FDA's Revolving Door: Reckoning and Reform

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Recent controversy over the FDA's approval of the Alzheimer's therapy Aduhelm (aducanumab) and the Duchenne muscular dystrophy therapy Exondys 51 (eteplirsen) called into question the impartiality and independence of high-level FDA regulators. Atypical associations between FDA regulators and pharmaceutical company sponsors, in addition to fierce internal disputes over the adequacy of the evidence, elicited criticism and triggered concern about potential undue influence at the FDA. The revolving door is one persistent source of undue influence that overshadows the discharge of FDA regulators' duties to the public. Exit from government to private-sector employment via the "revolving door" is a frequent occurrence at administrative agencies like FDA. This Article offers a scoping analysis of the revolving door at the FDA specifically. Drawing on insights from many disciplines, including legislative history of existing revolving door prohibitions, the scholarship on regulatory capture, the psychology of gift-giving, and fiduciary theory, this Article approaches an old problem with new insights and situates the discussion of the revolving door at the FDA in a contemporary context.

In the background of FDA decision-making lingers the time-limited nature of an official's tenure at the agency, which is especially true for political appointees on whom rest some of the agency's most critical decisions. To believe that a regulator will make decisions unaffected by the prospect of lucrative private-sector employment in a regulated industry places unrealistic faith in the idea that human behavior is the product of conscious choices over which we have full control. The dangers of the revolving door can be understood as a product of conscious and unconscious influence that generates a risk of bias in favor of regulated entities with whom private employment may later be sought. As with bias in adjudication, it is that risk, even in the absence of actual proven bias, that requires mitigating measures.

Even when regulators' decision-making remains fully aligned with the public interest, institutional legitimacy suffers whenever the potential for bias exists. This

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is especially true because those outside of the agency lack the information and expertise needed to make proper ex post assessments of the validity of highly specialized, highly technical decisions such as whether to approve a new drug or biologic therapy. The corrosive effects of the revolving door on public perceptions of agency decision-making thus prove resistant to easy solutions. Ultimately, this Article argues in favor of conceptualizing the FDA's revolving door as an institutional problem, even when it acts through the decisions of individual regulators. Because revolving door-induced conflicts of interest find expression through exercises of discretion, layered and multifarious checks on the discretion on senior FDA officials offer the public the greatest assurance of impartiality in the outcomes that matter most to the nation's health and welfare.

INTRODUCTION

A more than century-old problem continues to plague government at all levels: the movement of government officials through the so-called "revolving door" between government and the private sector. The frequency and fluidity with which government employees alternate between public-serving roles and private-sector roles, sometimes but not always representational in nature, remain an enduring cause of consternation and mistrust. Time-limited restrictions on

representational activities and influence-peddling after officials leave government employment have provided an imperfect bandage for a lasting problem.[1] The U.S. Food and Drug Administration (FDA), guardian of the safety and effectiveness of our nation's pharmaceutical therapies and overseer of a variety of consumer products, is not immune from the revolving door phenomenon, especially as it entails government-to-industry job transitions.[2] An investigation by the peer-reviewed journal *Science* of 16 FDA medical examiners who later left the agency found that 11 took post-government employment with the companies that they had formerly regulated.[3] Jeffrey Siegel, for example, an FDA regulator who oversaw review of the New Drug Application ("NDA") for Genentech's Actemra (tocilizumab) while at the FDA, later joined Genentech as Global Head of Rheumatology and Rare Diseases.[4] Former FDA Commissioner Dr. Scott Gottlieb joined the Board of Directors of Pfizer within four months of announcing his resignation as FDA commissioner in early March of 2019, a rapid pivot back to industry that drew pointed criticism from many.[5] Among Gottlieb's achievements as commissioner was a Biosimilars Action Plan to promote the development of follow-on versions of biologic products.[6] Pfizer happens to be a

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1. *See, e.g.*, *Revolving Door Prohibitions*, NAT'L CONF. OF STATE LEGISLATURES (Aug. 24, 2021), https://perma.cc/L9GN-MYSK; Craig Holman & Caralyn Esser, *Slowing the Federal Revolving Door*, PUB. CITIZEN (July 22, 2019), https://perma.cc/S2A8-2Z3X (noting that most states have a one-year lobbying restriction after officials leave office but recommending at least a two-year period in order to cover the length of a legislative cycle).

2. Empirical documentation of the revolving door phenomenon at the FDA is limited. A study of fifty-five hematology-oncology medical reviewers employed by the FDA from 2001 to 2010 found that, of the nearly half who left the FDA, 15 (57.7%) were employed by or consulted for the biopharmaceutical industry. Jeffrey Bien & Vinay Prasad, Letter, *Future Jobs of FDA's Haematology-Oncology Reviewers*, 354 BRITISH MED. J. 1, 1-2 (2016) (commenting that "[t]he transition from regulator to advising companies seems logical, but it raises concern as to whether regulators act indefatigably in the public interest").

3. Charles Piller, *Is FDA's Revolving Door Open Too Wide?*, 361 SCIENCE 21, 21 (2018).

4. *See id.*; *see also* Laura Fraser, *A Collaborative Effort*, GENENTECH (June 7, 2016), https://perma.cc/396R-REKD. Actemra is FDA-approved to treat adults with moderate to severe rheumatoid arthritis who have responded inadequately to a tumor necrosis factor (TNF) antagonist. *Actemra Label*, U.S. FOOD & DRUG ADMIN., https://perma.cc/6JZE-2H7Q. The FDA's revolving door made headlines yet again recently when an official in the agency's Center for Tobacco Products chose to leave the agency for a position at tobacco behemoth Philip Morris. Christina Jewett, *F.D.A. Tobacco Science Official Takes Job at Philip Morris*, N.Y. TIMES (July 28, 2022, 9:27 AM), https://perma.cc/D5DH-L69M.

5. *See Scott Gottlieb Elected to Pfizer's Board of Directors*, PFIZER (June 27, 2019, 12:17 PM), https://perma.cc/HCW5-8Y7J; Laurie McGinley, Lenny Bernstein & Josh Dawsey, *FDA Commissioner Gottlieb, Who Raised Alarms About Teen Vaping, Resigns*, WASH. POST (Mar. 5, 2019, 3:03 PM EST), https://perma.cc/S7BQ-B9QZ; Eric Sagonowsky, *Cue the "Revolving Door" Criticism: Former FDA Commissioner Gottlieb Joins Pfizer's Board*, FIERCE PHARMA (June 28, 2019, 11:33 AM), https://perma.cc/W2YM-TYMU; Karen Hobert Flynn, *For Big Pharma, the Revolving Door Keeps Spinning*, THE HILL (July 11, 2019, 2:30 PM ET), https://perma.cc/7PVF-SVWV.

6. Scott Gottlieb, Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan (July 18, 2018), https://perma.cc/TU8U-G5CS.

leading maker of biosimilars.[7]

Gottlieb is not unique among FDA commissioners in availing himself of post-FDA employment in industry; in fact, news sources report that every former FDA commissioner but one from the early 1980s through Gottlieb's tenure ending in 2019 held a position in the pharmaceutical industry after leaving the FDA.[8] The most recent former FDA commissioner, Dr. Stephen Hahn, accepted executive positions in a biotech-focused venture capital firm, Flagship Pioneering, and a device company, YourBioHealth, after leaving his post at the FDA.[9] Flagship Pioneering happened to have founded Moderna, maker of a COVID-19 vaccine that received an Emergency Use Authorization ("EUA") during Hahn's tenure and that yielded Moderna billions of dollars in sales revenue.[10]

At first blush, it may seem reasonable for former top FDA regulators to put their knowledge and expertise to use where it is most relevant and most highly valued, which for many former FDA regulators is in the biopharmaceutical and biotechnology industries. And, for the more than 18,000 full-time civilian employees of the FDA, a post-agency job in a private-sector company of the kind the FDA regulates might be the most readily attainable and most logical career move.[11] But, for more than a century, the United States has had federal ethics laws that place limits on the private-sector, post-government employment of former government officials. These laws aim chiefly at deterring the use of confidential government knowledge to advance private-sector objectives and preventing unseemly use of government connections to influence the agencies, departments, or other seats of government from which employees depart.[12]

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7. *Pfizer 2017 Annual Review: Biosimilars*, PFIZER, https://perma.cc/LV4T-8K9S.

8. Katherine Ellen Foley, *Trust Issues Deepen as Yet Another FDA Commissioner Joins the Pharmaceutical Industry*, QUARTZ (July 1, 2019), https://perma.cc/RDH2-V8SK.

9. *See* Kyle LaHucik, *He Authorized Moderna's Vaccine 6 Months Ago. Now, Ex-FDA Chief Hahn Joins Biotech's Backer*, FIERCE BIOTECH (June 14, 2021, 7:51 PM), https://perma.cc/WPJ8-UQPQ; Conor Hale, *Former FDA Commissioner Hahn Takes Interim CMO Role at Flagship's YourBio Health*, FIERCE BIOTECH (Sept. 9, 2021, 4:33 PM), https://perma.cc/NU28-ENE3.

10. *See* Dan Diamond, *Trump's FDA Commissioner Takes Job at Moderna Backer*, WASH. POST (June 14, 2021, 7:40 PM EDT), https://perma.cc/UJV6-GYSZ; *see also Moderna COVID-19 Vaccines*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2021), https://perma.cc/H6NS-BB7M; Press Release, Moderna, Moderna Reports Third Quarter Fiscal Year 2021 Financial Results and Provides Business Updates (Nov. 4, 2021, 7:00 AM), https://perma.cc/3TCS-SEQ5 (reporting $5 billion in total revenue for the third quarter of 2021).

11. *See FDA at a Glance*, U.S. FOOD & DRUG ADMIN. (2021), https://perma.cc/3QK8-3H68 (noting that the FDA had more than 18,000 full-time equivalents as of November 2021).

12. *See* JACK MASKELL, CONG. RSCH. SERV., R42728, POST-EMPLOYMENT, "REVOLVING DOOR," LAWS FOR FEDERAL PERSONNEL 1-2 (2012); U.S. Off. of Gov't Ethics, Legal Advisory to Designated Agency Ethics Officials on the Introduction to the Primary Post-Government Employment Restrictions Applicable to Former Executive Branch Employees (Sept. 23, 2016), https://perma.cc/NLE3-BXFG [hereinafter U.S. Off. of Gov't Ethics, Legal Advisory] (noting a primary function of the federal ethics laws regulating post-government employment, namely to "guard[] against certain acts involving, or appearing to involve, the unfair use of prior Government employment"); *see also* Michael H. Chang, *Protecting the Appearance of*

An issue related to the revolving door is the influence of politics at the FDA, hardly a new concern[13] but one that has attracted renewed attention during the COVID-19 pandemic.[14] Scholars and former regulators have debated whether the FDA should have greater insulation from the executive branch and perhaps

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Propriety: The Policies Underlying the One-Year Ban on Post-Congressional Lobbying Employment, 5 KAN. J.L. & PUB. POL'Y 121, 121-22 (1996) (making a similar argument with respect to post-congressional lobbying restrictions and highlighting their utility in deterring both actual impropriety and the appearance of impropriety).

13. *See, e.g.*, Louis Lasagna & William M. Wardell, Commentary, *The FDA, Politics, and the Public*, 232 JAMA 141, 141-42 (1975) (remarking that "[s]ince it was begun in 1907, the [FDA] has often been the center of controversy," and recounting congressional hearings in which "FDA officials have been reprimanded for being too 'soft' on industry and too ready to approve new drugs"); Jeffrey M. Drazen, Michael F. Greene & Alastair J.J. Wood, *The FDA, Politics, and Plan B*, 350 NEW ENG. J. MED. 1561, 1561-62 (2004) (charging that "FDA's decision-making process is being influenced by political considerations" in the face of a decision to postpone recategorizing Plan B emergency contraceptives as over-the-counter drugs); Editorial, *Politics Trumps Science at the FDA*, 366 LANCET 1827, 1827 (2005) (highlighting atypical aspects of FDA's review process for an over-the-counter version of Plan B and expressing "growing concerns that the agency . . . has become too dependent on the industry it is supposed to regulate"); Daniel P. Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy*, 23 HEALTH AFFS. 52, 52-54 (2004) (conceptualizing FDA drug review as "a politically shaped exercise in information processing"); Editorial, *What Is Going on at the FDA?*, 366 LANCET 1137, 1137 (2005) (citing, in the wake of FDA Commissioner Lester Crawford's resignation, "persistent allegations of political meddling in FDA decisions," and calling FDA staff morale "dismal" and "dented by judgments that go against the findings of scientific committees"); Lawrence O. Gostin, Commentary, *FDA Regulation of Tobacco: Politics, Law, and the Public's Health*, 302 JAMA 1459, 1459-60 (2009) ("The [Family Smoking Prevention and Tobacco Control Act] entrenche[d] a continuing political influence of the industry [on tobacco regulation] with assured representation on [FDA's Tobacco Product] Scientific Advisory Committee."); Michael Siegel, *A Lost Opportunity for Public Health—The FDA Advisory Committee Report on Menthol*, 364 NEW ENG. J. MED. 2177, 2178 (2011) (criticizing the Tobacco Products Scientific Advisory Committee's decision not to recommend a ban on menthol cigarettes despite evidence that they increase smoking prevalence, thereby enabling the FDA to "avoid making [a] politically toxic move"); Daniel Carpenter, *FDA Transparency in an Inescapably Political World*, 45 J.L. MED. & ETHICS 29, 29-31 (2017) [hereinafter Carpenter, *FDA Transparency in an Inescapably Political World*]; Rick Berke & Sheila Kaplan, *Former FDA Chief Margaret Hamburg Speaks Out About Califf, Cruz, and Congress*, STAT (Mar. 16, 2016), https://perma.cc/99HY-XBWB (reporting an interview with former FDA Commissioner Dr. Margaret Hamburg in which she was quoted as saying: "I want to underscore the importance of protecting the FDA from politicization. FDA frequently finds itself working at the interface of science, health care, public health, and politics. This can be precarious terrain . . . ."); Eli Y Adashi, Rohit S. Rajan & I. Glenn Cohen, *When Science and Politics Collide: Enhancing the FDA*, 364 Science 628, 628-29 (2019) (commenting that "[s]ince the late 1960s . . . the FDA has been the subject of creeping politicization and a progressive loss of independence" and that, recently, "partisan political interposition has grown increasingly worrisome").

14. *See, e.g.*, Joshua Sharfstein, Commentary, *How the FDA Should Protect Its Integrity from Politics*, 585 NATURE 161, 161 (2020) (criticizing the FDA as "yet to consult . . . [an advisory] committee for a major decision on COVID-19" and writing that "FDA has disclosed little about how it is making decisions"); Peter Suwondo, Timothy Westmoreland & Howard P. Forman, *Ten Urgent Reforms to Protect the CDC and FDA from Harmful Political Interference*, HEALTH AFFS. FOREFRONT (Nov. 24, 2020), https://perma.cc/B9SE-SMYU.

even be remodeled as an independent agency.[15] Some have suggested "drawing a line between [the FDA's] broad policy decisions, which elected and appointed officials may appropriately influence, and decisions about specific applications before the agency, which should be shielded from such influence."[16] Yet the practicality of a workable division between overarching policy on the one hand and specific applications or scientific evaluations, on the other, is dubious. Policy inevitably trickles down to affect specific decisions, including decisions on drug applications before the FDA.[17] Ultimately, the "scientific components"[18] of the FDA's work cannot be meaningfully detached from its value-laden decisions about the rapidity of drug approvals, for example, or the level of evidence needed to approve them. Politics may or may not have a more legitimate role to play in FDA decision-making than does industry influence, but undoubtedly it represents a nonnegligible influence that informs the agency's work. Any discussion of politicization of the FDA should be reframed as part of a larger discussion over the various forces and unseen influences that affect FDA decision-making and the degree to which each should be tolerated, eliminated, or mitigated.

This Article proceeds in five Parts. Part I frames the discussion of revolving-door concerns with respect to the FDA by highlighting recent controversy over some of the FDA's decisions on drug applications that have called into question the neutrality and independence of high-level FDA regulators. This Article is not meant to suggest that any particular FDA official has engaged in improper acts or was improperly motivated by outside influences. Rather, this Article seeks to address a larger problem raised by these high-profile controversies: the potential for industry-related conflicts of interest (and this Article focuses on one

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15. *See* Robert M. Califf, Margaret Hamburg, Jane E. Henney, David A. Kessler, Mark McClellan, Andrew C. von Eschenberg & Frank Young, *Seven Former FDA Commissioners: The FDA Should Be an Independent Federal Agency*, 38 HEALTH AFFS. 84, 84-86 (2019); Holly Fernandez Lynch, Steven Joffe & Matthew S. McCoy, Letter to the Editor, *The Limits of Acceptable Political Influence over the FDA*, 27 NATURE MED. 188, 189 (2021); Adashi et al., *supra* note 13, at 629-30; Dorit Reiss, Opinion, *Free the FDA and the CDC from Political Pressure*, CNN (Sept. 4, 2020, 12:01 PM EDT), https://perma.cc/6QJM-8R4W.

16. Lynch et al., *supra* note 15, at 189.

17. For example, in a memo regarding the FDA's contested approval of eteplirsen for Duchenne muscular dystrophy, discussed *infra*, Acting Chief Scientist Dr. Luciana Borio noted that, according to another FDA official familiar with the approval of eteplirsen, Dr. Janet Woodcock "frequently talked about the effects of a decision regarding eteplirsen in terms of overarching policy (e.g., the need to be more flexible for ultra-rare diseases)." Letter from Luciana Borio, MD, Acting Chief Scientist, Food & Drug Admin. Off. of the Comm'r, U.S. Dep't of Health & Hum. Servs., to Robert Califf, MD, Comm'r of Food & Drugs, Food & Drug Admin. Off. of the Comm'r, U.S. Dep't of Health & Hum. Servs. 10 (Aug. 8, 2016), https://perma.cc/R5FG-8UJ3 [hereinafter Letter from Borio to Califf]. Some might argue that it is the duty of agency administrators like Dr. Woodcock to heed overarching policy considerations in the resolution of particular matters before the agency. Indeed, there is a strong argument to be made that broad, normative considerations can and should inform and guide agency decision-making at a more granular level.

18. Lynch et al., *supra* note 15, at 189.

particular source of conflict, the prospect of post-agency employment in industry) to influence—intentionally or unintentionally, consciously or unconsciously—senior FDA officials' most critical decisions. Part II reviews the primary federal statutory provisions that address the revolving door between government and the private sector, considers reactions to post-employment restrictions in legislative history, and puts forth a conception of post-agency employment in industry as a form of regulatory capture. Part III utilizes insights from behavioral science and critical realist scholarship to examine what impact potential future employment in industry could have on agency officials while in office and whether this impact can be properly mitigated by traditional strategies such as time-limited cooling-off periods, blind reliance on good intentions, or efforts at transparency. Part IV examines the fiduciary role of agencies such as the FDA and reframes agency discretion in light of the familiar principal-agent problem. Part V considers various mechanisms to address the risk of biased decision-making that the revolving door generates and ultimately argues in favor of additional process safeguards that can serve as a check on exercises of discretion at the agency.

I. RECENT CONTROVERSY AT THE FDA

The COVID-19 pandemic has placed a spotlight on the critically important work of the FDA to approve therapeutics, including drugs, vaccines, and other biologics, that promote the public's health. Yet, over the past two years, the FDA has come under fire for approval decisions that many within and outside of the agency have criticized as lacking sufficient evidence of safety or efficacy. The FDA issued, and fewer than twelve weeks later revoked, an EUA for antimalarial drugs hydroxychloroquine and chloroquine, determining in June 2020 "based on a review of new information and a reevaluation of information available at the time the EUA was issued" that the criteria for EUA authorization were no longer met.[19] In its revocation decision, the FDA concluded that "it is no longer reasonable to believe that . . . [hydroxycholorquine and chloroquine] may be effective in treating COVID-19, nor is it reasonable to believe that the known and potential benefits of these products outweigh their known and potential risks."[20] The FDA acknowledged on its website that "[t]he EUA was based upon limited evidence that the medicines may provide benefit,"[21] and that randomized

19. *See* Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Deputy Assistant Sec'y, Off. of Assistant Sec'y for Preparedness & Response, U.S. Dep't of Health & Hum. Servs., (June 15, 2020), https://perma.cc/CFS6-GL8N [hereinafter Letter from Hinton to Disbrow]; *see also* Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Rick Bright, Dir. of the Biomedical Advanced Rsch. & Dev. Auth., Off. of Assistant Sec'y for Preparedness & Response, U.S. Dep't of Health & Hum. Servs., (June 15, 2020), https://perma.cc/KTU6-E6RJ.

20. Letter from Hinton to Disbrow, *supra* note 19.

21. *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems*,

clinical trial data had failed to show evidence of clinical benefit in hospitalized COVID-19 patients, while serious and sometimes fatal arrythmias—well-known side effects of these drugs—were observed.[22] Whether the EUA was properly granted in the first place remains an open question, but the incident sparked criticism from former FDA officials and others who considered the decision rash and potentially politically motivated.[23]

In June 2021, the FDA approved the Alzheimer's treatment Aduhelm (aducanumab)[24] over objections from the FDA advisory committee assembled to review it and over a chorus of objections from "senior agency officials [who] resoundingly agreed that there wasn't enough evidence it worked."[25] Hailed by the agency as the "first therapy to target and affect the underlying disease process of Alzheimer's,"[26] Aduhelm received approval under an expedited review pathway termed accelerated approval, which permits approval of drugs and biologics serving an unmet medical need on the basis of a surrogate endpoint, "a marker . . . thought to predict clinical benefit."[27] That marker in the case of

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U.S. FOOD & DRUG ADMIN. (July 1, 2020), https://perma.cc/WU6H-DBCF [hereinafter *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine*]. In a Q&A, former acting FDA Commissioner Joshua Sharfstein acknowledged that "[t]here wasn't much information to support [hydroxychloroquine's] use at the time [that FDA issued the EUA]." *What Is Emergency Use Authorization?*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Oct. 20, 2020), https://perma.cc/GN9F-MS8G.

22. *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine*, *supra* note 21.

23. *See* Charles Piller, *Former FDA Leaders Decry Emergency Authorization of Malaria Drugs for Coronavirus*, SCIENCE (Apr. 7, 2020, 6:20 PM), https://perma.cc/W2FG-24QR. In an opinion poll conducted in 2020, only roughly half of adults surveyed believed the FDA's decisions are based on science, while more than one-quarter believed that the FDA's decisions are politically motivated. *See* Gaby Galvin, *Over One in Four Adults Say FDA's COVID-19 Decisions Are Politically Influenced as Agency Faces Scrutiny*, MORNING CONSULT (Sept. 1, 2020, 5:26 PM ET), https://perma.cc/5CYS-NV6D.

24. *FDA Grants Accelerated Approval for Alzheimer's Drug*, U.S. FOOD & DRUG ADMIN. (June 7, 2021), https://perma.cc/NG7Q-YC4Q. Aduhelm is technically not a "drug" within FDA parlance; it is a biologic, and the FDA approved its biologic license application. Letter from Billy Dunn, Director, Off. of Neurosci., Ctr. for Drug Evaluation & Rsch., to Priya Singhal, Vice President of Glob. Safety & Regul. Scis., Biogen, Inc., (June 7, 2021), https://perma.cc/3VL9-YGGB [hereinafter Letter Approving Aduhelm's Biologics License Application].

25. Pam Belluck, Sheila Kaplan & Rebecca Robins, *How an Unproven Alzheimer's Drug Got Approved*, N.Y. TIMES (Oct. 20, 2021), https://perma.cc/8WC7-3G26. Per news reporting, ten of the eleven advisory committee members voted in November 2020 against Aduhelm's approval and cited a lack of sufficient evidence that it "could slow cognitive decline." Andrew Joseph, *Third Member of FDA Expert Committee Resigns over Controversial Alzheimer's Therapy Decision*, STAT (June 10, 2021), https://perma.cc/6VC5-GFLU.

26. *FDA Grants Accelerated Approval for Alzheimer's Drug*, *supra* note 24.

27. *Accelerated Approval*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://perma.cc/AG67-SMKZ. Aduhelm also received a "fast track" designation, which is designed to help expedite drugs and biologics serving an unmet medical need and treating a serious condition by enabling "earl[ier] and [more] frequent communication between the FDA and a drug company" and rolling review of its application. *See Fast Track*, U.S. FOOD & DRUG ADMIN. (Jan, 4, 2018), https://perma.cc/N9Y4-PJ9U; *FDA Grants Accelerated Approval for Alzheimer's Drug*, *supra* note 24.

