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INTRODUCTION

Nicholas England was a healthy 22-year-old. Two weeks after he started taking the allergy medication Singulair, he was found dead. The cause of death was suicide. Merck, the drug's manufacturer, and federal regulators received over 80 reports of user self-harm but failed to provide a black box warning on the prescription label.[1]

This reality is not a product of science or chance. Instead, it involves a mechanized and deliberate operation by American pharmaceutical companies to proliferate new drugs into the health care system, maintain growth in prices, and enlarge corporate profits, regardless of the consequences. Known colloquially as Big Pharma, these firms are the largest industry contributor to political activities.[2] In order to implement desired objectives, Big Pharma utilizes its vast pool of resources to influence the decisions of lawmakers and bureaucrats. Administrative agencies are the prime target.

Within these regulatory bodies, the ideals of public health have become subservient to the immediate and long-term needs of industry. In order to trace the origin and development of this political reality and expound upon its significance, both agencies and Big-Pharma must be regarded as political actors operating in furtherance of their own self-interest. The public interest warrants an investigation into the means by which Big Pharma has hijacked the regulatory system, leading to the question: how do pharmaceutical companies influence government regulations when attempting to get their products to market? An apt review of evidence stemming from legal, regulatory, and financial sources indicates that pharmaceutical companies strategically influence government regulations by seizing control of information channels through the tactical funding of clinical trials and circumvention of established research protocols.

Part I of this paper will discuss the contemporary understanding of regulatory capture as both a legal acquiescence and strategic political maneuver, including key concepts specifically relevant to public health. Part II will examine Big-Pharma's underlying strategy to possess supremacy over information channels, the lifeline of the regulatory system. Parts III and IV will address the tactics by which companies gain control of these channels: direct drug trial sponsorship and research protocol subversion. Lastly, Part V will propose suitable policy remedies that promote an agency-industry relationship based on the public interest as opposed to strict commercialism.

[1] Levine, Dan, et al., "A Son Died, His Parents Tried to Sue. How US Courts Protect Big Pharma," Reuters, June 26, 2023, https://www.reuters.com/investigates/special-report/usa-lawsuits-merck-singulair/. para. 1.

[2] "Lobbying Industries." OpenSecrets, n.d. https://www.opensecrets.org/federal-lobbying/industries?cycle=a. "Industries"

LITERATURE REVIEW

REGULATORY CAPTURE: IN GENERAL

Contemporary political scientists have observed the tendency of special interest groups to manipulate the actions of regulatory bodies through a phenomenon known as "regulatory capture". Industries can shape existing regulations, weaken their enforcement, and dilute their legal significance, all in an effort to create a favorable political environment for their societal and commercial benefit.[3] The manner in which capture occurs varies across industries yet becomes identifiable when regulators can no longer function without the constant presence of outside "persuasion". [4] Once this threshold is reached, agencies depart from their public interest responsibility and reorient themselves towards self-interested pursuits, prioritizing both their own goals and those of special interests.[5]

Statutory frameworks can provide a stimulus for capture. Scholars have recognized the multitude of ways in which the legal organization of agencies naturally invites the influence of special interest groups, jeopardizing vital agency functions (e.g., rule-making, licensing). This type of "legal relationship" is known as "*ex-ante* regulatory capture", a method which allows industry to shape regulatory outcomes before they take effect.[6]

Politically, flawed agency organization can provide actors with the necessary motivation to usurp the regulatory process. While it is widely accepted that these motivations are most often economic, the varying ways that corporate actors pursue capture can vary across industries and government agencies.[7] They may involve legislative lobbying efforts or be confined to the agency itself. This paper's analysis concerns only the latter approach, namely the pharmaceutical industry's actions within public health bodies themselves, a bijective type of relationship.

REGULATORY CAPTURE IN PUBLIC HEALTH: A GAP IN UNDERSTANDING

Research has sparsely focused on the relationship between Big Pharma and federal public health agencies with regard to illicit capture; small-scale investigations have uncovered multiple conflicts of interest on the part of agency budgets, employment arrangements, and regulatory processes.[8] This appearance of capture often fails to garner widespread attention in popular media and academia, posing destructive consequences for the genuine scientific research and development of drugs; scrutiny from the public

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[3] Etzioni, Amitai. "The Capture Theory of Regulations- Revisited." *Society* 46, no. 4 (2009): 319-323. https://doi.org/https://doi.org/10.1007/s12115-009-9228-3. 319-320.

[4] Hempling, Scott. "Regulatory Capture: Sources and Solutions." *Emory Corporate Governance & Accountability Review* 1 (2014): 23-35. https://scholarlycommons.law.emory.edu/cgi/viewcontent.cgi?article=1003&context=ecgar 25.

[5] Forrence, Jennifer, Levine, Michael, "Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis," *Journal of Law, Economics, and Organization* 6, no. Special Issue (1990): 167-198. https://www.jstor.org/stable/764987. 169.

[6] Boehm, Frederic. "Regulatory Capture Revisited–Lessons from Economics of Corruption." *Anti-Corruption Training & Consulting (ACTC), and Research Center in Political Economy (CIEP, Universidad Externado de Colombia)* (2007). https://www.researchgate.net/profile/Frederic-Boehm/publication/228374655_Regulatory_Capture_Revisited-Lessons_from_Economics_of_Corruption/links/02e7e52b88445beb72000000/Regulatory-Capture-Revisited-Lessons-from-Economics-of-Corruption.pdf. 15.

[7] "Regulatory Capture." The Concise Encyclopedia of Business Ethics, July 22, 2023. https://conciseencyclopedia.org/entries/regulatory-capture/.

[8] Steinbrook, Robert. "Financial Conflicts of Interest and the NIH." *New England Journal of Medicine* 350, no. 4 (2004): 327-330. https://doi.org/https://doi.org/10.1056/nejmp038247. 328.

tends to be met with silence.[9] Because the conversation ends here, public health officials and consumers are unable to comprehend the extent of pharmaceutical influence in the regulatory realm.

