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ARTICLE

Shattering the Mirage: The FDA's Early COVID-19 Pandemic Response Demonstrates a Need for Reform to Restore Agency Credibility

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Abstract

The power afforded to the administrative state is heavily reliant on public trust and the perception of evidence-based agency decision-making. Organizational reputation is key to preserving regulatory power. However, recent investigations reveal that existing scientific integrity policies may not be sufficient to preserve the credibility of many federal agencies. In fact, a significant number of career scientists across various entities – including the FDA – have observed unreported incidents of political interference. While political influence exerted by the executive branch to set policy goals and determine agency priorities can be beneficial, political pressures must not undermine public trust in scientific agencies. Recently, public perception regarding the FDA's COVID-19 response threatened to weaken the agency's longstanding reputation as the gold standard of review. The COVID-19 pandemic publicized vulnerabilities that exist across agencies, as well as those that are unique to the FDA. The FDA's evolution as an increasingly public health-focused agency that must function in the landscape of politicized science exposes the agency to a greater risk of political interference. After all, the FDA's involvement in public health requires increased participation in non-ideal, value-based decision-making. Throughout its history, the FDA has managed to maintain its reputation through its firm responses to scandal. The COVID-19 pandemic provides a platform for the FDA to – once again – look introspectively and institute safeguards addressing vulnerabilities that plagued the agency's pandemic response. This Article examines the FDA's early COVID-19 response to propose reforms that promote meaningful transparency, public accountability, and scientific integrity.

Keywords: FDA; COVID-19 Pandemic Response; Political Interference; Politicized Science; Administrative State; Public Health Law

Introduction

While the end of the COVID-19 pandemic may be near,[1] the United States' response to the public health crisis has received significant criticism since 2019. Public opinion generally perceived the United States' early pandemic response to be ineffective.[2] Prevention shortcomings, supply shortages, and testing delays were recurring issues.[3] However, major concerns primarily revolved around the politicization of science, especially the potential for non-expert executive branch guidance to shape public health

[1] *See, e.g.*, *WHO Says Pandemic's End May Be Near*, US News (Sept. 12, 2022, 6:57 PM), https://www.usnews.com/news/health-news/articles/2022-09-15/who-says-pandemics-end-may-be-near; Christopher Murray, *COVID-19 Will Continue but the End of the Pandemic Is Near*, 399 Lancet 417, 419 (2022).

[2] Alec Tyson et al., *U.S. Public Now Divided over Whether to Get COVID-19 Vaccine*, Pew Rsch. Ctr. (Sept. 17, 2020), https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/ [perma.cc/CE4Z-DZW2].

[3] Anthony Zurcher, *Coronavirus Response: Things the US Has Got Right – and Got Wrong*, BBC (May 13, 2020), https://www.bbc.com/news/world-us-canada-52579200 [perma.cc/Y986-Q7YA].

measures.[4] For example, serious questions arose around the long-term consequences of executive branch efforts to undermine the scientific community by issuing inaccurate information and disputed emergency guidance.[5] Controversies that threatened to undermine the impartiality of scientific agency engagement in public health decision-making were also worrisome, given the importance of organizational reputation in preserving regulatory power – especially during times of crisis.[6] Alarm at the politicization of science in regulatory agencies gave rise to several inquiries by Congress and the White House, though no major reform was proposed to address the issue.[7]

Even when no public health emergencies exist, lack of evidence-based policymaking within scientific agencies can be an issue.[8] In fact, the actions of Trump administration officials across various agencies prompted allegations of political interference even before the emergence of COVID-19 in 2019.[9] Yet, general issues with evidence-based policymaking are often exacerbated by differences in how policymakers and scientists make decisions during times of crises.[10] Public health crises often create circumstances that are "uniquely vulnerable to a proliferation of disinformation, misinformation, and medical mistrust."[11] After all, it takes time to accumulate and disseminate the critical evidence necessary to plan an effective and comprehensive public health response.[12] During public health emergencies,

[4]Jeff Tollefson, *How Trump Damaged Science – and Why it Could Take Decades to Recover*, 586 Nature 190, 194 (2020); *see also* Alex Fitzpatrick & Elijah Wolfson, *COVID-19 Has Killed Nearly 200,000 Americans. How Many More Lives Will Be Lost Before the U.S. Gets it Right?*, TIME (Sept. 10, 2020), https://time.com/5887432/coronavirus-united-states-failure/ [https://perma.cc/YM7W-RQ3X].

[5]Tollefson, *supra* note 4, at 193-94.

[6]Daniel Carpenter, Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA 33-70 (2010).

[7]*See, e.g.,* Letter from Orice Wiliams Brown, Managing Dir. Cong. Rels., U.S. Gov't Accountability Off., to Elizabeth Warren, Senator, U.S. Senate (Oct. 16, 2020), https://www.warren.senate.gov/imo/media/doc/21-0015%20Warren.pdf [perma.cc/JW4Z-MQBT] (noting that the Government Accountability Office accepts the request to investigate political interference in the FDA); Press Release, The White House, The White House Announces Scientific Integrity Task Force Formal Launch and Co-Chairs (May 10, 2021), https://www.whitehouse.gov/ostp/news-updates/2021/05/10/the-white-house-announces-scientific-integrity-task-force-formal-launch-and-co-chairs/ [perma.cc/8K2J-QL8B] (describing the formation of a White House Office of Science and Technology Policy Scientific Integrity Task Force to review scientific integrity policies in federal agencies); Press Release, Nancy Pelosi, Speaker of the House, Pelosi Names Select Members to Bipartisan House Select Committee on the Coronavirus Crisis (Apr. 29, 2020), https://www.speaker.gov/newsroom/42920 [perma.cc/XXM6-XL2L] (announcing the appointment of members to a bipartisan congressional effort aiming to "examine all aspects of the federal response to the coronavirus.").

[8]Matthew Herper, *Did the Obama Administration Throw the FDA Under the Bus?*, Forbes (Dec. 9, 2011), https://www.forbes.com/sites/matthewherper/2011/12/09/did-the-obama-administration-throw-the-fda-under-the-bus/ [https://perma.cc/46XP-GWSY]. For example, the Bush and Obama administrations were accused of exerting external political influence on the FDA when regulations limited the over-the-counter availability of Plan B One-Step emergency contraceptive. *Id. The FDA Is No Place for Politics*, 13 Nature Structural & Molecular Biology 379, 379 (2006) [hereinafter *The FDA is No*].

[9]*See, e.g.*, *Silencing Science Tracker*, Colum. L. Sch., https://climate.law.columbia.edu/Silencing-Science-Tracker [perma.cc/L2CN-ZYWM]. The Silencing Science Tracker, a joint initiative by the Climate Science Legal Defense Fund and Columbia University's Sabin Center for Climate Change Law, has documented over 500 "government attempts to restrict or prohibit scientific research, education or discussion, or the publication or use of scientific information" since November 2016. *Id.* Over 50 of these documented instances of "silencing science" were directly attributed to the "White House" during President's Trump term. Noted offenses are labelled as relating to: budget cuts, bias and misrepresentation, personnel changes, research hindrance, and government censorship. *Id.*

[10]Bernard C. K. Choi et al., *Can Scientists and Policy Makers Work Together*, 59 J. Epidemiology & Community Health 632, 633-34 (2005) (noting that perspectives between scientists and policymakers differ in areas relating to the treatment of uncertainty, language, time, etc.); Deborah D. Stine, Cong. Rsch. Serv., RL34454, Science and Technology Policymaking: A Primer, 7-10, 27-38 (2009) (noting that challenges to science and technology policy decision-making involve: policymakers' concerns about accountability, agency influence on scientific agendas, and the societal and economic implications of science-based decisions).

[11]Jessica Jaiswal et al., *Disinformation, Misinformation, and Inequality-Driven Mistrust in the Time of COVID-19: Lessons Unlearned from AIDS Denialism*, 24 Aids & Behav. 2776, 2776 (2020).

[12]*Id.*

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implementing often limited and incomplete scientific recommendations into time-sensitive health policy becomes increasingly difficult.[13] For example, lapses in evidence-based policymaking at various levels of the federal government were previously a concern during the HIV/AIDS and opioid epidemics, just as in the recent COVID-19 pandemic.[14] While concerns regarding agency decision-making during the COVID-19 pandemic were not necessarily novel, they were unparalleled in their excessively partisan, public, and prejudicial nature. Hence, though the potential for political interference in administrative agencies predates both COVID-19 and the Trump administration, the early pandemic response presents a good case study with which to examine systematic issues exposing decision-making in scientific agencies to undue political influences.

Ultimately, the perception of political interference can be just as – if not more – dangerous than the reality, given that "organizational reputations animate, empower, and constrain the manifold agencies of government," so that regulatory powers are highly dependent on agency reputations.[15] In fact, "[t]he conception of the agency-as-expert is one of the cornerstones of the U.S. administrative process."[16] This Article will specifically examine the consequences of political pressure on the United States Food and Drug Administration's ("FDA's") early pandemic response, in order to better assess what measures may be necessary to rein in the influence of politicized science on regulatory agencies in the wake of COVID-19. As the FDA continues to be actively involved in addressing threats posed by COVID-19, we will characterize *early* response efforts as measures that took place during the first year of the public health crisis. Specifically, this Article will primarily discuss agency activities that occurred between January 31, 2020 – the date of the United States Department of Health and Human Services' ("HHS's") public health emergency declaration – and January 20, 2021 – President Trump's final day in office.[17] However, later developments in the FDA's response to COVID-19 following the Trump administration will also be noted in this Article if relevant to contextualizing threats to agency integrity and opportunities for future reform.

The FDA has long been heralded as the gold standard of review globally for biopharmaceutical research and development.[18] In fact, the FDA rested at the pinnacle of the federal government's efforts to maintain scientific integrity prior to the COVID-19 pandemic, which is not surprising given that the FDA is widely recognized as "the world's most powerful regulatory agency."[19] The FDA's roles in promoting public health revolve around ensuring the safety, efficacy, and security of the nation's food supply, cosmetics, biological products, medical devices, etc.[20] One of the FDA's primary functions during an emergency is regulating the medical products designed to prevent, diagnose, and treat

[13]Sarah E. Kreps & Douglas L. Kriner, *Model Uncertainty, Political Contestation, and Public Trust in Science: Evidence from the COVID-19 Pandemic*, 6 Sci. Advances, 1, Oct. 21, 2020, at 1, 1.

[14]Andrew Kolodny, *How FDA Failures Contributed to the Opioid Epidemic*, 22 AMA J. Ethics 743, 7435-47 (2020); Frank E. Young, *The Role of the FDA in the Effort Against AIDS*, 103 Pub. Health Rep. 242, 242-45 (1988).

[15]Carpenter, *supra* note 6, at 33.

[16]Wendy E. Wagner, *A Place for Agency Expertise: Reconciling Agency Expertise with Presidential Power*, 115 Colum. L. Rev. 2019, 2024 (2015).

[17]January 20, 2021 – rather than January 31, 2021 – is utilized because President Trump's final day in office serves as a natural endpoint for our discussion. *See* U.S. Dep't of Health & Hum. Servs., Determination That a Public Health Emergency Exists (Jan. 31, 2020), https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx [perma.cc/DD4X-SWGA].

[18]Thomas R. Fleming et al., *The Role, Position, and Function of the FDA – The Past, Present, and Future*, 18 Biostatistics, 417, 418 (2017).

[19]Carpenter, *supra* note 6, at 11, 22 (describing the FDA's reputation and noting its public image encapsulates strong themes of trustworthiness, scientific accuracy, and vigilance that simultaneously "inspire[] [both] praise and fear.").

[20]Fleming, *supra* note 18, at 417 ("The FDA recognizes [its] mission is to be 'responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation … [The] FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.'").

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communicable diseases.[21] Hence, the agency played a key role during the COVID-19 pandemic. Despite the FDA's strong reputation, many criticized the agency's processes for communicating and reviewing COVID-19 countermeasures. In the past, scientists and policymakers have generally been perceived as working together within agencies to effectively address complex public health issues that require interdisciplinary cooperation; however, the repeated and well-publicized politicization of science under the Trump administration threatened public confidence in the trustworthiness of COVID-19-related collaborations between agency scientists and policymakers.[22]

In a public health emergency, the role of science in shaping public policy becomes increasingly critical to addressing the long-term and short-term health consequences of a crisis. When policies do not adequately prioritize input from the scientific community, distrust arises, and lives are placed at risk. To minimize such distrust, science-based regulatory bodies, such as the FDA, generally aim to ensure that rigorous standards of scientific integrity are preserved amid the torrent of diverse political, social, economic, and legal considerations. However, the prioritization of science by regulatory bodies is not enough to maintain public confidence. Instead, as widespread vaccine hesitancy during the COVID-19 pandemic has shown, the public's perception of regulatory agencies as trustworthy may be just as essential as the actual prioritization of science.[23] After all, circumstances frequently arise in which there is neither enough time nor resources to ensure ideal decision-making processes are undertaken. Even within scientific agencies, explanations for many types of decisions may be difficult to articulate effectively. Given the vast array of circumstances that require non-ideal decision-making, "rational agencies may have good reason to decide in a manner that is inaccurate, irrational, or arbitrary."[24] Hence, within administrative law, "hyper-rationalism … is very much the exception, not the rule," as the Supreme Court generally grants agencies the authority to engage in decision-making that appears "rationally arbitrary."[25]

While scientific integrity is often prioritized within scientific agencies, such agencies are hardly immune to external industry considerations. Senior officials at the FDA tend to be pro-industry in order to "survive."[26] For example, "Curtis Wright, the FDA official who oversaw the process for OxyContin's review … [seemed to have at times] 'given up his role as impartial federal regulator and become a sort of in-house advocate for Purdue [Pharma].'"[27] Unsurprisingly, Wright would work for Purdue Pharma after leaving the FDA.[28] In fact, many FDA officials eventually join private industry after leaving their

[21] *See* The State of U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Infectious Disease Outbreaks, FDA (2018), https://www.fda.gov/news-events/congressional-testimony/state-us-public-health-biopreparedness-responding-biological-attacks-pandemics-and-emerging [perma.cc/ZX5J-JWVX]. Other functions the FDA serves in response to pandemics and emerging infectious disease outbreaks include "[p]roviding regulatory advice, guidance and technical assistance to sponsors developing medical countermeasures, as well as to U.S. government partners, international regulators, and international organizations such as the World Health Organization; [s]upporting efforts to establish and sustain an adequate supply of medical countermeasures, including averting supply disruptions when feasible and, in certain situations, allowing products to be used beyond their labeled expiration dates when supported by appropriate scientific evaluation; [e]nabling access to medical countermeasures that are not yet approved—when necessary—through an appropriate mechanism, including through FDA's Emergency Use Authorization authority; [p]roactively identifying and resolving regulatory challenges associated with medical countermeasure development and ensuring that FDA regulations and policies adequately support timely medical countermeasure development and enable preparedness and response activities and capabilities; [f]ostering the professional development of FDA scientists to ensure that FDA personnel maintain the skills and abilities to support the medical countermeasure mission; and [s]upporting regulatory science to create the tools, standards, and approaches necessary to develop and assess the safety, efficacy, quality, and performance of medical countermeasures." *Id.*

[22] *See, e.g.,* Kreps & Kriner, *supra* note 13, at 7 (discussing that prior to the COVID-19 pandemic, even critics believed that science would be prioritized by agencies during public health emergency situations); Andre Fies, *Does Politics Influence the CDC?*, ABC News (June 1, 2007), https://abcnews.go.com/Health/Politics/story?id=3235565&page=1 [perma.cc/J23K-ABKE].

[23] *See* Kreps & Kriner, *supra* note 13, at 1-9.

[24] Jacob Gersen & Adrian Vermeule, *Thin Rationality Review,* 114 Mich. L. Rev. 1355, 1356 (2016).

[25] Adrian Vermeule, Law's Abnegation: From Law's Empire to the Administrative State 154 (2016).

[26] Farhad Manjoo, Opinion, *America Desperately Needs a Much Better F.D.A.*, N.Y. Times (Sept. 2, 2021), https://www.nytimes.com/2021/09/02/opinion/fda-drug-approval-trust.html?smid=em-share [perma.cc/4B7Z-FG6A].

[27] *Id.*

[28] *Id.*

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agency positions.[29] Between 2001 and 2010, over half of the FDA hematology-oncology reviewers who left the agency worked on behalf of or became consultants for pharmaceutical companies.[30] Yet, concerns regarding industry influence are not just limited to individual employees. Contractors that the FDA employs may also have strong industry ties. For example, "thousands of internal [McKinsey and Co. ("McKinsey")] documents [relating to consulting activities that transpired over a 15-year period between 2004 and 2019] … [show] that the firm repeatedly allowed employees who served pharmaceutical companies, including opioid makers, to also consult for the F.D.A."[31] McKinsey was even actively "tout[ing] … inside access [to the FDA] in pitches to private clients."[32] Concerningly, "a porous firewall [appears to have existed] between the consulting firm's work for private companies and for the authorities that oversee them."[33] Aside from such obvious conflicts of interest, there are also other ways in which pharmaceutical companies can exert pressure onto the agency. For example, on July 7, 2021, following Biogen Inc.'s "secret campaign," the FDA controversially approved Aduhelm as a treatment for Alzheimer's disease through the FDA Accelerated Approval Program, despite the previous failure of two large clinical trials.[34]

Despite the occasionally murky interplay between the FDA and industry officials, the FDA is usually vigilant about such issues. Significant efforts are generally made to promote "cooperative" arms-length relations between scientific agencies and the industries they regulate.[35] The importance of maintaining arms-length relations cannot be overstated, as "[i]ndependence from the companies that sell regulated products is essential to the F.D.A.'s effectiveness and credibility."[36] Hence, threats to agency neutrality by third-party industry players are often swiftly resolved. Even when industry influences threatened to bias FDA officials during the bribery scandal of 1989 ("Generic Drug Scandal"), such threats were resolved directly by increasing oversight, transparency, and regulation.[37] Similarly, in response to recent evidence unearthing McKinsey's undisclosed conflicts of interest, the FDA quickly announced that the agency would not contract with the consulting firm pending an investigation into the company's relations with Purdue Pharma and other opioid manufacturers.[38] However, the threats to agency integrity posed by political influence – especially that exercised by the executive branch – can be more difficult to address than those posed by industry influence, given the inherently political nature of the agencies that constitute the administrative state.

