Executive Capture of Agency Decisionmaking

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The scientific credibility of the administrative state is under siege in the United States, risking distressful public health harms and even deaths. This Article addresses one component of this attack—executive interference in agency scientific decisionmaking. It offers a new conceptual framework, "internal agency capture," and policy prescription for addressing excessive overreach and interference by the executive branch in the scientific decisionmaking of federal agencies. The Article's critiques and analysis toggle a timeline that reflects recent history and that urges forward-thinking approaches to respond to executive overreach in agency scientific decisionmaking. Taking the Trump Administration and other presidencies as test cases, it scrutinizes who should control, or alternatively advance or limit, an agency's scientific decisions, which are distinct from its policymaking decisions. With its "internal agency capture" framework and the COVID-19 pandemic as its backdrop, the Article illustrates the phenomenon of excessive executive overreach at work in the scientific decisionmaking of the U.S. Food and Drug Administration ("FDA"), glaringly reflected in the Agency's decisions on reproductive medicines and protocols to respond to the pandemic. This Article demonstrates that covert internal capture can mislead the public, pose serious risks to individual and public health, undermine the arm's-length neutrality and objectivity of agencies, and result in lasting consequences for agency legitimacy and reputation.

The Article considers existing methods to oversee and provide a check on internal agency capture and describes the limitations of these approaches. It offers a novel solution, the creation of a new and independent Scientific Integrity Office, which would address many of these limitations and promote the important values of accountability, credibility, and public trust.

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INTRODUCTION

> FDA's credibility is its most crucial asset . . . . The perception of political considerations overruling scientific judgment, even just in a single case, inevitably raises concerns about the legitimacy of decision making in every case.
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> —Institute of Medicine of the National Academies[1]

In the early months of the COVID-19 pandemic, the Trump Administration pressured the U.S. Food and Drug Administration ("FDA") to authorize unproven treatments; prohibited the Centers for Disease Control and Prevention ("CDC") from holding briefings for the American public, such as to provide guidance about wearing masks; instructed the CDC to alter its guidance on testing despite disagreement from public health officials; downplayed case numbers and deaths; and implemented many other politically motivated policies

1. INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 9, 90 (2007).

over the objections of public health officials.[2] Tragically, the Administration initially minimized the severity of the virus despite clear evidence to the contrary. Indeed, by the end of April 2020, deaths in the United States from COVID-19 had already surpassed U.S. fatalities in the Vietnam War.[3] The interference, and its fatal consequences, continued throughout Trump's presidency. January 2021, his last month in office, remains the deadliest month of the pandemic in the United States.[4] The U.S. death toll surpassed 400,000 on President Trump's last full day in office—more fatalities than World Wars I and II combined.[5] One of President Trump's own advisors, Dr.

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2. *See* Press Release, Select Subcomm. on the Coronavirus Crisis, At Hearing, GAO and Experts Detail Trump Administration's Unprecedented Political Interference in Coronavirus Response (Apr. 29, 2022), https://coronavirus.house.gov/news/press-releases/hearing-gao-and-experts-detail-trump-administration-s-unprecedented-political [https://perma.cc/65S3-KVJB] (discussing the Trump Administration's efforts to interfere with the COVID-19 response); Press Release, Select Subcomm. on the Coronavirus Crisis, Clyburn Demands Answers from Redfield on Trump Administration Officials' Interference with CDC's Pandemic Response (Nov. 12, 2021), https://coronavirus.house.gov/news/press-releases/clyburn-demands-answers-redfield-trump-administration-officials-interference-cdc [https://perma.cc/Y6C7-RUAS] (detailing the Trump Administration's prevention of CDC public briefings); *The Trump Administration's Pattern of Political Interference in the Nation's Coronavirus Response*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (July 26, 2021), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/7.26.2021%20Timeline%20of%20Political%20Interference%20-%20final.pdf [https://perma.cc/F65L-MB9S] (describing how the Trump Administration altered the CDC testing guidelines); *Excerpts from Transcribed Interview of Dr. Robert Redfield*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (Apr. 29, 2022), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Redfield%20TI%20excerpts%20final.pdf [https://perma.cc/SKN8-8FCK] (detailing the Trump Administration's refusal to allow CDC briefings); Ryan Chatelain, *Pandemic Officials Say Trump Administration Could Have Prevented Many Deaths*, SPECTRUM NEWS NY1 (Mar. 30, 2021, 10:17 AM), https://www.ny1.com/nyc/all-boroughs/health/2021/03/29/pandemic-officials-say-trump-administration-marginalized-them—interfered—could-have-prevented-many-deaths [https://perma.cc/9PTL-SFC4] ("Brett Giroir, the nation's coronavirus testing czar, admitted the administration repeatedly lied to the public in March 2020 when it said anyone who wanted a test could get one."). For examples involving the FDA, see *infra* Part II.B; *A "Knife Fight" with the FDA: The Trump White House's Relentless Attacks on FDA's Coronavirus Response*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (Aug. 2022), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.08.24%20The%20Trump%20White%20House%E2%80%99s%20Relentless%20Attacks%20on%20FDA%E2%80%99s%20Coronavirus%20Response.pdf [https://perma.cc/C525-JKDM] [hereinafter *A "Knife Fight" with the FDA*].

3. Nina Strochlic, *U.S. Coronavirus Deaths Now Surpass Fatalities in the Vietnam War*, NAT'L GEOGRAPHIC (Apr. 28, 2020), https://www.nationalgeographic.com/history/article/coronavirus-death-toll-vietnam-war-cvd [https://perma.cc/FS4W-HDL2].

4. *Daily Updates of Totals by Week and State*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm (last visited Sept. 20, 2022) [https://perma.cc/TYQ2-J3JK] (data as of Sept. 20, 2022; sort Table 1 by "United States" and "Monthly").

5. Strochlic, *supra* note 3; Will Stone, *On Trump's Last Full Day, Nation Records 400,000 COVID Deaths*, KAISER FAM. FOUND. (Jan. 19, 2021), https://khn.org/news/nation-records-400000-covid-deaths-on-last-day-of-donald-trump-presidency/ [https://perma.cc/2R3Z-52UK]. It is important to acknowledge that as of November 4, 2022, an additional 668,667 people have died

Deborah Birx, acknowledged that many deaths could have been prevented were it not for President Trump's interference with the work of scientific agencies and experts.[6] As these examples and others described in this Article demonstrate, executive interference in agency science involves more than just executive overreach. It concerns life and death.

An important normative premise of this Article is that the integrity of agency scientific decisionmaking, separate and apart from ultimate policy conclusions, must be protected from undue political interference. As discussed below, there are times when policy decisions must be made in the face of scientific uncertainty or when expedited action is necessary. But when that occurs, policy decisions must not be cloaked as scientific decisions.[7] Examples from the FDA that demonstrate the negative consequences of political interference in agency science illustrate why it is necessary for agencies to retain a certain degree of autonomy to protect the integrity of their scientific analysis and decisionmaking.[8] They illume the tense relationship between politics and science, and expose how that relationship can get thrown off-kilter by myriad forces: influence from outside the government; influence from another branch of the government; or influence from within the executive branch, such as by the President or political appointees.

Administrative law scholarship has extensively considered the theory of "agency capture," generally defined as a phenomenon in which an agency is unduly influenced by the industry it regulates, causing the agency to make decisions that promote industry interests at the expense of the agency's congressionally defined mission.[9] Yet capture

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from COVID-19 in the United States since President Biden took office, for a total of 1,068,667 deaths. *COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#datatracker-home (last visited Nov. 5, 2022) [https://perma.cc/A2WK-67J5]. While this might blunt criticism of the Trump Administration's handling of the pandemic, the Trump Administration's initial response was pivotal, making its failings all the more consequential and affecting the country's ability to combat the virus in profound ways. As this Article illustrates, the politicization of the virus and pandemic response, set in motion by President Trump, persists. Instead of uniting to combat the virus, COVID-19 policies became partisan issues, which complicated the Biden Administration's ability to combat the pandemic.

6. *See* Chatelain, *supra* note 2 (detailing President Trump's failure to act and the consequences therein).

7. *See infra* notes 124, 472 and accompanying text.

8. *See infra* Part II (for FDA examples); *see also infra* notes 124, 472 and accompanying text.

9. *See* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971) (arguing that "regulation is acquired by the industry and is designed and operated primarily for its benefit"); *see also* PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT (Daniel Carpenter & David A. Moss eds., 2014) (collecting administrative law scholarship addressing regulatory capture); Michael A. Livermore & Richard

by outside industry, which this Article refers to as "external agency capture," represents just one threat to the autonomy and integrity of an agency's scientific decisions. As the COVID-19 examples demonstrate, executive-level[10] interference can also excessively or unduly influence agency scientific decisionmaking, thereby threatening an agency's pursuit of its mission.

This Article introduces the concept of "internal agency capture" and provides the first examination of executive-level interference in agency scientific decisionmaking through that lens. "Internal agency capture" refers to agency capture by government actors, such as the President or other White House officials, with respect to scientific decisionmaking.[11] An internally captured agency may make decisions that advance the executive's political or ideological interests even when contrary to the agency's mission and the public interest.[12]

It might seem paradoxical to suggest that an agency, a creature of the executive, could be captured by that executive. Those who adhere to the unitary executive theory—that the President holds virtually unlimited power to control and direct the entire federal executive branch—may debate the use of the term "capture" to describe the issues discussed in this Article, question whether an executive agency can be

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L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1342–44, 1343 n.17 (2013) (collecting definitions); Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 CHI. KENT L. REV. 1039, 1060–67 (1997) (describing capture theories); Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-Fault Fix*, 35 N.Y.U. REV. L. & SOC. CHANGE 793, 808–12 (2011) (describing FDA vulnerability to capture); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669, 1684–87 (1975) (describing the causes, scope, and limits of capture by well-organized groups).

10. This Article uses the term "executive" or "the White House" to include the President and other White House offices and officials, such as the Chief of Staff, White House Counsel, presidential advisors, and others. This Article thus includes influence and control of agencies by the President directly, as well as by those who engage with agencies on the President's behalf and at his direction.

11. This Article focuses on executive-level internal agency capture. Internal agency capture can, however, include capture by other government actors, such as members of Congress (sometimes on behalf of industry). In 2009, for example, the FDA reviewed the clearance of Menaflex, a knee implant that was cleared even though the FDA's scientific reviewers concluded the device was not safe and should not be cleared. The FDA's report detailed departures from its typical processes, including "failure to respond appropriately to external pressure on decision-makers." *See* U.S. FOOD & DRUG ADMIN., REVIEW OF THE REGEN MENAFLEX®*: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION—PRELIMINARY REPORT 2 (2009), https://www.nytimes.com/interactive/projects/documents/f-d-a-review-of-the-regen-menaflex-device#p=1 [https://perma.cc/2DXP-PSDA] (detailing the FDA's procedural failures). Others reported that the FDA received "extreme," "unusual," and "persistent pressure" from New Jersey congressmen. *Id.* at 8–9; *see* Gardiner Harris & David M. 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/Z6H6-R6BZ] (discussing legislative pressure on the FDA).

12. *See infra* note 127 and accompanying text.

"captured" by the executive, or argue that the executive may or should "capture" (i.e., fully control) executive agencies. This Article acknowledges and adds to these debates by examining who can—or should—control, or alternatively advance or limit, an agency's scientific decisionmaking, and by proposing the new framework of internal agency capture to conceptualize the issue.[13]

As this Article illustrates, there is a line between appropriate executive involvement and improper executive interference that obstructs an agency's ability to make expert and impartial scientific decisions. The capture framing becomes particularly useful when thinking about solutions. The literature on capture, for example, provides potential institutional design solutions and exposes the need to consider tradeoffs between solving internal agency capture versus external agency capture. Viewing the problem through the lens of capture inspires creative thinking that might bring about a solution that addresses the myriad forms and sources of capture. By motivating a solutions-oriented approach, the capture framing provides a critical yet currently missing part of the scholarship on executive authority. Additionally, this Article's capture orientation offers an important counterpoint to the scholarship that promotes the benefits of extensive, or even unlimited, presidential control over executive agencies.[14]

The scope of the President's authority to control, direct, or otherwise influence agencies is a long-debated topic.[15] This Article accepts that the President possesses the authority to exert some influence over executive agencies, that presidential involvement can

13. For further discussion of the unitary executive theory, see *infra* notes 14, 78, and accompanying text.

14. *See, e.g.*, STEVEN G. CALABRESI & CHRISTOPHER S. YOO, THE UNITARY EXECUTIVE: PRESIDENTIAL POWER FROM WASHINGTON TO BUSH 3–4 (2008) (laying out the value of a unitary executive from a historical perspective); Steven G. Calabresi, *Some Normative Arguments for the Unitary Executive*, 48 ARK. L. REV. 23 (1995) (describing the evolution of the unitary executive and its benefits from the Framers to modern day); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2331–46 (2001) (embracing a system of presidential control called "presidential administration").

15. This Article rejects the unitary executive theory, even while recognizing that the President does have some authority over executive agencies. As further discussed in Part I.B, the focus and intent of this Article is not to debate in detail the merits of each theory of executive authority. Instead, it identifies the various theories and the rich scholarship that engages in the debate. *See infra* Part I.B and accompanying footnotes; *see also, e.g.*, CALABRESI & YOO, *supra* note 14, at 3; Cary Coglianese, *Presidential Control of Administrative Agencies: A Debate Over Law or Politics?*, 12 U. PA. J. CONST. L. 637 (2010); Kagan, *supra* note 14; Robert V. Percival, *Who's in Charge? Does the President Have Directive Authority over Agency Regulatory Decisions?*, 79 FORDHAM L. REV. 2487 (2011) [hereinafter Percival, *Who's in Charge?*]; Robert V. Percival, *Presidential Management of the Administrative State: The Not-So-Unitary Executive*, 51 DUKE L.J. 963 (2001) [hereinafter Percival, *Presidential Management*].

promote the public interest,[16] and that this authority expands during national emergencies.[17] It argues, however, that executive interference in agency scientific decisionmaking represents a uniquely problematic issue, particularly when it occurs covertly.[18] Absent public scrutiny, the benefits of presidential control disappear, and agencies can become sympathetic or vulnerable to partisan politics and presidential pressure.

Much of the administrative law literature focuses on the President's overt control or influence over agency policymaking and rulemaking, particularly in the field of environmental law.[19] Debates about the scope of the President's authority over agencies rarely draw

16. Similarly, agency capture by industry is not always negative. *See* Dorit Rubinstein Reiss, *The Benefits of Capture*, 47 WAKE FOREST L. REV. 569 (2012) (discussing the stigmatization of industry capture and the potential benefits of capture).

17. The U.S. Constitution does not explicitly provide for emergency rule; these powers are implied or provided by statutes. *See* L. ELAINE HALCHIN, CONG. RSCH. SERV., 98-505, NATIONAL EMERGENCY POWERS 1–3 (2021), https://www.everycrsreport.com/files/2021-04-08_98-505_17c267f2aa9c2b3462f44e0bba79e6a8fbc945a9.pdf [https://perma.cc/XZM7-HD54] (detailing the history and mechanics of emergency powers); Elizabeth Goiten, *Emergency Powers, Real and Imagined: How President Trump Used and Failed to Use Presidential Authority in the COVID-19 Crisis*, 11 J. NAT'L SEC. L. & POL'Y 27, 29–30 (2020) (illustrating implied and statutorily delegated emergency powers). Even in emergencies, there are limits. *See, e.g.*, Hamdi v. Rumsfeld, 542 U.S. 507, 536 (2004) ("We have long since made clear that a state of war is not a blank check for the President when it comes to the rights of the Nation's citizens."); Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 643–44 (1952) (Jackson, J., concurring) ("There are indications that the Constitution did not contemplate that the title Commander-in-Chief of the Army and Navy will constitute him also Commander-in-Chief of the country, its industries and its inhabitants.").

18. In the context of executive interference in agency decisionmaking, this Article uses the term "overt" to refer to public, readily apparent actions taken by the executive, such as executive orders, presidential memoranda, public statements, etc. In contrast, "covert" actions are those made outside of the public eye or through less transparent or direct means, such as off-the-record, nonpublic meetings or implicit threats or demands, such as those made via social media, etc.

19. Examples discussed in the literature often involve the Environmental Protection Agency ("EPA") and the role of the Office of Management and Budget's ("OMB") Office of Information and Regulatory Affairs ("OIRA"), which is responsible for conducting regulatory reviews for the Executive Office of the President. All presidents since Richard Nixon have used some form of regulatory review. For further discussion about the programs and their evolution, see Kagan, *supra* note 14, at 2274–2319, detailing regulatory review by Presidents Reagan, H.W. Bush, and Clinton; Percival, *Who's in Charge?*, *supra* note 15, discussing the implications of presidential removal power for executive oversight and influence over executive agency decisionmaking; and Percival, *Presidential Management*, *supra* note 15, explaining the distinction between presidential removal power of agency heads and presidential authority over agency decisions. *See also* Exec. Order No. 12,291, 3 C.F.R. 127 (1982) (requiring cost-benefit analyses for all proposed and final regulations); Exec. Order No. 12,866, 3 C.F.R. 638 (1994) (subjecting only "significant regulatory actions" to OMB review); Exec. Order No. 13,563, 3 C.F.R. 215 (2012) (reaffirming the basic principles of Exec. Order No. 12,866); Modernizing Regulatory Review, 86 Fed. Reg. 7223 (Jan. 26, 2021) (reaffirming the basic principles of Exec. Orders Nos. 12,866 and 13,563); Wendy E. Wagner, *A Place for Agency Expertise: Reconciling Agency Expertise with Presidential Power*, 115 COLUM. L. REV. 2019, 2019 (2015) [hereinafter Wagner, *A Place for Agency Expertise*] (discussing political pressures on agency expertise in the promulgation of "science-intensive" rules).

distinctions between policymaking and rulemaking, on the one hand, and scientific decisionmaking, on the other. Policymaking and policy choices "inevitably and properly entail[ ] the accommodation of competing interests, the joining of value disputes, and political responsiveness."[20] And while difficult to define, for the purposes of this Article and with respect to agency decisions, the term "scientific" refers to decisions based primarily on the collection and analysis of data through valid and reliable research methodologies.

This Article fills that gap in the literature, explaining why this distinction matters when considering the propriety of executive control over different types of agency decisions. It does so by probing the negative consequences of largely covert or implicit executive interference in agency scientific decisionmaking. The Article focuses on FDA decisions about drug approvals and authorizations,[21] providing an important and useful contribution to the existing literature, which focuses extensively on environmental law. Moreover, it shows that even if interference does not produce a direct or immediate effect, significant indirect and lasting negative consequences may materialize, such as the erosion of agency accountability, credibility, and public trust[22]—three values that executive involvement and control allegedly promote. These consequences are particularly likely with covert influence.[23]

Such real-world consequences illustrate the serious externalities that can result from executive interference in agency scientific decisionmaking. Importantly, such interference does not achieve, and therefore cannot be justified by, the three values mentioned above. These three values encompass a wide range of issues and concerns that may arise due to executive interference, including the politicization of science, the demoralization and silencing of government scientists, unsound public health decisions, and public confusion about the true

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20. CHRISTOPHER F. EDLEY, JR., ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY 102 (1990).

21. For brevity, any reference to FDA drug "approval" in this Article also includes drugs authorized for emergency use. That said, an emergency use authorization is not an approval but rather an authorization to distribute and use an unapproved drug or an approved drug for an unapproved use during a declared emergency. *See* 21 U.S.C. § 360bbb-3(a).

22. In this Article, "accountability" refers to whether the public knows who is responsible for a particular agency action or decision and therefore who can be held accountable for that action or decision (e.g., through elections). The concepts of "credibility" and "public trust" are related, with "credibility" being a narrower term and more often used to refer to the reliability and believability of a specific agency decision rather than the public's broader views of the agency overall. "Public trust" is broader and comprised of a number of considerations in addition to credibility, such as impartiality; legitimacy; integrity; public acceptance; and public comfort/willingness to follow decisions, guidance, and recommendations made by government entities.

23. *See* Nina A. Mendelson, *Disclosing "Political" Oversight of Agency Decision Making*, 108 MICH. L. REV. 1127, 1159 (2010) (noting that inadequate transparency reduces the President's accountability for agency rulemaking he influences).

reasons and motivations that undergird agency scientific decisions and public health guidance. The COVID-19 pandemic and the Trump Administration's frequent disregard for scientific integrity render executive interference in agency scientific decisionmaking a pressing issue that demands our attention.[24]

To further illuminate these issues, this Article examines executive-level internal agency capture of the FDA's scientific decisionmaking processes, focusing on the Agency's review and approval of pharmaceuticals.[25] It shows that these concerns are not limited to the pandemic and are not merely a "Trump phenomenon."[26] On the contrary, this problem emerges in both Republican and Democratic administrations.[27] The scholarship most critical of executive interference in agency science typically focuses on Republican

24. The Trump Administration's interference in agency science spanned many issues, including violations of scientific integrity at agencies like the EPA, CDC, and FDA. Examples include:

- Removing the EPA's web page on climate change;
- Censoring scientific reports;
- Doctoring a map to avoid acknowledging that Trump was wrong about a hurricane's path and pressuring scientists to back his false claim;
- Interfering in federal coronavirus research; and
- Pressuring regulators to approve COVID-19 vaccines and therapeutics.

See Lisa Friedman, *E.P.A. to Review Attacks on Science Under Trump*, N.Y. TIMES (Mar. 24, 2021), https://www.nytimes.com/2021/03/24/climate/trump-science-epa.html [https://perma.cc/68XE-RSK2]. *See generally supra* note 2 (highlighting President Trump's interference in agency COVID-19 response); *Science Under President Trump: Voices of Scientists Across 16 Federal Agencies*, UNION OF CONCERNED SCIENTISTS: CTR. FOR SCI. & DEMOCRACY 1 (Aug. 2018), https://www.ucsusa.org/sites/default/files/attach/2018/08/science-under-trump-report.pdf [https://perma.cc/RU6V-4STF] (detailing President Trump's continuous pattern of choosing politics over science on key science-based issues). Relatedly, President Trump's health-related policies, including his "disdain for science," not only "impeded the response to the COVID-19 pandemic, causing tens of thousands of unnecessary deaths" but also had myriad repercussions across a range of health outcomes. Steffie Woolhandler et al., *Public Policy and Health in the Trump Era*, 397 LANCET COMM'NS 705, 705–06 (2021) (listing some of the key policies of the Trump Administration that threatened health).

25. This Article uses the terms "drug" or "pharmaceutical" to include drugs and biologics, including vaccines.

26. 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/ [https://perma.cc/KXG8-TDT3] ("Political interference at the [FDA] 'has been an issue in past administrations Republican and Democratic.' " (quoting Margaret Hamburg, former FDA Commissioner)). Of course, President Trump in many ways took a new, uniquely dangerous, and unusually public approach to meddling in the affairs of scientific agencies. *See infra* notes 133–134 and accompanying text.

27. For a detailed discussion of examples of executive interference spanning both Democratic and Republican administrations, see *infra* Part II.

presidents, particularly George W. Bush.[28] This Article, however, introduces how presidents of both parties engage in this practice, such as the Obama Administration's interference in the FDA's decisions about emergency contraception.[29] Furthermore, although this Article focuses on the FDA, the issues discussed—and what to do about them—reverberate across other federal agencies.

Despite many criticisms of the second Bush Administration's[30] interference in agency scientific decisionmaking, the alarms still sound more than a decade later. The issue, therefore, deserves revisiting. In today's world of hyperpartisanship, complete insulation of an agency's scientific experts from political pressures seems increasingly infeasible. Yet, the integrity of agency scientific decisionmaking, separate and apart from ultimate policy conclusions, must be protected to ensure agency accountability, credibility, and public trust. Doing so requires a new approach.[31]

The Article develops in three parts. Part I briefly describes the conventional theory of agency capture by outside industry or interest groups ("external agency capture") before turning to a more detailed discussion of executive authority over agencies and introducing the concept of internal agency capture. Part II analyzes cases of executive interference in FDA scientific decisionmaking across administrations. Part III then considers the tradeoffs between different mechanisms for addressing interference in agency scientific decisionmaking and proposes a novel solution, a Scientific Integrity Office, a nonpartisan, independent body that incorporates enhanced oversight and statutory protections to promote three important values: accountability, credibility, and public trust.

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28. *See, e.g.*, CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (2006) (detailing the Republican trend of choosing interest group priorities over scientific authority); SETH SHULMAN, UNDERMINING SCIENCE: SUPPRESSION AND DISTORTION IN THE BUSH ADMINISTRATION (2006) (describing multiple examples of the second Bush Administration's prioritization of advocacy group interests over science); James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV 939, 940 (2008) (discussing the second Bush Administration's erosion of the FDA's independence); Brie Sherwin, *The Upside Down: A New Reality for Science at the EPA and Its Impact on Environmental Justice*, 27 N.Y.U. ENV'T L.J. 57 (2019) (laying out the Trump Administration's attacks on the EPA's scientific independence). For examples of the second Bush Administration's "widespread tampering" with global warming data, see Jody Freeman & Adrian Vermeule, Massachusetts v. EPA: *From Politics to Expertise*, 2007 SUP. CT. REV. 51, 55.

29. *See infra* Section II.A.1; *see also* Richard Monastersky, *Obama's Science Legacy: Uneven Progress on Scientific Integrity*, 536 NATURE 386, 386 (2016) ("[C]ritics say that Obama's White House has not shied away from exerting political influence over science.").

30. For clarity, this Article refers to the George H.W. Bush Administration as the "first Bush Administration" and the George W. Bush Administration as the "second Bush Administration."

31. *See infra* Part III.A (proposing a Scientific Integrity Office and describing its advantages over existing alternatives).

I. AGENCY CAPTURE: EXTERNAL AND INTERNAL THREATS TO SCIENTIFIC INTEGRITY

Federal agency missions, and how agencies carry out their missions, are guided by their congressionally charged mandates. Most agency missions seek to promote the public interest through the agency's regulatory activities.[32] The FDA's mission includes "protect[ing] the public health by ensuring that . . . [human] drugs are safe and effective"[33] and "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[34]

This Article shows that agency capture—from any source—threatens an agency's pursuit of its mission. Capture is most pernicious, however, when it undermines scientific factfinding and decisionmaking, undermines agency legitimacy, or occurs in covert ways insulated from public review. This Part first briefly describes external agency capture and its effect on the FDA. It then turns to the focus of this Article: executive interference and internal agency capture.

A. External Agency Capture: Threats from the Outside

Scholars point to Professor Marver H. Bernstein's 1955 book, *Regulating Business by Independent Commission*, as laying the foundation for agency capture theory.[35] External agency capture[36] can

32. *See, e.g.*, *Mission, Role and Pledge*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/organization/mission.htm (last updated Apr. 29, 2022) [https://perma.cc/YX9L-EA83] ("[P]rotect America from health, safety and security threats . . . ."); *About Us*, U.S. DEP'T OF LAB., https://www.dol.gov/general/aboutdol (last visited Sept. 20, 2022, 6:20 PM) [https://perma.cc/LYY3-SD7Q] ("[F]oster, promote, and develop the welfare of the wage earners, job seekers, and retirees of the United States . . . ."); *Our Mission and What We Do*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/aboutepa/our-mission-and-what-we-do (last updated June 13, 2022) [https://perma.cc/82DF-STMY] ("[P]rotect human health and the environment.").

33. 21 U.S.C. § 393(b)(2)(B).

34. *Id.* § 393(b)(1).

35. MARVER H. BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION (1955).

36. *See supra* note 9 and accompanying text. Two relatively recent non-FDA examples of external agency capture include: (1) the 2010 Deepwater Horizon oil spill, which involved capture of the Minerals Management Service ("MMS"); and (2) the economic recession of the late 2000s, influenced by capture of the Securities and Exchange Commission ("SEC"). *See Protecting the Public Interest: Understanding the Threat of Agency Capture, Hearing Before the Subcomm. on Admin. Oversight & the Cts. of the Comm. on the Judiciary*, 111th Cong. 2 (2010) (opening statement of Sen. Sheldon Whitehouse, Chairman, Subcomm. on Admin. Oversight) https://www.govinfo.gov/content/pkg/CHRG-111shrg64724/pdf/CHRG-111shrg64724.pdf [https://perma.cc/9P2F-7PPH] (commenting on "the disasters that can ensue when an agency has been captured," such as "MMS, whose failures and shocking behavior led to the horrors of the oil spill in the Gulf" and "the SEC, asleep at the switch as financial services companies created exotic

occur through myriad avenues, such as lobbying by regulated companies and interest groups or, more subtly, by "penetrat[ing] into the heart of regulatory political subculture via the so-called revolving door," through which "regulatory officials begin their careers in industry, then work for some years in the regulatory agency until they are promoted back into industry at a higher level than they were at previously."[37]

Scholars debate the scope and scale of regulatory capture. Some argue that the problem is overstated,[38] while others claim it is no longer a "bug but rather a feature" of the administrative state.[39] As to the FDA, Professor Daniel Carpenter suggests that although pharmaceutical companies "have exercised considerable influence in the policy process and on the FDA, they have generally resisted the accrual of regulatory power to the FDA, contrary to what [the] capture explanations suggest."[40] Instead, he argues that business-friendly or deregulatory

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and irresponsible financial products that took our economy to the brink of disaster"); Daniel Kaufmann, *Corruption and the Global Financial Crisis*, BROOKINGS (Jan. 27, 2009), https://www.brookings.edu/opinions/corruption-and-the-global-financial-crisis/ [https://perma.cc/9XWL-KT8F] (providing examples of how regulatory capture in the financial sector led to the financial crisis of the 2000s); Gerald P. O'Driscoll, *The Gulf Spill, the Financial Crisis and Government Failure*, WALL ST. J. (June 13, 2010, 6:55 PM), https://www.wsj.com/articles/SB10001424052748704575304575296873167457684 [https://perma.cc/QWL2-CMRP] (stating that "MMS operated as a rubber stamp for BP," calling it "a striking example of regulatory capture: Agencies tasked with protecting the public interest come to identify with the regulated industry and protect its interests against that of the public. The result: Government fails to protect the public. That conclusion is precisely the same for the financial services industry"). *But see* Christopher Carrigan, *Captured by Disaster? Reinterpreting Regulatory Behavior in the Shadow of the Gulf Oil Spill*, *in* PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 239, 240 (Daniel Carpenter & David A. Moss eds., 2014) ("[T]he importance of capture to explaining the Gulf oil spill may be overstated.").

37. John Abraham, *The Pharmaceutical Industry as a Political Player*, 360 LANCET 1498, 1498 (2002); *see* Charles Piller, *FDA's Revolving Door: Companies Often Hire Agency Staffers Who Managed Their Successful Drug Reviews*, SCI. (July 5, 2018), https://www.science.org/content/article/fda-s-revolving-door-companies-often-hire-agency-staffers-who-managed-their-successful [https://perma.cc/6Y29-GDJQ] (explaining the revolving door through examples of former FDA experts working for the drug industry). *But see* David Zaring, *Against Being Against the Revolving Door*, 2013 U. ILL. L. REV. 507 (arguing that the revolving door's harms are overstated and its potential benefits overlooked).

38. *See, e.g.*, J.R. DeShazo & Jody Freeman, *Public Agencies as Lobbyists*, 105 COLUM. L. REV. 2217, 2297 (2005) ("[T]he evidence that agency capture is a widespread phenomenon is thin. . . . [C]apture is likely to be partial and inconsistent—rarely are groups powerful enough to determine decisionmaking in every case.").

39. Jonathan P. Caulkins & Peter Reuter, *Ending the War on Drugs Need Not, and Should Not, Involve Legalizing Supply by a For-Profit Industry*, 21 AM. J. BIOETHICS 31, 33 (2021); *see also* Merrill, *supra* note 9, at 1060 ("By the time the late 1960s rolled around, agency capture had come to be regarded as something more akin to the universal condition of the administrative state."); Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 88 (2006) ("[S]cholars may have to start taking seriously the possibility of agency capture.").

40. DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 10 (2010).

policies more often result from the influence of scientific organizations, consumer activists, and organized patient groups.[41] Yet influence from these various nongovernmental entities simply represents another form of external capture. Further, even if external actors do not *fully* capture the FDA, concerns remain. For example, a 2011 survey of 997 FDA scientists found that forty percent believed Agency decisions were overly influenced by business interests and fifty-five percent thought Agency decisions were overly influenced by political interests.[42] Given the vital nature of protecting the public health, serious harms—both substantive and reputational—can result from just one instance of capture.

Many describe the FDA's controversial and premature approval of the Alzheimer's drug Aduhelm (aducanumab) as the result of regulatory capture.[43] The FDA approved Aduhelm on June 7, 2021, for the treatment of all stages of Alzheimer's disease, although it was only tested in patients with mild cognitive impairment or mild dementia stages of the disease.[44] The FDA approved Aduhelm under the

41. *Id.*

42. UNION OF CONCERNED SCIENTISTS, VOICES OF SCIENTISTS AT THE FDA: MEASURING PROGRESS ON SCIENTIFIC INTEGRITY (2012), https://www.ucsusa.org/sites/default/files/2019-09/fda-survey-report-2011.pdf [https://perma.cc/88E5-VDL4]. Some believe "user fees" increase the risk of capture. The FDA collects user fees from companies that produce certain human pharmaceuticals. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 736, 106 Stat. 4491 (codified at 21 U.S.C. § 379(h)). When an agency is funded, in part, by regulated industry, the concern is that it will be captured by industry because it depends on their continued payment of fees. *See, e.g.*, INST. OF MED., *supra* note 1, at 73–74.

