LITIGATING AUTHORITY FOR THE FDA

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ABSTRACT

The Food and Drug Administration (FDA), like most federal agencies, is a captive client. Its "lawyer," the Department of Justice (DOJ), ultimately decides whether and when to sue. When FDA goes to court, a DOJ lawyer decides what arguments to make, and whether to appeal if they lose. But Congress could, and perhaps should, change this arrangement. In this Article, I discuss the prospect of independent litigation authority—the authority to conduct litigation without DOJ—for the FDA.

Because FDA and DOJ must cooperate to litigate cases, their working relationship profoundly influences federal policy, especially enforcement decisions. Drawing on twenty semi-structured interviews with former DOJ and FDA attorneys, I provide the first qualitative empirical account of the interaction between these powerful agencies. I find that three key tensions between the agencies shape enforcement policy: (1) DOJ makes use of its authority to decline and delay FDA referrals and to direct key decision-making in litigation, limiting FDA's preferred implementation of the Food, Drug, and Cosmetic Act; (2) the agencies have distinct, yet overlapping, enforcement priorities; and (3) DOJ control can result in more *enforcement, with DOJ pursuing cases without consulting FDA, or over FDA's objection, and pushing FDA to take on others. Drawing upon these findings, I propose and defend a reallocation of litigation authority in which Congress would grant FDA independent authority over civil—but not criminal—litigation.*

This Article uses litigation authority to link theories of public enforcement with scholarship on interagency relationships. The example of FDA and DOJ illustrates how relationships between agencies can shape federal enforcement policy. Enforcement policy is determined not simply by monolithic agencies or administrations, but also by interactions among

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individual agencies with different missions, authority, and expertise, overruling and deferring to each other's preferences on a case-by-case basis. Understanding interagency relationships likewise requires interrogating enforcement policy as a site of interagency contestation, with the decisions of DOJ and FDA lawyers embodying divergent policy preferences stemming from their agencies' institutional identities. By uncovering how FDA enforcement policy results from many individual discretionary decisions, each subject to negotiation, this Article seeks to better understand both interagency relationships and the process of public enforcement.

The question of who controls agency litigation also implicates foundational issues of regulatory power. This Article anchors those debates in the experiences of the public servants who have spent their careers navigating the pathways of authority Congress created. Their novel insights allow for a more nuanced discussion of agency independence, litigation authority, and the legitimacy of regulatory power.

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INTRODUCTION

When the Food and Drug Administration (FDA) goes to court, it depends on the Department of Justice (DOJ), by law, to conduct all formal aspects of litigation.[1] To sue a drug manufacturer, FDA must convince a DOJ attorney to file the complaint.[2] When FDA gets sued over a regulation, a

1. 28 U.S.C. § 516 ("Except as otherwise authorized by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General."); 28 U.S.C. § 519 ("Except as otherwise authorized by law, the Attorney General shall supervise all litigation to which the United States, an agency, or officer thereof is a party . . . ."); 5 U.S.C. § 3106 ("Except as otherwise authorized by law, the head of an Executive department . . . may not employ an attorney or counsel for the conduct of litigation . . . but shall refer the matter to the Department of Justice.").

2. *See* Charles R. McConachie, *The Role of The Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act*, 31 FOOD DRUG COSM. L.J. 333, 333–34 (1976) (explaining how DOJ "review[s] recommendations of the FDA" and takes legal action "where appropriate . . . for apparent

DOJ attorney stands up in court to defend it.[3] DOJ holds ultimate control over filings, arguments, and appeals.[4] Indeed, all FDA actions—rules, warning letters, or guidance—can be challenged in court or ignored. At that point, FDA's only option to seek compliance or defend its policies is litigation, where all decisions ultimately rest with DOJ.[5]

This arrangement, common to most federal regulatory agencies, is not preordained. Some agencies, most of them independent agencies, litigate their own cases how and when they choose, rather than relying on DOJ to litigate on their behalf.[6] Arguing for FDA independence in 2019, seven former FDA Commissioners urged Congress to grant the agency litigation authority, along with other reforms designed to insulate it from political pressure.[7] The report added to a growing discourse around FDA independence.[8] Litigation authority, the Commissioners thought, was "key" to making FDA an independent agency.[9] FDA's actions in response to the COVID-19 pandemic led to more public discussion of independence, spurred by criticism of the agency's apparent susceptibility to presidential control.[10]

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violations"); John R. Fleder, *The Role of the Department of Justice in Enforcement Matters Relating to the Food and Drug Administration*, 46 FOOD DRUG COSM. L.J. 781 (1991).

3. *See* Susan M. Olson, *Challenges to the Gatekeeper: The Debate over Federal Litigation Authority*, 68 JUDICATURE 71, 72 (1984) ("In federal government litigation, the Justice Department plays gatekeeper between the courts and agencies.").

4. *See* Neal Devins & Michael Herz, *The Uneasy Case for Department of Justice Control of Federal Litigation*, 5 U. PA. J. CONST. L. 558, 580 (2003) ("[T]he agency is a captive client; it cannot choose to use its own lawyers or retain a different 'firm.'").