Aduhelm is beta-amyloid plaque, a central nervous system protein aggregation that accumulates in Alzheimer's disease.[28] Importantly, however, Aduhelm was not initially reviewed under the accelerated approval pathway; instead, the final decision to approve it under this pathway was made in the spring of 2021 at the discretion of top FDA officials and without input from the advisory committee.[29] The FDA subjects drugs and biologics approved under accelerated approval to requirements for Phase IV (postmarketing) clinical trials to confirm clinical benefit, and it indicates on its website that "[a]pproval of a drug may be withdrawn or the labeled indication of the drug changed if trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug."[30] As a condition of Aduhelm's approval, the FDA has required Biogen to conduct just such a randomized clinical trial to verify the therapy's clinical benefit.[31]

Within days of Aduhelm's approval, several members of the FDA advisory committee that reviewed the therapy resigned.[32] The committee had previously voted "no" on the question of whether Aduhelm's study results were "primary evidence of effectiveness" of the therapy to treat Alzheimer's disease and instead "recommended that there should be substantial evidence relating specific biomarkers to disease progression before there is a determination that the clearance/reduction of these biomarkers are truly related to clinical benefit (cognitive improvement)."[33] One advisory committee member who was among the resignees remarked on Twitter that "[a]ccelerated [a]pproval is not supposed to be the backup that you use when your clinical trial data are not good enough

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28. *See, e.g.*, NAT'L INST. OF HEALTH, WHAT HAPPENS TO THE BRAIN IN ALZHEIMER'S DISEASE? (reviewed May 16, 2017), https://perma.cc/8VEY-WHM9.

29. Bill Chappell, *Three Experts Have Resigned from an FDA Committee over Alzheimer's Drug Approval*, NPR (June 11, 2021, 7:04 PM ET), https://perma.cc/D28R-NGYB; Matthew Herper, Damian Garde & Adam Feuerstein, *Newly Disclosed FDA Documents Reveal Agency's Unprecedented Path to Approving Aduhelm*, STAT (June 22, 2021), https://perma.cc/26V8-H4V8. Reporting, however, suggests that the FDA may have contemplated accelerated approval at least as early as 2019. 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://perma.cc/S7QK-ZG4X; G. Caleb Alexander et al., Perspective, *Revisiting FDA Approval of Aducanumab*, 385 NEW ENG. J. MED. 769, 770 (2021) ("The [advisory] committee was never consulted about beta-amyloid's suitability as a surrogate.").

30. *Accelerated Approval*, *supra* note 27.

31. *FDA Grants Accelerated Approval for Alzheimer's Drug*, *supra* note 24; *see also* Letter Approving Aduhelm's Biologics License Application, *supra* note 25, at 3 (instructing the company to "conduct a randomized, controlled trial to evaluate the efficacy of aducanumab-avwa compared to an appropriate control").

32. Chappell, *supra* note 29.

33. *Final Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting*, CTR. FOR DRUG EVALUATION & RSCH., FOOD & DRUG ADMIN. (Nov. 6, 2020), https://perma.cc/Y2W6-6LXV; *see also* Gil D. Rabinovici, *Controversy and Progress in Alzheimer's Disease—FDA Approval of Aducanumab*, 385 NEW ENG. J. MED. 771, 772 (2021) ("The committee voted decisively that the data in totality did not provide sufficient evidence of efficacy and recommended against approval.").

for regular approval."[34] The abrupt resignations and subsequent public comments from resignees on various news and social media outlets served as an open rebuke of the FDA's decision on Aduhelm.[35]

What otherwise might have been a widely lauded milestone in the history of drug approvals had quickly become mired in controversy. In addition to the public airing of the agency's internal disagreement over the drug's merits, concerns emerged about Aduhelm's price in light of its uncertain efficacy and the questionable relationship between the agency and drug maker Biogen.[36] News reporting uncovered a series of meetings and interactions between Biogen employees and key FDA officials, including Dr. Billy Dunn, the FDA's Director of the Office of Neuroscience within the Center for Drug Evaluation and Research ("CDER").[37] The interactions allegedly formed part of a coordinated "campaign" by Biogen, designed to achieve FDA approval of Aduhelm, in which FDA regulators "played an extraordinarily proactive role" to help the drug gain approval.[38] Multiple federal investigations ensued: the House Committee on Oversight and Reform opened an investigation within weeks of Aduhelm's

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34. Aaron Kesselheim (@akesselheim), TWITTER (June 7, 2021, 11:25 AM), https://perma.cc/F7WX-RXJ9.

35. *See id.*; *see also*, *e.g.*, Deena Beasley, *Two Members of U.S. FDA Advisory Panel Resign over Alzheimer's Drug Approval*, REUTERS (June 9, 2021, 2:43 PM PDT), https://perma.cc/H3WZ-QFFD; *Doctor Says FDA Decision Was So Egregious He Resigned*, CNN, https://perma.cc/FP66-CZWC (reporting an interview with Dr. Joel Perlmutter, an advisory committee resignee, who stated: "I found this decision [approval of Aduhelm] so egregious that I resigned the day they made that announcement."). In a *New England Journal of Medicine* commentary piece regarding the approval, several advisory committee members doubled down on their expression of disapproval, writing that "FDA's decision is at odds with the evidence and with the agency's biostatistical review" and encouraging "expeditious" investigation into the decision "so as to learn how this regulatory failure occurred and to ensure that it doesn't occur again." Alexander et al., *supra* note 29, at 771.

36. *See* Juliette Cubanski & Tricia Neuman, *FDA's Approval of Biogen's New Alzheimer's Drug Has Huge Cost Implications for Medicare and Beneficiaries*, KAISER FAM. FOUND. (June 10, 2021), https://perma.cc/PNR7-XDTQ (noting a $56,000 annual list price for Aduhelm in mid-2021 and estimating that, if one million Medicare beneficiaries were treated with the drug, spending could exceed $57 billion in a single year). Under pressure from various stakeholders, Biogen announced in late December 2021 that it would reduce the annual cost of Aduhelm to $28,200, and it projected that 50,000 patients would initiate Aduhelm therapy in 2022. *Biogen Announces Reduced Price for ADUHELM ® to Improve Access for Patients with Early Alzheimer's Disease*, BIOGEN (Dec. 20, 2021), https://perma.cc/9K36-PK7D. In January 2022, the Center for Medicare and Medicaid Services ("CMS") announced a proposal to cover monoclonal antibodies directed toward amyloid (such as Aduhelm) only for Medicare patients enrolled in "qualifying" clinical trials. Press Release, Ctr. for Medicare & Medicaid Servs., CMS Proposes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (Jan. 11, 2022), https://perma.cc/T9VD-3TSK. CMS officials cited the agency's evidence-based analysis and "the potential for harm to patients" from Aduhelm therapy as underpinning their proposed coverage determination. *Id.*

37. Feuerstein et al., *supra* note 29.

38. *Id.*

approval,[39] and in August 2021, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) announced an investigation focused on the FDA's accelerated approval pathway.[40] In December 2022, the Committee on Oversight and Reform, in conjunction with the House Committee on Energy and Commerce, released a staff report concluding its eighteen-month investigation that corroborated "atypical procedures and deviat[ions] from the agency's own guidance" during Aduhelm's review.[41] Among the report's findings were a high volume of interactions between the FDA and Biogen, many of which the agency failed to document in accordance with agency procedure, if at all.[42]

Aduhelm is not the only recently approved therapy that has incited controversy and prompted public scrutiny of the agency and its relationship with the pharmaceutical industry.[43] In 2016, the accelerated approval of Exondys 51 (eteplirsen), a messenger RNA-targeted therapy for Duchenne muscular dystrophy, led an official within the FDA—then-Director of the Office of Drug Evaluation-I Dr. Ellis Unger—to formally appeal the FDA's decision, a rare course of action within the agency.[44] Eteplirsen increases levels of functional

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39. *See* Press Release, House Comm. on Oversight & Reform, Chairs Maloney and Pallone Announce Investigation of Biogen's Alzheimer's Drug Aduhelm (June 25, 2021), https://perma.cc/E7Q7-6JNQ.

40. *See Review of the FDA's Accelerated Approval Pathway*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., https://perma.cc/R8PX-8G4J. The complete OIG report is expected in 2023.

41. STAFF OF H. COMM. ON OVERSIGHT & REFORM AND H. COMM. ON ENERGY & COM., THE HIGH PRICE OF ADUHELM'S APPROVAL: AN INVESTIGATION INTO FDA'S ATYPICAL REVIEW PROCESS AND BIOGEN'S AGGRESSIVE LAUNCH PLANS, 117th Cong., at 3 (2022), https://perma.cc/2PU2-6S38.

42. *Id.* In June 2019, the agency chose to establish a "bilateral collaborative workstream" with Biogen, *id.* at 17, after which the agency engaged in a high frequency of interactions with the company that facilitated Aduhelm's ultimate approval. The investigation uncovered more than one-hundred interactions between the FDA and Biogen over a one-year period, including upwards of forty "working group" meetings, not all of which were properly recorded, as well as more than sixty-five unrecorded calls and emails. *Id.*; *see also id.* at 15-18. Notably, the House report casts some doubt on the FDA's purported justification for the collaborative workstream (namely, the public health imperative of Alzheimer's and the therapy's promise), finding that it was not until several months after the decision to work collaboratively with Biogen that new data analyses indicated a likelihood of Aduhelm's approval. *See id.* at 16-17.

43. *See, e.g.*, Roy Guharoy & Edward Krenzelok, Letter to the Editor, *FDA's Commitment to Transparency*, 78 AM. J. HEALTH SYS. PHARMACY 1550, 1550 (2021) (criticizing the FDA's issuance in November 2020 of an EUA for baricitinib in combination with remdesivir for COVID-19 based on "only minimal data and no published data" and the issuance of an EUA to a COVID-19 monoclonal antibody therapy for COVID-19 (casirivimab/imdevimab) despite a lack of peer-reviewed data).

44. Letter from Robert M. Califf, Comm'r of Food & Drugs, to Janet Woodcock, Dir. of the Ctr. for Drug Evaluation & Rsch, Ellis Unger, Dir. of the Off. of Drug Evaluation I, and Luciana Borio, Chair of the Agency Sci. Disp. Process Rev. Bd. (Sept. 16, 2016), https://perma.cc/R5FG-8UJ3 [hereinafter Letter from Robert M. Califf].

dystrophin, a protein nearly absent in Duchenne's patients.[45] Unger argued that the approval was imprudent on both scientific and policy grounds; in his view, the study results were inadequate to demonstrate that eteplirsen's effect on dystrophin production was "reasonably likely to predict clinical benefit."[46] Instead, he reasoned that "the effect size . . . appears to be too small to provide benefit," noting "I can find no precedent of an accelerated approval for a marketing application where the effect size on the surrogate endpoint is as small as 0.3%."[47] Despite ultimately approving eteplirsen, Dr. Janet Woodcock, then-Director of the CDER and recent Acting Commissioner, reportedly recognized that "serious and significant flaws [existed] in the study design" of trials to assess the therapy.[48] Ultimately, Dr. Woodcock deemed the evidence sufficient for approval, especially in light of the otherwise unmet need for treatment of this rare pediatric disease.[49] Then-Commissioner Robert Califf (also the current Commissioner under the Biden Administration) ultimately deferred to the decision of Dr. Woodcock, whose precise role in the Aduhelm controversy remains unclear.[50]

A key commonality between the Aduhelm and eteplirsen controversies is the use of accelerated approval: both therapies were approved on the basis of a surrogate endpoint, and disagreement existed as to whether each therapy's effect on the surrogate endpoint was reasonably likely to predict clinical benefit in

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45. *About Duchenne Muscular Dystrophy*, NAT'L HUM. GENOME RSCH. INST., https://perma.cc/U7E7-GA4W.

46. *See infra* text accompanying note 47.

47. Agency Scientific Dispute, Appeal from Ellis F. Unger, Dir. of the Off. of Drug Evaluation-1, Ctr. for Drug Rsch. & Evaluation, U.S. Food & Drug Admin., to G. Matthew Warren, Dir. of the Off. of Sci. Integrity, U.S. Food & Drug Admin., p. 19 (July 18, 2016), https://perma.cc/R5FG-8UJ3 [hereinafter Agency Scientific Dispute, Appeal from Ellis F. Unger]. Unger expressed concerns that Woodcock prejudged the matter of eteplirsen's approval even before receiving final review memoranda from him or the Division. *See* Letter from Borio to Califf, *supra* note 17, at 17. In his appeal, Unger also warned of the dangers of approving ineffective therapies and the difficulty of later withdrawing a drug approved via accelerated approval, even when clinical benefit ultimately cannot be shown. He wrote: "FDA has not succeeded in withdrawing the marketing of a single drug for lack of verification of clinical benefit following accelerated approval. The reality is that if eteplirsen is given accelerated approval, it is highly likely to remain on the market indefinitely, irrespective of whether or not efficacy is verified." Agency Scientific Dispute, Appeal from Ellis F. Unger, *supra*, at 22.

48. Letter from Borio to Califf, *supra* note 17, at 11.

49. Center Director Decisional Memorandum, NDA #206488, from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food and Drug Admin., 1-5, https://perma.cc/R5FG-8UJ3.

50. Letter from Robert M. Califf, *supra* note 44, at 6, 9 ("The record . . . reflects . . . that Dr. Woodcock has fully considered the patient population, lack of alternative therapies, and relevant information and analyses, and has concluded that the data are sufficient to meet the accelerated approval standard. . . . I defer to Dr. Woodcock's conclusion that accelerated approval in this case does not represent . . . a lowering of the bar [for approval]."); *see also* Sheryl Gay Stolberg & Sheila Kaplan, *Biden Chooses Robert Califf to Lead F.D.A., Despite Drug Industry Ties*, N.Y. TIMES (Nov. 12, 2021), https://perma.cc/64HV-MAHC.

order to meet the statutory standards for accelerated approval.[51] Commissioner Califf drew the internal dispute regarding eteplirsen to a close by concluding that reasonable minds could disagree about whether change in a surrogate endpoint is "'reasonably likely' to predict a clinical benefit."[52] In other words, he framed the decision as an exercise of professional judgment and official discretion,[53] thereby defending the therapy's approval and establishing a precedent of deference to the Director of the CDER and a precedent supporting a capacious interpretation of the statutory standards for accelerated approval.[54]

There is, however, another significant commonality between the controversies involving eteplirsen and Aduhelm: both implicate extensive and unusual levels of involvement of top FDA officials in the drug approval process.[55] This important aspect of the controversies goes beyond any debate regarding accelerated approval and instead draws attention to individual decision-making and discretionary authority accorded top FDA officials. If an accelerated approval decision comes down to professional judgment, as

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51. "The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product . . . upon a determination that the product has an effect on a surrogate endpoint that is *reasonably likely to predict clinical benefit*, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is *reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit*, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval.'" 21 U.S.C. § 356 (c)(1)(A) (emphasis added).

52. Letter from Robert M. Califf, *supra* note 44, at 4.

53. *Id.* at 4 ("I conclude that Dr. Unger and Dr. Woodcock have each exercised reasonable scientific judgment in reaching differing conclusions on whether the effect on dystrophin production seen in the studies in Sarepta's application reasonably predicts clinical benefit for the relevant subpopulation of Duchenne patients.").

54. *Id.* at 6 "[T]he history of the FDA includes a consistent precedent of final decision-making about medical products at the Center level. Overruling the Center Director is exceedingly rare and, in my view, would be appropriate only if the Center Director's decision could not be supported by the available data . . . ."; 21 U.S.C. § 356 (c)(1)(A); *see also* Letter from Robert M. Califf, *supra* note 44, at 5 ("[Dr. Woodcock] is clearly employing and interpreting the full range of appropriate information, comprising a 'totality of evidence' approach . . . . Because of the uncertainties . . . [associated] with a surrogate that has not been validated, it is clear that Dr. Woodcock's decision also utilized the flexibility afforded under the relevant statutory provisions, including consideration of the life-threatening nature of the disease and the lack of alternative treatments.").

55. In addition to contesting eteplirsen's approval, Unger voiced specific concerns about "the level of involvement of the Center Director in the review of the New Drug Application for eteplirsen." Letter from Robert M. Califf, *supra* note 44, at 6. The enumerated concerns included the Director's "[i]ntense involvement" in eteplirsen's early review, her "[e]xtensive involvement in planning and participating in the Advisory Committee meeting," and favorable decisions by the Director prior to the completion of colleagues' reviews. *Id.* Commissioner Califf's letter summarily dismissed the concerns as not "atypical for Dr. Woodcock's management of the Center" and not "in conflict with the job requirements for Center Directors at the FDA." *Id.* at 8. The concerns regarding Woodcock's role in eteplirsen's approval mirror those raised regarding Dunn's role in Aduhelm's approval. *See* Feuerstein, Herper & Garde, *supra* note 29.

Commissioner Califf contended, then it begs the question why the OIG has apparently chosen to focus its investigation on the legitimacy of accelerated approval rather than on the FDA officials whose judgment produced the contested approval decision. Put differently, the controversy related to accelerated approval derives from an exercise of judgment based on more limited evidence than would be needed for a standard approval; that exercise of judgment may have been subject to unwanted bias, and potential bias should be a matter of concern to the OIG.[56]

Imprudent agency decisions to approve new therapeutics due to conflicts of interest have the potential to cause harm to patients and could cost patients and public programs billions of dollars for ineffective or even dangerous drugs.[57] The relationship between the FDA and industry gives rise to conflicts of interest; yet, that relationship is perhaps inevitable. The FDA is uniquely positioned among federal agencies to work in close collaboration with industry, which is an important stakeholder for the agency. The FDA is a gatekeeper to every new drug and biologic approval—an arduous, technically demanding, and expensive process that long precedes submission of an NDA or Biologics License Application ("BLA") (and their abbreviated counterparts for generics and biosimilars) and often extends far beyond the date of market approval due to industry and agency obligations for post-marketing surveillance. The absence of a collaborative relationship between industry and the FDA would portend disaster for both parties.

At the same time, however, the FDA's decision to approve or reject a drug or biologic application impacts the financial success of one of the largest and most powerful industries in the United States. The FDA's grant of approval is a critical milestone for a pharmaceutical company; without it, a company cannot achieve a return on its investment. In effect, the FDA's symbiosis with industry has become a double-edged sword, giving rise to conflicts of interest and inducing what scholars have termed "regulatory capture," a phenomenon by which regulation favors the interests of regulated entities as a result of "the intent and action of the [regulated] industry itself."[58]

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56. *See* Michael J. Hayes and Vinay Prasad, Essay, *Financial Conflicts of Interest at FDA Drug Advisory Committee Meetings*, 48 HASTINGS CTR. REP. 10, 11 (2018) (noting that drugs such as oncology drugs, which are "judged based on gray evidence—findings from randomized studies or from studies assessing only surrogate end points—leave more room for judgment and rais[e] the potential for bias").

57. *See, e.g.*, Alexander et al., *supra* note 29, at 771 ("Although FDA regulation is separate from coverage and reimbursement questions, the scientifically unjustified label may lead to billions of dollars in unnecessary Medicare expenditures, even if a national coverage determination is ultimately made.").

58. DANIEL CARPENTER & DAVID A. MOSS, PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 13 (2014); Michael A. Livermore & Richard L. Revesz, *Can Executive Review Help Prevent Capture?*, *in* PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 420, 426 (2014) ("Taking a relatively broad view, . . . capture can be understood to occur when organized groups successfully act to vindicate their interests through government policy at the expense of the

Of course, the FDA does far more than approve or reject drug and biologic applications.[59] It also monitors drug safety after marketing begins and issues safety alerts when they are warranted;[60] it can request drug recalls and oversees the drug recall process;[61] it conducts criminal investigations and enforcement for counterfeit, misbranded, and adulterated products,[62] to name just a few of its responsibilities in the pharmaceutical domain. And the FDA's regulation bears on industries far broader than the pharmaceutical industry, including makers of over-the-counter drugs, supplements, medical devices, tobacco products, food, nutritional products, and animal feed, among others.[63] There are thus myriad ways in which a lack of neutrality in FDA officials' dealings with industry could

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public interest. Agency capture is a special case in which regulators within the bureaucracy have been influenced by organized special interest groups to adopt policies that are out of line with the broad public interest."); *see infra* section II.B; *see also* Ernesto Dal Bo, *Regulatory Capture: A Review*, 22 OXFORD REV. ECON. POL'Y 203, 214-19 (2006); Toni Makkai & John Braithwaite, *In and Out of the Revolving Door: Making Sense of Regulatory Capture*, 12 J. PUB. POL'Y 61, 61-62, 64-67 (1992) (describing various conceptions of capture, including sympathy with the regulated industry, identification with the regulated industry, and the degree of regulatory "toughness" when it comes to compliance, and ultimately arguing that capture is a "multidimensional concept").

59. When the FDA rejects an application for market approval of a drug, it issues a "complete response letter" to the drug company (i.e., applicant), detailing "all of the specific deficiencies that the agency has identified in an application or abbreviated application." 21 C.F.R. 314.110(a)(1); *see also* Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications, 73 Fed. Reg. 39,588, 39,588 (July 10, 2008) (announcing, in the form of a final rule, the change from "not approvable" letters to complete response letters "to indicate the review cycle for an application is complete and . . . the application is not ready for approval"). The complete response letter may contain "recommend[ed] actions" that the applicant can take "to place the application or abbreviated application in condition for approval." 21 C.F.R. 314.110(a)(4). Complete response letters are not made public, a choice for which the agency has faced criticism. *See* Matthew Herder, Opinion, *Reviving the FDA's Authority to Publicly Explain Why New Drug Applications Are Approved or Rejected*, 178 JAMA INTERNAL MED. 1013, 1013-14 (2018) (explaining that the FDA does not make public "complete response letters" sent to companies after a drug is rejected and, as a rule, declines to disclose its reasons for rejecting a drug, despite possessing authority to do so); Peter Lurie et al., *Comparison of Content of FDA Letters Not Approving Applications for New Drugs and Associated Public Announcements from Sponsors: Cross Sectional Study*, 350 BRITISH MED. J. 1, 4-6, 8 (2015) (finding inconsistency in the issuance of industry press releases after FDA rejects a drug application and calling press releases "an incomplete source of reasons for FDA non-approval of applications"); *see also* Robert Steinbrook, Editor's Note, *Another Reason for Greater Transparency at the U.S. Food and Drug Administration*, 181 JAMA INTERNAL MED. 529, 529 (2021) (discussing a similar lack of transparency around "refuse to file" letters sent by the FDA to drug companies when an application is incomplete).

60. *See Drug Alerts and Statements*, U.S. FOOD & DRUG ADMIN. (Mar. 30, 2022), https://perma.cc/YHH8-2UEP.

61. *See Recalls, Market Withdrawals, & Safety Alerts*, U.S. FOOD & DRUG ADMIN. (Apr. 14, 2022), https://perma.cc/S92K-KCGZ.

62. *See Criminal Investigations Case Activity*, U.S. FOOD & DRUG ADMIN. (Aug. 30, 2018), https://perma.cc/PK2E-5MW6.

63. *See Regulated Products*, U.S. FOOD & DRUG ADMIN. (Dec. 1, 2021), https://perma.cc/CY3B-CDZ8.

surface in agency decisions. This Article focuses on the biopharmaceutical industry and on one particular type of conflict of interest—that arising from private-sector, post-government employment of FDA regulators—in order to bring to light a persistent source of conflict overshadowing the discharge of FDA regulators' duties to the public.

II. FEDERAL REVOLVING DOOR LAWS AND THE THEORY OF REGULATORY CAPTURE

A. The "Revolving Door" Between Government and the Private Sector

> *The shuttle by top Washington lawyers between Government and private practice is fabled. They move back and forth, alternately serving public and self. Other professionals shuttle freely among Federal agencies, their defense contractors, think tanks, consulting firms, universities, and state and city agencies. The cozy ties between these former (and future) officials and their erstwhile colleagues are a troubling reality of capital life.*[64]

The phenomenon described in this excerpt from a 1979 *New York Times* article has been termed the "revolving door," the movement of government officials between public- and private-sector employment, and in particular, from the role of regulator to the status of an employee or representative of a regulated interest. Revolving door entry into government from the private sector is sometimes differentiated from the revolving door transition out of a government role into the private sector.[65] Various aspects of the revolving door raise concern: First, government regulators with prior ties to private-sector industries they regulate may approach their regulatory work with partiality toward their former employers. Private-sector work experience may cause regulators to identify with or feel sympathy toward the regulated entity, or at the least, to better understand the perspective of the regulated business.[66] Second, a government regulator with no prior ties to the regulated industry stands in a position to later gain employment in a regulated industry, raising a risk of bias toward the very business entities that may one day be the source of a former regulator's livelihood. The latter revolving door problem—that is, the transition from government to a regulated industry or to a position that serves the regulated industry—is the focus of this Article, although both revolving door entry and exit produce a similar risk of actual and perceived bias while working in a public-serving capacity.