43. *See, e.g.*, Kathy Y. Liu & Robert Howard, *Can We Learn Lessons from the FDA's Approval of Aducanumab?*, 17 NATURE REVS. NEUROLOGY 715, 715 (2021) (stating that due to the relationship between the FDA and Biogen, the company "potentially benefited from . . . insufficient safeguards to mitigate regulatory capture"); Michael Carome, *Outrage of the Month: FDA's Inappropriate Close Collaboration with Biogen on Alzheimer's Disease Drug*, PUB. CITIZEN (Jan. 1, 2021), https://www.citizen.org/article/outrage-of-the-month-fdas-inappropriate-close-collaboration-with-biogen-on-alzheimers-disease-drug/ [https://perma.cc/L8YR-LAE2] (arguing that "Exhibit A" of regulatory capture at the FDA "is the unprecedented and inappropriate close collaboration between the FDA and Biogen regarding [Aduhelm]"); Celine Castronuovo, *Biogen Alzheimer's Drug Gets Spotlight in FDA User Fee Hearing*, BLOOMBERG L. (Feb. 3, 2022), https://news.bloomberglaw.com/health-law-and-business/biogen-alzheimers-drug-gets-spotlight-in-fda-user-fee-hearing [https://perma.cc/6CU4-C8LW] ("The Aduhelm approval has exacerbated concerns over whether the industry user fees present a conflict of interest and limit the FDA's ability to rule objectively on product approvals."); Gregg Gonsalves, Christopher Morten, Reshma Ramachandran & Joseph S. Ross, *The FDA is in Desperate Need of Some Soul-Searching*, WASH. POST (June 17, 2021), https://www.washingtonpost.com/opinions/2021/06/17/fda-aducanumab-alzheimers-drug-approval-erodes-confidence/ [https://perma.cc/2PRR-YAHJ] (questioning whether the FDA has been captured by industry).

44. *ADUHELM Prescribing Information*, U.S. FOOD & DRUG ADMIN. § 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf (last updated June 2021) [https://perma.cc/3U8F-SDS5]; Press Release, Biogen, FDA Grants Accelerated Approval for ADHUELM™ as the First and Only Alzheimer's Disease Treatment to Address a Defining Pathology of the Disease (June 7, 2021), https://investors.biogen.com/news-releases/news-release-

Accelerated Approval Program based on a "surrogate endpoint"—reduction of amyloid plaque—a common finding in the brains of Alzheimer's patients.[45] Use of a surrogate endpoint means the drug has not shown a direct effect on the disease itself.[46]

Praise and backlash resulted immediately. Patients and patient organizations, desperate for hope, applauded the approval.[47] Yet many in the scientific and medical communities expressed concerns, including three members of the FDA advisory committee that reviewed Aduhelm who resigned after its approval.[48] Of particular concern, evidence

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details/fda-grants-accelerated-approval-aduhelmtm-first-and-only [https://perma.cc/B5T2-NTCW].

45. Under Accelerated Approval, drugs for serious conditions that fill an unmet medical need can be approved based on a surrogate endpoint. Accelerated approval drugs must verify a clinical benefit in confirmatory trials. 21 U.S.C. § 356(c); 21 C.F.R. §§ 314.500-314.510 (2022). If confirmatory trials do not demonstrate efficacy, the FDA can withdraw the drug from the market. 21 C.F.R. § 314.530 (2022).

46. A "surrogate endpoint" does not measure clinical benefit but is thought to predict, or correlate with, clinical benefit. A clinical endpoint directly measures whether patients "feel or function better, or live longer." *Surrogate Endpoint Resources for Drug and Biologic Development,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development (last updated July 24, 2018) [https://perma.cc/Z3YF-V8ZJ].

47. *See, e.g.*, Press Release, Alzheimer's Ass'n, Alzheimer's Association Welcomes FDA Approval of Aducanumab (June 7, 2021), https://www.alz.org/news/2021/alzheimers-association-fda-approval-aducanumab [https://perma.cc/8JTL-NG9Q]; Press Release, Alzheimer's Found. of Am., Alzheimer's Foundation of America Statement on FDA Approving First New Alzheimer's Medication in Nearly 20 Years (June 7, 2021), https://alzfdn.org/alzheimers-foundation-of-america-statement-on-fda-approving-first-new-alzheimers-medication-in-nearly-20-years/ [https://perma.cc/SV68-PNRE]; Christina Vogt, *FDA Okays New Alzheimer's Drug, Despite Controversy*, EVERYDAY HEALTH (July 8, 2021), https://www.everydayhealth.com/alzheimers-disease/fda-oks-new-alzheimers-drug-despite-controversy/ [https://perma.cc/8L53-LEXP]; *see also FDA Approves First New Alzheimer's Drug in 18 Years*, FISHER CTR. FOR ALZHEIMER'S RSCH. FOUND. (June 8, 2021), https://www.alzinfo.org/articles/treatment/fda-approves-first-new-alzheimers-drug-in-18-years/ [https://perma.cc/7P92-W8FV] (noting that many patient advocacy groups urged the FDA to approve Aduhelm because of the lack of other treatment options).

48. Dr. Aaron Kesselheim, who resigned, called it "probably the worst drug approval decision in recent U.S. history." Letter from Aaron Kesselheim, Professor of Med., Brigham & Women's Hosp./Harvard Med. Sch., to Janet Woodcock, Acting Comm'r, U.S. Food & Drug Admin. (June 10, 2021), https://pbs.twimg.com/media/E3jKN4GWYAUGj9U.png [https://perma.cc/X42L-L5VC]; *see also* David Knopman, Comment on Biologics License Application, Docket No. FDA-2018-N-0410 (Oct. 29, 2020), https://www.regulations.gov/document/FDA-2018-N-0410-0034 [https://perma.cc/FR2K-65FJ] ("[T]he evidence that aducanumab [slows or reverses Alzheimer's] is terribly weak. . . . it will offer improvement to none, it will harm some of those exposed, and it will consume enormous resources."); *What Do You Think of the New Alzheimer's Drug Approval?*, MEDSCAPE (June 14, 2021), https://www.medscape.com/viewarticle/953025 [https://perma.cc/LT3U-KZ86] (finding that seventy-three percent of physicians responding to a survey either strongly disagreed (forty-three percent) or disagreed (thirty percent) with Aduhelm's approval (results filtered by profession for "Medical Doctor/Physician")); *see also* Adam Feuerstein, Matthew Herper & Damian Garde, *Inside 'Project Onyx': How Biogen Used an FDA Back Channel to Win Approval of Its Polarizing Alzheimer's Drug*, STAT (June 29, 2021), https://www.statnews.com/2021/06/29/biogen-fda-alzheimers-drug-approval-aduhelm-project-onyx/ [https://perma.cc/8PK3-RTCZ] (mentioning the advisory committee resignations).

suggests that the FDA's decision was unduly influenced by the drug's sponsor (Biogen, Inc.), patient advocacy organizations, and patients and their caregivers.[49] Although early engagement between the FDA and sponsors is encouraged, the degree of collaboration and reports of off-the-record meetings between the Agency and Biogen raised serious questions about whether they adhered to standard procedures.[50]

In March 2019, the sponsors discontinued two Phase 3 clinical trials after analyses found the drug unlikely to show a benefit.[51] After consulting with the FDA and conducting a new analysis of one of the failed trials, however, Biogen filed a regulatory application with the Agency.[52] The FDA then approved Aduhelm through the accelerated approval pathway, a pathway typically used when efficacy studies are ongoing. But here, one of the studies had already failed.[53] Further, the FDA's advisory committee voted against full approval[54] and was not asked to consider accelerated approval.[55] In fact, the FDA told the

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49. The FDA specifically considered that patients "expressed 'their willingness to accept some uncertainty about clinical benefit to get earlier access to a potentially clinically valuable drug.' " Pam Belluck, Sheila Kaplan & Rebecca Robbins, *How an Unproven Alzheimer's Drug Got Approved*, N.Y. TIMES, https://www.nytimes.com/2021/07/19/health/alzheimers-drug-aduhelm-fda.html (last updated Oct. 20, 2021) [https://perma.cc/96AB-FD8U].

50. Many reports noted the unusual review process. *Aduhelm May Not Cure Alzheimer's, but It Might Help Fix Drug Prices*, ECONOMIST (July 15, 2021), https://www.economist.com/united-states/2021/07/15/aduhelm-may-not-cure-alzheimers-but-it-might-help-fix-drug-prices [https://perma.cc/XXA2-DVUJ]; Pam Belluck & Rebecca Robbins, *Three F.D.A. Advisers Resign over Agency's Approval of Alzheimer's Drug*, N.Y. TIMES, https://www.nytimes.com/2021/06/10/health/aduhelm-fda-resign-alzheimers.html (last updated Sept. 2, 2021) [https://perma.cc/25U7-7GLA]; Feuerstein et al., *supra* note 48; Liu & Howard, *supra* note 43; Ned Pagliarulo & Jacob Bell, *HHS Watchdog to Review FDA Accelerated Approval Process After Aduhelm Controversy*, BIOPHARMA DIVE (Aug. 4, 2021), https://www.biopharmadive.com/news/aduhelm-hhs-inspector-general-review-accelerated-approval/604461/ [https://perma.cc/W4SM-8A22].

51. Press Release, Biogen, Biogen and Eisai to Discontinue Phase 3 ENGAGE and EMERGE Trials of Aducanumab in Alzheimer's Disease (Mar. 21, 2019), https://investors.biogen.com/news-releases/news-release-details/biogen-and-eisai-discontinue-phase-3-engage-and-emerge-trials [https://perma.cc/E74W-68LG].

52. Press Release, Biogen, Biogen Plans Regulatory Filing for Aducanumab in Alzheimer's Disease Based on New Analysis of Larger Dataset from Phase 3 Studies (Oct. 22, 2019), https://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease [https://perma.cc/2AJG-KEQC].

53. Matthew Herper, Damian Garde & Adam Feuerstein, *Newly Disclosed FDA Documents Reveal Agency's Unprecedented Path to Approving Aduhelm*, STAT (June 22, 2021), https://www.statnews.com/2021/06/22/documents-reveal-fda-unprecedented-aduhelm-decision/ [https://perma.cc/8QE3-BR29].

54. U.S. FOOD & DRUG ADMIN, CTR. FOR DRUG EVALUATION & RES., FINAL SUMMARY MINUTES OF THE PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEETING (2020), https://www.fda.gov/media/145690/download [https://perma.cc/9XT2-52B2].

55. Patrizia Cavazzoni, *FDA's Decision to Approve New Treatment for Alzheimer's Disease*, U.S. FOOD & DRUG ADMIN. (June 7, 2021), https://www.fda.gov/drugs/news-events-human-drugs/fdas-decision-approve-new-treatment-alzheimers-disease [https://perma.cc/YH3S-GQ2U]; Gianna Melillo, *How Biogen's Aduhelm Approval Marks Precipitous Turning Point for the FDA*,

advisory committee that the Agency was "not using the amyloid as a surrogate for efficacy."[56] Advisory committee recommendations are not binding, but the FDA rarely goes against the recommendations.[57] When it does, the Agency typically takes a *more* restrictive approach (e.g., issuing an unfavorable decision after a favorable advisory committee recommendation) rather than a less restrictive approach as it did with Aduhelm.[58]

A detailed investigation by *STAT* uncovered further evidence of an unusually close relationship between Biogen and the FDA, describing abnormal off-the-record meetings and atypical support and advocacy from within the Agency for Aduhelm's approval.[59] One former Biogen employee stated they "knew from the interest levels within FDA that the agency was always going to find a way to approve Aduhelm."[60]

Significant concerns about Aduhelm's price[61] triggered government action. Acting FDA Commissioner Dr. Janet Woodcock defended the decision but acknowledged possible missteps.[62] She requested an independent investigation by the Inspector General at the Department of Health and Human Services ("HHS") into the approval

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AM. J. MANAGED CARE (July 14, 2021), https://www.ajmc.com/view/how-biogen-s-aduhelm-approval-marks-a-precipitous-turning-point-for-the-fda [https://perma.cc/F4FM-VMAE]; Kesselheim, *supra* note 48.

56. *See* U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RES., CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEETING 140 (2020), https://www.fda.gov/media/145691/download [https://perma.cc/3EN4-5JZ7].

57. A study of 376 advisory committee meetings from 2008–2015 found that the FDA did not adopt the committee's recommendations eighty-three times (twenty-two percent). Audrey D. Zhang, Jason L. Schwartz & Joseph S. Ross, *Association Between Food and Drug Administration Advisory Committee Recommendations and Agency Actions, 2008–2015*, 97 MILBANK Q. 796, 802–03 (2019).

58. Of eighty-three disagreements, the FDA took a more restrictive approach than the advisory committee in sixty-two cases (seventy-five percent). *Id.* at 803–05. A follow-up review of eighty-three meetings from 2016–July 2019 found similar results: the FDA agreed with the approval recommendations of the advisory committee in sixty-eight cases (eighty-two percent), and most discordance involved the FDA taking a more conservative approach. Michael Cipriano, *US FDA, Advisory Committees Rarely Disagree*, PINK SHEET (July 15, 2019), https://pink.pharmaintelligence.informa.com/PS125638/US-FDA-Advisory-Committees-Rarely-Disagree [https://perma.cc/547H-SSDG].

59. For a detailed account, see Feuerstein et al., *supra* note 48.

60. *Id.*

61. The initial $56,000 per year price tag far exceeded the $3,000 to $8,400 per year benchmark from the Institute for Clinical and Economic Review. Melillo, *supra* note 55. Biogen later announced it would cut the price to $28,200 per year. Tom Murphy, *Biogen Cuts the Price Tag on Its Alzheimer's Drug in Half*, ASSOCIATED PRESS NEWS (Dec. 20, 2021), https://apnews.com/article/biogen-alzheimers-drug-price-cut-9dab1bdb5001c0ddcedc981fbc3437b6 [https://perma.cc/L5NH-55JZ].

62. Rachel Cohrs, *FDA Chief Janet Woodcock Acknowledges Agency May Have Misstepped in Process Leading up to Alzheimer's Drug Approval*, STAT (July 14, 2021), https://www.statnews.com/2021/07/14/woodcock-fda-may-have-misstepped-process-alzheimers-drug-approval/ [https://perma.cc/V8MV-VW68].

process and interactions between Biogen and the FDA.[63] Two House committees launched reviews,[64] and Senators Bill Cassidy and Elizabeth Warren called for a hearing to examine the implications for Medicare and other health programs.[65]

Amidst the controversy, the FDA approved a labeling update to limit Aduhelm's indication to patients with mild cognitive impairment or mild dementia and to emphasize there are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease.[66] Nevertheless, consequences continued to reverberate throughout the

63. Letter from Janet Woodcock, Acting Cmm'r, U.S. Food & Drug Admin., to Christi A. Grimm, Acting Inspector Gen., Off. of Inspector Gen., Dep't of Health & Hum. Servs. (July 9, 2021), https://twitter.com/DrWoodcockFDA/status/1413540801934774283/photo/1 [https://perma.cc/EVV7-JGB4].

64. Press Release, House Comm. on Oversight & Reform, Chairs Maloney and Pallone Announce Investigation of Biogen's Alzheimer's Drug Aduhelm (June 25, 2021), https://oversight.house.gov/news/press-releases/chairs-maloney-and-pallone-announce-investigation-of-biogen-s-alzheimer-s-drug [https://perma.cc/6PNX-H4AS]; *see also* Letter from Carolyn B. Maloney, Chairwoman, Comm. on Oversight & Reform, & Frank Pallone, Jr., Chairman, Comm. on Energy & Com., to Michel Vounatsos, Chief Exec. Officer, Biogen Inc. (July 12, 2021), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-07-12.CBM%20Pallone%20to%20Vounatsos-Biogen%20re%20Aduhelm.pdf [https://perma.cc/9PEX-3NQW] (requesting documents about Biogen's relationship with the FDA).

65. Letter from Bill Cassidy, U.S. Sen., & Elizabeth Warren, U.S. Sen., to Hon. Ron Wyden, Chair, Comm. on Fin., & Hon. Mike Crapo, Ranking Member, Comm. on Fin. (June 23, 2021), https://www.cassidy.senate.gov/imo/media/doc/21-06-23%20Letter%20to%20SFC%20Alzheimer's%20Drug%20Hearing.pdf [https://perma.cc/3W4P-VHFF].

66. *ADUHELM Prescribing Information*, U.S. FOOD & DRUG ADMIN. § 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s003lbl.pdf (last updated July 2021) [https://perma.cc/23LA-3Y45]; Press Release, Biogen, FDA Approves Updated ADUHELM™ Prescribing Information to Emphasize Population Studied in Clinical Trials (July 8, 2021), https://investors.biogen.com/news-releases/news-release-details/fda-approves-updated-aduhelmtm-prescribing-information-emphasize [https://perma.cc/HMM8-7HSN].

American health system.[67] Indeed, Aduhelm's approval prompted debates about potential reforms to the accelerated approval pathway.[68]

The exact reason for the close relationship between Biogen and the FDA in this case remains unclear, but it serves as one among many examples of external agency capture of the FDA, whereby the FDA flouted ordinary agency procedures and scientific consensus.[69] Other examples raising questions about capture of the FDA include the accelerated approval of Sarepta's Exondys 51 for the treatment of Duchenne Muscular Dystrophy;[70] FDA's troubling actions (and

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67. In November 2021, for example, officials from the Centers for Medicare and Medicaid ("CMS") reported that about half of the $21.60 per month increase in Medicare Part B outpatient premiums for 2022 was in preparation for potential coverage of Aduhelm. Ricardo Alonso-Zaldivar, *Alzheimer's Drug Cited as Medicare Premium Jumps by $21.60*, ASSOCIATED PRESS (Nov. 12, 2021), https://apnews.com/article/medicare-health-care-costs-medication-alzheimers-disease-health-27a6250da20a6ba6af4820525c64afc4 [https://perma.cc/KA64-TGTF]. And in April 2022, CMS finalized a national policy for coverage of Aduhelm and "any future monoclonal antibodies directed against amyloid approved by the FDA with an indication for use in treating Alzheimer's disease." Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Finalizes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (Apr. 7, 2022), https://www.cms.gov/newsroom/press-releases/cms-finalizes-medicare-coverage-policy-monoclonal-antibodies-directed-against-amyloid-treatment [https://perma.cc/78TJ-EZEG]. Under this policy, for drugs like Aduhelm that receive accelerated approval, Medicare will only provide coverage for patients enrolled in clinical trials approved by the FDA or the National Institutes of Health ("NIH"). *Id.* In light of these coverage limitations, CMS was directed to reconsider the 2022 premium increase, but HHS later announced that "[d]ue to the legal and operational hurdles in adjusting Medicare premiums midstream in 2022," savings from lower spending would be passed to beneficiaries in 2023. Press Release, U.S. Dep't of Health & Hum. Servs., Statement from HHS Secretary Becerra: 2022 Medicare Part B Premium Increase Attributable to Alzheimer's Drug Aduhelm Will Be Adjusted and Incorporated into Upcoming 2023 Medicare Premium Determination (May 27, 2022), https://www.hhs.gov/about/news/2022/05/27/statement-hhs-secretary-becerra-2022-medicare-part-b-premium-increase-attributable-to-alzheimers-drug-aduhelm-will-be-adjusted-incorporated-into-upcoming-2023.html [https://perma.cc/9BL8-WSPV].

68. Caitlin Owens, *Controversial Alzheimer's Drug Approval Ignites FDA Reform Debate*, AXIOS (Mar. 21, 2022), https://www.axios.com/fda-prescription-drugs-pharmaceuticals-alzheimers-eda9798c-9003-4d17-804e-c1ebf7a0a2f6.html [https://perma.cc/Z4FW-LNPT].

69. Capture of the FDA extends beyond the pharmaceutical industry. *See, e.g.*, Reiss, *supra* note 16, at 591–92 (citing examples from the food industry).

70. Exondys 51's pivotal trial included only twelve patients and showed only a marginal benefit. The advisory committee and FDA's scientific reviewers were against full and accelerated approval. Dr. Janet Woodcock, however, then head of the Center for Drug Evaluation and Research ("CDER"), disagreed and approved the drug. Bill Chappell, *3 Experts Have Resigned from an FDA Committee over Alzheimer's Drug Approval*, NPR, https://www.npr.org/2021/06/11/1005567149/3-experts-have-resigned-from-an-fda-committee-over-alzheimers-drug-approval (last updated June 11, 2021, 7:04 PM) [https://perma.cc/YN64-RR7Z]; Ed Silverman, *Behind the Sarepta Drug Approval Was Intense FDA Bickering*, STAT (Sept. 19, 2016), https://www.statnews.com/pharmalot/2016/09/19/sarepta-fda-duchenne-behind-the-decision/ [https://perma.cc/2JS6-HYJJ]; *see also* Letter from Luciana Borio, Acting Chief Scientist, to Robert Califf, Comm'r of Food & Drugs 3–4, 11, 16 (Aug. 8, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_summary%20review_redacted.pdf [https://perma.cc/Q2BK-N9DM] (reporting statements made by Dr. Woodcock that suggested she was influenced by the sponsor's financial and business interests when reviewing the drug, such as her statement that "if Sarepta did not receive

inactions) relating to opioids;[71] and the approval of Lotronex, a treatment for irritable bowel syndrome.[72]

B. Internal Agency Capture: Executive Interference in Agency Scientific Decisionmaking

Internal agency capture, whereby government actors such as the President or other White House officials exert undue influence over agencies and cause them to make decisions contrary to their missions, is as significant and concerning as external agency capture, if not more so. Both Democratic and Republican presidents have sought to influence and control the administrative state throughout its history, particularly as it expanded during the latter half of the twentieth century.[73] A formal approach to executive regulatory review thus developed, with all presidents since Richard Nixon using some form of regulatory review. Major shifts began during the Reagan Administration[74] and "a distinctive form of administration and administrative control" emerged during the Clinton Administration.[75] Curtailing regulation represents a common objective, but presidential control can also serve pro-regulatory outcomes.[76] Republicans tend to be more anti-regulation and Democrats more pro-regulation, but not always.[77]

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accelerated approval for eteplirsen, it would have insufficient funding to continue to study eteplirsen and the other similar drugs in its pipeline").

71. *See, e.g.*, Caulkins & Reuter, *supra* note 39, at 33 (describing the potential role of regulatory capture in the opioid epidemic).

72. Lotronex was taken off the market approximately ten months after approval, after being linked to severe intestinal problems and several deaths. The FDA allowed it back on the market less than two years later after thousands of patients and patient advocacy groups protested the withdrawal, including at least one organization with undisclosed funding from the drug sponsor. Advisory committee members expressed concern about the lack of certain restrictions on the use of the drug, and one FDA employee expressed concerns about unhealthy corporate influences. *See* Richard Horton, Commentary, *Lotronex and the FDA: A Fatal Erosion of Integrity*, 357 LANCET 1544 (2001) (explaining Lotronex's approval, problems, and removal from the market); Ray Moynihan, *Alosetron: A Case Study in Regulatory Capture, or a Victory for Patients' Rights?*, 325 BRIT. MED. J. 592 (2002) (describing concerns that the FDA was bending to corporate influences).

73. *See* Kagan, *supra* note 14, at 2253, 2277, 2281 (explaining President Reagan, President Bush, and President Clinton's control over the administrative state).

74. *See supra* note 19 and accompanying text (describing the evolution of regulatory review).

75. Kagan, *supra* note 14, at 2250.

76. *Id.* at 2249 ("Where once presidential supervision had worked to dilute or delay regulatory initiatives, it served in the Clinton years as part of a distinctly activist and pro-regulatory governing agenda.").

77. President Nixon, for example, drove the modern environmental movement by creating the EPA. *See* Meir Rinde, *Richard Nixon and the Rise of American Environmentalism*, SCI. HIST. INST.: DISTILLATIONS (June 2, 2017), https://www.sciencehistory.org/distillations/richard-nixon-and-the-rise-of-american-environmentalism [https://perma.cc/2L28-WATZ].

Scholars continue to debate the scope of the President's authority over administrative agencies. At one extreme, the "unitary executive" theory asserts that the President possesses virtually unlimited power to control and direct the entire federal executive branch, including administrative agencies.[78] On the other end are those who argue that the President lacks directive authority over regulatory decisions unless expressly provided by Congress.[79] The view that the President may act as an "overseer," but not a "decider," also falls at this end.[80] Many theories fall between the extremes, including that embraced by Justice Elena Kagan, which holds that statutes entrusting regulatory decisions to executive agency heads should be interpreted to grant the President directive authority unless the statute expressly restricts it.[81] This Article does not revisit these arguments in detail. Instead, it accepts certain assumptions and asserts that protecting the autonomy of agency scientific decisionmaking is not irreconcilable with executive involvement in some agency decisions or the recognition that politics frequently pervades agency policymaking and rulemaking.[82]

First, this Article rejects the unitary executive theory but accepts that the President holds some authority over executive agencies. Indeed, the President's constitutional obligation to "take Care that the Laws be faithfully executed"[83] suggests that if an agency acts contrary to law, the President must step in.[84] Further, the Supreme Court recently suggested that even politically motivated presidential direction is appropriate in the context of agency policymaking, stating

78. *See* CALABRESI & YOO, *supra* note 14, at 3; Steven G. Calabresi & Saikrishna B. Praskash, *The President's Power to Execute the Laws*, 104 YALE L.J. 541, 664 (1994) ("The Framers and ratifiers consciously and deliberately chose to put one person in charge of executing *all* federal laws."); Steven G. Calabresi & Kevin H. Rhodes, *The Structural Constitution: Unitary Executive, Plural Judiciary*, 105 HARV. L. REV. 1153, 1165 (1992) ("[Unitary executive theorists] conclude that the President alone possesses *all* of the executive power and that he therefore can direct, control, and supervise inferior officers or agencies who seek to exercise discretionary executive power." (footnote omitted)); Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1, 8 (1994) (describing "modern unitarians" as those who "contend[ ] that the President has plenary or unlimited power over the execution of administrative functions, understood broadly to mean all tasks of law-implementation").

79. Percival, *Who's in Charge?*, *supra* note 15, at 2488; Percival, *Presidential Management*, *supra* note 15.

80. Peter L. Strauss, *Overseer, or "The Decider"?: The President in Administrative Law*, 75 GEO. WASH. L. REV. 696, 704–05 (2007); *see also* Cass R. Sunstein, *The Myth of the Unitary Executive*, 7 ADMIN. L.J. AM. U. 299, 306 (1993) (arguing that the President lacks authority to tell an agency head what to do).

81. Kagan, *supra* note 14, at 2326–28.

82. *See infra* notes 114–122 and accompanying text (describing the distinction between policymaking and rulemaking, on the one hand, and scientific decisionmaking, on the other).

83. U.S. CONST. art. II, § 3.

84. *See* Percival, *Who's in Charge?*, *supra* note 15, at 2493 ("Certainly a President who removes agency heads for failing to follow the law is on sound constitutional ground . . . .").

that "a court may not set aside an agency's policymaking decision solely because it might have been *influenced by political considerations or prompted by an Administration's priorities*."[85] Additionally, some federal statutes explicitly authorize the President to make certain decisions or oversee agency officials.[86] As to the FDA, the only explicit authority granted to the President by the Food, Drug, and Cosmetic Act ("FDCA") is appointment of the FDA Commissioner with the advice and consent of the Senate.[87] The FDCA delegates other powers to the Secretary of HHS or the FDA Commissioner (both political appointees) but not to the President himself.[88] Many of these authorities are further delegated within the FDA.[89]

Second, executive involvement in agency decisionmaking, while harmful when it subverts an agency's mission or undermines scientific factfinding and decisionmaking, can in theory and practice be beneficial and enhance accountability, credibility, and public trust.[90] These

85. Dep't of Com. v. New York, 139 S. Ct. 2551, 2573 (2019) (emphasis added).

86. *See, e.g.*, 42 U.S.C. § 9604 (authorizing the President to direct actions to respond to the release of hazardous substances); *see also* Kevin M. Stack, *The President's Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263, 277–82 (2006) (identifying statutes expressly giving the President the authority to oversee agency officials).

87. 21 U.S.C. § 393(d)(1). The provisions for emergency use authorizations ("EUAs") state that the provisions do not "impair[ ] the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution." *Id.* § 360bbb-3(j)(1).

88. For new drug approvals, the FDCA grants significant authority to the Secretary of HHS and none to the President. *Id.* § 355. These authorities have been delegated to the FDA Commissioner and further delegated to the FDA's review divisions. U.S. FOOD & DRUG ADMIN., SMG 1410.10, FDA STAFF MANUAL GUIDES, VOL. II – DELEGATIONS OF AUTHORITY, REGULATORY – DELEGATIONS OF AUTHORITY TO THE COMMISSIONER OF FOOD AND DRUGS (2016), https://www.fda.gov/media/81983/download [https://perma.cc/FRR5-RBEZ]; U.S. FOOD & DRUG ADMIN., SMG 1410.104, FDA STAFF MANUAL GUIDES, VOL. II – DELEGATIONS OF AUTHORITY, REGULATORY – HUMAN DRUGS, APPROVAL OF NEW DRUG APPLICATIONS AND THEIR SUPPLEMENTS (2012), https://www.fda.gov/media/84863/download [https://perma.cc/8WE9-85BQ] [hereinafter SMG 1410.104].

89. SMG 1410.104, *supra* note 88 (delegating authority to various directors and deputy directors to approve new and supplemental drug applications and delegating authority over regulatory actions for approved drugs).

90. *See, e.g.*, Mendelson, *supra* note 23, at 1137–38 ("In theory, the President has the incentive to transmit broader electoral preferences to agencies, the ability to take more of a national perspective on policy issues, and the ability to be more responsive to the voters' will compared with Congress."); Matthew C. Stephenson, *Optimal Political Control of the Bureaucracy*, 107 MICH. L. REV. 53, 59 (2008) (discussing arguments that presidential control promotes accountability "because the president is the institutional actor most responsive to the preferences of a national majority"); Paul R. Verkuil, *Jawboning Administrative Agencies: Ex Parte Contacts by the White House*, 80 COLUM. L. REV. 943, 953 (1980) ("Accountability is a crucial aspect of the executive power as expressed in article II."). This assumes, perhaps incorrectly, that the President is concerned with the views of all Americans rather than a smaller subgroup (e.g., his supporters). This assumption may also be less valid for presidents not seeking or eligible for another term in office.

benefits, however, depend largely on transparency. Justice Kagan placed significant weight on "candid" presidential involvement as a means of enhancing accountability, arguing that presidential control is the "most open to public examination and most responsive to public opinion."[91] Presidential involvement, however, is not always transparent, and presidents possess many mechanisms to shield their influence from public view.[92] There can be no accountability, credibility, or trust without transparency. As such, the possible benefits of presidential control disappear with covert interference.

Last, whatever the scope of the President's authority over agencies, that authority expands during national emergencies. Even then, there are important limits. The Supreme Court has long made clear that even war does not provide "a blank check for the President when it comes to the rights of the Nation's citizens."[93] Some may question whether rights are at issue in a typical agency capture problem. Yet, while Congress and the judiciary may situate rights on paper, agencies often play a critical role in whether those rights go beyond paper and become more than illusory.[94] Further, limitations matter because the President's national emergency powers may be abused,[95] as evinced by President Trump's declaration of a national

91. Kagan, *supra* note 14, at 2382, 2384–85. Relatedly, Professor Wendy Wagner argues that for policy decisions to receive appropriate public scrutiny for purposes of accountability, "science-policy decisionmakers must be extremely forthright in distinguishing policy judgments from scientific facts." Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1628 (1995) [hereinafter Wagner, *The Science Charade*]. This would include transparency about the executive's influence or control over the policy decisions being made.

92. *Cf.* Cary Coglianese, *The Emptiness of Decisional Limits: Reconceiving Presidential Control of the Administrative State*, 69 ADMIN. L. REV. 43, 69–75 (2017) [hereinafter Coglianese, *The Emptiness of Decisional Limits*] (describing strategies presidents can use to escape criticism that they improperly overrode an agency decision); Dana Gold & Lauren Kurtz, *What You Know About Trump's Assault on Science Was Just the Tip of the Iceberg*, SCI. AM. (July 13, 2021), https://www.scientificamerican.com/article/what-you-know-about-trumps-assault-on-science-was-just-the-tip-of-the-iceberg/ [https://perma.cc/63L5-HBUC] (mentioning examples of the Trump Administration's interference in agency science and stating that the examples "are just the cases that couldn't be covered up. There were countless more that were never made public").

93. Hamdi v. Rumsfeld, 542 U.S. 507, 536–37 (2004) (holding that due process requires U.S. citizens held as enemy combatants be given meaningful opportunity to contest the factual basis for their detentions); *see also supra* note 17 and accompanying text (describing presidential power during emergencies).

94. Reproductive rights provide one example. To the extent the Supreme Court says there is a right to contraceptives, if a part of the government responsible for making some of those rights a reality (e.g., the FDA) binds the hands of those seeking to exercise those rights, such as by imposing medically unnecessary restrictions on approved contraceptives, then whatever rights the Supreme Court recognizes are more illusory than real. The influence of agencies rings true in many other contexts, such as voting rights, whereby the Department of Justice plays a significant role in whether individuals can exercise their right to vote.

