret History of Fort Detrick, the CIA's Base of Mind Control Experiments*, POLITICO (Sept. 15, 2019), https://www.politico.com/magazine/story/2019/09/15/cia-fort-detrick-stephen-kinzer-228109; *Secret Testing in the United States*, PBS, https://www.pbs.org/wgbh/americanexperience/features/weapon-secret-testing/#:~:text=The%20start%20of%20the%20Cold,national%20vulnerabilities%20to%20biological%20warfare.

experiments during the Cold War era, documenting harm to the public interest in the name of national security and public safety.[295]

3. Biological Weapons Testing During the Cold War Era

Scientists began a series of domestic tests across the U.S. to understand vulnerability to biological weapons attacks, investigate potential dispersion patterns of biological agents, methods of application, and effects of exposure to the public.[296] In 1953, the Army Chemical Corps created the St. Jo program, which staged mock anthrax attacks in cities such as St. Louis, Minneapolis, and Winnipeg, Canada, designed to simulate cold weather similar to the Soviet Union.[297] Scientists placed generators atop moving cars that released anthrax bacteria over the cities.[298] Subsequent tests involved assessing dispersal patterns from aircrafts to understand range of bacteria travel and the "feasibility for covering large areas of the country with biological weapons agents."[299] Scientists conducted other tests in highly concentrated public areas, such as releasing serratia marcescens bacteria in Washington's National Airport, over the city of San Francisco, and shattering lightbulbs filled with serratia marcescens in the New York subway system.[300] At the time, scientists asserted the bacteria was harmless.[301]

Most of the American public remained unaware of exposure to potential biological weapons, leading to confusion when members of the public became ill, hospitalized, or developed long-term complications allegedly relating to exposures.[302] After release of serratia marcescens in San Francisco, eleven people were hospitalized at Stanford Hospital with cardiac and urinary infections, and one patient died.[303] The U.S. Army convened a panel to assess the program following the hospitalizations, concluding the

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[295] Cold War Era Human Subjects Experiments, *supra* note 294, at 6-7, 10-11, 21-22, 70-71, 133; *See also* MILLER, *supra* note 294; Kinzer, *supra* note 294; *Secret Testing in the United States*, *supra* note 294.

[296] Miller, *supra* note 294; Kinzer, *supra* note 294; Cold War Era Human Subjects Experiments, *supra* note 294, at 11, 88.

[297] Kinzer, *supra* note 294; Miller, *supra* note 294, at 35-42.

[298] Kinzer, *supra* note 294; Miller, *supra* note 294, at 35-42.

[299] Kinzer, *supra* note 294.

[300] Miller, *supra* note 294, at 35-42; Kinzer, *supra* note 294; Cold War Era Human Subject Experimentation, *supra* note 294, at 11, 86-88, 132.

[301] Cold War Era Human Subject Experiments, *supra* note 294, at 11; Millers, *supra* note 294, at 42.

[302] Cold War Era Human Subject Experimentation, *supra* note 294.

[303] *Id.* at 132.

outbreak of infections was merely "coincidental" and ordered the program to continue.[304]

4. Nuclear Radiation Testing During the Cold War Era

In addition to large scale dispersal of biological weapons, the U.S. Atomic Energy Commission in conjunction with the USPHS conducted a variety of nuclear radiation experiments, including nationwide atmospheric nuclear radiation testing and total body irradiation.[305] In one set of tests, aircrafts dispersed thousands of pounds of zinc cadmium sulfide over 239 U.S. cities.[306]

Decades after testing in 1994, a U.S. Army Chemical and Biological Defense Commander testified to Congress that the projects entailed releasing "metals with a sulfur compound," that "acute effects are relatively benign," "fairly innocuous," and the Pentagon classified this exposure to zinc cadmium sulfide as "harmless."[307] At the Army's request, the CDC also conducted a review of the public's exposure during these tests, concluding they posed "negligible risk" to the public.[308]

Despite the Army and CDC's assurances, a litany of scientific testimony during the Congressional hearing supported the opposite conclusion. Scientists submitted academic articles dating back to 1932 that extensively documented how cadmium enters the body, stating that even small amounts are sufficient to cause damage, how cadmium is "far from harmless," "a dangerous substance that should be avoided even in small amounts," and documented how exposure can induce pneumonia and permanent lung damage in humans.[309] According to current classification by the Occupational Health and Safety Administration, low levels of exposure to cadmium can cause flu-like symptoms such as fever, chills, muscle pain, and lung damage.[310] Presently, the Agency for Toxic Substances and Disease Registry classifies cadmium as a probable human carcinogen.[311]

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[304] *Id.*

[305] *Id.* at 6-7, 10-11, 21-22, 70-71, 133.

[306] *Id.*

[307] *Id.* at 78-79, 131.

[308] Cold War Era Human Subject Experiments, *supra* note 294, at 22-31, 78-79.

[309] *Id.* at 172-82.

[310] *Cadmium*, OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/cadmium/health-effects.

[311] *Cadmium Toxicity*, AGENCY TOXIC SUBSTANCES & DISEASE REGISTRY, https://www.atsdr.cdc.gov/csem/cadmium/cover-page.html.

5. In re Cincinnati Radiation Litigation

In 1960, the DOD and USPHS partnered with physicians at Cincinnati General Hospital to fund research designed to study the effects of total body irradiation to increase scientific understanding of the potential impact of nuclear warfare and radiation on battlefield troops.[312] Physicians employed by the DOD, the City of Cincinnati, and the University of Cincinnati recruited 87 patients who had cancer and began testing the effects of radiation exposure in the Human Radiation Experiments.[313] Physician researchers aimed to assess what constituted the maximum level of radiation before the participants experienced adverse health effects, methods to shield participants from deleterious effects of radiation, and the impact of radiation to participants' cognitive abilities and central nervous system.[314]

Physician researchers selected indigent patients with low levels of educational attainment for participation; and the majority of participants were black.[315] During the informed consent process, researchers told the participants they were receiving treatment for their cancer and would be "participating in scientific research" without additional detail.[316] However, researchers did not design the protocol to include any treatment; rather, investigators designed the study solely to assess the psychological and physical effects of radiation to increase generalizable knowledge.[317] Participants were not terminal patients, nor where they close to death.[318] Researchers omitted information on significant risks of radiation exposure, such as bone marrow infection, nausea, vomiting, burns, pain, and carcinogenicity.[319] The Human Radiation Experiments shortened participants' life expectancies, induced physical and emotional suffering, and led to the death of several participants.[320]

Decades later, participants discovered the nature of the Human Radiation Experiments and filed suit against the physicians involved. Plaintiffs alleged a variety of claims including negligence, malpractice,

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[312] In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 802 (S.D. Ohio 1995); Cold War Era Human Subject Experiments, *supra* note, 294, at 70-71.