[29] *Id.*

[30] *Id.*

[31] Chris Hamby et al., *McKinsey Opened a Door in Its Firewall Between Pharma Clients and Regulators*, N.Y. Times (Apr. 13, 2022), https://www.nytimes.com/2022/04/13/business/mckinsey-purdue-fda-records.html [perma.cc/S8TM-FUFA].

[32] *Id.* ("McKinsey's disclosures [were described] as 'isolated and vague' and not in accordance with the firm's own policy.").

[33] *Id.* A lack of sufficient disclosure purportedly left the FDA unaware of the extent of the conflicts of interest at issue. *Id.*

[34] John Tozzi, *Biogen Alzheimer's Drug Spurs Lawmakers to Demand Documents*, Bloomberg (July 13, 2021, 9:07 AM), https://www.bloomberg.com/news/articles/2021-07-12/biogen-alzheimer-s-drug-spurs-lawmakers-demand-for-documents [perma.cc/RD9Y-YEM4].

[35] Peter Barton Hutt, *Historical Themes and Developments at FDA over the Past Fifty Years*, *in* FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies 17, 20 (Holly Fernandez Lynch & I. Glen Cohen eds., 2015) [hereinafter FDA in the Twenty-First Century].

[36] Joshua M. Sharfstein, *Congress Has to Ask How Much McKinsey Hurt the F.D.A.*, N.Y. Times (Apr. 26, 2022), https://www.nytimes.com/2022/04/26/opinion/mckinsey-fda-opioids.html [perma.cc/VWM6-H3RE].

[37] Garth Boehm et al., *Development of the Generic Industry in the US after the Hatch-Waxman Act of 1984,* 3 Acta Pharmaceutica Sinica B 297, 299-300 (2013).

[38] Hamby et al., *supra* note 31 ("The opioid manufacturer Purdue Pharma, beleaguered and in financial trouble, wanted to revamp its business, and an executive [at McKinsey and Co.] sought out Dr. Smith … But the corporate reorganization was not Dr. Smith's only assignment at the time. He was also helping the Food and Drug Administration overhaul its office that approves new drugs — the same office that would determine the regulatory fate of Purdue's new line of proposed products."); Sharfstein, *supra* note 36; Dan De Luce, *FDA to Halt McKinsey Contracts amid Federal Probes into Opioid Work*, NBC News (Apr. 26, 2022, 7:41 PM), https://www.nbcnews.com/news/fda-halt-mckinsey-contracts-federal-probes-opioid-work-rcna26160 [perma.cc/7DLP-5WL3].

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Part II of this Article will provide some background on the FDA's history as an agency. This brief history will highlight the agency's response to key controversies that threatened its reputation. Providing an overview of the challenges the agency formerly overcame through reform will be useful in understanding how the agency can navigate novel threats. While the most recent challenges to the agency's scientific integrity have been described as "deeply troubling,"[39] many concerns about the FDA's reputation for integrity that resurfaced during the COVID-19 pandemic bring to mind "the troubled era of the FDA," which lasted through the early 1980s.[40] Part III will specifically discuss the FDA's involvement in the United States' early COVID-19 pandemic response under the Trump administration. Part IV will explore how the FDA's responsibilities as an agency interplay with politicized science. Specifically, this discussion will focus on how the FDA's broad public health and political functions make it difficult to restore confidence in the FDA without reform. Part V will provide a more general discussion on the relationship between the White House and the administrative state. Presidential administration is recognized as governance in which "the regulatory activity of the executive branch agencies … [becomes] an extension of the President's own policy and political agenda."[41] While political interference can be catastrophic to the credibility of scientific agencies, the use of political influence by the executive branch to set policy goals and priorities within agencies can also be beneficial. Hence, Part VI will argue that the benefits of political and public accountability associated with presidential administration do not warrant a dramatic restructuring of scientific agencies, like the FDA, despite the threat posed by political interference. Rather, reforms should promote meaningful transparency, public accountability, and scientific integrity. Specifically, this Article suggests that executive and legislative branches promote reforms that prioritize increased transparency related to agency rulemaking and decision-making processes. A clearer delineation between the roles of career scientists and political appointees within the decision-making processes of the FDA and other scientific agencies will also be useful. Part VII concludes with a short summary of key takeaways.

The gold standard: past and present

Since 1839, Congress has authorized chemical analyses of agricultural products in an effort to regulate food safety.[42] During the Progressive Era, Congress passed the Federal Food and Drugs Act of 1906 in direct response to the public outrage spurred by Upton Sinclair's *The Jungle,* which exposed unhygienic conditions within the food industry.[43] This legislation granted regulatory authority to an organizational antecedent of the FDA.[44] The 1906 Pure Food and Drugs Act prompted a "monumental shift in the use of government powers to enhance consumer protection."[45] However, while this legislation instituted consumer protection laws prohibiting "the manufacture, sale, or transportation

[39]*7 Former FDA Commissioners: The Trump Administration is Undermining the Credibility of the FDA*, Wash. Post (Sept. 29, 2020, 5:16 PM), https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/ [perma.cc/4HU7-KFVH].

[40]Philip J. Hilts, Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation 178 (2003).

[41]Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245, 2248, 2281-82 (2001).

[42]*FDA Leadership: 1907 to Today,* U.S. Food & Drug Admin., https://www.fda.gov/about-fda/fda-history/fda-leadership-1907-today [perma.cc/2GDR-N4AP]; Hutt, *supra* note 35, at 17-18. Congress provided funds to the Patent Office to facilitate "the collection of agricultural statistics[] and for other agricultural purposes." *Id.* Within the Patent Office, officials would soon establish an Agricultural Division and a Chemical Laboratory, the predecessor of the FDA. *Id.* Supervision was given to the United States Department of Agriculture ("USDA") in 1862. *Id.* The Chemical Laboratory was re-named and re-structured several times until it officially became known as the FDA in 1930. *Id.*

[43]*Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. Food & Drug Admin., https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement [perma.cc/KTD2-PSVK]; Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, 768 (repealed 1938).

[44]Hutt, *supra* note 35, at 17-18.

[45]*80 Years of the Federal Food, Drug, and Cosmetic Act*, U.S. Food & Drug Admin. (July 11, 2018), https://www.fda.gov/about-fda/virtual-exhibits-fda-history/80-years-federal-food-drug-and-cosmetic-act [perma.cc/D99X-WU5Q].

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of adulterated, misbranded, poisonous, or deleterious foods, liquors, drugs, and medicines," it failed to offer avenues to ensure the safety and efficacy of regulated products.[46]

The FDA's inability to regulate Elixir Sulfanilamide, despite documented reports of its toxicity, eventually contributed to the deaths of 107 individuals — mostly children — and resulted in public outcry that led Congress to act once again.[47] The Federal Food, Drug, and Cosmetic Act of 1938[48] significantly expanded the agency's regulatory authority by replacing the Federal Food and Drugs Act of 1906.[49] The Federal Food, Drug, and Cosmetic Act of 1938 was passed to "overhaul[] the public health system" and equip the FDA with the oversight and enforcement powers necessary to ensure foods, drugs, medical devices, and cosmetics were being manufactured to meet quality standards.[50] Since the statute's passage, the role of the FDA as a regulatory, scientific, and public health agency has continued to expand through the passage of various pieces of legislation like the Public Health Service Act, Kefauver-Harris Drug Amendments, Food and Drug Administration Modernization Act of 1997 ("Modernization Act"), Food and Drug Administration Amendments Act of 2007, etc.[51]

Since the end of the twentieth century, the FDA has been widely heralded as the gold standard of review, even though the agency frequently faced pressure from special interest groups.[52] However, the FDA has not been immune from criticism since then. The Progressive Era vision of the FDA as a scientific agency that would not be subjected to political corruption and undue political interference has been repeatedly challenged.[53] Through the early 1980s, the FDA was adjusting to the more rigorous scientific standards set by the 1962 Kefauver-Harris Amendments, which required drug manufacturers to establish the safety and efficacy of new products prior to marketing.[54] During this time, the agency's decision-making was consistently plagued by "political intrusions," "personality conflicts among officials," and "management crises that became embarrassingly public."[55]

Under the Reagan administration in the 1980s, the FDA's staff shrank by nine percent, oversight by HHS was heavily resisted, and trust within the agency floundered significantly, as bribery, corruption, and favoritism were exposed.[56] The Reagan administration famously utilized political referrals to staff vacancies within the agency's science advisory boards.[57] During this time, the AIDS/HIV epidemic was

[46]J.W. Kille, *Regulatory Toxicology, in* A Comprehensive Guide to Toxicology in Nonclinical Drug Development 499, 507-08 (Ali Said Faqi ed., 2nd ed. 2017).

[47]*See id.* at 508.; Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 Ann. Internal Med. 456, 456 (1995).

[48]Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§301-399).

[49]Kille, *supra* note 46, at 507-08.

[50]Kille, *supra* note 46, at 508.

[51]*Milestones in U.S. Food and Drug Law*, U.S. Food and Drug Admin. (Jan. 31, 2018), https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law [https://perma.cc/V3EV-93B5]; *Food and Drug Administration Amendments Act (FDAAA) of 2007*, U.S. Food and Drug Admin. (Mar. 29, 2018), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007 [perma.cc/VT3E-L7AJ].

[52]Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296; Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; *see* Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 Food & Drug L.J. 127, 129 (1999); Richard A. Merrill, *Modernizing the FDA: An Incremental Revolution*, 18 Health Affs. 96, 97-98 (1999).

[53]Kate Cook, The Presidential FDA: Politics Meet Science, 1-2 (2001) (unpublished Third Year Paper, Harvard University) (on file with the Harvard Law School Library).

[54]F.M. Scherer, *The Pharmaceutical Industry, in* 1 Handbook of Health Economics 1297, 1309-10 (A.J. Culyer & J.P. Newhouse eds., 2000).

[55]Hilts, *supra* note 41, at 178.

[56]Opinion, *The Generic Drug Scandal*, N.Y. Times, Oct. 2, 1989, https://www.nytimes.com/1989/10/02/opinion/the-generic-drug-scandal.html [perma.cc/P2HY-AVMM] [hereinafter *The Generic Drug Scandal*]; Milt Freudenheim, *Exposing the F.D.A.*, N.Y. Times Sept. 10, 1989), https://www.nytimes.com/1989/09/10/business/exposing-the-fda.html [perma.cc/74WH-DX2P].

[57]Emily Berman & Jacob Carter, *Policy Analysis: Scientific Integrity in Federal Policymaking Under Past and Present Administrations*, 13 J. Sci. Pol'y & Governance, Sept. 2018 at 8-9.

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raging, thereby contributing to concerns that inefficient and slow drug review processes within the FDA were contrary to consumer interests.[58] Following public outcry and protests organized by the AIDS Coalition to Unleash Power ("ACT-UP"), including the 1988 "Seize Control of the FDA" demonstration, the FDA improved the efficiency with which it reviewed AIDS/HIV drugs by developing Parallel Track and Accelerated Approval programs.[59]

The scandals of the 1980s culminated in the Generic Drug Scandal. From 1984 to 1989, fraud and corruption at the FDA involved numerous generic drug companies bribing FDA reviewers to approve abbreviated new drug applications ("ANDAs") in a way that manipulated the agency's "first in, first reviewed" policy.[60] In some cases, ANDAs were approved despite the submission of fraudulent and fabricated data.[61] In response to corruption exposed during the Generic Drug Scandal, more than seventy percent of individuals surveyed in a 1989 Gallup poll expressed decreased confidence in the generic drug industry.[62] Hence, the FDA undertook an aggressive approach to restoring public confidence, which involved a very large product analysis effort by the agency that sent a clear message to industry leaders.[63] Following these actions, one analyst even remarked that "'everybody is scared to death about the FDA because they know the FDA [now] means business.'"[64] Congress also passed the Generic Drug Enforcement Act of 1992 in response to this scandal, which equipped the FDA with permission to debar businesses or individuals, withdraw ANDAs, suspend drug distribution, and extract civil penalties.[65]

President Clinton often utilized various agencies, including the FDA, as tools to implement domestic policy goals.[66] Administrative and legislative efforts to quell corruption are not new to the FDA. Troubled periods within the FDA's history — such as the onslaught of scandals that plagued the agency during the 1980s — ultimately prove the strength of the agency's response to corruption. The Clinton administration seized on such momentum to improve the agency by directing important reforms and expanding the agency's powers. For example, President Clinton supported and saw the passage of the Modernization Act, described as the first major piece of agency reform since the 1962 Kefauver-Harris amendments.[67] This legislation significantly accelerated the drug approval system, simplified the process for reviewing medical devices, improved the accuracy of food labeling, and increased access to trials for those with life-threatening and debilitating illnesses.[68] Apart from supporting efforts to promote agency efficiency, the Clinton administration also spearheaded efforts to expand the FDA's role as a public health agency by making it a central component of its 1996 campaign promises to restrict the tobacco industry's marketing to children.[69]

[58]Tasleem J. Padamsee, *Fighting an Epidemic in Political Context: Thirty-Five Years of HIV/AIDS Policy Making in the United States,* 33 Soc. Hist. Med. 1001, 1004-08 (2018).

[59]Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 Am. J. L. & Med. 687, 688, 693 (2016).

[60]Boehm et al., *supra* note 37, at 299. ANDAs are used for generic drug applications, which must "scientifically demonstrate that their product performs in the same manner as the innovator drug," but do not need to "include preclinical (animal) and clinical (human) data to establish safety and effectiveness." *Abbreviated New Drug Application (ANDA)*, U.S. Food and Drug Admin. (Jan. 14, 2022), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda [perma.cc/YA6V-WECE].

[61]Boehm et al., *supra* note 37, at 299.

[62]*Id.*

[63]*Id.*

[64]*Id.* (quoting *Investigation a Bitter Pill for Drug Industry*, Seattle Times, Nov. 4, 1992, at H3.)

[65]Generic Drug Enforcement Act of 1992, Pub. L. No. 102-282, 106 Stat. 149; John R. Fleder, *The History, Provisions, and Implementation of the Generic Drug Enforcement Act of 1992*, 49 Food & Drug L.J. 89, 89-92 (1994).

[66]Cook, *supra* note 53, at 3.

[67]Deborah G. Parver, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 Admin. L. Rev. 1249, 1250-57 (1999).

[68]*Id.*

[69]*See* Peter T. Kilborn, *Clinton Approves A Series of Curbs on Cigarette Ads,* N.Y. Times (Aug. 24, 1996), https://www.nytimes.com/1996/08/24/us/clinton-approves-a-series-of-curbs-on-cigarette-ads.html [perma.cc/3XAS-4VAT].

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In 1996, as part of his attempts to use agencies to further policy objectives, President Clinton issued an arguably unconstitutional executive order directing the FDA to restrict tobacco access and advertising; this was subsequently followed by agency regulations asserting authority over tobacco regulation.[70] In *FDA v. Williamson Tobacco Corporation*, the Supreme Court determined that the attempted regulation of tobacco products exceeded the agency's congressional mandate.[71] However, President Clinton's efforts did set the groundwork for future federal legislation (in the form of the 2010 Family Smoking Prevention and Tobacco Control Act), wherein Congress provided the FDA explicit authority to oversee the tobacco industry.[72] Since the Clinton administration, however, no president has made the FDA a central component of campaign efforts, despite presidential efforts to engage in some level of reform following scandal.

Even after the Clinton administration, there remained some notable scandals that threatened the scientific integrity of the FDA. For example, political interference under the Bush administration initially prevented the FDA from accepting scientific recommendations to allow over-the-counter access to levonorgestrel, an emergency contraception also known as Plan B One-Step.[73] Significant public pressure and judicial intervention eventually forced the agency to approve the over-the-counter use of the product for women aged eighteen years and older.[74] However, even after the over-the-counter approval of Plan B One-Step, concerns remained that the age restriction limiting access to those over the age of eighteen was arbitrary and contrary to scientific recommendations.[75] In general, "the George W. Bush administration severely compromised public access to government science and scientific experts … [as] the administration repeatedly prevented federal scientists from publicly sharing their expertise, rewrote scientific reports to support predetermined policy decisions, and delayed the release of inconvenient scientific findings."[76] Under the Bush administration, numerous instances arose in which the FDA ignored scientific recommendations and participated in various drug safety controversies – including the approval of controversial antidepressants and antibiotics, despite significant risk of adverse side-effects and issues with data integrity attributed to fraud.[77]

Some of the heaviest criticism levied against the agency during this time revolved around concerns regarding the FDA's improper risk assessment of Vioxx (also known by the generic name rofecoxib), a painkiller that contributed to between 88,000 to 139,000 heart attacks.[78] Despite both (1) a 1996 study discussing the adverse effects of the drug on heart health and (2) a 2000 study indicating that Vioxx seemed to double the risk of heart attacks and strokes, the FDA ignored concerns by mid-level officials about the safety of the drug and never removed it from the market.[79] Vioxx's approval severely undermined public trust in the FDA.[80] Concerns were further exacerbated at the time because the position of United States Commissioner of Food and Drugs ("FDA Commissioner") remained unfilled for several years, and President Bush failed to "spen[d] [any] political capital defending the

[70] *Id.* at 10-12.