95. The National Emergencies Act does not define what constitutes a national emergency and does not require congressional approval, making the authority easier to abuse. 50 U.S.C. §§ 1601-1651.

emergency on the Mexico border to access billions of dollars to build a border wall after Congress refused to provide the funds.[96]

Another supposed benefit of presidential involvement is that it can reduce external agency capture.[97] Yet it can also provide a conduit for external agency capture.[98] That is, industry can capture the President, who then exerts control over agencies to compel decisions that favor industry. The President's motivations to do so include earning industry members' votes and financial support.[99] This relationship between external and internal capture—and whether one mitigates or exacerbates the other—becomes important when considering potential solutions.[100]

Internal agency capture also occurs through the President's appointment power when the President "place[s] loyal, ideologically

96. Nancy Pelosi, Speaker of the House, and Chuck Schumer, Senate Democratic Leader, criticized this as "a power grab by a disappointed president, who has gone outside the bounds of the law to try to get what he failed to achieve in the constitutional legislative process." Scott Horsley, *Many Presidents Have Declared Emergencies – But Not Like Trump Has*, NPR (Feb. 15, 2019, 3:19 PM), https://www.npr.org/2019/02/15/695203852/many-presidents-have-declared-emergencies-but-not-like-trump-has [https://perma.cc/L2CS-3J3D]; *see also* Peter Baker, *Trump Declares a National Emergency, and Provokes a Constitutional Clash*, N.Y. TIMES (Feb. 15, 2019), https://www.nytimes.com/2019/02/15/us/politics/national-emergency-trump.html [https://perma.cc/KP6L-KAYT] (citing key differences between President Trump's declaration and those of prior presidents). Similar issues arose during the "War on Terror," when the executive branch took positions suggesting the "whole world [was] a battlefield." Wayne McCormack, *U.S. Judicial Independence: Victim in the "War on Terror,"* 71 WASH. & LEE L. REV. 305, 338–39, 339 n.165 (2014).

97. *See, e.g.*, Livermore & Revesz, *supra* note 9, at 1340 ("The threat of capture has been linked to the need to increase presidential authority, because presidents are claimed to be less subject to capture risk.").

98. In *Sierra Club v. Costle*, the court acknowledged but did not address this concern. 657 F.2d 298, 405 & n.520 (D.C. Cir. 1981) (referencing "conduit" conversations, whereby "administration or inter-agency contacts serve as mere conduits for private parties in order to get the latter's off-the-record views into the proceeding"); *see also, e.g.*, Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1305 (2006) ("[I]t would be naïve to assume that the President is immune to public choice pressures. He is not. Like any elected official, the President will be particularly attentive to those groups that can provide him with the resources, support, or votes to win elections or promote his political agenda."); Verkuil, *supra* note 90, at 951 ("[The] fear is that government regulation will be co-opted by private groups through the intercession of the White House.").

99. *See, e.g.*, James V. Grimaldi & Thomas B. Edsall, *Fundraiser Denies Link Between Money, Access*, WASH. POST (May 17, 2004), https://www.washingtonpost.com/archive/politics/2004/05/17/fundraiser-denies-link-between-money-access/461214ec-a142-489a-afca-dc90515cff57/ [https://perma.cc/L7NV-26TT] (noting EPA policy changes favoring a company controlled by one of President Bush's larger political donors); Pete Yost, *Bush Shelved Plan to Ban Gas Additive*, BOS. GLOBE (Feb. 16, 2004), http://archive.boston.com/news/nation/articles/2004/02/16/bush_shelved_plan_to_ban_gas_additive/ [https://perma.cc/V3R6-CL93] ("The [second] Bush administration quietly shelved a proposal to ban a gasoline additive that contaminates drinking water in many communities, helping an industry that has donated more than $1 million to Republicans.").

100. *See infra* Part III.

compatible people in pivotal positions . . . whose job it is to exercise control."[101] Presidents wield much power over political appointees. Unless Congress provides otherwise, the President can remove political appointees for any or no reason at all.[102] Political appointees are often aligned with the President's goals and carry out his preferences with no further direction. Or they "may accede to [the President's] preferences because they feel a sense of personal loyalty and commitment to him; because they desire his assistance in budgetary, legislative, and appointments matters; or in extreme cases because they respect and fear his removal power."[103] Problematically, filling key positions with politically and ideologically aligned officials may result in appointees who are unqualified or even hostile to their agency's mission.[104] Particular concerns emerge when appointees act contrary to the agency's mission in order to carry out the President's goals, sometimes over the objections of expert career staff.[105]

Covertly channeling executive interference through political appointees can cloak agency decisions with unearned legitimacy, credibility, and trustworthiness. This matters. "An organization or institution that is deemed legitimate, expert, or effective" may receive deference to and trust in its decisions.[106] Due to information asymmetries between pharmaceutical companies and the public, FDA decisions fulfill an important signaling role, such as by indicating to the public that the benefits of a drug outweigh its risks when used as approved by the FDA. But when the executive, rather than the FDA, controls or unduly influences the FDA's decisions, the FDA fails to fulfill its important signaling role.

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101. Terry M. Moe & Scott A. Wilson, *Presidents and the Politics of Structure*, 57 LAW & CONTEMP. PROBS. 1, 18 (1994).

102. Percival, *Who's in Charge?*, *supra* note 15, at 2490 ("If an agency head refuses to accommodate the President's policy preferences, there is no constitutional problem with the President removing him from office."). There is no "for cause" limitation on removal of the HHS Secretary or FDA Commissioner.

103. Kagan, *supra* note 14, at 2298.

104. President Trump was criticized for nominating and appointing officials who seemed opposed to the missions of the agencies they would lead. *See* Meg Jacobs, *Trump is Appointing People Who Hate the Agencies They Will Lead*, CNN, https://www.cnn.com/2016/12/10/opinions/government-is-the-problem-jacobs/index.html (last updated Dec. 12, 2016, 10:40 AM) [https://perma.cc/VTH5-M57H] (citing Scott Pruitt (EPA), Betsy DeVos (Department of Education), Tom Price (HHS), and Andrew Puzder (nominated for Secretary of Labor) and providing examples from other presidents).

105. *See* O'Reilly, *supra* note 28, at 961 ("[T]here are times when the visions of the incoming decider and the FDA career officials will diverge; in such situations, the career staffer's craftiness will only go so far.").

106. CARPENTER, *supra* note 40, at 49; *see* O'Reilly, *supra* note 28 (connecting trust in an agency with increased judicial deference).

Yet, a public that remains unaware of executive interference will continue to trust the signaling from the FDA. This can harm individual and public health if executive interference compels the FDA to approve a drug that is not actually safe. Negative consequences also transpire if executive interference obstructs approval of a safe and effective drug. And if the public does learn of the interference, they may then view the FDA as illegitimate, ineffective, or untrustworthy. In turn, a lack of trust in an agency like the FDA can also have negative consequences for health. COVID-19 illustrated how a public that questions the FDA's credibility may not trust or follow its guidance on mitigation measures, such as vaccines.[107] This issue plagued the CDC in many ways. The CDC's inconsistent mask guidance and evidence of executive interference, for example, harmed the CDC's credibility, causing many to question whether to trust and follow its guidance.[108]

As to accountability, does the argument favoring presidential involvement stack up? In addition to transparency issues that make accountability unlikely, relying on the American electoral process to ensure the public can hold an interfering executive accountable is questionable.[109] Since 2000, the Electoral College delivered two

107. Decisions by the FDA and evidence of potential executive interference early in the COVID-19 pandemic illustrate this concern. For example, in response to a September 2020 survey—which found that twenty-eight percent of U.S. adults believed the FDA's decisions on potential COVID-19 treatments and vaccines were politically influenced—Arthur Caplan, head of the Division of Medical Ethics at New York University's School of Medicine, noted the potential consequences of the erosion of public trust in the FDA. Caplan stated that the FDA "is now viewed by many with deep suspicion" and that "[h]aving health agencies 'compromised—and they are, across the board—takes away a key weapon in the battle against Covid.' " Gaby Galvin, *Over 1 in 4 Adults Say FDA's COVID-19 Decisions Are Politically Influenced as Agency Faces Scrutiny*, MORNING CONSULT (Sept. 1, 2020, 5:26 PM), https://morningconsult.com/2020/09/01/fda-influence-science-political-trump-poll/ [https://perma.cc/7JJB-PFUF]. In a poll published in May 2021, twenty-four percent of respondents expressed "not very much" or no trust in the recommendations of the FDA. The FDA received the second-highest percentage of this response, behind only its parent agency, HHS (twenty-eight percent). *See* ROBERT WOOD JOHNSON FOUND. & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, THE PUBLIC'S PERSPECTIVE ON THE UNITED STATES PUBLIC HEALTH SYSTEM 5 (2021), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf [https://perma.cc/5VFU-UMZV] (surveying respondents about their trust in key groups in health and healthcare).

108. *See, e.g.*, Pamela S. Sinicrope et al., *Factors Associated with Willingness to Wear a Mask to Prevent the Spread of COVID-19 in a Midwestern Community*, PREVENTATIVE MED. REPS., Dec. 2021, at 1, 4 (finding that trust in the CDC was linked to mask wearing); Thespina Yamanis, *Clear, Consistent Health Messaging Critical to Stemming Epidemics and Limiting Coronavirus Deaths*, THE CONVERSATION (Apr. 8, 2020, 8:10 AM), https://theconversation.com/clear-consistent-health-messaging-critical-to-stemming-epidemics-and-limiting-coronavirus-deaths-134529 [https://perma.cc/UBA2-PWQE] ("[W]hen health messaging is vague, inconsistent or unrealistic, it engenders . . . confusion, misinformation and non-cooperation . . . .").

109. Livermore & Revesz, *supra* note 9, at 1346 ("It is important not to be too sanguine about the desirability of maximizing presidential oversight [over agency actions].").

presidents who lost the popular vote.[110] In the twentieth century, five presidents obtained only a plurality of votes.[111] The American electoral system encourages candidates to focus on a handful of "swing states" rather than the entire electorate, and candidates often focus on "financially generous constituen[ts]" at the expense of the public interest, both prior to and after taking office.[112] Further, by the time the next election occurs, new crises may have emerged and diminished any once-felt sense of urgency to hold the President accountable for improper interference. And importantly, ongoing attacks on voting rights raise serious concerns about relying on a process that remains not equally accessible to all voters and disproportionately harms communities of color.[113] Notwithstanding these and other criticisms, this is the current electoral system in the United States. Thus, any approach that seeks to mitigate executive interference must take this reality into account.

Moreover, while executive interference in policymaking and rulemaking has its own problems,[114] of greater concern is interference

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110. George W. Bush (2000) and Donald J. Trump (2016). John Woolley & Gerhard Peters, *Presidential Election Margin of Victory*, AM. PRESIDENCY PROJECT https://www.presidency.ucsb.edu/statistics/data/presidential-election-mandates (last updated Nov. 7, 2020) [https://perma.cc/LQ7B-UDXB].

111. Woodrow Wilson (1912 & 1916), Harry S. Truman (1948), John F. Kennedy (1960), Richard Nixon (1968), and William J. Clinton (1992 & 1996). *Id.*; *see also* Livermore & Revesz, *supra* note 9, at 1346–47 (mentioning other ways presidential elections can be distorted).

112. *See* Kathryn Harrison, *Regulatory Excellence and Democratic Accountability*, *in* ACHIEVING REGULATORY EXCELLENCE 56, 58 (Cary Coglianese ed., 2017) (describing how elected regulators are more likely to eschew publicly beneficial regulations compared to independent bureaucrats); John D. Graham & Paul R. Noe, *Beyond Process Excellence: Enhancing Societal Well-Being*, *in* ACHIEVING REGULATORY EXCELLENCE, *supra*, at 72, 84–85 (describing the noncompetitive nature of U.S. elections except in a few "battleground states"); *see also* Wendy Wagner, *Regulating by the Stars*, *in* ACHIEVING REGULATORY EXCELLENCE, *supra*, at 36, 38 (suggesting that regulators offer a different perspective on policymaking than elected officials). Studies show that elected officials are more responsive to donor interests than constituent interests. Further, the largest donors tend to be white men. *See generally* SEAN MCELWEE, BRIAN SCHAFFNER & JESSE RHODES, WHOSE VOICE, WHOSE CHOICE?: THE DISTORTING INFLUENCE OF POLITICAL DONOR CLASS IN OUR BIG-MONEY ELECTIONS (2016), https://www.demos.org/sites/default/files/publications/Whose%20Voice%20Whose%20Choice_2.pdf [https://perma.cc/PY88-G5DV]; Martin Gilens & Benjamin I. Page, *Testing Theories of American Politics: Elites, Interest Groups, and Average Citizens*, 12 PERSPS. ON POL. 564 (2014).

113. *See* Alexa Ura, *Gov. Greg Abbott Signs Texas Voting Bill into Law, Overcoming Democratic Quorum Breaks*, TEX. TRIB., https://www.texastribune.org/2021/09/01/texas-voting-bill-greg-abbott/ (last updated Sept. 7, 2021, 1:00 PM) [https://perma.cc/Y7UP-N7MM] (describing how a Texas voting bill restricted how and when voters can cast ballots). *See generally Voting Laws Roundup: February 2022*, BRENNAN CTR. FOR JUST. (Feb. 9, 2022), https://www.brennancenter.org/our-work/research-reports/voting-laws-roundup-february-2022 [https://perma.cc/P7BE-JJ76]; *Voting Laws Roundup: December 2021*, BRENNAN CTR. FOR JUST., https://www.brennancenter.org/our-work/research-reports/voting-laws-roundup-december-2021 (last updated Jan. 12, 2022) [https://perma.cc/W63R-6LZ9].

114. *See, e.g.*, Mendelson, *supra* note 23, at 1140–41 (discussing arguments that presidential oversight undermines the legitimacy of agency decisions); Verkuil, *supra* note 90, at 949–52

with scientific decisions that, although influenced by agency policy, are not policies themselves.[115] Such scientific decisions include the FDA's scientific review and approval decisions about pharmaceuticals. Debates about the scope of the executive's authority over agencies do not frequently draw this distinction between executive authority over policymaking and rulemaking on the one hand, and executive authority over scientific decisionmaking, on the other.[116]

Yet this distinction matters. Agency policies and rules, such as the amount and type of evidence required to prove safety and efficacy, necessarily influence the FDA's scientific decisionmaking, just as science can influence policy.[117] For example, these policies reflect nonscientific values about the level of risk we deem acceptable, which can vary depending on the targeted disease or condition.[118] But the actual application of value-laden policies, and the resulting decisions

(discussing concerns about how and to what extent the White House should influence agency policy); Wagner, *A Place for Agency Expertise*, *supra* note 19, at 2045–60 (describing problems associated with presidential influence through OIRA review, which remains largely informal and invisible); *see also EPA's New Ozone Standards: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 110th Cong. 109 (2008), https://www.govinfo.gov/content/pkg/CHRG-110hhrg47126/pdf/CHRG-110hhrg47126.pdf [https://perma.cc/3LK4-73TR] (citing Representative Henry A. Waxman, who described the EPA's decision to deny California's request to regulate automotive greenhouse gas emissions as "pure politics"). In this Article, I am mindful that agencies have roles in both making policy at the administrative level and implementing laws and policies set forth by Congress. In this latter ministerial role, agencies can act as conduits for agendas driven by entities external to the agency. In both instances, there can be undue external influences, including from the executive, whereby an agency finds itself in the position of implementing a new law or rule that is hostile to the agency's mission on its face or through its method of implementation.

115. As defined previously, for purposes of this Article and with respect to agency decisions, the term "scientific" refers to decisions based primarily on the collection and analysis of data through valid and reliable research methodologies.

116. *But see generally* Holly Fernandez Lynch, Steven Joffe & Matthew S. McCoy, *The Limits of Acceptable Political Influence over the FDA*, 27 NATURE MED. 188, 189 (2021) (referring to the "science-versus-politics dichotomy").

117. *Cf.* SCI. INTEGRITY FAST-TRACK ACTION COMM. OF THE NAT'L SCI. AND TECH. COUNCIL, PROTECTING THE INTEGRITY OF GOVERNMENT SCIENCE 11–12 (2022), https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf [https://perma.cc/962E-TR9E] [hereinafter SCI. INTEGRITY FAST-TRACK ACTION COMM.] (describing the "science-policy interface"). As Christopher Edley, Jr. argues, agency actions and determinations are a mix of adjudicatory fairness, scientific expertise, and politics, which are categories that are hard to distinguish and separate. EDLEY, *supra* note 20, at 3, 72–73. Indeed, according to Edley, "politics is lurking in almost every agency decision and in every corner of administrative law." *Id.* at 170.

118. The accelerated approval pathway, for example, reflects a judgment that accepting different types of evidence or lesser evidence of efficacy is acceptable when the risks of *not* approving a drug are so high (e.g., death) and there are no other treatment options. *See Accelerated Approval*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval (last updated Jan. 4, 2018) [https://perma.cc/2KER-UDST] (explaining accelerated approval). EUAs reflect similar values about acceptable benefit-risk ratios during public health emergencies. *See* 21 U.S.C. § 360bbb-3.

about pharmaceutical safety and efficacy based on evidentiary data, are not policies or rules—they are matters of science.[119] Justice Kagan alluded to this distinction, stating "there is no good reason for a President to displace or ignore purely scientific determinations . . . . The exercise of presidential power in this context would threaten a kind of impartiality and objectivity in decisionmaking that conduces to both the effectiveness and the legitimacy of the administrative process."[120] To enhance credibility and public trust, these decisions must be left to those "who possess expertise in the regulatory matters entrusted to them."[121] Thus, even if presidents possess the authority to influence, or even control, agency policymaking, such authority should not extend to scientific decisionmaking.[122]

Unquestionably, there may be times when policy decisions must be made in the face of scientific uncertainty or when policy decisions do not fully align with current scientific evidence.[123] But when that occurs, such political decisions must be transparent—it must be clear that they are *policy* decisions. They should not be cloaked as *scientific* decisions, and policymakers must resist falling prey to the "science charade."[124]

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119. *Cf.* Michele E. Gilman, *The President as Scientist-in-Chief*, 45 WILLAMETTE L. REV. 565, 591 (2009) ("Science is not a matter of public opinion.").

120. Kagan, *supra* note 14, at 2357. Kagan similarly urged presidential restraint in regulatory actions that depend heavily on scientific methodology and conclusions. *Id.* at 2354–57.

121. Percival, *Presidential Management*, *supra* note 15, at 966.

122. For example, President Clinton's agenda included reducing teen smoking. There is a fundamental difference between his executive action "authorizing [the FDA] to initiate a broad series of steps all designed to stop sales and marketing of cigarettes and smokeless tobacco to children," and a hypothetical scenario in which President Clinton directs the FDA to approve a specific smoking cessation drug. *The President's News Conference*, 2 PUB. PAPERS 1237 (Aug. 10, 1995), https://www.govinfo.gov/content/pkg/PPP-1995-book2/pdf/PPP-1995-book2-doc-pg1237.pdf [https://perma.cc/JM9B-6AZZ]. President Clinton undoubtedly expected the FDA to abide by his order, but the Agency retained some discretion in carrying out that order. In contrast, an order from the President to approve a specific drug would not leave the Agency with much discretion and would replace the conclusions of the FDA's scientific experts with those of the President about whether a drug is safe and effective.

123. *See, e.g.*, SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117, at 34 ("The results of scientific work from an agency scientist . . . do not necessarily reflect agency policy."); *see also* EDLEY, *supra* note 20, at 75 ("Science alone, to the extent one can conceive of it, cannot determine what to do with . . . uncertainties.").

124. Wagner, *The Science Charade*, *supra* note 91, at 1617 ("Although camouflaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces, doing so ultimately delays and distorts the standard-setting mission, leaving in its wake a dysfunctional regulatory program."); *see also* EDLEY, *supra* note 20, at 191 (suggesting that agencies disclose the role of politics in their decisions to avoid "invit[ing] a confusion of political and scientific justifications for [an] agency action"). *See generally infra* note 472 and accompanying text. Of course, whether "objective" science exists is debatable. *See* Cary Coglianese & Gary Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1264 n.38 (2004).

Failing to make these important distinctions clear to the public can ultimately undermine public trust.[125]

The potential benefits of executive involvement do not support executive interference in agency scientific decisionmaking, particularly when it lacks transparency, misleads the public about the true reasons for an agency decision, overrides the decisions of expert scientists, or results in decisions that conflict with the Agency's congressionally charged mandate.[126] A president's political interests do not necessarily translate to actions that promote an agency's mission or the public interest.[127] Further, events over the last two decades suggest that executive interference in agency scientific decisionmaking is increasingly common, raising serious concerns and a need for action.[128] Part II turns to examples from the FDA, which illustrate how executive interference in agency scientific decisionmaking harms, rather than promotes, accountability, credibility, and public trust.

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125. *See* 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/7X4R-GTBU] (noting how the CDC's failure to make clear the distinction between science and policy undermines trust).

126. As argued by Professor Percival:

> [B]y allowing the president to countermand agency decisions, accountability would be blurred because in many cases the public would be unable to understand whether a decision was the product of the agency's expertise or a presidential directive . . . . If the president can secretly dictate the decisions [agencies] must make, accountability could suffer.

Presidential Management, *supra* note 15, at 1009–10; *see also* Gilman, *supra* note 119, at 569 ("[A] President who distorts, suppresses, or manipulates science can undermine all of these benefits, and when he substitutes his judgment for that of government scientists, executive accountability suffers.").

127. The Clean Air Interest Rule ("CAIR") issued during the second Bush Administration provides an example of when political considerations "contribute[d] to regulatory outcomes inconsistent with faithful implementation of a societal well-being standard." Graham & Noe, *supra* note 112, at 80. CAIR required coal-fired power plants to reduce emissions of sulfur dioxide and nitrogen dioxide by sixty to seventy percent, even though the OMB and EPA argued the cost-benefit analysis supported a sulfur cap of ninety percent. *Id.* One likely reason for the lower threshold was because West Virginia, a state crucial to the election of President Bush in 2000, is heavily dependent on coal. The second Bush Administration was hesitant to issue burdensome regulations that might cause electric utilities to shift from coal to natural gas, thereby harming West Virginia's economy and, along with it, its support for the President. *Id.* at 80–81.

128. Kathryn A. Watts, *Controlling Presidential Control*, 114 MICH. L. REV. 683, 697 (2016) (noting the unprecedented nature of the second Bush Administration's interference in scientific matters); *cf.* Freeman & Vermeule, *supra* note 28, at 52, 92–96 (arguing that a line of cases in the mid-2000s expressed "the Court majority's increasing worries about the politicization of administrative expertise, particularly under the [second] Bush administration"); Lisa Heinzerling, *The FDA's Plan B Fiasco: Lessons for Administrative Law*, 102 GEO. L.J. 927, 930 (2014) ("[T]he Plan B experience does not stand alone, and the larger lessons remain highly relevant in other contemporary settings.").

II. EXECUTIVE INTERFERENCE IN FDA SCIENTIFIC DECISIONMAKING

Agency capture extends well beyond its reaches and entanglements at the FDA. That said, the FDA's relatively unique stature among government agencies must be recognized. In *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*, Professor Daniel Carpenter provides a thorough account of the FDA's distinctive status, exemplified by its generally positive reputation throughout history when compared to many other government agencies and institutions; the perception of the Agency's scientific expertise; and its relative power over regulated industry, in that it essentially wields veto power over a company's ability to bring a product to market.[129] This reputation gives FDA decisions a cloak of legitimacy, engenders public trust, and renders courts likely to grant significant deference to Agency decisions.[130]

This power and reputation provide reason for particular concern about executive interference in the FDA's scientific decisionmaking, given its potential to erode the credibility of an agency with great power and influence over many facets of life, spanning the economy, politics, national security, the practice of medicine, scientific research, and public and individual health. In 2010, Carpenter noted that the next ten years were critical for the FDA and its reputation.[131] Numerous events since that time, compounded by the pandemic and increasing political polarization, suggest the FDA's reputation remains in danger.[132]

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129. *See generally* CARPENTER, *supra* note 40; *see also* O'Reilly, *supra* note 28, at 940 & nn.2–3, 949; Adrian Vermeule, *Conventions of Agency Independence*, 113 COLUM. L. REV. 1163, 1208 (2013) (noting that over time, "[t]he FDA had developed an outstanding reputation for impartial expertise").

130. *See generally* O'Reilly, *supra* note 28 (discussing judicial deference historically given to the FDA and arguing that "political direction" of the Agency decreases the likelihood that courts will continue to exercise such deference).

131. Sarah Sweeney, *Peering into the Gearworks of FDA*, HARV. GAZETTE (Apr. 29, 2010), https://news.harvard.edu/gazette/story/2010/04/peering-into-gearworks-of-fda/ [https://perma.cc/DCT4-ATQG].

132. *See, e.g.*, Beth Snyder Bulik, *FDA Reputation Takes Another Hit After Scathing Aducanumab Advisory Panel Meeting*, FIERCE PHARMA (Nov. 9, 2020), https://www.fiercepharma.com/marketing/fda-reputation-takes-another-hit-after-scathing-alzheimer-s-drug-adcomm [https://perma.cc/JX43-T7KN]. Studies suggest polarization has increased in the United States. *See* Michael Dimock & Richard Wike, *America Is Exceptional in Its Political Divide*, PEW TR. MAG. (Mar. 29, 2021), https://www.pewtrusts.org/en/trust/archive/winter-2021/america-is-exceptional-in-its-political-divide [https://perma.cc/UQR6-M2QB] (arguing that the COVID-19 pandemic has shown how deeply divided U.S. politics are versus other nations); Lexi Boxell, Matthew Gentzkow & Jesse M. Shapiro, *Cross-Country Trends in Affective Polarization* 2 (Nat'l Bureau of Econ. Rsch., Working Paper No. 26669, 2021), https://www.nber.org/system/files/working_papers/w26669/w26669.pdf [https://perma.cc/97B4-

The Trump Administration's interference in agency science was extensive,[133] with some of the most troubling interference occurring during the COVID-19 pandemic. At times he succeeded, but consequences still materialized when he did not, with agencies losing credibility and public trust. President Trump's interference was uniquely aggressive, broad, and public, exemplified by his use of Twitter to disparage or claim responsibility for certain agency actions, to openly demand that agencies take specific actions, and to publicly tout the safety and efficacy of COVID-19 products before FDA review or even in opposition to FDA decisions. The scope and blatancy of the Trump Administration's interference make it easy to assume that it simply illustrates another unique feature of a presidency that was atypical in many ways.[134] Yet that belief is misguided, and the unusual manner of President Trump's interference should not provide reason to ignore executive interference beyond the Trump Administration. Such interference occurred in past administrations and continues to occur. Problematically, the true extent of executive interference in agency decisions remains unknown because it frequently occurs through covert means. But even where evidence of interference remains elusive, there are sometimes such large disconnects between a decision and the underlying science that executive interference seems likely to have occurred. Furthermore, even if relatively infrequent, executive interference in agency scientific decisionmaking—and violations of scientific integrity more generally—"can have an outsized, detrimental impact on decision-making and public trust in science."[135]

To further explore the issue and illustrate that executive interference extends beyond the Trump Administration, this Part describes cases of executive interference in FDA approval decisions across administrations. These examples make clear that executive interference often occurs covertly and that the likelihood of executive interference increases when the issues are politically, socially, and ethically controversial. Recent examples involve reproductive health and COVID-19, but forthcoming medical innovations will raise new and difficult questions, generating considerable political and ethical debate

Q3R6] (finding that affective polarization has increased in the United States over the past four decades).

133. *See, e.g.*, Lindsey Dillion et al., *The Environmental Protection Agency in the Early Trump Administration: Prelude to Regulatory Capture*, 108 AM. J. PUB. HEALTH S89 (Supp. 2 2018) (providing examples of the Trump Administration's efforts to influence agency actions prior to the pandemic); *see also supra* note 2.

134. *See, e.g.*, James P. Pfiffner, *The Unusual Presidency of Donald Trump*, 8 POL. INSIGHT 9 (2017).

135. SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117, at xi.

and giving rise to a new class of FDA decisions likely to provoke political interference.[136]

A. Reproductive Health

Issues of reproductive health raise some of the most politically contentious questions of our time, making them "particularly vulnerable to sacrifice for political expediency."[137] All three branches of government play important roles in expanding or restricting access to reproductive healthcare.

The discourse surrounding reproductive rights often focuses on state law. Yet concern only about state law overlooks agency regulation of reproduction, which often glides under the surface of explicit legislative enactments. In this space, executive politics can infiltrate decisions that would elsewhere be guided by scientists and medical experts. The executive branch may use agencies to carry out agendas that undermine reproductive rights, although agency-level regulation can also advance reproductive rights. Historically, however, the FDA too often capitulated to executive overreach in matters of reproductive health, losing sight of its congressionally charged mission and failing to adhere to a fundamental norm of administrative law: "treat[ing] like cases alike."[138] Instead, science acts as subterfuge to justify restrictions on otherwise safe and effective medicines. The FDA's regulation of emergency contraception and medication abortion, involving both Democratic and Republican administrations, represent two salient examples discussed in this Section.

1. Emergency Contraception

The FDA's handling of emergency contraception provides a prime example of the FDA conceding to political pressures.[139] Here, covert executive interference "cast[ ] a shadow on the legitimacy of

136. *See generally* MARGARET L. EATON & DONALD KENNEDY, INNOVATION IN MEDICAL TECHNOLOGY: ETHICAL ISSUES AND CHALLENGES (2007) (examining the ethical, legal, and social problems that arise with new and emerging medical technologies). These products may, for example, aim to enhance otherwise healthy bodies instead of curing, treating, or mitigating diseases. *Id.* at 21.

137. Sarah Christopherson & Olivia Snavely, *The FDA's Convoluted Stance on Abortion Pills Doesn't Protect Patients — It Endangers Them*, NAT'L WOMEN'S HEALTH NETWORK (May 8, 2020), https://nwhn.org/the-fdas-convoluted-stance-on-abortion-pills-doesnt-protect-patients-it-endangers-them/ [https://perma.cc/T32Z-BQVR].

138. Westar Energy, Inc. v. F.E.R.C., 473 F.3d 1239, 1241 (D.C. Cir. 2007).

139. *See, e.g.*, CARPENTER, *supra* note 40, at 741; Heinzerling, *supra* note 128, at 938–43; O'Reilly, *supra* note 28, at 964–67; Vermeule, *supra* note 129, at 1207–09; Watts, *supra* note 128, at 706–11.

agency action and interfere[ed] with science."[140] The drug's journey to over-the-counter ("OTC") availability took over a decade and required multiple trips to court, with evidence of the second Bush Administration and the Obama Administration meddling in scientific decisions.

Plan B and Plan B One-Step are FDA-approved emergency contraceptives to reduce the chance of pregnancy when taken within seventy-two hours after unprotected sex.[141] The drug's potential side effects are generally mild and short term, and it does not have any known serious or long-term side effects.[142] The FDA approved Plan B in 1999 as a prescription-only drug.[143] In 2001, medical and public health groups filed a citizen petition requesting that the FDA make Plan B available without a prescription (i.e., OTC).[144] In 2003, Plan B's sponsor submitted a supplemental new drug application ("sNDA"), also requesting an OTC switch.[145] When reviewing an OTC switch application, the FDA must decide whether the drug is safe to use without the supervision of a licensed practitioner.[146]

A joint FDA advisory committee voted unanimously that Plan B was safe for OTC use and voted twenty-three to four to approve the switch.[147] As noted previously, the FDA is not bound by advisory committee recommendations but follows them in most cases.[148] Here, however, the FDA denied the citizen petition and issued a "Not

140. Watts, *supra* note 128, at 706–11. Even though now well-known and discussed, the interference in Plan B was largely covert at the time it occurred and only later came to light through judicial and congressional intervention and investigation.

141. Plan B, now discontinued, consisted of two 0.75 mg pills taken twelve hours apart. *Drugs@FDA: FDA-Approved Drugs, NDA No. 021045*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021045 (last visited Sept. 22, 2022) [https://perma.cc/L3TJ-FUK9]. Plan B One-Step, which remains available, consists of one 1.5 mg pill. *Plan B One-Step Label*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021998Orig1s006lbl.pdf [https://perma.cc/8YF3-5NJ2] [hereinafter *Plan B One-Step Label*].

142. *See Plan B One-Step Label*, *supra* note 141; Tummino v. Torti, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).

143. *See Torti*, 603 F. Supp. 2d at 522.

144. *Id.* at 526; GRETCHEN GOLDMAN, GENNA REED, MICHAEL HALPERN, CHARISE JOHNSON, EMILY BERMAN, YOGIN KATHARI & ANDREW ROSENBERG, PRESERVING SCIENTIFIC INTEGRITY IN FEDERAL POLICYMAKING: LESSONS FROM THE PAST TWO ADMINISTRATIONS AND WHAT'S AT STAKE UNDER THE TRUMP ADMINISTRATION 15 (2017), https://www.ucsusa.org/sites/default/files/attach/2017/01/preserving-scientific-integrity-in-federal-policymaking-ucs-2017.pdf [https://perma.cc/32PL-5U77].

145. *Torti*, 603 F. Supp. 2d at 528; GOLDMAN ET AL., *supra* note 144, at 15.

146. 21 U.S.C. § 353(b)(1)(A).

147. *Torti*, 603 F. Supp. 2d at 528.