[313] In re Cincinnati Radiation Litigation, 874 F.Supp. at 803-04.

[314] *Id.*

[315] *Id.*

[316] *Id.*

[317] *Id.*

[318] *Id.* at 802.

[319] In re Cincinnati Radiation Litigation, 874 F.Supp. at 802.

[320] *Id.* at 804.

fraud, battery, negligent infliction of emotional distress, constitutional violation of substantive due process, and a conspiracy to deprive plaintiffs of their constitutional rights.[321]

Defendants asserted that participants came to the hospital voluntarily, chose to accept radiation "treatment," and could have left during any time.[322] Defendants sought qualified immunity and filed for a motion to dismiss.[323]

The Ohio district court swiftly rejected defendants' reasoning, noting physicians falsely misrepresented the nature of participation to subjects by informing them they were receiving treatment rather than participating in research, which undermined the defense of voluntary participation.[324] The court denied defendants' motion for qualified immunity and denied the motion to dismiss.[325] The court found adequate facts to support a potential claim for violation of substantive due process, and provided extensive discussion of why forcibly exposing a nonconsenting person to an unwanted medical procedure constitutes an invasion of bodily integrity and unjust interference with personal liberty.[326] Quoting John Locke and Thomas Jefferson, the court opined the very purpose of law is designed to protect against coercion by the government, restrain government action, and protect liberty and self-determination in matters of personal health.[327] In dicta, the court stated the Human Radiation Experiments amounted to a state sponsored invasion of bodily integrity, demonstrating callous indifference and a conscious disregard for the rights and welfare of the participants.[328] These actions, according to the court, could support plaintiffs' allegations that defendants engaged in a conspiracy to deprive plaintiffs of their constitutional rights.[329]

Finally, the court addressed whether defendants' conduct constituted a constitutional violation based on research ethics guidelines and law that existed when researchers began the Human Radiation Experiments.

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[321] *Id.* at 805-05.
[322] *Id.* at 811-12.
[323] *Id.*
[324] *Id.* at 811-12.
[325] In re Cincinnati Radiation Litigation, 874 F.Supp. at 814, 822.
[326] *Id.* at 812.
[327] *Id.* at 815-16.
[328] *Id.* at 804, 812, 818.
[329] *Id.* at 830. Plaintiffs alleged violation of 42 U.S.C. 1985(3), stating that defendants engaged in a conspiracy to violate their privileges and immunities under the law.

Although the research occurred prior to modern human subjects research law, the court noted that the Nuremburg Code and guidelines set forth by the National Institutes of Health in the 1950s set forth specific expectations such as informed consent, prohibition against deceit or fraud, and a requirement to avoid undue suffering.[330]

6. Lessons on Science in the Name of National Security

The examples of biological weapons testing and nuclear radiation experiments reflect a narrowly focused mission, propelling decisions that promote research designed to increase national security and gain scientific leverage against enemy forces. Particularly during times of international conflict and security threats, scientists, physicians, and government officials exhibited the mindset that protecting the public interest not only justified, *but required*, research using human participants. Indeed, when members of Congress questioned General William Creasy in 1994 about the bioweapons program, he responded this type of test could *only* be conducted without informed consent; it would be impossible to obtain consent.[331] The subtext beneath his statement reveals an urgency and exceptionalism justifying the necessity of this research wherein powerful stakeholders determine that the sacrifice of some people is strategically necessary in the process of gaining knowledge to secure the nation as a whole.

The Cold War biological weapons testing and radiation experiments constitute the ultimate example of an extensive conspiracy. The experiments were marked by complete secrecy that they even existed and entailed collaboration among multiple government agencies and professionals such as scientists, physicians, and government officials. Records also demonstrate clear minimum standards for conducting human subjects research and indicated exposing participants and the public to grave harm without their knowledge or consent would constitute a clear violation of research ethics.[332] Key stakeholders including the DOD, scientists, physicians, USPHS, and the CDC minimized and downplayed potential harm to participants despite extensive documentation of immense suffering, long term health risks, and deaths.

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[330] *Id*. at 819-21.

[331] Cold War Era Human Subject Experimentation, *supra* note 294, at 132.

[332] *Id.* at 118-19 (describing the principle of informed consent and minimal standard of shielding participants from grave bodily harm).

Thus, stakeholders designed and conducted the research not due to an absence of standards, but rather the perception that these requirements *did not apply* based on perceived exigency and the critical scientific value of research. Importantly, the mission statement driving the DOD, CDC, and USPHS suggests that stakeholders could reasonably believe their actions correctly aligned with the purpose of each agency.[333] Each agency's present mission prioritizes national security, increasing health security, and developing public health science.[334] Organizational ethics that focus on the communitarian level support the proposition that sacrificing the health and welfare of some for perceived utilitarian benefit is not only permissible, but potentially necessary and honorable.[335] To be sure, organizations designed to protect national security are vital; yet they must operate within a framework that recognizes the individual dignity, worth, and liberty of each person as a primary value rather than a secondary (or contingent) aim subordinate to national interests.

B. Contemporary Research Ethics and Subtle Deficiencies

1. A Snapshot of Research Ethics Today

While historical examples of research ethics violations exhibit glaring deficiencies such as precluding participants from effective treatment or inducing deliberate physical harm, modern research ethics violations entail subtle deviations from research ethics. These violations include conducting research outside the scope of initial consent,[336] representing that the research

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[333] *Id.* at 128, 144.