Before Big Pharma's strategies and tactics can be unearthed and evaluated, it is essential to recognize the inter-agency components involved. Among their many responsibilities, agencies such as the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) are responsible for testing and approving research chemicals and medical products for human use. This process is shaped by a multitude of rules, guidelines, and oversight directives that these agencies establish and enforce. Information channels constitute the body of scientific studies, theories, and discourse that agencies rely upon to perform their duties, most of which center around drug applications and approvals.[10] The Code of Federal Regulations (CFR) prescribes research protocols, a streamlined system of clinical trials which govern the testing, development, and marketing of medicinal drugs, therapeutics, and vaccinations. Logistical barriers and the volume of applications prevent agencies from obtaining all types of information independently, resulting in a reliance on industry to supply certain clinical data.[11] The complexity of information during the research phase requires agencies to exercise scientific judgment and discretion over the data applicants provide, albeit with a "broad perspective" that is designed to remain fluid.[12] Due to this laxity, information channels are subject to weaponization by Big Pharma which has asserted a corporatized dominion over public health agencies.[13] The timeline of this inquiry concerns episodes from 2015 through the present; relevant and robust evidence emerges during this period, supporting concentrated analysis and policy recommendations.

STRATEGY: CONTROL OF AGENCY INFORMATION CHANNELS

Big Pharma's maneuvers are not confined to a single branch of health care, nor is it exclusive to one agency. Instead, they encompass a broad political operation with roots in the 1990's.[14] Through a multifaceted methodology, regulatory outcomes can be traced back to the underlying strategies and tactics of pharmaceutical companies and their commercial agendas. Uncovering these methods requires understanding the relationship between motivation and behavior. In other words, what do drug manufacturers value? Information. The primary goal of pharmaceutical firms is to get all products to market quickly[15] with little to no disruptions, delays, or unforeseeable costs. Companies admit the

[9] Thacker, Paul D. "How a flood of corporate funding can distort NIH research." *Washingtonpost.com*, June 22, 2018. *Gale Academic OneFile* https://link.gale.com/apps/doc/A543978967/AONE?u=setonhallu&sid=googleScholar&xid=e968e292. para. 2-3.

[10] Zettler, Patricia, Riley, Margaret Foster, Kesselheim, Aaron, "Implementing a Public Health Perspective in FDA Drug Regulation" *Food and Drug Law Journal* 73, no.2 (2018): 221-256. https://doi.org/10.31228/osf.io/pc4b6. 236.

[11] Person, Dr. Randolph Gordon, et al. "New Era of Public Health Partnerships" Deloitte Insights, July 11, 2023. https://www2.deloitte.com/us/en/insights/industry/public-sector/government-trends/2022/global-health-partnerships-collaboration.html.

[12] Zettler op. cit., 237.

[13] Vertinsky, Liza. "Article: Pharmaceutical (Re)Capture," *Yale Journal of Health Policy, Law & Ethics,* 20, 146 (Spring, 2021). https://advance.lexis.com/api/document?collection=analytical-materials&id=urn:contentItem:64NT-4JY1-JYYX-6433-00000-00&context=1516831. 163.

[14] Mervis, Jeffrey. "U.S. Lawmakers Want NIH and CDC Foundations to Say More About Donors – AAAS." *Science*, n.d. https://www.science.org/content/article/us-lawmakers-want-nih-and-cdc-foundations-say-more-about-donors. para. 2.

[15] Fillman, Jennifer. "Getting Products to Market Fast with the 3PL Title Model", Pharmaceutical

high costs associated with drug research and development and warn against bureaucratic infringement of medical innovation.[16] By recognizing the centrality of an agency's self-instructive procedures, Big-Pharma can insert their objectives directly into the approval process. A strategy of this sort depends on controlling the information and data that determines whether or not a given drug receives commercial authorization and ultimately full licensing.

LAWSUITS EXPOSE BIG PHARMA'S INTENTION

Federal lawsuits between drug manufacturers and patients reveal the important role of agency information channels and industry's control over them. In an August 2023 Complaint filed in the U.S. District Court for the Western District of Louisiana, Plaintiff Jaclyn Bjorklund alleged that Defendants Eli Lilly & Co. and Novo Nordisk Inc., manufacturers of the weight loss drug Ozempic, failed to identify "stomach paralysis" and other gastrointestinal disorders as potential side effects of taking the medication.[17] The FDA granted approval to the drug in 2023. Despite medical literature from 2020 which found incidences of stomach paralysis after taking Ozempic, Defendants never disclosed such findings to the FDA, despite the agency itself receiving similar reports.[18] The clinical information used in the FDA's decision to grant approval included this 2020 literature.[19]

A second lawsuit filed in 2021 features a similar fact pattern. Jeanette Milburn, a user of the blood thinner medication Elmiron, filed a Complaint in the U.S. District Court for the Eastern District of Kentucky against Janssen Pharmaceuticals, alleging the drug caused a severe eye injury known as maculopathy, the progressive weakening of muscles around the retina causing vision loss.[20] In 1996, the drug received FDA approval following several rejections.[21] Numerous reports of maculopathy were in the Defendant's possession as part of the drug's clinical record yet were never disclosed to the FDA.[22] Relying on an incomplete information record, the drug's approval was granted; the agency had no knowledge of these adverse reactions.

Both cases illustrate material medical facts that were either manipulated or omitted entirely from agency information channels. Because regulations require the disclosure of adverse drug reactions before an outcome of approval[23], doing so could extend the investigatory trial phase and prevent a pharmaceutical product from reaching market. Big-

Commerce, n.d. https://www.pharmaceuticalcommerce.com/view/getting-products-to-market-fast-with-the-3pl-title-model. para 2.

[16] *Bristol Myers Squibb Company v. Becerra* (United States District Court for the District of New Jersey, Filed 16 August 2023) "Memorandum of Law in Support of Plaintiff's Motion For Summary Judgement" 3. https://storage.courtlistener.com/recap/gov.uscourts.njd.513814/gov.uscourts.njd.513814.36.3.pdf

[17] *Jaclyn Bjorklund v. Novo Nordisk, Inc., et al.* (United States District Court for the Western District of Louisiana, Filed 2 August 2023) "Complaint and Demand For Jury Trial" 7. https://www.forthepeople.com/sites/default/files/2023-08/Morgan%20%26%20Morgan%20Ozempic%20Bjorklund%20complaint%208.2.23.pdf

[18] *Ibid.,* 13.

[19] *Ibid.,* 14.