[71] *Id.* at 18-19.

[72] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1776 (2009).

[73] Gretchen Goldman et al., Ctr. for sci. & democracy at the Union of concerned scientists, Preserving Scientific Integrity in Federal Policymaking: Lessons from the Past Two Administrations and What's at Stake under the Trump Administration 15 (2017).

[74] *Id.* at 15-16.

[75] *Id.*

[76] *Id.* at 18-21.

[77] Matthew Herper, *Why Presidents Don't Shape the FDA,* Forbes (Nov. 2, 2012), https://www.forbes.com/sites/matthewherper/2012/11/02/why-presidents-dont-shape-the-fda/ [perma.cc/R9LG-3DRQ]; Jerry Avorn et al., *The FDA Amendments Act of 2007 – Assessing Its Effects a Decade Later,* 379 New Eng. J. Med. 1097, 1097-98 (2018).

[78] Douglas C. Nelson, *Vioxx Scandal Sparks Criticism of the FDA*, 17 Loy. Consumer L. Rev. 249, 249-52 (2005).

[79] *See id.*; Avorn et al., *supra* note 76, at 1097. Ultimately, it was the drug's manufacturer that withdrew Vioxx from the market following a 2004 study showing significant increases in myocardial infraction and stroke in patients. Merck Sharp & Dohme Corp.; Withdrawal of Approval of New Drug Applications for VIOXX (Rofecoxib) Tablets and Suspension, 87 Fed. Reg. 56,061 (Sept. 13, 2022).

[80] *See* Meredith Wadman, *Troubling Reports Tarnish Credibility of US Drug Agency,* 12 Nature Med. 1223, 1223 (2006).

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FDA."[81] Amid these issues, the "FDA [was] heading into 2005 facing the most difficult challenge to its credibility as a regulatory agency since the generic drug scandal at the end of the 1980s."[82] A Harris poll from May 2006 reported that only thirty-six percent of the public believed that the FDA's efforts to promote drug safety were good/excellent.[83] To restore public trust, Congress implemented various drug safety initiatives through the FDA Amendments Act of 2007, which has since been described as the "most important drug-safety legislation in a century."[84] Most notably, to address concerns raised by Vioxx, this legislation established the risk evaluation and mitigation strategy ("REMS") program and allowed the FDA to require post-approval studies from drug developers.[85]

Following the turmoil caused by Vioxx and the lack of FDA leadership under the Bush administration, President Obama made scientific integrity a core component of his 2009 inaugural address by promising to "restore science to its rightful place."[86] President Obama issued the Presidential Memorandum of March 9, 2009 (Scientific Integrity) that directed the White House Office of Science and Technology Policy ("OSTP") to "develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch" within 120 days.[87] However, despite the appearance of a centralized federal effort to prioritize science, there was great variability in the development of scientific integrity policies by agencies, as the OSTP's four-page recommendations were "vague and insufficiently directive to agencies" by the time they were issued on December 17, 2010 (long after the original 120-day deadline).[88]

Despite strong messaging promoting scientific integrity, the Obama administration was criticized for failing to address allegations of political interference by the HHS in the FDA's emergency contraception recommendations. Specifically, concerns were raised when HHS Secretary Kathleen Sebelius overruled the FDA's recommendation that over-the-counter access to Plan B One-Step be granted to women without implementing any age limit.[89] In *Tummino v. Hamburg*, a federal district court ordered the FDA

[81]Herper, *supra* note 77.

[82]Michael McCaughan, *FDA Creditability Crisis: 1990 Generic Drug Scandal May Be Blueprint for 2005*, Pink Sheet (Jan. 1, 2005), https://pink.pharmaintelligence.informa.com/PS045160/FDA-Credibility-Crisis-1990-Generic-Drug-Scandal-May-Be-Blueprint-For-2005.

[83]Wadman, *supra* note 80.

[84]Stephen Northrup, *Looking Back and Looking Ahead: Vioxx, Drug Safety, and the Legacy of Sen. Michael Enzi*, Stat (Dec. 21, 2020), https://www.statnews.com/2020/12/21/vioxx-drug-safety-legacy-senator-michael-enzi/ [perma.cc/C3RM-BF5P] (quoting Gregory D. Curfman et al., *Safer Drugs for the American People*, 357 New Eng. J. Med. 602, 602 (2007)); *see* Avorn et al., *supra* note 77.

[85]Avorn et al., *supra* note 77, at 1098; Northrup, *supra* note 84. REMS is a "drug safety program that … can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." *Risk Evaluation and Mitigation Strategies | REMS*, U.S. Food & Drug Admin., (Aug. 8, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [perma.cc/E86C-YDM5].

[86]Macon Phillips, *President Barack Obama's Inaugural Address*, Obama White House Archives (Jan. 21, 2009, 1:27 PM), https://obamawhitehouse.archives.gov/blog/2009/01/21/president-barack-obamas-inaugural-address [perma.cc/5KLM-DYZJ]. President Obama issued a memorandum directing the Director of the Office of Science and Technology Policy to develop policy recommendations to: guarantee that "selection and retention of candidates for science and technology positions in the executive branch … [was] based on the candidate's knowledge, credential, experience, and integrity;" require that "each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;" provide that "each agency should appropriately and accurately reflect [scientific or technological information considered in policy decisions];" ensure that where possible "[e]ach agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;" provide that "[e]ach agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised," etc. Memorandum from The White House: Office of the Press Sec'y for the Heads of Exec. Dep'ts and Agencies (Mar. 9, 2009) (on file with Obama White House Archives).

[87]*Id.*

[88]*Id.*

[89]Janice Hopkins Tanne, *FDA Finally Approves Plan B—But with Restrictions*, 333 BMJ 461, 461 (2006); *see* Kathleen Rest & Michael Halpern, *Politics and the Erosion of Federal Scientific Capacity: Restoring Scientific Integrity to Public Health Science*, 97 Am. J. Pub. Health 1939, 1939-44 (2007).

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to make the emergency contraception widely available without age restrictions, after noting scientific opinions indicating that "'any objective review makes it clear that Plan B One-Step is more dangerous to politicians than to adolescent girls.'"[90] However, the Obama administration still hesitated to comply with the directive by attempting to appeal the ruling.[91] Eventually, the Obama administration dropped its appeal, and the FDA approved the use of Plan B One-Step for all women of child-bearing age.[92] This outcome did not change the fact that Sebelius became "the first health secretary ever to overrule the FDA publicly."[93]

Under the Obama administration, the agency published scientific integrity policies; however, even following such reform, it remains "difficult to find any significant issue faced by [the] FDA that [was] not ultimately a matter of policy, informed by both scientific and legal considerations."[94] Yet, despite external non-governmental and governmental efforts to exert influence, the FDA has generally been able to preserve its reputation as the gold standard of review by prioritizing "efficacy and safety."[95] For example, the "'science eventually won out'" even in the case of the Plan B One-Step scandal.[96] After all, as "the agency has few political appointees and is relatively decentralized," presidential ability to influence FDA policy is usually restricted.[97] However, just because the agency has been able to maintain its reputation over the past few decades does not mean that threats to the scientific integrity can be ignored.

As part of its deregulatory efforts, the Trump administration repeatedly sought to limit the meetings of scientific advisory committees, control the information and language used by federal scientists, limit professional development of federal scientists, ignore scientific information, encourage the violation of scientific integrity policies, and discount cost-benefit analysis models.[98] These activities, along with other "deregulatory pressure from the White House [during this time], … had profound effects on several federal agencies."[99] However, prior to the COVID-19 pandemic, the FDA still largely resisted political interference by the Trump administration between 2017 and 2019.[100] Even though the Trump administration significantly reduced FDA enforcement activity – including the issuance of warning letters, which inform a manufacturer about violations related to tainted food and drug products to demand corrections, and Official Action Indicated reports, which recommend regulatory action following the identification of concerning conditions – such concerning trends were widely attributed to a lack of cooperation by the Department of Justice, rather than issues within the agency, itself.[101] However, the expanded reliance on the FDA during the COVID-19 pandemic did threaten to severely undermine public trust, once again.

Political interference affecting agency decision-making can take many forms, including: "(1) suppressing, distorting, or otherwise misusing scientific information; (2) controlling federal scientists; (3) limiting public access to scientific information; and (4) changing the way scientific information is

[90]Tummino v. Hamburg, 936 F. Supp. 2d 162, 170-171 (E.D.N.Y. 2013) (quoting *The Politics of Emergency Contraception*, 366 New Eng. J. Med. 101, 102 (Jan. 12, 2012)); Goldman, *supra* note 73, at 16.

[91]Goldman, *supra* note 73, at 16.

[92]*Id.*

[93]*Id.* at 15-16.

[94]Hutt, *supra* note 35, at 28.

[95]Jerry Avorn, *FDA Standards – Good Enough for Government Work?*, 353 New Eng. J. Med. 969, 971 (2005); *see* Alta Charo, *Speed Versus Safety in Drug Development*, *in* FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies 251, 252-53 (Holly Fernandez Lynch & I. Glen Cohen eds. 2015).

[96]Richard Monastersky, *Obama's Science Legacy: Uneven Progress on Scientific Integrity*, 456 Sci. Am. 386, 386-87 (2016).

[97]Charles Piller, *Exclusive: FDA Enforcement Actions Plummet Under Trump*, Science (July 2, 2019), https://www.sciencemag.org/news/2019/07/exclusive-fda-enforcement-actions-plummet-under-trump [perma.cc/A4U4-E2X4].

[98]Berman & Carter, *supra* note 57.

[99] Piller, *supra* note 97.

[100]*See generally* Sheila Kaplan & Katie Thomas, *F.D.A. Chief Goes Against the Administration Stereotype*, N.Y. Times (Feb. 11, 2018), https://www.nytimes.com/2018/02/11/health/gottlieb-fda-drugs.html?action=click&module=RelatedCoverage&pgtype=Article&region=Footer [perma.cc/CYU5-TENM].

[101]*C.f.* Piller, *supra* note 97.

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incorporated into the decision-making process."[102] Over the course of the COVID-19 pandemic, the Trump administration was accused of all four violations. However, as demonstrated in Part II's short background on some of the FDA's major scandals, the potential for political interference to implicate agency decisions and embroil the FDA in partisan battles that could irreparably harm public perception is not a novel concern.[103] If one views the agency's activities during the pandemic in light of the FDA's history, threats to the FDA's integrity serve as an opportunity for reform that will ultimately strengthen the agency.

Early COVID-19 pandemic response efforts

In late 2019, China identified the first cases of SARS-CoV-2 transmission resulting in COVID-19.[104] Following the World Health Organization's ("WHO's") global health declaration, the HHS Secretary announced a public health emergency in response to the COVID-19 outbreak on January 31, 2020.[105] The spread of COVID-19 soon reached pandemic proportions with the WHO officially designating the outbreak as a pandemic on March 11, 2020.[106] Subsequently, on March 13, 2020, President Trump declared a national emergency.[107]

Regulatory science plays an important role in addressing many diverse public health issues, especially during emergency conditions.[108] For example, during a pandemic or emerging infectious disease outbreak, the FDA may issue Emergency Use Authorizations ("EUAs"), which permit unapproved medical products to be used during an ongoing public health emergency.[109] In a pandemic, EUAs play an important role in facilitating medical countermeasures.[110] In the wake of COVID-19, the FDA issued hundreds of EUAs for medical devices, therapeutics, drugs and biological products, in vitro diagnostics, serology tests, personal protective equipment, and vaccines.[111]

On March 28, 2020, the FDA granted a controversial EUA for two antimalarial drugs, chloroquine phosphate and hydroxychloroquine, after President Trump touted them as potential treatments for

[102]Rest & Halpern, *supra* note 89, at 1939; *see also* Berman & Carter, *supra* note 57 (noting that "patterns of scientific integrity violations" also include: "[i]nsufficiently filling executive branch positions that manage, conduct, or disseminate science or science-based regulations;" "[u]ndermining science-based regulations;" "[t]ampering with science or scientific reports;" and "[c]reating a hostile environment for scientific staff.")

[103]*See* Rest & Halpern, *supra* note 89.

[104]Ben Hu et al., *Characteristics of SARS-COV-2 and COVID-19*, 19 Nature Revs. Microbiology 141, 141 (2021).

[105]*Id.*; Admin. for Strategic Preparedness & Response, Health and Hum. Servs., Determination That a Public Health Emergency Exists (2020), https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx [perma.cc/E32P-7EVN].

[106]Hu et al., *supra* note 104, at 142.

[107]Proclamation No. 9994, Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, 85 Fed. Reg. 15337 (Mar. 13, 2020).

[108]*See* The State of U.S. Public Health Biopreparedness, *supra* note 23.

[109]21 U.S.C. § 360bbb-3; *see Emergency Use Authorization*, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas [perma.cc/AL7N-UW73] (last updated Nov. 9, 2022). Emergency use authorizations can be issued following "a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents." § 360bbb-3.

[110]*See Emergency Use Authorization*, *supra* note 109.

[111]*See, e.g.*, *id.*; *In Vitro Diagnostics EUAs - Serology and Other Adaptive Immune Response Tests for SARS-CoV-2*, FDA, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2 (Sept. 6, 2022) [perma.cc/J63C-ZEP9]; *Personal Protective Equipment EUAs*, FDA, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas (Sept. 29, 2022) [perma.cc/JB4W-4VJF].

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COVID-19.[112] The authorization provided no evidence justifying the FDA's decision.[113] Furthermore, in order to facilitate access to the drugs, the FDA also allowed overseas facilities already flagged for poor sanitation and data manipulation to participate in manufacturing, despite the agency's inability to actively inspect overseas facilities during the pandemic.[114] The FDA eventually revoked the EUAs for chloroquine phosphate and hydroxychloroquine, after concluding that the drugs were "unlikely to produce an antiviral effect" and that the "potential benefits … d[id] not outweigh … known and potential risks.""[115]

However, the fact that the FDA issued these particular EUAs had profound consequences on public perception of the agency. Specifically, the role of non-expert political advocacy groups in the EUA approval process for chloroquine phosphate and hydroxychloroquine resulted in concerns about long-term "public health costs, includ[ing] ineffective or harmful therapeutic use, reduced attention to other potentially beneficial therapeutics, … strained or rationed access to a therapy already used for other conditions, [and] reduced regulatory credibility."[116] The FDA's grant of an EUA for hydroxychloroquine was even the subject of a whistleblower complaint from Rick Bright, a former HHS official who believed that the FDA was pressured "to let politics and cronyism drive decisions over the opinions of the best scientists we have in government."[117] Concerns regarding political interference in agency decision-making also emerged when President Trump made statements touting the REGN-COV2 investigational antibody combination as a "cure" right before Regeneron Pharmaceutical applied for an EUA for the drug.[118] Following President Trump's endorsements of the COVID-19 treatments, any actions the FDA took to authorize chloroquine phosphate/hydroxychloroquine and, later, REGN-COV2 could be interpreted through a political lens.[119] This also threatened to undermine public trust in the FDA's scientific integrity.

The FDA engaged in some other questionable decision-making during the pandemic. For example, the FDA granted an EUA for convalescent plasma, despite insufficient evidence which misrepresented

[112]*See* Letter from Patty Murray, Senator, U.S. Senate, to Stephen M. Hahn, Comm'r of Food & Drugs, FDA (Apr. 16, 2020), https://www.help.senate.gov/imo/media/doc/04162020%20Letter%20from%20Senator%20Murray%20to%20Commissioner%20Hahn.pdf [perma.cc/D6AL-JCE2]. Senator Murray submitted a letter to the FDA Commissioner expressing that the approval of hydroxychloroquine lacked adequate evidence to support its efficacy. *Id.* Senator Murray raised concerns that this hasty decision-making threatened to "expos[e] patients to potentially severe adverse health effects and los[e] the public trust in the tests, drugs, and vaccines that are – and will be – critical for addressing the COVID-19 pandemic." *Id.*

[113]Kyle Thomson & Herschel Nachlis, *Emergency Use Authorizations During the COVID-19 Pandemic: Lessons from Hydroxychloroquine for Vaccine Authorization and Approval*, 324 JAMA 1282, 1282 (2020); Letter from FDA Chief Scientist Denise Hinton to Dir. of Biomedical Advanced Rsch. & Dev. Authority Rick Bright (Mar. 28, 2020), https://www.fda.gov/media/136534/download [perma.cc/2Q7H-PEFC].

[114]*See* Anna Edney, *Troubled Overseas Drugmakers Get Free Pass in Coronavirus Crisis*, Bloomberg (Apr. 9, 2020), https://www.bloomberg.com/news/articles/2020-04-09/troubled-overseas-drugmakers-get-free-pass-in-coronavirus-crisis?sref=kYsmDE6a [perma.cc/W2WP-QU3M].