[334] *Id.*

[335] *About*, U.S. DEP'T DEF., https://www.defense.gov/our-story/; *Mission, Role and Pledge*, CTR.'S DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/organization/mission.htm; *About Us*, U.S. PUB. HEALTH SERV., https://www.usphs.gov/about-us.

[336] A prominent example of conducting research outside the scope of consent includes the case of the *Tilousi v. Arizona State University*. Researchers at Arizona State University recruited participants to obtain health and DNA blood samples from the Havasupai Tribe ostensibly to conduct research on diabetes, but instead used the tribe's DNA to study population migration, inbreeding, and schizophrenia. In other research, I've provided detailed accounts of how deliberate omissions, misrepresentations, and violations of research ethics in this example resulted in dignitary and cultural harm to the tribe, simultaneously painting participants as hysterical while praising the investigator for "doing good science." *See* Katherine Drabiak, *Lessons from Havasupai Tribe v. Arizona State University Board of Regents*: *Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks*

mirrors clinical care,[337] or minimizing risk of participation.[338] Other areas of research capitalize on the promise of science as savior to erase disease and suffering, promising fantastic speculative benefits to induce acceptance of risky and controversial research, such as modifying the germline of human embryos or performing chimeric research.[339]

Despite seemingly minor deficiencies, some protocol may omit critical information as a strategic method for physicians or scientists to incentivize participation in the pursuit of their scientific goal. Investigators shield a secret of great importance from participants and work in concert to pursue what they perceive as imperative scientific progress. However, these violations still expose participants to undue risks, adversely impact participants' health and welfare, and undermine trust in scientific research.

Warranting Integration into Research Practice, 6 J. HEALTH & BIOMEDICAL L. 175-225 (2010); *see also* Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES (April 21, 2010), https://www.nytimes.com/2010/04/22/us/22dna.html.

[337] In the SUPPORT study, investigators at 22 medical centers across the U.S. recruited premature infants to investigate the optimal oxygen saturation level and randomly assigned infants set oxygen levels within a higher or lower range. The Office of Human Research Protections concluded that the study did not provide parents adequate informed consent because it presented that the study was providing the infants the ordinary standard of care. However, the protocol set oxygen saturation levels without assessing the infant's specific need or applying the physician's judgment. The infants with higher oxygen saturation levels suffered an increased risk of retinopathy and infants assigned lower oxygen saturation levels suffered an increased risk of death. *See* George Annas & Catherine Annas, *Legally Blind: The Therapeutic Illusion in the Support Study of Extremely Premature Infants*, 30 J. CONTEMP. L. & POL'Y 1-36 (2013).

[338] *Id.*; *see also* Grimes v. Kennedy Krieger Institute, 782 A.2d 807 (Md. Ct. App. 2001).

[339] This type of research occurred in two contexts of Mitochondrial Replacement Therapy and human genome editing of human embryos to create children. In both experimental contexts, scientists conducted highly risky research in secret, revealing the infants after birth. Researchers promised fantastic benefits and downplayed risks, raising a litany of legal and ethical concerns. *See* Katherine Drabiak, *Untangling the Promises of Human Genome Editing*, 46 J. L., MED. & ETHICS 991-1009 (2018); Katherine Drabiak, *Emerging Governance of Mitochondrial Replacement Therapy: Assessing Coherence Between Scientific Evidence and Policy Outcomes*, 20(1) J. HEALTH CARE L. 1-61 (2018).

2. Lead Abatement and Grimes v. Kennedy Krieger Institute

In 1993, Kennedy Krieger Institute in collaboration with Johns Hopkins University obtained funding from the EPA, the Maryland Department of Housing and Community Development, and the Baltimore City Health Department to study the effects of lead paint abatement in low-income housing in Baltimore, Maryland.[340] The project required that small children be present in the houses.[341] To facilitate that purpose, the landlords agreeing to participate in the studies were encouraged, if not required, to rent the properties to tenants who had young children.[342] At the time, the researchers involved were aware of the risks associated with lead exposure and the increased risk lead exposure posed to children.[343] Investigators designed the study that would assess the impact of different levels of lead abatement repair and maintenance to lead exposure by measuring samples such as dust, soil, water, and children's blood lead levels as a proxy.[344] The investigators selected children residing in these homes and compensated the families for participation.[345]

During the study, investigators obtained consent from parents to permit their children to participate and obtain the children's blood samples to measure lead levels. The informed consent communicated the purpose of the study was designed to measure "how well different practices work to reduce exposure to lead in paint and dust."[346] Two children who lived in homes whose blood lead level tests increased throughout the study filed a lawsuit, alleging claims including negligence, lack of informed consent, and research ethics violations.[347] The parents of the children asserted investigators did not inform them of the presence of lead in their home, the danger of lead, or connect that the children's blood tests monitored the

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[340] Grimes v. Kennedy Krieger Institute, 782 A.2d 807 (Md. Ct. App. 2001); Richard Morse, *Grimes v. Kennedy Krieger Institute* – Nontherapeutic Research with Children, 5(11) AMA VIRTUAL MENTOR 383-85 (2003).

[341] *Grimes*, 782 A.2d at 821.

[342] *Id.*

[343] *Id.* at 812-13.

[344] *Id.*

[345] *Id.* at 843.

[346] *Id.*

[347] *Grimes*, 782 A.2d at 843.

accumulation and increase in children's blood lead levels that occurred during the study.[348]

Importantly, the plaintiffs asserted that KKI performed the abatement procedures in a manner that *increased* rather than *decreased* lead dust in the home, resulting in their children's blood lead levels increasing throughout the study.[349] Plaintiff Ericka Grimes suffered from lead poisoning, but investigators did not communicate results of her blood lead level tests to her mother, Mrs. Hughes, until nine months after discovering in the study that her blood lead levels indicated she was suffering from lead poisoning.[350]

Indeed, investigators withheld information about risk of lead, the presence of lead in the home, and the children's blood lead levels because if the children left the home following investigators' identification of lead in the home or blood, this would undermine the very purpose of the study.[351] This also meant parents were unaware and could not appropriately respond to information that their child's blood lead level increased during the study.[352]

KKI moved for summary judgment, asserting it had no special duties to the children, but was acting merely as a community volunteer collecting dust and blood samples to check for lead.[353]

The Court of Appeals of Maryland held investigators did not obtain sufficient informed consent from parents.[354] The protocol failed to connect the reason that investigators were testing children's blood to measure the presence of lead, the success of the lead abatement, and the risks associated with lead exposure and accumulation in children.[355] As health policy experts Anna Mastroianni and Jeffrey Kahn noted, the protocol contained a stark deficiency because investigators knew lead exposure posed more than minimal risk to the children participating in the study, but did not

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[348] *Id.*; Morse, *supra* note 340, at 383.