[20] *Jeanette Milburn v. Janssen Pharmaceuticals, Inc., et al.* (United States District Court for the Eastern District of Kentucky, Filed 29 January 2021) "Complaint" 9. https://www.aboutlawsuits.com/wp-content/uploads/2021-1-29-elmiron-milburn-complaint.pdf

[21] *Ibid.,* 11.

[22] *Ibid.,* 18.

[23] "Clinical trials registration and results information submission," Code of Federal Regulations 42 Part 11, Subpart D: 156. https://heinonline.org/HOL/Page?collection=usjournals&handle=hein.cfr/cfr2016181&id=166&men_tab=srchresults

Pharma's commercial priorities would be stymied if such a risk became reality. Ozempic and Elmiron are the objects of industry's strategy; their economic lives determined by the FDA's information channel. If this channel was indeed "neutral", meaning compliant with all regulations and free of any applicant influence, the agency would have access to the entire clinical record, a vital portion of which was purposefully withheld by BigPharma. This neutral channel, untainted by the applicants, would have likely delayed Ozempic and Elmiron from being prescribed to patients given their dangerous side effects.

INTENTIONAL NON-DISCLOSURE

By law, the FDA is required to deny applications where information "shows that the drug is not safe".[24] This mandate cannot be executed as the agency has no way of distinguishing whether or not it is in possession of a full clinical record. As illustrated by the examples above, pharmaceutical applicants have the ability to selectively disclose data related to their product, creating a "compromised" information channel that renders the black-letter review process meaningless. Agencies receive only the information necessary to green light a drug, limiting their overall medical knowledge whilst relying on what is provided. FDA and other public health bodies thereby become paralyzed, subservient to and dependent upon the subjects they are tasked with regulating.

This relationship embodies the dynamics of a pure monopoly. Agencies find themselves with material that simplifies governance and educates the public health system while Big Pharma reaps the benefits of its calculated scheme to influence the regulatory process, creating a political version of symbiosis. Just as large conglomerate corporations seek to control a sector of the economy without competition, drug companies look to seize the information pipeline that guides regulation. In order to justify such behavior, businesses will argue that monopolistic practices provide greater efficiency and convenience for consumers[25], or in the case of pharmaceutical firms, for government agencies. But achieving the mutual benefits of industry-controlled information channels are neither the motivation nor strategy of Big Pharma; in fact, these benefits are largely irrelevant. Instead, the focus remains on eliminating barriers to commercial development and profitability. Information channels function as levees to protect the public; new medical products are the storm surge, destroying barriers to the drug marketplace.

TACTIC #1: INDUSTRY FUNDING OF CLINICAL TRIALS

Controlling clinical data within an agency depends on specific tactics that, through their execution, allow pharmaceutical companies to maintain their leverage over the drug approval process. If the strategy at hand aims to get products to market with as little scrutiny and obstruction by regulators as possible, then the traditional rules regarding clinical trials and research cannot be fully adhered to; they are far too bureaucratic and time consuming to meet industry's business demands. Because of agencies' dependence on Big Pharma for information, companies have the necessary means to persuade.

NIH CLINICAL TRIALS

[24] *Alliance for Hippocratic Medicine et al. v. FDA, et al.,* (United States Court of Appeals for the Fifth Circuit, 16 August 2023) "Appeal from United States District Court for the Northern District of Texas, OPINION Elrod, J.". https://www.ca5.uscourts.gov/opinions/pub/23/23-10362-CV1.pdf. 4.

[25] Federal Trade Commission. "Monopolization Defined – Business Justification", March 4, 2022. https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined. para. 1-2.

But persuasion of regulatory bodies is not an easy task, nor is it always identifiable on the surface level.[26] To obtain control over an information channel, industry must substitute impartial scientific findings with those that favor their own products, all in furtherance of favorable drug application outcomes. The responsibility of initiating and analyzing the results of clinical trials lies with NIH, the nation's primary public health research agency. According to NIH, 83% of its $48 billion fiscal budget supports research grants to universities and laboratories "for the American people".[27] Yet according to disclosures, only $31 billion, 64% of the budget, is spent on such grants.[28] These expenditures are made possible by congressionally appropriated funds.

Meanwhile, the private sector as a whole contributes an average of $83 billion per year in research and development[29], all of which ends up as part of the scientific record. In totality, over the course of several fiscal years, the government accounts for only 22% of clinical research investment while pharmaceutical companies account for 67%.[30] Despite the public interest attitude of NIH, the funding for over two-thirds of medical trials stems from industry, not from taxpayers. Given that information channels are Big Pharma's strategic target, their vast financial resources allow them to dilute the impact of public grant funding and pursue studies that bolster a drug's profile.

FDA DRUG APPROVAL PROCESS

FDA, an agency that determines whether or not to grant drug approvals, is also tainted by industry's funding of clinical trials. While corporations look to NIH as a way to manufacture the content of general medical studies, they must simultaneously affect the way FDA utilizes this information in the application process. Pharmaceutical companies pressure FDA to consider only the results of private investigative trials where the scientists conducting them are hired by firms with financial stake in the drug.[31] This occurs most prominently during phase three clinical trials, the final phase before approval deliberations. Private contributions called "user fees"[32], a type of royalty that enables Big Pharma to control how clinical trials are reviewed by FDA, are paid out by industry in closed door meetings to secure product approvals. [33]

[26] Carpenter, Daniel, Moss, David A. "Preventing Regulatory Capture: Special Interest Influence and How to Limit It". *Cambridge University Press* 2014. "Introduction", 1-22. https://www.tobinproject.org/sites/default/files/assets/Introduction%20from%20Preventing%20Regulatory%20Capture.pdf. 16.

[27] National Institutes of Health. "NIH Budget"., October 24, 2023. https://www.nih.gov/about-nih/what-we-do/budget. para. 1-2.

[28] National Institutes of Health n.d., "NIH Financial Management Report FY 2022". https://ofm.od.nih.gov/FMReport/FY22_NIH_Financial_Management_Report_Final_508c.pdf. *See* "NIH FY22 Invoice Payments Excluding Payroll."

[29] Congressional Budget Office. "Research and Development In The Pharmaceutical Industry"., April 2021. https://www.cbo.gov/publication/57126. para. 3.