[115]Thomson & Nachlis, *supra* note 113, at 1282; Letter from Denise Hinton, FDA Chief Scientist, to Gary Disbrow, BARDA Deputy Assistant Sec'y (June 15, 2020), https://www.fda.gov/media/138945/download [perma.cc/6PQW-CAWT].

[116]Thomson & Nachlis, *supra* note 113, at 1283.

[117]Kaitlan Collins et al., *Ousted Vaccine Director Files Whistleblower Complaint Alleging Coronavirus Warnings Were Ignored*, CNN (May 5, 2020), https://www.cnn.com/2020/05/05/politics/rick-bright-complaint/index.html [perma.cc/H7SW-LL38]. Rick Bright additionally claimed that he was transferred from his role as the Director of the Biomedical Advanced Research and Development Authority ("BARDA") in retaliation for filing the initial whistleblowing complaint. *Id.* While such claims were originally denied, a settlement between Rick Bright and the HHS was ultimately reached regarding the retaliation claims after he rendered his resignation. Press Release, U.S. Office of Special Counsel, OSC Announces Settlement Agreement Between HHS and Former BARDA Director Dr. Rick Bright After his Reassignment (Aug. 9, 2021), https://osc.gov/News/Pages/20-21-Settlement-Rick-Bright.aspx; *see also* Dan Diamond, *HHS Whistleblower Resigns from Government*, Politco (Oct. 16, 2020, 6:29 PM), https://www.politico.com/news/2020/10/06/hhs-whistleblower-rick-bright-resigns-426895.

[118]Holly Ellyatt, *Regeneron Requests Emergency Use Approval for Antibody Treatment Taken by Trump; Stock Rises 4% in Premarket*, CNBC (Oct. 8, 2020), https://www.cnbc.com/2020/10/08/regeneron-requests-eua-from-the-fda-for-coronavirus-treatment.html [perma.cc/8CH6-FG2S].

[119]Benjamin Siegel, *Senior Dem Concerned about Political Influence at FDA: Letter*, ABC News (Apr. 17, 2020), https://abcnews.go.com/Politics/senior-dem-concerned-political-influence-fda-letter/story?id=70210576 [perma.cc/9M2A-HX8Y].

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the treatment's effects on mortality.[120] Significant criticism was levied at the agency for overstatements regarding convalescent plasma's potential for risk reduction.[121] The FDA Commissioner even had to apologize for comments he made about the benefits of convalescent plasma on August 23, 2020, the day before the 2020 Republican National Convention.[122] Concerns regarding convalescent plasma also revolved around whether political considerations influenced the FDA's decision to grant an EUA without sufficient evidence, as "the grant of the EUA itself may make it more difficult for the FDA to obtain results from the randomized controlled trials it has stated will be needed to determine the product's efficacy."[123]

Compounding concerns regarding the FDA's scientific integrity resulted in an erosion of public trust and decreased vaccine confidence, as evidenced by the significant drop in the number of Americans willing to get a COVID-19 vaccine that was observed over the course of the first few months of the pandemic.[124] In May 2020, seventy-two percent of U.S. adults said they intended to get a COVD-19 vaccine, while those willing to get a vaccine had dropped to only fifty one percent by September 2020.[125] During this time, the FDA faced repeated criticism for failing to appropriately communicate the role of an EUA to the general public.[126] Communication and other issues undermining trust in the FDA's pandemic response were further exacerbated after statements were made about fast-tracking a COVID-19 vaccine by issuing an EUA before the end of Phase 3 clinical trials.[127] Fears were particularly heightened because of indications that the 2020 Trump presidential campaign hoped that the issuance of an EUA for a COVID-19 vaccine prior to the November 3rd election would serve as an "October surprise" and increase voter approval.[128]

To address some concerns regarding political interference, the FDA implemented stricter non-binding standards for granting vaccine EUAs. The Trump administration originally attempted to delay and prevent such standards from being published; however, in October 2020, the FDA eventually issued the Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry document.[129] Yet, this guidance did not fully mitigate concerns that the FDA's vaccine review would be affected by political motivations. Allegations persisted that the FDA Commissioner's job was being

[120]Rachel Sachs, *Understanding the FDA's Controversial Convalescent Plasma Authorization*, Health Affs. (Aug. 27, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200827.190308/full/ [perma.cc/96HM-BCW7].

[121]Anne Flaherty, *Convalescent Plasma Went from Promising to Politically Tainted: 3 Things to Know*, ABC News (Aug. 25, 2020), https://abcnews.go.com/Politics/convalescent-plasma-promising-politically-tainted-things/story?id=72599272 [perma.cc/F853-KZ7F].

[122]Andy Slavitt, *FDA Chief Apologizes for COVID-19 Plasma Exaggeration – But Trump's Endgame Is Clear*, NBC News (Aug. 31, 2020), https://www.nbcnews.com/think/opinion/fda-chief-apologizes-covid-19-plasma-exaggeration-trump-s-endgame-ncna1238721 [perma.cc/DF3K-3MJ3].

[123]*Id*; Sachs, *supra* note 120.

[124]Tyson et al., *supra* note 2.

[125]*Id.*

[126]Sandra Quinn et. al., *Communicating Effectively About Emergency Use Authorization and Vaccines in the COVID-19 Pandemic*, 111 Am. J. Pub. Health 355, 355 (2020).

[127]Jon Cohen, *Here's How the U.S. Could Release a COVID-19 Vaccine Before the Election – and Why That Scares Some*, Sci. (Aug. 28, 2020), https://www.sciencemag.org/news/2020/08/here-s-how-us-could-release-covid-19-vaccine-election-and-why-scares-some [perma.cc/XKV8-7THM].

[128]Liz Szabo & JoNel Aleccia, *Signs of an 'October Vaccine Surprise' Alarm Scientists*, NBC News (Sept. 21, 2020), https://www.nbcnews.com/health/health-news/signs-october-vaccine-surprise-alarm-scientists-n1240617 [perma.cc/EQ2F-5RWT].

[129]U.S. Food & Drug Admin., Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry (2020); *see also* Carl Zimmer & Noah Weiland, *In Reversal, White House Approves Stricter Guidelines for Vaccine Makers*, N.Y. Times (Oct. 15, 2020), https://www.nytimes.com/2020/10/06/health/covid-vaccine-guidelines.html [perma.cc/VR2L-B7H4]; Sharon LaFraniere & Noah Weiland, *White House Blocks New Coronavirus Vaccine Guidelines*, N.Y. Times (Oct. 23, 2020), https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html [perma.cc/RF7J-E82G]; Laurie McGinley et al., *Trump, White House Demand FDA Justify Tough Standards for Coronavirus Vaccine, Raising Concerns of Political Interference,* Wash. Post (Sept. 25, 2020, 8:23 PM), https://www.washingtonpost.com/politics/2020/09/25/coronavirus-vaccine-trump-interference/ [perma.cc/XHD6-DMHB].

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threatened by the White House unless EUAs were expedited, though these claims were later denied.[130] Furthermore, President Trump and multiple White House aides began to accuse the FDA of being a part of the "deep state" and engaging in efforts to slow down vaccine approval for political reasons.[131]

Concerns regarding the scientific integrity of the FDA during the COVID-19 pandemic have also largely been fueled by HHS actions. The FDA has never been an independent regulatory agency and is currently housed within the HHS.[132] Yet, the COVID-19 pandemic highlighted tensions between the HHS and the FDA that spurred apprehensions about the extent of the political influence exerted on the FDA. On September 15, 2020, HHS Secretary Alex Azar issued a memorandum preventing health-related agencies, including the FDA, from implementing any new rules regarding "foods, medicines, medical devices and other products, including vaccines" without his approval.[133] This policy change, which centralized HHS operations by "reserv[ing] to the Secretary" the ability to issue new rules, was especially concerning because of a pattern of executive branch interference in scientific agencies' policymaking processes.[134] Concerns regarding this policy change primarily revolved around the inefficiency of the process, rather than its ability to directly impact COVID-19 vaccine decision-making.[135]

Yet, even before this memorandum was issued, tensions between the HHS and FDA were escalating. For example, HHS Secretary Azar overrode FDA officials to relax testing rules during the pandemic.[136] On August 19, 2020, the HHS issued a unilateral policy change preventing the FDA from monitoring the quality of COVID-19 tests that companies developed for their own use.[137] This policy had widespread implications on the effectiveness of COVID-19 testing processes in university, commercial, and public health labs.[138] To demonstrate their discontent, FDA officials refused to announce the change in policy, forcing the HHS to issue its own statement. [139] This unilateral policy announcement publicly showcased inter-agency conflicts and a lack of centralization that consistently contributed to chaotic messaging surrounding the pandemic.[140] Concerns even arose that HHS Secretary Azar was strongly considering

[130]Jonathan Lemire et al., *White House Threatens FDA Chief's Job over Vaccine Approval*, AP News (Dec. 11, 2020), https://apnews.com/article/donald-trump-business-mark-meadows-coronavirus-pandemic-0902fbb041b0459e55da86be75b1457a [perma.cc/E4FQ-CVVB]; Emily Shapiro, *FDA Commissioner Hahn Denies Reports He Was Threatened with Firing*, ABC News (Dec. 12, 2020), https://abcnews.go.com/Politics/fda-commissioner-denies-reports-threatened-firing/story?id=74689216.

[131]Lev Facher, *Trump Has Launched an All-Out Attack on the FDA. Will Its Scientific Integrity Survive?*, Stat (Aug. 27, 2020), https://www.statnews.com/2020/08/27/trump-has-launched-an-all-out-attack-on-the-fda-will-its-scientific-integrity-survive/ [perma.cc/6UE3-U5H5].

[132]*See* Hutt, *supra* note 35, at 17-18. Since its creation, the FDA has been housed in various executive branch departments. *Id.* Before residing in the HHS, the FDA resided in the USDA (1862-1940), the Federal Security Administration (1940-1953), and the Department of Health, Education and Welfare (1953-1979). *Id.* After 1979, the FDA has remained housed within the HHS, a Cabinet-level department within the executive branch. *Health and Human Services Department,* Fed. Reg., https://www.federalregister.gov/agencies/health-and-human-services-department#:~:text=The%20Department%20of%20Health%20and,with%20the%20Nation's%20human%20concerns.--source [perma.cc/6MG5-W26G] (last visited Nov. 10, 2022).

[133]Sheila Kaplan, *In 'Power Grab,' Health Secretary Azar Asserts Authority Over F.D.A.*, N.Y. Times (June. 12, 2021), https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html [perma.cc/JZQ2-6QPD]. Melissa Quinn & Emily Tillett, *Gottlieb Says HHS Move to Centralize Control over Agencies "Makes No Sense,"* CBS News (Sept. 20, 2020, 12:16 PM), https://www.cbsnews.com/news/scott-gottlieb-hhs-centralize-control-agencies-fda-makes-no-sense-face-the-nation/ [perma.cc/CBN4-AZC4].

[134]*See* Kaplan, *supra* note 100; Quinn & Tillett, *supra* note 133.

[135]*See* Quinn & Tillett, *supra* note 133. Former FDA Commissioner Scott Gottlieb criticized the memorandum stating: "The timing of this is just really poor right now because it's going to distract the agency and frankly create headlines that could lead to the perception that the agency is being bullied." *Id.*

[136]Adam Cancryn & Sarah Owermohle, *HHS Chief Overrode FDA Officials to Ease Testing Rules*, Politco (Sept. 15, 2020, 3:21 PM), https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400 [perma.cc/WFJ7-4XWJ]; Amanda K. Sarata, Cong. Rsch. Serv., IN11548, HHS Announcement on FDA Premarket Review of Laboratory-Developed Tests (LDTs) 1 (2020).

[137]Cancryn & Owermohle, *supra* note 136.

[138]*See id.*

[139]*See id.*

[140]*See id.*

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removing FDA Commissioner Stephen Hahn from his position.[141] Tensions between the HHS and FDA continued to escalate throughout the Trump administration, ultimately culminating in public tweets by the FDA Commissioner in January 2021 expressing the FDA's intent not to comply with last-minute directives imposed by the HHS that aimed to reduce oversight capabilities by transferring regulatory powers to other departments.[142]

The appointment of several agency officials with partisan ties further politicized the way that decision-making during the COVID-19 pandemic was viewed.[143] For example, the appointment of Emily Miller, a conservative journalist and gun rights activist, to the role of assistant commissioner for media affairs raised concern when press statements appeared to have strong political undertones.[144] Miller was terminated from her position after 11 days, due to her role in spreading statements that erroneously represented the potential for convalescent plasma to serve as a COVID-19 treatment.[145]

In addition to concerns regarding Miller's appointment, the appointment of John Wagner, an FDA spokesperson who had previously served as a communications consultant for the 2016 Republican National convention and a deputy assistant secretary at the Department of Veteran Affairs, also raised questions.[146] Five days after Miller was fired, Wagner, a political appointee, was replaced as the head of the FDA's office of external affairs on an interim basis by Heidi Rebello, an FDA career official, due to increased scrutiny the FDA faced following Miller's misstatements regarding convalescent plasma.[147]

This Article primarily discusses activities that took place between the public health emergency declaration and President Trump's final day in office. However, the FDA continues to actively engage in COVID-19 response efforts. Mischaracterizing the FDA's and other scientific agencies' vulnerabilities as unique to the Trump administration is both erroneous and dangerous. Failing to address cases of political influence exerted on the FDA that pre- and post-date the Trump administration allows key problems to remain unaddressed, thereby contributing to the potential for future abuse. Agency susceptibility to undue political influence remains a very real and very pressing issue. For example, President Biden has also been accused of politicizing the COVID-19 pandemic during his first year in office, "sparking fear that political pressures will once again override the agency's expertise."[148] The next Part will discuss agency-specific vulnerabilities that make the FDA susceptible to political interference, regardless of which party controls the White House.

[141] *See id.*; Adam Cancryn & Dan Diamond, *An Angry Azar Floats Plans to Oust FDA's Hahn*, Politico (Oct. 22, 2020, 2:23 PM), https://www.politico.com/news/2020/10/22/azar-plans-oust-hahn-fda-431139 [perma.cc/WR5E-XDFA].

[142] Sarah Owermohle & Adam Cancryn, *FDA Fights for Independence in Trump Administration's Final Days*, Politico (Jan. 13, 2021, 12:25 PM), https://www.politico.com/news/2021/01/12/fda-independence-hhs-458515 [perma.cc/UQ2W-3DZA]. Specifically, the FDA refused to sign a Memorandum of Understanding that would transfer its ability to regulate genetically modified animals to the USDA, though the HHS still attempted to implement this policy. *Id.;* Stephen M. Hahn (@SteveFDA), Twitter (Jan. 19, 2021, 2:45 PM), https://twitter.com/SteveFDA/status/1351616813705154562 [perma.cc/V6WF-XJLG].

[143] Facher, *supra* note 131.

[144] *Id.* ("A press release sent soon after Miller joined the agency, announcing the emergency authorization of blood plasma as a Covid-19 therapy, took a political tone that unnerved longtime FDA observers"); Press Release, U.S. Food & Drug Administration, FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration's Fight Against Pandemic (Aug. 23, 2020), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment.

[145] *Id.*; Sheila Kaplan & Katie Thomas, *Two P.R. Experts at F.D.A. Have Been Ousted After Blood Plasma Fiasco*, N.Y. Times (Jan. 6, 2021), https://www.nytimes.com/2020/08/28/health/blood-plasma-fda.html [perma.cc/RDP6-WWBU]; FDA Spokesperson - ARCHIVED (@FDASpox_Archive), Twitter (Aug. 23, 2020, 9:27 PM), https://twitter.com/FDASpox_archive/status/1297706985039835136 [perma.cc/G8W4-734Y] ("Convalescent plasma has shown to be beneficial for 35% of patients. This risk reduction figure - shown in chart below - is from @MayoClinic data from expanded access program that was analyzed by FDAA for the emergency use authorization announced today.").

[146] *Second Trump Appointee Out at FDA amid Credibility Concerns*, US News (Sept. 2, 2020, 5:52 PM), https://www.usnews.com/news/health-news/articles/2020-09-02/second-trump-appointee-out-at-fda-amid-credibility-concerns.

[147] *Id.*

[148] Sarah Owermohle, *Biden's Top-down Booster Plan Sparks Anger at FDA*, Politico (Aug. 31, 2021, 6:04 PM), https://www.politico.com/news/2021/08/31/biden-booster-plan-fda-508149 [perma.cc/B7BG-7ZZ7].

The FDA's shifting roles in a landscape of politicized science

Since the agency's inception, "there have been heated disagreements about whether FDA decisions are scientific, policy, or legal in nature."[149] The FDA is often at the intersection of "warring demands of science[,] … business, and … the minefield of political Washington."[150] There have also been multiple instances in which the FDA's handling of politically-charged food and drug safety and efficacy issues – such as in cases of tobacco, birth control, and abortion – has been attributed to the erosion of trust in the role that science plays in scientific regulation.[151] There are many parallels between concerns raised during the COVID-19 pandemic and earlier instances of political interference and corruption. In reality, "[p]residents have sparred with the [FDA] for decades … But taken together, the actions [of the Trump administration during the COVID-19 pandemic] represent an extraordinary new frontier for presidential attacks on the [FDA's] scientific agency."[152] While the Trump administration has been accused of political interference across a broad spectrum of federal agencies, the FDA presents a strong case study because the agency has always been able to successfully implement substantial reform when faced with scandal.[153] The COVID-19 pandemic provides a good platform for the FDA to – once again – look introspectively and institute safeguards addressing vulnerabilities that have plagued the agency's pandemic response.