Another prefatory distinction warrants mention. The revolving door creates

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64. *Ethical Exits From a Cozy Shuttle*, N.Y. TIMES, Mar. 16, 1979, at 30, https://perma.cc/6DBN-9D9T.

65. *See, e.g.*, William T. Gormley Jr., *A Test of the Revolving Door Hypothesis at the FCC*, 23 AM. J. POL. SCI. 665, 666, 682 (1979); Makkai & Braithwaite, *supra* note 58, at 64-66.

66. ROGER G. NOLL, REFORMING REGULATION: STUDIES IN THE REGULATION OF ECONOMIC ACTIVITY 54 (1971).

a risk of more than one type of unwanted influence: the first is partiality or leniency that the incumbent regulator may display toward regulated entities; the second is the potential for a transfer of "insider" public-sector knowledge to a private-sector employer after leaving government; and the third is the potential for a former government official to leverage connections to the department or agency from which he or she has exited to the advantage of a private entity. This Article will focus primarily on the first type of influence and to a lesser extent on the second and third. Federal revolving door laws, discussed next, are chiefly keyed to addressing the third form of influence, representation of private interests before one's former agency or department.

Current federal post-employment restrictions regulating the revolving door between government and the private sector reside in 18 U.S.C. § 207. The origins of this statutory provision trace in part to federal ethics laws enacted in the 1960s, which were later amended by the Ethics in Government Act of 1978.[67] The Ethics in Government Act, enacted in the aftermath of the Watergate scandal, marked a major milestone in the development of modern ethics legislation governing public officials. In 1979, after the passage of the Ethics in Government Act but before the law took effect, the U.S. House of Representatives held hearings over concerns that the Act's post-government employment restrictions were ambiguous and unduly onerous, risking an exodus from government employment and potentially discouraging individuals from entering public service in the future.[68] Although portions of the Ethics in Government Act were repealed and replaced, the provisions imposing post-employment restrictions largely remain, albeit with subsequent amendments.[69]

Current measures that apply to all executive branch employees include a "lifetime ban on switching sides" and a two-year prohibition on representation for matters within an employee's official responsibility.[70] The lifetime ban consists of a permanent ban on knowingly making a communication or appearance before any government entity ("any officer or employee of any department, agency, court, or court-martial of the United States or the District of

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67. *See* MASKELL, *supra* note 12, at 1; *see also* David Zaring, *Against Being Against the Revolving Door*, 2013 U. ILL. L. REV. 507, 524 n.84 (noting the "Bribery, Graft, and Conflicts of Interest Act of 1962, which provided for the first one-year cooling off period").

68. *Restrictions on Post-Employment Activity of Former Federal Officers and Employees: Hearing on H.R. 3325 Before the Subcomm. on Admin. L. & Governmental Rels. of the H. Comm. on the Judiciary*, 96th Cong. 4-5, 23-24 (1979) [hereinafter *Restrictions on Post-Employment Activity, 1979 Hearing*].

69. *See* MASKELL, *supra* note 12, at 1; Zaring, *supra* note 67, at 525-26. The Ethics in Government Act also imposed financial disclosure requirements on legislative and executive branch personnel, established the Office of Government Ethics (OGE) within the Office of Personnel Management tasked with "preventing conflicts of interest on the part of officers and employees of any executive agency," Ethics in Government Act, Title IV, Pub. L. No. 95-521, 92 Stat. 1862 (1978), and empowered the Attorney General to appoint an independent special prosecutor with the power to investigate suspected wrongdoing by government employees, Ethics in Government Act, Title VI, Pub. L. No. 95-521, 92 Stat. 1868 (1978).

70. *See* MASKELL, *supra* note 12, at 3-4.

Columbia"[71]) on specific matters in which the employee "participated personally and substantially" while in government service[72] and for which the United States either "is a party or has a direct and substantial interest."[73] The two-year restriction on representation applies to "a particular matter" that had been under the employee's official responsibility within one year of termination of the employee's government service.[74] In contrast to the lifetime ban on switching sides, the two-year prohibition does not contain a requirement for an employee to be "personally and substantially" involved in the matter and therefore may apply to a wider range of matters.[75] A one-year restriction, often termed a "cooling-off period" or "no-contact bar,"[76] under 18 U.S.C. § 207(c)(1) prohibits senior employees from "knowingly mak[ing], with the intent to influence, any communication to or appearance before . . . the department or agency in which such person served . . . in connection with any matter."[77] Very senior executive branch personnel must comply with a two-year prohibition of the kind faced by senior employees under section 207(c)(1); in addition, they are prohibited from knowingly making a communication to or appearance before certain members of the executive branch in *any* federal department or agency for two years.[78] Violations of 18 U.S.C. § 207 are crimes punishable by imprisonment under 18 U.S.C. § 216.

In reaction to the passage of the Ethics in Government Act's expanded post-employment restrictions, many top government officials voiced objections to the restrictions. First, they could have a reach and scope far broader than legislators

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71. 18 U.S.C. § 207(a)(1).

72. *Id.* § 207(a)(1)(B).

73. *Id.* § 207(a)(1)(A). Section 207(a) applies to "[a]ny person who is an officer or employee . . . of the executive branch," including "special Government employees." *Id.*

74. *Id.* § 207(a)(2). There is also a one-year prohibition on knowingly representing, aiding, or advising regarding "ongoing trade or treaty negotiation[s]" if the employee "personally and substantially participated" in trade or treaty negotiations during the one year prior to leaving government service. *Id.* § 207(b)(1).

75. *See* MASKELL, *supra* note 12, at 4.

76. *Restrictions on the Post-Employment Activities of Federal Officers and Employees: Hearing on H.R. 4917 and H.R. 5043 Before the Subcomm. on Admin. L. & Governmental Rels. of the H. Comm. on the Judiciary*, 100th Cong. 113 (1988) [hereinafter *Restrictions on Post-Employment Activities, 1988 Hearing*] (referring to section 207(c)'s "no-contact bar"); *see id.* at 57 (statement of Rep. Lamar Smith), 228 (statement of Simon Lazarus, Partner, Powell, Goldstein, Frazer, and Murphy) (explaining the one-year cooling-off period). The one-year "cooling off" period contained in 18 U.S.C. § 207(c) was "intended to prevent former high-level officials from exerting influence at their old agency, rather than to prevent their using any particular knowledge they might have concerning matters in which they actually participated or which they supervised." *Id.* at 113 (statement of John C. Keeney, Acting Assistant Att'y Gen., Crim. Div., U.S. Dep't of Just.).

77. 18 U.S.C. § 207(c)(1). "Senior personnel" for purposes of section § 207(c)(1) include those with a rate of pay greater than or equal to 86.5% of the rate of pay for Level II of the Executive Schedule, members of the uniformed services with a pay grade O-7 and above, and certain persons appointed by the President or Vice President, among others. *Id.* § 207(c)(2).

78. *Id.* § 207(d).

intended.[79] Second, they could induce senior officials to exit government prematurely and prevent government employees from being gainfully employed after leaving government.[80] Third, they may discourage entry into government in the first instance.[81] Fourth and finally, they may impose an oppressive administrative burden on employees who in good faith attempt to avoid violations of the Act.[82]

Yet these objections must be weighed against the desirable effects of post-employment restrictions, which were motivated in part to address the frequency of the revolving door phenomenon that put in jeopardy the confidentiality and integrity of the government's work and that tended to erode public trust in government.[83] The existence of post-employment provisions was intended in part

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79. *See Restrictions on Post-Employment Activity, 1979 Hearing*, *supra* note 68, at 23, 36, 58, 85–86, 91.

80. *See id.* at 23, 26, 33, 47–48, 51–52, 57. Relatedly, others argued against the wisdom and fairness of a "vicarious disqualification" principle in Proposed Rule 1.11 of the Model Code of Professional Responsibility, now the Model Rules of Professional Conduct, in which an individual attorney's disqualification on a matter due to prior government employment was imputed to the law firm at which he or she worked. *See* Benjamin R. Civiletti, *Disqualifying Former Government Lawyers*, 7 LITIG. 8, 10 (1981); *Restrictions on Post-Employment Activity, 1979 Hearing*, *supra* note 68, at 13.

81. *See Restrictions on Post-Employment Activity, 1979 Hearing*, *supra* note 68, at 47-48, 55, 86; *see also* Norman J. Ornstein, *Washington 2: Watergate Backlash*, 11 CHANGE 52, 53 (1979) (voicing concerns regarding threatened resignations of government officials and a potential "chilling effect on recruitment to public service"). J. Jackson Walter, former director of the OGE and the first to hold this position after passage of the Ethics in Government Act created the Office, referred to the Act's post-employment restrictions as "of major concern to presidential personnel recruiters who must be able to reassure prospective nominees that government service will not destroy their future opportunities with non-governmental employers." J. Jackson Walter, *The Ethics in Government Act, Conflict of Interest Laws and Presidential Recruiting*, 41 PUB. ADMIN. REV. 659, 661 (1981).

82. *See Restrictions on Post-Employment Activity, 1979 Hearing*, *supra* note 68, at 24.

83. In a 1980 panel discussion regarding the recently passed Ethics in Government Act, one panelist provided statistics to illustrate the commonality of revolving door job transitions that motivated the passage of the legislation: Just over half (twenty-two of forty-two) of the regulatory commissioners appointed from 1971 to 1975 previously worked at companies that their agency regulated or at those companies' law firms, and just under half (17 of 36) of the commissioners who left government from 1971 to 1975 were subsequently employed in regulated industries or law firms. David Cohen, *Panel V: The "Revolving Door"—Should It Be Stopped?*, 32 ADMIN. L. REV. 383, 384-85 (1980). More than one quarter of the 1,406 employees and officers who exited the Defense Department from 1969 to 1973 were employed by the very contractors with which they had engaged at the Defense Department "or that were under their official jurisdiction." *Id.* at 385. With respect to the FDA, it was noted that "regulated companies or their law firms" employed 11 of 12 lawyers who departed the General Counsel's Office of the FDA (now the Office of Chief Counsel) for non-government employment between 1971 and 1976. *Id.* The statistics recounted here do not distinguish between those who subsequently took law firm employment versus industry employment, but that distinction, I would argue, is an important one. Whereas a law firm typically serves many clients beyond just those companies in one particular regulated industry—thus providing a former government attorney with an array of nonconflicting opportunities—employment at a company within a regulated industry is more directly and less avoidably fraught with conflict; *see also* Walter, *supra* note 81, at 663.

to manage public perceptions of the ability of government employees to unfairly benefit from their prior work.[84] In a 1979 hearing before the House Committee on the Judiciary, former Director of the Federal Office of Personnel Management Alan Campbell described this aspect of the law's underlying goals as it applied to the one-year cooling-off period:

> In terms of the 1-year bar, it seems to us appropriate that there be that kind of restriction in order to provide a clear signal that experience and activity will not be one in which a person could step from one side of the issue to the other side of the issue, and in that manner be able to take advantage of that situation. The 1-year bar is in many ways, I would argue, the most important provision in relationship to dealing with the public perception of how people who serve for a while in the Federal Government are able to take advantage of it.[85]

Despite a negative initial reaction to the restrictions among many professionals and government employees, the predicted en masse departure of government employees did not take place, and post-employment restrictions persisted.[86] Nearly ten years later, in 1988, officials from government and the private sector once again debated the merits of post-employment restrictions for federal employees in hearings before the House Judiciary Committee. Acting Assistant Attorney General of the Criminal Division of the Department of Justice ("DOJ") John Keeney testified before the House that "we believe the present section 207 strikes a delicate balance between public and private interests," noting that the "right to earn a living can, and should, be limited if there is a sufficient nexus between the former government employee's official responsibilities and a post-employment activity to create the potential for a conflict or for the exercise of improper influence."[87] Keeney went on to testify that:

> [A]ny bar on post-government employment activity should be grounded on the idea that the prohibited activity has a potential either for causing the employee to use specific information gained about a private party or the government while working on a matter, or for the employee to exert improper influence after leaving government service.[88]

Time-limited employment restrictions, which indisputably were meant to strike the balance that Keeney described between public and private obligations, apply to all but the permanent restriction of section 207(a)(1), which is triggered

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84. *See* U.S. Off. of Gov't Ethics, Legal Advisory, *supra* note 12, at 1-2.

85. *See Restrictions on Post-Employment Activity, 1979 Hearing*, *supra* note 68, at 20 (statement of Alan K. Campbell, Dir., Fed. Off. of Personnel Mgmt.). Indeed, the one-year no-contact ban has been called "the heart of the revolving door provision." Cohen, *supra* note 83, at 386.

86. Cohen, *supra* note 83, at 385-87.

87. *Restrictions on Post-employment Activities, 1988 Hearing*, *supra* note 76, at 114-15 (statement of John C. Keeney, Acting Assistant Att'y Gen., Crim. Div., U.S. Dep't of Just.).

88. *Id.* at 115.

by personal and substantial participation[89] in particular matters involving a specific party or parties.[90] Both 18 U.S.C. § 207(a)(1) and § 207(a)(2) are tethered to particular matters in which an employee participated or over which an employee had responsibility, and consequently, their scope is largely circumscribed. The one-year "no-contact" ban is far broader, but only concerns representation before the agency or department in which a high-level employee served.[91] Not directly addressed in section 207's prohibitions, however, is the possibility that the employee could exert improper influence *outside* of dealings with the government (or a foreign government). In other words, the prohibitions imposed in section 207 take aim at representation before a government department or agency, thereby leaving unaddressed the potential for a former government employee to exert improper influence indirectly or in a manner that does not involve representation before any branch or arm of government.

Importantly, the prohibitions are all post-hoc, taking effect during the period after the employee leaves office, seemingly without the direct intent to preempt conflicts of interest or achieve impartial decision-making while the employee remains in office. Existing post-employment restrictions thus appear inadequate to prevent biased decision-making by incumbent government regulators who may anticipate future employment in a regulated industry.[92]

Within the legal profession, rules of professional conduct prevent some of the same forms of prohibited conduct found in 18 U.S.C. § 207. Mirroring the language of 18 U.S.C. § 207(a)(1), Model Rule 1.11 forbids attorneys who formerly served as government employees or public officers from "represent[ing] a client in connection with a matter in which the lawyer participated personally and substantially as a public officer or employee," unless the former government employer consents to the representation,[93] or from using information obtained during government service to the disadvantage of the government.[94] The Model Rule goes on to impose obligations on the firm at which a so-called "disqualified" lawyer works to ensure that this lawyer is appropriately cordoned off from the matter, both with respect to representation

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89. 18 U.S.C. § 207(a)(1)(B).

90. *Id.* § 207(a)(1)(C).

91. *Restrictions on Post-employment Activities, 1988 Hearing*, *supra* note 76, at 57 (statement of Rep. Lamar Smith) (emphasizing that section 207's one-year cooling-off period was "just *agency-wide*, and did not contemplate a government-wide ban").

92. Walter recognized as much, writing in 1981 that "bias or prejudgment on policy issues is not, by itself, an issue under the conflict of interest statutes." Walter, *supra* note 81, at 663.

93. MODEL RULES OF PRO. CONDUCT r. 1.11(a)(2) (AM. BAR ASS'N 1983). The Justice Department has interpreted this rule to apply "even when the lawyer's subsequent representation would not be adverse to the government." Stacy M. Ludwig, *The Revolving Door: Professional Responsibility Considerations for Attorneys Entering or Leaving the Department of Justice*, 57 ETHICS 1, 4 (2009).

94. MODEL RULES OF PRO. CONDUCT r. 1.11(a)(1) (AM. BAR ASS'N 1983) (applying Rule 1.9(c) to former government employees).

and compensation.[95] Other rules, though not specific to former government employees, govern attorney representation when conflicts of interest arise with current or former clients.[96] Of course, government employees come from a range of professional backgrounds, the legal profession being only one of them, and attorneys may work in a non-legal capacity during or after government service. However, the Justice Department, for example, has interpreted Rule 1.11(a)'s "representation" language as extending beyond formal "attorney" positions to encompass work such as consulting.[97]

Writing in the context of federal financial disclosure requirements, which were a cornerstone of the Ethics in Government Act, the first director of the Office of Government Ethics ("OGE") J. Jackson Walter noted:

> At the center of this entire topic is the distinction, and the possibility of a clash, between an official's interest in his private economic affairs and the government's (and public's) interest in the proper administration of the official's office . . . . Although the conflict of interest laws are criminal statutes, the regulation of conflicts of interest is concerned with potential harm and is decidedly civil and prospective in nature.[98]

So too does this distinction apply in the context of post-government employment: individuals derive private financial benefit that may collide with the interests of the public and the government. It is worth questioning whether existing ethics regulations are sufficient to ensure "proper administration of an official's office" in the face of the prospect (and, for many, the likely eventuality) of post-agency employment in a regulated industry.

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95. *See id.* at r. 1.11(b), 1.11(c). Model Rule 1.11(c) also prohibits representation of a private client with interests adverse to a person about whom the government employee obtained confidential information. Ultimately, in Model Rule 1.11, screening of a disqualified former government attorney to ensure that the attorney does not work on the matter at issue, along with written notice to the government agency, is an acceptable means to avoid vicarious or "imputed" disqualification of an entire law firm, in conformity with the position recommended by former U.S. Attorney General Benjamin Civiletti. *See* Civiletti, *supra* note 80, at 56; Warren Fields, Note, *Vicarious Disqualification and the Model Rules of Professional Conduct*, 40 OKLA. L. REV. 231, 244 & n.94 (1987) (quoting MODEL RULES OF PRO. CONDUCT r. 1.10 cmt. 5 (AM. BAR ASS'N 1983)) ("[I]f the more extensive disqualification in Rule 1.10 were applied to former government lawyers, the potential effect on the government would be unduly burdensome.").

96. MODEL RULES OF PRO. CONDUCT r. 1.7 (AM. BAR ASS'N 1983) (barring representation when there is a concurrent conflict of interest, unless, among other controls, each client whose interests are affected provides written informed consent); r. 1.8 (pertaining to business transactions with a client and other forms of gift or compensation to or from a client, among other things); r. 1.9 (barring the colloquially termed "switching of sides" in representation, unless a former client provides informed consent).

97. *See* Ludwig, *supra* note 93, at 4-5.

98. Walter, *supra* note 81, at 660.

B. Post-Government Employment in Industry as Regulatory Capture

At roughly the time when federal ethics legislation was being developed and remodeled in the 1970s and 1980s, a body of scholarship began to emerge describing the phenomenon of regulatory capture, a theory that stems in great part from the work of economist George Stigler.[99] One scholar has summarized regulatory capture as follows: "Even when a regulatory body has been set up to prevent monopolistic abuse, regulation ends up being 'captured' by the firms it is supposed to discipline."[100] Professor Richard B. Stewart, who served as Assistant Attorney General in the Justice Department's Environment and Natural Resources Division, has described capture as a phenomenon in which agencies, "in carrying out broad legislative directives, . . . unduly favor organized interests, especially the interests of the regulated or client business firms and other organized groups at the expense of diffuse, comparatively unorganized interests such as [those of] consumers."[101] Stewart identified four causal factors for the "industry orientation" characteristic of capture. First, agency administrators "depend[] on industry cooperation in order to achieve [their] objectives," thus placing them "in an inherently weak position."[102] Second, in the process of crafting and honing regulation and regulatory control of an industry, agencies end up reducing competition in the regulated industry, thereby "buttress[ing] the position of the established firms."[103] Third, agencies have comparatively more modest resources, including "money, personnel, and political influence" than do regulated firms, making it in an agency's best interest to "compromise" with the entities it regulates."[104] Fourth, and perhaps most critically, organized interests typically have a greater "stake in the substance of agency policy" than would a single member of a more diffuse interest, such as a single consumer, and organized interests leverage their relative abundance of resources to achieve a greater impact on policy.[105]

With respect to the last causal factor Stewart identified, the FDA may be unique: there has been significant growth in the number and power of disease-specific patient advocacy groups, which constitute a form of collective representation of the "consumer interest" on matters of drug regulation before the FDA.[106] There has also been a recent movement within the agency,

99. *See* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 10-12 (1971); *see also* Bo, *supra* note 58, at 204-06; Jon Hanson & David Yosifon, *The Situation: An Introduction to the Situational Character, Critical Realism, Power Economics, and Deep Capture*, 152 U. PA. L. REV. 129, 202-05 (2003).

100. Bo, *supra* note 58, at 204.

101. Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1684-85 (1975).

102. *Id.* at 1685.

103. *Id.*

104. *Id.* at 1686.

105. *Id.*

106. *See, e.g.*, Beth Snyder Bulik, *ALS Ice Bucket Challenge Advocacy Group Calls for Speedy FDA Approval of Amylyx Now-Pending Drug*, FIERCE PHARMA (Sept. 15, 2021),

galvanized by legislation including the Food and Drug Administration Safety and Innovation Act of 2012[107] ("FDASIA") and the 21st Century Cures Act,[108] to include greater patient participation in the FDA's work.[109] Despite their increasing power and cohesion, patient groups remain relatively diffuse. It is therefore questionable whether patient groups can rival industry with respect to the influence they wield on the FDA's work.[110]

Through capture, regulated entities utilize political power and influence to shape regulation for their benefit, explaining in many cases the discordance between regulators' apparently public-serving goals and outcomes that

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https://perma.cc/C6X9-KSQ8 (reporting on the advocacy of the ALS Association before the FDA); Kyle T. Edwards, *The Role of Patient Participation in Drug Approvals: Lessons from the Accelerated Approval of Eteplirsen*, 72 FOOD & DRUG L.J. 406, 414 (2017) ("Following the success of the AIDS community in lobbying FDA, other disease-specific patient communities have attempted to replicate the model, working both from outside FDA, by harnessing the media and lobbying Congress, and from the inside, by engaging with FDA officials in drug development meetings and public hearings."); Lewis A. Grossman, Essay, *FDA and the Rise of the Empowered Consumer*, 66 ADMIN. L. REV. 627, 630 (2014) ("[M]odern consumers have acquired significant influence over the regulation of food and drugs and have generally exercised this influence in ways calculated to maximize their choice"); *see also* Grossman, *supra*, at 668-73 (recounting the strategic efforts of AIDS groups to influence FDA policy relating to antiretroviral therapies during the 1980s, which later became "a widely used model for direct involvement in FDA decisionmaking").

107. Pub. L. No. 112-144, 126 Stat. 993, 1124 (2012) ("The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions . . . ."); *see also Food and Drug Administration Safety and Innovation Act (FDASIA)*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), https://perma.cc/RK9V-FZP5 (summarizing FDASIA's measures to promote patient engagement, including a Patient Focused Drug Development program and a health information technology public-private working group).

108. Pub. L. No. 114-255, 130 Stat. 1033, 1083-86 (2016) (instructing the Secretary to prepare guidance documents for collection of "patient experience data" as part of the Patient-Focused Drug Development Program, including data capturing the impact of diseases on patients and their preferences regarding treatment).

109. *See* Edwards, *supra* note 106, at 417; Jordan Paradise, *21st Century Citizen Pharma: The FDA & Patient-Focused Drug Development*, 44 AM. J.L. & MED. 309, 319-326 (2018); Grossman, *supra* note 106, at 673-74.