[30] Bowen, Henry P., et al. "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals" *Therapeutic Innovation & Regulatory Science* 57, no. 1 (2022): 160–169. https://doi.org/10.1007/s43441-022-00451-8. 161. The statistic cited above encompasses "total U.S. medical and health R&D" despite the article's specific focus on "biopharmaceuticals" as distinguished from pharmaceuticals in general.

[31] Duplechin, Ryan J. "The Funding Effect: How Drug Manufacturers Design Clinical Trials to Produce Favorable Results – Bill of Health." Bill of Health – The Blog of the Petrie-Flom Center at Harvard Law School, May 3, 2019. https://blog.petrieflom.law.harvard.edu/2019/05/03/the-funding-effect-how-drug-manufacturers-design-clinical-trials-to-produce-favorable-results/. para. 4.

[32] White, C. Michael. "Why is FDA Funded In Part By The Companies it Regulates?" UConn Today, May 21, 2021. https://today.uconn.edu/2021/05/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-2/#. para. 1, 11.

[33] Jewett, Christina. "F.D.A. Relies on Funding from the Drug Companies it Oversees: [National Desk]." *New York Times,* Sep 16, 2022, Late Edition (East

Through these fees, industry becomes the de facto financier of FDA's entire regulatory mechanism.

Ocaliva, a medicine designed to reduce blood enzymes in the liver, was granted FDA approval in 2016. Pursuant to a federal law entitled the *Prescription Drug User Fee Act*, the manufacturer, Intercept Pharmaceuticals, incentivized the agency through direct payments to speed up the review process despite claims from skeptical physicians about the drug's true clinical benefit.[34] In a report from the Department of Health and Human Services' Office of Science & Data Policy, industry user fees represented 46% ($2.9 Billion) of FDA's total fiscal year 2022 budget ($6.2 Billion).[35]

Yet industry's monetary influence over clinical trials runs deeper than the agency-wide level. Major pharmaceutical companies have paid individual regulators on a personal level. Most are doctors and scientists who serve on monitoring committees tasked with overseeing and reviewing the results of application phase clinical trials. Between 2013-2016, AstraZeneca, a producer of cardiovascular therapies designed to treat heart disease, paid committee member Dr. Jonathan Halperin $200,000 in accommodation and consultation fees for his work on pending drug applications.[36] This type of compensation does not qualify as a royalty or user fee and thus does not appear in FDA's official budget. It is likely that the total amount of corporate money within the agency far exceeds government reported figures.

TACTIC #2: CIRCUMVENTION OF ESTABLISHED RESEARCH PROTOCOLS

Big Pharma's push to fund clinical trials is by itself tactically insufficient. To obtain control over the content and procedures of information channels, existing regulations which prescribe established research protocols for new drugs must be replaced with new procedures that allow for faster approval and decreased scrutiny.

INDUSTRY NARRATIVE VS. REGULATORY INTENT

Pharmaceutical representatives claim that the current regulatory climate has increased the amount of time and investment needed to bring innovative products to market, reducing patient access to drugs.[37] FDA trends reveal a different motivation. Since 1992, industry and anti-regulation think tanks have circumvented the traditional drug research process to bolster prices and diminish the knowledge pool among medical professionals.[38] Not only is the content of information channels affected; the ability of agencies to extrapolate data from these channels is also

Coast). https://www.proquest.com/newspapers/f-d-relies-on-funding-drug-companies-oversees/docview/2714551645/se-2. para. 2-3.

[34] Allen, Arthur. "Pharma-Funded FDA Gets Drugs Out Faster, But Some Work Only 'Marginally' and Most Are Expensive." Los Angeles Times, September 30, 2022. https://www.latimes.com/science/story/2022-09-30/pharma-funded-fda-gets-drugs-out-faster-but-some-work-only-marginally-and-most-are-expensive. para. 6-10.

[35] Rep., Office of Science & Data Policy, Department of Health and Human Services, *FDA User Fees: Examining Changes in Medical Product Development and Economic Benefits*, March 2023. https://aspe.hhs.gov/sites/default/files/documents/e4a7910607c0dd76c40aa61151d154f9/FDA-User-Fee-Issue-Brief.pdf para. 1.

[36] Piller, Charles, and You, Jia "Hidden Conflicts? Pharma Payments to FDA Advisors After Drug Approvals Spark Ethical Concerns." *Science*, July 5, 2018. https://www.science.org/content/article/hidden-conflicts-pharma-payments-fda-advisers-after-drug-approvals-spark-ethical. para. 2.

[37] Kepplinger, Erin E. ""FDA's Expedited Approval Mechanisms for New Drug Products." *Biotechnology Law Report* 34, no. 1 (2015) 15-37. https://doi.org/10.1089/blr.2015.9999. 15.

[38] Chen, Caroline. "FDA Repays Industry by Rushing Risky Drugs to Market." *ProPublica*, June 26, 2018.

prevented. If accessibility of effective drugs was the primary concern of Big Pharma, they would advocate for more intensive investigative trials. They have done just the opposite.

The protocols specified in public health regulations are an obstacle to swift pharmaceutical commercialization. As codified, these rules and procedures are not designed to benefit industry, but to protect the public.[39] CFR chapters 21 and 42 outline the application steps for new medicines. Research trial registration, results submission, and marketing are each covered by various sections within the chapter. Chapter 42, Part 11, page 156 mandates that all adverse reactions uncovered during clinical trials be reported a maximum of one year after the completion or suspension of such trial.[40] Chapter 21, Part 314, page 119 requires drug applicants to submit an annual report documenting any adverse reactions or changes to the chemical composition of the product via the manufacturing process.[41] These rules keep FDA aware of sudden changes to a drug's profile that can occur before or after its introduction to the market. Approval and licensing outcomes can be affected by any new information received, hence Big Pharma's strong aversion to such regulations.

A research and approval process that allows pharmaceutical companies to avoid frequent and highly meticulous disclosures are invaluable to their business interests. If industry's overarching strategy is to influence the information channels that agencies rely on, they must successfully advocate for new protocols that reduce the quantity of information applicants must provide while expediting regulatory decision making. This is precisely what has occurred.