A public health agency is a double-edged sword

Over the years, as its roles have expanded, the FDA has gradually transitioned from a regulatory agency sometimes serving public health interests to more of a public health agency.[154] "As a public health agency, the FDA … [goes beyond its traditional regulatory priorities and] ask[s] [broader questions, such as] whether delays in approval or safety problems can be prevented — a mandate that requires extensive and creative engagement with regulated industries, patient and consumer groups, and others."[155] As an increasingly public health-minded agency, the FDA addresses issues related to population health that would otherwise be contrary to the prioritization of apolitical science. The agency is also expected to "actively pursue opportunities to help advance science in the domains it regulates and address threats to the safety of medical products and food — even if those opportunities and threats lie outside the realm of the agency's usual routines."[156]

The Supreme Court has long acknowledged that the FDA's "overriding purpose [has become] to protect the public health," given the agency's function in "ensur[ing] that antibiotic products marketed serve the public with efficacy and safety.'"[157] While the FDA's commitment to efficacy and safety remains its priority, the FDA also plays an integral role in ensuring global health security and engages in diverse agency actions to implement national measures that mitigate public health emergencies.[158] In fact, the FDA's role during a public health emergency is distinctly public health-oriented, as exceptions are made to the rigorous standards of review for biopharmaceutical research and development via mechanisms, like EUAs, that require the prioritization of population health, rather than long-term data

[149]Hutt, *supra* note 35, at 28.
[150]Hilts, *supra* note 40, at 236.
[151]Rest & Halpern, *supra* note 89, at 1941.
[152]Facher, *supra* note 131.
[153]Berman & Carter, *supra* note 57.
[154]*See* Avorn et al., *supra* note 77, at 1097-99.
[155]Margaret A. Hamburg & Joshua M. Sharfstein, *The FDA as a Public Health Agency*, 360 New Eng. J. Med. 2493, 2493 (2009).
[156]*Id* at 2493-44.
[157]United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969).
[158]*See* Brooke Courtney et al., *Regulatory Underpinnings of Global Health Security: FDA's Roles in Preventing, Detecting, and Responding to Global Health Threats*, 12 Biosecurity & Bioterrorism 239, 240-41 (2014).

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collection.[159] This results in the agency needing to increasingly "make difficult decisions in the absence of ideal information."[160]

Recent FDA Commissioners have greatly expanded the FDA's position as a public health agency. For example, some FDA Commissioners have made comments about issues related to health policy, including excessive drug costs and pricing.[161] FDA Commissioner Margaret Hamburg even co-authored an article called "FDA as a Public Health Agency," which has been described as an "unprecedented editorial" that promised that the agency would address public health issues with transparency.[162] Over the next 100 years, the FDA's regulatory authority will continue to expand in avenues related to drug costs, diet, tobacco, post-market safety tests, ethics, and bioterrorism.[163] As the FDA becomes more involved in public health-related activities, the veil of political neutrality will continue to lift.

As the FDA's public health responsibilities grow, increased opportunities exist for political interference to affect agency decision-making, leading to arguably lower standards of review without always contributing to major improvements in public health.[164] Arguably, one avenue for reform could be to limit the FDA's seemingly ever-expanding public health roles. After all, concerns regarding the FDA's consideration of health policy issues during scientific decision-making often fuel public controversy whenever questionable conduct implicating the FDA occurs.[165] Such reform would be compatible with conservative efforts to rein in the powers afforded to the administrative state; however, such actions would create a vacuum in regulatory authority that other branches of government are ill-equipped to handle.

Constricting the expansion of the FDA's public health-based regulatory powers does not pose an ideal solution to addressing the vulnerabilities exposed during the COVID-19 pandemic, even if that would appear – at least superficially – to be the easiest solution. After all, the FDA was never truly apolitical. At least to some extent, the agency will always be required to undertake internal risk-benefit analyses that examine political, legal, social, and economic factors during decision-making.[166]Any congressional action to strip the FDA of its ability to engage in decision-making that does not strictly involve scientific inquiry would significantly reduce agency functionality, as the FDA has always operated at the intersection of political and scientific landscapes. Given the scientific expertise required to address

[159]*See* Courtney et al., *supra* note 158, at 241-42.

[160]Hamburg & Sharfstein, *supra* note 155, at 2494.

[161]Statement from FDA Comm'r Scott Gottlieb, M.D., on the Trump Admin.'s Plan to Lower Drug Prices (May 11, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-trump-administrations-plan-lower-drug-prices [https://perma.cc/LR8P-SBYT].

[162]Hamburg & Sharfstein, *supra* note 155, at 2495; Diana Zuckerman, *A Major Shortcoming in the Public Health Legacy of the Obama Administration*, 107 Am. J. Pub. Health 29, 29-30 (2017). Deregulatory pressure exerted by the White House included: (1) President Trump's pledge to "streamline the FDA" by reducing FDA regulations by at least 75% and (2) President Trump's executive order mandating the removal of two regulations for each new regulation implemented by any agency, including the FDA. Phil Hilts, *An FDA Weakened by Obama Will be Conflicted Under Trump*, Undark (Apr. 3, 2017), https://undark.org/2017/04/03/an-fda-weakened-by-obama-will-be-conflicted-under-trump/ [https://perma.cc/X2BA-NB6L].

[163]Fran Hawthorne, Inside the FDA: The Business and Politics Behind The Drugs We Take And The Food We Eat 285-310 (2005).

[164]Zuckerman, *supra* note 162, at 30 ("Health disparities, the opioid epidemic, and the skyrocketing costs of prescription medical treatments that are undermining the ACA, Medicare, and Medicaid, are three major public health issues. Those issues have gotten worse, not better, in the last years of the Obama Administration's FDA. Harmonization with other federal programs has not improved. The FDA will need to dramatically change course in the next administration to address those public health problems.").

[165]*See, e.g.,* Rachel Sachs, *The FDA's Approval of Aduhelm: Potential Implications Across a Wide Range of Health Policy Issues And Stakeholders*, Health Affairs Forefont (June 10, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210609.921363/full/ [https://perma.cc/YH3V-CJMN].

[166]*See, e.g.,* Holly Fernandez Lynch and I. Glenn Cohen, *Introduction, in* FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies 251, 252-53 (Holly Fernandez Lynch & I. Glen Cohen eds. 2015)., at 1-16; F.E. Young, *The Role of the FDA in the Effort against AIDS*, 103 Pub. Health Rep. 242, 245 (1988).

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increasingly complex public health issues related to pandemics, bioterrorism, and global security, limiting the FDA's current powers would merely transfer those concerns to another FDA-like agency that would need to be formed. Neither the White House nor Congress would be equipped with the expert or technical knowledge necessary to handle issues related to many of the public health threats that the FDA currently oversees.

Politicized science transcends partisanship

The integrity of all United States scientific agencies is contingent on agencies' reliance on evidence-based decision-making by qualified experts. However, the perception that scientific entities are immune from political interference and can function independently from external governmental and non-governmental influences is naïve, especially as the complexity of ongoing public health issues continues to grow.[167] Ultimately, value-free regulatory science is an unfeasible and unrealistic ideal.[168] Completely separating science from values during policymaking is impossible in scientific agencies. Nonetheless, the perception of scientific integrity must be maintained. The FDA's efforts under the Obama administration to promote scientific integrity by publishing scientific integrity policies successfully allowed agencies to pose as objective entities, even though the majority of scientists within the agency continued to express concerns about the extent in which political interests played a role in agency decision-making.[169] For example, as previously mentioned, political influence within the FDA was obvious during the agency's handling of the Plan B-One Step controversy, even after efforts to promote scientific integrity had been publicized by the Obama administration.[170]

Prior to the COVID-19 pandemic, most adolescents and adults maintained high levels of trust in scientific agencies like the FDA.[171] And, for the most part, this trust was well-deserved. Despite a few key lapses in decision-making, the ideals of scientific integrity within scientific agencies have been well-adhered to or, at minimum, consistently aspired towards. However, there exists danger in viewing lapses in scientific decision-making – such as those observed during the Vioxx scandal and throughout the COVID-19 pandemic – as isolated occurrences in public health. Public trust in regulatory bodies must be continuously re-affirmed.[172] After all, "[t]he central concept in a reputation-based perspective on regulation is that of an audience," to the extent that audiences can "empower or weaken the regulator."[173] Unfortunately, the COVID-19 pandemic appears to have shattered the fragile veneers of agency neutrality that lukewarm scientific integrity campaigns previously propagated.

The perception of a completely apolitical agency is wholly inaccurate, and – if allowed – the benefits of such an agency would be largely overstated. While recent examples of political interference in the FDA have threatened its reputation, other instances of external pressure being exerted on the agency have had more positive outcomes. One could even argue that many lauded accomplishments of the FDA are because of, rather than in spite of, external political influence. These accomplishments include activist group ACT UP's influence in accelerating access to AIDS/HIV medications through Parallel Track and Accelerated Approval initiatives, as well as President Clinton's initial attempt to bring tobacco regulation under the FDA's jurisdiction.[174] Although the latter was unsuccessful, the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.* later opened the door for Congress to expand the FDA's

[167]*See* Manuela Fernandez Pinto & Daniel Hicks, *Legitimizing Values in Regulatory Science*, 127(3) Env't. Health Persp. 035001-1, 035001-1-6 (2019).

[168]*Id.*

[169]Goldman, *supra* note 73, at 10.

[170]*See* Goldman, *supra* note 73.

[171]Sarah Kowitt, Allison Schmidt, Anika Hannan, & Adam Goldstein, *Awareness and Trust of the FDA and CDC: Results from a CDC Sample of US Adults and Adolescents*, 12 PLoS One e1077546, e1077546 (2017).

[172]J. Eric Oliver & Thomas Wood, *Medical Conspiracy Theories and Health Behaviors in the United States*, 174 JAMA 817, 817-818 (2014).

[173]*See* Carpenter, *supra* note 6, at 33.

[174]*See* Grossman, *supra* note 59; Cook, *supra* note 53.

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authority to regulate tobacco products and marketing.[175] However, "to accept that [external forces, including] the [presidential] administration[,] should retain some ability to influence the FDA is not to suggest that administration officials should have unfettered discretion to intervene, … [as] some FDA decisions can most effectively be made by those bearing … expertise."[176] Even industry players, who are arguably the most burdened by the FDA's strenuous oversight process, immensely value the credibility afforded by the agency's safeguards against outside pressures.[177]

As "[t]he F.D.A. depends almost wholly on industry's trustworthiness to regulate some 25 percent of the nation's consumer economy," controversies threatening the agency's reputation can never be taken lightly.[178] Hence, the FDA has a long history of undergoing swift reforms when faced with scandal.[179] For example, it was no small feat to restore public trust in the agency following the Generic Drug Scandal.[180] The passage of the Generic Drug Enforcement Act of 1992 and other agency efforts to root out corruption imparted a clear message: serious measures were being taken to restore public trust in the FDA's ability to regulate generic drugs.[181] However, the FDA has not been immune from criticism regarding undue industry-related influence since instituting such reforms. For example, despite Congress' seemingly firm response to the corruption exposed during the Generic Drug Scandal in the late 1980's, the effectiveness of the Generic Drug Enforcement Act of 1992 in mitigating future risks continued to be critiqued due to the FDA's lax implementation of certain statutory components.[182] Though such implementation-based concerns are not fully representative of the "change and credibility" that the statute's enactment afforded the agency, these issues appear to be part of a recurring trend.[183] Similarly, three years after the Vioxx scandal, critics argued that the FDA's failure to implement staff restructuring changes recommended in 2006 undermined attempts to improve drug safety and post-approval monitoring.[184]

Though reforms addressing the FDA's industry-related scandals have not always been perfectly implemented, the agency's efforts to tackle private third-party interference have generally been

[175]Food and Drug Admin. v. Brown and Williamson Tobacco Corp., 529 U.S. 120 (2000); C. Stephen Redhead and Vanessa Burrows, Cong. Rsch. Serv., RL32619, FDA Regulation of Tobacco Products: A Historical, Policy, and Legal Analysis (2008).

[176]Holly Fernandez Lynch, Steven Joffe, & Matthew McCoy, *The Limits of Acceptable Political Influence over the FDA*, 27 Nature Med 188, 189 (2021).

[177]Hilts, *supra* note 162 ("In the 1990's, Republicans led by then Speaker Newt Gingrich sought to drastically scale back FDA oversight and eliminate numerous safeguards designed to ensure the safety of drugs before they reach consumers. The paradoxical result of those Republican-led efforts? Drug companies panicked and fought the most drastic changes at the FDA, a regulatory body that, whatever its faults, provided drug makers a mantle of safety and credibility among the public. Some companies were so worried about losing that credibility that they even opened a Washington office dedicated to halting the Gingrich-era attack on the FDA … With Trump now promising to scale things back even more, some drug companies — though not all, by any means — are once again worried that Republicans are poised to run roughshod over the fine line between commercial expediency and the public's faith that the foods and medicines being peddled to them are safe. Indeed, some drug makers — many of whom see the FDA as an imperfect but necessary market equalizer — have openly suggested that some of Trump's promised changes are worrying.").

[178]*The Generic Drug Scandal*, supra note 56, at A18.

[179]*See* Berman & Carter, *supra* note 57.

[180]*See* Boehm, *supra* note 37.

[181]21 USC § 335(a). *See also infra* Section II.

[182]Energy and Commerce Committee, FDA's Faulty Safeguards Against Corruption: Concerns Over Debarment Use and Authority (2008), https://web.archive.org/web/20080430222238/; http://republicans.energycommerce.house.gov/Media/File/News/2.11.08_Republican_Report_on_FDA_Debarment_Process.pdf [perma.cc/AC25-7LWY]. Common critiques include the decentralized nature in which the FDA handles debarments, the FDA's failure to issue regulations instituting debarment provisions, the sparsity with which the FDA issued debarments, and the statute's failure to provide the FDA with the authority to debar companies that do not submit generic drug applications even if post-approval criminal conduct is discovered. *Id.*

[183]Jaime Hornecker, *Generic Drugs: History, Approval Process, and Current Challenges*, 34:6 US Pharmacist 26, 30 (June 18, 2009).

[184]*FDA yet to improve safety after Vioxx scandal*, NBC (Dec. 9, 2009), https://www.nbcnews.com/health/health-news/fda-yet-improve-safety-after-vioxx-scandal-flna1c9440485 [https://perma.cc/VD3K-CPUK].

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impressive.[185] However, while political interference by governmental forces is not a new concern within the FDA,[186] actions to mitigate undue political influence have been less concrete, given the complexity of the issue.[187] One of the main challenges delaying meaningful reform in this area is that the line between permissible political influence and impermissible political interference is a slippery one.

For illustration, in September 2020, twenty Republican senators requested that the FDA Commissioner prohibit the distribution of mifepristone, also known by the brand name Mifeprex, which is part of a common two-drug medication abortion regimen.[188] While, arguably, this letter did not change the agency's stance regarding the drug, similar examples of political influence likely contributed to the agency's history of implementing strict restrictions on the distribution and administration of mifepristone, despite ever-increasing evidence that the associated risks were low.[189] For years, a growing consensus among medical and scientific professionals believed that the accessibility of medication abortion was being "substantially and unnecessarily encumbered" by the FDA's REMS for mifepristone."[190] In fact, mifepristone's REMS was even challenged by the American Civil Liberties Union ("ACLU"), which argued that the REMS posed an undue burden on the right to abortion, given the arbitrary and severe nature of the restrictions in light of decades of data supporting the drug's safety and efficacy.[191]

Recently, after COVID-19 temporarily made in-person delivery of health care services impractical, the FDA finally yielded and permanently removed the in-person dispensing requirement for mifepristone on December 16, 2021.[192] Arguably, this action was years overdue. Even now, many argue that the REMS for mifepristone continues to be overly prohibitive and does not adequately account for existing data on the safety and efficacy of medication abortion regimens.[193] For example, even after removing the in-person dispensing requirement, the FDA "added an additional restriction requiring certification of the pharmacies meant to dispense mifepristone, [even though] [t]here are no data that … these certifications of patients, clinicians, and pharmacies adds clinical benefit to an already safe and effective medication with limited contraindications and adverse effects."[194] While it may be inappropriate to label the political pressures exerted on the FDA with regard to mifepristone's REMS as rising to the level of political interference, the agency has clearly and repeatedly been subjected to political pressure relating to issues concerning reproductive health. For example, the Senate's confirmation of President Biden's choice for FDA Commissioner was delayed because of criticism levied at the FDA for removing mifepristone's in-person dispensing requirement.[195]

The exertion of political influence onto agencies, including the FDA, is more widespread than generally acknowledged. However, it can be hard to define the exact moment when the political influence steps over the line and becomes impermissible interference. Regardless, clear instances of influence

[185]*See, e.g.,* Boehm, *supra* note 37, at 299; Parver, *supra* note 66.

[186]Rest & Halpern, *supra* note 89, at 1939.

[187]*See, e.g.,* Heidi Kitrosser, *Scientific Integrity: The Perils and Promise of White House Administration*, 79 Fordham L. Rev. 2395, 2406-24 (2011).