110. Industry capture of patient groups themselves would tend to counteract any effect patient groups may have as a counterpoint to industry interests. *Cf.* Edwards, *supra* note 106, at 414 ("The common interest in faster drug approvals shared by pharmaceutical companies and many patient groups facing a life-threatening disease with no effective treatment options means that patient advocacy groups often work closely with and receive substantial funding from pharmaceutical manufacturers and their lobbying organizations."). Patients' values and interests are also diverse, making organized representation difficult. *Cf.* Jason L. Schwartz, *Real-World Evidence, Public Participation, and the FDA*, 47 HASTINGS CTR. REP. 7-8 (2017) (questioning whether a single consumer member on an FDA advisory committee could "reasonably represent the 'consumer perspective' in light of the heterogeneous values and beliefs that shape patients' preferences regarding the risks and benefits of medical treatment"). Finally, as patients become more organized, increasing numbers of disease-specific patient advocacy groups may produce a collective action problem and so undercut the influence those groups have on the FDA. *See* Daniel P. Carpenter, *Groups, the Media, Agency Waiting Costs, and FDA Drug Approval*, 46 AM. J. POL. SCI. 490, 500-01 (2002).

ultimately favor the regulated. Economist and Professor Sam Peltzman, who built on the work of Stigler, summarized Stigler's economic theory of regulation as precipitating a transformation in views about regulation from a "benign view," in which regulation was a "promoter of the general interest," to an "ascendent image . . . of the regulator captured by the regulated."[111] Professors Jon Hanson and David Yosifon describe well Stigler's contribution:

> Stigler was challenging a long-held conventional wisdom that governments and their agencies create beneficial regulations. Underlying that conventional wisdom was the supposition that regulatory processes were fair and that regulators were dispositionally motivated to serve the public interest. Stigler's challenge to those suppositions was initiated by his discovery that, in fact, a sanguine view of our regulatory institutions had no empirical basis and that, if anything, those institutions' actions were counterproductive to their espoused goals . . . . Stigler contested the reassuring conventional wisdom that our institutions are neutral and well-functioning and rejected the idea that the stated goals of regulators are controlling.[112]

From the foundational work of scholars such as Stigler and Peltzman emerged an array of theoretical variations on capture: materialist versus non-materialist capture,[113] strong versus weak capture,[114] and deep versus shallow capture,[115] among others.[116]

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111. Sam Peltzman, *George Stigler's Contribution to the Economic Analysis of Regulation*, 101 J. POL. ECON. 818, 822 (1993); *see also* Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J.L. & ECON. 211, 212 (1976) ("'[P]roducer protection' represents the dominance of a small group with a large per capita stake over the large group (consumers) with more diffuse interests. The central question for . . . [Stigler's] theory then becomes to explain this regularity of small group dominance in the regulatory process (and indeed the political process generally)."). For a summary of early literature developing the theory of capture, see Wentong Zheng, *The Revolving Door*, 90 NOTRE DAME L. REV. 1265, 1270-72 (2015).

112. Hanson & Yosifon, *supra* note 99, at 205.

113. *See* David Freeman Engstrom, *Corralling Capture*, 36 HARV. J.L. & PUB. POL'Y 31, 31-32 (2013) (describing materialist capture as the "classic account" that derived from the work of Stigler, and later Peltzman and Richard Posner).

114. *See id.* at 33; Carpenter & Moss, *supra* note 58, at 11-12. As Professors Daniel Carpenter and David Moss describe the distinction, in cases of "strong capture," the public would be better off without the regulation, whereas in cases of "weak capture," the regulation retains a positive, albeit attenuated, net social benefit. *Id.*

115. *See* Hanson & Yosifon, *supra* note 99, at 213 (presenting Stigler's work as depicting "only a very shallow form of capture," and arguing that "*any* institutions or individuals capable of influencing existing wealth and power distributions will be subject to the pressures of capture"); *see id.* at 202-18.

116. Professor James Kwak has propounded a theory of "cultural capture," which bears resemblance to Hanson and Yosifon's theory of deep capture in attributing the influence of capture to irrational, situational forces on regulators as human beings. *See* James Kwak, *Cultural Capture and the Financial Crisis*, *in* PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 71, 76-93 (2014). Kwak concentrates specifically on the role of identity, status, and relationships in bringing about cultural capture. *Id.* at 80.

At its core, capture identifies the divergence between traditional perceptions of regulation as either neutral or favorable to the constituency a regulator claims to serve—the public—and a reality in which regulation furthers the interests of the regulated, a result which regulated entities effectively bring about. The preexisting theory of the rational, purely public-serving regulator can be regarded as a "regulatory fundamental attribution error," one that the work of Stigler and later scholars of capture theory, including Hanson and Yosifon, helped to debunk.[117] Hanson and Yosifon's scholarship helped elucidate that a reliance on disposition when assessing regulatory processes and outcomes is misplaced. Instead, it is power over *situation*, both exterior and interior, that produces a deeper, more insidious, and less readily acknowledged form of capture—what they refer to as "deep capture."[118]

As a theoretical construct, deep capture helps explain how it is that powerful forces exert influence, the extent to which that influence extends, and why it is often difficult to detect. Regulatory agencies are not the only institutions that capture infiltrates; in fact, there are arguably no institutions immune from such influence. Moreover, deep capture is not limited to institutions; instead, it extends to the "interior situation of relevant actors," including how they think and their perceptions of themselves and the world.[119] Powerful forces reinforce and amplify their power by exercising influence over "exterior and interior situational features . . . including those features that purport to be, and that we experience as, independent, volitional, and benign."[120] It is precisely the continued belief that disposition predominates—that our actions are fully volitional and autonomously chosen—that permits capture to permeate so deeply and yet remain unseen.

With respect to identity, regulators may "be more inclined to trust the side with which she identifies more." *Id.* at 83. Second, perceptions of industry as "high status" may predispose regulators toward the views and policy positions of industry as opposed to those of patients or consumers. *Id.* at 85-89. Third, regulators' current relationship with industry or expected future relationships with the regulated industry due to the revolving door may give rise to "relationship pressures" to favor industry interests in order to preserve social connections. *Id.* at 90-91.

117. The fundamental attribution error refers to the human "proclivity to ascribe the vast majority of our actions to disposition-based choice and to ignore the more significant role played by situational forces . . . in our environment and in our interiors." Adam Benforado & Jon Hanson, *The Costs of Dispositionism: The Premature Demise of Situationist Law and Economics*, 64 MD. L. REV. 24, 29 (2005); Hanson & Yosifon, *supra* note 99, at 212-13. In another work, Hanson and Chen argue that the macro script of corporate law treats "regulation and the regulatory process . . . as exogenous and reliable," although the backdrop of a larger "meta script" reveals that "regulation is actually endogenous: interests compete to determine who among the various regulatory constituents will be served by the regulation and at whose expense." Ronald Chen & Jon Hanson, *The Illusion of Law: The Legitimating Schemas of Modern Policy and Corporate Law*, 103 MICH. L. REV. 1, 111 (2004).

118. Hanson & Yosifon, *supra* note 99, at 213; *see id.* at 212-19.

119. *Id.* at 214-15.

120. *Id.* at 218 (emphasis omitted). Corporations, in particular, can be prime instruments to effect deep capture due to their concentrated wealth and singular goal of profit maximization. *Id.* at 220-21.

Post-agency employment in a regulated industry can be conceptualized as a form of deep capture: it is an important situational influence that can exert a powerful effect on the behavior and decisions of even the most well-intentioned regulator, without leaving any trace of an explicit quid pro quo. A regulator's intention or desire to remain impartial cannot negate the effects of capture. As Hanson and Yosifon perceptively recognized: "Deep capture makes clear that people's intentions and beliefs may have little to do with their behavior and that, insofar as they do, those intentions and beliefs are part of what interests compete to capture."[121] FDA regulators' intentions and beliefs may remain ostensibly levelled at the advancement of public interest while, in reality, placing industry priorities or self-interest above the interests of patients and consumers.

Conceptualizing prospective employment in the pharmaceutical and biotech industries as a form of deep capture helps make sense of recent FDA controversies and brings into focus the danger present in unchecked discretion of senior agency officials. Discretionary judgments by FDA regulators, such as whether to grant accelerated approval, may be far more susceptible to capture than are other components of the agency's work, such as rulemaking for example, which possesses stronger procedural safeguards and more systematic mechanisms for review, or issuance of guidance documents, which carry less decisive weight since they lack the force of law.[122] Yet the marks of deep capture are remarkably difficult to identify; a focus on disposition of the kind Hanson and Yosifon bemoaned risks cloaking capture in the garb of discretion. For example, unusually close associations between a regulator and a pharmaceutical company during the drug approval process could be chalked up to managerial preference or even deliberate thoroughness without perceiving the risk of capture that close associations tend to breed.

At a time when the FDA appears plagued by a continuing crisis of legitimacy, it is worth examining the situational forces that undergird and risk delegitimating the agency and its work;[123] post-agency employment in industry

121. *Id.* at 217.

122. *Cf.* Engstrom, *supra* note 113, at 35-36. Engstrom refers to "micro-levels of agency decision-making," which in his view warrant greater concern. *Id.* at 36; Stewart, *supra* note 101, at 1681-88 (conceptualizing the problem of capture as being one of agency discretion); *see also* Trudo Lemmens & Benjamin Freedman, *Ethics Review for Sale? Conflict of Interest and Commercial Research Review Boards*, 78 MILBANK Q. 547, 561 (2000) (commenting that "[c]onflict-of-interest rules are particularly important when regulations allow much discretion and rely on the fairness and independence of individual decision makers").

123. *Cf.* Chen & Hanson, *supra* note 117, at 4 (arguing that "[p]olicies that purport to be in the public interest, but that actually serve primarily the interest of the most powerful, risk being delegitimated"); *see also*, *e.g.*, *The Food and Drug Administration's Critical Mission and Challenges for the Future: Hearing before the H. Comm. on Oversight & Gov't Reform*, 110th Cong. 3 (2007) (statement of Henry A. Waxman, Chairman, House Comm. on Oversight & Gov't Reform) [hereinafter Hearing, *The Food and Drug Administration's Critical Mission and Challenges for the Future*] ("The warning signs are clear. FDA is an agency in crisis. We need to act now and to learn from the vast experience of those who have managed the agency through the years."); Grossman, *supra* note 106, at 634-35 (discussing the declining trust in government institutions and the medical establishment in the latter portion of the twentieth

is arguably one of those forces. Of course, regulated entities wield influence through a broad web of channels extending far beyond post-agency employment of FDA regulators.[124] (Post-agency employment may be among the least costly modes of influence, however, because it requires no up-front investment by the regulated and may yield benefits to regulated entities even if industry employment of a former regulator never materializes.[125])

One scholar has commented that the "[r]hetoric [of capture] . . . degrades our faith in government" and "undermines civic trust."[126] This could be true if capture were perceived where it did not in fact exist. But the reverse is equally, if not more, problematic. If capture were indeed taking place but remained unrecognized, the consequences would be far greater. In the domain of drug approvals, for example, a therapy with a price of tens of thousands of dollars annually (such as Aduhelm) could garner an approval without adequate evidence to demonstrate its safety or efficacy. Just as unrecognized capture can inflict harm, a recognition of capture may have a salutary effect.

An acknowledgement of the existence of capture should lead ineluctably to the question of whether capture is inevitable, and if so, *how much* capture should be tolerated. One way to approach the latter question is to develop proxies for

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century and citing research that in 2006, only 36% of survey respondents viewed the FDA in a positive light); Manas Mishra, *FDA Seeks Probe into Its Talks with Biogen Before Alzheimer's Drug Approval*, REUTERS (July 9, 2021, 7:05 PM), https://perma.cc/ZK2T-DLTJ (reporting on Dr. Janet Woodcock's request to the OIG for "an independent review" of interactions between FDA and Biogen during Aduhelm's review); Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS E743, E744 (2020) (noting that eight of ten experts on an FDA advisory committee that recommended against narrowing the indication of opioid labels to exclude chronic pain conditions had financial connections to pharmaceutical companies); Kolodny, *supra*, at E746 (observing that two FDA reviewers who were involved in approval of Purdue Pharma's oxycodone drug application later accepted employment at Purdue).

124. The influence of the pharmaceutical industry within health care is extensive and far-reaching, and many of the mechanisms of influence that the industry utilizes have a bearing, whether direct or indirect, on the work of the FDA. For an illustrative sample of recent publications documenting these mechanisms of influence, see Waqas Haque et al., *Conflicts of Interest of Editors of Medical Journals*, 13 PLOS ONE 1, 4 (2018); Genevieve Pham-Kanter, *Revisiting Financial Conflicts of Interest in FDA Advisory Committees*, 92 MILBANK Q. 446, 457 (2014); Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 JAMA 1921, 1923-24 (2006); Ray Moynihan et al., *Financial Ties Between Leaders of Influential U.S. Professional Medical Associations and Industry: Cross-Sectional Study*, 369 BRITISH MED. J. 1, 3-4 (2020); Timothy S. Anderson et al., *Characteristics of Biomedical Industry Payments to Teaching Hospitals*, 39 HEALTH AFFS. 1583, 1587 (2020).

125. Relatedly, Professor Yeon-Koo Che has described the phenomenon of "imperfect enforceability" of collusion between regulator and the regulated; in other words: "[T]he firm cannot give a contractual assurance to the regulator that her favor will be rewarded. Without a binding assurance, it may not be certain that the firm will, *ex post*, prefer the regulator who exerted the most favor rather than the one most qualified for the particular job." Yeon-Koo Che, *Revolving Doors and the Optimal Tolerance for Agency Collusion*, 26 RAND J. ECON. 378, 389 (1995).

126. Engstrom, *supra* note 113, at 39.

capture, such as the mode and frequency of interaction with regulated entities. Those proxies should be tracked and carefully monitored, and this form of monitoring already exists, albeit without explicitly identifying capture-avoidance as a goal. Agencies such as the FDA have protocols in place for their exchanges with drug companies during the course of drug development, for example.[127] Deviations from these protocols should be grounds for internal investigation and action. Within administrative law, the prohibition on ex parte contacts provides a clear model from which to strengthen procedure surrounding agency interactions with industry during drug development and review of drug applications.[128] Ex parte contacts with an agency official while a drug maker's NDA or BLA, for example, is under review should be placed on the record and should be potential grounds either for recusal of that agency official from the review process, or for reassessment of the NDA or BLA if the agency has already reached a decision by the time ex parte contacts are disclosed. Among the factors that should be part of an assessment of potential impropriety and proper remedies include "the gravity of the . . . communications[,] whether the contacts may have influenced the agency's ultimate decision[, and] whether the party making the improper contacts benefited from the agency's ultimate decision."[129] Ex parte

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127. *See, e.g.*, U.S. FOOD & DRUG ADMIN., BEST PRACTICES FOR COMMUNICATION BETWEEN IND SPONSORS AND FDA DURING DRUG DEVELOPMENT: GUIDANCE FOR INDUSTRY AND REVIEW STAFF 10 (2017), https://perma.cc/UC8L-VR32 ("Communications that involve sharing results and information at critical milestones during drug development or at the appropriate stage of development for a biosimilar product, or are necessary for a stalled development program to proceed, are best addressed in formal meetings between the FDA and sponsors (e.g., face-to-face meeting, teleconference, or written response only (WRO))."); *see also* Feuerstein, Herper & Garde, *supra* note 29 (quoting an Aduhelm advisory committee member as saying that "[i]f there truly were a meeting that was off the record, or off the books [between the FDA's Billy Dunn and a Biogen executive], . . . [it] would reinforce concerns that this was a highly atypical relationship between a drug manufacturer and a regulator").

128. *See* 5 U.S.C. § 557(d)(1)(A) ("[N]o interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding."). The Administrative Procedure Act (APA)'s prohibition on ex parte communications applies to all formal agency proceedings, including formal rulemaking and adjudication. Section 557(d) provides a remedy for ex parte communications: they must be placed on the record, 5 U.S.C. § 557(d)(1)(C), and the party that engaged in the ex parte contact may be asked to "show cause why his claim or interest . . . should not be dismissed . . . or otherwise adversely affected." 5 U.S.C. § 557(d)(1)(D); Pro. Air Traffic Controllers Org. v. Fed. Lab. Rels. Auth., 685 F.2d 547, 564 (D.C. Cir. 1982) ("[A]gency proceedings that have been blemished by ex parte communications have been held to be voidable.").

129. *Pro. Air Traffic Controllers*, 685 F.2d at 564-65. The FDA does indeed have regulations prohibiting ex parte communications in certain circumstances, *see* 21 C.F.R. § 10.55, but the relevant regulation addressing meetings and correspondences, *id.* § 10.65, appears not to forbid the kind of concerning communications that reportedly occurred between Biogen representatives and FDA regulators during Aduhelm's review. At the least, existing regulation suggests that the FDA was obligated to "promptly . . . file in the appropriate administrative file memoranda of meetings prepared by FDA representatives and all correspondence . . . that relate to a matter pending before the agency." *Id.* § 10.65(f).

contacts can be conceptualized as one means by which revolving door-induced bias can assume a tangible form.

Lessons from bias in adjudication can be taken one step further: the revolving door arguably endows FDA regulators with a substantial pecuniary interest, albeit an indirect one, in the outcome of the agency's decision to approve a drug.[130] Importantly, the relevant question in identifying a due process violation due to bias is not whether bias "actually, subjectively" exists, but rather "whether the average judge in his position is 'likely' to be neutral, or whether there is an unconstitutional 'potential for bias.'"[131] So too for revolving-door induced bias at agencies such as the FDA. Actual bias on the part of a regulator need not be proved; rather, the proper test is an objective one.[132] It is the potential for bias (or, more precisely, the probability of bias) that demands mitigating measures. Assessments of probability turn on the circumstances,[133] a matter that will be revisited later in the context of conflicts of interest and gift-giving.[134] The case law on due process and recusal provides an opportunity to revisit the foundational concept of deep capture; the Supreme Court recognized in these cases that a subjective probe for the "real motives at work"[135] in a judge's decision-making cannot be the Court's task due to the "difficulties of inquiring into actual bias, and the fact that the inquiry is often a private one."[136] In other words, a dispositional inquiry into actual motives is not reliable when disposition

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130. For example, a pharmaceutical company whose drug application is granted approval may later employ the very FDA regulator who was instrumental in securing the drug's approval. The employee who anticipates private-sector employment may be said to have an indirect pecuniary interest in the outcome of the drug review process. For key cases on bias in adjudication, see *Caperton v. A.T. Massey Coal Co.*, 556 U.S. 868 (2009) (involving, in the lower court, reversal of a verdict against Massey Coal by the Supreme Court of Appeals of West Virginia after the company's CEO made significant campaign contributions that may have helped clinch judicial election of a West Virginia Supreme Court justice before whom the case was decided, and holding that the justice should have recused himself due to a "serious, objective risk of actual bias"); and *Gibson v. Berryhill*, 411 U.S. 564, 578 (1973) (affirming the district court's holding that a state board of optometry composed only of independent practitioners could not engage in proceedings to revoke the licenses of employed optometrists because "success of the Board's efforts would possibly redound to the personal benefit of members of the Board," thus making the Board's efforts "biased by prejudgment and pecuniary interest"). It is not only direct pecuniary interests that must concern courts when a due process violation is raised, but also "a more general concept of interests that tempt adjudicators to disregard neutrality." *Caperton*, 556 U.S. at 878.

131. *Caperton*, 556 U.S. at 881.

132. *See id.* at 882-83.

133. *See id.* at 884 ("The inquiry centers on the contribution's relative size in comparison to the total amount of money contributed to the campaign, the total amount spent in the selection, and the apparent effect such contribution had on the outcome of the election.").

134. *See infra* section III.A.

135. *Caperton*, 556 U.S. at 883.

136. *Id.*; *see also id.* at 883-84 ("[T]he Court has asked whether, 'under a realistic appraisal of psychological tendencies and human weakness,' the interest 'poses such a risk of actual bias or prejudgment that the practice must be forbidden if the guarantee of due process is to be adequately implemented.'" (quoting Withrow v. Larkin, 421 U.S. 35, 47 (1975))).

itself can be captured and actual motives may not align with intentions.[137]

Assuming that a risk of capture is inherent in the very organization and operation of the administrative state, a key question is whether the relative risks and benefits to public versus private interests strike an acceptable balance from a societal perspective. What adjustments should, or must, be made to bring the relative benefits to public and private interests in line with an agency's goals? The FDA's website identifies its mission as the following: to "protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation," among other responsibilities.[138] The FDA also seeks to "advanc[e] the public health" through measures to "speed innovations that make medical products more effective, safer, more affordable."[139] The FDA's statutory mission is very similar: "[to] promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," and "with respect to such products, [to] protect the public health."[140]

As these mission statements make clear, the agency pursues a multiplicity of goals, which are subject to prioritization and which allow room for agency discretion.[141] Do promotion, protection, and advancement of the public health call for a maximization of public health? Or perhaps an *optimization* of public health? If either of those, then public health by what measure? Pharmaceutical and product safety and efficacy, certainly. But what of other factors such as regulatory efficiency, innovation, public access to therapies and therapeutic choice, and symbiosis with regulated entities and other stakeholders? If each of these goals would lend itself to a different public-private tradeoff, which tradeoff should prevail, and who should make that determination? If the balance is left to the discretion of high-level political appointees who change with each presidential administration and whose discretionary decision-making may be

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137. *See supra* text accompanying notes 112-21. Even Justice Felix Frankfurter, in a case in which he recused himself, described the subconscious forces that may prevent a judge from being a disinterested arbiter: "[O]n the whole judges do lay aside private views in discharging their judicial functions . . . . But it is also true that reason cannot control the subconscious influence of feelings of which it is unaware. When there is ground for believing that such unconscious feelings may operate in the ultimate judgment, or may not unfairly lead others to believe they are operating, judges recuse themselves. They do not sit in judgment . . . . The guiding consideration is that the administration of justice should reasonably appear to be disinterested as well as be so in fact." Pub. Utils. Comm'n v. Pollak, 343 U.S. 451, 466-67 (1952) (Frankfurter, J., concurring).

138. *What We Do*, U.S. FOOD & DRUG ADMIN., https://perma.cc/CNB5-WXC4.

139. *Id.*

140. 21 U.S.C. § 393.

141. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 14-15 (4th ed. 2014) (noting that "[n]otwithstanding the clear decision by Congress to put health promotion first and health protection second, the FDA, reflecting its heritage, has reversed this order in the mission statement that appears on the agency's website").

subject to capture, the agency may find itself unmoored from unwavering and assuredly public-serving goals.[142]

Though it seems to have enthralled scholars in its appeal to our intuition, regulatory capture has not escaped criticism following unsuccessful attempts to substantiate the theory with empirical evidence,[143] leading some to suggest that the better policy may be to "[l]et the revolving door spin,"[144] or at least to "make peace with the revolving door."[145] Avant-garde theories such as the human-capital hypothesis and the market-expansion hypothesis emerged to justify the paradoxical empirical finding that regulators who later accepted industry employment were more, not less, harsh as regulators.[146] Others have suggested that the revolving door phenomenon may have offsetting benefits such as increased regulatory compliance by private-sector firms that hire former regulators, perhaps because former regulators bring with them a more fulsome understanding of the importance of relevant regulation.[147] Despite continued

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142. Of course, another argument is that these sorts of tradeoffs are best left to agency discretion, even at the cost of inconsistency and vacillation across administrations, because Congress delegated to agencies the ability to exercise a policymaking function, and placing decision-making in the hands of politically appointed agency officials ensures democratic accountability.

143. *See, e.g.*, Zaring, *supra* note 67, at 546 (analyzing the subsequent employment of a group of prosecutors in the Southern District of New York and finding "no evidence that [they were] . . . rewarded [in the private sector] for going lightly on industry"); Sumit Agarwal et al., *Inconsistent Regulators: Evidence from Banking*, Q. J. ECON. 889, 930 (2014); Makkai & Braithwaite, *supra* note 58, at 68 (finding that nursing home inspectors' "aspirations to go out the revolving door" had "no effect on [regulatory] toughness"); Che, *supra* note 125, at 385 (developing a model in which "opening the revolving door increases incentives for monitoring effort").

144. Makkai & Braithwaite, *supra* note 58, at 72.

145. Zaring, *supra* note 67, at 546.

146. The human-capital hypothesis posits that regulators may attempt to signal their qualifications to industry employers through aggressive regulation. *See* Che, *supra* note 125, at 380; *see also* Ed de Haan et al., *The Revolving Door and the SEC's Enforcement Outcomes: Initial Evidence from Civil Litigation*, 60 J. ACCT. & ECON. 65, 67 (2015) (finding support for the human-capital hypothesis in a study of SEC lawyers working in civil litigation who later left the SEC for the private sector). The revolving door may provide an ex ante incentive for a regulator to invest in human capital that may be later deployed in the private sector, and to the extent that this investment also improves monitoring performance, it benefits the agency. Che, *supra* note 125, at 384-85. However, the revolving door may make an agency worse off when it leads a regulator to "divert[] . . . attention away from investing in human capital" and instead toward developing industry qualifications. *Id.* at 385. The market-expansion hypothesis suggests that regulators seek to "expand the industry's needs" rather than pander to them. Zheng, *supra* note 111, at 1269. "[R]evolving-door regulators' focus may not be on finding the best way to appeal to industry interests as the capture and human-capital theories suggest, but on finding the best way to maximize, through their own efforts, the market demand for their post-government services." *Id.*

147. *See* Sydney Lupkin, *A Look at How the Revolving Door Spins from FDA to Industry*, NPR (Sept. 28, 2016, 10:48 AM), https://perma.cc/4H8X-FD2C ("Former FDA employees with deep knowledge of the approval process can help make it go smoother by ensuring all the relevant research is complete and that the latest pathways to approval are understood."); Hadar Yoana Jabotinsky, *Revolving Doors—We Got It Backwards*, 89 U. CIN. L. REV. 432, 449

debate and inconclusive empirical evidence, regulatory capture continues to pervade discussions of the administrative state,[148] and new evidence continues to emerge that the revolving door may indeed negatively impact regulatory performance.[149] Although capture provides a framework to understand the risks that the revolving door spawns, definitive empirical support for capture need not be a stumbling block to meaningful reforms to address the revolving door when those reforms respond to a pressing public need for agency impartiality and align with the practical reality that regulators tend to flock to private-sector jobs in the regulated industry.