[349] *Grimes,* 782 A.2d at 828; Morse, *supra* note 340, at 383.

[350] *Grimes,* 782 A.2d at 826.

[351] *Id.* at 823-24.

[352] Anna Mastroianni & Jeffrey Kahn, *Risk and Responsibility: Grimes v. Kennedy Krieger Institute, and Public Health Research Involving Children*, 92(7) AM. J. PUB. HEALTH 1073, 1074 (2001); *see also* Leonard Glantz, *Nontherapeutic Research with Children: Grimes v. Kennedy Krieger Institute*, 92(7) AM. J. PUB. HEALTH 1070-73 (2001).

[353] *Grimes,* 782 A.2d at 832.

[354] *Id.* at 844, 846-50.

[355] *Id.*

communicate this to parents.[356] The court also held that parents cannot provide consent for their children to participate in nontherapeutic research that poses more than minimal risk.[357] In response, some scientists expressed concern that this ruling would hinder important future research projects.[358]

3. Lessons from Contemporary Research Ethics Violations

The case of *Grimes v. Kennedy Krieger Institute* and contemporary cases exemplifies the proposition that multiple highly trained and prestigious investigators working in concert may misrepresent key details, downplay risk, or omit critical information in the pursuit of scientific knowledge and prestige. Despite the importance of some types of research, some flaws originate from how investigators designed the protocol. In other areas of research, scientists may inflate potential benefits and promises while concealing significant risk because accurately disclosing risk would reveal the potential for inducing grave harm to participants. In these cases, no matter how novel and exciting the projected outcome, certain types of research should not be conducted at all if they would plainly violate human rights and participants' welfare.[359]

V. WHEN CONSPIRACIES IN MEDICINE CAUSE HARM

Medicine relies on innovation and discovery to increase physicians' understanding of the human body, the disease process, and how to effectively treat and cure patients.[360] Ideally, physicians and pharmaceutical companies translate scientific knowledge to improve clinical care for patients. However, this section provides two examples when key stakeholders in medicine – physicians and pharmaceutical companies – leveraged their knowledge and power to adversely affect the public's health.

First, this section describes a historical example when physicians acting through the American Medical Association used their influence to exclude non-allopathic providers from the healthcare market as a mechanism

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[356] Mastroianni & Kahn, *supra* note 352, at 1074.

[357] *Id.*

[358] *See* Merle Spriggs, *Canaries in the Mines: Children, Risk, Non-Therapeutic Research and Justice*, 30 J. MED. ETHICS 176-81 (2004).

[359] Evelyne Schuster*, Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENGLAND J. MED. 1437-40 (1997).

[360] Marc Shampo, *The Millennium and Medicine: The 10 Most Influential Persons*, 75(1) MAYO CLINIC PROC.'S 119-21 (2000).

for preserving power. According to the Seventh Circuit Court of Appeals, these actions amounted to a conspiracy against the chiropractic profession.[361]

Second, this section describes recent litigation alleging pharmaceutical companies impeded patient access to critical medications by engaging in anticompetitive business practices and conspiring with other manufacturers to raise drug prices for inappropriate financial gain in violation of federal and state laws. Conspiracies in medicine can hinder the scope of healthcare practice, limit patient choice, and raise costs.

A. History of Medicine: Licensing and the Role of American Medical Association

1. History of Medical Licensing

In 1846, the American Medical Association (AMA) was formed with the goal of improving medical education and the medical profession.[362] It sought to introduce minimal standards for medical education, save the profession from the influence of unscientific and unscrupulous providers, and enact a system of licensing.[363] During this time, a variety of medical providers existed, including homeopaths, naturopaths, osteopaths, and allopathic physicians.[364] The AMA lobbied states to enact licensing laws to ensure providers held certain minimum qualifications and education, had the requisite skill and ability to effectively treat the sick, and protect the public from ineffective therapies or remedies that would endanger the public health.[365] In theory, standardizing education and establishing requirements for the profession strengthens quality of care.

Despite the benefits of licensing, physician and health law professor Gregory Dolin notes that allopathic physicians began to use licensing as a tool to exclude other forms of medicine, minimize competition, and punish providers practicing non-allopathic medicine.[366] During the early 1900s, hundreds of chiropractors were arrested and imprisoned for the crime of

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[361] Wilk v. American Medical Association, 895 F.2d 352 (7th Cir. 1990).

[362] Gregory Dolin, *Licensing Health Care Professionals: Has the United States Outlived the Need for Medical Licensure?* 2 GEO. J. L. & PUBL. POL'Y 315, 317-18 (2004)

[363] *Id.*

[364] Steve Agocs, *Chiropractic's Fight for Survival*, 13(6) AMA VIRTUAL MENTOR 383, 384 (2011).

[365] Dolin, *supra* note 262, at 320-21.

[366] *Id.* at 322.