[188]Letter from Ted Cruz, Tex. Sen., to Stephen Hahn, F.D.A. Comm'r (Sept. 1, 2020), https://www.cruz.senate.gov/files/documents/Letters/2020.09.01%20--%20Pro-Life%20Mifeprex%20Letter%20to%20FDA%20-%20FSV.pdf.

[189]*See* Mifeprex REMS Study Grp., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Eng. J. Med. 790 (2017).

[190]*See, e.g., id.* at 790.

[191]Complaint at 29, Chelius v. Wright, No. 17-cv-00493-DKW-KSC, 2017 WL 4401999 (D. Haw. Oct. 3, 2017).

[192]Jennifer Karlin & Jamila Perritt, *It Is Time to Change the Standard of Medication Abortion,* 182 JAMA 491, 491 (2022); FDA, *Mifeprex (mifepristone) Information* (Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/ZT7S-RNPF].

[193]Karlin & Perritt, *supra* note 192, at 491.

[194]*Id.*

[195]Matthew Perrone, *FDA's Agenda in Limbo as Biden's Nominee Stalls in Senate*, AP News (Feb. 9, 2022), https://apnews.com/article/coronavirus-pandemic-joe-biden-science-business-health-bf45df150b1d6edafb43531852830dc7 [https://perma.cc/F8YB-3FWZ] (describing how senators felt pressured by anti-choice advocates to express their displeasure about changes made to the FDA's revisions of mifepristone's REMS).

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giving way to interference within the FDA do exist and have led to judicial intervention.[196] For example, politically influenced restrictions placed on the use of Plan B One-Step resulted in litigation during both the Bush and Obama administrations.[197] Another clear example of attempted political interference that occurred during the Bush administration involved four New Jersey Democratic senators using "unusual" and "extreme" political lobbying efforts to unduly influence FDA officials to depart from standard review practices and approve Menaflex, a knee repair patch.[198] Ultimately, however, whether political pressures exerted on the FDA actually rise to the level of political interference doesn't truly matter. Rather, as has been repeatedly emphasized, public perception regarding whether political interference occurred is the key to undermining or maintaining an agency's reputation. Reality and perception do not always have to align.

Political interference as a problem extending beyond the FDA

This Article has addressed vulnerabilities to political interference specific to the FDA, given its position as a highly reputable agency that increasingly navigates public health and politicized science landscapes. Other vulnerabilities exist. In fact, many challenges threatening the integrity and credibility of the FDA's decision-making processes are not unique to any one agency. For example, concerns regarding the role that "politics in science-intensive rules" play in agency decision-making are not limited to the FDA.[199]

Why are similar scientific integrity- and neutrality-based concerns widely observable across very different agencies? The root of the problem stems from the role of the administrative state in the American democracy, which continues to be debated even now. Several scholars argue that the broad powers that Congress affords agencies threaten the separation of powers by functioning as a "Fourth Branch" of government.[200] However, the regulatory powers given to the administrative state are an essential component of our country's prosperity.[201] As Justice Kagan eloquently expressed in her dissent in *Seila Law v. CFPB*, critics of the administrative state seemingly "commit[] the nation to a static version of governance, incapable of responding to new conditions and challenges."[202] In reality, the "basic concept that [] agencies should preside over specialized information is hard-wired into the design of the administrative state."[203]

Scientific regulatory agencies are especially essential when navigating the boundaries between the scientific and political domains.[204] However, critics' concerns regarding a lack of accountability and transparency are not invalid, as "science-intensive problems faced by federal agencies … [are often] policy-laden [and frequently require the selection of] the best alternative form among a wide range of choices."[205] The balancing act that agencies must often undertake when faced with such choices can encourage excessive executive branch interference and threaten agency independence.

[196]*See* Susan Wood, *Inappropriate Obstructions to Access: The FDA's Handling of Plan B*, 16 AMA. J. Ethics 295, 295-301 (2014).

[197]*Id.*; *see also* Tummino, 936 F. Supp. 2d.; Tummino v. Torti, 603 F. Supp. 2d 519 (E.D.N.Y. 2009).

[198]Editorial, *Science and Lobbying at the F.D.A.*, N.Y. Times (Oct. 3, 2009), https://www.nytimes.com/2009/10/03/opinion/03sat3.html [https://perma.cc/4RZX-XF5Q]; Gardiner Harris & David Halbfinger, *F.D.A. Reveals It Fell to a Push by Lawmakers*, N.Y. Times (Sept. 24, 2009), https://www.nytimes.com/2009/09/25/health/policy/25knee.html [https://perma.cc/B8GF-JJNZ].

[199]Wagner, *supra* note 16, at 2030-31.

[200]Richard Epstein, *Why the Modern Administrative State is Inconsistent with the Rule of Law*, 3 NYU J. L. Liberty 491, 491-92 (2008).

[201]Kagan, *supra* note 41, at 2342-43.

[202]Seila L. LLC v. Consumer Fin. Prot. Bureau, 140 S.Ct. 2183, 2226 (2020).

[203]Wagner, *supra* note 16, at 2023.

[204]David Demortain, *Expertise, Regulatory Science and the Evaluation of Technology and Risk: Introduction to the Special Issue*, 55 Minerva 139, 146 (2017).

[205]Wagner, *supra* note 16 at 2025.

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Vulnerabilities exist and persist across all scientific agencies

Although the COVID-19 pandemic has brought to the forefront concerns about the effects of political interference on science-based regulatory agencies, themes of partisan politics and undue influence on agency action are not unique to the pandemic response. On April 20, 2022, the United States Government Accountability Office ("GAO"), a non-partisan legislative agency often referred to as a "congressional watchdog,"[206] published its "review [of agency] scientific integrity policies and procedures" at four HHS agencies: the CDC, FDA, National Institutes of Health ("NIH"), and Office of the Assistant Secretary for Preparedness and Response ("ASPR").[207] As part of this review, the GAO also investigated "how allegations of political interference in scientific decision-making were addressed."[208] Though federal employees would admit to observing incidents of political interference, these incidents were often not reported because employees "fear[ed] retaliation, [were] unsure how to report issues, and believ[ed] agency leaders were already aware."[209] Ultimately, the GAO concluded that "the absence of specific procedures may explain why the four selected agencies did not identify any formally reported internal allegations of political interference from 2010 through 2021."[210] Shockingly, while the agencies all provided some training to staff related to scientific integrity policies, none of the four scientific agencies ever "define[d] political interference in scientific decision-making or describe [d] how it should be reported and addressed," even after the Obama administration's efforts to promote scientific integrity.[211] Meanwhile, "only [the] NIH include[d] information on political interference in scientific decision-making as part of its scientific integrity training."[212]

The threats posed by political interference on science have also previously affected other agencies, including the United States Fish and Wildlife Service ("FWS"), National Oceanic and Atmospheric Administration's Fisheries Division ("NOAA Fisheries"), and U.S. Environmental Protection Agency ("EPA").[213] Between 2004 and 2006, the Union of Concerned Scientists conducted five surveys across nine federal agencies, including the ones listed above, to assess the level of political interference within these agencies; survey results concluded that 699 of 1800 federal scientists feared retaliation for the open expression of ideas.[214] Within the FDA, alone, results revealed that over one-third of the 997 survey participants and eighteen percent of scientists indicated that they had "been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or their conclusions in a FDA scientific document."[215] Just under half of survey participants also reported to "know[ing] of cases where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal, or modification of FDA;" meanwhile, sixty-one percent of scientists had reported interference by political appointees in FDA decision-making.[216] Furthermore, between forty-six percent to seventy-three percent of the 7,000 federal scientists that were employed by the CDC, FWS, FDA, and NOAA Fisheries and participated in a 2015 survey by the Union of Concerned Scientists expressed the belief that political interests played too large of a role in agency decision-making.[217] A similar survey conducted in 2018 of

[206] *About*, GAO, https://www.gao.gov/about/ [https://perma.cc/T43J-3J67] (last visited Nov. 20, 2022).

[207] Gene L. Dodaro, Government Accountability Office, Scientific Integrity: HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference (2022) [hereinafter GAO Scientific Integrity Report].

[208] *Id.* at 1.

[209] *Id.* Testimony from employees was collected via semi-structured interviews and a confidential hotline. *Id.*

[210] *Id.*

[211] *Id.*

[212] *Id.*

[213] Rest & Halpern, *supra* note 89, at 1941.

[214] *Id.*; see, e.g., Union of Concerned Scientists, Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science (2006).

[215] *Rest & Halpern, supra* note 89, at 1941.

[216] *Id.*; Wadman, *supra* note 80, at 1223.

[217] Goldman, *supra* note 73, at 12. Notably, "awareness of agency scientific integrity policies was only moderately widespread among survey respondents, despite the four agencies having comprehensive scientific integrity policies in place." *Id.* at 11.

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63,000 federal scientists across sixteen federal agencies found that "[a]t some federal agencies, the situation for scientists [had since grown even] worse than it was during the Bush or Obama administrations."[218]

Concerns regarding the potential repercussions of unchecked presidential administration were brought to the forefront during the COVID-19 pandemic, as the perception of political interference threatened to undermine public trust in agencies like the FDA. Expert regulation in twenty-first century scientific agencies should always inspire to implement a "decision-making process that seeks both the best science and best policy through multiple explication and oversight requirements."[219] But during the pandemic, the agencies in charge of enforcing and implementing regulatory policies were repeatedly the subject of scrutiny due to concerns regarding undue political influence.[220]

Issues regarding the politicization of science within federal agencies that arose during COVID-19 are not unique to public health emergencies — nor are they unique to any singular agency.[221] Under the Obama administration, many federal agencies instated scientific integrity officers, developed internal scientific committees, and implemented scientific integrity policies; however, federal career scientists repeatedly noted that "the mere existence of scientific integrity policies, even when comprehensive and strong, [was] not sufficient to drive all the necessary changes to agency practices."[222] This is evidenced by ongoing issues relating to the effect of political influence on scientific analyses, constraints on scientific free speech, non-compliance with scientific integrity policies, and other threats to science-based decision-making.[223]

Presidential administration widely influences agency decision-making

The exertion of political pressure onto agencies through presidential administration – which began during the Reagan administration and was significantly expanded under the Clinton administration – is one of the dominant avenues through which the executive branch exercises political influence on expert agencies today.[224] This form of political influence was at the forefront of public concerns regarding the FDA's COVID-19 response. Understanding the broader role that presidential administration plays within the country is necessary to fully comprehend the threat to agency reputation posed by the perception of COVID-19-related political interference. Since the Clinton administration, presidential supervision of administrative action has repeatedly given way to presidential control, in which the executive branch triggers – rather than responds to – regulatory initiatives by setting the policy direction of agencies.[225] Presidential administration has all but guaranteed that policy goals of the executive branch influence agency actions to some extent.[226] While this kind of presidential administration has sometimes been hailed as effective decision-making, concerns do arise when control is exercised to drive science-based agency action.[227] But presidential administration need not, in and of itself, threaten agency neutrality.

Some scholars have raised concerns about the potential for scientific agencies to exercise unchecked extralegal and supra-legal powers to circumvent the traditional checks and balances system in place

[218]Center for Science and Democracy at the Union of Concerned Scientists, Science under President Trump: Voices of Scientists across 16 Federal Agencies (2018).

[219]Wagner, *supra* note 16, at 2028.

[220]*See, e.g.,* Kevin Bardosh et al., *The Unintended Consequences of COVID-19 Vaccine Policy: Why Mandates, Passports and Restrictions May Cause More Harm Than Good,* 7:5 BMJ Glob. Health 1, 9-11 (2022).

[221]*See* Rest & Halpern, *supra* note 89.

[222]Goldman, *supra* note 73, at 10.

[223]*Id.*

[224]Kagan, *supra* note 41, at 2246.

[225]*Id* at 2282.

[226]*Id.*

[227]*Id.* at 2339.

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within the United States.[228] However, advocates argue that the executive branch's influence on agency policymaking ensures some degree of accountability by elected officials, despite the fact that scientific agency heads are unelected political appointees.[229] Hence, useful roles for presidential administration within scientific agencies include promoting agency accountability, setting domestic policy goals, and encouraging efficiency (e.g., by applying political pressure onto the FDA to promote the recognition of priority drugs or to improve pathways that can increase access to life-saving technology).[230] Numerous examples exist of presidential administration positively influencing scientific integrity and the efficient allocation of resources. For example, just last year, President Biden committed to "'listen to the science'" and issued a Memorandum on Restoring in Government through Scientific Integrity and Evidence-Based Policymaking that sought to "build[] on" scientific integrity policies adopted during the Obama administration.[231]

Given the current status of the administrative state, presidential administration is no longer a dispensable phenomenon, nor should one desire to dispense with it. However, despite the benefits that can be associated with presidential administration, the core concern remains: presidential administration must not give way to presidential interference. There exist numerous problems in White House-championed policies attempting to address this issue. After all, even presidents who attempt to prioritize scientific integrity continue to allow agency vulnerabilities to persist out in the open.[232] In fact, despite efforts by the Obama and Biden administrations to promote scientific integrity policies, both administrations have been accused of supporting ultimately ineffective policies that were not appropriately implemented.[233] For example, scientific integrity policies promoted by the Obama administration were delayed, highly variable, and inconsistently applied.[234] These problems largely stemmed from the OSTP's "vague and insufficient[] directive[s] to agencies."[235] Adopted measures were often inadequate and did not do enough to insulate scientific agencies from abuse during the COVID-19 pandemic and – to a much lesser extent – President Obama's own administration.[236]

Even the most recent reforms encouraged by the White House continue to inadequately address core agency vulnerabilities to political interference. For example, even though issues with the scientific integrity policies promoted under the Obama administration have been well-documented, the Biden administration seems to be mainly focused on "restat[ing]" former legislative and executive branch policies, especially those previously released under the Obama administration between 2009 to 2010.[237] Though the Biden administration's efforts to restore scientific integrity in agencies may be well-meaning and will likely promote at least some positive outcomes, these policies are insufficient – predictably so. For example, while President Biden's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking clearly indicated President Biden's desire to

[228]Philip Hamburger, *Conceptional Framework, in* IS ADMINISTRATIVE LAW UNLAFUL? Ch. 2, at 23 (Univ. Chi. Press, 2014).

[229]*Id* at 24.

[230]*See* Daniel Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy*, 23 Health Affairs 52, 52 (2004).

[231]Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (Jan. 27, 2021) https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/ [https://perma.cc/6TQH-9C4N] [hereinafter Memorandum on Restoring Trust]; Jeff Tollefson, Max Kozlov, Amy Maxmen & Alexandra Witze, *Has Biden Followed the Science? What Researchers Say*, Nature (Jan. 20, 2022), https://www.nature.com/articles/d41586-022-00108-4 [https://perma.cc/C4BJ-CCX9].

[232]*See, e.g.,* Goldman, *supra* note 73.

[233]*See, e.g., id.*

[234]*Id.* at 7-9.

[235]*Id.*

[236]*Id.*

[237]David Malakoff, *Biden Orders Sweeping Review of Government Science Integrity Policies*, Science (Jan. 27, 2021), https://www.science.org/content/article/new-biden-scientific-integrity-policy [https://perma.cc/CR5X-HRJK].

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prioritize "evidence-based decisions guided by the best available science and data," many scientists are currently disappointed by the Biden administration's attempts to safeguard scientific integrity.[238] "Researchers … say that just because the president has embraced science doesn't mean his administration has always acted swiftly or sensibly on it."[239] In fact, the Biden administration has not been immune from notable lapses in COVID-19-related evidence-based decision-making, which we will discuss in more depth in Part VI.

Regardless of such lapses, criticisms levied at the Biden administration's efforts to promote scientific integrity in agencies largely revolve around concerns that policies fail to address the root causes of issues.[240] For example, President Biden established a very promising OSTP Task Force on Scientific Integrity ("Task Force") during his first week in office "to review agency scientific integrity policies; consider whether they prevent political interference in the conduct, management, communication, and use of science; and identify effective practices for improving their implementation."[241] While the Task Force's findings were highly anticipated, the published report ultimately fell short. The report provided recommendations on how to strengthen policies and restore trust in evidence-based decision-making, but "[c]ritics sa[id] that it does not go far enough."[242] For example, while the report identified the need to increase accountability for violations of scientific integrity policies, it did not include "details on what sort of consequences might be appropriate for those found to have violated scientific integrity," though the OSTP did – at least – recognize the need to continue examining ways to implement recommendations.[243]

The exertion of political pressures onto regulatory agencies, like the FDA, is undisputedly a bipartisan phenomenon, as we have observed via numerous examples throughout this Article. So, the White House's disappointing attempts to implement policies that meaningfully penalize political – and more specifically presidential – interference in agency decision-making should not be all that surprising. For example, in the past, even as expert agencies have made efforts to promote "more rigorous decision processes grounded in both science and public review," such efforts have been negated by a lack of transparency observed in the White House's Office of Information and Regulatory Affair's ("OIRA's") oversight efforts.[244] OIRA is the "central authority for the review of Executive Branch regulations."[245] As part of its responsibilities, OIRA "review[s] drafts of proposed and final regulations [and] … coordinates a retrospective review of regulation."[246] However, OIRA oversight of agency rules and regulations often results in numerous changes to rule-setting that extend beyond policy preference and affect "agencies' supporting, technical explanations … without providing any supporting explanation or evidence."[247]

Concerningly, the OIRA is now exhibiting "growing power … to oversee the work of the agencies."[248] For example, "[o]ne of the best-documented examples of OIRA's engagement in the scientific details of agency rules arises in the set of agency decisions that actually falls outside of the OIRA's jurisdiction—EPA's informal setting of nonbinding standards for various toxic substances."[249] Agency accountability

[238]Memorandum on Restoring Trust; Tollefson, *supra* note 231, at 491.