C. "Revolving Door" Lessons from Outside of the FDA

The post-employment restrictions applicable to FDA officials are the same as those applicable to other executive agency officials, as described in section II.A *supra*.[150] Revolving door concerns, however, are not at all unique to the FDA; instead, they pervade all levels and branches of government. A fruitful comparison may be drawn to procurement officials, although additional

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(2021); *see also* Dorit Rubinstein Reiss, *The Benefits of Capture*, 47 WAKE FOREST L. REV. 569, 583-85 (2012) (highlighting literature and examples making the case for greater collaboration between the public sector and industry).

148. *See, e.g.*, Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 18 (2010) (calling the task of "addressing capture . . . an urgent need" and arguing that "[t]he brightest prospect for doing so lies in intelligent agency design that moves beyond the simple focus on presidential removal decisions and other traditional features of agency independence"). *But see* Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 143 (1998) (arguing that traditional procedural features of agencies such as notice-and-comment rulemaking and regulatory negotiations are inapt vehicles for rent-seeking by special interests). Professor Steven Croley approaches skeptically the leverage that special interests can achieve through informal agency decision-making, *id.* at 144, yet this may be precisely the mechanism that has come to dominate industry influence at the FDA. The growing voice of public interest groups—and, in the context of the FDA, patient groups—which Croley anticipated in his 1998 article, *id.* at 144-45, may not offset regulated-entity rent-seeking because industry and patient groups conveniently share aligned goals when it comes to the rapid approval of new therapeutics, and industry exerts financial influence on patient groups themselves. *See supra* note 110.

149. *See, e.g.*, Haris Tabakovic & Thomas G. Wollmann, *From Revolving Doors to Regulatory Capture? Evidence from Patent Examiners* 3-5, 18-19 (Nat'l Bureau of Econ. Rsch., Working Paper No. 24,638, 2018) (finding evidence of capture at the U.S. Patent and Trademark Office, namely that patent examiners who move through the revolving door grant more patents overall and grant more patents to the firms in which they are later employed); Jess Cornaggia, Kimberly J. Cornaggia & Han Xia, *Revolving Doors on Wall Street*, 120 J. FIN. ECON. 400, 407 (2016) (finding evidence that credit rating analysts inflate ratings of the companies for which they later work in the period prior to taking employment in those companies).

150. *Post-Employment Restrictions*, U.S. FOOD & DRUG ADMIN. (Feb. 18, 2020), https://perma.cc/EZS4-97U5; *see also supra* text accompanying notes 70-78.

compensation restrictions apply to this class of officials.[151] With respect to government procurement, ethics laws are intended to prevent other contractors from unfairly gaining knowledge of competitors' bids or proposals, as well as confidential information regarding government "source selection," which could be used to the detriment of competitors:

> The Government has a substantial interest in maintaining a level playing field for all competitors for Government contracts and any perception that the process is unfair is likely to discourage potential competitors. The net result of diminished competition in Government procurements is increased costs to the Government, whether because of a higher contract price or less satisfactory products or performance.[152]

Notable here is the justification for ethics restrictions in the procurement context: the government's interest in a "level playing field" and fair process. By analogy, the FDA has an interest in maintaining a level playing field for all drug companies, among other regulated companies, that submit applications to the FDA. If a former FDA official promptly accepts work after leaving the agency at a company whose drug or device application received approval during the official's tenure, it parallels closely with the scenario of a procurement official who accepts employment with a private contractor to whom a valuable government contract was granted during the procurement official's tenure. Similarly, if a former FDA official subsequently confers on its industry employer critical knowledge of the drug review process, or even general knowledge of FDA's handling of applications for a similar class of drugs that have been in FDA's queue for review, it resembles (though somewhat less closely) unauthorized disclosure of contractor bid or proposal information. A perception of unfair process may discourage competing drug companies from submitting applications, ultimately resulting in fewer new drugs, higher drug prices, or lower drug quality, all else equal. The perception of undue influence, whether or not undue influence exists, could thereby diminish competition in the market for FDA-regulated products. Following this line of reasoning, placing restrictions on post-agency employment of FDA officials can be conceptualized as helping ensure a fair drug approval process and a competitive pharmaceutical

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151. *See* John D. Altenburg, Jr. & Sean M. Connolly, *The Revolving Door Dilemma*, 93 NAT'L DEF. 58, 58 (2008); 41 U.S.C. § 423(d); MASKELL, *supra* note 12, at 7; *Bush Administration Sends New Procurement Ethics Proposal to Congress*, INSIDE THE PENTAGON, June 28, 1990, at p. 8. Specifically, procurement officials are prohibited for one year after serving as a procurement contract officer, source selection authority, or in a similar role, from receiving compensation from contractors that were selected for contracts valued in excess of $10 million. 41 U.S.C. § 423(d)(1)(A). Another provision of 41 U.S.C. § 423 extends the one-year compensation prohibition to employees who "personally made . . . a decision" to award a contract, approve a payment, or pay or settle a claim with a particular contractor in excess of $10 million. *Id.* § 423(d)(1)(C). Reporting requirements also exist that are triggered when procurement personnel make "contacts" about potential post-government employment with a "bidder or offeror" on a government contract. *Id.* § 423(c); MASKELL, *supra* note 12, at 9.

152. *Bush Administration Sends New Procurement Ethics Proposal to Congress*, *supra* note 151, at 9.

marketplace, which are made that much more essential in light of the growing market power of the pharmaceutical industry.[153]

A discussion of the revolving door would be incomplete without at least a brief discussion of federal lobbying restrictions. Senior FDA officials may not necessarily engage in "lobbying activities" as that term is defined in the Lobbying Disclosure Act of 1995 when they take a position at a pharmaceutical or biotech company after departing the FDA.[154] "Lobbying contacts," which comprise "lobbying activities," refer to oral or written communications made on behalf of a client to a "covered" executive or legislative branch official regarding the following matters: federal rules, regulations, executive orders, legislation, or other policies or programs of the U.S. government; the execution of federal programs or policies; or the nomination or confirmation of a person before the Senate.[155] Members of the House and Senate, along with certain congressional staffers, must comply with a one- to two-year "cooling-off" period, during which they cannot conduct lobbying before members of Congress or legislative branch employees.[156] Despite these prohibitions, former members of Congress (and other former employees of the legislative branch) are not prevented from wielding knowledge or connections gained during government service to carry out non-advocacy activities or otherwise work for the benefit of private employers in a non-representational capacity. Thus, lobbying restrictions on former legislative branch employees and officials exhibit the same deficit that is present in the post-employment restrictions of executive branch employees: a focus on representation that in effect exempts various other forms of influence.

There has been activity recently at the state level to strengthen lobbying restrictions for former public officials. In 2018, Florida voters passed a constitutional amendment to lengthen the cooling-off period for lobbying by public officials to six years after leaving office.[157] The measures, which took

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153. Recent research has demonstrated that large pharmaceutical companies are more profitable than other large, public companies in the S&P 500, with the greatest difference being in the gross profit margin. Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan & Ekaterina Galkina Cleary, *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 JAMA 834, 841 (2020).

154. 2 U.S.C. §§ 1601-06. The Federal Regulation of Lobbying Act of 1946, which preceded the Lobbying Disclosure Act, was criticized as "ineffective, inadequate, and unenforceable." *Federal Regulation of Lobbying Act of 1946 Is Ineffective: Gen. Acct. Off., Testimony Before the Subcomm. on Oversight of Gov't Mgmt. of the Sen. Comm. on Governmental Affs.*, 102d Cong. (1991) (statement of Milton J. Socolar, Special Assistant to the Comptroller General). In particular, as a result of the Act's narrow definition of lobbying, only a fraction of those engaged in lobbying were required to register as lobbyists under the Act, *id.* at 5, which led the Special Assistant to the Comptroller General to recommend that Congress "[c]larify and expand the definition of lobbying" and create a system for oversight because "Congress can[not] expect full compliance with the act's disclosure requirements on a self-policing basis." *Id.* at 13.

155. 2 U.S.C. § 1602(8)(A).

156. *See* MASKELL, *supra* note 12, at 10-11.

157. *See Revolving Door Prohibitions*, *supra* note 1; Gray Rohrer, *Florida Voters Barred Ex-Lawmakers from Lobbying for Six Years, But Revolving Door Still Swings*, ORLANDO

effect in December 2022, will make Florida the state with the longest cooling-off period, far exceeding the six-month to two-year revolving door prohibitions found in most other states.[158] A Missouri ballot measure approved in 2018 as part of the "Clean Missouri" initiative extended the prohibition on lobbying of the Missouri state legislature after leaving office from six months to two years.[159] The measure also included changes to campaign finance and redistricting. Although the redistricting provisions were repealed in 2020,[160] the two-year lobbying restriction remains, despite legal challenges.[161]

Also notable are presidential "ethics pledges" that supplement statutory restrictions.[162] Both President Biden and President Trump issued by executive order an ethics pledge restricting lobbying activities of executive branch personnel and supplementing the restrictions of 18 U.S.C. § 207.[163] Both pledges included a two-year prohibition after appointment on participation in matters "directly and substantially related" to work done for a previous employer two years prior to appointment.[164] Unlike the Trump pledge, the Biden pledge extended the restrictions of 18 U.S.C. § 207(c)(1), discussed in section II.A,[165] from one year to two years. Senior and "very senior" appointees, according to the Biden pledge, also had to agree for a period of one year not to "materially

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SENTINEL (Dec. 7, 2020, 4:09 PM), https://perma.cc/RM3E-H3PS; Renzo Downey, *House Passes Heightened Lobbying Restrictions for Former Lawmakers and Judges*, FLA. POL. (Feb. 10, 2022), https://perma.cc/65MN-8HQJ.

158. *See Revolving Door Prohibitions*, *supra* note 1.

159. *Id.*; Tod Palmer, *Missouri Voters Pass Clean Missouri Reforms, Minimum Wage Hike*, KSHB (Nov. 7, 2018, 4:27 PM), https://perma.cc/9VPM-T9BX.

160. *See* Rudi Keller, *Voters Repeal Clean Missouri Redistricting Plan They Enacted in 2018*, COLUMBIA DAILY TRIB. (Nov. 4, 2020, 4:05pm), https://perma.cc/MAV4-2XZA.

161. MO. CONST. art. III, § 2(a) ("After December 6, 2018, no person serving as a member of or employed by the general assembly shall act or serve as a paid lobbyist, register as a paid lobbyist, or solicit prospective employers or clients to represent as a paid lobbyist during the time of such service until the expiration of two calendar years after the conclusion of the session of the general assembly in which the member or employee last served and where such service was after December 6, 2018."); Miller v. Ziegler, 582 F. Supp. 3d 640, 646-48 (W.D. Mo. 2022) (denying a motion for a temporary restraining order to enjoin enforcement of Missouri's newly enacted lobbying ban, finding that legislator-plaintiff did not have a likelihood of success on the merits of his First Amendment challenge to the lobbying ban, that the "[Missouri Ethics Commission] has a substantial interest in regulation of quid pro quo corruption," and that the lobbying ban is narrowly tailored).

162. For a history of ethics pledges and a description of those enacted by recent administrations, see CONG. RSCH. SERV., R44974, ETHICS PLEDGES AND OTHER EXECUTIVE BRANCH APPOINTEE RESTRICTIONS SINCE 1993: HISTORICAL PERSPECTIVE, CURRENT PRACTICES, AND OPTIONS FOR CHANGE 8-10 (2021).

163. Ethics Commitments by Executive Branch Personnel, 86 Fed. Reg. 7,029 (Jan. 20, 2021) [hereinafter Executive Order on Ethics Commitments by Executive Branch Personnel]; Ethics Commitments by Executive Branch Appointees, 82 Fed. Reg. 9333, 9333 (Jan. 28, 2017) (imposing a five-year post-employment restriction on executive agency employees for lobbying activities before the executive agency from which they depart).

164. Ki P. Hong et al., *President Biden Signs Executive Order Establishing Ethics Pledge*, SKADDEN (Feb. 1, 2021), https://perma.cc/QPS6-FC2M.

165. *See supra* text accompanying notes 76-77.

assist others" in making "communications or appearances" that would otherwise be prohibited if carried out by the appointees themselves, colloquially termed "shadow lobbying."[166]

Various theories have been put forth regarding the value of former government employees as lobbyists: one suggests that the network of connections such individuals enjoy is critical to their role as lobbyists, and another suggests that these individuals offer specialized expertise and familiarity with the inner workings of government that they bring to bear on policymaking for a subsequent employer or client.[167] Although the influence wrought through the revolving door phenomenon is often believed to occur through connections, a recent book on the subject of revolving door lobbying by Professors Timothy LaPira and Herschel Thomas argues that the value of lobbying comes from "process knowledge" rather than connections.[168] Lobbyists leverage expertise and familiarity with the intricacies of policymaking to confer on the organized interests for whom they work a form of "political insurance."[169] When lobbying is defined in the manner LaPira and Thomas propose, senior FDA officials who later work for a pharmaceutical company, for example, may indeed carry out a "lobbying-type" function by offering "process knowledge" and "political insurance" to their employers. Because such a lobbying-type influence on government is indirect, it likely falls outside of the "shadow lobbying" prohibition contained in the Biden pledge. Lobbying is perhaps best conceptualized as a spectrum of influence. Private-sector employment of former government regulators that does not qualify as lobbying per se, or even "shadow lobbying," may nonetheless constitute a troubling form of influence that warrants restriction or oversight.

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166. *See* Executive Order on Ethics Commitments by Executive Branch Personnel, *supra* note 163, at 7,030; Robert Rizzi & Jason Abel, *Breaking Down Biden's Ethics Pledge for Political Appointees*, STEPTOE (Jan. 27, 2021), https://perma.cc/3XGQ-MBMZ; Robert L. Walker & Hannah J. Miller, *President Biden Issues Ethics Executive Order for Appointees; Trump Revokes Ethics Pledge for His Administration*, WILEY (Jan. 21, 2021), https://perma.cc/7K5W-MDEU.

167. *See* Jordi Blanes I Vidal, Mirko Draca & Christian Fons-Rosen, *Revolving Door Lobbyists*, 102 AM. ECON. REV. 3731, 3731-32 (2012).

168. TIMOTHY M. LAPIRA & HERSCHEL F. THOMAS, REVOLVING DOOR LOBBYING: PUBLIC SERVICE, PRIVATE INFLUENCE, AND THE UNEQUAL REPRESENTATION OF INTERESTS 7 (2017). *Compare id.* at 10-17 (tracking the rise of revolving door lobbying among "covered officials" who leave Congress and attributing the rise in part to an outsourcing of expertise in Congress to lobbyists), *with* Carlotta Alfonsi, Opinion, *Taming Tech Giants Requires Fixing the Revolving Door*, HARV. KENNEDY SCH. REV. (Feb. 18, 2020), https://perma.cc/YVS9-BAFJ (commenting that big tech has used revolving door hiring to "cultivate[] a network of influential advocates both inside and outside of government," and that "lobbyists' connections, not their knowledge of institutions, are what earns them higher financial rewards").

169. LAPIRA & THOMAS, *supra* note 168, at 4-6.

III. BEHAVIORAL INSIGHTS INTO THE RISKS POSED BY PROSPECTIVE POST-GOVERNMENT EMPLOYMENT IN INDUSTRY

"We are moved far more by forces that we do not appreciate . . . and far less by forces to which we attribute behavior . . . ."[170]

The crux of the issue that animates this Article is whether, and to what extent, potential future employment in a regulated industry influences the decisions of incumbent regulators. Most people would like to believe that they can separate themselves from outside influences and remain impervious to potentially corrupting forces. Yet the belief that we can shield ourselves voluntarily from making conflicted choices when conflicts of interest are present implies a dispositionist model of human behavior, one in which, "by their very nature[,] humans enjoy the freedom to order their actions as they see fit."[171] Dispositionism treats human conduct as "the free expression of individuals' preferences and will."[172] However, conflicts of interest are by their very nature situational considerations, making a purely dispositionist account of human behavior and human decision-making necessarily incomplete in the presence of conflicts and their situational progenitors. The inadequacies of a dispositionist model and the existence of situational forces create circumstances ripe for deep capture because, "if the depth of our dispositionism [itself] can be influenced by situation[,] . . . then profit-maximizing firms [and other special interests] will exercise their power over situation to promote it."[173]

In the background of agency decision-making lingers the time-limited nature of an official's tenure at the agency, which is especially true for political appointees on whom some of the agency's most critical decisions rest. To believe that a regulator will make decisions unaffected by the prospect of lucrative private-sector employment in a regulated industry places unrealistic faith in the idea that human behavior is the product of conscious choices over which we have full control.[174] It also gives short shrift to the fact that regulators' decisions will tend to be given the benefit of the doubt when viewed through a dispositionally

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170. Jon Hanson & David Yosifon, *The Situational Character: A Critical Realist Perspective on the Human Animal*, 93 GEO. L.J. 1, 22 n.69 (2004) [hereinafter Hanson & Yosifon, *The Situational Character*].

171. *Id.* at 10.

172. *Id.* at 14; Benforado & Hanson, *supra* note 117, at 34-37 ("[T]he dominant dispositionist-actor model assumes that people have stable preferences and make willful choices based on those preferences." *Id.* at 31.). In contrast to a dispositionist model of behavior, situationism recognizes the limits of human rationality, the existence of systematic biases in decision-making arising from human psychology and cognition, and the impact of situational forces on human behavior, such as the institutions that order society and the environments in which we find ourselves. *See id.* at 42-45.

173. Hanson & Yosifon, *The Situational Character*, *supra* note 170, at 22; *see also* David G. Yosifon, *The Consumer Interest in Corporate Law*, 43 U.C. DAVIS L. REV. 253, 269 (2009).

174. *See* Hanson & Yosifon, *The Situational Character*, *supra* note 170, at 30-34.

motivated lens, even when those decisions have been tainted by bias.[175]

The best of intentions cannot overcome the potential for conflicts of interest to affect decision-making, at least in part because biased decision-making is often the result of unconscious processes. Researchers have described the problem as follows: "While most people think conflicts of interest are a problem of overt corruption, that is, that professionals consciously and intentionally misrepresent the advice they give so as to secure personal gain, considerable research suggests that bias is more frequently the result of motivational processes that are unintentional and unconscious."[176] When the existence of unconscious bias goes unrecognized, recipients of advice tend to underestimate the degree to which that advice may be biased.[177] Similarly here, to the extent that the public, and regulators themselves, do not recognize the unconscious bias that may result from regulators' post-government employment in a regulated industry, they will tend to underestimate its distorting effects on individual- and institution-level decision-making. Study after study within the healthcare context has illuminated associations between industry-related conflicts of interest among physicians and researchers and study outcomes that appear to favor industry, providing evidence to suggest that financial connections to industry may indeed elicit pro-industry bias.[178] There is no reason to believe that regulators with financial connections

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175. *See* Yosifon, *supra* note 173, at 265-66 ("Human beings are powerfully, though usually unconsciously, motivated to view themselves, the groups with which they associate, and even the social system in which they live, in a positive and affirming fashion.").

176. Daylian M. Cain et al., *The Dirt on Coming Clean: Perverse Effects of Disclosing Conflict of Interest*, 34 J. LEGAL STUD. 1, 5 (2005).

177. *See id.*

178. *See, e.g.*, Nasim Ahmed Khan et al., *Association of Author's Financial Conflict of Interest with Characteristics and Outcome of Rheumatoid Arthritis Randomized Controlled Trials*, 58 RHEUMATOLOGY 776, 778 (2019) (finding that receipt of honoraria or consulting fees was associated with a positive outcome for industry-funded randomized controlled trials in rheumatology, but finding that a randomized controlled trial with an author possessing any financial conflict of interest was not associated with a positive outcome); Andreas Lundh et al., Review, *Industry Sponsorship and Research Outcome*, 16 COCHRANE DATABASE SYSTEMATIC REVS. 2, 14 (2017) (finding, based on an analysis of twenty-nine papers that included 4,583 studies, that "industry sponsored studies more often had favorable conclusions than non-industry sponsored studies, RR: 1.34 (95% CI: 1.19 to 1.51)"); Ahmed Waqas et al., *Conflicts of Interest and Outcomes of Clinical Trials of Antidepressants, An 18-Year Retrospective Study*, 116 J. PSYCHIATRIC RSCH. 83, 84 (2019); Rosa Ahn et al., *Financial Ties of Principal Investigators and Randomized Controlled Trial Outcomes: Cross Sectional Study*, 356 BRIT. MED. J. 1, 4-5 (2017); Haris Riaz et al., *Conflicts of Interest and Outcomes of Cardiovascular Trials*, 117 AM. J. CARDIOLOGY 858, 859 (2016) (finding that 80% of 114 studies examined had at least one investigator with competing interests, 69% were sponsored by industry, and a statistically significant number of studies had an outcome favoring the intervention); Roy H. Perlis et al., *Industry Sponsorship and Financial Conflicts of Interest in the Reporting of Clinical Trials in Psychiatry*, 162 AM. J. PSYCHIATRY 1957, 1958 (2005) (finding that author conflict of interest was significantly associated with positive trial outcomes for psychiatry clinical trials); Lee S. Friedman & Elihu D. Richter, *Relationship Between Conflicts of Interest and Research Results*, 19 J. GEN. INTERNAL MED. 51, 53 (2004) (finding a statistically significant association between studies whose authors had a conflict of interest and positive study findings).

to industry—whether past, present, or anticipated to arise in the future—are somehow immune from the influence observable in other contexts.

A pattern of post-agency employment in regulated companies could exert unconscious influence on newly appointed regulators, and on *who* seeks to become a regulator and why. If the modest salaries of government employees are hitched to the prospect of highly profitable future employment in industry, it would give life to a new and undesirable motive for entering public service. Yet there is a larger interest at stake in the revolving door than mere private benefit to a former regulator. The integrity of government is at risk when a pattern of post-government employment in industry occurs both because of effects (including actual, perceived, and potential effects) on decision-making, but also because of the message that is sent to regulated entities about the manner in which they may interact with and influence government regulators. For government regulators as well as for government attorneys:

> [Their] duty is not to a client but to the set of institutions through which society is governed and the public interest in pursued. Thus, in choosing a course of action, the government lawyer must ask himself not only: "How will my behavior affect the performance of my job in government?," but also: "How will my behavior affect the performance of government in general?"[179]

The revolving door, itself a form of capture, may increase the likelihood of capture in other aspects of the agency's work and detract from the larger goals the agency purports to accomplish. The gatekeeping function of the FDA to approve drugs before they can be made available on the market distinguishes it in an important respect from other regulatory agencies and may make it more prone to capture.[180]

A. The Revolving Door Through the Lens of Gift-Giving

The academic literature on gift-giving also proves relevant to the question of whether anticipated post-government employment in industry could influence the decisions of incumbent regulators. Intensifying concern in the 1980s and 1990s that extravagant gifts from industry to physicians such as travel to conferences and even lesser gifts such as free meals or honoraria might influence physicians' prescribing practices prompted calls for a ban on all industry gifts to

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179. *Developments in the Law: Conflicts of Interest in the Legal Profession*, 94 HARV. L. REV. 1244, 1415 (1981).

180. The grant of marketing approval is akin to licensing, and in that respect, the FDA's work could be compared to the work of the Federal Communications Commission when granting broadcast licenses, for example. It could also be compared to the issuance of patents by the U.S. Patent and Trademark Office, for which there has been some recent literature providing support for the existence of capture. *See* Tabakovic & Wollmann, *supra* note 149.

doctors and teaching hospitals.[181] Policies in the 2000s imposed various constraints on industry sponsorship of professional meetings and continuing education.[182] In the context of the practice of medicine, the Institute of Medicine—now the National Academy of Medicine—defines a conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[183] Often, "goals and obligations are at risk of being compromised by

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181. *See* Eugene M. Bricker, Opinion, *Industrial Marketing and Medical Ethics*, 320 NEW ENG. J. MED. 1690, 1691 (1989) ("For physicians, the acceptance of enticements carries the risk of bias and the loss of objectivity. If physicians are to be their patients' best advocates, they must be able to approach each therapeutic decision unfettered by conscious or unconscious obligations."); Mary-Margaret Chren, Seth Landefeld & Thomas H. Murray, Special Communication, *Doctors, Drug Companies, and Gifts*, 262 JAMA 3448, 3448 (1989) ("[W]henever a physician accepts a gift from a drug company, an implicit relationship is established between the physician and the company or its representative. Inherent in the relationship is an obligation to respond to the gift; this obligation may influence the physician's decisions with regard to patient care or possibly even erode the physician's character."); Ashley Wazana, Review, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 375-76 (2000) (examining sixteen studies in the published literature and finding evidence of frequent interactions between physicians and the pharmaceutical industry, as well as evidence that those interactions influence prescribing practices and formulary addition requests); Nicolae Morar & Natalia Washington, *Implicit Cognition and Gifts: How Does Social Psychology Help Us Think Differently About Medical Practice?*, 46 HASTINGS CTR. REP. 34-35 (2016). For scholarship discussing restrictions on industry gifts to doctors and teaching hospitals, see, for example, Jason Dana & George Loewenstein, Commentary, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 254 (2003) (arguing that even small gifts from industry to physicians should be prohibited); and Dana Katz, Arthur L. Caplan & Jon F. Mertz, *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 10 AM. J. BIOETHICS 11, 13-15 (2010) ("[F]rom a moral and regulatory perspective, policies that determine the acceptability of a gift according to its size are unsound." *Id.* at 15.).