DEVELOPMENT OF INDUSTRY-FRIENDLY PROTOCOLS

FDA has conceded to this industry tactic and largely welcomed it. Through pharmaceutical corporate capture, FDA has adopted a number of alternative drug approval programs which in large part supplant the rigorous rules detailed above. Two in particular allow Big Pharma significant autonomy with minimal agency oversight: the Accelerated Approval Program (AAP) and Emergency Use Authorization (EUA).

AAP's creation stems directly from a popular but misleading industry narrative: patients should have immediate access to innovative and potentially lifesaving medicines. This perspective is directly incorporated into regulatory language. CFR Chapter 21, Subpart H defines the "scope" of AAP as applicable to "certain new drug products that have been studied for their safety and effectiveness…that provide meaningful therapeutic benefit to patients".[42]

Given that pharmaceutical companies want to exercise control over information channels and present data which elevates their particular product, the FDA standard of

https://propublica.org/article/fda-repays-industry-by-rushing-risky-drugs-to-market. para. 22-23.

[39] Lezotre, Pierre-Louis. "Introduction." In *International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective*, 1–5. Amsterdam: Elsevier, 2014. https://www.sciencedirect.com/topics/medicine-and-dentistry/pharmaceuticals-regulation. 1.

[40] "Clinical trials registration and results information submission," Code of Federal Regulations 42 Part 11, Subpart D: 164. https://heinonline.org/HOL/Page?collection=cfr&handle=hein.cfr/cfr2022191&id=174&men_tab=srchresults.

[41] "Applications for FDA approval to market a new drug," Code of Federal Regulations 21 Part 314: 119. https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf.

[42] "Accelerated approval of new drugs for serious or life-threatening illnesses," Code of Federal Regulations 21 Part 314, Subpart H: 172. https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf.

review for AAP is significantly reduced compared to traditional research protocols. Under AAP, FDA may grant approval to a drug "on the basis… of clinical trials establishing that the drug product… has an effect… that is reasonably likely… to predict clinical benefit."[43] Meanwhile, applications via conventional rules bind FDA to specific sequential steps, permitting approval only after "a complete review of the data submitted."[44]

The discrepancies between the two procedures are extreme. AAP permits FDA to take the word of applicants at face value and base their decision off of speculative evidence of drug efficacy. Otherwise, the agency would be required to review clinical studies via a formal institutional review board[45] over an extended time period, contrary to industry's wishes.

Big Pharma's initiative to create AAP bodes well for their symbiotic relationship with FDA. In a report entitled *Guidance for Industry: Expedited Programs for Serious Conditions- Drugs and Biologics*, the agency lauds the ability of drug applicants to meet with review teams on a regular basis to discuss "study design" and the "extent of safety data required to support approval."[46] Regulators have become the friend of industry; their newfound collaboration made possible by AAP.

But a particular aspect of AAP directly supports Big Pharma in a manner that ordinary research protocols do not. Following market authorization, the FDA requires drug sponsors to complete confirmatory trials to verify clinical safety and effectiveness.[47] Because drugs can enter market with an incomplete clinical record that is based on the mere probability of success, companies are relieved from having to analyze and disclose the results of studies before they can profit from a medication.

Per the 2022 *Food and Drug Omnibus Reform Act*, agencies determine the timeline on which manufacturers must begin confirmatory trials.[48] This broad grant of discretion plays into Big Pharma's hands. Industry can defer costs and avoid the revelation of potentially damaging data regarding a drug already in circulation. According to the Department of Health and Human Services Office of Inspector General, more than one-third of AAP drug applications have incomplete confirmatory trials[49], another third of which are over one year past the original scheduled date of completion.[50] Such a loophole poses grave consequences for care providers and patients who cannot look to FDA for assurance that a drug meets quality and safety standards.

The EUA program possesses many of the same characteristics as AAP. While previously a little-known regulatory procedure, the COVID-19 pandemic, and subsequent efforts by industry to develop vaccines and therapeutics raised EUA's status as a tool that

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[43] *Ibid*., 173.

[44] "FDA action on applications and abbreviated applications," Code of Federal Regulations 21 Part 314, Subpart D: 149. https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf.

[45] *Ibid*., 141.

[46] Rep., Food and Drug Administration, Department of Health and Human Services, *Guidance for Industry: Expedited Programs for Serious Conditions- Drugs and Biologics,* May 2014. https://www.fda.gov/media/86377/download. 9.

[47] Naci, Huseyin, Smalley, Katelyn R., and Kesselheim, Aaron S., "Characteristics of Pre-Approval and Post-Approval Studies for Drugs Granted Accelerated Approval by the US Food and Drug Administration." *JAMA* 318, no. 7 (2017): 626–636. https://doi.org/10.1001/jama.2017.9415. 627.

[48] "FDORA Changes to the FDA Accelerated Approval Program," Cooley Global Law Firm, January 31, 2023. https://www.cooley.com/news/insight/2023/2023-01-31-fdora-changes-to-the-fda-accelerated-approval-program. para. 9.

[49] Rep., Office of Inspector General, Department of Health and Human Services, *Delays in Confirmatory Trials for Drug Applications Granted FDA's Accelerated Approval Raise Concerns*, 2022. https://oig.hhs.gov/oei/reports/OEI-01-21-00401.pdf. para. 3.

[50] *Ibid*., para. 4.

could quickly get health products to consumers. In 2020, as the country faced a shortage of COVID antibody tests, FDA began issuing umbrella EUA authorizations for multiple manufacturers, without direct evaluation of each test's effectiveness,[51] and in violation of statutory provisions.