148. *See supra* notes 57–58 and accompanying text.

Approvable Letter"[149] to the sponsor, asserting that the data did not adequately show that young adolescents could safely use Plan B without professional supervision.[150]

Plan B's sponsor amended the sNDA twice, first requesting OTC status for women sixteen and older and then for women seventeen and older.[151] The FDA denied both despite nearly uniform agreement among the FDA's scientific reviewers that the drug was safe for nonprescription use by women of all ages.[152] Then-Commissioner Andrew C. von Eschenbach oddly cited "enforcement concerns," stating that "because of 'the difficulty of enforcing an age-based restriction on the availability of [Plan B] . . . 18 . . . is the more appropriate cutoff point to best promote and protect the public health.' "[153] In June 2006, the FDA also denied the citizen petition.[154] The Agency approved nonprescription use of Plan B for women eighteen and older in August 2006 but required that the drug be kept behind the pharmacy counter.[155] This was the first time the FDA imposed a behind-the-counter restriction for a low-risk OTC drug.[156]

The FDA's handling of Plan B caused at least two resignations: Dr. Susan Wood, Director of the FDA's Office of Women's Health, and Dr. Frank Davidoff, an advisory committee member.[157] Dr. Wood asserted that the FDA's decision "overturn[ed] the clear scientific and clinical evidence, [and] contradict[ed] both the FDA mission and [her] commitment to women's health."[158] Senators Patty Murray and Hillary Clinton referred to her resignation as "the latest in a long list of examples of the Bush administration suppressing science when it doesn't fit their political agenda."[159]

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149. A "Not Approvable Letter" (since replaced by "Complete Response Letters") typically described deficiencies and meant the FDA could not approve the application as submitted. *See* Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications, 73 Fed. Reg. 39588, 39590 (July 10, 2008).

150. *FDA's Decision Regarding Plan B: Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-decision-regarding-plan-b-questions-and-answers (last updated Dec. 7, 2015) [https://perma.cc/UCL2-5H8B].

151. *Torti*, 603 F. Supp. 2d at 523.

152. *Id.*

153. *Id.* at 550.

154. *Id.* at 536.

155. *Id.* at 535–36.

156. Heinzerling, *supra* note 128, at 964.

157. *Torti*, 603 F. Supp. 2d at 535.

158. *Id.*

159. Gardiner Harris, *Official Quits on Pill Delay at the F.D.A.*, N.Y. TIMES (Sept. 1, 2005), https://www.nytimes.com/2005/09/01/us/official-quits-on-pill-delay-at-the-fda.html [https://perma.cc/EEJ5-J2S9].

In a challenge to the denial of the citizen petition, the district court concluded that the FDA's decisions were arbitrary, capricious, and not the result of good-faith decisionmaking because the Agency considered "impermissible political and ideological considerations."[160] The court ordered the FDA to approve nonprescription Plan B for women seventeen years and older and to reconsider its decision for women younger than seventeen.[161] The FDA lowered the age to seventeen,[162] but the drug remained behind the counter and required proof of age to purchase.[163] The court supported its conclusions with a 2005 Government Accountability Office ("GAO") report, which investigated the FDA's decision to issue a Not Approvable Letter contrary to the recommendations of the advisory committee and FDA review staff.[164] Many important facts emerged only because of congressional intervention and the GAO report, illustrating the difficulty of proving covert political interference.[165]

Plan B's sponsor submitted another sNDA in 2011 to remove all age limits, which the FDA's scientific reviewers approved.[166] Then-Commissioner Margaret Hamburg agreed with the approval.[167] Nevertheless, HHS Secretary Kathleen Sebelius—who does not have a medical or scientific background—overruled the decision, claiming the data did "not establish that prescription dispensing requirements should be eliminated for all ages."[168] Of specific concern was the alleged

160. *Torti*, 603 F. Supp. 2d at 523, 544. Of course, courts are also criticized—even by their own jurists—for impermissible politicization, particularly on reproductive health issues. *See, e.g.*, Ed Pilkington, *The 'Stench' of Politicization: Sonia Sotomayor's Supreme Court Warning*, GUARDIAN (Dec. 4, 2021), https://www.theguardian.com/us-news/2021/dec/04/us-supreme-courrt-sonia-sotomayor-abortion [https://perma.cc/ZBD4-BL6A] (quoting Justice Sotomayor, who asked, "Will this institution survive the stench that this creates in the public perception that the constitution and its reading are just political acts?").

161. *Torti*, 603 F. Supp. 2d at 550.

162. *Plan B Label*, U.S. FOOD & DRUG ADMIN. 1 (Aug. 23, 2006), https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021045s011lbl.pdf [https://perma.cc/R6WS-BFQE].

163. Tummino v. Hamburg, 936 F. Supp. 2d 162, 164 (E.D.N.Y. 2013).

164. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., FOOD & DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 3 (2005), https://www.govinfo.gov/content/pkg/GAOREPORTS-GAO-06-109/pdf/GAOREPORTS-GAO-06-109.pdf [https://perma.cc/RUM3-BS89] [hereinafter PLAN B GAO REPORT] (explaining that the GAO was asked, in part, to examine the FDA's decision to "not approve the switch" and to compare the decision to other "proposed . . . switches").

165. Heinzerling, *supra* note 128, at 950–52 (describing congressional involvement and the GAO report).

166. *Hamburg*, 936 F. Supp. 2d at 166–67.

167. *Id.* at 167.

168. *Id.*

lack of data on "label comprehension and actual use" for all ages, particularly eleven- and twelve-year-olds.[169]

Controversy and criticism ensued immediately. President Obama endorsed the Secretary's decision but said he was not involved in the process.[170] He also mentioned the importance of "apply[ing] some common sense to various rules" about OTC medicines.[171] Yet applying the same "common sense" to other OTC medicines would mean that many OTC drugs should not actually be available without a prescription. Dr. Curtis Rosebraugh, then-Deputy Director of the Division of OTC drugs, explained this inconsistency:

> A decision by the Agency to withhold OTC marketing of Plan B for reasons of theoretical abuse by a very small segment of the population despite the great benefit that could be derived from easier access could have ramifications for how we regulate other OTC drugs . . . a natural progression of this line of regulatory reasoning would require that the Agency remove OTC marketing status for many drugs with known abuses including dextromethorphan because of reports of adolescent abuse, laxatives because of abuse by people suffering from bulimia, analgesics because of abuse with subsequent health ramifications, or acetaminophen because of its use in suicides.[172]

Many viewed the Secretary's decision as a political strategy for the Obama Administration to avoid an election-year controversy.[173] Indeed, "[a]ny objective review makes it clear that Plan B is more dangerous to politicians than to adolescent girls. Thus, we once again have a situation in which political considerations are forming the basis of public health policy—resulting in another sad day for women."[174]

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169. *Id.*

170. Press Release, The White House, Off. of the Press Sec'y, Statement by the President (Dec. 8, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/12/08/statement-president [https://perma.cc/PK46-NWVU].

171. *Id.*

172. *Hamburg*, 936 F. Supp. 2d at 174 (emphasis omitted).

173. Dr. Wood stated that "[b]ecause this decision occurred in a presidential election year, it seems likely that full OTC approval was blocked to avoid political controversy." Susan F. Wood, *Inappropriate Obstructions to Access: The FDA's Handling of Plan B*, 16 AM. MED. ASS'N J. ETHICS 295, 298 (2014); *see also* GOLDMAN ET AL., *supra* note 144, at 16 (asserting that "[i]n advance of the 2012 election, President Obama . . . attempted to justify the decision"); Sam Baker, *Left 'Speechless' As Sebelius Overrules FDA on Access to Morning-After Pill*, THE HILL (Dec. 7, 2011), https://thehill.com/policy/healthcare/197825-sebelius-overrules-fda-blocks-access-to-plan-b [https://perma.cc/442P-7JNJ] (noting that because some Republicans believed Plan B causes abortions, "[i]f the FDA decision had gone forward . . . Obama could have come under criticism from the Republican field of presidential candidates for making abortion more accessible"); Gardiner Harris, *White House and the F.D.A. Often at Odds*, N.Y. TIMES (Apr. 2, 2012), https://www.nytimes.com/2012/04/03/health/policy/white-house-and-fda-at-odds-on-regulatory-issues.html [https://perma.cc/EA6E-GVS7] (acknowledging that Secretary Sebelius "drew criticism that she had put politics ahead of science when she overruled an agency decision that would have allowed over-the-counter sales of a contraceptive that helps prevent pregnancy after sexual intercourse").

174. Alastair J.J. Wood, Jeffrey M. Drazen & Michael F. Green, *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101, 102 (2012).

In a second court challenge, the court held that the decisions of the Secretary and the FDA were "arbitrary, capricious, and unreasonable."[175] The court did not decide whether President Obama influenced the decision, but noted that (1) the Secretary is a member of the President's cabinet, (2) the decision was made during an election year, and (3) "the motivation for the Secretary's action was obviously political."[176] He ordered the FDA to make Plan B available without a prescription, age restrictions, or point-of-sale restrictions (e.g., no "behind-the-counter" requirements).[177] After the Obama Administration initially appealed the decision,[178] the FDA approved Plan B One-Step on June 20, 2013, for nonprescription use without age or point-of-sale restrictions.[179]

The court's thorough opinions, supplemented by the GAO report, detail numerous procedural irregularities and political influences, some of which were described above. Additional evidence providing a strong inference of covert executive interference follows below.

First, senior officials were unusually involved in decisions typically left to the FDA's scientific reviewers, some of which occurred publicly, while others occurred behind the scenes.[180] Indeed, Secretary Sebelius became the first HHS Secretary to overrule an FDA decision in such a public manner.[181] This forced the FDA "to ride roughshod over the policies and practices that it has consistently applied in considering" OTC switch applications.[182] Additionally, Dr. Galson,

175. *Hamburg*, 936 F. Supp. 2d at 197.

176. *Id.* at 170.

177. *Id.* at 197.

178. Notice of Appeal, Tummino v. Hamburg, 936 F. Supp. 2d. 162 (E.D.N.Y. 2013) (No. 12-CV-00763-ERK-VVP). The Obama Administration dropped the appeal in June 2013. *See* Letter from Loretta E. Lynch, U.S. Att'y, E. Dist. of New York, to the Hon. Edward R. Korman, Sr. Dist. J., E. Dist. of New York (June 10, 2013) (advising the court that the government was voluntarily withdrawing its appeal).

179. *Plan B One-Step Label*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021998Orig1s003lbl.pdf (last accessed Nov. 5, 2022) [https://perma.cc/4FCL-U4NY]; Letter from Shaw T. Chen, Acting Dir., Div. of Nonprescription Clinical Evaluation, Off. of Drug Evaluation, Ctr. For Drug Evaluation & Rsch., to Amy Hummel, Assoc. Dir., Reg. Affairs, Teva Branded Pharm. Prods. R&D, Inc. (June 20, 2013), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/021998Orig1s003ltr.pdf [https://perma.cc/M5CA-N6YN] (letter from the FDA approving Plan B One-Step for nonprescription use without point-of-sale or age restrictions).

180. Tummino v. Torti, 603 F. Supp. 2d 519, 523, 537 (E.D.N.Y. 2009).

181. Wood et al., *supra* note 174, at 101; *see also* GOLDMAN ET AL., *supra* note 144 at 15–16 (noting that Secretary Sebelius "became the first health secretary ever to overrule the FDA publicly"). HHS has less publicly overridden FDA decisions in other contexts. *See* PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 222–23 (2003) (providing an example about the sale of raw milk).

182. Tummino v. Hamburg, 936 F. Supp. 2d. 162, 169 (E.D.N.Y. 2013).

Acting Director of the Center for Drug Evaluation and Research ("CDER"),[183] signed the Not Approvable Letter. Such letters are typically signed by the directors of the relevant FDA offices, not the Director of CDER.[184] In fact, of ninety-four action letters issued from 1994 to 2004 relating to OTC switch applications, the Plan B Letter was the only one signed by CDER's Director.[185] Further, testimony indicates that Dr. Galson believed he would be removed from his position if he did not sign the Letter.[186]

Second, evidence suggests that the White House, acting through the FDA's Office of the Commissioner, influenced the decisions for political reasons.[187] Meetings of the Commissioner's Office discussed the application's "political sensitivity," and in 2003, then-Commissioner Mark McClellan discussed the pending application with Jay Lefkowitz, Deputy Assistant to the President for Domestic Policy.[188] Dr. McClellan also provided several updates to White House policy staff throughout the process.[189] FDA officials testified that Dr. Galson and Dr. Woodcock, then-Acting Deputy Commissioner, told them that the Bush White House was involved in the decision "and that it was made very clear that there were a lot of constituents who would be very unhappy with . . . an over-the-counter Plan B."[190] Discussions with the White House are abnormal for this type of decision.[191] Further, Dr. Woodcock conveyed to others within the Agency that issuing a Not Approvable Letter was the "only way . . . to appease the [second Bush] administration's constituents."[192] Politics, rather than science, thus drove these decisions.

Third, politics and ideology "played a determinative role" in the selection of advisory committee members.[193] During the second Bush Administration, qualified nominees were rejected by the Commissioner's Office in favor of individuals active in Right to Life causes.[194] This included Dr. W. David Hager, who equated Plan B to abortion, refused to prescribe Plan B to his patients on moral grounds,

183. *Torti*, 603 F. Supp. 2d at 529 (indicating that Dr. Galson was Acting Director).

184. *Id.* at 537; *see also* PLAN B GAO REPORT, *supra* note 164, at 29–30.

185. PLAN B GAO REPORT, *supra* note 164, at 30.

186. *Torti*, 603 F. Supp. 2d at 529.

187. *Hamburg*, 936 F. Supp. 2d at 170.

188. *Torti*, 603 F. Supp. 2d at 527.

189. *Id.*

190. *Id.* at 529.

191. *Id.* at 547.

192. *Id.* at 530.

193. *Id.* at 527.

194. *Id.* at 528. At least two of the members raising concerns about young adolescents were appointed to achieve an "ideological balance." *Id.*

and, when discussing his role in the Plan B decision, stated that "God has used me to stand in the breach."[195]

Fourth, the FDA's denials went against the recommendations of the advisory committee and the decisions of the FDA's scientific reviewers. Of twenty-three OTC switch applications reviewed by advisory committees from 1994 to 2004, Plan B was the only application not approved after a committee recommended approval.[196]

Fifth, the FDA repeatedly delayed its decisions. Evidence suggests that on at least two occasions the Agency acted only to facilitate the confirmations of two Acting Commissioners, after Senators Murray and Clinton held up their confirmations because of the FDA's delays on Plan B.[197]

Finally, inconsistent with standard practice, Agency officials refused to extrapolate data from an actual use study in older adolescents to younger adolescents, despite previously informing the sponsor it could do so.[198] Relatedly, denying the application based on concerns about young adolescent use and behaviors was "novel and did not follow FDA's traditional practices."[199] The decisions were inconsistent with the Agency's approach to other more dangerous OTC medications available to adolescents. Critics stated that it was clearly

> based on politics rather than science. It [could not] be based on issues of safety, since a 12-year-old can purchase a lethal dose of acetaminophen in any pharmacy for about $11, no questions asked. The only documented adverse effects of a $50 dose of levonorgestrel are nausea and delay of menses by several days.[200]

Even absent evidence of direct presidential interference, Plan B provides an illustrative example where executive-level politics played a "delegitimizing and corrupting role" in the FDA's scientific decisionmaking.[201] Further, it demonstrates the difficulty of uncovering covert executive interference. Here, the detailed record resulted from "atypical interventions" by Congress and the courts,[202] and this example remains symbolic of a larger and troubling trend of political interference in FDA science.

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195. SHULMAN, *supra* note 28, at 49–50.

196. *Torti*, 603 F. Supp. 2d at 528.

197. *Id.* at 534–36, 546.

198. *Id.* at 526–27, 547–48.

199. PLAN B GAO REPORT, *supra* note 164, at 22. CDER's Acting Director acknowledged it was unprecedented to consider adolescents' cognitive development as a reason to issue a Not Approvable Letter for an OTC application. *Id.* at 25.

200. Wood et al., *supra* note 174, at 102.

201. Watts, *supra* note 128, at 710–11.

202. Heinzerling, *supra* note 128, at 929.

2. Medication Abortion: Mifepristone and Abortion Exceptionalism[203]

The FDA's atypical treatment of mifepristone, a form of medication abortion, represents another example of how executive politics influence and interfere with the FDA's scientific decisionmaking. Democratic and Republican administrations have both been accused of engaging in political interference, allowing politics to trump science, and endangering the health of pregnant persons in the process.[204]

Clinical studies of mifepristone in the United States began in 1983 but were halted after the drug's manufacturer, Roussel Uclaf, stopped providing the drug for U.S. abortion research.[205] This decision was influenced by an "import alert" issued by the first Bush Administration, which prohibited patients from importing mifepristone for personal use.[206] The import alert likely resulted, in part, from

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203. "Abortion exceptionalism" describes "the tendency of legislatures and courts to subject abortion to unique, and uniquely burdensome, rules." Caitlin E. Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047, 1048 & n.2 (2014).

204. *See, e.g.*, Benten v. Kessler, 799 F. Supp. 281, 286 (E.D.N.Y. 1992) (stating that the first Bush Administration's ban on the importation of mifepristone "was based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety"); Melanie Israel, *Chemical Abortion: A Review*, HERITAGE FOUND. 4–5 (Mar. 26, 2021), https://www.heritage.org/sites/default/files/2021-03/BG3603.pdf [https://perma.cc/9J7Y-D8AU] (criticizing the Clinton Administration's involvement with mifepristone); *Mifepristone: The Impact of Abortion Politics on Women's Health and Scientific Research*, NARAL PRO-CHOICE AM. 4 (Jan. 1, 2017), https://www.prochoiceamerica.org/wp-content/uploads/2017/01/1.-Mifepristone-The-Impact-of-Abortion-Politics.pdf [https://perma.cc/3EQ4-R7FP] (stating that the appointment of Dr. W. David Hager, "an avowed anti-choice proponent," to the Advisory Committee for Reproductive Health Drugs, "demonstrated the [second] Bush administration's eagerness to inject politics into science"); Press Release, Chris Smith, Congressman, House of Reps., Obama Administration Gives Another Gift to Abortion Industry (Mar. 30, 2016), https://chrissmith.house.gov/news/documentsingle.aspx?DocumentID=398811 [https://perma.cc/VBP5-UZR8] (accusing President Obama of "bow[ing] to pressure from his abortion cronies"); Giselle Hengst & Corrine Ahrens, *Weekly Pulse, Aug 23-28: Trump COVID Plan Guided by Politics, Not Public Health; Hurricane Laura's Aftermath*, MS. MAG. (Aug. 27, 2020), https://msmagazine.com/2020/08/27/weekly-pulse-aug-23-28-trump-covid-plan-guided-by-politics-not-public-health-hurricane-lauras-aftermath/ [https://perma.cc/R4FV-PLJ4] (asserting that the Trump Administration's COVID-19 response, including retention of mifepristone's in-person requirements, was "guided by politics, not public health"); *Chemical Abortion: FDA Ignores 'Inconvenient' Science and Data Confirming Public Health Threat*, CHARLOTTE LOZIER INST. (Dec. 16, 2021), https://lozierinstitute.org/chemical-abortion-fda-ignores-inconvenient-science-and-data-confirming-public-health-threat/ [https://perma.cc/5T6X-ZKFJ] ("[T]he Biden FDA is cherry-picking flawed data to give the abortion industry a Christmas gift." (quoting Stephen Billy, Executive Director of the Charlotte Lozier Institute, the education and research arm of the Susan B. Anthony List, a well-known anti-abortion group)).

205. JUDITH A. JOHNSON, CONG. RSCH. SERVS., RL30866, ABORTION: TERMINATION OF EARLY PREGNANCY WITH RU-486 (MIFEPRISTONE) 2 (2001), https://www.everycrsreport.com/files/20010223_RL30866_c6c423f682c56ed7c586755595c02d5202ddf6bd.pdf [https://perma.cc/9S3A-XVC4].

206. *Id.* at 1–2; Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 577 (2001).

political pressure, although the FDA cited safety concerns as the official reason.[207]

A woman challenged the ban in 1992 after the government seized her imported mifepristone.[208] The district court categorized the import alert as an agency rule and concluded that the seizure was illegal because it was promulgated without notice and comment.[209] In doing so, the court also stated that the ban was likely "based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."[210] The U.S. Supreme Court, however, ultimately upheld the seizure.[211]

After taking office, President Clinton ordered HHS and the FDA to review the import alert, directing them to rescind it if the drug met the personal importation criteria.[212] He also directed them to "promptly assess initiatives by which [HHS] can promote the testing, licensing, and manufacturing in the United States of [mifepristone] or other antiprogestins."[213] According to President Clinton, mifepristone "has been held hostage to politics."[214]

Mifepristone's manufacturer remained hesitant to seek approval in the United States, fearing product liability litigation and boycotts of its other products.[215] After lengthy negotiations, the company donated a license to sell the drug in the United States to a nonprofit organization.[216] Before reaching this agreement, the company requested that President Clinton write the company a letter asking it to assign the license.[217] President Clinton wrote the letter and urged the company to finalize its negotiations.[218]

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207. *Benten*, 799 F. Supp. at 286; JOHNSON, *supra* note 205, at 2.

208. *Benten*, 799 F. Supp. at 283.

209. *Id.* at 288–90.

210. *Id.* at 286.

211. Benten v. Kessler, 505 U.S. 1084 (1992).

212. Importation of RU-486, 58 Fed. Reg. 7459, 7459 (Jan. 22, 1993).

213. *Id.*

214. Noah, *supra* note 206, at 578.

215. *Id.* at 579.

216. *Id.*

217. Memorandum from Kevin Thrum, Chief of Staff, White House, to Carol Rasco, Dir., Domestic Pol'y (May 11, 1994), *in* JUDICIAL WATCH, THE CLINTON RU-486 FILES: THE CLINTON ADMINISTRATION'S RADICAL DRIVE TO FORCE AN ABORTION DRUG ON AMERICA, Tab D (2006), https://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf [https://perma.cc/G2TZ-RVQT].

218. Letter from President Bill Clinton to Edouard Sakiz, Chairman, Supervisory Bd. of Roussel Uclaf (May 16, 1994), *in* JUDICIAL WATCH, THE CLINTON RU-486 FILES: THE CLINTON ADMINISTRATION'S RADICAL DRIVE TO FORCE AN ABORTION DRUG ON AMERICA, *supra* note 217, at Tab E.

Unquestionably, the Clinton Administration's involvement facilitated clinical trials and the filing of a marketing application with the FDA. Initially, the manufacturer did not seek FDA approval because of the first Bush Administration's anti-abortion policies.[219] "It was only when President Clinton changed the governmental policy and specifically asked Roussel to make the procedure available here, that [Roussel], out of respect for the President of the United States, agreed to make every effort to comply with his request."[220] Essentially, politics, not science, took a leading role.

After filing a new drug application in 1996, an FDA advisory committee voted unanimously that the drug's benefits outweighed its risks when used under close medical supervision.[221] The FDA approved mifepristone under the brand name Mifeprex in 2000 for the termination of pregnancy through forty-nine days' gestation.[222] Interestingly, the FDA approved mifepristone under 21 C.F.R. § 314, Subpart H, which provides "accelerated approval" for "new drugs for serious or life-threatening illnesses."[223] The FDA acknowledged that use of this pathway had "nothing to do with" accelerating mifepristone's approval but rather was used to allow the FDA to impose distribution restrictions on the drug.[224] Under these restrictions, only qualified physicians could prescribe mifepristone, patients had to attest they understood the potential risks of the drug, and the drug had to be dispensed and administered in the presence of a health professional.[225] According to the FDA's Commissioner, "[p]olitics had no role in this decision."[226]

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219. JOHNSON, *supra* note 205, at 4–5.

220. *Id.* (quoting *RU-486, Status Report on the U.S. Commercialization Project, Transfer of Antiprogestin Technology to the United States: Hearing Before the H. Comm. on Small Bus.*, 103d Cong. 16 (1994)).

221. *Id.* at 5 & n.24.

222. Letter from Ctr. for Drug Evaluation & Res. to Sandra P. Arnold, Vice President, Corp. Affs., Population Council (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf [https://perma.cc/M2BV-Y7CC].

223. 21 C.F.R. §§ 314.500-560 (2022).

224. *RU-486: Demonstrating a Low Standard for Women's Health?: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the Comm. on Gov't Reform*, 109th Cong. (2006) (statement of Dr. Janet Woodcock, Deputy Comm'r for Operations, Food & Drug Admin., U.S. Dep't of Health & Hum. Servs.), https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm [https://perma.cc/9HPW-98BJ].

225. JOHNSON, *supra* note 205, at 9–10.

226. Gina Kolata, *U.S. Approves Abortion Pill: Drug Offers More Privacy, and Could Reshape Debate*, N.Y. TIMES (Sept. 29, 2000), https://www.nytimes.com/2000/09/29/us/us-approves-abortion-pill-drug-offers-more-privacy-and-could-reshape-debate.html [https://perma.cc/2W5Z-DWW9].

Amendments to the FDCA in 2007 established "Risk Evaluation and Mitigation Strategies" ("REMS").[227] The FDA can require a REMS for "medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks."[228] Mifepristone's original REMS required women to visit a healthcare facility three times: (1) for administration of the first dose of mifepristone; (2) to determine if the termination was complete and, if not, for administration of misoprostol; and (3) to confirm termination of the pregnancy.[229]

In 2015, the sponsor proposed changes to mifepristone's labeling and REMS. Based on fifteen years of adverse event reports, the FDA determined "that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely."[230] The FDA approved changes to (1) modify dosing; (2) increase the gestational limit to seventy days' gestation; (3) allow nonphysician providers to become certified to prescribe mifepristone; and (4) remove the language requiring that misoprostol be taken in a healthcare facility.[231] The new regimen thus required one trip to a qualified facility to pick up the medication, which could then be self-administered elsewhere.[232] Effectively, providers could use telemedicine to evaluate patients and prescribe the drug, but patients still needed to obtain the medication in person from specific authorized sites (clinics, medical offices, or hospitals), thereby preventing use of standard retail or mail

227. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 901 (codified as amended at 21 U.S.C. § 355-1).

228. *Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last updated Dec. 17, 2021) [https://perma.cc/TFK6-JK7U]. The FDA can also require "elements to assure safe use" ("ETASU") if necessary to mitigate a specific serious risk. *See* 21 U.S.C. § 355-1(f)(1)(B), (f)(3).

229. U.S. GOV'T ACCOUNTABILITY OFF., FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 7 (2018); *see also NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg,* U.S. FOOD & DRUG ADMIN. (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf [https://perma.cc/JT6L-WFDE] (requiring patients to attest they will take Mifeprex in their provider's office on day one, then take misoprostol in their provider's office two days later, and then return to the provider's office on day fourteen).

230. Ctr. for Drug Evaluation & Rsch., *Application Number: 020687Orig1s020 Medical Review(s)*, U.S. FOOD & DRUG ADMIN. 8 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [https://perma.cc/6EPM-TYU7].

231. Ctr. for Drug Evaluation & Rsch., *Application Number: 020687Orig1s020 Summary Review*, U.S. FOOD & DRUG ADMIN. 24–26 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf [https://perma.cc/D6V3-G4SN]. The Form no longer required patients to attest they will take either Mifeprex or misoprostol in their provider's office. *See id.*

232. Joint Stipulations of Facts ¶ 29, Chelius v. Becerra, No. 17-cv-00493-JAO-RT (D. Haw. Apr. 15, 2021).

pharmacies. Safety concerns could not justify this restriction. It did not promote the safe or effective use of the drug, as it neither ensured patients took the drug immediately nor monitored them for adverse events.[233] Ultimately, it merely restricted access to an otherwise safe and effective medicine.

The FDA also retained a "Patient Agreement Form," even though the FDA's scientific reviewers concluded that it "does not add to safe use conditions . . . and is a burden for patients."[234] The involvement of senior FDA officials played a key role in the Form's retention. Dr. Woodcock, Director of CDER at the time, requested its retention after a request from then-Commissioner Dr. Robert Califf, who concluded that the Form "would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care."[235] The Commissioner's involvement "in the granular details of a REMS, even down to the inclusion of an agreement form, and for the head of CDER to openly acknowledge it, was a shocking break from the norm – and almost certainly represents the tip of the iceberg of political interference."[236] Such atypical senior official involvement is reminiscent of Plan B.

In 2017, the American Civil Liberties Union ("ACLU") challenged the REMS,[237] arguing that it harms patients by requiring a medically unnecessary trip, potentially delaying or even precluding an abortion.[238] During the COVID-19 pandemic, the American College of Obstetricians and Gynecologists ("ACOG") also challenged the REMS, arguing that it subjected patients to an unnecessary risk of contracting COVID-19 by requiring patients to travel to pick up the medication in

233. *See MIFEPREX Prescribing Information*, U.S. FOOD & DRUG. ADMIN. 2–3 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf [https://perma.cc/B5PM-MEZA]; *see also* F.D.A. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 580 (2021) (Sotomayor, J., dissenting) ("Women must still go to a clinic in person to pick up their mifepristone prescriptions, even though physicians may provide all counseling virtually, women may ingest the drug unsupervised at home, and any complications will occur long after the patient has left the clinic."); Am. Coll. of Obstetricians & Gynecologists v. F.D.A., 472 F. Supp. 3d 183, 221 (D. Md. 2020) (explaining that the "In-Person Dispensing Requirement" does not control when mifepristone is taken), *order clarified by* 2020 WL 8167535, at *1 (D. Md. Aug. 19, 2020); Janel Miller, *FDA Waives Mifepristone's In-Person Dispensing Requirements*, HEALIO (Apr. 13, 2021), https://www.healio.com/news/primary-care/20210413/fda-waives-mifepristones-inperson-dispensing-requirement [https://perma.cc/RBU9-V693] (explaining that modifying the in-person dispensing requirement for mifepristone did not increase safety concerns).

234. Ctr. for Drug Evaluation & Rsch., *supra* note 231, at 25.

235. Joint Stipulations of Facts, *supra* note 232, ¶¶ 38–41.

236. Christopherson & Snavely, *supra* note 137.

237. Complaint, Chelius v. Wright, No. 17-cv-00493-DKW (D. Haw. Oct. 3, 2017).

238. *Id.* ¶¶ 17–20.

person.[239] A district court enjoined enforcement of the in-person requirements,[240] but the Supreme Court granted the Trump Administration's request to stay the preliminary injunction, allowing the FDA to continue enforcement.[241]

After President Biden took office, the FDA stated it would "exercise enforcement discretion" during the COVID-19 public health emergency with respect to the in-person dispensing requirements.[242] Effectively, this allowed providers in states without laws that otherwise ban this practice to dispense the drug using telehealth protocols and through retail or mail pharmacies. Then, on December 16, 2021, in response to a review conducted for the ACLU litigation, the FDA announced it would permanently remove the in-person dispensing requirement, thereby allowing mifepristone to be sent via mail pharmacies.[243] The FDA did not, however, eliminate the Patient Agreement Form and maintained the requirement that providers be certified to prescribe the drug.[244] The Agency also *added* a requirement that pharmacies dispensing the drug be certified.[245] The shifting treatment of mifepristone under Democratic and Republican administrations strongly suggests that politics, not science, is a driving force behind the regulation of mifepristone.

The unique treatment of mifepristone compared to drugs of similar or inferior safety further implies the influence of politics. Mifepristone is safer than many medications not subject to similar restrictions, including Viagra and penicillin, and it is also safer than

239. Complaint ¶¶ 10–11, Am. Coll. of Obstetricians & Gynecologists v. F.D.A, No. 20-cv-01320-TDC (D. Md. May 27, 2020).

240. Am. Coll. of Obstetricians & Gynecologists v. F.D.A., 472 F. Supp. 3d 183, 233 (D. Md. 2020), *order clarified by* No. TDC-20-1320, 2020 WL 8167535, at *1 (D. Md. Aug. 19, 2020).

241. F.D.A. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (2021). Justices Breyer, Kagan, and Sotomayor would have denied the petition. *Id.* at 578–79 (Sotomayor, J., dissenting).

242. Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, to Maureen G. Phipps, Chief Exec. Off., Am. Coll. of Obstetricians & Gynecologists, & William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021), https://www.aclu.org/letter/fda-response-acog-april-2021 [https://perma.cc/4Y8L-D7H7].

243. *See Questions & Answers on Mifeprex*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex (last updated Dec. 16, 2021) [https://perma.cc/HDY9-CTNK]; Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021), https://www.aclu.org/sites/default/files/field_document/fda_letter_to_chelius.pdf [https://perma.cc/G86X-5XRA].

244. *See* U.S. FOOD & DRUG ADMIN., *supra* note 243.