[239]Tollefson, *supra* note 231, at 491.

[240]*Id.* at 492.

[241]Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science (2022).

[242]Tollefson, *supra* note 231, at 492.

[243]*Id.*

[244]Wagner, *supra* note 16, at 2019.

[245]*See Information and Regulatory Affairs*, The White House, https://www.whitehouse.gov/omb/information-regulatory-affairs/ [https://perma.cc/5ASP-UNVB] (last visited Nov. 20, 2022).

[246]*Id.*

[247]Wagner, *supra* note 16, at 2019.

[248]*Id.* at 2021.

[249]*Id.* at 2040 ("Initially, OIRA—not EPA—determined how the standards should change in response to interagency comments, set the pace of the standard-setting, and classified the interagency communications under the deliberative process privilege … Even after 2009 when then-EPA Administrator Lisa Jackson restricted OIRA's role, OIRA continued to serve as a vigorous participant.").

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requires that the executive branch has power to review and oversee regulations to some extent. However, given the incentives for presidential administration, OIRA oversight may not offer sufficient insulation from threats to scientific decision-making posed by executive branch-sponsored political interference.

Given that issues related to political interference are very complex, the fact that the executive branch has repeatedly failed to prioritize the implementation of meaningful policies protecting agencies from undue political influence is not necessarily deliberate. Reforms that sufficiently mitigate political threats to agency integrity are hard to institute, as they cannot be one-dimensional. It may simply be too much to expect that presidents curtail their own ability to exert influence on agencies in anticipation of distant threats posed by their successors that could also be addressed through agency or legislative action. Success requires cohesive efforts by multiple governmental entities. This Article concludes by examining potential reforms that may address some key concerns related to political interference and heavy-handed presidential administration. While some proposed reforms are specific to the FDA, most are generalizable to other agencies. After all, presidential administration and the threat of political interference affects a broad spectrum of agencies. Hence, reforms targeting transparency, public accountability, and scientific integrity can be widely applied and standardized across scientific agencies.

Transparency, public accountability, and scientific integrity

Various parties have suggested numerous reforms to fortify the FDA's independence, given that "[t]he dual nature of the FDA's decision-making means that it cannot avoid political considerations."[250] Among these are calls for increased HHS oversight of the FDA; however, in light of the COVID-19 pandemic, more recent proposals for reform have concentrated on the potential to restructure the FDA as an independent entity free from political interference.[251]

Both types of proposals pose significant challenges. Increased HHS oversight may limit the degree of industry influences exerted on the FDA, but it does not address broader concerns related to political interference.[252] Meanwhile, an independent FDA may minimize the effects of undue political interference, but such reform increases the risk of regulatory capture, exposes the agency to greater industry pressure, and decreases public accountability.[253] In reality, any dramatic restructuring of the agency is both premature and likely detrimental to the delicate balance between scientific and external interests currently maintained. Such reforms "would leave the FDA's career staff with expansive day-to-day responsibility to navigate the value judgments inherent in their policymaking and product-approval decisions."[254] Increasing career-scientists' involvement in political decisions would arguably exacerbate current concerns regarding scientific integrity. [255]

Another concern is that insulating the FDA from political influence by increasing agency independence also insulates the agency from public accountability, without guaranteeing insulation from officials' own interests to promote pro-industry or partisan agendas. This would make the FDA ripe for regulatory capture by the powerful pharmaceutical lobby. "Regulatory capture is the result or process by which regulation, in law or application, is consistently or repeatedly directed away from the public interest and toward the interests of the regulated industry, by the intent and action of the industry

[250]Lynch, *supra* note 176, at 189 ("Various proposals call for removing the FDA from HHS, increasing the agency's budgetary independence, stabilizing the commissioner's role to allow discharge only for cause, adopting cross-administration terms for the commissioner, moving to a multi-member board leadership model, and otherwise modeling the FDA on independent agencies such as the Social Security Administration.")

[251]Jetson Leder-Luis, *Regulatory Discretion and Corruption in the FDA*, Glob. Anti-coruption Blog (Sept. 25, 2017), https://globalanticorruptionblog.com/2017/09/25/regulatory-discretion-and-corruption-in-the-fda/ [https://perma.cc/W84H-9TTJ].

[252]Lynch, *supra* note 176, at 189.

[253]*Id.*

[254]*Id.*

[255]*Id.*

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itself."[256] While regulatory capture is not always as catastrophic as some allege, regulatory capture is still generally believed to "weaken[] public trust in government and contributes to a sense that our political system is not capable of meeting the challenges it faces."[257] Future reforms need to protect the FDA from undue political influence, without subjecting the agency to increased industry pressures. Hence, rather than focusing on agency independence, reforms need to curtail political pressures through other means.

Ultimately, expectations of value-free regulatory science are both idealistic and unrealistic, as agencies are inherently political given the influence of the executive branch on agency actions. After all, "even appointed officials with relevant scientific expertise, such as the FDA Commissioner, are likely to have interests in advancing the political goals of the administration that appointed them, which in turn may bias their judgment or raise concerns about contradicting, mischaracterizing or rushing the science needed to inform decisions."[258] In fact, the recent confirmation of FDA Commissioner Robert Califf is a clear example of the "increasing politicization of the nomination process" for appointed positions in scientific agencies.[259] Hence, the goal should not be to aspire for non-political agencies, but rather to aspire for non-partisan entities that are able to remain insulated from inherently partisan distractions through increased transparency, public accountability, and scientific integrity. Future reform efforts will need to be more aggressive in assuring the American public that scientific agency decision-making processes are protected and adhered to. After all, "[i]n science, as in the law, process matters — it is not mere ceremony."[260]

Meaningful transparency is needed to ensure public accountability

Through efforts to strengthen agency transparency and public accountability, scientific agencies, like the FDA, can ensure continued public trust in decision-making processes. While presidential administration and executive branch oversight are essential parts of the administrative state, increased transparency and accountability are needed to ensure that "the expert agency and White House … make a mutually beneficial team – each bringing important, but differing perspectives to bear on science-intensive rules."[261] Such initiatives are essential, as many instances of presidential administration are not overt and changes made to agency decision-making processes are relatively invisible to the public.[262] In order to be successful, new transparency and public accountability policies must be advanced to require true freedom of information.[263]

Previously, the Obama administration recognized this need and embarked on a "stated quest for transparency" by issuing an Open Government Memorandum committing the administration to "creating an unprecedented level of openness in government" that aimed to "promot[e] accountability."[264] However, the unwillingness of multiple agencies to adopt the specific recommendations that were developed by the

[256]Daniel Carpenter & David Moss, Preventing Regulatory Capture 13 (2013).

[257]*Id.* at 2.

[258]Lynch, *supra* note 176, at 189.

[259]Perrone, *supra* note 195 (noting that advocates worry that this trend "will leave [agencies] further adrift without clear direction"); Alice Miranda Ollstein & Lauren Gardner, *Abortion Pill Fight Could Ensnare Biden's FDA Pick*, Politico (Jan. 19, 2022), https://www.politico.com/news/2022/01/19/abortion-pill-robert-califf-fda-527326 [https://perma.cc/PM2P-P6FX] (noting concerns that unrelated changes to mifepristone's REMS requirements could "derail" the FDA Commissioner's confirmation); Matthew Perrone & Kevin Freking, *Senate Confirms Biden's FDA pick Despite Political Divisions*, AP News (Feb. 15, 2022), https://apnews.com/article/joe-biden-business-health-barack-obama-robert-califf-7602db3a1196dda90d6745d0b1002c9c [https://perma.cc/9TF8-3ESV].

[260]Jason Karlawish & Joshua D. Grill, *The approval of Aduhelm risks eroding public trust in Alzheimer research and the FDA*, 17 Nature Rev. Neurology 9, 523-24 (2021); Lena Sun, *CDC, under Fire for Covid Response, Announces Plans to Revamp Agency*, Wash. Post (Apr. 4, 2022, 4:37 PM), https://www.washingtonpost.com/health/2022/04/04/walensky-cdc-revamp-pandemic/ [https://perma.cc/5JN5-G9HT]; John Bonifield, *CDC Director Announces Sweeping Review of Agency*, CNN (Apr. 4, 2022, 6:32 PM), https://www.cnn.com/2022/04/04/health/cdc-review/index.html [https://perma.cc/ADN4-M4V5].

[261]Wagner, *supra* note 16, at 2019.

[262]*Id.*

[263]*See* Jennifer Shkabatur, *Transparency With(out) Accountability: Open Government in the United States,* 31 Yale L. Pol'y Rev. 80, 92 (2019).

[264]*Id.*

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2010 Transparency Task Force, which was created as part of President Obama's Open Government Initiative, resulted in "confusion and mistrust."[265] In an effort to improve transparency, the Institute of Medicine also issued recommendations for the FDA in 2015 that encouraged the publication of redacted but analyzable datasets, protocols, and clinical study reports following drug approval.[266] And, in 2017, faculty from several reputable institutions – including John Hopkins Bloomberg School of Public Health, Harvard Medical School/Brigham and Women's Hospital, Yale Medical School, and Yale Law School – formed a FDA Transparency Working Group funded by the Arnold Foundation to publish recommendations to improve FDA regulatory transparency.[267] The proposed reforms focused on areas related to the "application process, analysis and decision-making, [the] review process, [the] correction of misleading information, and data from scientific studies of medical products."[268] While all eighteen recommendations from this FDA Transparency Working Group could have been adopted by the FDA without congressional action, these recommendations were not acted upon.

Recent efforts by the FDA to improve regulatory transparency include the development of a failed pilot program that sought to partner with manufacturers between 2018 to 2020 to provide components of clinical study reports to the public.[269] However, apart from this program, the agency has devoted little energy to adopting transparency reforms.[270] Various recommendations for increasing agency transparency in light of the COVID-19 pandemic have already been proposed and include: (1) "issu[ing] public explanations for clinical holds related to the safety and effectiveness of COVID-19 therapies within 10 days of the action;" (2) "amend[ing] regulations to require the disclosure of clinical and statistical reviews and a published explanation when the FDA does not approve a product;" (3) "amend [ing] emergency use authorization guidance to require disclosure of the detailed scientific basis for authorization to qualified researchers within 30 days of issuance;" and (4) "disclos[ing] masked and de-identified pooled datasets relevant to COVID-19 vaccines and therapeutics to qualified researchers."[271] These recommendations also remain unaddressed by the agency.

With the greater responsibility placed on public health agencies during the COVID-19 pandemic, the need for ever-increasing levels of transparency is apparent. Apart from issues related to political interference, "[p]roblems resulting from [the] lack of transparency [within the FDA] … include [the] incorporation of poor quality, fabricated, fraudulent data into publications, recommendations for 'evidence-based care,' clinical guidelines, formularies, and standard-of-care declarations;" hence, it is imperative that the agency exerts more substantive effort to increase transparency.[272] The need for increased regulatory transparency has been acknowledged for many years now; however, efforts to promote such transparency within the FDA have been described as an "abysmal failure," due to the

[265]Lawrence Huntoon, *FDA: A Disturbing Lack of Transparency*, 25 J. Am. Physicians & Surgeons 34, 36 (2020) ("Just as one can lead a horse to water but cannot make it drink, one can make recommendations to FDA to improve transparency, but one cannot force it to adopt and implement them.").

[266]Amy Kapczynski & Jeanie Kim, *Clinical Trial Transparency: The FDA Should and Can Do More*, 25 J. L. Med. & Ethics 33, 33-34 (2018).

[267]Joshua Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, 25 J. L. Med. & Ethics 7, 8 (2018); Amy Wallace, *Scientists Urge More Transparency from FDA*, United Press Int'l (Mar. 13, 2017, 4:30 PM), https://www.upi.com/Health_News/2017/03/13/Scientists-urge-more-transparency-from-FDA/4471489433540/ [https://perma.cc/5NLZ-BULM].

[268]Sharfstein, *supra* note 267; Joshua Sharfstein & Michael Stebbins, *Enhancing Transparency at the US Food and Drug Administration: Moving Beyond the 21st Century,* 317 JAMA 1621, 1621-22 (2017).

[269]Liam Bendicksen, Joshua M. Sharfstein & Aaron S. Kesselheim, *Increase Transparency at the FDA: We Need Sunlight to Fight the Pandemic*, STAT (Sept. 21, 2020), https://www.statnews.com/2020/09/29/increase-transparency-at-the-fda-we-need-sunlight-to-fight-the-pandemic/ [https://perma.cc/G7PT-2UGE].

[270]*Id.*

[271]*Id.*

[272]Ass'n. of Am. Physicians & Surgeons, *FDA 'Black Box' Lacks Transparency, Writes Editor of the Journal of American Physicians and Surgeons*, Globe Newswire (June 22, 2020, 10:41 PM), https://www.globenewswire.com/news-release/2020/06/22/2051402/0/en/FDA-Black-Box-Lacks-Transparency-Writes-Editor-of-the-Journal-of-American-Physicians-and-Surgeons.html [https://perma.cc/UG22-JBA8].

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agency's unwillingness to adopt external recommendations.[273] It can only be hoped that the COVID-19 pandemic spurs more concentrated efforts to implement transparency initiatives.

As is reiterated throughout this Article, audience perception is key to preserving an agency's reputation and regulatory power. Transparency and public accountability will be important tools for restoring public trust in scientific agencies post-COVID-19. However, "[w]hat the public should see in a transparent agency is much more than what should get disclosed to patients, and transparency means much more than disclosure of data."[274] Data-sharing is not enough to ensure accountability without effective implementation, as "the content of online transparency policies – and not only their rhetoric – should focus on accountability-related information."[275] As part of future reforms, agencies, like the FDA, should also publicly and consistently share "structured information on their decision-making processes and on their performance – the two categories of information that are most pertinent for public accountability purposes."[276] The release of such information will be imperative, as research has shown that transparency issues plaguing the FDA tend to revolve around rulemaking and guidance development.[277] While there are several ways to promote the public disclosure of such information, ultimately:

> [a] robust transparency policy in rulemaking and guidance development would require the agency to disclose not merely the 'data' that entered into its decision making but also the many sources of industry and other special interest influence, to disclose conflicts of interest, … and to disclose more fully communications between agency officials and between agency officials and industry officials and affiliated academics.[278]

Changes to transparency policies generally involve actions that can be adopted internally by agencies, themselves. However, there are also simultaneous opportunities for the White House to promote public accountability and encourage agency correspondence with the public.[279] For example, during the COVID-19 pandemic, health agencies were sometimes restricted from engaging with the public directly.[280] To promote transparency and public accountability, the White House should encourage more career scientists to directly engage in public communications.[281]

Insulating science from value-based judgments promotes integrity

Previously, we discussed reforms that would promote public accountability and transparency. Reforms promoting scientific integrity will also be important, as existing policies are not sufficient to preserve the FDA's reputation as the gold standard. Following its investigation into political interference at the FDA, the GAO recently recommended that the FDA Commissioner ensure that: (1) "procedures for reporting and addressing potential political interference in scientific decision-making are developed and documented, including adding a definition of political interference" and (2) "FDA employees and contractors performing scientific activities are trained on how to report allegations of political interference in scientific decision-making."[282] While these recommendations are essential, they represent the bare

[273]Huntoon, *supra* note 265, at 36.

[274]Daniel Carpenter, *FDA Transparency in an Inescapably Political World*, 45 J. L. Med. & Ethics 29, 29 (2017).

[275]Shkabatur, *supra* note 263, at 81.

[276]*Id.*

[277]*Id.*; Thomas J. Hwang, Jerry Avorn, Daniel Carpenter & Aaron S. Kesselheim, *Quantifying The Food And Drug Administration's Rulemaking Delays Highlights The Need For Transparency*, 33:2 Health Affs. 309, 314 (2014).

[278]Carpenter, *supra* note 274, at 30.

[279]Peter Suwondo, Timothy Westmorel & Howard P. Forman, *Ten Urgent Reforms To Protect The CDC And FDA From Harmful Political Interference*, Health Affs. (Nov. 24, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20201120.456386 [https://perma.cc/UX35-W37Q].

[280]280 *Id.*

[281]*Id.*

[282]GAO Scientific Integrity Report, *supra* note 207, at 18.

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minimum changes required. More work needs to be done to adequately insulate the FDA from future threats of political interference.