EUA is directly responsible for the influx of vaccines and boosters which followed the pandemic. Despite claims from FDA that vaccinations would undergo significant scrutiny under EUA, studies were intentionally conducted among low-risk populations, unrepresentative of those populations most likely to receive the COVID vaccine.[52] Lauding these trials as successes and releasing their findings to the public can spawn misconceptions while masking design flaws.[53]

PITFALLS OF ACCELERATED APPROVAL

Individual case studies reveal the extent of Big Pharma's disdain for typical research protocols and their embrace of expedited approval programs. Mifepristone, a contro-versial drug that is used to terminate pregnancies, was approved by the FDA in 2000 via AAP, despite a series of adverse reactions including "bleeding, infection, incomplete abortions, and ongoing pregnancy" which in some instances required surgery.[54] Following a 2016 reevaluation of Mifepristone's profile, FDA approved a REMS (Risk Evaluaiton and Mitigation Strategy). The rule mandates that prescribers and users of Mifepristone acknowledge the risk of adverse reactions[55], effectively shielding manufacturers against further safety testing which may be pursued by FDA or corporate competitors.[56]

Leqembi, a drug that aims to slow mental decline in Alzheimer's patients, was granted AAP approval by the FDA in 2023. Following several clinically insignificant trials[57], 17 percent of subjects experienced brain bleeding while three individual deaths were linked to the drug. [58] Despite these discoveries, Leqembi remains available to patients as a treatment for an annual cost of $26,500.[59]

A second Alzheimer's medication, Aducanumab, is an antibody tasked with reducing plaque buildups in the brain during disease progression. Following a unanimous FDA vote against official approval, the drug was granted conditional AAP in 2021 with the agency anticipating completion of a satisfactory post-approval trial to verify clinical benefit.[60] Investigatory trials failed to result in positive clinical endpoints, leading oncology

[51] Iwry, Jonathan. "FDA Emergency Use Authorization: A Brief History from 9/11 to COVID-19." *Food and Drug Law Institute* Fall 2021. https://www.fdli.org/2021/09/fda-emergency-use-authorization-a-brief-history-from-9-11-to-covid-19/. para. 18.

[52] Singh, Jerome Amir, and Upshur, Ross E.G. "The Granting of Emergency Use Designation to COVID-19 Candidate Vaccines: Implications for COVID-19 Vaccine Trials" *Lancet Infectious Diseases* April 2021; Vol 21: 103-109. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832518/pdf/main.pdf. 104.

[53] *Ibid*., 106.

[54] *Alliance for Hippocratic Medicine et al. v. FDA et.al.* op. cit. 6.

[55] *Ibid*., 8.

[56] Robins Kaplan LLP Law Firm. "Rems and Antitrust: Latest Litigation Lessons: Resources." June 3, 2015. https://www.robinskaplan.com/resources/publications/2015/06/rems-and-antitrust. para. 2. Recent case law out of the Third Circuit Court of Appeals has shed light on Big Pharma's strategy to use REMS as a means to eliminate the potential of competition from rival drug manufacturers. Since REMS agreements restrict distribution of a particular drug, offering samples to other pharmaceutical companies for testing is viewed as a liability by the dominant drug manufacturer, effectively barring competitors from developing a clinically superior drug.

[57] Weixel, Nathaniel. "What To Know About The New Alzheimer's Drug, Leqembi." The Hill, July 9, 2023. https://thehill.com/policy/healthcare/4086063-what-to-know-about-the-new-alzheimers-drug-leqembi/. para. 8.

[58] *Ibid*., para. 17-18.

[59] *Ibid*., para. 11.

[60] Steinbrook, Robert. "The Accelerated Approval of Aducanumab for Treatment of Patients With

experts to call for the drug's voluntary withdrawal if confirmatory trials come back negative.[61] Aducanumab costs patients $56,000 per year.[62]

While these examples involve a variety of drugs, they each portray industry's true mindset. By producing high priced drugs with minimal medical evaluation, an unchecked commercial pipeline is generated. A regulatory system that is slow, detailed, and scientifically critical is not conducive to lucrative business operations.

Research and development lie at the heart of public health. By creating a new system of clinical testing, one that allows for pre-approval marketing of experimentally unsubstantiated products, Big Pharma reveals its true intention: commercialism should take precedence over genuine care. AAP and EUA not only circumvent established protocols; they are the fruits of an influence strategy where leverage over agency information is paramount.

ANALYSIS: IMPLICATIONS FOR PUBLIC HEALTH AND APPLICABLE POLICY REMEDIES

REGULATORY CAPTURE AND CORRUPTION

Big Pharma's underlying strategy and accompanying tactics present a series of implications for regulators, consumers, and all who interact with the health care system. Given that unrestricted commercial growth is the chief priority of drug companies, it is essential to consider these findings in light of a single political perspective: corruption, a powerful word that involves "the abuse of public office for private gain."[63] Infiltrating an internal system of intelligence necessary for government regulation is in itself a corruptive maneuver, notwithstanding the vast infusion of corporate money and disregard for legal rules within public health agencies.

From the lens of pharmaceutical companies, this method of influence turns agencies into pawns where only a singular priority prevails, that of business. Political responsibilities of the administrative state become handicapped and irrelevant, regardless of what statutes, regulations, or courts say. The "iron-triangle" of lawmakers, bureaucrats, and special interests remains solidified; all attempts at traditional reform are stopped dead in their tracks. Because politics involves the "making of authoritative policy"[64], a regulatory system defined by the public interest cannot serve Big Pharma's goal of bringing new drugs to market as quickly as possible. The only rational response by industry must involve an attempt to corrupt, confirming the fundamental principle behind the capture theory of regulation.

Institutional corruption within public health agencies amounts to a "distortion" of responsibility that fails to guard the public.[65] If agencies understand the value of information channels, their logical response to corruptive attempts by industry should be to protect such channels. But as previously

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Alzheimer Disease." *JAMA Intern Med.* 181 No. 10, 1281. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2782122. para. 1.

[61] *Ibid*., para. 3.

[62] *Ibid*., para. 2.

[63] Dibley, Arjuna, and Mistree, Dinsha. "Corruption and the Paradox of Transparency." Stanford Law School. https://law.stanford.edu/wp-content/uploads/2018/07/Mistree-Dibley-Corruption.4.18.18.pdf. 4.

[64] Farris, Charles D. "The Political System: An Inquiry Into The State of Political Science By David Easton." *The Journal of Politics* 15, no. 4 (1953): 544–547. https://doi.org/10.2307/2126540. 545.

[65] Light, Donald W., et al., "Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs" *Journal of Law, Medicine & Ethics* Fall 2013 No. 3., 590-600. https://www.populationmedicine.org/sites/default/files/inline-files/2013%20Institutional%20Corruption%20of%20Pharmaceuticals%20%2B%20the%20Myth%20of%20Safe%20%2B%20Effective%20Drugs%2C%20JLME%2C%20Light%20Lexchin%20Darrow.PDF. 591.

uncovered, corruption is symbiotic. Big Pharma as a political actor works in tandem with agencies as government actors.