5. *See infra* Part II.

6. *See* Kirti Datla & Richard L. Revesz, *Deconstructing Independent Agencies (and Executive Agencies)*, 98 CORNELL L. REV. 769, 799–801 (2013) (listing agencies with litigation authority and their substantive statutes). Agencies with full or partial litigation authority include: the Federal Energy Regulatory Commission, discussed *infra* notes 282–286, the Federal Trade Commission, discussed *infra* notes 102–109, the Securities and Exchange Commission, the Federal Election Commission, the Department of Defense, and the Consumer Financial Protection Bureau. *Id.* at 800.

7. *See* ASPEN INST., SEVEN FORMER FDA COMMISSIONERS RECOMMEND: FDA SHOULD BE AN INDEPENDENT AGENCY 15 (2019) (recommending "[l]itigation authority, in coordination with the U.S. Department of Justice") [https://perma.cc/LYC4-C6CZ]; *see* Robert M. Califf et al., *Seven Former FDA Commissioners: The FDA Should Be an Independent Federal Agency*, 38 HEALTH AFFS. 84 (2019).

8. *See* Eli Y. Adashi, Rohit S. Rajan & I. Glenn Cohen, *When Science and Politics Collide: Enhancing the FDA*, 364 SCIENCE 628 (2019).

9. ASPEN, *supra* note 7, at 15.

10. *See Open Letter to Stephen M. Hahn, M.D., Commissioner of the Food and Drug Administration: #ProtectTheFDA*, https://docs.google.com/forms/d/e/1FAIpQLSdXaVo9BWAhMMej_KUL2sTB6jt3H2j90aagVXymWWS-luudzA/viewform [https://perma.cc/W7GJ-5YD6]; Stephen Hahn (@SteveFDA), TWITTER (Jan. 17, 2021, 1:15 PM) (considering, as FDA Commissioner, "whether FDA would be better able to fulfill its mission if it were an independent agency"), https://twitter.com/ SteveFDA/status/1350884397910786049 [https://perma.cc/WW85-JVQ5]; Sheila Kaplan, Sharon LaFraniere, Noah Weiland & Maggie Haberman, *How the FDA Stood Up to the President*, N.Y. TIMES, (Oct. 20, 2020), https://www.nytimes.com/2020/10/20/health/covid-vaccines-fda-trump.html?action -click&module=News&pgtype=Homepage [https://perma.cc/26RE-8A6T];

FDA indeed presents a compelling case for controlling its own litigation. It is the paradigmatic scientific decisionmaker, leveraging its broad authority to regulate global industries on the basis of highly technical, time-sensitive assessments.[11] Its litigation decisions hinge on questions of science and public health policy.[12] FDA has a strong claim that, if any agency ought to have the power to make its own decisions in court, it should. It is, by many accounts, the preeminent public health agency in the world.[13] But it relies on DOJ to file basic enforcement actions against contaminated products.

Scholars have debated whether DOJ affects the policies of government agencies through its gatekeeping authority over litigation. Some question the basis for DOJ control of federal litigation,[14] and propose that it may affect agencies' substantive programs.[15] But there is no in-depth agency case study looking at how, or even *if*, it actually does.[16] Existing work

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Nisarg Patel, *Opinion, It's Time to Make the FDA Independent*, POLITICO (June 17, 2020), https://www.politico.com/news/agenda/2020/06/17/independent-fda-hydroxychloroquine-326166 [https://perma.cc/HE2W-9ZWW].

11. *See* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010) (providing a sweeping historical account of how FDA has wielded its vast scientific expertise and legal authority over the twentieth century).

12. *See* Margaret A. Hamburg & Joshua M. Sharfstein, *The FDA as a Public Health Agency*, 360 NEW ENG. J. MED. 2493, 2493–94 (2009) (identifying "protecting the public health" as the agency's "overriding purpose" and listing enforcement among the "difficult decisions" FDA must make "in the absence of ideal information") (citing United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969) (recognizing that the Food, Drug, and Cosmetic Act's "overriding purpose [is] to protect the public health")).

13. *See, e.g.*, CARPENTER, *supra* note 11, at 1–2 (arguing that "the FDA rules the entire global pharmaceutical market" with a "global economic and scientific reach . . . that other agencies in foreign nations consciously emulate or resist"); Theodore W. Ruger, *After the FDA: A Twentieth-Century Agency in a Postmodern World*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 76, 77 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015) ("Few agencies have been as successful at achieving their stated regulatory goals, and few have enjoyed the reputation for technocratic expertise that the FDA has long held among the press and the public.").

14. Devins & Herz, *supra* note 4, at 559 (casting "a fresh eye on the standard arguments for DOJ control of litigation" and concluding that "the case is not nearly as compelling as generally assumed").

15. *See* Michael Herz & Neal Devins, *The Consequences of DOJ Control of Litigation on Agencies' Programs*, 52 ADMIN. L. REV. 1345, 1360 (2000) ("There is thus every reason to be concerned about the substantive consequences for particular agencies' programs that flow from granting DOJ litigation authority.").