245. *Id.*

carrying a pregnancy to term.[246] Of drugs with REMS requiring patients to obtain the medication in person, mifepristone was the only one that could then be taken outside the supervision of a healthcare provider.[247] Furthermore, mifepristone's other approved indication—treatment of high blood sugar in certain adults with Cushing's syndrome[248]—has not been subject to a REMS. It has always been available at retail pharmacies or through mail pharmacies, even though this indication provides for long-term daily use at a much higher dose than when used for pregnancy termination. The FDA has even acknowledged the lower rate of adverse events when mifepristone is used to terminate a pregnancy.[249]

The troubling and exceptional treatment of mifepristone and the restrictions' disproportionate effects on vulnerable populations became glaringly obvious during COVID-19. During the pandemic, the in-person dispensing requirement further limited abortion access because individuals feared exposure to the virus, and some healthcare facilities became mostly or entirely reliant on telehealth. As a result, the nearest facility authorized to dispense mifepristone could be prohibitively far for some patients.[250] At all times—pandemic and nonpandemic—these restrictions disproportionately impact historically marginalized and vulnerable populations, including low-income persons, people of color, persons with disabilities, the LGBTQ+ community, persons living in rural areas with limited access to clinics, and those with travel barriers such as reliance on public transportation or difficulty securing childcare.[251] COVID-19 exacerbated these effects.[252] Further

246. *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018*," ADVANCING NEW STANDARDS IN REPROD. HEALTH 2 (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf [https://perma.cc/4CAZ-TJ5N].

247. *See supra* note 230 and accompanying text (explaining that patients were not required to take mifepristone immediately).

248. *KORLYM® (mifepristone) 300 mg Tablets*, U.S. FOOD & DRUG ADMIN. 1 (Nov. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202107s008lbl.pdf [https://perma.cc/RUC7-B4NB].

249. Ctr. for Drug Evaluation & Rsch., *supra* note 230, at 10.

250. If patients could not obtain mifepristone prior to the ten-week threshold, surgical abortions were not available in some states that suspended surgical abortions during COVID-19, defining it as a nonessential or elective procedure. *See* Laurie Sobel, Amrutha Ramaswamy, Brittni Frederiksen & Alina Salganicoff, *State Action to Limit Abortion Access During the COVID-19 Pandemic*, KAISER FAM. FOUND. (Aug. 10, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/state-action-to-limit-abortion-access-during-the-covid-19-pandemic/ [https://perma.cc/WKN9-82EQ].

251 *See Induced Abortion in the United States*, GUTTMACHER INST. (2019), https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf [https://perma.cc/FQA8-UXDN].

252. Am. Coll. of Obstetricians & Gynecologists v. F.D.A., 472 F. Supp. 3d 183, 196–97 (D. Md. 2020), *order clarified by* No. TDC-20-1320, 2020 WL 8167535, at *1 (D. Md. Aug. 19, 2020).

compounding the problem, the risks of COVID-19 were amplified in many of these populations.[253]

During the pandemic, HHS and the FDA waived certain in-person requirements for other drugs, including powerful opioids, and the CDC "advised medical providers to use telemedicine 'whenever possible' because it is 'the best way to protect patients and staff from COVID-19.' "[254] Despite recognizing the risks associated with in-person healthcare during the pandemic, the Trump Administration "refused to extend that same grace to women seeking medication abortions."[255]

The fluctuating treatment of mifepristone depending on the President in charge—together with the FDA's regulation and oversight of mifepristone compared to drugs with similar, or even inferior, safety profiles—illustrates the illogicality of the FDA's exceptional treatment of mifepristone and strongly suggests that implicit or explicit executive interference grounded in politics and ideology rather than science played a role in the FDA's decisions about mifepristone. Regardless of whether the interference pushed for or against access to mifepristone, it improperly politicized the FDA's scientific decisionmaking processes about a safe and effective drug. Political interference from either side muddles an already controversial issue, harms public trust in the FDA, and calls into question whether FDA decisions are grounded in science or in politics and ideology despite the Agency's frequent pronouncements that it follows the science.[256] When the executive "has the power to undermine scientific integrity to suit its ideological agenda, then agencies arguably become[ ] nothing more than political arms of an administration, incapable of carrying out their missions and purposes."[257] Unlike other forms of essential healthcare, reproductive healthcare remains subject to the swinging pendulum of executive politics. This harms, rather than protects and promotes, public health. Further, it violates foundational principles of administrative law and

253. *Id.* at 196.

254. F.D.A. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 580 (2021) (Sotomayor, J., dissenting).

255. *Id.*

256. *Cf.* Marie Solis, *The FDA is Restricting Access to the Easiest, Safest Form of Abortion*, VICE (Sept. 4, 2019, 5:00 AM), https://www.vice.com/en/article/vb5vzd/fda-abortion-pill-regulations-controversy [https://perma.cc/YWQ3-B52W] ("People begin to question the legitimacy of the FDA as a scientifically based entity when there's so much public outcry urging the FDA to do its job appropriately . . . . " (quoting Andrea Miller, President, Nat'l Inst. for Reprod. Health)). As noted by Professor Wagner, these claims may be inadvertent and well-meaning, or they may be a deliberate attempt to overemphasize the role of science and downplay the role of politics in agency decisionmaking. *See* Wagner, *The Science Charade*, *supra* note 91, at 1714.

257. Sherwin, *supra* note 28, at 70.

the rule of law: that like cases be treated alike[258] and that the law should be predictable and nonarbitrary.[259]

B. COVID-19

Governmental action and inaction during the COVID-19 pandemic highlight the difficulty of drawing lines between positive and negative executive involvement in agency scientific decisionmaking. During a public health emergency, executive involvement can help facilitate a coordinated and efficient government response.[260] But when taken too far, or when claims of science are used to shield difficult policy decisions, lasting harms to public health and agency credibility transpire.

One area where the Trump Administration arguably could have been more involved was early decisions about diagnostic tests. Early virus containment required a sufficient number of effective tests to detect, notify, and quarantine infected individuals. Initially, the CDC used its own test, turning away commercial and academic laboratories that offered to quickly develop and distribute tests.[261] Troublingly, evidence soon indicated that the CDC's tests were contaminated and did not work.[262] HHS Secretary Alex Azar faulted the FDA, saying "he never knew about their decision not to allow outside labs to create their own tests," while "the FDA blamed Azar and said they sought permission to work with external labs but were turned down, in order to stay consistent with the White House's efforts to play down the virus."[263] The Trump Administration, likely driven by the political motive to downplay the virus,[264] failed to intervene to help coordinate a

258. Westar Energy, Inc. v. F.E.R.C., 473 F.3d 1239, 1241 (D.C. Cir. 2007).

259. *See, e.g.*, Richard H. Fallon, *"The Rule of Law" as a Concept in Constitutional Discourse*, 97 COLUM. L. REV. 1, 7–8 (1997) (explaining that the rule of law should make legal consequences known upfront); Robert Stein, *Rule of Law: What Does It Mean?*, 18 MINN. J. INT'L L. 293, 296–303 (2009) (discussing the meaning of the rule of law).

260. "Executive underreach" can be just as problematic as "executive overreach," particularly during emergencies. *See* David E. Pozen & Kim Lane Scheppele, *Executive Underreach, in Pandemics and Otherwise*, 114 AM. J. INT'L L. 608, 613 (2020) (describing examples of President Trump's executive underreach during COVID-19).

261. ANDY SLAVITT, PREVENTABLE: THE INSIDE STORY OF HOW LEADERSHIP FAILURES, POLITICS, AND SELFISHNESS DOOMED THE CORONAVIRUS RESPONSE 78–79 (2021).

262. *Id.*

263. *Id.* at 79–80.

264. As observed by Andy Slavitt:

> The president would announce the new opening strategy and from there leave it to the states to implement. It seemed to be a clever political strategy, because it would help Trump avoid taking continued blame from blue-state governors and begin to shift the blame to them. If there was a high death toll or if there was insufficient testing, it wouldn't be on the Trump administration.

response utilizing multiple tests. Here, the Administration could have stepped in as an "overseer," guiding the agencies' development of a unified and efficient approach to testing and directing them to consider tests from external labs. The FDA, however, would have remained the "decider" about which specific tests met the criteria for authorization.

Much of the executive interference during the COVID-19 pandemic did not benefit public health, nor did it enhance agency accountability, credibility, or public trust. The interference did not always succeed, but the public displays of overt interference and insider reports of covert interference nevertheless affected agency credibility and public trust at a critical time. And successful interference and the prioritization of President Trump's political interests over public health resulted in significant harms and even death, "threaten[ing] to leave the country with an unabated tragedy."[265]

Examples abound of executive interference in agency science during the COVID-19 pandemic. A July 2021 report from the House Select Subcommittee on the Coronavirus Crisis,[266] for example, detailed eighty-eight separate instances of the Trump Administration's interference in the nation's pandemic response.[267] This Section unpacks examples of executive interference in FDA scientific decisionmaking

Id. at 115.

265. Letter from Elizabeth Warren, U.S. Sen., Richard Blumenthal, U.S. Sen., & Edward J. Markey, U.S. Sen., to the Hon. Michael E. Horowitz, Acting Chair, Council of the Inspectors Gen. on Integrity & Efficiency 3–5 (Aug. 25, 2020) https://www.warren.senate.gov/imo/media/doc/2020.08.25%20Letter%20to%20PRAC%20re%20politicization%20of%20COVID%20response.pdf [https://perma.cc/UHE8-8FAH]; *see also supra* note 6 and accompanying text; SLAVITT, *supra* note 261, at 199.

266. The House established this Subcommittee to provide congressional oversight of the Trump Administration's response to COVID-19. *About*, SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS, https://coronavirus.house.gov/about (last visited Sept. 22, 2022) [https://perma.cc/W7FP-NPH8].

267. *The Trump Administration's Pattern of Political Interference in the Nation's Coronavirus Response*, SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (July 26, 2021), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/7.26.2021%20Timeline%20of%20Political%20Interference%20-%20final.pdf [https://perma.cc/KK66-BP4D]; *see also A "Knife Fight" with the FDA*, *supra* note 2 (reporting the pressure exerted by the Trump Administration on the FDA during the pandemic). There are also examples from other contexts where the Trump Administration made decisions not squarely motivated to protect public health but rather to advance other policy goals such as curbing immigration and dismantling asylum protections. *See, e.g.*, Goitein, *supra* note 17; Michael D. Shear & Zolan Kanno-Youngs, *Trump Administration Plans to Extend Virus Border Restrictions Indefinitely*, N.Y. TIMES (May 13, 2020), https://www.nytimes.com/2020/05/13/us/politics/trump-coronavirus-border-restrictions.html [https://perma.cc/U74R-U9NG]; Ed Yong, *How the Pandemic Defeated America*, ATLANTIC (Aug. 4, 2020), https://www.theatlantic.com/magazine/archive/2020/09/coronavirus-american-failure/614191/ [https://perma.cc/U72V-9LAX]. Information from the Subcommittee's activities can be found at: *Subcommittee Activity,* SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS, https://coronavirus.house.gov/subcommittee-activity (last visited Sept. 22, 2022) [https://perma.cc/6H6Z-2PQN].

during COVID-19. As the country emerges from the pandemic, whether the Agency will regain lost trust and its long-standing reputation of making impartial, credible decisions remains unclear. Much will depend on decisions made going forward.

1. Hydroxychloroquine and Chloroquine

Executive interference and pressure on the FDA started early in the pandemic, as the search commenced for potential treatments. This became very apparent as President Trump began touting hydroxychloroquine, a drug approved by the FDA for various indications but not COVID-19.[268]

On March 19, 2020, President Trump stated that hydroxychloroquine has "been around for a long time, so we know that . . . it's not going to kill anybody."[269] He claimed that clinical trials were producing "very, very encouraging early results," and promised to make the drugs "available almost immediately."[270] When Dr. Anthony Fauci, Director of the National Institutes of Allergy and Infectious Diseases ("NIAID") at the National Institutes of Health ("NIH"), stated that hydroxychloroquine was *not* effective against COVID-19 and that evidence was anecdotal, President Trump interjected, saying he was "a big fan" of the drug, so "we'll see what happens."[271]

Then, on March 21, 2020, President Trump tweeted that hydroxychloroquine could be "one of the biggest game changers in the history of medicine."[272] He pressured the FDA and others, tweeting that hydroxychloroquine should "be put in use IMMEDIATELY. PEOPLE ARE DYING, MOVE FAST[.]"[273] On March 23, 2020, Dr. Rick Bright,

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268. *See PLAQUENIL Prescribing Information*, U.S. FOOD & DRUG ADMIN. 2 (May 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/009768s053lbl.pdf [https://perma.cc/Y7SZ-ZSAA] (listing the medical conditions for which hydroxychloroquine has been approved to treat, which do not include COVID-19).

269. Libby Cathey, *Timeline: Tracking Trump Alongside Scientific Developments on Hydroxychloroquine*, ABC NEWS (Aug. 8, 2020, 7:12 AM), https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553 [https://perma.cc/9M8G-VRPJ].

270. *Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and Human Services Submitted by Dr. Rick Bright*, U.S. OFF. OF SPECIAL COUNS. 41 (2020), https://s3.documentcloud.org/documents/6882560/Rick-Bright-Whistleblower-Complaint.pdf [https://perma.cc/E7JN-FQRD] [hereinafter *Bright Complaint*].

271. Cathey, *supra* note 269.

272. Donald Trump (@realDonaldTrump), TWITTER (Mar. 21, 2020, 10:13:08 AM), *archived*, Brendan Brown, TRUMP TWITTER ARCHIVE V2, https://www.thetrumparchive.com/ [https://perma.cc/5Y9F-9BRA]; Cathey, *supra* note 269. Because President Trump's Twitter account was suspended, all tweets are available at https://www.thetrumparchive.com/ and on file with the author.

273. Donald Trump (@realDonaldTrump), TWITTER (Mar. 21, 2020, 10:13:09 AM), *archived*, Brown, *supra* note 272.

then-Director of the Biomedical Advanced Research and Development Authority ("BARDA") and HHS Deputy Assistant Secretary for Preparedness and Response, "received an urgent directive from HHS General Counsel Bob Charrow, passed down from the White House, to drop everything and make [chloroquine] widely available to the American public."[274]

Initially, the government planned to establish a national Expanded Access Investigational New Drug ("IND") protocol for chloroquine that would use software created by Oracle, a company co-founded by Larry Ellison, a prominent Trump donor.[275] Media reports indicate that Ellison helped convince President Trump the drugs were effective.[276] Further, FDA Chief Counsel Stacy Amin urged HHS and the FDA to move forward with the protocol to coincide with President Trump's forthcoming announcement of the Oracle partnership.[277] President Trump undoubtedly wanted a political win with the American public and a prominent donor.

FDA officials expressed concerns about a nationwide Expanded Access IND, which would provide broader but less controlled access compared to an emergency use authorization ("EUA").[278] Amidst questionable evidence and criticism,[279] the EUA approach prevailed. The FDA issued the EUA on March 28, 2020, for the use of hydroxychloroquine and chloroquine for the treatment of hospitalized

274. *Bright Complaint*, *supra* note 270, at 41.

275. *Id.* at 40–41; *see also* Helen Coster, *Factbox: Oracle Chairman Larry Ellison's History of Support for Trump*, REUTERS (Sept. 14, 2020, 11:21 AM), https://www.reuters.com/article/us-china-bytedance-tiktok-oracle-factbox/factbox-oracle-chairman-larry-ellisons-history-of-support-for-trump-idUSKBN2652RV [https://perma.cc/HR9P-2RNX] (outlining past support of President Trump by Oracle and Oracle chairman Larry Ellison).

276. *See Bright Complaint*, *supra* note 270, at 41–42, 41 n.28; Yasmeen Abutaleb, Laurie McGinley & Josh Dawsey, *Oracle to Partner with Trump Administration to Collect Data on Unproven Drugs to Treat COVID-19*, WASH. POST (Mar. 24, 2020, 7:49 PM), https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5_story.html [https://perma.cc/5MP5-WDX2]; Peter Baker, Katie Rogers, David Enrich & Maggie Haberman, *Trump's Aggressive Advocacy of Malaria Drug for Treating Coronavirus Divides Medical Community*, N.Y. TIMES (Apr. 6, 2020), https://www.nytimes.com/2020/04/06/us/politics/coronavirus-trump-malaria-drug.html [https://perma.cc/YJQ6-EVNF]; Joseph Tsidulko, *Oracle's Larry Ellison Promoted Antimalarial Drug to Trump: Report*, CRN (Apr. 7, 2020, 6:32 PM), https://www.crn.com/news/cloud/oracle-s-larry-ellison-promoted-antimalarial-drug-to-trump-report [https://perma.cc/Q3Q2-BHUP].

277. *Bright Complaint*, *supra* note 270, at 42–43.

278. *Id.* at 41, 43.

279. *See, e.g.*, Charles Piller, *Former FDA Leaders Decry Emergency Authorization of Malaria Drugs for Coronavirus*, SCI. (Apr. 7, 2020), https://www.science.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus [https://perma.cc/78SN-6Q5Z].

adult and adolescent COVID-19 patients who could not participate in a clinical trial.[280]

Mounting evidence suggested that the drugs were not effective and potentially dangerous.[281] This did not convince President Trump, however, who exaggerated the drug's safety and efficacy and promoted the drugs for unauthorized purposes, such as outpatient use and prevention of COVID-19.[282] For example, he claimed that "thousands and thousands of frontline workers" used hydroxychloroquine to prevent COVID-19.[283] President Trump insisted that people questioned the "unbelievable" drug for political reasons[284] and even suggested that Democrats preferred that people remain ill "because they think I'm

280. Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Dr. Rick Bright, Dir. of Biomedical Advanced Rsch. & Dev. Auth., Off. of Assistant Sec'y for Preparedness & Response, U.S. Dep't of Health & Hum. Servs. (Mar. 28, 2020), https://www.fda.gov/media/136534/download [https://perma.cc/Y6CF-Q8CG].

281. *See FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or Clinical Trial Due to Risk of Heart Rhythm Problems*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2020), https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or [https://perma.cc/Q5DS-QRH6]; Dan M. Roden, Robert A. Harrington, Athena Poppas & Andrea M. Russo, *Considerations for Drug Interactions on QTc in Exploratory COVID-19 Treatment*, 141 CIRCULATION e906 (2020) (warning against combination hydroxychloroquine and azithromycin due to a dearth of studies of effects of combination on arrythmia risk and potential for both to provoke proarrhythmia); Eli S. Rosenberg et al., *Association of Treatment with Hydroxychloroquine or Azithromycin with In-Hospital Mortality in Patients with COVID-19 in New York State*, 323 JAMA 2493 (2020) (finding that treating patients hospitalized with COVID-19 with hydroxychloroquine and azithromycin did not have a significant effect on in-hospital mortality); Mayla Gabriela Silva Borba et al., *Effect of High vs Low Doses of Chloroquine Diphosphate as Adjunctive Therapy for Patients Hospitalized with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection*, JAMA NETWORK OPEN, April 2020, at 1, 11 (recommending against higher doses of hydroxychloroquine to treat severe COVID-19 due to heart irregularities and increased lethality).

282. *See Bright Complaint*, *supra* note 270, at 44.

283. *Remarks by President Trump in Cabinet Meeting*, THE WHITE HOUSE (May 19, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-cabinet-meeting-17 [https://perma.cc/5S48-RBKG] [hereinafter *Remarks by President Trump May 19*]; *see also Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing*, THE WHITE HOUSE (Apr. 5, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-19/ [https://perma.cc/ECK2-GUA8] (providing remarks of President Trump during which he claimed that countries using hydroxychloroquine to treat malaria had "very little" COVID-19 and stated that he might take it for prevention); Jane C. Timm, *Trump Says He's Taking Hydroxychloroquine to Prevent COVID-19*, NBC NEWS, https://www.nbcnews.com/politics/donald-trump/trump-says-he-s-taking-hydroxychloroquine-prevent-covid-19-despite-n1209706 (last updated May 18, 2020, 8:14 PM) [https://perma.cc/4F5Q-MTRF].

284. *Remarks by President Trump in a Meeting with U.S. Tech Workers and Signing of an Executive Order on Hiring American*, THE WHITE HOUSE (Aug. 3, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-meeting-u-s-tech-workers-signing-executive-order-hiring-american/ [https://perma.cc/F72Y-HY3L] [hereinafter *Remarks by President Trump August 3*]; *see also Remarks by President Trump May 19*, *supra* note 283 ("It's gotten a bad reputation only because I'm promoting it. . . . If anybody else were promoting it, they'd say, 'This is the greatest thing ever.' ").

going to get credit if . . . hydroxychloroquine works."[285] He said a study raising safety concerns was "false," "phony," and "obviously" not performed by "friends of the administration."[286]

The FDA revoked the EUA on June 15, 2020, after concluding that the drugs were unlikely to be effective against COVID-19 and that in light of ongoing reports of serious cardiac adverse events and other safety concerns, it was "no longer reasonable to believe that the known and potential benefits" of the drugs "outweigh[ed] the known and potential risks associated with" using the drugs as a COVID-19 treatment.[287] The revocation itself is not troubling. On the contrary, it would have been more problematic if the FDA had not revoked the EUA given the evidence. Indeed, the law requires the FDA to "periodically review" an EUA and revise or revoke it if, for example, evidence suggests the potential benefits do not outweigh the risks.[288] The true problem was the FDA's initial authorization based on questionable evidence amidst intense pressure from the Trump Administration, which raised significant questions about the credibility of the Agency's decision.[289]

Unsurprisingly, President Trump continued to promote the drugs. Over the course of two days in late June 2020, he tweeted more than a dozen times to tout the drugs' benefits; suggest that Democrats politicized the drugs; and claim that Dr. Fauci, the media, the "left wing," and others "suppressed" evidence.[290] President Trump also pressured the FDA to reissue the EUA or otherwise make hydroxychloroquine available, tweeting: "The highly respected Henry

285. *Remarks by President Trump in a Fox News Virtual Town Hall*, THE WHITE HOUSE (May 4, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-fox-news-virtual-town-hall/ [https://perma.cc/8REA-PDDG].

286. *Remarks by President Trump May 19*, *supra* note 283.

287. Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Deputy Assistant Sec'y, Dir. of Med. Countermeasure Programs, Biomedical Advanced Rsch. & Dev. Auth., Off. of Assistant Sec'y for Preparedness & Response, U.S. Dep't of Health & Hum. Servs. 11–12 (June 15, 2020), https://www.fda.gov/media/138945/download [https://perma.cc/M5RF-Z2UJ].

288. 21 U.S.C. § 360bbb-3(c)(2), (g).

289. Indeed, even if the Trump Administration's pressure did not actually affect the FDA's initial decision to authorize the drugs, it certainly appeared to do so. The mere appearance of an agency being influenced by political pressures can damage public trust and confidence in agency decisionmaking just as much as actual influence.

290. *See* Donald Trump (@RealDonaldTrump), TWITTER (Jul. 26–27, 2020), *archived*, Brown, *supra* note 272; *see also Remarks by President Trump in Press Briefing*, THE WHITE HOUSE (July 28, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-july-28-2020/ [https://perma.cc/Y7W6-PRHS] [hereinafter *Trump Press Briefing July 28*] (mentioning he had taken hydroxychloroquine); *Remarks by President Trump, August 3*, *supra* note 284 (same).

Ford Health System just reported, based on a large sampling, that HYDROXYCHLOROQUINE cut the death rate in certain sick patients very significantly. The Dems disparaged it for political reasons (me!). Disgraceful. Act now @US_FDA."[291] Despite these pressures, the FDA did not reissue the EUA. Nevertheless, the disconnect between the President and federal agencies leading the COVID-19 response sent a problematic message to the public during a time demanding a unified approach that the public could trust.

Promotion of an unproven and potentially unsafe drug by a person in a position of power like the President risks serious and even fatal consequences, particularly when the public craves answers amidst a raging pandemic.[292] In March 2020, for example, a woman was hospitalized and her husband died after trying to prevent COVID-19 by ingesting a nonpharmaceutical version of chloroquine, which the couple used after hearing President Trump talk about chloroquine's potential benefits.[293] President Trump's statements "resonated" with the woman because she used it to treat her koi fish and she thought, "[h]ey, isn't that the stuff they're talking about on TV?"[294] Another dangerous consequence arose when use of hydroxychloroquine and chloroquine for COVID-19 caused shortages for patients using the drugs for approved indications, such as lupus and rheumatoid arthritis.[295] Of course, it is impossible to know the true number of lives that may have been lost to COVID-19 due to the politicization of COVID-19 treatments, which has led some to opt for "anti-establishment alternative[s] to treatments"

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291. Donald Trump (@realDonaldTrump), TWITTER (Jul. 6, 2020, 10:32:35 PM), *archived*, Brown, *supra* note 272; *cf. also A "Knife Fight" with the FDA*, *supra* note 2, at 1, 12–13 (reporting testimony of then-FDA Commissioner Dr. Hahn about how Peter Navarro, White House Office of Trade and Manufacturing Policy Director, exerted inappropriate pressure on him to reissue the hydroxychloroquine EUA).

292. *Cf.* Kacper Niburski & Oskar Niburski, *Impact of Trump's Promotion of Unproven COVID-19 Treatments and Subsequent Internet Trends: Observational Study*, 22 J. MED. INTERNET RSCH. e20044 (2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685699/ [https://perma.cc/3CEN-KRQZ] (finding that powerful people can influence public purchases, including controversial items).

293. Erika Edwards & Vaughn Hillyard, *Man Dies After Taking Chloroquine in an Attempt to Prevent Coronavirus*, NBC NEWS (last updated Mar. 23, 2020, 4:53 PM), https://www.nbcnews.com/health/health-news/man-dies-after-ingesting-chloroquine-attempt-prevent-coronavirus-n1167166 [https://perma.cc/AH28-6B9H].

294. *Id.*

295. *See* Elizabeth Cohen & Marshall Cohen, *After Trump's Statements About Hydroxychloroquine, Lupus and Arthritis Patients Face Drug Shortage*, CNN, https://www.cnn.com/2020/04/07/health/hydroxychloroquine-shortage-lupus-arthritis/index.html (last updated Apr. 7, 2020, 5:05 PM) [https://perma.cc/L69U-2C9U]; *FDA Recognizes Hydroxychloroquine and Chloroquine Shortages*, LUPUS FOUND. OF AM. (Mar. 31, 2020), https://www.lupus.org/news/fda-recognizes-hydroxychloroquine-and-chloroquine-shortages [https://perma.cc/FDV2-ZEP8].

that do not treat or prevent serious illness or death and may be dangerous.[296]

Amidst the hydroxychloroquine controversy, the Trump Administration removed Dr. Bright from his positions as Director of BARDA and HHS Deputy Assistant for Preparedness and Response and transferred him to a more limited role at NIH.[297] Dr. Bright filed a whistleblower complaint, alleging government wrongdoing and claiming retaliation for raising his concerns about the government's COVID-19 response and for urging against the government's investment in "drugs, vaccines[,] and other technologies that lack scientific merit."[298] He specifically mentioned his opposition to a broad use for hydroxychloroquine and chloroquine, which he believed lacked scientific merit "even though the Administration promoted it as a panacea."[299] He acknowledged signing the EUA request but stated that he did so only because he was "directed to" and noted that the request "was not at his or BARDA's behest."[300] Dr. Bright detailed numerous instances of executive interference, including pressure to make decisions that would benefit prominent Trump donors and the promotion of hydroxychloroquine and chloroquine for unauthorized purposes.[301] Unsurprisingly, President Trump lambasted Dr. Bright, calling him a "fake" whistleblower, a "creep," and an unliked, not respected "disgruntled employee" who "should no longer be working for our government!"[302]

The executive interference in the first therapeutic EUA for COVID-19 and the controversy surrounding that EUA set a worrisome

296. Philip Bump, *Ivermectin is the Signature Example of Politics Trumping Health*, WASH. POST (Mar. 31, 2022, 10:58 AM), https://www.washingtonpost.com/politics/2022/03/31/ivermectin-is-signature-example-politics-trumping-health/ [https://perma.cc/8KKM-VW4M]. These "anti-establishment treatments" include hydroxychloroquine and ivermectin.

297. *Read: Statement from Leader of Federal Vaccine Agency About His Reassignment*, CNN, https://www.cnn.com/2020/04/22/politics/read-whistleblower-vaccine-development/index.html (last updated Apr. 22, 2020, 4:52 PM) [https://perma.cc/MM79-MDR6] [hereinafter *Bright Reassignment Statement*]; *see also Bright Complaint*, *supra* note 270, at 2–3.

298. *Bright Reassignment Statement*, *supra* note 297; *see also Bright Complaint*, *supra* note 270, at 49.

299. *Bright Complaint*, *supra* note 270, at 2.

300. *Id.* at 43–44.

301. *See id.* at 41.

302. Nicholas Florko, *Trump Administration Fires Back at Ousted Vaccine Expert as He Testifies on His Role in U.S. Coronavirus Response*, STAT (May 14, 2020), https://www.statnews.com/2020/05/14/trump-fires-back-rick-bright/ [https://perma.cc/4FHA-C55H]; Donald Trump (@realDonaldTrump), TWITTER (May 17, 2020, 10:15:08 PM), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (May 17, 2020, 10:15:09 PM), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (May 17, 2020, 10:15:09 PM), *archived*, Brown, *supra* note 272.

tone early in the pandemic, raising significant concern about the credibility of the FDA's subsequent decisions and fostering an "anti-expert instinct" that continued throughout the pandemic.[303] The potential for long-term reputational harm remains possible.[304]

2. Convalescent Plasma

Early in the pandemic, convalescent plasma was thought to be a potentially lifesaving COVID-19 treatment. The idea, however, "took on a life of its own before there was evidence that it worked," and the Trump Administration "seized on plasma as a good-news story" during a time of widespread fear.[305] Notwithstanding the fallout from the hydroxychloroquine controversy, the Trump Administration continued to interfere in agency science, exerting both overt and covert pressure on the FDA to make the treatment widely available.

Amidst spotty evidence and scientific disagreement, the FDA authorized convalescent plasma for emergency use on August 23, 2020, with President Trump calling it a "historic breakthrough."[306] The EUA's timing surprised many, coming less than one week after being put on hold when government officials—including Dr. Fauci and Dr. Francis Collins, Director of the NIH—intervened, asserting the data were too weak to support an EUA.[307] President Trump called the hold a "political

303. Bump, *supra* note 296.

304. *Cf.* Beth Snyder Bulik, *FDA Faces a Reputation Crisis Amid Trump Pressure for Fast COVID Action—and That's Bad News for Pharma*, FIERCE PHARMA (Aug. 24, 2020, 2:43 PM), https://www.fiercepharma.com/marketing/fda-reputation-line-trump-deep-state-charge-and-ensuing-eua-for-covid-plasma-therapy [https://perma.cc/HC3C-8KCK] (describing criticism of the FDA and the risk to its reputation after repeatedly complying with Trump's controversial COVID solutions); Giuliana Viglione, *Four Ways Trump Has Meddled in Pandemic Science – and Why It Matters*, NATURE (Nov. 3, 2020), https://www.nature.com/articles/d41586-020-03035-4 [https://perma.cc/P4PV-Q8LT] (describing concerns regarding Trump's interference with the federal pandemic response and resulting damage to the reputation of federal scientific agencies); *Lessons Learned – or Not – from Hydroxychloroquine Mishap*, RELIAS MEDIA (Oct. 1, 2020), https://www.reliasmedia.com/articles/146932-lessons-learned-or-not-from-hydroxychloroquine-mishap [https://perma.cc/2D2V-NPW5] (discussing the damage to the FDA's reputation caused by perceptions of political influence on the agency).

305. Katie Thomas & Noah Weiland, *The COVID-19 Plasma Boom Is Over. What Did We Learn From It?*, N.Y. TIMES (Apr. 17, 2021), https://www.nytimes.com/2021/04/17/health/covid-convalescent-plasma.html [https://perma.cc/D2YP-XBL6].

306. *Remarks by President Trump in Press Briefing*, THE WHITE HOUSE (Aug. 23, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/ [https://perma.cc/SHT5-Q22U].

307. Noah Weiland, Sharon LaFraniere & Sheri Fink, *F.D.A.'s Emergency Approval of Blood Plasma Is Now on Hold*, N.Y. TIMES, https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html (last updated Jan. 6, 2021) [https://perma.cc/PTU2-FB7D]; Letter from Elizabeth Warren, U.S. Sen., & Edward J. Markey, U.S. Sen., to Stephen M. Hahn, Comm'r of Food & Drugs, U.S. Food & Drug Admin. (Aug. 25, 2020), https://www.warren.senate.gov/imo/media/doc/2020.08.25%20Letter%20to%20FDA%20re%20Blood%20Plasma%20EUA.pdf [https://perma.cc/4RTZ-3JUS] [hereinafter Warren & Markey Letter].

decision," claiming "people over there" (i.e., the FDA) "want to do it after [election day]."[308] Similar to the hydroxychloroquine and chloroquine EUAs, the appearance of executive interference marred the FDA's decision, regardless of whether it was actually influenced by, or a result of, the Trump Administration's pressure.

President Trump reportedly called Dr. Collins on August 19, telling him to "[g]et [the EUA] done by Friday."[309] Around this time, Peter Navarro, President Trump's trade advisor, accused the FDA of being part of the "[d]eep [s]tate," a sentiment echoed by President Trump, who claimed the "deep state" at the FDA delayed development of COVID-19 treatments and vaccines.[310] The FDA issued the plasma EUA one day before the Republican National Convention, raising questions about the Trump Administration's role in the decision.[311]

Statements by President Trump and other Administration officials strongly imply that political pressure influenced, or attempted to influence, the FDA's decision. President Trump explicitly took credit for the EUA, suggesting he pressured the FDA to get the Agency to act "very quickly."[312] Shortly before the FDA issued the EUA, Mark Meadows, White House Chief of Staff, hinted at a forthcoming announcement, which he said resulted from President Trump "mak[ing]

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308. Noah Higgins-Dunn & Christina Farr, *Trump Says FDA Hold on Blood Treatment Therapy Use for Coronavirus Patients 'Could Be a Political Decision*,' CNBC, https://www.cnbc.com/2020/08/19/trump-says-fda-hold-on-blood-treatment-therapy-use-for-coronavirus-patients-could-be-a-political-decision.html (last updated Aug. 20, 2020, 8:52 AM) [https://perma.cc/SGC6-WXCX]; *see also* Nicholas Florko, *FDA, Under Pressure from Trump, Authorizes Blood Plasma as COVID-19 Treatment*, STAT (Aug. 23, 2020), https://www.statnews.com/2020/08/23/fda-under-pressure-from-trump-expected-to-authorize-blood-plasma-as-covid-19-treatment/ [https://perma.cc/YTW6-YHJL].