182. *See* David Grande, Perspective, *Limiting the Influence of Pharmaceutical Industry Gifts on Physicians, Self-Regulation or Government Intervention?*, 25 J. GEN. INTERNAL MED. 79, 79-80 (2010) (describing guidelines that emerged in the 2000s from the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Association (AMA), and the American Association of Medical Colleges (AAMC), which generally permitted gifts under $100 but limited marketing at academic medical centers); David M. Studdert, Michelle M. Mello & Troyen A. Brennan, *Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry—Self-Regulation in the Shadow of Federal Prosecution*, 351 NEW ENG. J. MED. 1891, 1894-97 (2004) (comparing the various provisions of guidelines in the early 2000s from PhRMA, the AMA, the American College of Physicians, the Accreditation Council for Continuing Medical Education, and OIG restricting industry interactions with physicians).

183. INST. OF MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 46 (Bernard Lo & Marilyn J. Field eds. 2009). With respect to medical practice and clinical research, "[p]rimary interests include promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education." *Id.* In the context of the FDA and its interaction with the pharmaceutical and biotech industries, primary interests include protecting the integrity of the drug and device approval process, ensuring the safety and effectiveness of pharmaceutical drugs and devices on the market, and safeguarding the public's health and welfare. Government regulators, similar to government lawyers, "serve[] the interests of many different entities: [their] supervisor[s] in the department or agency, the

the undue pursuit of financial gain or other secondary interests."[184] Elsewhere, secondary interests have been described as including financial interests as well as "intangible" interests in "professional advantage, prestige, or power."[185] Financial conflicts, in contrast to other forms of personal advantage, tend to be detectable and therefore avoidable.[186]

Conflicts of interest exist along a continuum wherein the magnitude of the conflict varies with "(1) the likelihood that professional decisions made under the relevant circumstances would be unduly influenced by a secondary interest,"[187] in other words the probability of bias, "and (2) the seriousness of the harm or wrong that could result from such influence."[188] By either measure, private-sector, post-government employment in a regulated industry exists on the far end of this spectrum. Employment is not a one-time, small-dollar benefit, as is a pharmaceutical company gift to a physician, for example. Instead, it confers large and ongoing private financial benefits, in addition to power and prestige. It also enables the former regulator to add value to a private company through a deep understanding of the inner workings of an agency, how key decisions are made, and who makes them. Finally, it poses serious harm to the institutional legitimacy of the agency and of government more generally.

If future employment in industry were conceptualized as a gift or reward to a regulator for favorable treatment during her tenure, then it would, as a matter of course, be taken more seriously in terms of the conflict of interest it poses.[189] Gifts are a mechanism of social control and subordination, and they tend to create in recipients the feeling of a need to reciprocate.[190] If a senior FDA regulator were to turn down industry employment after leaving the agency, the regulator would in essence "refuse[e] to play the role of grateful recipient," thereby

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agency itself, the statutory mission of the agency, the entire government of which that agency is a part, and the public interest." *Developments in the Law: Conflicts of Interest in the Legal Profession*, *supra* note 179, at 1414.

184. INST. OF MED., *supra* note 183, at 44. For alternate definitions of conflicts of interest, which tend to cohere around the existence of a collision between personal or private interests on the one hand and professional responsibilities and obligations on the other, see Lemmens & Freedman, *supra* note 122, at 553-54.

185. *See* Lemmens & Freedman, *supra* note 122, at 554.

186. *Id.* at 559.

187. INST. OF MED., *supra* note 183, at 52. The Institute of Medicine identified factors that determine the likelihood of undue influence, among them the value of the secondary interest and a professional's degree of discretion. *Id.* at 53-55.

188. *Id.* at 52. The seriousness of the harm depends on the value of the primary interest jeopardized by the conflict. *Id.* at 55.

189. *See* Che, *supra* note 125, at 388-89.

190. *See* Barry Schwartz, *The Social Psychology of the Gift*, 73 AM. J. SOCIOLOGY 1, 3-5, 8-9 (1967) ("Gift exchange is governed by the norm of reciprocity . . . . [E]very gift-exchanging dyad (or larger group) is characterized by a certain 'balance of debt' which must never be brought into equilibrium . . . ." *Id.* at 8.); ROBERT B. CIALDINI, INFLUENCE: THE PSYCHOLOGY OF PERSUASION 13 (2009) ("The [reciprocity] rule says that we should try to repay, in kind, what another person has provided us. By virtue of the . . . rule, . . . we are *obligated* to the future repayment of favors, gifts, invitations, and the like.").

signaling to industry a lack of cooperation that stands in opposition to the collaborative posture many FDA regulators assume while at the agency.[191] In other words, if post-agency employment in industry is indeed a form of gift, regulators may feel obliged to accept it, even when moral or ethical imperatives would lead them to decide otherwise.

Literature on gift-giving suggests that "every gift-giving dyad is characterized by a moral dominance of one member over another."[192] If the first gift-giver occupies a position of moral dominance over the recipient, then the question becomes who furnishes the first gift—in this case, industry or the regulator. A "first gift" of post-government employment, conferred on the former regulator, would place the industry-employer in a position of moral dominance. That dominance may in turn create a sense of obligation on the part of the former regulator to impart regulatory knowledge and insights to the industry-employer after the transition to private-sector employment, as a means to fulfill the obligation to reciprocate. If, on the other hand, the "first gift" were to come from a government regulator (in the form of a drug approval or favorable regulatory treatment, for example), the regulator would possess moral dominance in the gift-giving dyad, generating in the industry-recipient a sense of obligation to reciprocate that could materialize in the form of an offer of post-government employment.

Relevant to this line of analysis is the relative size of a gift.[193] If the first gift were a new drug approval (or a speedier or less costly approval than might otherwise have occurred), the attendant profits to a drug company could be on the order of many billions.[194] Recent research has estimated the research and development costs to bring a new therapy to market average $1.6 billion and can

191. *Cf.* Schwartz, *supra* note 190, at 6 (equating the return of a gift close in value to the one initially given with "refusal to *accept*," and suggesting that this return "expresses a refusal to play the role of grateful recipient").

192. *Id.* at 9.

193. At this juncture, due process caselaw involving questions of recusal of biased adjudicators finds an interesting application. Recall from the discussion in section II.B that courts look to the objective risk of actual bias to determine whether due process rights may have been violated. The notable case *Caperton v. A.T. Massey Coal Co.* (discussed in note 130, *supra*) involved campaign contributions to a judicial contender to a state supreme court by an executive of a company that had an appeal pending before the very court to which the contender was eventually elected. 556 U.S. 868, 872-73 (2009). The Court, in reasoning that "the Constitution require[d] recusal" of the newly elected justice, *id.* at 887, found significant the "contribution's relative size in comparison to the total amount of money contributed to the campaign, the total amount spent in the election, and the apparent effect such contribution had on the outcome of the election," *id.* at 884.

194. A drug approval could be less costly if the drug were approved on the basis of less evidence, involving, for example, fewer clinical trials, fewer well-controlled trials, or smaller trials than might otherwise be required. The widely acknowledged defects in eteplirsen's clinical trial design and consequent inadequacies in the data obtained from those trials provide an example of the difficulties confronting regulators when trials and their results fall short of the agency's "gold standard" expectations. Of course, Duchenne muscular dystrophy is a rare disease, which means that smaller clinical trials cannot be dispositive of evidentiary insufficiency.

exceed $2 to 3 billion for some therapeutic agents.[195] A single "pivotal" clinical trial supplying scientific evidence for FDA approval has been estimated to cost $19 million.[196] A decision to deem flawed trial data sufficient rather than require a company to redo a clinical trial would undoubtedly confer significant savings.

Returning to the example of eteplirsen, the FDA approved the therapy under the accelerated approval pathway in 2016, with an understanding that its sponsor, Sarepta Therapeutics, would be required to conduct confirmatory clinical trials.[197] Now, six years later, the therapy's drug label retains the warning: "Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials."[198] The Institute for Clinical and Economic Review (ICER), an independent non-profit devoted to comparative-effectiveness and cost-effectiveness research of pharmaceuticals and other health treatments, concluded after examining subsequent clinical trial data on eteplirsen: "There is no high- or moderate- quality evidence demonstrating improvements in function with eteplirsen . . . . We consider the evidence to be insufficient ("I"), as certainty of net benefit based on currently available evidence is low."[199] Yet, consistent with the predictions of the FDA regulator who challenged eteplirsen's approval, no apparent efforts have been made to remove eteplirsen from the market.[200] Despite a lack of proven effectiveness, eteplirsen has been ranked by some reports to be among the most expensive therapies in the United States in recent years, with a list price that approximates one million dollars per year.[201] And eteplirsen is only one among many drugs approved via accelerated approval for

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195. Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 848 (2020).

196. Thomas J. Moore, Hanzhe Zhang, Gerard Anderson & G. Caleb. Alexander, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the U.S. Food and Drug Administration, 2015-2016*, 178 JAMA INTERNAL MED. 1451, 1454 (2018) (basing its results on an analysis of 138 pivotal trials for fifty-nine novel therapeutic agents, and finding an estimated median trial cost of $19.0 million (interquartile range: $12.2 million-$33.1 million)).

197. *FDA Grants Accelerated Approval to First Drug for Duchenne Muscular Dystrophy*, U.S. FOOD & DRUG ADMIN. (Sept. 29, 2016), https://perma.cc/DU5K-9P2F.

198. *Prescribing Information,* EXONDYS 51 (ETEPLIRSEN), https://perma.cc/V6AM-WPKV.

199. INST. FOR CLINICAL & ECON. REV., FINAL EVIDENCE REPORT: DEFLAZACORT, ETEPLIRSEN, AND GOLODIRSEN FOR DMD 39 (2019), https://perma.cc/GB9L-9M9S.

200. *See* Agency Scientific Dispute, Appeal from Ellis F. Unger, *supra* note 47, at 22.

201. Kyle Blankenship, *Want Bang for Your Buck? Don't Look to Sarepta's Pricey DMD Therapy, Exondys, ICER Says*, FIERCE PHARMA (May 23, 2019, 12:06 PM), https://perma.cc/H3DQ-9NCP; *Top Five Most Expensive Drugs in the US*, PHARMACEUTICAL TECH. (June 24, 2019), https://perma.cc/9DSL-BRZS. Recent financials show that Sarepta earned $100 million from Exondys 51 (eteplirsen) in a single quarter. *Sarepta Therapeutics Announces Fourth Quarter and Full-Year 2019 Financial Results and Recent Corporate Developments*, GLOBAL NEWSWIRE (Feb. 26, 2020, 4:05pm), https://perma.cc/TQ7G-8JQP (reporting revenue from Exondys 51 of "$100 million in the fourth quarter and $381 million for full year 2019").

which confirmatory trials have yet to be completed.[202]

When a drug is approved based on indirect evidence of efficacy, as is the case for drugs approved via accelerated approval due to the use of surrogate endpoints, the size of the "gift" to a drug company of a premature or imprudent approval (including both cost savings from avoiding additional trials prior to marketing and product revenue after marketing) is quite large relative to the total costs of drug development. When viewed in this light, it is no surprise that a drug company may offer employment to a former regulator whose favorable treatment helped a drug application secure approval or whose decisions on the whole advanced the company's financial position; an offer of employment becomes a small price to pay in relation to a company's degree of indebtedness.

B. The Power of Valence: Approval Versus Rejection

Another matter specific to the FDA is worth addressing here, and that relates to the special conflicts that may arise in the setting of a drug approval. The very nature of drug approval intrinsically enjoys a positive valence, whereas a denial of approval possesses a negative one; this itself can bias decision-making when a choice between the two is a close call. In addition to being intrinsically favorable because it expands the corpus of therapeutic options, a therapy's approval attracts positive attention both to the agency and to the pharmaceutical company that markets a newly approved drug. The FDA can announce, and in part take credit for, a notable drug approval (or EUA, for example) and speak favorably of the therapy's potential to improve patients' health and of the agency's role in making that therapy available safely to the public.[203] A pharmaceutical company, in turn, is buoyed by the future revenue stream that ineluctably follows from a newly approved drug. Announcement of a favorable FDA decision often raises stock prices,[204] enriches existing investors, draws

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202. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OEI-01-21-00401, DELAYS IN CONFIRMATORY TRIALS FOR DRUG APPLICATIONS GRANTED FDA'S ACCELERATED APPROVAL RAISE CONCERNS 1-2 (2022), https://perma.cc/VSJ8-H9C9.

203. *See, e.g.*, *Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19*, U.S. FOOD & DRUG ADMIN. (Dec. 22, 2021), https://perma.cc/L43R-TUJ6 (announcing an EUA for Pfizer's Paxlovid (nirmatrelvir/ritonavir), an oral therapy for treatment of COVID-19, and calling the authorization "a major step forward in the fight against this global pandemic"). Physician and health policy expert Dr. Peter Bach has noticed that new oncology therapies "are too often characterized to the public as miraculous and awe inspiring. CART-T treatments, because of their remarkable science, may be particularly likely to be described in terms that overstate the benefits while understating the harms." Peter B. Bach et al., Opinion, *FDA Approval of Tisagenlecleucel: Promise and Complexities of a $475,000 Cancer Drug*, 318 JAMA 1861, 1862 (2017). Similarly, announcement of a new drug approval, whether by the FDA or by industry, may tend to overemphasize a drug's benefits while understating or neglecting to mention a drug's potential harms.

204. *See* Jean-Claude Bosch & Insup Lee, *Wealth Effects of Food and Drug Administration (FDA) Decisions*, 15 MANAGERIAL & DECISION ECON. 589, 593-94 (1994); Julian Donovan, The Impact of Drug and Firm Attributes on Stock Price Movements Around

additional investment, and improves the company's financial outlook and the public's perception of a company's prominence. Patients and organized patient interests, too, celebrate new drug approvals as providing a source of hope and the promise of improved health for affected patients who often suffer from incurable ailments.[205] A deeply ingrained conception of an approved drug application as "success" and a rejected application as "failure" in the eyes of various stakeholders bakes into the drug approval process an inherent risk of distorted decision-making by all parties involved. In other words, all stakeholders are inclined toward what they perceive to be a "positive" outcome: drug approval.[206]

IV. AGENCY DISCRETION AND THE PRINCIPAL-AGENT PROBLEM

There is good reason to accept the view that regulatory agencies are captured by industry and that regulators are influenced, consciously or unconsciously, by the prospect of employment in a regulated industry. Nonetheless, the ardent believer in human rationality can reach the same ultimate conclusion—that new measures to address the revolving door are needed—using a different and more traditional theoretical frame: principal-agent theory. Principal-agent is a familiar

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FDA Drug Approval Decisions 2-3, 24-25 (Apr. 3, 2018) (Undergraduate Award, Western University) (on file with Western Libraries); *Why Investors and Traders Need to Track PDUFA Dates*, WALL ST. HORIZON, https://perma.cc/KA6N-FZ9X (last visited Dec. 29, 2021) ("[Y]ou may see a steady increase in a stock price leading up to a[n] FDA decision when consensus is that an approval is imminent . . . . [T]he expected date for an FDA approval, or non-approval, of a drug is a significant corporate event that should be known and observed if you want to make informed investment and/or trading decisions in biotech.").

205. *See, e.g.*, J. Glascock et al., Review, *Cure SMA and Our Patient Community Celebrate the First Approved Drug for SMA*, 24 GENE THERAPY 498, 498 (2017) ("Having an approved therapy means everything to the community and all of the families, to the families that have lost children, to the families that have children, for newly diagnosed families, for families that have been around for many years, any improvement is everything for any individual with SMA."); Michael S. Sinha & Stephen Latham, *Patient Advocacy Organizations and FDA Drug Approval: Lessons from Aduhelm*, STAT (July 23, 2021), https://perma.cc/ZJ2J-HSK7 (noting that the CEO of the Alzheimer's Association, after the FDA's approval of Aduhelm, "condemned the 'negative voices' concentrating on the flaws in the FDA's approval [process] as 'not pro-patient'").

206. An alternative viewpoint is that the agency tends to be biased not in favor of drug approval but *against* it due to concerns about approving unsafe drugs that may harm the FDA's reputation for protecting consumer safety. *Cf.* Carpenter, *supra* note 110, at 491-92 ("To protect its reputation, the FDA aims to minimize the danger of adverse drug reactions from approved products."). Relatedly, Carpenter has modeled the FDA's decision to approve drugs as an optimal stopping problem in which the FDA must weigh the value of waiting to approve a drug (which yields greater certainty about a drug's benefits and risks) against the political costs of waiting. *Id.* at 492-93. While useful conceptually, this analysis does not answer the question of whether the agency on the whole exhibits an inclination in favor of approval or rejection, and it is possible that any predisposition toward accepting or rejecting a drug application varies depending on the drug and other factors that Carpenter identifies, including the underlying condition, the existence of alternative treatments, media coverage, and the presence and power of disease advocacy groups. *See id.* at 498-501.

configuration of the fiduciary relationship: a principal endows authority in an agent to act on the principal's behalf.[207] Yet the delegation of authority,[208] information asymmetries,[209] imperfect monitoring of the agent,[210] and a divergence of interests[211] all jeopardize the agent's ability to act reliably and consistently in the principal's interest. The relationship is thus fraught with an inherent risk that an agent will abuse the power bestowed on him.[212] The confluence of these enumerated risks—delegation of authority, information asymmetry, imperfect monitoring, and divergent and potentially conflicting interests—takes its most dangerous form not when an agent follows dictates, but rather when an agent exercises discretion. Insightful scholarship by Professors

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207. Professor Robert Sitkoff describes the principal-agent problem as "aris[ing] whenever one person, the *principal*, engages another, the *agent*, to undertake imperfectly observable discretionary actions that affect the wealth of the principal." Robert H. Sitkoff, *The Economic Structure of Fiduciary Law*, 91 B.U. L. REV. 1039, 1040 (2011). Principal-agent theory has been described as a "flexible family of models," Sean Gailmard, *Accountability and Principal-Agent Theory*, *in* THE OXFORD HANDBOOK OF PUBLIC ACCOUNTABILITY 90, 90 (Mark Bovens, Robert E. Goodin & Thomas Schillemans eds., 2014), sharing certain common precepts, one of which is that the relationship can be modeled using game theory based on several factors: the existence of a "set of actors; possible actions they can take; and how they evaluate consequences of those actions," *id.* at 91. For a more detailed discussion of the principal-agent relationship and associated legal duties, see Deborah A. DeMott, *Fiduciary Principles in Agency Law*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW 23, 23-41 (Evan J. Criddle, Paul B. Miller & Robert H. Sitkoff eds., 2019).

208. As Professor Tamar Frankel explains, a cardinal characteristic of the fiduciary relationship is that "the fiduciary serves as a substitute for the entrustor [i.e., principal]." Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 808 (1983). Yet the authority of the fiduciary is constrained in two important ways: first, the authority to act derives from another source (either the entrustor or a third party), and second, the fiduciary is empowered to act only to the extent of the delegation and for the purpose for which the delegation was made. *Id.* at 808-09. Frankel notes that the "*structure* and *nature*" of the fiduciary relationship breeds an unavoidable risk of misuse of power arising from the potential for a mismatch between the "[narrower] purpose for which the fiduciary is allowed to use his delegated power" and the broader "purposes for which he is capable of using that power." *Id.* at 810.

209. *See* Gailmard, *supra* note 207, at 92; Jacob E. Gersen & Matthew C. Stephenson, *Over-Accountability*, 6 J. LEGAL ANALYSIS 185, 190 (2014).

210. *See, e.g.*, Robert Cooter & Bradley J. Freedman, *The Fiduciary Relationship: Its Economic Character and Legal Consequences*, 66 N.Y.U. L. REV. 1045, 1049 (1991) (noting, with respect to monitoring, that "[d]irect monitoring of the agent by the principal may be prohibitively costly or require expert knowledge," and "[w]hen the principal cannot observe . . . acts directly, she must infer them from outcomes," a task that is "imperfect because outcomes depend upon the agent's conduct and also upon chance"); Sitkoff, *supra* note 207, at 1041 (noting that a principal's lack of "specialized skills" often detracts from his or her capacity to monitor the agent); Samuel Issacharoff & Daniel R. Ortiz, *Governing Through Intermediaries*, 85 VA. L. REV. 1627, 1639 (1999).

211. *See* Sitkoff, *supra* note 207, at 1040, 1042-43; Gersen & Stephenson, *supra* note 209, at 186.

212. *See* Frankel, *supra* note 208, at 810; D. Gordon Smith, *The Critical Resource Theory of Fiduciary Duty*, 55 VAND. L. REV. 1399, 1407 (2002) ("'Fiduciary duty' connotes an obligation to refrain from self-interested behavior that constitutes a wrong to the beneficiary as a result of the fiduciary exercising discretion with respect to the beneficiary's critical resources." (emphasis omitted)).

D. Gordon Smith and Jordan Lee has identified discretion as a "universally recognized . . . essential aspect of fiduciary relationships"[213]—a "crucial part of the fiduciary bargain."[214] Discretion, and the duty of loyalty which curtails its exercise, sit at the heart of the fiduciary relationship.[215] Yet the centrality of discretion to the proper fulfillment of fiduciary duties threatens the very functioning of the relationship itself. Put differently, identifying discretion as a "crucial part of the fiduciary bargain" as Smith and Lee have called it, helps explain the vulnerability of the fiduciary relationship to outside influences, including the fiduciary's own self-interest.

A bedrock of the fiduciary relationship is the duty of undivided loyalty owed to the principal; in fact, the duty of loyalty has been labeled the "essence of fiduciary duty" designed to "protect[] . . . against opportunistic behavior by fiduciaries,"[216] and characterized as "a sensitive and 'inflexible' rule of fidelity."[217] This duty is violated when an agent acts to advance her own interests at the expense of those of the principal, including when an agent undertakes to secure personal benefits as a result of the fiduciary relationship or that might otherwise have accrued to the principal.[218] A corollary to the duty of loyalty is the rule against self-dealing: an agent must "either . . . refrain from self-dealing or . . . disclose the material facts of the transaction and how the fiduciary's conflict might compromise the fiduciary's judgment."[219]

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213. D. Gordon Smith & Jordan C. Lee, *Fiduciary Discretion*, 75 OHIO ST. L.J. 609, 610 (2014); *see also id.* at 609-14.

214. *Id.* at 611.

215. *See id.* at 612-13.

216. Smith, *supra* note 212, at 1402. Professor D. Gordon Smith has argued that, unlike the duty of care (which is owed by many), the duty of loyalty is "distinctive" in the fiduciary relationship and goes beyond the duty of good faith and fair dealing owed in other contexts, such as by parties to a contract. *Id.* at 1409-10.

217. Birnbaum v. Birnbaum, 539 N.E.2d 574, 576 (N.Y. 1989) (describing the duty of loyalty as a "sensitive and 'inflexible' rule of fidelity, barring not only blatant self-dealing, but also requiring avoidance of situations in which a fiduciary's personal interest possibly conflicts with the interest of those owed a fiduciary duty" (quoting *In re* Ryan's Will, 52 N.E.2d 909, 923 (N.Y. 1943)); *see also* Meinhard v. Salmon, 164 N.E. 545, 546 (N.Y. 1928) ("Uncompromising rigidity has been the attitude of the courts of equity when petitioned to undermine the rule of undivided loyalty . . . .").