"practicing medicine without a license."[367] Chiropractors mobilized and worked with state legislatures to pass distinct licensure laws regulating the chiropractic profession. Today, all fifty states have separate laws regulating the practice of allopathic medicine and chiropractic, and some states also have laws governing licensure for alternative healing professions.[368]

Unlike allopathic medicine, chiropractic emphasizes the body's innate healing ability. The American Chiropractic Association defines chiropractic as a health care profession that focuses on disorders of the musculoskeletal system and the nervous system, and how these disorders affect our health.[369]

AMA members began broadcasting the message that only allopathic medicine was supported by evidence and other types of medicine were unscientific and dangerous.[370] In 1957, the AMA adopted principles of medical ethics, stating it was unprofessional and violated physician ethics for allopathic providers to work with, or refer to, non-allopathic providers.[371]

The AMA began to target chiropractors, and convened the Committee on Quackery in 1963.[372] During discovery in *Wilk v. American Medical Association*, attorneys uncovered an internal AMA memoranda, which stated its goal aimed to "eliminate" and "destroy" the competition.[373] One document outlined the AMA's plan to "contain the chiropractic profession," "encourage ethics complaints against doctors of chiropractic," oppose health insurance coverage for chiropractic, oppose referral agreements, refuse access to sharing equipment in hospitals or hospital privileges, and prevent joint teaching and research efforts.[374] To accomplish these goals, the AMA initiated an information campaign and wrote articles in medical journals, influenced physician education, and ghostwrote content for popular media including the Ann Landers advice column to portray

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[367] Agocs, *supra* note 364, at 386.

[368] *Id.*; Michael Cohen & Harry Nelson, *Licensure of Complementary and Alternative Practitioners*, 16(6) AMA VIRTUAL MENTOR 374, 375 (2011).

[369] *About Chiropractic*, AM. CHIROPRACTIC ASS'N, https://handsdownbetter.org/about-chiropractic/.

[370] Agocs, *supra* note 364, at 384.

[371] *Id.*; Wilk v. American Medical Association, 895 F.2d 352, 356 (7th Cir. 1990).

[372] Agocs, *supra* note 364, at 384; Wilk v. American Medical Association, 895 F.2d 352, 356 (7th Cir. 1990).

[373] Agocs, *supra* note 364, at 386; *Wilk*, 895 F.2d at 356-57.

[374] Agocs, *supra* note 364, at 386; *Wilk*, 895 F.2d at 356-57.

chiropractic providers as unscientific quacks.[375] Referring to chiropractors as "rabid dogs," the AMA sought to tarnish chiropractors' reputation in the eyes of both allopathic physicians and the public.[376]

2. Wilk v. American Medical Association

In 1976, chiropractor Chester Wilk and three other chiropractors filed suit against the AMA, alleging violation of the Sherman Act.[377] Wilk alleged that AMA's actions constituted an illegal restraint of trade and boycott against chiropractors. The district court, and Court of Appeals for the Seventh Circuit agreed, and ordered injunctive relief against the AMA.[378] The Seventh Circuit Court of Appeals described AMA's extensive plan to destroy chiropractic's reputation, and stated AMA's tactics aimed to directly interfere with chiropractic's market power for providing healthcare services, particularly for patients with musculoskeletal problems.[379] The court noted AMA's plan also raised the costs for chiropractors to operate by excluding them from hospitals and barring privileges to use equipment, forbidding referrals from allopathic providers, and restricting interprofessional work.[380]

At the district court level, the AMA raised the patient care defense, asserting its actions arose from altruistic concerns to protect the public from fraud, deception, and unscrupulous providers.[381] The district court rejected this defense, holding the AMA failed to demonstrate elements for that defense because it did not establish the concern for patient safety could be addressed in a less restrictive way and did not demonstrate the concern was objectively reasonable.[382] Indeed, the Court of Appeals noted evidence that some allopathic physicians believed that chiropractic was *more* effective at treating certain musculoskeletal problems.[383]

The court held the AMA was not motivated solely by concerns for public welfare, but its intent was to destroy a competitor by engaging in a "pervasive, nationwide, and effective conspiracy."[384] The court agreed with Wilk that the AMA's actions amounted to an unreasonable restraint of trade

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[375] Agocs, *supra* note 364, at 386.
[376] *Id.* at 386-87.
[377] Wilk v. American Medical Association, 895 F.2d 352 (7th Cir. 1990).
[378] *Id.* at 352.
[379] *Id.* at 360.
[380] *Id.*
[381] *Id.* at 361-62.
[382] *Id.*
[383] *Wilk*, 895 F.2d at 361-62.
[384] *Id.* at 352, 364.

in violation of the Sherman Act.[385] The Court of Appeals upheld the injunction to cease the campaign against chiropractic and ordered AMA to take additional steps to publicly repair the reputational damage to chiropractors.[386]

Despite the benefits of medical licensing and standardization of medicine, *Wilk v. American Medical Association* illustrates a history of how allopathic physicians conspired to destroy competition as a means of preserving power. As Dolin observes, the conspiracy to eliminate non-allopathic providers including chiropractors not only harmed the chiropractic profession but hindered public access to a potentially beneficial field of providers. Weaponizing licensing may also harm the public interest by stifling and delaying discoveries, penalize innovation in medicine, and it may force rejection of original concepts.[387]

B. Contemporary Medicine: Antitrust Allegations and *In Re Generic Pharmaceutical Pricing Litigation*

1. Healthcare Spending and Costs

Pharmaceutical manufacturers make critically important discoveries and bring essential medicines to market. However, in some instances, access to medications comes at significant cost. According to the Centers for Medicare and Medicaid Services, in 2018 U.S. outpatient spending on prescription drugs totaled $355 billion.[388] Despite massive medication expenditures, the U.S. ranks far below comparable countries on health outcomes such as hospital admissions for chronic disease, medical error, and premature death rate.[389]

In the past decade, the prices that patients pay for prescription drugs have increased dramatically, far above the rise of inflation as measure by the

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[385] *Id*.

[386] *Id.*, at 368-69. Despite the district court's finding for Wilk and order for injunction, AMA still listed chiropractors under the heading of "non-scientific practitioners" in educational materials designed for physicians.

[387] Dolin, *supra* note 362, at 326.

[388] *National Health Expenditure Fact Sheet*, CTR.'S MEDICARE & MEDICAID SERV.'S (2020), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

[389] Nisha Kurani et al., *How Does the Quality of the U.S. Healthcare System Compare to Other Countries*? KAISER FAM. FOUND. (Aug. 20, 2020), https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-start.