309. Sharon LaFraniere, Noah Weiland & Michael D. Shear, *Trump Pressed for Plasma Therapy. Officials Worry, Is an Unvetted Vaccine Next?*, N.Y. TIMES (Sept. 12, 2020), https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html [https://perma.cc/6HDU-9PCK].

310. Jonathan Swan, *Scoop: The Trump-Navarro Mind Meld on the FDA*, AXIOS (Aug. 23, 2020), https://www.axios.com/trump-peter-navarro-fda-deep-state-12563e41-de4a-4635-9319-ff0eca41f126.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top [https://perma.cc/P8DS-FC4G]; Donald Trump (@realDonaldTrump), TWITTER (Aug. 22, 2020, 7:49 AM) ("The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives! @SteveFDA"), *archived*, Brown, *supra* note 272.

311. Press Release, Nat'l Med. Ass'n, NMA Forms COVID-19 Task Force Take the Politics out of Vaccine Development (Sept. 21, 2020), https://www.nmanet.org/news/527978/NMA-Forms-COVID-19-Task-Force-Take-the-Politics-Out-of-Vaccine-Development.htm [https://perma.cc/8V3G-PVPF].

312. *Donald Trump Remarks at North Carolina Airport Transcript August 24*, REV (Aug. 24, 2020), https://www.rev.com/blog/transcripts/donald-trump-remarks-at-north-carolina-airport-transcript-august-24 [https://perma.cc/49B2-U4M3].

sure that [the FDA] felt the heat."[313] Similarly, Navarro told reporters that "[w]e have been fighting for weeks now, weeks, to get that decision."[314]

During the EUA announcement, FDA Commissioner Dr. Stephen Hahn misstated and exaggerated plasma's potential benefits.[315] He later clarified his statements and denied any political influence.[316] Nevertheless, the initial errors and exaggerations raised concerns about executive interference and reflected the danger of caving to executive pressure and acting too quickly.[317]

After the authorization, scientists and public health officials continued to question plasma's effectiveness and expressed concerns that political pressure caused the FDA to issue the EUA too quickly. Public health organizations, agencies, and experts cited "very low-quality evidence"[318] and "insufficient evidence . . . to recommend either for or against" the treatment in certain populations.[319] Dr. Paul Offit, an expert in virology and immunology and a member of the FDA's vaccine advisory committee, believed the President "bullied" the FDA "into approving something that they didn't want to approve earlier."[320] Unlike the hydroxychloroquine and chloroquine EUA, the plasma EUA remains in place as of this writing, with amendments to narrow its scope based on additional data.[321] Nevertheless, the controversy and evidence of political influence further damaged the FDA's credibility.

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313. *'This Week' Transcript 8-23-20: Mark Meadows, Kate Bedingfield*, ABC NEWS (Aug. 23, 2020, 8:45 AM), https://abcnews.go.com/Politics/week-transcript-23-20-mark-meadows-kate-bedingfield/story?id=72551139 [https://perma.cc/Q6FA-5VQA].

314. Anne Flaherty, *Convalescent Plasma Went from Promising to Politically Tainted: 3 Things to Know*, ABC NEWS (Aug. 25, 2020, 2:57 PM), https://abcnews.go.com/Politics/convalescent-plasma-promising-politically-tainted-things/story?id=72599272 [https://perma.cc/W5WQ-V5G7].

315. *Id.*; *see also* SLAVITT, *supra* note 261, at 201 ("Hahn grossly exaggerated the success of the treatment.").

316. Flaherty, *supra* note 314; *see also* SLAVITT, *supra* note 261, at 201–02 (describing the White House's actions pressuring the FDA to approve convalescent plasma).

317. *See* Flaherty, *supra* note 314.

318. Berkeley Lovelace Jr., *Scientists Doubt Convalescent Plasma Touted by Trump Is a 'Breakthrough' Coronavirus Treatment*, CNBC (Aug. 24, 2020, 12:00 PM) (quoting Soumya Swaminathan, Chief Scientist, World Health Org.), https://www.cnbc.com/2020/08/24/scientists-doubt-convalescent-plasma-touted-by-trump-is-a-breakthrough-coronavirus-treatment.html [https://perma.cc/6K4S-BNV3].

319. *COVID-19 Convalescent Plasma*, NAT'L INST. HEALTH 250, 250, https://files.covid19treatmentguidelines.nih.gov/guidelines/section/section_68.pdf (last updated Apr. 29, 2022) [https://perma.cc/5JJC-8ZKG].

320. Flaherty, *supra* note 314; *see also* Warren & Markey Letter, *supra* note 307 (requesting FDA documents to help them understand whether the "EUA was motivated by politics").

321. Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, U.S. Food & Drug Admin., to Dawn O'Connell, Assistant Sec'y for Preparedness & Response, U.S. Dep't Health & Hum. Servs. (Dec. 28, 2021), https://www.fda.gov/media/141477/download [https://perma.cc/3JUA-ZVSK].

3. The Push for Vaccines

The hydroxychloroquine and plasma controversies raised significant concern that the Trump Administration would improperly interfere with the FDA's scientific conclusions and decisions about COVID-19 vaccines.[322] President Trump frequently used Twitter to overtly pressure the FDA and to accuse the Agency of delaying vaccines for political reasons.[323] He often claimed the FDA was delaying vaccines until after the 2020 election.[324]

Evidence of covert executive pressure was also uncovered. The *New York Times* reported that Jared Kushner, President Trump's senior advisor, pressured Secretary Azar to accelerate vaccine development and that the Administration insisted on a vaccine before Election Day.[325] Reports also indicate that Secretary Azar considered firing Dr. Hahn after he defied President Trump and Secretary Azar by supporting stricter standards for vaccine EUAs and for "aggressively and publicly push[ing] back on the idea of approving a vaccine prematurely."[326] Meadows reportedly told Dr. Hahn that Dr. Hahn

322. *See* Facher, *supra* note 26 (explaining that officials were concerned about the Trump Administration interfering with the FDA's approval decisions surrounding COVID-19 vaccines); LaFraniere et al., *supra* note 309 (remarking that the rush to announce the emergency approval of plasma resulted in "serious mistakes").

323. *See, e.g.*, Donald Trump (@realDonaldTrump), TWITTER (Dec. 11, 2020, 7:11 AM) (calling the FDA a "big, old, slow turtle" and telling it to "[g]et the dam vaccines out NOW"), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (Nov. 30, 2020, 9:46 AM) (directing the FDA to "act quickly" after Moderna applied for an EUA), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (Sept. 23, 2020, 8:08 AM) (telling the FDA to "move quickly"), *archived*, Brown, *supra* note 272.

324. *See, e.g.*, Donald Trump (@realDonaldTrump), TWITTER (Nov. 9, 2020, 7:43 PM) ("The @US_FDA and the Democrats didn't want to have me get a Vaccine WIN, prior to the election, so instead it came out five days later – As I've said all along!"), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (Nov. 9, 2020, 7:40 PM) ("As I have long said, @Pfizer and the others would only announce a Vaccine after the Election, because they didn't have the courage to do it before. Likewise, the @US_FDA should have announced it earlier, not for political purposes, but for saving lives!"), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (Oct. 6, 2020, 9:09 PM) ("New FDA Rules make it more difficult for them to speed up vaccines for approval before Election Day. Just another political hit job! @SteveFDA"), *archived*, Brown, *supra* note 272; Donald Trump (@realDonaldTrump), TWITTER (Aug. 22, 2020, 7:49 AM) ("The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd."), *archived*, Brown, *supra* note 272.

325. Sharon LaFraniere, Katie Thomas, Noah Weiland, Peter Baker & Annie Karni, *Scientists Worry About Political Influence over Coronavirus Vaccine Project*, N.Y. TIMES (Aug. 2, 2020), https://www.nytimes.com/2020/08/02/us/politics/coronavirus-vaccine.html [https://perma.cc/7P4Y-6FUP].

326. *The Trump Administration's Pattern of Political Interference in the Nation's Coronavirus Response*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS 1, 20 (July 26, 2021) (quoting SLAVITT, *supra* note 261, at 203 (alterations in original)), https://coronavirus.house.gov/

would lose his job if he did not authorize the vaccine on December 11, 2020.[327] The FDA appeared to acquiesce, authorizing the Pfizer vaccine on December 11, reportedly a day earlier than planned.[328] Even though issuing the EUA one day early seems unproblematic, it signaled that the FDA caved to executive pressure, reinforcing concerns about executive interference in FDA decisionmaking.[329]

President Trump's frequent claims that a vaccine might be available by October or November 2020 also fueled concerns.[330] Such claims contradicted statements by many experts, including Moncef Slaoui, the scientific lead of Operation Warp Speed at the time,[331] who said the FDA was "very unlikely" to authorize a vaccine by early November.[332] After a vaccine received authorization in December 2020, President Trump took credit, claiming: "*[M]y Administration and I* developed a vaccine many years ahead of wildest expectations."[333] He urged Americans to not let President-elect Biden "take credit for the vaccines because the vaccines were *me*, and *I pushed people* harder than they've ever been pushed before."[334] Throughout the FDA's response to COVID-19 under the Trump Administration, the FDA frequently

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sites/democrats.coronavirus.house.gov/files/7.26.2021%20Timeline%20of%20Political%20Interference%20-%20final.pdf [https://perma.cc/6PNY-S5PK].

327. *Id.* at 24.

328. *Id.*

329. *Cf.* Asawin Suebsaeng & Sam Stein, *Trump Grows Increasingly Angry with FDA, Wonders if COVID Vaccine Makers Are 'Democrats'*, DAILY BEAST (Dec. 11, 2020, 6:26 PM), https://www.thedailybeast.com/trump-grows-increasingly-angry-with-fda-wonders-if-covid-vaccine-makers-are-democrats [https://perma.cc/M6DL-88QZ] ("[T]he mere idea that the White House was applying pressure to the head of the FDA on the eve of the vaccine's introduction was massively problematic, to the degree that it would breed mistrust in the vaccine's safety.").

330. *See* Sarah Owermohle, *Trump Contradicts Health Officials, Says 'Probably' a Covid-19 Vaccine in October*, POLITICO (Sept. 4, 2020, 6:28 PM), https://www.politico.com/news/2020/09/04/trump-coronavirus-vaccine-october-409248 [https://perma.cc/ZWD4-65MS] (reporting that President Trump "again suggested" that a vaccine would be available by the end of the year, and would "probably" be available in October).

331. Operation Warp Speed was a federal effort to accelerate the development of COVID-19 vaccines. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO 21-319, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES (2021), https://www.gao.gov/assets/gao-21-319.pdf [https://perma.cc/H7JJ-VHDH] (describing Operation Warp Speed as a partnership between HHS and the Department of Defense that "aimed to help accelerate the development of a COVID-19 vaccine").

332. Owermohle, *supra* note 330.

333. *Statement from the President*, TRUMP WHITE HOUSE (Dec. 27, 2020) (emphasis added), https://trumpwhitehouse.archives.gov/briefings-statements/statement-from-the-president-122720/ [https://perma.cc/GDZ9-REN7].

334. *Remarks by President Trump During Thanksgiving Video Teleconference with Members of the Military*, TRUMP WHITE HOUSE (Nov. 27, 2020) (emphasis added), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-thanksgiving-video-teleconference-members-military/ [https://perma.cc/F63T-N29T].

pledged it would "not cut corners" and would follow the science.[335] Dr. Hahn, however, later acknowledged that the FDA faced "a substantial amount of pressure" from the White House, stating that he "heard loud and clear from the White House – President Trump and others – that they wanted FDA to move faster."[336]

Controversies did not end, however, when President Biden took office. For example, many questioned the Biden Administration's August 2021 announcement of its plan to offer booster shots to all Americans beginning in September 2021. Although he stated that the booster shot rollout was subject to independent evaluations and recommendations by the FDA and CDC,[337] this was largely lost in the messaging. The announcement created a clear public expectation that boosters would be available in September 2021, and the decision to make the announcement prior to the FDA's and CDC's reviews and recommendations raised concerns about the potential influence on the agencies' decisions.[338] Dr. Offit described it as "the administration's

335. *AMA, FDA Video Update: The Critical Role of Health Care Professionals During COVID-19*, AM. MED. ASS'N 4 (Aug. 10, 2020), https://www.ama-assn.org/print/pdf/node/54876 [https://perma.cc/4LA9-J5P5]; *see also COVID-19: An Update on the Federal Response - FDA Opening Remarks*, U.S. FOOD & DRUG ADMIN. (Sept. 22, 2020), https://www.fda.gov/news-events/congressional-testimony/covid-19-update-federal-response-fda-opening-remarks-09232020 [https://perma.cc/XYE8-UPXV] ("On behalf of the 17,000 plus employees of the FDA, I want to make the following commitments today to the American public . . . . Decisions to authorize or approve any such vaccine or therapeutic will be made by the dedicated career staff at FDA, through our thorough review processes and science will guide our decisions.").

336. Sarah Owermohle, *Outgoing FDA Chief: The Agency Fought 'Substantial' Pressure Under Trump*, POLITICO (Jan. 19, 2021, 1:59 PM), https://www.politico.com/news/2021/01/19/fda-trump-pressure-coronavirus-vaccine-460402 [https://perma.cc/V2V6-7LAK]; *see also A "Knife Fight" with the FDA*, *supra* note 2 (describing testimony of Dr. Hahn and other evidence suggesting inappropriate pressure on the FDA to influence decisions relating to COVID-19 treatments and vaccines); *cf.* Deidre McPhillips & Devan Cole, *Outgoing NIH Director Says Trump and Other Republicans Pressured Him to Endorse Unproven Covid-19 Remedies and to Fire Fauci*, CNN, https://www.cnn.com/2021/12/19/politics/francis-collins-trump-political-pressure-republicans/index.html (last updated Dec. 19, 2021, 8:48 PM) [https://perma.cc/8VBE-LPQJ] (noting that the outgoing NIH director reported facing political pressure to endorse unproven COVID-19 remedies and to fire Fauci).

337. Press Release, U.S. Food & Drug Admin., Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots (Aug. 18, 2021), https://www.fda.gov/news-events/press-announcements/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots [https://perma.cc/5SG4-ZNLG].

338. *See* Dan Diamond, Joel Achenbach, Lena H. Sun & Tyler Pager, *Biden Team Tries to Get Ahead of the Virus — and Maybe the Science — with Decision on Booster Shots*, WASH. POST (Aug. 20, 2021, 10:38 AM), https://www.washingtonpost.com/health/2021/08/20/biden-coronavirus-booster-shots-criticism/ [https://perma.cc/RUR7-4F8W] ("While Biden acknowledged the plan was 'pending approval' from the Food and Drug Administration and experts who advise the Centers for Disease Control and Prevention, the president mostly portrayed it as a done deal, saying that tens of millions of booster shots would become available the week of Sept. 20."); Bob Herman, *The Pharmaceutical Experts Are Getting Ignored*, AXIOS (Aug. 23, 2021), https://www.axios.com/drug-experts-vaccines-cdc-fda-aduhelm-ignored-836df07a-fe98-4ef8-84e3-d4a1c5400bd9.html

booster plan," rather than the FDA's plan, stating that the Administration "backed themselves up against the wall a little bit."[339] In an attempt to act as an "overseer" of the booster shot plan, the Biden Administration mangled the public messaging, raising concerns about the role of politics in later decisions of the FDA and CDC. There were ways to guide and coordinate the booster shot plan without giving the appearance that the Administration overstepped into matters of science.[340]

Shortly after President Biden's announcement, two high-level vaccine officials—Dr. Marion Gruber, Director of the FDA's Office of Vaccine Research and Review ("OVRR") and Dr. Philip Krause, Deputy Director of OVRR—announced their retirements.[341] Sources reported that their decisions were due in part to frustration with the Biden Administration's booster shot announcement and feeling that the Administration sidelined the FDA.[342] Many challenged the need for booster shots and noted the decisions were made in reverse—typically, the Administration's announcement would come after the FDA and CDC made their decisions.[343]

[https://perma.cc/T9PB-P6EC] (remarking that the Biden administration announced that booster shots would be available starting in September, before expert drug committees could review the vaccines and make independent recommendations); Robert Langreth, *Biden Plan Prods Scientists to Back Boosters Despite Murky Data*, BLOOMBERG (Aug. 20, 2021, 4:45 PM), https://www.bloomberg.com/news/articles/2021-08-20/biden-plan-prods-scientists-to-back-boosters-despite-murky-data [https://perma.cc/9LEJ-ZEMS] (observing "signs of pressure" around the CDC's Advisory Committee on Immunization Practices). *But see* Diamond et al., *supra* note 338 (noting some health officials applauded the decision).

339. *Amid Tension on Booster Shots, 2 Top FDA Officials Announce Retirement*, ADVISORY BD. (Sept. 1, 2021), https://www.advisory.com/daily-briefing/2021/09/01/fda-officials [https://perma.cc/34P8-V57V].

340. Messaging matters. For example, President Biden could have stated that his Administration was working with the FDA and CDC to develop a rollout plan for booster shots, without making commitments about dates or eligible populations. Those decisions are based on scientific data and are best left to the experts.

341. Zachary Brennan, *In a Major Blow to Vaccine Efforts, Senior FDA Leaders Stepping Down*, ENDPOINTS NEWS, https://endpts.com/breaking-in-a-major-blow-to-vaccine-efforts-senior-fda-leaders-stepping-down-report/ (last updated Sept. 1, 2021, 6:54 AM) [https://perma.cc/26F4-E4T4].

342. *Id.*

343. *See* Philip R. Krause et al., *Considerations in Boosting COVID-19 Vaccine Immune Responses*, 398 LANCET 1377, 1379 (2021) (recommending that any "decisions about the need for boosting or timing of boosting should be based on careful analyses of adequately controlled clinical or epidemiological data, or both"); Helen Branswell, *U.S. Officials' Decision on COVID-19 Booster Shots Baffles — and Upsets — Some Scientists*, STAT (Aug. 18, 2021), https://www.statnews.com/2021/08/18/u-s-decision-on-covid-19-booster-shots-baffles-and-upsets-some-scientists/ [https://perma.cc/CBL4-ZXU2] (commenting that some critics worried that the Administration's decisions were made before the FDA and CDC had ruled on the need for a booster).

Initially, the FDA authorized booster shots of the Pfizer vaccine[344] and the CDC's advisory panel recommended booster shots only for a subset of the population (i.e., people sixty-five and older, living in nursing homes, and people eighteen to sixty-four with underlying medical conditions).[345] The CDC's advisory panel voted against booster shots for people aged eighteen to sixty-four at elevated risk due to living or working conditions.[346] Nevertheless, the eligibility criteria were widened to include this population after the CDC Director overruled the CDC's advisory panel decision.[347] The CDC Director can overrule the advisory panel's recommendations but rarely does so.[348]

Tensions between the Administration and government scientists, along with bungled messaging, further confused a public exasperated by a seemingly never-ending pandemic and entrenched skepticism amongst the vaccine hesitant.[349] Importantly, it raised

344. Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, Food & Drug Admin., to Pfizer Inc. (July 8, 2022), https://www.fda.gov/media/150386/download [https://perma.cc/CR4Z-FRV4] (reporting that in its September 22, 2021 revision, the FDA authorized the administration of a single booster dose of the Pfizer vaccine). The FDA and CDC later considered and authorized booster shots for the Moderna and J&J vaccines in October 2021. Press Release, Ctrs. for Disease Control & Prevention, CDC Expands Eligibility for COVID-19 Booster Shots (Oct. 21, 2021), https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html [https://perma.cc/87P9-BCRG]; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines (Oct. 20, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines [https://perma.cc/SQ85-2CNW].

345. Helen Branswell, *Advisory Committee Recommends Wide Swath of Americans Be Offered COVID-19 Vaccine Boosters*, STAT (Sept. 23, 2021), https://www.statnews.com/2021/09/23/covid19-vaccine-boosters-cdc-acip/ [https://perma.cc/83F7-BJQG].

346. *Id.*

347. Lev Facher & Helen Branswell, *Biden's Chaotic Messaging on COVID-19 Boosters Is Pitting the White House Against the Government's Scientific Advisers*, STAT (Sept. 24, 2021), https://www.statnews.com/2021/09/24/biden-covid-19-boosters-pitting-white-house-against-scientific-advisers/ [https://perma.cc/KT7G-UKHY].

348. *Id.*

349. Philp R. Krause, Marion F. Gruber & Paul A. Offit, *We Don't Need Universal Booster Shots. We Need to Reach the Unvaccinated*, WASH. POST (Nov. 29, 2021, 6:00 AM), https://www.washingtonpost.com/outlook/2021/11/29/booster-shots-universal-opinion/ [https://perma.cc/G8NA-MLLJ] ("[T]he push for boosters for everyone could actually prolong the pandemic: The campaign includes exaggerated accounts of the waning efficacy of the vaccines, giving the public—including the vaccine-hesitant—reason to think that the shots are less effective than originally advertised."); Laura McGinley & Lena H. Sun, *White House Gets Most of What It Wants on Boosters. But It Also Gets Confusion*, WASH. POST (Sept. 24, 2021, 7:59 PM), https://www.washingtonpost.com/health/2021/09/24/pfizer-booster-shot/ [https://perma.cc/9BCW-2URP]; Carissa Wolf, Frances Stead Sellers, Ashley Cusick & Kim Mueller, *Changing Recommendations for Boosters Lead to Confusion for the Vaccinated and Their Doctors*, WASH. POST (Sept. 25, 2021, 9:46 AM), https://www.washingtonpost.com/health/2021/09/25/covid-vaccine-booster-confusion/ [https://perma.cc/3A5X-VBNP]; *see also* Carmel Shachar, *Promote Trust, Avoid Fraud: Lessons in Public Health Messaging from the Booster Roll Out*, HARV. L. PETRIE-FLOM CTR.: BILL OF HEALTH (Nov. 30, 2021), https://blog.petrieflom.law.harvard.edu/2021/11/30/covid-

questions about President Biden's campaign pledge to always "follow the science."[350]

At the time of this writing, the continual evolution of COVID-19 vaccines and related guidance and recommendations, such as the government's response to new variants, mean that vaccine research and analysis remain ongoing, as does the potential for executive interference. Thus far, however, the FDA has largely, though not entirely, resisted executive interference with scientific decisions about vaccines. Nevertheless, consequences still materialize even when the interference does not influence the FDA's ultimate decisions. These consequences include vaccine hesitancy, diminished public trust and confidence, and potentially long-lasting reputational damage.[351]

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vaccine-booster-messaging/ [https://perma.cc/ME7C-AFRG] (noting how discrepancies in messaging over time caused "whiplash and uncertainty" and may have undermined the public's trust).

350. Lev Facher, *Biden Pledged to 'Follow the Science.' But Experts Say He's Sometimes Fallen Short*, STAT (Sept. 1, 2021), https://www.statnews.com/2021/09/01/biden-pledged-follow-the-science-but-hes-fallen-short/ [https://perma.cc/JC58-8P9N]; Facher & Branswell, *supra* note 347. More recently, some questioned whether the delay in authorizing vaccines for children under five was due to political and logistical considerations rather than scientific evidence. As reported by *Politico*:

> Administration health officials had once hoped to authorize first shots for young children at the beginning of this year. But scientific setbacks and *broader practical concerns* within the [FDA] have slowed progress, the people with knowledge of the matter said.
>
> Now, regulators are leaning toward postponing any action until the early summer, arguing that it would be *simpler and less confusing* to simultaneously authorize and promote two vaccines to the public, rather than green-lighting one on a faster timetable and the other down the road. . . .
>
> [T]he deliberations represent the latest instance where the [Biden] administration has struggled to align scientific considerations with political realities. . . .
>
> FDA officials have argued it's a . . . complicated calculation. They worry that authorizing a single vaccine and then, soon thereafter, another one *might make it harder for the administration to promote the shots and undermine confidence in their effectiveness*.

Adam Cancryn, *Waiting for a Covid Vaccine for Your Under-5 Kid? It May Take a Bit Longer.*, POLITICO (Apr. 21, 2022, 4:30 AM) (emphasis added), https://www.politico.com/news/2022/04/21/biden-kids-vaccine-covid-00026798 [https://perma.cc/8UXG-M9W7]; *see also* Beth Mole, *Fauci Confirms Parents' Nightmare: FDA May Delay COVID Vaccines for Kids Under 5*, ARS TECHNICA (Apr. 22, 2022, 12:10 PM), https://arstechnica.com/science/2022/04/fauci-confirms-parents-nightmare-fda-may-delay-covid-vaccines-for-kids-under-5/ [https://perma.cc/X3SP-TH28] (reporting on an interview with Dr. Fauci who, while stating that he is not involved in the FDA's decision, indicated that the FDA's "delay was intended to avoid confusion about the vaccines"). FDA laws and regulations do not contemplate consideration of such logistical or political considerations surrounding vaccine administration and promotion in the Agency's review for authorization or approval. Such considerations are reminiscent of the Plan B decisions, when then-Commissioner Andrew C. von Eschenbach oddly cited "enforcement concerns" when the FDA denied the sponsor's request to lower the age from eighteen to sixteen or seventeen. *See supra* note 153 and accompanying text.

351. *See, e.g.*, Press Release, Kaiser Fam. Found., Poll: Most Americans Worry Political Pressure Will Lead to Premature Approval of a COVID-19 Vaccine; Half Say They Would Not Get

Importantly, the examples discussed in this Part are not exhaustive but rather illustrate a broader and increasingly concerning trend of executive interference in the FDA's scientific decisionmaking.[352] To restore public trust, confidence, and the FDA's "outstanding reputation for impartial expertise,"[353] the past cannot be prologue.

III. CONTROLLING EXECUTIVE INTERFERENCE

The preceding Parts make clear that agencies encounter competing demands and political interference from the executive and elsewhere, and that interference occurs overtly (e.g., executive orders, presidential memoranda) and covertly (e.g., off-the-record meetings, implicit threats to officials' positions, tacit threats or demands via social media). Also evident is that interference in agency scientific decisionmaking—by any source—can threaten an agency's pursuit of its mission, risk distressful public health harms and even deaths,[354]

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a Free Vaccine Approved Before Election Day (Sept. 10, 2020), https://www.kff.org/coronavirus-covid-19/press-release/poll-most-americans-worry-political-pressure-will-lead-to-premature-approval-of-a-covid-19-vaccine-half-say-they-would-not-get-a-free-vaccine-approved-before-election-day/ [https://perma.cc/K64A-VHSF] [hereinafter KFF Press Release] (concluding that poll results captured "a drop in the public's trust of the nation's public health institutions" and ability to provide reliable information about the coronavirus); *High COVID-19 Vaccine Acceptance Among Infection Preventionists*, ASS'N FOR PROS. INFECTION CONTROL & EPIDEMIOLOGY (Feb. 2021), https://eadn-wc04-3087653.nxedge.io/cdn/wp-content/uploads/2021/02/Graphic-APIC_SURVEY-RESULTS_2021%E2%80%9302-09_05-1.pdf [https://perma.cc/NZY5-222W] (finding that speed-to-market and insufficient study were the main concerns contributing to vaccine hesitancy or vaccine declination among healthcare personnel).

352. *See, e.g.*, Jonathan Swan, *Trump Eyes New Unproven Coronavirus "Cure,"* AXIOS (Aug. 16, 2020), https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html [https://perma.cc/TF6R-8H57] (reporting nonpublic meetings between President Trump, White House officials, and industry personnel regarding oleandrin, a botanical pushed as a COVID-19 treatment, and suggesting that President Trump said FDA should approve it); *see also* Peter Cary, *Controversial J&J Drug Pushed by Trump Is Nixed from VA's Pharmacy List*, CTR. FOR PUB. INTEGRITY (June 21, 2019), https://publicintegrity.org/politics/controversial-anti-depression-drug-pushed-by-president-trump-is-nixed-from-vas-pharmacy-list/ [https://perma.cc/TB8M-4V4B] (describing President Trump's involvement in and promotion of a depression treatment (Spravato), which the White House pushed Veterans Affairs to purchase and use despite questionable evidence).

353. Vermeule, *supra* note 129, at 1208.

354. For example, executive interference that pressures the FDA to approve or authorize an unsafe drug can cause harm or even death. *See, e.g.*, Cathrine Axfors et al., *Mortality Outcomes with Hydroxychloroquine and Chloroquine in COVID-19 from an International Collaborative Meta-Analysis of Randomized Trials*, NATURE COMMC'NS (2021), https://www.nature.com/articles/s41467-021-22446-z.pdf [https://perma.cc/NN3M-TJPL] (observing no mortality benefit of hydroxychloroquine and potentially severe adverse effects, especially related to cardiac arrhythmia); *supra* notes 6, 294, and accompanying text (noting that people have taken chloroquine to avoid coronavirus, but died from ingesting the substance). Conversely, executive interference that pressures the FDA to *not* approve or to unnecessarily restrict access to a safe and effective drug can negatively affect health, such as preventing access to necessary reproductive

disproportionately impact vulnerable populations,[355] prolong public health emergencies,[356] and damage agency credibility in the short and long term.

Leading to this Part, this Article described the ongoing debate about the scope of presidential authority over agencies. Public concern about executive interference in the FDA's scientific decisionmaking during the COVID-19 pandemic[357] demonstrates the enduring importance of this debate, and the pandemic illustrates exactly how politics and public health are intertwined.[358] Even while executive involvement in agency decisionmaking may at times enhance accountability, credibility, and public trust, it does the opposite when it co-opts science in pursuit of political goals or uses it as a shield for tough policy decisions. The ongoing politicization of science and public health, and the negative consequences that result, create cause for concern and action. The essential role that public health agencies play in our daily lives makes their accountability, credibility, and trustworthiness worthy of protection. The inquiry, therefore, becomes how to address executive interference in agency scientific decisionmaking.

It is difficult to draw lines between appropriate and inappropriate executive-level involvement and to uncover improper

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healthcare. *See, e.g.*, *supra* notes 238, 250, and accompanying text (arguing that the mifepristone REMS had no scientific basis and could cause harm to those seeking abortion care).

355. As discussed in Section II.A.1, restrictions on medication abortion disproportionately impact low-income communities, communities of color, as well as other historically marginalized and vulnerable populations.

356. Declining public trust in agencies like the FDA and CDC during COVID-19 likely exacerbated and prolonged the pandemic by increasing vaccine hesitancy and decreasing compliance with other public health guidance. For example, unvaccinated Americans were a major factor in the surge of the Delta variant in the United States during the summer and fall of 2021. The surge led to reinstatement of mask mandates, delayed office reopenings, and caused some schools to revert to remote learning. When members of the public do not trust the agencies making decisions, they "won't agree 'to change their lives, take preventive [measures], [or] take vaccines.' " Selena Simmons-Duffin, *Poll Finds Public Health Has a Trust Problem*, NPR (May 13, 2021, 12:01 AM) (quoting Robert Blendon, Professor, Harvard T.H. Chan School of Public Health), https://www.npr.org/2021/05/13/996331692/poll-finds-public-health-has-a-trust-problem [https://perma.cc/P4SF-9X4C]; *see also supra* note 107 and accompanying text (discussing how the public doubted the credibility of the FDA's coronavirus decisions, leading to distrust).

357. KFF Press Release, *supra* note 351 (finding that sixty-two percent of Americans worried that political pressure from the Trump Administration would cause the FDA to rush approval of a COVID-19 vaccine without adequate proof of safety and effectiveness).

358. There are many examples throughout the FDA's history of how public health and politics are intertwined. *See, e.g.*, *supra* Part II.A (describing examples from reproductive health); STEVEN EPSTEIN, IMPURE SCIENCE (1996) (analyzing the political and social nature of the AIDS epidemic and response); Robert A. Kagan & William P. Nelson, *The Politics of Tobacco Regulation in the United States*, *in* REGULATING TOBACCO 11, 12–39 (Robert L. Rabin & Stephen D. Sugarman eds., 2001); Dan M. Kahan & Ashley R. Landrum, *A Tale of Two Vaccines—and Their Science Communication Environments*, *in* THE OXFORD HANDBOOK OF THE SCIENCE OF SCIENCE COMMUNICATION 165, 165 (Kathleen Hall Jamieson et al. eds., 2017) (describing political and social controversy over the FDA's fast-track approval of the Human Papillomavirus vaccine).

interference.[359] But tough problems do not beget easy solutions. This Part evaluates new and existing mechanisms to uncover, mitigate, and thwart improper interference in agency scientific decisionmaking and to promote accountability, credibility, and public trust. Of course, the ideal solution would eliminate improper interference from all sources. For many reasons, however, that is unlikely. No solution alone can solve the problem entirely, and every solution involves trade-offs.