218. Among the various offshoots and permutations of the duty of loyalty, the corporate opportunity doctrine forbids corporate fiduciaries such as directors, officers, or majority shareholders of a corporation from usurping corporate opportunities for their own private benefit. *See generally* Michael Begert, Comment, *The Corporate Opportunity Doctrine and Outside Business Interests*, 56 U. CHI. L. REV. 827, 831-36 (1989). In the law of trusts, a trustee must administer a trust solely in the interest of the beneficiaries, a principle which has been criticized. *See* John H. Langbein, *Questioning the Trust Law Duty of Loyalty: Sole Interest or Best Interest?*, 114 YALE L.J. 929, 932 (2005). But an alternative—"allow[ing] inquiry into the merits of a trustee's defense that the conduct in question served the best interest of the beneficiary," despite also inuring to the benefit of the trustee herself, *id.* at 988—opens the door to a host of unsupportable justifications for self-interested behavior if applied more broadly in the fiduciary context.

219. Sitkoff, *supra* note 207, at 1043. In the same vein, a trustee must not purchase trust property for himself. *See* Ten Eyck v. Craig, 62 N.Y. 406, 419-20 (N.Y. 1875) ("[O]ne who

Whenever a government official makes a decision motivated, even subconsciously, by a desire for, or anticipation of, future employment in a regulated company, the duty of loyalty is implicated; the regulator's conduct in accepting a post-government position at a regulated entity, especially one with some connection to his former work as a regulator, could be viewed as a form of self-dealing and a violation of the fiduciary duty of loyalty owed to the public.

Indeed, fiduciary theory of principal-agent has found robust application in administrative law, where scholars have posited that government officials and the administrative state stand in a fiduciary relationship to the public.[220] "Implicit in this public entrustment," writes Professor Evan Criddle, "is the expectation that agencies, like private-law fiduciaries, will align their performance with the expressed and implicit interests of their beneficiaries, exercising their discretion to promote the beneficiaries' welfare."[221] In the broadest sense, the public, via Congress, has bestowed on the FDA the authority to make decisions to promote public health through the regulation of food and drugs, and FDA regulators thereby function as agents on behalf of the public. Of course, Congress delegates authority to administrative agencies such as the FDA to carry out statutory mandates, and, as an executive branch agency, the FDA is headed by a commissioner of Food and Drugs, removable at will by the President, and led by various officials, some of whom are political appointees. The FDA commissioner and other agency officials therefore stand as agents to the President, to the Congress, and to the public.

It is commonly believed that administrative agencies offer governance advantages that other branches lack by virtue of their concentrated expertise, resources, flexibility, and accountability to other branches.[222] Yet the divergence in interests between agencies *qua* agents and their principals (whether conceived of as other branches of government or the public) generates persistent tension that threatens to undermine the proper functioning of the administrative state. Professors Jacob Gersen and Matthew Stephenson deconstruct the principal-

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undertakes to act for another in any matter, shall not in the same matter act for himself . . . . The reason of the rule . . . is to bar more effectually every avenue to fraud . . . . The rule is founded in the highest wisdom. It recognizes the infirmity of human nature, and interposes a barrier against the operation of selfishness and greed . . . . The rule is not limited in its application to those who are trustees strictly, holding the legal title to the thing purchased. It applies to agents and persons standing in relations of trust and confidence to others, which involve duties inconsistent with their dealing with the property as their own." (citation omitted)).

220. *See, e.g.*, Evan J. Criddle, *Fiduciary Foundations of Administrative Law*, 54 UCLA L. REV. 117, 121 (2006) ("Agencies . . . are bound by a duty of fidelity to their statutory mandates, and duties of care and loyalty to their statutory beneficiaries . . . . [A]dministrative agencies' emerging fiduciary duties complement the political branches' residual controls and reinforce the social norms that shape agency behavior."); *see id.* at 135-36; Gersen & Stephenson, *supra* note 209, at 185-86.

221. Criddle, *supra* note 220, at 136.

222. *See, e.g.*, David S. Rubenstein, *"Relative Checks": Towards Optimal Control of Administrative Power*, 51 WM. & MARY L. REV. 2169, 2183-84 (2010); Barkow, *supra* note 148, at 19-20; Criddle, *supra* note 220, at 163.

agent problem in administrative agencies and highlight another key tension:

> The basic problem is that principals are at an informational disadvantage relative to their agents . . . . [F]or many decisions, the agents have better information about the likely consequences of different courses of action. Indeed, this is one of the major reasons for a principal to delegate to an agent in the first place. Even after a decision is made, the principal may be unsure whether the agent did the right thing. This is particularly true when the "right thing" depends on probabilistic judgments about consequences, and when policy consequences are hard to discern.[223]

The informational disadvantage and consequent uncertainty that principals experience when assessing the decisions of their agents apply in the context of approval of new drugs, a task that demands highly specialized medical, scientific, and regulatory expertise. Approval or rejection of an application for a new drug, or grant or denial of an EUA, for example, may lead members of the public to question, as many of them have done, whether the agency made the "right" decision—a question that may be unanswerable by the lay public. In some sense, the problem stems from the very structure of administrative agencies as agents, with all of the attendant limitations of that relationship;[224] but in another sense, the problem can be narrowed to the challenges of correctly evaluating and assessing agency decisions after the fact, especially those involving probabilistic judgments and prediction, as Gersen and Stephenson astutely recognize. Part V returns to this matter as one of the central challenges for FDA governance and institutional trustworthiness in light of the ubiquity of the revolving door.

V. ADDRESSING THE RISK OF UNDUE INFLUENCE FROM THE REVOLVING DOOR: OPTIONS AND PROSPECTS FOR REFORM

The FDA is arguably one of the nation's most important government agencies. It oversees products constituting at least one-fifth of all U.S. consumer spending.[225] The FDA's reach has been called "enormous"[226] and its work "vital"[227] by champions and critics alike. In the face of its gargantuan mission, the FDA must manage issues confronting every government agency, including

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223. Gersen & Stephenson, *supra* note 209, at 190.

224. *See supra* text accompanying notes 209-13.

225. *See* Califf et al., *supra* note 15, at 84 (noting that agency-regulated products "account for twenty cents of every dollar spent in the US"); Robert M. Califf, *Remarks of the FDA Commissioner: The Food and Drug Law Institute's 59th Annual Conference*, 71 FOOD & DRUG L. J. 201, 201 (2016) (recounting that statistic).

226. INST. OF MED., CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 1 (2007) [hereinafter INST. OF MED., CHALLENGES FOR THE FDA].

227. *See, e.g.*, Califf, *supra* note 225, at 201 (referring to the "vital work done by FDA . . . [that] touches the lives of virtually every American"); Farhad Manjoo, Opinion, *America Desperately Needs a Much Better FDA*, N.Y. TIMES (Sept. 2, 2021), https://perma.cc/6W8E-P2CG (criticizing recent FDA missteps involving opioids, Aduhelm, and COVID-19 therapies, and branding the agency's mission "more vital than ever").

time and resource constraints that limit what the agency can feasibly accomplish and that force the agency and its staff to make difficult tradeoffs involving its limited budget, staff, and resources.[228] The agency must also manage delicate relationships with regulated industries from which cooperation and regulatory compliance are undeniably sought.

Along with responsibility for regulation of products essential to the economy and to human existence comes a high degree of public scrutiny—and perhaps rightly so—when a decision of the FDA misfires or a product by happenstance turns out to be unsafe or ineffective. Many recent examples can be cited of drugs removed from the market or restricted in their labeling only after causing unfortunate harm to many.[229] Yet, even when harm happens, it is not always an easy task to label an agency decision as mistaken based on the information available at the time the decision was made. The FDA's decisions are complex, requiring expertise that few have and evaluation of data to which only the agency may have access. Such information asymmetry tends to lessen the public's ability to fully and accurately evaluate the FDA's decision-making. Did the FDA indeed approve Aduhelm too hastily, for example? Was the approval of eteplirsen based on insufficient evidence, or did the lack of treatment alternatives for Duchenne muscular dystrophy justify the decision to approve? Should the FDA have issued an EUA for hydroxychloroquine in the first instance? Although members of the public may pass judgment on these decisions, lay judgment suffers from inherent informational limitations.

The evaluative dilemma, as one might call it—that is, the difficulty that individuals external to an agency face in assessing agency decisions—is made only more acute when conflicts of interest exist, such as those arising from the revolving door. Faced with little information by which to assess the FDA's decisions, members of the public may wrongly attribute well-founded but injurious decisions to pro-industry bias. And, regrettably, the public is left with little ability to confirm or disprove the actual occurrence of bias even as agency-

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228. In a 2007 legislative hearing on challenges facing the FDA held before the House Committee on Oversight and Government Reform, Chairman Henry Waxman in introductory remarks called the FDA "vastly under-funded, relying on an already shrinking budget to tackle a rapidly expanding list of responsibilities." Hearing, *The Food and Drug Administration's Critical Mission and Challenges for the Future*, *supra* note 123, at 3. Former FDA Chief Counsel Peter Barton Hutt expressed similar concerns about the scarcity of agency resources. *See Science and Mission at Risk: FDA's Self-Assessment: Hearing Before the Subcomm. on Oversight & Investigations of the House Comm. on Energy & Com.*, 110th Cong. 31 (2008) (statement of Peter Barton Hutt, Senior Counsel, Covington & Burling LLP) ("In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them.").

229. *See* Thomas N. Tiedt, *The Drug Safety System Conundrum*, 62 FOOD & DRUG L.J. 547, 548 (2007) ("High-profile market withdrawals of high-revenue prescription drugs spurred by the notoriety of life-threatening drug reactions identified after FDA approval and broad patient use have cost the pharmaceutical industry billions of dollars in lost annual revenues (e.g., Vioxx, Bextra, Baycol, Rezulin, Lotonex, Propulsid, Seldane, Pondimin, Redux).").

to-industry job transitions become increasingly commonplace.[230] The prospect of the revolving door thus poses a grave risk to the agency: At worst, it produces *actual* bias that manifests itself in decisions favoring industry at the expense of the public. At best, it produces a lingering aura of perceived or potential bias that may have a detrimental impact on the public's assessments of the FDA's work. Regardless of the occurrence of actual bias, perceived or potential bias is a delegitimating force that undermines the agency's efforts and reduces confidence in its decisions. In 1971, a staff paper entitled *Reforming Regulation* that evaluated the proposals of President Nixon's Advisory Council on Executive Organization[231] made reference to the familiar problem of the revolving door:

> [T]he FDA shares the problem of most regulatory agencies that most of the job opportunities available to their employees after they leave government service are in the regulated industry. This is bound to raise the suspicion that staff members are overly responsive, or at least subconsciously sympathetic, to the needs and claims of the industry simply because in the long run they will probably be working in the industry.[232]

Nearly forty years later, in 2007, a House hearing convened a panel of four FDA commissioners—Donald Kennedy, David Kessler, Frank Young, and then-Commissioner Andrew von Eschenbach—to address, among other things, "scientific integrity" at the agency, specifically the concern that "key decisions at FDA have been made under the cloud of real or perceived political interference."[233] Former Commissioner Young spoke of a "revolving door syndrome" at the FDA that leads to relatively short stints of employment among top agency personnel and that may compromise stable leadership.[234] In the absence of a lifetime ban on all post-FDA employment in regulated industries—a policy that could greatly reduce revolving door–induced conflicts of interest but that few would endorse—conflicts of interest will continue to cast a shadow on the FDA's work.

What should be done to address the problem of perceived or potential bias due to post-agency job transitions to industry? A lengthier cooling-off period for

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230. *See, e.g.*, Manjoo, *supra* note 227 (lambasting the frequency of the revolving door phenomenon at the FDA, including the "cushy second career as a consultant to the drug industry" that awaits many former regulators, and citing as an example an FDA official in charge of OxyContin's review who later left the agency to work for Purdue Pharma).

231. The Advisory Council on Executive Organization was a body charged with reviewing the executive branch and formulating suggestions for its improvement. *See President's Advisory Council on Executive Organization*, NAT'L ARCHIVES, https://perma.cc/6ZP2-SD64.

232. NOLL, *supra* note 66, at 54.

233. Hearing, *The Food and Drug Administration's Critical Mission and Challenges for the Future*, *supra* note 123, at 3.

234. *Id.* at 22 (statement by Frank E. Young, Former Comm'r, U.S. Food & Drug Admin.). Young also commented on the FDA's "unpredictable regulatory process [for evaluation of drugs and biologics] complicated by high staff turnover," which, he noted "inevitably leads to a greater cost of the development of new therapies and stifles innovation of new drugs and biologics." *Id.* at 24.

senior agency officials, or a cooling-off period that prohibits a wider range of activities extending beyond representation to encompass utilization of agency knowledge for the benefit of private interests, could be beneficial, and these options will be discussed in more detail below. But, if the prospect of eventual private-sector employment is merely shifted a few years down the road, that is unlikely to meaningfully reduce any tendency of an incumbent regulator to exhibit, consciously or unconsciously, partiality toward industry. Instead, this Article suggests that the better approach is to treat the revolving door problem as one among many sources of potential industry influence on the FDA's work and to implement a set of institutional safeguards that help keep that influence in check and limits its impact on outcomes. In particular, to the extent that the risks posed by post-government employment in a regulated industry come to fruition through unchecked exercises of discretion, limiting ad hoc discretion by FDA administrators and establishing mechanisms to check individual exercises of discretion will help mitigate the risk of biased decision-making.

The next section briefly discusses transparency and enhanced post-employment restrictions as mitigation measures before turning to internal and external checks on discretionary decision-making.

A. Transparency and Enhanced Post-Employment Restrictions

There has been a push within the FDA for increased transparency and continued calls for greater transparency from those outside the agency.[235]

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235. For several examples of the agency's own efforts to increase transparency, see *FDA Continues to Support Transparency and Collaboration in Drug Approval Process as the Clinical Data Summary Pilot Concludes*, U.S. FOOD & DRUG ADMIN. (Mar. 26, 2020), https://perma.cc/Z66V-483T (describing a completed pilot program that tested "a new process for selecting, redacting, and posting on the FDA's public website summaries of information that the agency uses in making marketing approval decisions"); Alexander C. Egilman, Amy Kapczynski, Margaret E. McCarthy, Anita T. Luxkaranayagam, Christopher J. Morten, Matthew Herder, Joshua D. Wallach & Joseph S. Ross, *Transparency of Regulatory Data Across the European Medicines Agency, Health Canada, and US Food and Drug Administration*, 49 J.L. MED. & ETHICS 456, 459 (2021); *FDA Takes Steps to Improve Efficiency, Transparency of Tobacco Product Application Review Process as Part of Comprehensive Framework to Reduce the Disease and Death Related to Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Aug. 14, 2018), https://perma.cc/X2ZT-4JNL. For recent calls for greater transparency from scholars and others outside of the FDA, see Liam Bendicksen, Joshua M. Sharfstein & Aaron S. Kesselheim, Opinion, *Increase Transparency at the FDA: We Need Sunlight to Fight the Pandemic*, STAT (Sept. 29, 2020), https://perma.cc/BR7H-FFKY (recommending several policy proposals to increase transparency including disclosure of the scientific basis for EUAs and related datasets, and formal explanation when the FDA does not approve a drug product, vaccine, or device); Carpenter, *FDA Transparency in an Inescapably Political World*, *supra* note 13, at 30 (encouraging a "robust transparency policy" that includes disclosure of "the many sources of industry and other special interest influence, . . . conflicts of interest among staff (their former careers) and advisers and consultants, and . . . communications between agency officials and between agency officials and industry officials and affiliated academics"); Jason L. Schwartz, *Evaluating and Deploying COVID-19 Vaccines—The Importance of Transparency, Scientific Integrity, and Public Trust*, 383 NEW

Transparency could offer a partial remedy to the revolving door dilemma, albeit one of indeterminate effectiveness. Professor Archon Fung and colleagues have explored the governance concept of "targeted transparency,"[236] the purpose of which is to "reduce specific risks or performance problems through selective disclosure."[237] Targeted transparency, however, can "do more harm than good" when information is "incomplete, inaccurate, obsolete, confusing, or distorted."[238] Transparency measures can also fail when "users . . . simply do not care about the new information to which transparency gave them access."[239] To the extent that eventual disclosure of post-agency employment in industry (which in effect already occurs due to reporting by the news media on subsequent career moves of top agency officials) does not provide information upon which the public will act or know how to act, it arguably will fail to have any effect. Members of the public will either disregard such disclosures, especially if they are common, or will be unsure how to adjust their view of a regulator and that regulator's decision-making in light of a disclosure.[240]

If there are no consequences to holding post-agency employment in a regulated industry but eventual disclosure, that does little to ensure that whatever effect post-agency employment might have on in-office decision-making will be

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ENG. J. MED. 1703, 1704 (2020) (mentioning a federal bill that would require public reporting of data received by an FDA advisory committee in review of COVID-19 vaccines prior to licensing or authorizing a COVID-19 vaccine); Herder, *supra* note 59, at 1013; Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, 45 J.L. MED. & ETHICS 7, 10-17 (2017).

236. ARCHON FUNG, MARY GRAHAM & DAVID WEIL, FULL DISCLOSURE: THE PERILS AND PROMISE OF TRANSPARENCY 5-7, 82 (2007).

237. *Id.* at 5.

238. *Id.* at 7.

239. Stephen Kosack & Archon Fung, *Does Transparency Improve Governance?*, 17 ANN. REV. POL. SCI. 65, 72 (2014).

240. *See* FUNG, GRAHAM & WEIL, *supra* note 236, at 51, 53. Disclosure in other settings within health care has encountered similar criticism that the public is left unable to discern the gravity of the disclosure and its potential to generate bias. For example, Professor Richard Saver, writing on the subject of the Open Payments Database for public reporting of payments to healthcare providers in accordance with the Physician Payments Sunshine Act, pointedly highlighted the fact that "end-users do not necessarily understand, just from the . . . category descriptor [associated with a payment], when a financial relationship presents greater risks of bias and undue influence . . . . Although patients can make additional inquiries . . . after viewing a payment report in the Open Payments Database, many users will not even know what additional contextual questions to ask." Richard S. Saver, *Deciphering the Sunshine Act: Transparency Regulation and Financial Conflicts in Health Care*, 43 AM. J.L. & MED. 303, 314-15 (2017); *see also id.* at 318-19. However, if the targets whose behavior disclosure aims to change are agency officials themselves, then an effect may be seen (and the hoped-for effect would be greater care exercised to avoid biased decision-making). *Cf.* George Loewenstein, Sunita Sah & Daylian M. Cain, Viewpoint, *The Unintended Consequences of Conflict of Interest Disclosure*, 307 JAMA 669, 670 (2012) [hereinafter Loewenstein, Sah & Cain, *The Unintended Consequences of Conflict of Interest Disclosure*] ("To the extent that disclosure works, it typically does so by influencing the behavior of those whom the disclosure is about more than those to whom the disclosure has been made.").

kept in check.[241] In fact, anticipated disclosure could have precisely the *opposite* of the desired effect, providing FDA regulators with a moral license to continue partial decision-making or generating a paradoxical increase in bias to offset expected discounting of their decisions, a phenomenon termed strategic exaggeration.[242] Implicit in the restrictions of 18 U.S.C. § 207 seems to be the foundational premise that mere disclosure is not enough.[243]

Greater transparency in other facets of the FDA's work, such as the data on which the FDA bases its decisions and the rationale behind its decisions, could help allay fears of biased decision-making due to the conscious and subconscious enticements of the revolving door.[244] Take, for example, the collaborative workstream that the FDA and Biogen jointly undertook nearly two years prior to Aduhelm's approval.[245] The House report on Aduhelm leaves unanswered how often the agency conducts collaborative workstreams with pharmaceutical companies of the kind offered to Biogen. On one view, if such workstreams are not offered to all sponsors, they should not be offered to any. Even if the agency were to determine that only a subset of investigational new drugs (INDs) or drug applications warrant such intensive intervention, transparent standards ought to be established to delineate in what circumstances a workstream will be triggered. This is in the interest of fairness to drug sponsors—including those sponsors that do not receive the benefit of a workstream to facilitate data analysis and approval

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241. *See* Cain et al., *supra* note 176, at 5-6 (explaining that people tend not to discount information sufficiently after a conflict of interest is disclosed and may therefore rely on biased advice to a greater extent than they should); *see id.* at 20 (finding in an experimental study of disclosure that disclosure "benefited the providers of information but not its recipients"); Dana & Loewenstein, *supra* note 181, at 254 (arguing that "[d]isclosure can only be effective if those informed can rationally update their beliefs—discount the advice they receive from [those] who disclose conflicts of interest—in light of the disclosure"); George Loewenstein, Daylian M. Cain & Sunita Sah, *The Limits of Transparency: Pitfalls and Potential of Disclosing Conflicts of Interest*, 101 AM. ECON. REV. PAPERS & PROC. 423, 423-24 (2011) [hereinafter Loewenstein, Cain & Sah, *The Limits of Transparency*].

242. *Cf.* Loewenstein, Sah & Cain, *The Unintended Consequences of Conflict of Interest Disclosure*, *supra* note 240, at 669-70 (discussing strategic exaggeration and moral licensing as adverse effects of disclosure in the context of advice provided to patients by physicians who possess financial conflicts of interest); Cain et al., *supra* note 176, at 7. Elsewhere, Professor George Loewenstein and colleagues have explained that "[i]n principle, disclosure should allow the recipient of advice to discount that advice." Loewenstein, Cain & Sah, *The Limits of Transparency*, *supra* note 241, at 423. They define strategic exaggeration as "the tendency of advisors to inflate the bias in their advice to counteract any discounting that might occur because of disclosure," *id.*, and they describe moral licensing as the tendency for "people [to] feel 'licensed' to act immorally in subsequent interactions" after they exhibit moral behavior, *id.* at 424.

243. An official's employment in industry prior to entering government service may also pose conflicts. That matter is not taken up directly in this Article.

244. *See* sources cited *supra* note 235. *But see* Caroline F. Plott & Joshua M. Sharfstein, Commentary, *Global Regulatory Agencies and Data Transparency*, 49 J.L. MED. & ETHICS 486, 487 (2021) (mentioning downsides of transparency, including the possibility that disinformation could result from "poor quality research" conducted based on clinical study data released by agencies such as the FDA).

245. *See supra* note 42.

— as much as it is a matter of sound agency policy and a deterrent to conflict of interest-induced bias.

Transparency measures often aim not at the source of the bias, but instead at the *outputs* of potentially biased decision-making. Arguably, the public and the agency should care most about the ultimate decisions the FDA makes that impact consumers and patients. Greater transparency into *why* the FDA made a decision to approve or reject a drug application, for example, can reduce fears of industry bias skewing outcomes and can help establish a record on which FDA decisions may later be challenged.

Transparency as a remedy for conflicts of interest is fundamentally limited. Another item on the menu of policy options is enhanced post-employment restrictions. Arguably, the FDA has experienced growth in its power and influence over the last several decades due to an increase in new drug and biologic approvals,[246] increasing use of expedited review pathways,[247] steady growth in drug prices,[248] and the expansion and growing financial dominance of the pharmaceutical and biotech industries.[249] With increased power comes increased responsibility, higher stakes decisions, and increased incentives for regulatory capture. Adjustments to conflict of interest laws to lengthen and enhance post-government employment restrictions for senior FDA officials could be one course of action to address the risk of capture head-on. Recent ballot initiatives to lengthen revolving door prohibitions on lobbying at the state level suggest that there may be a similar appetite among voters for enhanced employment restrictions after officials transition away from work within government agencies.[250]

A flat prohibition for a period of time on senior FDA officials' employment

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246. *See* Jonathan J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 JAMA 164, 171 (2020).

247. The pace of new drug approvals has increased, as has the number of drugs approved under expedited review pathways. *See* Darrow et al., *supra* note 246, at 173 (finding that "the proportion of drugs approved using at least 1 special review program increased substantially over time, exceeding 80% in 2018"); Aaron S. Kesselheim et al., *Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987-2014: Cohort Study*, 351 BRITISH MED. J. 1, 4-5 (2015) (conducting time-trend analyses and finding a 2.6% annual increase in the mean number of expedited programs per newly approved agent from 1987 to 2014).

248. *See, e.g.*, Juliette Cubanski & Tricia Neuman, *Prices Increased Faster than Inflation for Half of All Drugs Covered by Medicare in 2020*, KAISER FAM. FOUND. (Feb. 25, 2022), https://perma.cc/7WVY-BR6W; Emily K. White, *Killing U.S. Slowly: Curing the Epidemic Rise of Cancer Drug Prices*, 72 FOOD & DRUG L.J. 189, 191-93 (2017).

249. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 16-20 (2017). The biopharmaceutical sector tends to outperform sizably other sectors. According to a recent report from the Government Accountability Office, the average profit margin of the twenty-five largest pharmaceutical and biotech companies was 20.1% in 2015, compared to an average margin of 8.6% for all other drug companies, *id.* at 18, and 6.7% for the largest five-hundred companies across industries, *id.* at 19.