Consumer Price Index.[390] A study in the *Journal of the American Medical Association* found that from 2008 to 2015, the prices for the most commonly used prescription drugs increased by 164%.[391] Notable price increases occurred in several product categories: such as the price for epinephrine autoinjectors, insulin, and generic drugs.[392] In 2016, Mylan made headlines when it spiked the price of its EpiPen AutoInjector by 400%, raising the price from an average of $57 to $500 overnight.[393] The rising cost of insulin led physician Dr. Kasia Lipska to plead in a *New York Times* editorial, "break up the insulin racket."[394] Finally, according to research by physician Dr. Aaron Kesselheim and colleagues, many generic drug prices also reflect recent massive price increases. According to Kesselheim and colleagues, from 2008 to 2015, the cost of 400 generic drugs increased more than 1000%.[395] Rather than strategic (and legally permissible) corporate pricing decisions, recent litigation portrays price spikes as a product of alleged fraud, collusion, and conspiracy by pharmaceutical executives.[396]

2. In Re Generic Pharmaceutical Pricing Litigation

In Re Generic Pharmaceuticals Pricing Litigation alleges manufacturers engaged in anticompetitive pricing strategies to allocate market share and fix prices in violation of the Sherman Act and state consumer protection laws. The claims described in Plaintiffs' Complaint allege secret collusion and conspiracy as a mechanism of producing corporate financial gain by relying upon anticompetitive business practices in violation of antitrust law.

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[390] Aaron Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316(8) J. AM. MED. ASS'N 858, 866 (2016).

[391] *Id.*

[392] *See* Katherine Drabiak, *Manipulating the Prescription Drug Market: Spiking Prices, Inducing Demand, and Costs to the Public*, J. HEALTH CARE L., *forthcoming 2022.*

[393] Willingham, *supra* note 3.

[394] Lipska's research demonstrating the following price increases for insulin from 2010 -2015: Sanofi's price rose 168%, Novo Nordisk rose 169%, and Eli Lilly's price rose 325%. Kasia Lipska, *Break Up the Insulin Racket*, N.Y. TIMES (Feb. 20, 2016), https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html; Pl.s' Compl., *Chaires v. Sanofi*, No. 1:17-cv-10158 (D. Mass. Filed Jan. 30, 2017), at 2.

[395] Kesselheim, *supra* note 390, at 860.

[396] Drabiak, *supra* note 392.

3. Background on the Sherman Act and Antitrust Law

In 1890, Congress passed the Sherman Act, designed to promote free and unfettered competition.[397] The Sherman Act prohibits any contract or conspiracy in restraint of trade, and any "monopolization, attempted monopolization, or conspiracy" that amounts to an "unreasonable" restraint of trade.[398] Unlawful actions under the Sherman Act include "plain arrangements" to "fix prices, divide markets, or rig bids."[399] These three actions constitute *per se* legal violations.[400] The Federal Trade Commission (FTC) describes price fixing as an agreement among competitors to raise, lower, or stabilize prices without legitimate justification.[401] Bid rigging refers to advance agreements to determine business contracts rather competing for contracts in the market.[402] Finally, the FTC defines customer allocation as plain agreements not to compete among businesses or specific agreements about market shares.[403] Enforcement includes civil liability and or criminal penalties.[404] Antitrust laws are designed to promote vigorous competition while providing consumers the benefits of lower prices, higher quality products, and consumer choice among products.[405] State laws also contain similar provisions that prohibit restraint of trade and unfair competition.[406]

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[397] Sherman Act, 15 USCA § 1 (2004); *see also The Antitrust Laws*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws.

[398] Sherman Act, 15 USCA § 1 (2004); *see also The Antitrust Laws*, *supra* note 397..

[399] *The Antitrust Laws, supra* note 397.

[400] *Id.*

[401] *Price Fixing*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/price-fixing.

[402] *Bid Rigging*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/bid-rigging.

[403] *Market Division or Customer Allocation*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/market-division-or.

[404] *Id.*

[405] *Id.*

[406] *See The Antitrust Laws*, *supra* note 397; *see also* Pl.'s Third Am. Compl., *In re Generic Drug Litigation* (D.Conn. June 10, 2020), https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Redacted-Public-Derm-Complaint.PDF, at 480-541.

4. In Re Generic Pharmaceutical Pricing Litigation: Civil Claims

In December of 2016, forty-seven states (now fifty-one states and U.S. territories) filed a lawsuit against twenty pharmaceutical manufacturer defendants, alleging a conspiracy to artificially inflate and manipulate prices, reduce competition, and unreasonably restrain trade for generic drugs sold across the United States.[407] While the original complaint focused on only a few products and a handful of defendants, over the past several years state prosecutors led by the Connecticut Attorney General amended the complaint to include more than 200 generic products, dozens of manufacturers, and individually named defendants who served in pivotal executive sales and marketing roles.[408]

The complaint alleges that defendants engaged in two interrelated practices: First, it asserts defendants established and maintained artificial allocation of product market share. Second, it alleges defendants communicated and adhered to specific pricing strategies.[409] Allegations set forth in the complaint build upon information obtained from confidential witnesses involved in the alleged conduct, and discovery of thousands of documents, such as internal emails, memoranda, text messages, and eleven million telephone call records.[410]

The Connecticut Attorney General asserts that defendants communicated to establish rules of engagement for participating in the market, which included a formula to determine a set allocation of market share.[411] In competitive markets, market share would ordinarily be

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[407] Press Release, *Court Unseals States' Latest Generic Drug Complaint, Including Excerpts from "Diary of Collusion" Meticulously Documenting Widespread Price-Fixing*, OFF. ATT'Y GEN. CONN. (Jan. 28. 2010), https://portal.ct.gov/AG/Press-Releases/2021-Press-Releases/Court-Unseals-Latest-Generic-Drug-Complaint; *see also* Kwanghyuk Yoo, *Pharmacy Benefit Managers and Generic Pharmaceuticals Pricing Conspiracy: Unveiling Lock-In Mechanisms, Structural Shortcomings, and Antitrust Evidence*, 64 S.D. L. REV. 42-93,45-46 (2019) (describing allegations set forth in Plaintiffs' Complaint in *In Re Generic Drug Litigation*).

[408] Pl.s' Third Am. Compl., *In re Generic Drug Litigation*, *supra* note 406.