Because of the dangers of capture from any source, it is important to consider how responses to executive-level internal capture may affect external capture and other forms of internal capture. Any solution must (1) restore and enhance the accountability, credibility, and public trust of agency scientific decisionmaking and (2) provide a consistent and comprehensive mechanism to oversee and control various forms of interference in agency scientific decisionmaking, including executive interference. To achieve the goals of enhanced accountability, credibility, and public trust, and to address limitations of existing mechanisms and previous proposals, this Part begins by proposing a new and comprehensive approach: the creation of a new and independent body, the "Scientific Integrity Office" ("SIO"). It then explains the limitations of existing and previously proposed mechanisms to further illustrate the advantages of the SIO. Even while this Part does not attempt to enumerate the minute details of the SIO, the proposal and discussion in this Part provide a valuable thought experiment about how to enhance agency scientific integrity and autonomy in scientific decisionmaking.[360]

A. Scientific Integrity Office

The proposed SIO, a nonpartisan, congressionally created body, incorporates enhanced oversight and statutory protections to achieve

359. Indeed, in certain circumstances, what is considered "improper," or a form of capture, will itself be contested. *See* Cary Coglianese, *The Elusiveness of Regulatory Capture*, REGUL. REV. (July 5, 2016), https://www.theregreview.org/2016/07/05/coglianese-the-elusiveness-of-regulatory-capture/ [https://perma.cc/JDK4-7H5T]; *see also* SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117, at 8 ("Determining whether particular action constitutes a violation of scientific integrity policy requires careful consideration. The line between appropriate intervention and interference is often not clear without deeper analysis."); Coglianese, *The Emptiness of Decisional Limits*, *supra* note 92, at 56 (discussing the line-drawing problem).

360. The various mechanisms discussed in this Part are not exhaustive, and there are certainly other possibilities that could be explored. Furthermore, while this Article focuses on scientific decisionmaking by "scientific agencies" like the FDA and the CDC, the objectives undergirding the SIO could, and arguably should, expand to all federal agencies "[b]ecause evidence-based policymaking happens across government." SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117, at i.

accountability, credibility, and public trust.[361] Inspiration for the SIO can be found from Margo Schlanger's "Offices of Goodness," which are offices within agencies that "pay attention not only to [the agencies'] mission[s], but also to some other constraining or even conflicting value," which she refers to as "Goodness."[362] The "Goodness" focused on by the SIO would be promoting the scientific integrity of agency scientific decisionmaking to foster accountability, credibility, and public trust. Unlike Offices of Goodness, however, the SIO would be an external entity rather than an office situated within an agency. For reasons noted throughout this Part, an external and autonomous structure promotes impartial review and conclusions.

The SIO would also have similarities to the "Scientific Integrity Task Force" established by President Biden in a memorandum issued on January 27, 2021.[363] President Biden established the Task Force to combat political interference in scientific work by federal agencies and to review recent failings.[364] The Task Force issued its first report in January 2022, identifying approaches and providing initial recommendations to strengthen the ability of federal agencies to protect scientific integrity.[365]

A significant, if not fatal, limitation of the Task Force and presidential memoranda more generally, however, is that presidential memoranda are of limited influence once the issuing President leaves office. President Obama, for example, issued a similar scientific integrity memo.[366] President Trump did not, and the preceding discussion makes clear that his Administration frequently violated scientific integrity, illustrating the short-term influence of President Obama's memo. This limitation raises concerns that the important

361. As noted, the description of the SIO in this Part provides just the start of a much longer discussion of how to structure and fully operationalize the SIO.

362. Margo Schlanger, *Offices of Goodness: Influence Without Authority in Federal Agencies*, 36 CARDOZO L. REV. 53, 54–55 (2014). For further discussion of the characteristics of and tools available to Offices of Goodness, see *id.* at 60–62, 92–103. *See also* David E. Bernstein, *Antidiscrimination Laws and the Administrative State: A Skeptic's Look at Administrative Constitutionalism*, 94 NOTRE DAME L. REV. 1381, 1413 (2019) (citing Schlanger's Offices of Goodness model when proposing "constitutional watchdog offices devoted to protecting constitutional rights from agency overreach within antidiscrimination agencies").

363. *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*, THE WHITE HOUSE (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/8RM7-D7EB] [hereinafter Biden Scientific Integrity Memo].

364. *Id.*

365. SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117.

366. *Memorandum for the Heads of Executive Departments and Agencies*, OBAMA WHITE HOUSE (Mar. 9, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 [https://perma.cc/VPG4-TJA2].

work done by the Task Force thus far[367] could be lost in a different administration. The SIO, in contrast, would be a nonpartisan, congressionally created body that would not require action by future presidents to remain in existence (such as through an executive order or memo). The SIO would be charged specifically with overseeing agency scientific integrity, with explicit authorization to oversee and review executive interference. In addition to reviewing suspected interference, the SIO could also be empowered to provide guidance to agencies or agency personnel with concerns about interference and how to prevent it. Establishing a permanent SIO with these authorities would be a significant step toward achieving the important goals and recommendations put forth by the Task Force thus far.

Importantly, the SIO should also have the authority to oversee interference from nonexecutive sources, including Congress, other politicians, and industry. If, as some argue, executive authority over agencies can reduce external capture,[368] then any solution to internal capture must consider the effect on external capture. Mitigating internal capture while simultaneously exacerbating external capture will defeat the purpose of any solution. If external capture goes unaddressed or increases, damage to agency credibility and trustworthiness will endure. Authorizing the SIO to consider all forms of capture will also address concerns about the difficulty of distinguishing between external and internal capture in certain situations.[369]

The SIO would have some similarities to the GAO, but unlike the GAO's broad scope,[370] the SIO would focus specifically on scientific integrity and political interference in agency scientific decisionmaking. Another reason counseling against reliance on the GAO is that the head of the GAO, the Comptroller General, is appointed by the President with the advice and consent of the Senate.[371] Even though the Comptroller General is chosen by the President from a list of candidates selected by a bipartisan bicameral congressional commission and is not removable at the President's will, the head of an entity like the SIO, which is tasked with tackling executive interference, should be

367. SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117.

368. *See supra* notes 97–99 and accompanying text.

369. Some may argue, for example, that the President's motivation to interfere with or control agencies always derives from some external political pressure, such as from financially generous industry donors. In that view, internal capture will almost always arise from external capture.

370. For a list of topics covered by the GAO, see *View Topics*, U.S. GOV'T ACCOUNTABILITY OFF., https://www.gao.gov/topics (last visited Aug. 23, 2022) [https://perma.cc/F6BU-ZPDS].

371. 31 U.S.C. § 703.

insulated from the President and chosen without executive involvement. For similar reasons relating to appointment and removal, relying solely on the Offices of Inspectors General is not ideal.[372]

A better approach for the SIO would involve a nonappointed career official or group of career officials, such as a commission or board (i.e., civil servants). This approach may also help prevent leadership positions from going unfilled (a common occurrence in presidentially appointed positions) and reduce the risk that the SIO goes dormant or has its powers diminished.[373] If appointed rather than hired as a civil servant, politics will necessarily infiltrate the process. The officials could serve set terms, such as ten or fifteen years. Importantly, because partisan-driven oversight will not improve agency credibility and public trust, SIO officials and employees must be hired without regard for political affiliation, and employees must have civil service protections.[374]

A primary purpose of the SIO is to facilitate the discovery of covert interference with a more streamlined and efficient procedure.[375]

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372. "Establishment Inspectors General" ("IGs") are appointed by the President with the advice and consent of the Senate and may only be removed by the President. 5 U.S.C. § 3(a)-(b); *The Inspectors General*, COUNCIL INSPECTORS GEN. ON INTEGRITY & EFFICIENCY 2, 13 (July 14, 2014) (listing IGs in "establishment agencies"), https://www.ignet.gov/sites/default/files/files/IG_Authorities_Paper_-_Final_6-11-14.pdf [https://perma.cc/933A-4RJW]. At certain designated federal entities, the heads of the agency appoint and can remove IGs. 5 U.S.C. § 8G(c); *The Inspectors General*, *supra*, at 2, 13 (listing IGs in "designated federal entities").

373. *Cf.* Ed Yong, *The Next Plague Is Coming. Is America Ready?*, ATLANTIC (July/Aug. 2018), https://www.theatlantic.com/magazine/archive/2018/07/when-the-next-plague-hits/561734/ [https://perma.cc/NGY8-BZ2P]. Yong notes various vacancies and departures of key officials during the Trump Administration from certain executive groups, highlighting that

> [t]he President's Council of Advisers on Science and Technology, a group of leading scientists who consult on policy matters, is dormant. The Office of Science and Technology Policy, which has advised presidents on everything from epidemics to nuclear disasters since 1976, is diminished. The head of that office typically acts as the president's chief scientific consigliere, but to date no one has been appointed.

Id.

374. The National Academy of Sciences ("NAS") Council provides another leadership model that could be considered. Congress established the NAS in 1863 as a private, nongovernmental organization. *Organization*, NAT'L ACAD. SCIS., http://www.nasonline.org/about-nas/organization/ (last visited Aug. 23, 2022) [https://perma.cc/E92Z-2YYF]. Initially, NAS membership included forty-nine scientists from the states remaining in the Union. *History*, NAT'L ACAD. SCIS., http://www.nasonline.org/about-nas/history/ (last visited Aug. 23, 2022) [https://perma.cc/5FZ9-KVG2]. Today, the NAS is governed by a seventeen-member Council. Members are elected, and current membership totals around 2,400 members and 500 international members. *Membership Overview*, NAT'L ACAD. SCIS., http://www.nasonline.org/about-nas/membership/ (last visited Aug. 23, 2022) [https://perma.cc/RT5J-DUL5].

375. This fixes a current problem found by a GAO report examining the procedures in place at the CDC, FDA, NIH, and the Office of the Assistant Secretary for Preparedness and Response to address potential political interference in agency decisionmaking. In the report, the GAO described a relatively ad hoc, case-by-case procedure for reporting and addressing this issue. U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-104613, SCIENTIFIC INTEGRITY: HHS AGENCIES NEED TO DEVELOP

The SIO should be empowered with the authority to initiate a review on its own or at Congress's request.[376] Furthermore, given the public importance of these issues and to increase the likelihood of uncovering covert interference, the SIO should accept requests from any person, including agency employees or members of the public. Agency employees may not want to be formal "whistleblowers" or report concerns to someone within their own agency, so this would provide a valuable alternative mechanism for reporting concerns. To protect agency employees and encourage reporting, the requester's name should be kept confidential. Importantly, retaliation against reporters should be prohibited by statute and subject to penalties.[377] The process for requesting SIO review should be easy and accessible. Information about how to request a review must be disseminated broadly to ensure the procedure does not go underutilized, as that would impede achievement of the SIO's goals.[378]

The overarching objectives of the SIO may appear similar to the Information Quality Act ("IQA"), also referred to as the Data Quality Act, which was passed by Congress in 2001 to "ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies."[379] Essentially, the IQA requires federal agencies to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with"

PROCEDURES AND TRAIN STAFF ON REPORTING AND ADDRESSING POLITICAL INTERFERENCE 9 (Apr. 2022) [hereinafter GAO SCIENTIFIC INTEGRITY REPORT].

376. This addresses another limitation of relying on the GAO, as requests for GAO reports must come from congressional committees, subcommittees, or members of Congress. *See Reports & Testimonies*, GOV'T ACCOUNTABILITY OFF., https://www.gao.gov/about/what-gao-does/reports-testimonies (last visited Aug. 23, 2022) [https://perma.cc/NJ8Y-PHW6].

377. Protection from retaliation represents an important component of any solution that involves reporting political interference. In the GAO Scientific Integrity Report, respondents from the CDC and FDA stated that fear of retaliation was one reason "they did not report potential political interference in scientific decision-making." GAO SCIENTIFIC INTEGRITY REPORT, *supra* note 375, at 12.

378. Knowledge and ease of use are important. The GAO Scientific Integrity Report found that respondents from the CDC and FDA were unsure how to report potential political interference in scientific decisionmaking that they observed. *Id.*

379. Information Quality Act, Pub L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153 to -154 (Dec. 21, 2000). For a more detailed overview of the IQA, see Daren Bakst, *Strengthening the Information Quality Act to Improve Federally Disseminated Public Health Information*, 75 FOOD & DRUG L.J. 234, 241–53 (2020); and Alexander Nathan Hecht, *Administrative Process in an Information Age: The Transformation of Agency Action Under the Data Quality Act*, 31 J. LEGIS. 233 (2005).

certain guidelines that the IQA required agencies to issue.[380] The procedures must also provide an appeals process.[381]

Despite similar objectives (namely, scientific integrity), the SIO provides important advantages to the IQA. First, the IQA remains relatively obscure and not well known.[382] Second and more importantly, the SIO provides autonomy and impartiality that the IQA lacks.[383] The IQA establishes internal review procedures, through which agencies themselves decide whether and how to issue corrections in response to a given request. In doing so, agencies maintain a great deal of discretion, which raises concerns that agencies might respond inappropriately to pressures from industry groups or others, or otherwise decline to issue corrections for inappropriate reasons.[384] This potentially facilitates, rather than mitigates, capture.[385] The SIO, in contrast, provides an external and impartial process, two features that are necessary components of any solution that seeks to bolster public trust.[386] And while important for each agency to have their own policies

380. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002); Hecht, *supra* note 379, at 252.

381. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8459; Hecht, *supra* note 379, at 252, 257.

382. Spencer S. Hsu, *Wielding Obscure Federal Data Quality Law, Group Challenges Trump Treasure Tax Cut Claims*, WASH. POST (Nov. 14, 2017), https://www.washingtonpost.com/local/public-safety/wielding-obscure-federal-data-quality-law-group-challenges-trump-treasury-tax-cut-claims/2017/11/14/f5af3b08-c892-11e7-aa96-54417592cf72_story.html [https://perma.cc/6JP8-HJUU].

383. For additional critiques of the IQA, see Hecht, *supra* note 379, at 260–62. Autonomy and impartiality are particularly important when concerns about interference involve senior agency officials, who may be political appointees. As noted by the first report issued by the Scientific Integrity Fast-Track Action Committee (i.e., President Biden's Scientific Integrity Task Force), "[b]ecause senior leaders are likely in the management chain of designated [scientific integrity officials] or other agency management, agency officials may be less willing to pursue violations and have fewer opportunities for imposing meaningful sanctions." SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117, at 9.

384. *See* Jeffrey C. Lerner, *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research*, 28 J. LEGAL MED. 283, 287 (2007); *see also* Bakst, *supra* note 379, at 245 ("The correction process is guided by standards that appear to give agencies significant flexibility.").

385. As Hecht notes, industry may use the IQA to "delay[ ] or derail[ ] agency action." Hecht, *supra* note 379, at 234; *see also* Bagley & Revesz, *supra* note 98, at 1316 ("There have been numerous suggestions that [the IQA] reflect[s] efforts to inject industry further into the rulemaking process, and particularly that the IQA's petition requirements will interfere with notice-and-comment rulemaking, impose delay, and have a sharp antiregulatory impact."); Hsu, *supra* note 382 (noting criticisms that the law "can be abused to bog down or block new health, safety and environmental rules").

386. The effect of the IQA also remains questionable. As one commentator notes: "The law does not have the teeth that some hoped for, and there does not seem to be much motivating agencies or OMB to take the IQA seriously." Bakst, *supra* note 379, at 250. Bakst argues that reforms are needed for the IQA to be more effective. *See id.* at 271. A 2015 GAO report analyzing 2010–2014 data found that sixty-eight percent of eighty-seven requests for correction resulted in no changes

and procedures to address political interference,[387] the external and comprehensive process provided by the SIO also mitigates concerns about imposing additional requirements and burdens on agencies, which already encounter time and resource constraints.[388]

In addition to impartiality, protecting and enhancing accountability, credibility, and public trust require transparency. The SIO's reports and conclusions should be reported to Congress, sent directly to any parties implicated by the report,[389] and made available to the public. The SIO should also publish annual reports providing the number of requests received, number of reviews undertaken, number of reviews completed, number of cases in which the SIO found evidence of interference, and whether any further action was taken (e.g., by Congress or the courts). Congress, the courts, agencies, and the public could use information from the SIO for many purposes: to inform legislation, regulations, or policies; to provide evidence for litigation or further investigation; to inform the public about the factors influencing agency decisions; to establish benchmarks for future behavior; and to discourage the recurrence of inappropriate interference.

The transparency provided by the SIO will help the public hold the appropriate actors accountable and can motivate changes in behavior. That said, this transparency is insufficient on its own. Congress should therefore enact legislation explicitly prohibiting off-the-record communications with the President, White House officials, and other actors outside of the FDA (e.g., other politicians) during the drug review and approval process. Subject to appropriate redactions and narrowly interpreted exceptions (e.g., for national security or to protect trade secrets), any such communications must be on the record

made by the agencies. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-110, INFORMATION QUALITY ACT: ACTIONS NEEDED TO IMPROVE TRANSPARENCY AND REPORTING OF CORRECTION REQUESTS 17 (Dec. 2015), https://www.gao.gov/assets/gao-16-110.pdf [https://perma.cc/T2FL-M8XF].

387. *See* GAO SCIENTIFIC INTEGRITY REPORT, *supra* note 375.

388. As of April 2022, neither the FDA, the CDC, nor the NIH had procedures specific to reporting and addressing political interference in agency scientific decisionmaking. *See id.* at 13; *see also* Karl S. Bourdeau, *Information Quality Act Challenges to Flawed Use of Science*, 19 NAT'L RES. & ENV'T. 41, 46–47 (2005) (noting concerns about the IQA imposing an "unwarranted burden on limited agency resources"); Letter from Eddie Bernice Johnson, Chairwoman, Comm. on Sci., Space & Tech., to Russel Vought, Acting Dir., Off. Mgmt. & Budget (June 13, 2019), https://science.house.gov/imo/media/doc/6.13.19%20Letter%20to%20Acting%20Director%20Vought.pdf [https://perma.cc/Y8HM-CY43] ("[W]e are concerned that the Memorandum's new requirements for addressing [Requests for Correction] would create a significant burden of new responsibilities for federal agencies.").

389. For example, in the Plan B scenario discussed in Section II.A.1, the SIO's report would be sent directly to the FDA and to Plan B's manufacturer, as well as to the party who requested the review.

and included in documents published by the FDA (e.g., in the Agency's decision memorandum).[390]

In addition to mitigating covert executive interference, prohibiting off-the-record communications addresses concerns about procedural fairness that might arise when drug sponsors are not privy to communications that affect decisions about their products. If a degree of executive involvement remains appropriate in certain situations—provided it does not amount to undue interference—there seems little reason for it to occur in a covert fashion. As noted, appropriate exceptions or redactions (e.g., for national security or to protect trade secrets) would be available, but such exceptions should be read narrowly. Full transparency must be the default.

Congress should also consider codifying, with certain modifications, aspects of President Biden's Scientific Integrity memo and other reports since issued by the government.[391] This will ensure they remain in place after he leaves office. These include requiring agencies to:

- Develop and periodically update a publicly available scientific integrity policy.[392]
- Develop and document internal procedures for reporting and addressing potential political interference in scientific decisionmaking.[393]
- Designate a "Chief Science Officer," responsible for scientific issues relating to agency research programs, and a "Scientific Integrity Official," responsible for scientific integrity policies and procedures. Both must be career employees and not political appointees.[394]
- Conduct mandatory and ongoing education and training of agency personnel about scientific integrity policies, including how to report suspected violations, and provide protections for those who report violations.[395] All agency personnel, including senior leaders and political appointees, should receive training tailored to their specific roles.
- Publish an annual report on the agency's website with the number of investigations and appeals involving alleged

390. Even when the detailed substance of a discussion must be withheld, the occurrence of the discussion could generally still be noted in the record.

391. *See, e.g.*, GAO SCIENTIFIC INTEGRITY REPORT, *supra* note 375; SCI. INTEGRITY FAST-TRACK ACTION COMM., *supra* note 117.

392. Biden Scientific Integrity Memo, *supra* note 363, § 3(b).

393. GAO SCIENTIFIC INTEGRITY REPORT, *supra* note 375, at 18.

394. Biden Scientific Integrity Memo, *supra* note 363, § 6.

395. *Id.* § 3(c)(v); GAO SCIENTIFIC INTEGRITY REPORT, *supra* note 375, at 18.

deviations from the agency's scientific-integrity policies, and the resolution of those cases, if completed.[396]

Like any solution, the SIO is not perfect and involves tradeoffs.[397] But through its combination of statutory protections and enhanced oversight over myriad sources of capture, it arguably provides the best option to achieve the goals of accountability, credibility, and public trust. It also addresses limitations of other mechanisms, such as those described above, as well as congressional and judicial oversight, which might also be considered as means to uncover, mitigate, and thwart executive interference in agency scientific decisionmaking. As Professor Harold Koh astutely stated, "[t]o thrive in a global world, we need an energetic executive, to be sure, but checked by an energetic Congress and overseen by a searching judicial branch."[398] As discussed next, while there are advantages to relying on these existing mechanisms, there are also clear limitations. Interbranch dynamics can undermine, rather than enhance, accountability, credibility, and public trust.[399] Thus, new mechanisms, such as the SIO, must be considered.

Importantly, the SIO represents *part* of the solution, not *the* solution. The mechanisms that follow remain important components of any approach to mitigating executive interference, and the SIO does not intend to replace them. Rather, a combination approach should be considered because no approach will solve the issue of executive interference on its own, and existing mechanisms have proven inadequate. The SIO thus represents a new and valuable tool to

396. Biden Scientific Integrity Memo, *supra* note 363, § 3(c)(vi).

397. For example, although the SIO's structure and processes for uncovering, reporting, and investigating executive interference aim to increase the likelihood such interference will be uncovered, there is no guarantee that the creation of the SIO will uncover all covert executive interference, given the many mechanisms presidents possess to shield their influence from public view. *See* Coglianese, *The Emptiness of Decisional Limits*, *supra* note 92, at 69–75. And of course, the creation and maintenance of the SIO, as well as the SIO's ability to perform its functions well, require a strong commitment from the rest of the government—now and in the future—to support the SIO and its work through adequate funding and other resources. Such ongoing support and funding cannot be guaranteed, particularly if a future administration places less value on scientific integrity.

398. Harold Hongju Koh, *Setting the World Right*, 115 YALE L.J. 2350, 2354 (2006); *see also* Nadine Strossen, *Problematic Post 9/11 Judicial Inactivism: Immunizing Executive Branch Overreaching*, *in* CONFRONTING TERROR: 9/11 AND THE FUTURE OF AMERICAN NATIONAL SECURITY 229, 233 (Dean Reuter & John Yoo eds., 2011) ("Conduct that the courts do not halt may proceed unimpeded.").

399. As Professor Schlanger notes, many observe that "the power of the presidency has expanded to the point that tripartite separation of powers model, which relies on Congress and the courts to rein in the Executive Branch, may not be up to the task." Schlanger, *supra* note 362, at 59.

mitigate and prevent executive interference in agency scientific decisionmaking.

B. Congressional Oversight and Investigation

To control improper executive interference, some may ask: Why not simply rely on Congress's authority to oversee and investigate the executive and the implementation of laws and public policy?[400] Implicit in Congress's constitutional power to make laws lies the power to ensure they are faithfully executed. Myriad Supreme Court decisions, laws, and congressional rules further inform this authority.[401] Congressional oversight and investigation can increase transparency and public awareness and provide the public with information needed to hold the executive accountable.[402] At its best, scholars suggest congressional oversight is "matchless in its importance,"[403] "can have wide-ranging effects on a presidential administration,"[404] and "can lead to genuine changes in public policy."[405] This authority creates tension between the legislative and executive branches,[406] but such tension is a necessary feature of our tripartite system of government.

Existing committees, including subcommittees and select and special subcommittees, currently oversee and investigate the executive branch on many issues. These committees could therefore oversee and investigate executive interference in agency scientific decisionmaking that inhibits an agency's ability to achieve its statutorily defined missions, provided the issue falls within the committee's jurisdiction. Alternatively, Congress could create a select or special subcommittee

400. CHRISTOPHER M. DAVIS, TODD GARVEY & BEN WILHELM, CONG. RSCH. SERV., RL30240, CONGRESSIONAL OVERSIGHT MANUAL 1 (Mar. 31, 2021), https://sgp.fas.org/crs/misc/RL30240.pdf [https://perma.cc/D5X8-RS9R].

401. *See id.* at 6–17, 26 (providing an overview of Congress's oversight authorities); Andrew McCanse Wright, *Constitutional Conflict and Congressional Oversight*, 98 MARQ. L. REV. 881, 893–901 (2014) (describing various sources of Congress's authority to conduct oversight).

402. *Cf.* Charles Tiefer, *Congressional Oversight of the Clinton Administration and Congressional Procedure*, 50 ADMIN. L. REV. 199, 216 (1998) ("For all its shortcomings . . . there is no substitute for congressional oversight in our democracy. Without it, our public life would be considerably impoverished."); Wright, *supra* note 401, at 902–03 (describing various purposes of congressional oversight).

403. Tiefer, *supra* note 402, at 215.

404. Frances E. Lee, *Presidents and Party Teams: The Politics of Debt Limits and Executive Oversight, 2001-2013*, PRESIDENTIAL STUD. Q. 775, 784 (2013).

405. Douglas Kriner, *Can Enhanced Congressional Oversight Fix "the Broken Branch"?*, 89 B.U. L. REV. 765, 773 (2009).

406. *See generally* LOUIS FISHER, CONSTITUTIONAL CONFLICTS BETWEEN CONGRESS AND THE PRESIDENT (Univ. Press of Kan., 6th ed. 2014); Wright, *supra* note 401, at 893–94, 897 (arguing that Congress and the executive operate with fundamentally different, and largely incompatible, views of Congress's oversight authorities).

focused exclusively on overseeing and investigating executive interference in agency science. This would mimic the House Select Subcommittee on the Coronavirus Crisis[407] but would extend beyond COVID-19 to facilitate continual oversight of non-COVID matters.

The benefits of relying on existing authorities include relatively minimal start-up and implementation costs. Congressional oversight and investigation are established, generally accepted, broad, and far-reaching practices.[408] When effective, congressional oversight can "expose[ ] instances of agency neglect and even corruption" and root out "destructive forces within the agency."[409] But even with such clear authority and potential benefits, congressional oversight does not always materialize in checks on executive branch overreach at the agency level. There are at least five limitations to this approach that the SIO would aim to eliminate or mitigate.

First, committees, and the actions they take, tend to be partisan.[410] A wealth of scholarship shows a correlation between divided government and the volume and intensity of congressional oversight.[411] Effective oversight first requires a member with sufficient interest and investment in the issue to seek information or call for an investigation. Thereafter, committee actions depend heavily on the cooperation of other members and the administration, which will be influenced by the makeup of the committee and the party of the administration. Thus, even if the intensity of oversight increases with a divided government, polarization and partisanship can inhibit effective oversight.[412] Members of the President's party may refuse to

407. *See* SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS, *supra* note 266.

408. *See, e.g.*, Trump v. Mazars USA, 140 S. Ct. 2019, 2031 (2020) ("The congressional power to obtain information is 'broad' and 'indispensable.' " (quoting Watkins v. United States, 354 U.S. 178, 187, 215 (1957))); *see also* MORTON ROSENBERG, CONG. RSCH. SERV., 95-646, INVESTIGATIVE OVERSIGHT: AN INTRODUCTION TO THE LAW, PRACTICE AND PROCEDURE OF CONGRESSIONAL INQUIRY 2 (Apr. 7, 1995), https://digital.library.unt.edu/ark:/67531/metadc26092/m1/1/high_res_d/95-464_1995Apr07.pdf [https://perma.cc/VT6D-TJ5S].

409. Richard J. Lazarus, *The Neglected Question of Congressional Oversight of EPA:* Quis Custodiet Ipsos Custodes (*Who Shall Watch the Watchers Themselves?)*, 54 LAW & CONTEMP. PROBS. 205, 226 (1991).

410. *Cf.* Lee, *supra* note 404, at 779 ("[A]lmost anything that helps a president politically is harmful to the political interests of his opposition party in Congress. By the same token, anything that harms a president politically will generally redound to the opposition party's political benefit."); *id.* at 787 ("[P]atterns in congressional oversight of the president leave no doubt that partisan interests drive congressional behavior."); *see also* Wright, *supra* note 401, at 886–89 (noting the partisan character of oversight and investigation).

411. *See* Wright, *supra* note 401, at 886 n.19, 886–89, 903.

412. Professor Lee notes that even when the values at stake are universal, "it is manifestly evident that" certain issues are "pursued in Congress for partisan purposes" and, in some cases, members of the President's party refuse to acknowledge scandals. Lee, *supra* note 404, at 786.

cooperate or acknowledge possible improprieties, accusing the other party of "manufactur[ing]" a crisis or conducting a "witch hunt" or "fishing expedition."[413] Making a highly partisan issue such as executive interference even more partisan and polarizing through congressional oversight and investigation raises doubts that it will engender public trust and confidence in the process or results.

Second and relatedly, the partisan and constituency interests of individual members "usually prevent them from acting collectively to preserve congressional power—or, what is almost the same thing, to deny authority to the other branches of government."[414] Indeed, "too often, partisan incentives to support a President of the same party trump institutional incentives to defend Congress's institutional prerogatives by vigorously overseeing the actions of the executive branch."[415] Scholars suggest that when the President's party controls Congress ("unified government"), congressional investigatory activities are particularly muted.[416] Professors Douglas Kriner and Liam Schwartz, for example, found that a shift from a unified to divided government resulted in a five-fold increase in the number of congressional hearings and quadrupled their duration.[417] Moreover, "institutional analysis, like history, suggests a fair degree of leeway from [Congress] for presidential attempts to direct administrative policies."[418]

Third, creating a new select subcommittee requires a vote. Therefore, particularly during a unified government, it may prove difficult to establish a committee specifically tasked with overseeing executive interference.[419] Without the establishment of a select subcommittee to investigate excessive executive-level interference in agency processes and rulemaking, the chances of mitigation decrease significantly.

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413. *Id.*; *see also* Christina Marcos, *House Votes to Create Select Subcommittee to Oversee Coronavirus Response*, THE HILL (Apr. 23, 2020, 4:42 PM), https://thehill.com/homenews/house/494340-house-votes-to-create-select-committee-to-oversee-coronavirus-response [https://perma.cc/5A72-S2GU] (noting that some Republican lawmakers viewed the Select Subcommittee on the Coronavirus Crisis as "an attempt to find ways to make the president look bad ahead of the November election").

414. Kagan, *supra* note 14, at 2314.

415. Kriner, *supra* note 405, at 783.

416. *Id.* at 782–84.

417. Douglas Kriner & Liam Schwartz, *Divided Government and Congressional Investigations*, 33 LEGIS. STUD. Q. 295, 307 (2008).

418. Kagan, *supra* note 14, at 2315; *see also* Koh, *supra* note 398, at 2359 (discussing the War on Terror and noting Congress's general failure to stand up to the President's assertions of unilateral power).

419. Unsurprisingly, the House voted almost entirely along party lines to create the Select Subcommittee on the Coronavirus Crisis. Marcos, *supra* note 413.

Fourth, many existing committees have potential jurisdiction over these issues. Thus, absent the creation of a specific committee with sole jurisdiction, a coordinated and efficient approach could be difficult. Fragmented and uncoordinated oversight can push agencies in opposite directions or in ways that contradict agencies' missions.[420]

Fifth, one must ask "who shall watch the watchers themselves?"[421] Congress, and its individual members, are subject to capture and may also interfere in agency decisions.[422] Many Americans lack confidence in Congress[423] and some scholars describe it as "the broken branch."[424] As observed by Professor Andrew McCanse Wright:

> Social science literature and public policy commentary are rife with lamentations that Congress has abdicated its oversight responsibilities to the benefit of a growing and unchecked Executive Branch. Some commentators suggest that there are significant disincentives to conducting robust oversight. It can be an unpleasant experience. Others take the view that congressional structure and incentives lead to emphasis on less meaningful oversight.[425]

Further, the intensity of Congressional oversight varies over time, like "a swinging pendulum."[426] Therefore, leaving Congress with

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420. Having dozens of committees with jurisdiction over homeland security, for example, resulted in a "dysfunctional" system of oversight. Fights over jurisdiction hindered Congress's ability to "focus on national security problems and protect[ ] American lives." Joan V. O'Hara, James A. Murphy, II, Jacobus A. Vreeburg, Steven Giaier, Derek Maurer, Michael Geffroy & Tyler K. Lowe, *Turf Wars: How a Jurisdictional Quagmire in Congress Compromises Homeland Security*, 18 LEGIS. & PUB. POL'Y 1, 5 (2015). Those same issues could recur with oversight of executive interference in agency science, preventing Congress from focusing on what matters: scientific integrity and public health. *But see* Anne Joseph O'Connell, *The Architecture of Smart Intelligence: Structuring and Overseeing Agencies in the Post-9/11 World*, 94 CALIF. L. REV. 1655, 1731 (2006) (arguing that redundancy can be beneficial).

421. Lazarus, *supra* note 409.

422. *Id.* at 220 ("[T]o influence agency behavior, an interest group may try to persuade a subcommittee chair to hold an oversight hearing at which the group could air its concerns."); *see also* Seymour Scher, *Conditions for Legislative Control*, 24 J. POL. 526, 534 (1963) ("[A] committee member's concern for promoting and protecting interests that are subject to agency regulation will incline him to leave the agency alone if those interests are not faring badly."); *supra* note 11.