The popular perception of FDA, CDC, and NIH is notably distinguished from other regulatory bodies. Because these entities are tasked with protecting "health", they occupy a significant physical and emotional space in the body politic of the United States. COVID-19 revealed the high levels of trust given to public health officials and the drug/vaccine approval process.

These sentiments are beneficial to corruption in the short-term. Specific industry tactics such as the private funding of clinical trials and defective research protocols fail to attract political attention in the midst of an ongoing global health crisis. Critical examination of public health governance may threaten the progress made against COVID-19.

Yet in the long term, corruption of this sort is devastating to public health and the national interest. Even though health care and drug manufacturing has long been susceptible to corruption [66], the extent of Big Pharma's actions are cause for great concern. Patients, doctors, and caregivers are left in the dark with no reliable place to turn for answers about their medications. Agencies themselves are no longer sources of impartial information. Instead, a corporatocracy reigns supreme.

INADEQUACY OF EXISTING REFORMS

However, this reality does not suggest that corruption is an eternal plight. Policy solutions are capable of reigniting a regulatory system focused on public interest. But corruption will endure if proposed reforms fail to target the strategic object of industry: information channels. Enacting new legislation mandating transparency will not break Big Pharma's grip over government agencies; it will only strengthen it.

Recent attempts have failed in this regard. The 2022 *FDA Omnibus Reform Act* (Reform Act) provided FDA new enforcement power for AAP approved drugs. It also requires applicants to submit post-approval studies no less than 180 days after completion.[67]

This law is deficient in two respects, both of which will motivate Big Pharma to continue its scheme. First, accelerated regulatory programs like AAP represent an inherent structural weakness of FDA. The statute works within the confines of a broken research protocol that industry has exploited for its own advantage. Reforming drug reporting and revocation timelines is an empty pursuit. AAP was created at the behest of pharmaceutical companies and exists for the primary purpose of introducing high-cost medications to patients, which in turn burdens other health care resources.[68] The Reform Act incidentally endorses AAP and demonstrates the government's willingness to maintain it as a preferable regulatory mechanism.

But the law's most fatal flaw is substantiated by the findings of this inquiry. It refuses to extinguish corrupt information channels inside of agencies. Even a 180-day rule for applicants to submit clinical data does not change the fact that industry still controls what data is submitted, how it is collected, and who reviews it. The "new FDA enforce-

[66] Griffin, Cailey, and Amy Mackinnon. "Report: Corruption in U.S. at Worst Levels in Almost a Decade." Foreign Policy, January 28, 2021. https://foreignpolicy.com/2021/01/28/report-transparency-international-corruption-worst-decade-united-states/. para. 7.

[67] "FDA Omnibus Reform Act: Examining the Policy Changes." Latham & Watkins, January 9, 2023. https://www.lw.com/admin/upload/SiteAttachments/Alert%203050.pdf. para. 6.

[68] Wallid, Gellad F., Kesselheim, Aaron S. "Accelerated Approval and Expensive Drugs – A Challenging Combination" *New England Journal of Medicine* "Perspective" May 25, 2017. 2001-2004. https://www.nejm.org/doi/pdf/10.1056/NEJMp1700446?articleTools=true. 2003.

ment powers" outlined in the Reform Act are merely a series of mandatory notifications to prescribers. They are constructed to nonchalantly reveal an applicant's neglect when conducting confirmatory trials.[69] Not substantive in effect, these provisions shift the burden of quality drug research away from pharmaceutical companies. Agencies are now the cover for industry's own derelictions.

TARGETED REFORMS OF INFORMATION CHANNELS

Viable solutions must embody three components: a central recognition of information channels as the source of corporate capture, changes to clinical trial review procedures, and a grant of market police power to the FDA. Each of these elements are conditioned upon one another; any comprehensive reform package must be all-inclusive.

Corruption in the clinical trial review process stems from the imaginary impartiality of individual regulators who are forced to balance their own professional reputations with commercial pressures and external attitudes that demand pharmaceutical innovation.[70] Civil service reform that eliminates regulators' personal ties with industry is crucial to a drug application process that is wholly institutional rather than collaborative. Agency employees tasked with overseeing the drug application process must be completely dissolved of any past, present, or future connection with pharmaceutical companies, including all employment arrangements, compensation, non-profit activities, and collegial networking. This requirement ensures that all medical professionals within agencies are career public officials.

Opponents of such a plan will likely predict a future shortage of doctors and scientists willing to work solely in public health, thus jeopardizing the regulatory system. But this damage has already been done. Current levels of agency staff are already failing to carry out their public interest mandate, succumbing instead to private interests. To ensure a steady stream of public medical professionals, agencies can provide more lucrative benefits and educational opportunities to employees. The quality of scientific scrutiny is more valuable than the quantity of individuals conducting it.

Civil service reform represents only a preliminary policy for eliminating regulatory capture and corruption. Diminishing the corruptive power of Big Pharma necessitates the reconstruction of information channels which must exist independently of private interests during the drug application process.

As sources of agency funding, user fees and royalties compromise information channels and the research protocols therein. Immediate abolition is warranted. Inspector General(s) within the FDA and CDC should possess the legal authority to bring administrative proceedings against companies and or employees who have engaged in or have conspired to engage in a collusive relationship for the benefit of industry. Should this type of conduct be proven by a review of applicable evidence, the pending drug application would be suspended by the agency in addition to pecuniary penalties for the guilty party.

The mandate of Inspector General(s) as interagency watchdogs encompasses direct oversight of information channels where Big Pharma exercises its influence. To preserve a public interest regulatory environment, clinical information used in trials must be

[69] 21 U.S.C. §356b "Reports of post-marketing studies" (e) https://www.law.cornell.edu/uscode/text/21/356b.

[70] Herder, Matthew. "Pharmaceutical Drugs of Uncertain Value, Lifecycle Regulation at the US Food and Drug Administration, and Institutional Incumbency" *Milbank Quarterly* Vol. 97, No. 3, 2019. 820-857. https://www.jstor.org/stable/pdf/45218867.pdf?refreqid=fastly-default%3A315141a1decd829f529694f27510d295&ab_segments=0%2Fbasic_search_gsv2%2Fcontrol&origin=&initiator=&acceptTC=1. 821-822.

separated from industry access prior to the submission of a drug or medical product application.