[409] *Id.* at 36-38 (discussing market share and ceding market share for new entrant), 48 (discussing the two-part strategy of allocating a fair share then increasing prices), 48-50 (discussing strategy to hold back when a competitor increases price), 80-82 (discussing phone conversations between defendants Perrigo and Fougera about price and subsequent price increases of Betamethasone Dipropionate).

[410] *Id.* at 7.

[411] *Id.* at 36.

determined by winning or maintaining business of customers. Similarly, market share may vary widely and undergo modifications when new entrants appear in the market and may differ based on manufacturer price. Defendant Taro, which is a manufacturer of topic dermatological products, created a graphic representation and chart, which provides specific market share percent based on number of competitors and time in the market, awarding greater market share to the earlier market entrants.[412] Plaintiffs allege Taro and other defendants relied on this chart for determining percent of market share when entering a new market, such as when Taro became the third entrant into the Lidocaine market.[413] Both internal communications and communications between manufacturers refer to this practice as "playing nice in the sandbox," which refers to agreeing to a set market share then acting to avoid increasing market share above the arrangement.[414]

Additionally, plaintiffs allege that ceding market share and holding consistent allocations permits manufacturers to charge supracompetitive prices.[415] In internal emails between employees at defendant Fougera, one executive explained the process of voluntarily yielding the market as a means to hold prices high.[416] In 2010, Fougera operated exclusively providing Imiquimod, a topical anti-tumor medication. When an additional manufacturer Perrigo entered the market, one executive at Fougera explained the process in an internal company email, stating: "Perrigo is satisfied with the 35-40% market share" because if "the market settles out at the current prices, we are in a much better position than a higher share at a lower price."[417] Internal emails further explained Perrigo should be satisfied with this share, because "any further attempts to gain share would result in driving prices down."[418]

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[412] *Id*.

[413] *Id.* at 37 (In an internal launch summary for Lidocaine, Taro was the third entrant, and was "preceded by Sandoz (~55% share) and Hi-Tech (~45% share)." The internal launch communication stated "Taro had targeted 20-25% share and had achieved 26.3% share…which it stated was "consistent with a traditional 3 player market").

[414] Pl.s' Third Am. Compl., *In re Generic Drug Litigation* (D.Conn. June 10, 2020), https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Redacted-Public-Derm-Complaint.PDF, at 33, 39-40, 86, 91-92.

[415] *Id.* at 38, see also 91-92.

[416] *Id.* at 63.

[417] *Id*.

[418] *Id*.

Once each manufacturer agreed to a specific market share, the complaint alleged that defendants communicated planned price increases as a means to artificially inflate prices offered by each defendant, under common agreement. In one example, Perrigo, Fougera, and Teva each manufactured Betamethasone Dipropionate, a topical steroid cream for skin conditions such as eczema.[419] When Teva exited the market, a senior executive at Fougera emailed an employee at Perrigo, communicating: "Current WAC [wholesale acquisition cost] is $6.50, that will need to go up significantly. Thinking $40 or so."[420] Phone records prosecutors pulled during discovery demonstrate a series of multiple phone calls following the email between key executives at Perrigo and Fougera the same day as the email.[421] About two weeks later, Perrigo increased the wholesale acquisition cost of Betamethasone Dipropionate 504%, raising the price to $37.50.[422] Three days after Perrigo's price increase, Fougera held an internal meeting to discuss price increases.[423] That same day, discovery phone call logs show multiple calls between key executives at Fougera and Perrigo.[424] Five days after Fougera's pricing meeting, it similarly raised the price of Betamethasone Dipropionate, to $39.99.[425]

The complaint describes multiple examples alleging Defendants colluded to agree upon market share, acted to avoid increasing market share above specified percent values, and conspired to raise prices in lockstep with other manufacturers in the market. Plaintiffs assert joint and several liability against Defendants in violation of the Sherman Act, alleging a horizontal conspiracy to allocate markets and fix prices.[426] Additionally, Plaintiffs allege state law violations corresponding to state specific protections governing trade practices and prohibiting anticompetitive conduct amounting to antitrust violations.[427]

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[419] *Id.* at 80

[420] Pl.s' Third Am. Compl., *In re Generic Drug Litigation* (D.Conn. June 10, 2020), at 80, https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Redacted-Public-Derm-Complaint.PDF.

[421] *Id.* at 80-81.

[422] *Id.*

[423] *Id.* at 81.

[424] *Id.*

[425] *Id.*

[426] Pl.s' Third Am. Compl., *In re Generic Drug Litigation* (D.Conn. June 10, 2020), at 430-78, https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Redacted-Public-Derm-Complaint.PDF.

[427] *Id.* at 480-541.

Plaintiffs requested an injunction against further actions constituting anticompetitive conduct or unfair and deceptive acts, disgorgement of ill-gotten gains, damages, and civil penalties.[428]

Defendants adopted multiple strategies through the course of litigation, first filing a motion to dismiss based on lack of evidence of actual agreement and asserting lack of direct facts to unlawful agreement of parallel conduct.[429]

The court granted partial motion to dismiss against specific defendants but denied motions to dismiss against a majority of defendants, permitting the action to proceed.[430] At the time of this writing, the litigation is still pending.

5. Criminal Antitrust Allegations Against Generic Pharmaceutical Manufacturers

The civil enforcement litigation led by Connecticut parallels a criminal investigation by the Department of Justice (DOJ) into antitrust violations. According to the DOJ, it uncovered price fixing, bid rigging, and customer allocation schemes by multiple generic pharmaceutical manufacturers.[431] Based on evidence uncovered during this investigation, the DOJ criminally charged seven manufacturers.[432] At the time of this writing, five manufacturers entered into deferred prosecution agreements, in which defendants collectively agreed to pay over $426 million in criminal penalties for collusion that affected over $1 billion of generic drug sales.[433]

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[428] *Id.* at 542.

[429] *See also* In Re Generic Pharmaceuticals Pricing Antitrust Litigation, 338 F.Supp.3d 404, 441 (E.D. Pa. 2018) (discussing parallel conduct), 445-46 (discussing timing of conduct as sequential business decisions rather than parallel conduct).

[430] Pl.s' Third Am. Compl., *In re Generic Drug Litigation*, *supra* note 406*,* at 454.