250. *See supra* text accompanying notes 157-61.

in industry is likely to face the familiar charges that individuals will be deterred from entering government service, private interests in gainful employment will be unduly trammeled, and agency-industry cooperation will suffer.[251] These concerns, however, may be overblown; there is no strong argument to be made that agency-industry cooperation depends in any real sense on whether a high-level regulator may later assume a role in industry. To suggest that a cooperative relationship between agency and industry cannot exist if the revolving door is closed for a lengthier period of time only lends support to the notion that one or both parties view the revolving door as a "strings-attached" benefit. And the charge that some individuals may be dissuaded from entering government service should not override the more pressing need for institutional legitimacy and impartial decision-making.

More stringent post-employment restrictions would undoubtedly sacrifice the private interests of former regulators. A primary goal, as discussed, is greater public confidence in the impartial regulation of food and drugs. Yet studies have cast doubt on the wisdom of stringent revolving door laws due to unintended effects on the quality of regulators and regulatory effectiveness.[252] As an alternative to enhanced post-employment restrictions, FDA officials could be asked to self-regulate by declining to accept employment in industry, at least for a period of time, as some have done voluntarily.[253] Reliance on self-regulation, however, can hardly be thought a dependable solution to a problem that implicates the institutional legitimacy of one of the world's most powerful government agencies.

B. Checks on Agency Discretion

Professor Lawrence Lessig has called the "economy of influence" the "great threat to our republic today."[254] He compares the problem of government corruption arising from the influence of money in politics to a "dependency;" like a physical dependency, it gives rise to "a pattern of interaction" that is self-

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251. Writing about conflicts of interest in health care and medicine, Professor Richard Epstein has argued that "[t]he conflict of interest question does not mix well with absolute bans, which kill useful cooperation." Richard A. Epstein, *Conflicts of Interest in Health Care: Who Guards the Guardians?*, 50 PERSPS. BIOLOGY & MED. 72, 86 (2007).

252. *See, e.g.*, Marc T. Law & Cheryl X. Long, *Revolving Door Laws and State Public Utility Commissioners*, 5 REGUL. & GOVERNANCE 405, 417-20 (2011) (finding evidence that post-employment restrictions imposed on public utility regulators were associated with a significant reduction in the likelihood that those regulators were experts in their fields).

253. Former Commissioner Margaret Hamburg described her post-agency employment decisions in this light: "I am not considering doing any boards of any company big or small that was regulated by the FDA for a couple of years—a cooling-off period—even though some of the smaller biotech companies are technically really interesting and it would be fascinating to see from the other side." *See* Berke & Kaplan, *supra* note 13. This form of self-restraint could be a model for future commissioners.

254. LAWRENCE LESSIG, REPUBLIC, LOST: HOW MONEY CORRUPTS CONGRESS—AND A PLAN TO STOP IT 7, 17 (2011).

reinforcing and that can be difficult to resist.[255] Lessig's framing is useful because he shifts the focus from the individual to the institution, thereby elevating the gravity of the problem and underscoring that it is not properly addressed by maligning the choices or predisposition of individuals. He writes:

> It is this pattern that explains . . . corruption without assuming evil or criminal souls at the helm. It will help us, in other words, understand a pathology that all of us acknowledge (at the level of the institution) without assuming a pathology that few could fairly believe (at the level of the individual).[256]

Lessig paints "dependency" in metaphorical terms as a deviating force that "draw[s] the institution away from the purpose it was intended to serve: [t]he people."[257] Lessig's diagnosis of the "economy of influence" finds useful application in the context of executive branch agencies such as the FDA. Though unelected, agency administrators stand subject to the same deviating force of powerful and wealthy interests.

Acknowledging the problem of revolving door influence as an institutional one, even when it acts through the decisions of individual regulators, points toward solutions at the institutional level. Institutional corrective mechanisms include both intra-agency checks and extra-agency checks. Each will be discussed in turn.

1. Intra-agency Checks

Intra-agency checks could include creating procedures within the agency that allow concerned FDA scientists or other staff who seriously question one of the agency's decisions to initiate a process for reconsideration. Dr. Ellis Unger attempted such an appeal of eteplirsen's approval before the FDA's Scientific Dispute Process Review Board, but the appeal was ultimately unsuccessful and appears to have created a dangerous precedent of near-complete deference to the Director of CDER on drug approvals.[258] According to an FDA staff manual guide, the Scientific Dispute Process Review Board is a standing committee within the FDA chaired by the Chief Scientist that may receive disputes when a party "believes that a significant *scientific* issue has not been adequately addressed by Center dispute resolution processes."[259] Although the dispute must

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255. *Id.* at 17; *see also id.* at 142-47. Importantly, Lessig highlights that there need not be a quid pro quo "transaction" for corruption to exist: "the core argument of this book . . . [is] that the most significant and powerful forms of corruption today are precisely those that thrive without depending upon quid pro quos for their effectiveness." *Id.* at 107.

256. *Id.* at 17.

257. *Id.* at 19; *see also id.* at 89.

258. *See* Agency Scientific Dispute, Appeal from Ellis F. Unger, *supra* note 47; *see also supra* text accompanying notes 44-54.

259. U.S. FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDES, VOLUME IV—AGENCY PROGRAM DIRECTIVES 3 (2021), https://perma.cc/F4N5-WX6L (emphasis added).

be scientific in nature, the staff manual defines "scientific" broadly to include "interpretation of science and decisions taken upon that interpretation."[260] The Review Board, which has representation from the FDA's Office of Scientific Integrity and various ombudspersons,[261] has the feel of a (perhaps perfunctory) ethics committee review rather than a true appeals process. It is therefore unclear whether the Scientific Dispute Process Review Board was a suitable forum for the sort of appeal Unger sought. When an appeal is brought before the Review Board, the FDA commissioner has authority to make a final decision on the following matters:

> [O]n whether a Center followed its processes[;] whether the Center provided an adequate opportunity to the initiator to express his or her concerns; whether all relevant evidence bearing on the scientific question at issue has been considered; and whether the dispute should be remanded to the Center Director for corrective action.[262]

The first two matters (whether the Center followed its own processes and whether it provided the initiator adequate opportunity to express concerns) are procedural in nature, and the third only broaches whether all relevant evidence was *considered*. Thus, it is doubtful that an appeal of this sort would entail reexamination of existing evidence for a final agency action such as approval of a new drug application, for example. Although the Scientific Dispute Process Review Board may serve an important purpose within the agency, the FDA may be better served by formalizing an internal pathway to appeal agency decisions on the merits based on a broader set of grounds, including potential conflicts of interest. An important question here would be the appropriate standard of review for such an appeal. There should be a consistently applied standard of review, and it is unclear whether a deferential one would ferret out mistaken or conflicted decisions.

A clear-cut internal appeals process in which agency decisions can be reevaluated on the merits, and cultivation of an environment in which staff and experts feel comfortable engaging such a pathway, may offer great benefits in cases of genuine disagreement or concerns that undue influence, for example, skewed an outcome. The evaluative dilemma that members of the public face when they attempt to assess the accuracy of the FDA's decisions militates in favor of an internal appeals process that places agency staff, who possess greater expertise, at the helm of appeal requests.[263] Some might regard an internal

260. *Id.* at 4.

261. *Id.* at 3.

262. *Id.* at 5-6; *see also id.* at 11 (diagramming in the form of a flow chart the scientific dispute appeals process, which indicates that the challenged Center decision will be upheld as final if the Commissioner determines process was followed).

263. *See supra* text accompanying notes 223-24, 229-30. The FDA, including CDER in particular, recognizes the interdisciplinary nature of its review process and has recently revamped existing procedures for when an FDA employee cannot "align" behind an FDA action or decision. *See* CTR. FOR DRUG EVAL. & RSCH., MANUAL OF POLICIES AND PROCEDURES, EQUAL VOICE: COLLABORATION AND REGULATORY AND POLICY DECISION-

pathway to appeal agency decisions as duplicative, especially given the extensive and many-layered drug review process that the FDA undertakes in the first instance. There is also the possibility that such a pathway could be too easily coopted by disgruntled or strongheaded employees. These potential critiques notwithstanding, an appeals pathway has the potential to function as a key process safeguard for some of the most challenging drug and biologic applications and may find particular usefulness for therapies reviewed under accelerated approval when unmet need is great but evidence may be more limited. (In order to reduce the likelihood of frivolous challenges, appeals can be made harder to invoke, such as by requiring more than one individual within the agency to agree to initiate the appeal.)

To be sure, an appeals process may stymie a subset of drug approvals. But, as the high price of new drugs and the steep cost of drug development demonstrate, FDA approvals are a high-stakes matter. The financial and practical consequences of an injudicious drug approval should temper concerns about inefficiency or process ossification.

Second, the agency could give greater weight to the input of outside experts who sit on advisory committees. Currently, advisory committees provide only recommendations, which the agency may or may not adopt.[264] Agency procedure could be adjusted such that advisory committee determinations are presumptively accepted absent extraordinary circumstances or a reasoned justification.[265] Granting FDA advisory committees a greater degree of authority

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MAKING IN CDER 6 (2022), https://perma.cc/GB9K-8G5F (defining "alignment" as a "state of general support for a decision" rather than "full agreement or consensus"). This procedure entails formulating a written statement of disagreement (a "dispute statement"), which is administratively filed, and seeking review by the "next highest" official, either within or across a management chain. *Id.* at 9-10. Unresolved disputes may be elevated to the director of CDER and reviewed before an ad hoc panel. *See id.* at 14-15.

264. 21 C.F.R. § 14.5.

265. If advisory committee determinations are given greater weight in agency decisions such that committee recommendations are presumptively accepted, it will be even more critical to rigorously enforce financial conflict of interest rules for FDA advisory committee members. The FDA considers experts hired to serve on advisory committees to be "special government employees" (SGEs). *See* 18 U.S.C. § 208(b)(3). Advisory committee members must file financial disclosure reports and are subject to screening and possible exclusion unless a waiver is granted under 18 U.S.C. § 208(b)(3). U.S. DEP'T OF HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR THE PUBLIC, FDA ADVISORY COMMITTEE MEMBERS, AND FDA STAFF: PUBLIC AVAILABILITY OF ADVISORY COMMITTEE MEMBERS' FINANCIAL INTEREST INFORMATION AND WAIVERS 4, 12 (2014), https://perma.cc/VQC8-YMGP. Advisory committees must also comply with the provisions of the Federal Advisory Committee Act. Pub. L. No. 92-463, 86 Stat. 770 (1972). SGEs must disclose current investments as well as employment, consulting work, contracts, and grants of the SGE, his or her spouse, minor children, general partner, employer, or prospective employer that indicate "current involvement or [a] financial link with the meeting/task issues (including competing companies)." U.S. DEP'T OF HEALTH & HUM. SERVS., CONFIDENTIAL FINANCIAL DISCLOSURE REPORT FOR SPECIAL GOVERNMENT EMPLOYEES 1, https://perma.cc/PMP8-7LBB. For a summary of FDA's assessment process for advisory committee members' conflicts of interest, see Ian J. Kellogg, *Prescription for a Cure: Does the FDA's Draft Guidance Adequately*

in the drug review process would diminish the ability of senior FDA officials to nudge an application prematurely into the "approved" category despite advisory committee objections about a therapy's safety or efficacy.

Third, it is worth considering whether the FDA may be better organized as a multimember commission rather than an agency headed by a single Commissioner of Food and Drugs, and to what extent this sort of change in agency structure might counteract external forms of influence. Professors Ganesh Sitaraman and Ariel Dobkin have argued for the superiority of the single-director agency structure both because of greater efficiency and "clearer lines of responsibility," which lead ultimately to the agency head.[266] To the extent that expeditious FDA action is desirable, a single-director structure may indeed be superior.[267] But, if there are concerns that the pendulum has swung too far in the direction of hurried and injudicious drug approvals, a multimember commission may produce a welcome reduction in pace, especially for those NDAs or BLAs

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Manage Advisory Committee Members' Conflicts of Interest, 19 STAN. L. & POL'Y REV. 300, 306-12 (2008).

Whether conflict of interest screening of advisory committee members improves FDA decision-making has been contested. A study of FDA advisory committee member voting patterns found that committees with financial conflicts were more likely to have voted in a manner consistent with the agency's ultimate decision, but were more likely to *disagree* with the agency's decision to approve a drug. JOSEPH GOLEC & JAMES C. COOPER, GEO. MASON UNIV. L. & ECON. CTR., FDA ADVISORY COMMITTEES: CONFLICTS OF INTEREST AND VOTING RELATIVE TO BENCHMARKS 10-11 (2015), https://perma.cc/267F-3XLZ. The authors took such findings to mean that financial conflicts in advisory committees do not appear to cause bias: "[t]he presence of conflicts appears to have no statistically measurable impact on the accuracy of [advisory committee] decision-making." *Id.* at 24. However, the study's proxies of "accurate" decision-making including the FDA's ultimate decision, *id.* at 6, and investor judgment, *id.* at 7, may be unreliable since they are not truly exogenous indicators of "accurate" decisions.

266. Ganesh Sitaraman & Ariel Dobkin, *The Choice Between Single Director Agencies and Multimember Commissions*, 71 ADMIN. L. REV. 719, 723 (2019).

267. *Cf.* William E. Kovacic & David A. Hyman, *Competition Agency Design: What's on the Menu?*, 8 EUROPEAN COMPETITION J. 527, 531 (2012) ("A single executive is . . . more likely to quickly reach a decision and implement it . . . ."). A matter related but technically distinct from whether the FDA should be organized as a multimember commission is whether it should be reorganized as an independent agency rather than an executive branch agency. (Though independent agencies are typically headed by multimember commissions, they are not required to be organized as such. Nor must executive branch agencies have a single head.). In 2019, seven former FDA commissioners authored an article advocating for the FDA to be made an independent agency, no longer within the Department of Health and Human Services, in order to avoid "administrative bottlenecks" and bolster the independence of the agency's science-based decisions. Califf et al., *supra* note 15, at 84-85. Interestingly, the former commissioners recommended retaining a single, presidentially appointed agency head, *id.* at 85, likely for reasons of efficiency, which would contrast with other independent agencies such as the Federal Trade Commission or the Securities and Exchange Commission. Some have argued that independent agencies do not achieve very much in the way of independence from political control, for reasons that include the dependence of agencies without full litigating capacity on the Department of Justice, whose authority ultimately flows from the President. *See* Alan B. Morrison, *How Independent are Independent Regulatory Agencies?*, 1988 DUKE L.J. 252, 254.

that are particularly divisive within the agency.

Would an FDA with lengthier periods of review for certain NDAs and BLAs be a more effective agency or a less effective one? The answer would depend on whether lengthier periods of review are called for and whether they ultimately lead the agency to reach "better" decisions for those applications while accounting for delays until safe and effective drugs reach the market. (Again, though, there are inherent limitations on the ability of the public to evaluate whether the agency reached the "right" decision on any particular application before it, making an assessment of agency effectiveness challenging.) Writing on the topic of independent agencies, Professor Paul Verkuil has characterized multimember "collegial bodies" that are often at the helm of independent agencies as "more concerned with values of fairness, acceptability and accuracy than with the single dimension of efficiency," and as "consensual, reflective, and pluralistic" in their decision-making.[268] Sitaraman and Dobkin concede that multimember commissions may offer the benefit of more deliberative decision-making but question whether that is in fact the case when commissioners approach their roles with a partisan mindset.[269] Although the multimember structure may function as a bulwark against political influence on the agency head, this may not be true to the extent that the commissioners are chosen, and later make decisions, based on party lines.

Various other factors make the choice between a single-director head and a multimember commission for an agency such as the FDA a difficult one. Rapid turnover in single-director agency heads not only implicates revolving door concerns but also raises concerns about consistency in agency policy and consistency in direction.[270] An agency might achieve greater continuity and consistency via multiple commissioners with overlapping terms rather than a succession of single directors who lead for only short stints. On the other hand, to the extent that resource constraints continue to afflict the FDA, the greater difficulty multimember commissions commonly face in meeting statutory deadlines may tip the scales in favor of retaining a single-director structure.[271]

Fourth, with respect to intra-agency checks, an expanded and strengthened system for postmarketing surveillance can function as an indirect check on FDA's decisions with respect to new drug and biologic approvals. The logic here is that robust postmarketing surveillance can counteract hasty drug approvals by ensuring more vigilant monitoring for safety and efficacy concerns and swifter action to enforce changes to drug labels or withdraw drugs that prove unsafe or

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268. Paul R. Verkuil, *The Purposes and Limits of Independent Agencies*, 1988 DUKE L.J. 252, 260. Professors William Kovacic and David Hyman summarize the benefits of multimember commissions as including "diversified expertise, greater resistance to capture and heightened legitimacy." Kovacic & Hyman, *supra* note 267, at 531.

269. Sitaraman & Dobkin, *supra* note 266, at 723-24.

270. *See* Kovacic & Hyman, *supra* note 267, at 531 ("Multi-member boards are . . . less subject to abrupt shifts in policy in the wake of an election that results in a change in power.").

271. *See* Sitaraman & Dobkin, *supra* note 266, at 728-29.

inefficacious. The case for enhanced postmarketing surveillance has been made quite well from the standpoint of drug safety.[272] The ability of a more robust postmarketing surveillance system to serve as an indirect check on industry influence arising from revolving door concerns constitutes yet another benefit of this much-needed reform.

2. Extra-agency Checks

The FDA's approval of a new drug is not itself considered a "final agency action" within the meaning of the Administrative Procedure Act ("APA") and agency regulation, and therefore it is not subject to direct judicial review.[273] However, the FDA considers as a final agency action its response to a petition or citizen petition requesting, among other actions, withdrawal of a drug from the market or rejection of a drug application.[274] A citizen petition is a request to the Commissioner of Food and Drugs to "issue, amend, or revoke a regulation or order," or alternatively, to "take or refrain from taking any other form of administrative action."[275] The Commissioner must issue a response within 180 days approving the petition, denying it, providing a tentative response, or dismissing it as moot.[276] Filing of a petition or citizen petition and the FDA's

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272. *See, e.g.*, Brian K. Chen & Y. Tony Yang, *Post-Marketing Surveillance of Prescription Drug Safety: Past, Present, and Future*, 34 J. LEGAL MED. 193 (2013); Janet Woodcock et al., *Role of Postmarketing Surveillance in Contemporary Medicine*, 61 ANN. REV. MED. 1, 2 (2011) ("Efficient postmarketing surveillance systems must be designed to discover all . . . types of preventable harm . . . . The surveillance system must support investigations of factors such as dose-response relationships; the role of drug-drug, drug-disease, and drug-food interactions; and the possibility of medication error.").

273. "A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b).

274. DEP'T OF HEALTH & HUM. SERVS., U.S. FOOD & DRUG ADMIN., REPORT TO CONGRESS: ENCOURAGING EARLY SUBMISSION OF CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION 1 (2009) ("Responses to petitions are considered final agency action that can be challenged in court."). "[T]wo conditions must be satisfied for agency action to be 'final': First, the action must mark the consummation of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Holistic Candlers & Consumers Ass'n v. FDA, 664 F.3d 940, 943 (D.C. Cir. 2012) (quoting Bennett v. Spear, 520 U.S. 154, 177-78 (1997)) (subsequently concluding that FDA warning letters do not meet these two criteria). The FDA does not consider a complete response letter, on the other hand, to be a final agency action, a position which drug manufacturers have contested. *See* Douglas B. Farquhar & Sara W. Koblitz, *Can a CRL Be Final Agency Action: One Step Closer to Finding Out*, HYMAN, PHELPS & MCNAMARA FDA L. BLOG (July 6, 2021), https://perma.cc/4UGD-UMNK.

275. 21 C.F.R. § 10.30(b)(3). The ability to file a citizen petition thus fulfills the APA's mandate that agencies give interested persons "the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

276. 21 C.F.R. § 10.30(e)(2). Certain petitions are subject to shorter response times. The agency must respond within 150 days to a 505(q) petition seeking to delay approval of a

final administrative action on the petition are thus a necessary precursor to a court challenge: "FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss[] . . . any issue which has not previously been determined by the agency . . . ."[277]

It is fairly commonplace for brand drug manufacturers to file 505(q) citizen petitions requesting that the FDA take action to delay a pending abbreviated new drug application ("ANDA") for a generic equivalent of a brand-name drug.[278] Although the FDA's final approval of an ANDA is not dispositive of ripeness,[279] final approval may make a challenge more likely to be ripe for judicial review to the extent that hardship to the plaintiff is more direct or imminent.[280] Challenges to NDA or BLA approvals are less frequent than challenges to ANDA or abbreviated Biologics License Application ("aBLA") approvals. However, nothing in theory prevents an interested party from challenging an NDA or BLA approval in court provided that a final administrative decision has been rendered in accordance with 21 C.F.R. § 10.45 and other requirements such as standing and ripeness are satisfied.

The actions of other agencies and insurers can also serve as an important check on the FDA's decision-making. CMS coverage decisions, for example, can function as an indirect safeguard against miscalculated or rushed drug approvals. CMS announced in January 2022 that Aduhelm will be covered only for Medicare patients enrolled in "qualifying" clinical trials, which illustrates its power to restrict access to FDA-approved therapies.[281] CMS's limited coverage

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pending application, for example. U.S. FOOD & DRUG ADMIN., CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(Q) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY 2 (2019), https://perma.cc/Y49B-C7L2. The regulatory language envisions a potential challenge to an NDA: "This section applies to a citizen petition or petitions for stay of action that meets all of the following criteria: (1) [t]he petition requests that the Commissioner take any form of action that could, if taken, delay approval of . . . a new drug application submitted through the pathway described by section 505(b)(2) of the Federal Food, Drug and Cosmetic Act . . . ." 21 C.F.R. § 10.31(a).

277. 21 C.F.R. § 10.25(b).

278. *See* Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 327 (2017).

279. Cephalon, Inc. v. Sebelius, 796 F. Supp. 2d 212, 216 (D.D.C. 2011).

280. *See id.* at 217; Pfizer Inc. v. Shalala, 183 F.3d 975, 978, 980 (D.C. Cir. 1999) (granting summary judgment to the government after Pfizer challenged the FDA's acceptance of Mylan's ANDA for Procardia XL (nifedipine), on the grounds that Pfizer suffered no imminent hardship from the FDA's acceptance of Mylan's ANDA—or the FDA's later tentative approval of the ANDA—and therefore Pfizer's claims were not ripe for review).

281. *See supra* note 36. In the case of eteplirsen, some insurers—notably Anthem—chose not to cover the therapy soon after it was approved due to concerns about its efficacy, but later allowed coverage provided that specific clinical criteria are met. *See* Bruce Japsen, *Anthem Says It Won't Cover Sarepta's Musuclar Dystrophy Drug*, FORBES (Oct. 7, 2016, 12:27 PM), https://perma.cc/LUX3-4YCH (reporting on Anthem's initial coverage decision); Suzanne Elvidge, *Anthem Reverses Course, Agrees to Cover Sarepta's Duchenne Drug*, BIOPHARMA DIVE (Nov. 13, 2017), https://perma.cc/ZH74-6SZK (noting that Anthem's coverage policy requires DMD patients to meet certain clinical criteria, including a requirement for ambulatory capacity and a genetic mutation compatible with eteplirsen's mechanism of action).

determination for Aduhelm was based in part on concerns about the relative risks and benefits of the therapy; yet, it stands at odds with the FDA's still-valid decision to approve the treatment as safe and effective for its labeled indication. Whether CMS should have authority to establish conditional access to FDA-approved treatments when it determines that risks remain insufficiently studied, or whether the FDA should request that sponsors produce additional data prior to drug approval, is a matter for debate. Other agencies with a hand in drug coverage and reimbursement may exert a similar check, such as the Health Resources and Services Administration ("HRSA") that administers the 340B Drug Pricing Program and sets the associated 340B ceiling price for certain outpatient drugs.[282]

CONCLUSION

Industry influence may explain much of the recent controversy surrounding the FDA's contested drug approval and EUA-related decisions: hasty approvals based on limited evidence could reflect an individual or institutional favoring of industry interests. The "revolving door" movement of government regulators to positions in regulated entities is one important mechanism by which industry can exert undue influence on incumbent regulators. Theoretical foundations from across disciplines help demonstrate that a regulator's good intentions cannot stave off the potential for bias. Even in the absence of actual bias, perceived or potential bias due to the prevalence of the revolving door tends to erode public trust and confidence in the FDA's decisions and therefore weighs in favor of mitigating measures. The revolving door is best conceptualized as an institutional problem. Attendant risks come to fruition through unchecked exercises of discretion; therefore, instituting a variety of different checks on agency decision-making can keep the hazards that accompany the revolving door at bay.

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282. *See 340B Drug Pricing Program*, HEALTH RES. & SERVS. ADMIN. (2022), https://perma.cc/BQM4-SHD9.