423. A 2021 poll found that forty-seven percent of Americans had "very little" confidence in Congress, and only twelve percent had a "great deal" (five percent) or "quite a lot" (seven percent) of confidence. In comparison, sixty-four percent had a "great deal" (thirty-five percent) or "quite a lot" (twenty-nine percent) of confidence in science, and only eleven percent had "very little." *Confidence in Institutions*, GALLUP (2021), https://news.gallup.com/poll/1597/confidence-institutions.aspx [https://perma.cc/KY6V-2XG5].

424. *See, e.g.*, NORMAN ORNSTEIN & THOMAS E. MANN, THE BROKEN BRANCH: HOW CONGRESS IS FAILING AMERICA AND HOW TO GET IT BACK ON TRACK (2006); Kriner, *supra* note 405.

425. Wright, *supra* note 401, at 906; *see also* Russ Feingold, *It's Time to Tear Up the Executive Branch's Blank Check*, BRENNAN CTR. FOR JUST. (July 22, 2021), https://www.brennancenter.org/our-work/analysis-opinion/its-time-tear-executive-branchs-blank-check [https://perma.cc/TP2L-ABB9] (arguing that Congress has abandoned its oversight responsibilities in the context of national security).

426. Kriner, *supra* note 405, at 775; *id.* at 776 (noting inconsistent use of committee hearings).

the responsibility for oversight of executive interference in agency science will likely result in inconsistent oversight that fails to promote accountability, credibility, and public trust.

Creating a new committee with exclusive jurisdiction over the issue would mitigate some, but not all, of the enumerated limitations.[427] Congress would likely need to amend the jurisdictions of other committees to clarify a new committee's sole jurisdiction. Doing so would reduce duplication and avoid the pitfalls of relying on a fragmented, multicommittee approach. Nevertheless, the SIO remains superior because it will not face the same partisan roadblocks and infighting as congressional oversight and investigation, and it would also have the authority to oversee congressional interference in agency scientific decisionmaking. The SIO's nonpartisan structure; authority to oversee interference in agency scientific decisionmaking from myriad sources, including Congress; and its authority to initiate an investigation without a request or approval from Congress remain preferable given the partisan and politicized nature of congressional oversight described above.

C. Judicial Oversight

If congressional oversight and investigation are insufficient, what about judicial review? Courts demonstrate a long history of reviewing agency decisions under different levels of deference,[428] and the judiciary undoubtedly possesses the authority to address agency actions and inactions, including those involving political interference.[429] The district court's Plan B decisions discussed in Part II.A. provide a prime example of a judicial check on executive interference, which the court accomplished by probing the record thoroughly to determine whether politics unduly influenced the FDA's decisions. *Massachusetts v. EPA* offers perhaps one of the best examples from the Supreme Court. In that case, the Court held that the EPA failed to justify adequately its denial of a petition for rulemaking relating to greenhouse gas emissions that was filed by private plaintiffs and a coalition of states.[430] Among other reasons, the EPA argued that it lacked authority to set

427. *Cf.* O'Hara et al., *supra* note 420, at 5 (arguing for the consolidation of congressional authority over homeland security to one committee in the House and one in the Senate).

428. *See, e.g.*, Auer v. Robbins, 519 U.S. 452 (1997); Chevron v. Nat'l Res. Def. Council, Inc., 467 U.S. 837 (1984); Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945).

429. Professors Freeman and Vermeule, for example, discuss a period during which the Court's majority appeared to be increasingly concerned about executive interference in agency expertise. *See* Freeman & Vermeule, *supra* note 28. As discussed in this Article, however, covert executive interference is hard to prove and, thus, not often addressed in court decisions.

430. 549 U.S. 497, 534 (2007).

greenhouse gas emission standards because of the "great[ ] economic and political repercussions" of doing so.[431] According to the EPA, Congress needed to speak with "exacting specificity" before the EPA could regulate greenhouse gases.[432] In the majority's view, however, the EPA impermissibly based its decision not to regulate greenhouse gases on political preferences, rather than its evaluation of relevant science.[433] Likely important to the Court's review and conclusions, this case arose amidst growing concerns about the second Bush Administration's widespread meddling in agency science, especially global warming.[434]

Food and Drug Administration v. Brown & Williamson Tobacco Corporation provides another example.[435] There, the Supreme Court took on agency action rather than inaction, holding that the FDA overstepped its authority by regulating the sale of tobacco products to children and adolescents. The regulations represented a major shift from the Agency's longstanding view that it lacked jurisdiction over tobacco products, and they were promulgated under the Clinton Administration in pursuit of a major goal of President Clinton's agenda: reducing youth smoking.[436] The Court acknowledged the "seriousness of the problem" but held that, considering the FDCA as a whole in conjunction with other tobacco-specific legislation, Congress, "for better or for worse," plainly had not granted the FDA authority to regulate tobacco products as customarily marketed.[437] Although the Court did not mention political interference, an essential takeaway from this case is that the FDA cannot overstep its congressionally defined authorities even when it would align with presidential preferences or would otherwise be wise to do so.

Judicial review takes on particular importance during national emergencies, such as wars or pandemics. In such times, "when the public mind is agitated, when . . . conspiracies and treasons excite alarm, it is the duty of a court to be peculiarly watchful . . . [and] to poise the scales of justice, unmoved by the arm of power, undisturbed

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431. *Id.* at 512.

432. *Id.*

433. *Id.* at 533–34.

434. For further discussion about the political, legal, and cultural context in which the case arose, see Freeman & Vermeule, *supra* note 28, at 54–64.

435. 529 U.S. 120 (2000).

436. Prior to this point, the FDA "repeatedly and consistently assert[ed] that it lacks jurisdiction" to regulate tobacco products. *Id.* at 156.

437. *Id.* at 159, 161. Later amendments to the FDCA provided the FDA with certain authority to regulate tobacco products. *See, e.g.*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

by the clamor of the multitude."[438] Yet, despite the judiciary's ability to constrain agencies that overstep their congressionally provided authorities, the courts are not infallible. Throughout history, courts have shown great deference, sometimes inappropriately so, to the executive branch during times of war or to protect national security. Thus, even as they play a crucial role in this domain, courts do not always live up to the "peculiarly watchful" standard. Nor are they necessarily reliable, accessible, or consistent. Importantly, absence of a court decision condemning presidential behavior cannot itself vindicate a president's actions.[439] There are many judicial doctrines courts rely on to avoid a full assessment of executive wrongdoing, including standing, deference to the President, refusal to consider "political questions," and numerous privileges.[440] Some scholars even suggest courts are "derelict" in their duty to supervise the executive branch.[441] As a result of these factors and other limitations described below, courts alone are unlikely to enhance accountability, credibility, and public trust.

First, although courts should be nonpartisan, they are routinely and increasingly criticized for making policy[442] and "imposing their political preferences in defiance of settled law," thereby "mangling the Constitution."[443] In recent years, critics, and even some of the Justices,[444] have condemned the politicization of the Court and the

438. United States v. Bollman, 24 F. Cas. 1189 (C.C.D.D.C. 1807) (No. 14,622).

439. Dawn Johnsen, *Toward Restoring Rule-of-Law Norms*, 97 TEX. L. REV. 1205, 1206 (2020).

440. *Id.*; McCormack, *supra* note 96, at 328–401 (reviewing six doctrines courts used to avoid reviewing counterterrorism policies); Stephen I. Vladeck, *The Demise of Merits-Based Adjudication in Post-9/11 National Security Litigation*, 64 DRAKE L. REV. 1035, 1040–73 (2016) (enumerating twelve doctrines or other obstacles courts relied on to avoid resolving lawsuits challenging post-9/11 national security or counterterrorism policies).

441. David E. Bernstein, *The Abuse of Executive Power: Getting Beyond the Streetlight Effect*, 11 FIU L. REV. 289, 289 (2016); *see* McCormack, *supra* note 96 (arguing that the judiciary has virtually relinquished its valuable role of judicial review in holding the executive branch accountable); Strossen, *supra* note 398, at 233–35 (noting cases where the court did not exercise judicial review of executive branch actions after 9/11).

442. *See, e.g.*, Ian Millhiser, *What Trump Has Done to the Courts, Explained*, VOX, https://www.vox.com/policy-and-politics/2019/12/9/20962980/trump-supreme-court-federal-judges (last updated Sept. 29, 2020, 10:32 PM) [https://perma.cc/Y572-AXNG]; Tim Roemer & Derek Kilmer, *Congress Must Reclaim Its Article I Powers in Order to Earn Back Public Trust*, THE HILL (Nov. 30, 2020, 9:00 AM), https://thehill.com/blogs/congress-blog/politics/527927-congress-must-reclaim-its-article-i-powers-in-order-to-earn-back?rl=1 [https://perma.cc/BRT8-VMB6].

443. Jack M. Balkin, *Why Liberals and Conservatives Flipped on Judicial Restraint: Judicial Review in the Cycles of Constitutional Time*, 98 TEX. L. REV. 215, 237 (2019).

444. During oral arguments for *Dobbs v. Jackson Women's Health Organization*, which addressed Mississippi's fifteen-week abortion ban, Justice Sotomayor noted the danger of the Court's apparent change on abortion rights and the rule of law more generally, asking whether the Court will "survive the stench that this creates in the public perception that the Constitution and its reading are just political acts?" *See* Transcript of Oral Argument at 15, Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022) (No. 19-1392),

Court's increasing and arguably improper use of emergency orders (the "shadow docket").[445] Unsurprisingly, court decisions are increasingly polarizing and viewed with skepticism. The perception of a politicized judiciary inhibits courts' ability to engender public trust.[446] A nonpartisan SIO, with officials and employees not beholden to any president or political ideology—unlike Article III judges who are nominated by the President and confirmed by the Senate in an increasingly politicized process—helps mitigate this problem.

A second and significant limitation involves the many hurdles that litigants must overcome to access the courts.[447] Litigants must first initiate and take on the substantial time and cost of litigation. They must then overcome barriers such as standing, mootness, and ripeness. Such obstacles may prove insurmountable, and courts may use them to avoid review. Moreover, if executive interference does not ultimately influence the agency's decision, no case transpires. In such a case, some might argue there exists no need for judicial review—"no harm, no foul"—but there remains value in knowing whether executive interference occurred because transparency can enhance accountability, credibility, and trust. There would be no such procedural hurdles with the SIO, which would provide as much, if not more, transparency as judicial review. Further, the SIO's review would not hinge on whether the executive interference ultimately impacted an agency decision.

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https://www.cnn.com/2021/12/01/politics/read-transcript-dobbs-jackson-womens-health/index.html [https://perma.cc/G4HB-EC8Y]; Pilkington, *supra* note 160.

445. *See, e.g.*, Louisiana v. Am. Rivers, 142 S. Ct. 1347, 1349 (2022) (Kagan, J., dissenting) (arguing that the majority again defied the requirements for granting emergency relief, rendering the Court's "emergency docket not for emergencies at all" but rather "only another place for merits determinations—except made without full briefing and argument"); Stephen I. Vladeck, Opinion, *Roberts Has Lost Control of the Supreme Court*, N.Y. TIMES (Apr. 13, 2022), https://www.nytimes.com/2022/04/13/opinion/john-roberts-supreme-court.html [https://perma.cc/L53C-VEJA] (discussing the Court's use of the shadow docket); Moira Donegan, *The US Supreme Court Is Deciding More and More Cases in a Secretive 'Shadow Docket*,' GUARDIAN, https://www.theguardian.com/commentisfree/2021/aug/31/supreme-court-us-cases-shadow-docket (last updated Sept. 1, 2021, 2:36 PM) [https://perma.cc/5Y2T-KBQG].

446. For example, a July 2022 survey conducted after the June 2022 decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), found that forty-three percent of Americans have "hardly any confidence at all" in the Supreme Court, up from twenty-seven percent in April 2022. *Americans Have Lost Confidence in the Supreme Court*, AP-NORC (July 25, 2022), https://apnorc.org/projects/americans-have-lost-confidence-in-the-supreme-court/ [https://perma.cc/ADH8-N8C9]. In a September 2021 poll, confidence in the entire federal judiciary (i.e., all levels of the federal court system) was just one point higher (fifty-four percent) than its previous low of fifty-three percent in 2015. *See* Jeffrey M. Jones, *Approval of U.S. Supreme Court Down to 40%, a New Low*, GALLUP (Sept. 23, 2021), https://news.gallup.com/poll/354908/approval-supreme-court-down-new-low.aspxv [https://perma.cc/7NY5-XG35].

447. *See* Bernstein, *supra* note 362, at 1410–11 (noting some of the "problem[s] with relying on courts to discipline agencies").

Third, if a case makes it to court, an agency may cobble together sufficient reasoning to support its decision, even if executive interference provided the true motive. This is particularly likely with covert interference. Therefore, even if executive interference drove the agency's decision, this may not matter:

> [W]hat if the reason the agency gives is itself a lawful reason? What if the reason the agency gives is also supported by the relevant factual evidence? Does it matter, then, if the agency's stated reason is not its true reason?
>
> Surprisingly, the answer may be no. In its widely discussed decision in *Sierra Club v. Costle*, the D.C. Circuit held that ex parte contacts with White House personnel (including the President) regarding a rulemaking proceeding not only need not be disclosed, but that the "undisclosed Presidential prodding" could "direct an outcome that is factually based on the record, but different from the outcome that would have obtained in the absence of Presidential involvement." So long as the public record compiled for the rule actually supported the ultimate decision, the rule could stand.[448]

Fourth and relatedly, courts consistently decline to, or say they cannot, "probe the mental processes of the [administrator]."[449] Thus, even when executive interference seems undeniable, if the agency puts forth a valid nonpolitical reason for the decision, courts may look no further. Uncovering the truth may require "atypical interventions," which courts may be unwilling to undertake.[450] As a result, covert interference continues, shielded from the public eye, thus hindering the public's ability to hold the executive accountable. Unlike judicial review, the SIO would not be limited to a party's on-the-record arguments and documents. On the contrary, the SIO should be expected to "probe the mental processes" of the relevant actors and would have the authority to request and review any information deemed relevant and necessary to its inquiry.

Last, courts frequently hesitate to intrude in certain contexts, such as executive actions involving foreign policy or national security.[451]

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448. *See* Heinzerling, *supra* note 128, at 973 (quoting Sierra Club v. Costle, 657 F.2d 298, 408 (D.C. Cir. 1981)).

449. United States v. Morgan, 313 U.S. 409, 422 (1941) (quoting Morgan v. United States, 304 U.S. 1, 18 (1938)); *see also* Kent Corp. v. N.L.R.B., 530 F.2d 612, 620–21 (5th Cir. 1976) (applying the *Morgan* precedent to the National Labor Relations Board's prosecutorial processes); Nat'l Nutritional Ass'n v. F.D.A., 491 F.2d 1141, 1144–46 (2d Cir. 1974) (finding insufficient evidence of bad faith to warrant further inquiry of the FDA Commissioner's decision given the *Morgan* prohibition on probing the mental process of decisionmakers); Nat'l Courier Ass'n v. Bd. of Governors of Fed. Rsrv. Sys., 516 F.2d 1229, 1242 (D.C. Cir. 1975) (citing *Morgan*, 313 U.S. at 422).

450. *See* Heinzerling, *supra* note 128, at 929.

451. *See, e.g.*, Arar v. Ashcroft, 585 F.3d 559, 575 (2d Cir. 2009) ("The Supreme Court has expressly counseled that matters touching upon foreign policy and national security fall within 'an area of executive action "in which courts have long been hesitant to intrude" ' absent congressional authorization." (quoting Lincoln v. Vigil, 508 U.S. 182, 192 (1993)); Ctr. for Nat'l Sec. Stud. v. U.S. Dep't of Just., 331 F.3d 918, 928 (D.C. Cir. 2003) ("[T]he judiciary is in an extremely poor position to second-guess the executive's judgment in [the] area of national security.").

For example, shortly after the terrorist attacks of September 11, 2001, federal courts generally "accepted as Gospel" the executive branch's reasoning and "universally acquiesced" to the second Bush Administration about the President's inherent constitutional war powers.[452] Critics argued that the judiciary "abdicated one of its core constitutional functions" by invoking various doctrines to avoid deciding cases on the merits.[453] Yet the lack of judicial review did not mean the underlying actions were lawful.[454] Rather, the absence of review resulted from obstacles that courts viewed—sometimes unnecessarily or inappropriately—as barring them from reaching the merits.[455] The Supreme Court showed similar deference when it reviewed a nationwide preliminary injunction that prevented enforcement of President Trump's "Travel Ban." The five-Justice majority applied the highly deferential rational basis review and vacated the injunction.[456]

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452. Andrew Cohen, *Justice in a Time of Terror: Bending the Branches*, ATLANTIC (Sept. 2, 2011), https://www.theatlantic.com/national/archive/2011/09/justice-in-a-time-of-terror-bending-the-branches/244343/ [https://perma.cc/9VXQ-B26H]. *See generally* Vladeck, *supra* note 440, at 1040–73. The Obama Administration similarly asserted several nonjusticiability arguments. Strossen, *supra* note 398, at 231, 316–17 nn.5–8.

453. Cohen, *supra* note 452; *see also* McCormack, *supra* note 96; Strossen, *supra* note 398, at 234; Vladeck, *supra* note 440, at 1037–38. Over time, some courts took a more probative and less deferential approach as they "notice[d] a gulf between what executive branch officials were asserting in court and what the objective truth was revealing beyond the courtroom." Cohen, *supra* note 452; *see also* Koh, *supra* note 398, at 2360 (describing the Supreme Court's decision in *Hamdan v. Rumsfeld* as a "signal that the pendulum is finally swinging away from institutional acquiescence in executive overreaching"). Furthermore, when the Supreme Court *did* decide cases on the merits (e.g., *Hamdan v. Rumsfeld*), it sometimes curbed executive overreach. Strossen, *supra* note 398, at 233.

454. Vladeck, *supra* note 440, at 1040–68. As Strossen notes:

> The dangers of judicial inactivism are not obvious because they are couched in rulings that do not substantively address the violations at issue, let alone expressly reject the legal challenges on the merits. Instead, the rulings invoke various justiciability doctrines that preclude the courts from resolving the claims. The result is that plaintiffs' complaints are simply dismissed, which has the same practical impact as a negative ruling on the merits: the plaintiffs receive no relief, the defendants are free to proceed with their challenged conduct, and no judicial sanction deters. The justiciability doctrines are judicially created, defined by vague criteria, and unpredictably and inconsistently applied. Critics—including Supreme Court Justices—complain that judges can too easily invoke these doctrines to reject substantively disfavored claims without having to rule on the merits.

Strossen, *supra* note 398, at 230; *see also* McCormack, *supra* note 96, at 306 ("Time and again, challenges to assertedly illegal conduct on the part of government officials have been turned aside, either because of overt deference to the government or because of special doctrines such as the state secrets privilege and standing requirements.").

455. Vladeck, *supra* note 440, at 1037, 1041.

456. Trump v. Hawaii, 138 S. Ct. 2392 (2018); *see also* Johnsen, *supra* note 439, at 1209 ("Rather than closely scrutinizing the President's action in light of the evidence of discriminatory motivation, the Court held it would consider the question only behind a veil of deference to the

The judiciary took a similarly deferential approach in certain cases during the COVID-19 pandemic.[457] As described in Section II.A.2, for example, the Supreme Court allowed the FDA to continue enforcing the in-person mifepristone requirements during COVID-19. In doing so, Chief Justice Roberts stated "[h]ere as in related contexts concerning government responses to the pandemic, my view is that courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.' "[458] Deference serves an important role in many situations, but the Court granted this deference despite a record "bereft of any reasoning" to support the government's decision.[459] Too much deference produces problematic results[460] and raises serious questions about relying on courts to serve as an adequate and consistent check on executive interference.

President . . . given that the President's national-security rationale sufficed to survive that minimal review."). President Trump tried to take advantage of this deference when he declared a national emergency on the Mexico border to access funds denied by Congress. President Trump referenced his likelihood of prevailing in court when he stated:

> [T]hey will sue us in the Ninth Circuit even though it shouldn't be there, and we will possibly get a bad ruling, and then we'll get another bad ruling, and then we'll end up in the Supreme Court and hopefully we'll get a fair shake and we'll win in the Supreme Court just like the [Travel] Ban.

PBS NewsHour, *WATCH: 'We'll End Up in the Supreme Court,' Trump Predicts for Emergency Declaration,* YOUTUBE (Feb. 15, 2019), https://youtu.be/lYqkzWGWkiE [https://perma.cc/A6YG-QXAA].

457. *See, e.g.*, Erwin Chemerinsky & Michele Goodwin, *Civil Liberties in a Pandemic: The Lessons of History*, 106 CORNELL L. REV. 815 (2021) (expressing concern about deference shown to the government during COVID-19); Lindsay F. Wiley, *Democratizing the Law of Social Distancing*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 50, 56 (2020) (noting that early in the pandemic, most courts "were hesitant to second-guess executive decisions made under conditions of scientific uncertainty and great peril. On the whole, they took a very forgiving stance toward sweeping public health responses").

458. F.D.A. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 579 (2021) (Roberts, J., concurring).

459. *Id.* at 584 (Sotomayor, J., dissenting). Strossen observes:

> Even assuming that a national crisis can justify the executive branch's most vigorous exercise of its power to protect the nation, the judicial branch would then have a countervailing duty to exercise its judicial review power with corresponding vigor, to ensure that the executive branch does not overstep its power or violate individual rights.

Strossen, *supra* note 398, at 232.

460. *Cf.* Chemerinsky & Goodwin, *supra* note 457 (arguing that the use of the deferential standard of review set forth in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), during a pandemic grants too much deference to the government and can significantly threaten liberty); McCormack, *supra* note 96, at 314 ("The failure to stand up for the little guy is what concerns me about the role of the courts and their loss of judicial independence."); Sherwin, *supra* note 28, at 95 ("[W]e must question whether deference is even necessary if the agency is no longer relying on scientific evidence.").

There is no guarantee that the SIO, or any other entity for that matter, would not be similarly inclined to defer to the executive in certain situations. That said, the SIO's explicit charge and authorization from Congress to review matters of executive interference should help clarify that the SIO is expected to probe executive actions. Furthermore, the SIO's review could take into consideration extenuating circumstances, such as national emergencies, which may justify greater executive involvement in agency decisionmaking than would otherwise be expected or acceptable.

D. Restructuring the FDA as an Independent Agency

Those concerned about political interference in FDA decisions have also suggested restructuring the FDA to make it an independent agency.[461] This idea has some merit, as Congress can design agencies in ways that seek to "insulate their decisions from presidential politics."[462] Nevertheless, there are drawbacks and reasons to doubt that an independent FDA would be less vulnerable to improper interference.

Importantly, independent agencies are not immune from executive interference. President Trump's efforts to push the Federal Trade Commission ("FTC") to take action against social media companies, who he alleged were censoring conservatives, provides one example. This represented "an unusually direct effort by a president to bend a legally independent agency to his agenda."[463] Concerns were also raised about President Trump's attempts to interfere with and influence the Federal Communications Commission ("FCC"), another

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461. *See, e.g.*, Robert M. Califf, Margaret Hamburg, Jane E. Henney, David A. Kessler, Mark McClellan, Andrew C. von Eschenbach & Frank Young, *Seven Former FDA Commissioners: The FDA Should Be An Independent Federal Agency*, 38 HEALTH AFFS. 84 (2019); Nisarg Patel, *It's Time to Make the FDA Independent*, POLITICO (June 17, 2020, 1:41 PM), https://www.politico.com/news/agenda/2020/06/17/independent-fda-hydroxychloroquine-326166 [https://perma.cc/E3TM-E3LE]; Matthew Perrone, *Former FDA Chief on the Case for a More Independent Agency*, L.A. TIMES (Aug. 16, 2021, 12:25 PM), https://www.latimes.com/science/story/2021-08-16/former-fda-chief-on-the-case-for-a-more-independent-agency [https://perma.cc/4G2V-U84R]. *But see, e.g.*, Lynch et al., *supra* note 116, at 189.

462. Verkuil, *supra* note 90, at 964 & n.109.

463. Leah Nylen, John Hendel & Betsy Woodruff Swan, *Trump Pressures Head of Consumer Agency to Bend on Social Media Crackdown*, POLITICO (Aug. 21, 2020, 6:40 PM), https://www.politico.com/news/2020/08/21/trump-ftc-chair-social-media-400104 [https://perma.cc/2J9P-8BQE]. These efforts were overt and covert, including (1) President Trump's executive order directing the FTC to "consider taking action . . . to prohibit unfair or deceptive acts or practices in or affecting commerce" and to consider whether complaints of online censorship "allege violations of law;" and (2) reports of a White House meeting with FTC Chair Joseph Simons. Exec. Order No. 13925, Preventing Online Censorship, 85 Fed. Reg. 34079 (May 28, 2020); Nylen et al., *supra*.

independent agency.[464] This is not a new problem, as President Reagan was also reported to have summoned Mark Fowler, then Chairman of the FCC, to a secret meeting at the White House to discuss FCC regulations known as the "Financial Interest and Syndication Rules."[465] Given this reality, an entity like the SIO would still be needed to review executive interference.

Relatedly, external capture of independent agencies remains possible. Restructuring the FDA as an independent agency will not reduce industry's interest in influencing agency decisions. On the contrary, it might render the agency more susceptible to external capture.[466] The fact that independent agencies remain vulnerable to both external and internal capture raises particular concerns because scholarship suggests that independent agencies receive less congressional oversight than executive agencies, thus weakening one important check on internal and external capture.[467] The SIO would thus still be needed to review improper interference, and the reforms proposed by this Article would further address these issues by prohibiting off-the-record communications and requiring various forms of transparency in agency decisionmaking.

Moreover, the constitutionality of independent agencies and the scope of the President's authority over independent agencies also remain under debate,[468] with Supreme Court precedent going both ways.[469] From a practical perspective, making the FDA an independent

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464. *See* Erik Wemple, Opinion, *Trump Forces FCC Chairman to Declare Loyalty to First Amendment*, WASH. POST (Oct. 17, 2017, 2:24 PM), https://www.washingtonpost.com/blogs/erik-wemple/wp/2017/10/17/news-blast-fcc-chairman-favors-the-first-amendment/ [https://perma.cc/M5SM-GRZG] (discussing the FCC chairman's response to President Trump's tweets threatening NBC's license after NBC published a report that President Trump favored increasing the U.S. nuclear stockpile).

465. Douglas Frantz, *Both Sides in TV Rule Fight Give FCC Star Treatment*, L.A. TIMES (Dec. 13, 1990, 12:00 AM), https://www.latimes.com/archives/la-xpm-1990-12-13-mn-8647-story.html [https://perma.cc/W5GZ-CMSZ].

466. *See supra* note 97 and accompanying text.

467. *See* Brian D. Feinstein, *Designing Executive Agencies for Congressional Influence*, 69 ADMIN. L. REV. 259, 285, 288 (2017) (finding that Congress is "less likely to oversee agencies headed by leaders with fixed terms and qualification requirements," which are common features of independent agencies).

468. Cass R. Sunstein & Adrian Vermeule, *Presidential Review: The President's Statutory Authority over Independent Agencies*, 109 GEO. L.J. 637, 664 (2021).

469. *See, e.g.*, Humphrey's Ex'r v. United States, 295 U.S. 602 (1935) (upholding restrictions on the President's authority to remove a Federal Trade Commissioner only for "inefficiency, neglect of duty, or malfeasance in office"); Wiener v. United States, 357 U.S. 349 (1958) (concluding that the President lacks the authority to remove individuals from the War Claims Commission at will); Morrison v. Olson, 487 U.S. 654 (1988) (upholding "good cause" removal requirement); Seila L. LLC v. C.F.P.B., 140 S. Ct. 2183 (2020) (concluding that restrictions on the President's authority to remove the Consumer Financial Protection Bureau's single Director violated constitutional separation of powers).

agency would require significant restructuring. That is, the FDA could not become an independent agency by simply adding removal protections for the Commissioner, because the Supreme Court has held that such a structure violates the separation of powers.[470] Lastly, there are benefits to executive involvement in certain situations, such as higher-level policy development[471] and interagency coordination. Done well and with transparency, executive involvement during public health emergencies can facilitate a rapid, coordinated, and efficient response.

Importantly, the SIO proposal does not intend to act as a complete bar on executive involvement, particularly when policy decisions must be made rapidly to protect public health and save lives, which may require action amidst scientific uncertainty. Rather, the SIO aims to ensure that any such *policy* decisions made by political actors are transparent and not cloaked as if they are *scientific* decisions made by agencies, as they too often have been.[472] Further, even if we believe that FDA scientific decisionmaking should be completely insulated from politics, removing all hints of politics from agency decisionmaking may prove impossible. Part of the SIO's role, therefore, would be to determine when *involvement* becomes *undue interference*.

With all things considered, the approach outlined in Part III.A., the creation of an SIO, offers a better alternative and an important supplement to the methods discussed in the remainder of Part III. To

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470. *Seila Law*, 140 S. Ct. at 2201–06.

471. *See* Lynch et al., *supra* note 116, at 188–89 ("The FDA cannot make decisions on the basis of science alone, and political considerations sometimes do have a role to play.").

472. *See supra* notes 123–125 and accompanying text. The controversy over booster shots provides one example. Initially, the Biden Administration's push for booster shots appeared to get ahead of the science. Arguably, this was a *policy* decision by the Administration (i.e., to try to get ahead of the virus and prevent future surges) rather than a decision based entirely on existing scientific evidence. The decision, however, was not clearly portrayed as a policy decision and many believed the Biden Administration "got ahead of the science." But as time went by, mounting evidence suggested the Biden Administration's call for widespread booster shots might actually be "right" based on the scientific data. Thus, there are times where we need not, and perhaps should not, wait for scientific "certainty"—if there even is such a thing, particularly in an ever-evolving pandemic. *See* Jacqueline Howard, *Mounting Evidence Highlights the Importance of COVID-19 Boosters*, CNN (Dec. 9, 2021, 12:49 PM), https://www.cnn.com/2021/12/08/health/pfizer-booster-data-omicron-vaccinated-definition/index.html [https://perma.cc/88WX-73SL]; Andy Slavitt, Opinion, *It's Time to Start Requiring Booster Shots*, WASH. POST (Dec. 21, 2021, 1:29 PM), https://www.washingtonpost.com/opinions/2021/12/21/its-time-start-requiring-booster-shots/ [https://perma.cc/G93W-UUAU] ("If you are in a position to decide whether to create a vaccination requirement, you do not need to wait for definitive data from the [CDC]."); *see also* Freeman & Vermeule, *supra* note 28, at 81 ("[M]aking a slightly worse-informed decision now can be better than waiting if there are opportunity costs or interim losses from a nondecision. . . . When stakes are high (as when a nondecision might lead to significant irreversible negative consequences), the cost of delaying a decision could be substantial.").

promote accountability, credibility, and public trust, the SIO seeks to address the limitations of the existing and proposed mechanisms discussed in this Part by insulating the process from the executive, minimizing the role of politics in the process, enhancing transparency, increasing public involvement, and fortifying the process with statutory mandates and protections. Each potential solution rests on a foundational position of this Article: that the integrity of agency scientific decisionmaking, separate and apart from ultimate policy conclusions, must be protected from undue political interference. If it is determined, however, that political considerations are inescapably inherent in all agency decisions, including scientific decisions, then a much larger shift would be to explicitly acknowledge the role of politics and other nonscientific factors and to establish a clear framework for how agencies should consider those factors. A framework would provide transparency and accountability by establishing guidelines for when and how agencies should consider such factors. This would be a substantial shift from current practice and require much further thought, significant statutory and regulatory changes, and potential agency restructuring.[473]

CONCLUSION

The COVID-19 pandemic laid bare a pressing issue faced by many agencies: executive-level interference in agency scientific decisionmaking. The Trump Administration's actions during the COVID-19 pandemic exposed the distinct negative consequences of executive interference in agency science: short- and long-term harms to agency accountability, credibility, and public trust. This Article clarifies that such interference is neither new nor limited to the Trump Administration—it occurs under both Democratic and Republican presidents.

This Article addresses these concerns through the lens of internal agency capture and highlights pathways forward. Specifically, it proposes the establishment of a nonpartisan, congressionally created Scientific Integrity Office explicitly charged with overseeing and

473. Further consideration of this approach is beyond the scope of this Article. It is considered, to some extent, by other scholars. *See, e.g.*, FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION (2002); Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135; Craig J. Konnoth, *Drugs' Other Side-Effects*, 105 IOWA L. REV. 171 (2019); Gary Marchant, Ann Meyer & Megan Scanlon, *Integrating Social and Ethical Concerns into Regulatory Decision-Making for Emerging Technologies*, 11 MINN. J.L. SCI. & TECH. 345 (2010); Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Regulation*, 73 FOOD & DRUG L.J. 221 (2018).

reviewing political interference in agency scientific decisionmaking. As with all proposed reforms, the SIO is not perfect, involves trade-offs, and will face challenges in implementation. But even if implementation looks different than proposed in this Article or occurs years in the future, we must not allow ourselves to be defeated by partisanship. There is value in beginning a dialogue that may work toward ending improper executive interference in agency scientific decisionmaking. Reforms to address executive interference in agency scientific decisionmaking represent a key part of moving forward; preparing for the next public health emergency; ensuring agencies can fulfill their missions to act in the public interest; and enhancing agency accountability, credibility, and public trust.