[431] *See Antitrust Division Spring Update 2021*, U.S. DEP'T JUST. (March 24, 2021), https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes.

[432] *Id.*

[433] Deferred prosecution agreements entail an agreement between the prosecutor and manufacturer that provides a mechanism to resolve the criminal charges. *See* Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 SYRACUSE L. REV. 439, 458-59 (2019) (asserting non prosecution agreements and deferred prosecution agreements constitute an insufficient corporate deterrent to criminal acts); *see generally* Cindy Alexander and Mark Cohen, *The Evolution of*

In addition to charges against manufacturers, the DOJ criminally charged four executives relating to violations of antitrust law.[434] Three of the four executives pled guilty, and the remaining defendants await trial.[435] The DOJ stated: "American consumers have the right to generic drugs sold at prices set by competition, not collusion" and it intends to hold both manufacturers and individuals accountable for conduct that violates federal antitrust law.[436]

6. Analysis of Antitrust Violations, Conspiracies, and Medication Prices

Hundreds of pages of Plaintiffs' civil complaint describe common actions, phrasing, and conduct from multiple different manufacturers relating to different products allegedly aimed at achieving two main goals: (1) to establish and preserve agreed upon market share, and (2) artificially set higher prices. The Complaint alleges Defendants acted in concert and engaged in secret negotiations shielded from public view as a means of securing corporate financial gain, violating principles of market competition and the Sherman Act.

Anticompetitive actions by pharmaceutical manufacturers adversely impacts patients, the healthcare system, and the market. Cases that involve collusion and conspiracies can artificially stunt product choices such as availability of certain prescription drugs or prevent certain medication from even entering the market. Investigating allegations of collusion and conspiracy through the justice system provides a mechanism for transparency

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Corporate Criminal Settlements: An Empirical Perspective on Non-Prosecution, Deferred Prosecution and Plea Agreement, 52 AM. CRIM. L. REV. 537 (2015) (describing non prosecution agreements and deferred prosecution agreements as a means to address corporate crime).

[434] *Antitrust Division Spring Update 2021*, U.S. DEP'T JUST. (March 24, 2021), https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes.

[435] *Id.*

[436] *See Pharmaceutical Company Admits to Price Fixing in Violation of Antitrust Law, Resolves Related False Claims Act Violations*, U.S. DEP'T JUST. (May 31, 2019), https://www.uspsoig.gov/sites/default/files/document-library-files/2019/DOJ%20News%205-31-19.pdf;
see also Generic Pharmaceutical Company Admits to Fixing Price of Widely Used Cholesterol Medication, U.S. DEP'T JUST. (May 7, 2020), https://www.justice.gov/opa/pr/generic-pharmaceutical-company-admits-fixing-price-widely-used-cholesterol-medication.

and fairness, increasing the public's ability to access necessary and beneficial medicine.

C. Lessons for Medicine

The power to control the market in medicine can encompass which practitioners the law permits to provide healthcare services, the standards that determine what interventions constitute an appropriate means of diagnosing and treating disease, and what medications are available for patients in need.

The history of medicine demonstrates the importance of licensing as a tool to promote minimum standards and enhance patient care, but also provides a cautionary tale of how a coalescence of healthcare providers can exclude qualified providers under the guise of public safety by labeling practices as *unscientific* or *quackery*. Hidden motivations to dominate the healthcare market have the potential to mislead the public about the viability and benefits that alternative healthcare providers offer.

In the case of pharmaceutical manufacturers, allegedly engaging in secret negotiations about market allocation and conspiring to raise prices in lockstep through illegal anticompetitive means can produce significant corporate financial gain. However, business models that rely on dishonesty and collusion adversely impact the public interest. In this instance, alleged secret agreements produced high medication prices, impeded patient access to critical medication, and introduced additional inefficient cost burden to the healthcare system.[437]

VI. CONCLUSION

Trust the science. Follow the experts. Do not be misled by quacks, conspiracy theorists, and fake news. Throughout history, experts in science, medicine, and public health held immense power to define the parameters of what constitutes acceptable and respected science, pathologize dissent and disparage disagreement. Experts strategically utilize common phrases such as: the *true* evidence supports their position; scientific evidence offers the weight of consensus because all experts agree; experts promise that science will deliver a remarkable remedy; the solution is safe and effective; and their recommendation is what will protect the population from disease and alleviate human suffering. Remembering mistakes and errors in science and medicine reinforces the concept of science as a discipline that requires continuous evolution to capitalize on its promises. Challenging established

[437] *See also* Drabiak, *supra* note 392.

scientific norms – particularly when the established belief system causes harm – stirs controversy and vehement opposition.

Dissent, debate, and conspiracy theories in science can signal loss of trust, the emergence of new concepts, divergent interpretations of the evidence and policy objectives, well-founded fears of misconduct, and even criminal wrongdoing. Conspiracies in science may involve powerful stakeholders acting in concert to withhold critical information from the public as a mechanism to preserve power, obtain prestige, or produce financial gain. In each area of public health, research, and medicine, stakeholders prioritized a policy objective such as promoting benevolent preventive public health policy, allaying public fears, gaining leverage in the struggle against disease at all costs, accepting secrecy as amoral and necessary to protect public safety, and exerting a heavy hand in the market to control medical care. Stakeholders in each of these examples acted in a manner that they believed was acceptable, necessary, or even morally correct yet induced significant harm and suffering. Science must reorient its ethics to operate in a framework that recognizes the dignity, worth, and liberty of each individual person as a primary value rather than a contingent or secondary aim subordinate to the utilitarian pursuit of "progress," knowledge, or power.

Permitting criticism, doubt, or concerns constitutes an integral part of assessing the strength and merit of evidence when forming scientific policy. Ensuring access to transparent, objective, and thorough information without filter or censorship provides essential guardrails. Public discourse can mitigate the potential for coercion, misuse of power, and restrain the threat of scientific and political institutions elevating amorphous policy objectives above the rights and welfare of individual people. Democracy requires vigilant assessment of scientific policymaking to ensure the process is grounded in credible evidence, protects the vulnerable, promotes accountability, and furthers justice.