When considering potential reforms that promote scientific integrity, the main issues revolve around: "whether these value judgments should be left to the … career scientists or whether – and if so, to what extent – they legitimately may be influenced by the president's administration."[283] The science-versus-politics dichotomy can be "extreme" within the FDA and other scientific agencies.[284] However, while many argue that the exertion of control by agency experts is "fundamentally in conflict" with presidential administration, this is not necessarily the case. [285] At least to some extent, it is possible to promote reforms that separate expert scientific analyses from political decision-makers' value-based judgments during key parts of an agency's decision-making processes.[286] Safeguarding scientific data and publications from political appointees by providing appointees only high-level summaries of material and/or limiting access to documents until immediately before public dissemination are some – perhaps overly simplified – examples of how the threat of undue influence can be mitigated in some agencies.[287] Regardless of form, however, such reforms should focus on ensuring the separation of different types of decision-making.[288] Then, "[b]y delineating the collaborators—by placing micro-experts (e.g., agency technical staff) in open dialogue with the macro-experts (e.g., White House staff)—each can contribute to the collective problem-solving while still contending with the information and positions of the other."[289] Such delineation will be especially effective if implemented in health-related scientific agencies, as resulting "aggregate accountability" can efficiently address conflicts among a variety of complex stakeholders.[290]

Many science-policy scholars may be hesitant to adopt such reforms as they may not always seem feasible. For example, "[t]he National Academy's effort to demarcate risk assessment (the 'science') from risk management (the 'policy') in the 1980s was largely discredited as practically impossible given the interwoven judgments needed in assessing risk."[291] However, while strategies attempting to separate science from policy during key parts of an agency's decision-making process may be difficult to implement, they are not impossible. The EPA is an example of an agency that has already successfully implemented such protective safeguards. [292] Specifically, the EPA instituted various firewalls to separate political appointees from career scientists preparing reports related to setting ambient air quality standards.[293]

The key to the success of such reforms revolves around taking a targeted approach to securing independent decision-making by politicians and career scientists "at discrete points in the decision-making process, particularly when experts amass and summarize the available evidence to inform a larger policy question."[294] Future reforms within the FDA and other scientific agencies should also

[283]Lynch, *supra* note 176, at 189.
[284]*Id.*
[285]Wagner, *supra* note 16, at 2060.
[286]*Id.* at 2060-61.
[287]Suwondo, *supra* note 280.
[288]Wagner, *supra* note 16, at 2062.
[289]*Id.* at 2061.
[290]*Id.* at 2062.
[291]*Id.*
[292]*Id.* at 2064.
[293]*Id.*
[294]*Id.* at 2062-63 ("Policymakers, for example, should formulate the questions that technical analysts research, but the job of assembling and evaluating the quality of the evidence bearing on the question(s) is appropriately conducted by agency experts. Technical analysts can also be involved in creating competing models to synthesize the evidence, provided this work is accompanied by clear explanations of the underlying assumptions and other framing choices made in the development of the models. The result of these expert assessments is thus not a quantitative "answer" but a rigorous summary of the available research and alternatives … This expert review of the evidence will inform but not constrain policy choices made throughout the decision-making process. The policymaker still must frame the initial question(s) that drives the expert analysis of the evidence. The policymaker also must make the needed policy choices at the end and throughout the decision process.")

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encourage diverse viewpoints to be exchanged between and among these two groups of decision-makers both publicly and transparently.[295] Other potential inner-agency reforms include: utilizing firewalls to protect and preserve staff technical reports from non-public political input; documenting all suggestions and comments received from the White House; allowing for public comment and review of relevant scientific analyses; and mandating that input from political branches is requested for certain components of the decision-making process.[296] These suggested reforms not only promote a separation between scientific and value-based judgments, but they also allow for opportunities to address gaps in transparency and public accountability that we previously discussed. [297]

Many opportunities for legislative reforms also exist, especially as current mechanisms (e.g., "whistleblower laws, inspector general authorities, and federal policies concerning research misconduct," etc.) have failed to sufficiently prevent political interference.[298] While the GAO has recognized the need for agencies to define political interference in scientific decision-making, Congress could also address issues by providing concrete definitions for impermissible political interference and enforcement mechanisms to prevent such unlawful activity.[299] Some other related legislative reforms could include: "mak[ing] it unlawful for any government employee or contractor to knowingly censor, misrepresent, or materially alter federal funded health research or recommendations for partisan political ends;" "mak[ing] it unlawful to discriminate or retaliate against federal health officials for disseminating scientific information that they reasonably believe to be true and that has passed agencies' rigorous scientific peer-review processes;" "requir[ing]… leadership … to [frequently] … report to Congress on [the use of enforcement mechanisms deterring political interference] and their agencies' compliance or noncompliance;" and "authoriz[ing] all departmental inspectors general to investigate and prosecute [political interference-related] violations."[300]

Furthermore, Congress could directly amend the Administrative Procedure Act to require thorough documentation of non-scientific commentary of scientific reports, as if such activities qualified as ex parte contact.[301] Another avenue for legislative reform includes instituting a scientific integrity office to facilitate the process of collecting and investigating any political interference-related complaints within federal agencies, such as reports that political pressures influenced technical analyses.[302] Rather than creating a new scientific integrity office, Congress could also seek to limit political interference within scientific agencies by re-funding the Office of Technology Assessment ("OTA"). The OTA was previously positioned as "a well-respected non-partisan agency responsible for helping Congress navigate science and technology issues … [and provided] independent assessments of various technologies and scientific developments … serv[ing] as [the] basis for policymaking and legislation."[303]

Specifically, with regard to the FDA: the OTA could examine agency decisions and publicly disclose its assessments of "scientific merit … [and] the scientific validity of FDA decisions to approve or authorize such technologies for public use."[304] While it is unclear whether the OTA, as currently codified in 2 U.S. Code § 471 et seq., would have the authority to review FDA decisions, Congress could amend § 472(c) of the Technology Assessment Act to guarantee that the OTA would be able to serve as an "enhanced check" during public health emergency decision-making processes, especially in relation to the FDA's review of EUAs.[305] Any amendments to § 472(c) of the Technology Assessment Act would

[295] *Id.* at 2060-61.
[296] *Id.* at 264-66.
[297] Shkabatur, *supra* note 263, at 81.
[298] Suwondo, *supra* note 280.
[299] *Id.*
[300] *Id.*
[301] Wagner, *supra* note 16, at 2068.
[302] *Id.*
[303] Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *An Institutional Solution to Build Trust in Pandemic Vaccines*, 31 Harv. Pub. Health. Rev. (2021), https://hphr.org/31-article-heled/ [https://perma.cc/2J4N-7QLG] ("The OTA was established by Congress in the Technology Assessment Act of 1972 and was active until it was defunded in 1995.")
[304] *Id.*
[305] *Id.*

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ideally grant the OTA broad powers that would apply across all agencies engaged in scientific inquiries, not just the FDA.[306]

Congress could also mitigate risks regarding OIRA's growing potential to improperly influence regulations for political purposes by "repositioning OIRA as an agency committed to ensuring that agency decision *processes* are scientifically rigorous – rather than engaging in the substantive technical details of individual rules."[307] In this way, a proponent of political interference by the executive branch could be used to curtail undue influence by safeguarding adherence to scientific integrity within decision-making processes. While agency and legislative reforms curtailing political interference are preferred, the executive branch also has a responsibility to curb political interference, regardless of presidential self-interest.

Restoring the FDA's reputation requires immediate reform

When a scientific agency's reputation is called into question, measures must quickly and efficiently be taken to restore its credibility. Recognizing the need to address criticism related to the COVID-19 response, the CDC announced on April 4, 2022 that a HHS administrator would conduct "a sweeping review of the… agency" in an effort to "evaluate the CDC's structure, systems and processes."[308] With this review, the CDC hoped to "develop new systems and processes to deliver [agency] science and program to the American people, along with a plan for how [the] CDC should be structured to facilitate [its] public health work."[309] Despite media coverage claiming that this initiative had the potential to "revamp" the CDC, the tangible goals of this review were originally vague.[310] While the effort was a welcome step in the right direction, it is yet to be determined how effective the review will be in promoting progress, as many of the recommendations published at the conclusion of the four-month review will take time to implement effectively.[311] The FDA has yet to announce its intention to undertake similar initiatives, though there is a need for the FDA to reassert its commitment to scientific integrity.

Under the Biden administration, numerous high-profile instances have arisen that continue to erode public confidence in the FDA. Not all these instances relate to COVID-19. As previously mentioned, the FDA recently approved an Alzheimer's Disease drug for the first time in twenty years.[312] This decision appeared to "disregard th[e] scientific process … [that] allows scientists, clinicians, and patients to trust the results of research and regulatory science."[313] Such controversy ultimately led to concerns that the approval of Aduhelm would reduce trust in the agency's ability to serve as the gold standard of review and disrupt the FDA's future use of the Accelerated Approval Program.[314] Concerns regarding exorbitant

[306]*Id.*

[307]Wagner, *supra* note 16, at 2067.

[308]Bonifield, *supra* note 260; Sun, *supra* note 260.

[309]Bonifield, *supra* note 260.

[310]Sun, *supra* note 260.

[311]Centers for Disease Control and Prevention, CDC Moving Forward Summary Report (2022) (basing recommendations on major findings identifying the need for (1) "sharing scientific findings and data faster," (2) "translating science into practical, easy to understand policy," (3) "prioritizing public health communications," (4) "developing a workforce prepared for future emergencies," and (5) "promoting results-based partnerships").

[312]Paul Gadiock et al., *FDA Grants Historic Approval for Alzheimer's Disease Therapy in Permissive Decision*, JD Supra (June 11, 2021), https://www.jdsupra.com/legalnews/fda-grants-historic-approval-for-7511072/ [https://perma.cc/2AKQ-89KT]. The approval of Aduhelm quickly gave rise to speculation that there would be more opportunities for companies attempting to commercialize therapies for high-value indications with less data. Sachs, *supra* note 166. Whether Aduhelm's approval truly indicated a shift in the FDA's internal policies regarding the commercialization of innovative therapeutics is yet to be determined, but the implications of the decision to approve Aduhelm through the Accelerated Approval Program could not have been completely ignored by reviewers during the decision-making process. *Id.*

[313]Jason Karlawish & Joshua Grill, *The Approval of Aduhelm Risks Eroding Public Trust in Alzheimer Research and the FDA*, 17 Nature Rev. Neurology 523, 523 (2021); Sachs, *supra* note 165.

[314]Sachs, *supra* note 165.

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drug pricing, the availability of scientific evidence on drug efficacy, the low likelihood of insurance coverage, and policy implications regarding the future rigor of the FDA's use of the Accelerated Approval Program all impacted public perception in the wake of Aduhelm's approval, spurring speculation regarding the motivations behind the FDA's decision.[315] Public distrust was exacerbated when other governmental entities appeared to be wary of the FDA's actions in relation to Aduhelm. For example, Medicare decided to restrict coverage for Aduhelm, even though "Medicare prescription drug plans [usually] cover[] the majority of novel therapeutics in the year following FDA approval."[316] The U.S. House Committee on Oversight and Reform and the U.S. House Energy Committee also released a report that found irregularities in Aduhelm's approval process and an inappropriate level of collaboration between the FDA and Biogen Inc., as some interactions between the two entities even appeared to breach the FDA's own documentation protocols.[317]

Aduhelm is not the only recent example of government agencies and branches opposing each other and the FDA.[318] As previously mentioned, while the focus of this Article is on the Trump administration's early COVID-19 pandemic response, the Biden administration has also been accused of exerting political pressure onto the FDA.

> An illustrative example of miscommunication, lack of coordination, and politicization was the first booster rollout … In August 2021, President Biden said the [a]dministration would begin offering boosters en masse on September 20th, pending … FDA and CDC authorization. A couple of weeks later, the FDA and CDC tried reining in the White House, saying that there wasn't enough data yet to make a blanket recommendation on boosters … [A]t the end of September 2021, the two government agencies themselves issued contradictory recommendations on boosters, which led to confusion. First, a panel to the FDA recommended booster shots for those over 65, at high risk of Covid-19 complications, or employed in sectors that put [them] at risk of severe Covid-19 … Subsequently, about a week later, a different panel, the Advisory Committee on Immunization Practices (ACIP) – which is part of and advises CDC – stated that people employed in professions that may expose them to more risk of severe Covid-19, ought *not* to get boosters. A day later, the CDC director Walensky overruled ACIP.[319]

The Biden administration's premature communications regarding COVID-19 vaccine boosters have since been widely criticized, especially by FDA regulators and advocates. It was reported that the resignation of "two top FDA vaccine regulators [in August 2021] … was rooted in anger over the agency's lack of autonomy in the booster planning."[320] Other reports indicate that "FDA officials [were] scrambling to collect and analyze data that clearly demonstrate[d] the boosters' benefits before the administration's September 20 deadline for rolling them out to most adults."[321] In fact, "[m]any outside experts, and some within the agency, [even saw] uncomfortable similarities between the Biden team's top-down booster plan and former President Donald Trump's attempts to goad the FDA into

[315] *Id.*

[316] Daniel Shaw, Sanket Dhruva & Joseph Ross, *Coverage of Novel Therapeutic Agents by Medicare Prescription Drug Plans Following FDA Approval*, 17 J. Managed Care & Specialty Pharmacy 1230, 1234 (2018); Rachel Cohrs, *Medicare Finalizes its Restrictions on New Alzheimer's Drug, Despite Pressure from Drugmakers*, Stat (Apr. 7, 2022), https://www.statnews.com/2022/04/07/medicare-final-decision-alzheimers-coverage-biogen-aduhelm/ [https://perma.cc/BM8G-NT9L].

[317] Staffs of the Committee on Oversight and Reform and Committee on Energy and Commerce, The High Price of Aduhelm's Approval: An Investigation into FDA's Atypical Review Process and Biogen's Aggressive Launch Plans (2022).

[318] Joshua Cohen, *Covid-19 Fallout: Ruinous Effects Of Politicization Of Public Health Agencies, Such As The CDC*, Forbes (Apr. 1, 2022), https://www.forbes.com/sites/joshuacohen/2022/04/01/covid-19-fallout-ruinous-effects-of-politicization-of-public-health-agencies-such-as-the-cdc/?sh=1e3aaac35269 [https://perma.cc/GYG6-EXVE].

[319] *Id.*

[320] Owermohle, *supra* note 148.

[321] *Id.*

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accelerating its initial authorization process for Covid-19 vaccines and push through unproven virus treatments."[322]

Political interference occurs across party lines, even in emergency settings. Though some characterizations of the Biden administration's communications around COVID-19 boosters argue that the messaging represents politicized "hijack[ing]," other characterizations view the incident as rooted in miscommunication.[323] Again, perception is key. In either case, the confusion around the COVID-19 booster plans ultimately shows that the exertion of political pressure to influence scientific agency decision-making is not limited to a single political party. Miscommunication, premature announcements, or other blunders can still subject agencies to undue political influence. Regardless of intention, the consequences of the confusing messaging surrounding the COVID-19 boosters are apparent. Even in mid-April 2022, public health policy officials continued to warn that "[e]ver-changing guidance on Covid-19 boosters could widen disparities in uptake for low-income and minority groups that tend to face barriers to health information and are often among the last to get vaccinated."[324] Ultimately, given the importance of audience perception in relation to a reputation-based perspective on regulation,[325] even the unintentional exertion of political pressure can be incredibly dangerous. The aftereffects of the pandemic on public perception of the FDA are likely to be long-lasting, especially as certain political controversies plaguing the FDA persist.

Conclusion

Political interference has affected how scientific agencies, like the FDA, has handled both past and present public health threats. Historically, agency reform has tended to follow very public and problematic scandals. However, the COVID-19 pandemic made the ongoing potential for undue political influence to be exerted on federal scientific agencies painfully clear. Partisan pressures on agencies like the FDA repeatedly threaten to dismantle public trust in regulatory bodies. The complacency that has followed recent instances of political interference simply because "science eventually won out" in most instances is unacceptable, as it paves the way for further abuses without any assurance that scientific integrity will always be prioritized.[326]

Arguably, the FDA achieved its reputation as the gold standard of review because it effectively addressed prior lapses in scientific decision-making. The strength of this agency has always been in its ability to learn from mistakes, which is why it poses such a good case study in the wake of rising concerns around the political influence exerted on scientific agencies. While the Trump administration's attempts to influence FDA regulatory decisions during the pandemic were well-publicized and intensely covered by media outlets, the FDA's ability to withstand much of the political pressure exerted on it to accelerate the approval of vaccine EUAs might limit the incentive to implement timely and/or substantive agency reform. Even though disaster was averted, reform is still urgently needed. Definitive action is necessary to prevent future partisan efforts to engage in political interference that threatens the integrity of scientific decision-making within the FDA.

Given the need for "effective enforcement," many scholars agree that "[l]egislative solutions … are not enough."[327] Rather, "[a]gencies themselves must [also] adopt principles and policies that value a culture of scientific openness and give agency scientists the ability to communicate their findings without a

[322]*Id.*

[323]Cohen, *supra* note 318.

[324]Celine Castronuovo, *Evolving Covid Booster Guidelines Threaten to Widen Inequities*, Bloomberg (Apr. 26, 2022), https://news.bloomberglaw.com/health-law-and-business/evolving-covid-booster-guidelines-threaten-to-widen-inequities [https://perma.cc/7GGF-VDPP].

[325]*See* Carpenter, *supra* note 6, at 33.

[326]Monastersky, *supra* note 96, at 387.

[327]Rest & Halpern, *supra* note 89, at 1941-42.

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political filter."[328] In the future, reform efforts by both the executive and legislative branches should be focused on clearly defining, separating, and delineating the roles of science and policy within agency decision-making processes in a transparent manner. By encouraging the agency to engage in meaningful transparency, increased opportunities for public accountability can restore trust in the FDA. Furthermore, by more clearly separating the officials, mechanisms, and procedures involved in scientific inquiries from those associated with more public health-based policy inquiries, it is possible to safeguard the role of science within agency decision-making without conflating the two. While many of the suggested reforms listed in this Article could and should apply for all scientific agencies, the FDA can especially benefit from such reforms, given the FDA's shift towards becoming an increasingly political public health agency.

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[328] *Id.*

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