Here, the function of Inspector General(s) is akin to an airport security agent who isolates an individual's possessions from their person before safety screening begins. Pharmaceutical companies will be unable to tailor scientific data to a specific review process; their isolation from information channels predates any application they may seek.

Pharmacists, physicians, and care providers are likely to object to a completely independent information channel, arguing that such a policy prevents outside medical expertise from guiding agency decisions. Yet this solution does not place all information channels in a vacuum inaccessible to the scientific community. Its goal is to prevent prejudicial data from corrupting drug application reviews. If newly discovered innovations are truly in the interest of scientific advancement and the pursuit of knowledge, there is no need for pharmaceutical companies to attach such innovations to a specific product application. Breakthrough findings will work their way into agency information channels naturally with corresponding drugs and treatments emerging out of genuine patient demand rather than commercial enterprise.

Yet the most extensive solution to the domain of public health corruption is also the most indispensable, making it more likely to encounter significant political obstruction in the form of lobbying and further capture efforts.

FDA does not possess a unilateral power to withdraw illegal or failed drugs from the marketplace without first consulting manufacturers. The agency's role in drug recalls involves passive oversight as opposed to direct intervention. "FDA's role in a recall is to oversee a company's recall strategy, assess the adequacy of the company's action and classify the recall".[71] A recall is defined as "an action executed by a manufacturer…to remove a defective or harmful drug product from the market."[72] Each recall action is conducted voluntarily by the manufacturer in question unless the FDA exercises its limited mandatory authority which does not extend to all types of pharmaceuticals.[73] But even this mandatory power is statutorily weak. The responsibility to ultimately cease production and prevent prescription of a dangerous drug still lies with the manufacturer, not agency officials.[74]

The FDA, like other federal agencies, cannot advance the public interest without a broad police power that allows regulators to enter the market of goods and use federal resources to seize unsafe drugs and medical products. From industry's perspective, the government's possession of this tool is a deterrent to corruptive behavior. A drug removed from the market solely by the FDA due to negligence, defect, fraud, or medical deception poses disastrous consequences for any company engaged in such conduct, in terms of both law and public relations. The damage Big Pharma has caused to the health care system justifies such an unprecedented measure.

In anticipation of legal opposition, an FDA market police power will not usurp constitutional protections to private property that

[71] Center for Drug Evaluation and Research. "FDA's Role in Drug Recalls." U.S. Food and Drug Administration, n.d. https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls. para. 1.

[72] Terrie, Yvette C. "Overview of the FDA's Drug Recall Process." U.S. Pharmacist – The Leading Journal in Pharmacy, September 17, 2019. https://www.uspharmacist.com/article/overview-of-the-fdas-drugrecall-process. para. 2.

[73] Akin Gump. "A Client's Guide to FDA Recalls - Akin Gump.", 2019. 1-6. https://www.akingump.com/a/web/103223/aokyt/akin-gump-a-client-s-guide-to-fda-recalls-4-10-2019.pdf. 2-3.

[74] 21 U.S.C. §360bbb-8d "Notification, nondistribution, and recall of controlled substances" (a)(5) https://www.law.cornell.edu/uscode/text/21/360bbb-8d.

pharmaceutical companies enjoy, nor will their right to due process be abridged. However, legal challenges by a manufacturer to a drug seizure must be deferred until the safety of patients, consumers, and users can be confirmed, meaning no such drug can remain marketable in the interim.

POLITICAL IMPLICATIONS OF REFORM

Politically, these reforms represent a reorganization of power. Dominant industry control of drug applications, approvals, and commercialization is replaced *ipso facto* with regulatory supremacy. It is plausible that lobbying activities by Big Pharma will continue to increase following a proposal of this sort, in keeping with overall trends[75]. Regulatory capture of information channels may also become more aggressive if this legal solution garners support for enactment.

Hurdles to these solutions are inevitable. But the prospect of significant headwinds does not diminish the revelations herein nor should it slow the pursuit of change. The United States health care system, led by the actions of Big Pharma, has transformed for the worst, concerned with profit as opposed to care. Returning to a place where health care outcomes are valued over commodification is not possible without "addressing the social, commercial, and political determinants of health."[76] These proposals expose where such factors have been abused by industry and seek to resurrect a regulatory model based on public welfare.

Non-implementation will only exacerbate the existing regulatory capture of public health agencies. The political implications of an unchecked public-private partnership are detrimental to every individual citizen of the United States. From the moment of birth, all people become consumers of health care. Medications are central to the treatment of ailments, diseases, and disorders. By choosing to consciously ignore the perilous state of public health regulations, a medical industrial complex is cultivated. Patient care would be rendered meaningless; lives commodified in furtherance of perpetual corporate financial gain.

CONCLUSION

The question of how Big Pharma influences government regulations arose from reports of tragic drug accidents, an increasingly prevalent part of mainstream discourse. But unveiling the surgical methods undertaken by companies to bend the rules in their favor defies traditional political research methods. Only the combination of federal lawsuits, codified regulations, and specific drug profiles can piece the puzzle together. It turns out that information channels, the lifeline of public health agencies, are seriously damaged. Industry's commercial narrative has prevailed.

In a nation where unelected powers can undermine the common interest with ease, a powerful response from those victimized is the only rational counteraction. If health is truly the most fundamental liberty an individual can enjoy, any effort to manipulate it calls for automatic condemnation. With insight into the nuances of Big Pharma's behavior, the prospect of reversing this course is more than a daydream. It is a legitimate political endeavor aimed at restoring the inalienable sanctity of human wellness.

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[75] "Lobbying Industries." https://www.opensecrets.org/federal-lobbying/industries?cycle=a. op cit. "1998-2023".

[76] Darrow, William W. "The Decline and Disorganization of Public Health in the United States: Social Implications" *The International Journal of Social Quality* Vol. 5, No. 2. (Winter 2015): 29-45. https://www.jstor.org/stable/pdf/44174148.pdf?refreqid=fastly-default%3Ade9bae72a78bdff36e478d0991c28a52&ab_segments=0%2Fbasic_search_gsv2%2Fcontrol&origin=&initiator=search-results&acceptTC=1. 40.

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