16. Some scholars assume that "[b]y acting as counsel on behalf of agencies, the DOJ is able to influence their substantive programs." Bijal Shah, *Executive (Agency) Administration*, 72 STAN. L. REV. 641, 656 (2020) (citing Herz & Devins, *supra* note 15, at 1346). But empirical evidence of this influence is scarce. Herz & Devins, *supra* note 15, at 1346, posit only that DOJ "control [of] agency litigation *might* have such an effect" (emphasis added). The personal interviews Susan Olson conducted with government lawyers "confirm and flesh out the range of positions on the issue" but "cannot be claimed to be enough to provide new systematic data." Olson, *supra* note 3, at 75. *See also* Elliott Karr, *Independent Litigation Authority and Calls for the Views of the Solicitor General*, 77 GEO. WASH. L. REV. 1080 (2009) (focusing on the FTC's litigation authority before the Supreme Court).

focuses instead on litigation authority's role in discrete episodes of high-profile litigation,[17] including litigation between executive and independent agencies,[18] and how it may shift power within agencies themselves.[19]

This Article uses the case of FDA—an executive agency on the precipice of independence—to uncover how DOJ control of agency litigation, especially enforcement decisions, shapes agency policymaking. To do so, I draw on anonymous semi-structured interviews with twenty former government attorneys—ten each from DOJ and FDA—totaling over twenty-two hours of qualitatively-analyzed discussion, shedding light unavailable from any published sources.[20] Using their responses I sketch, for the first time in detail, the working relationship between the powerful agencies that must coordinate to enforce the federal food and drug laws of the United States,[21] and how that relationship shapes the implementation of the FDA's substantive statute.

I find that DOJ control of FDA litigation in fact shapes FDA policy, with the interview responses centering around three main themes. First, DOJ's final say-so limits FDA's preferred implementation of the Food, Drug, and Cosmetic Act (FDCA), the main statute FDA is tasked with administering.[22]

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17. *See, e.g.*, Neal Devins, *Political Will and the Unitary Executive: What Makes an Independent Agency Independent?*, 15 CARDOZO L. REV. 273, 285–312 (1993) (discussing the Equal Employment Opportunity Commission's conflict with DOJ over race-conscious affirmative action); Alane Tempchin, *Fall from Grace:* Federal Election Commission v. NRA Political Victory Fund *and the Demise of the FEC's Independent Litigating Authority*, 10 ADMIN. L.J. AM. U. 385 (1996) (discussing one case); Neal Devins & Michael Herz, *The Battle That Never Was: Congress, the White House, and Agency Litigation Authority*, 61 L. & CONTEMP. PROBS. 205, 209–10 (1998) (pointing to an amicus brief by DOJ presenting the views of the "United States" on certain environmental regulations that EPA "no doubt" would have written differently).

18. Shah, *supra* note 16, at 654–59. Shah argues that "litigation against independent agencies has helped shift power toward the priorities of executive agencies, at the expense of independent agencies." *Id.* at 647.

19. Elizabeth Magill & Adrian Vermeule, *Allocating Power Within Agencies*, 120 YALE L.J. 1032, 1060–61 (2011) (arguing that "statutes that grant independent litigating authority to an agency will also affect the allocation of authority among professionals within it" by consolidating responsibility in the agency's general counsel).

20. The Yale University Institutional Review Board granted the study an "exemption determination" under 45 C.F.R. 46.104(2)(iii) (on file with author). Methods are discussed *infra* Part III.

21. John R. Fleder supplies an excellent firsthand account of the DOJ's formal role in FDA enforcement actions and the attendant policy considerations. Fleder, *supra* note 2. This Article offers empirical evidence suggesting that the agencies' preferences and interactions shape federal policy through the legal tools and enforcement processes Fleder describes.

22. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399, has profoundly shaped the American economy. According to Lewis A. Grossman, "The quasi-constitutional nature of the FDCA is reflected not only in the important, deeply-entrenched government structures and functions it has created, but also in its corresponding effect of restricting American consumers' choices within some of the most essential product categories in the human economy." Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J.L. & MED. 687, 691 (2016).

Participants described how DOJ sometimes declined to pursue FDA cases, or delayed filing them. The agencies regularly disagree over what kinds of arguments to make, whether to appeal adverse judgments, and other litigation decisions. Furthermore, the expectation of DOJ review shapes FDA referrals to align more with DOJ priorities.

Second, the agencies have distinct enforcement priorities. Although there is overlap, FDA tends to prioritize health and safety violations, while DOJ tends to favor promotional cases, such as prosecutions for illegal marketing of drugs and devices for indications not approved by FDA ("off-label" promotion).[23] Some respondents predicted that an untethered FDA would likely bring more low-level seizure and injunction actions than it can today and might show far less interest in promotional violations than DOJ has. I argue that the agencies' divergent interpretations of the statute result from their underlying missions.[24] FDA, as a public health agency, views the statute as a tool to protect public health, while DOJ views it as an extension of its existing authority to prosecute fraud.

Third, and most surprisingly, DOJ control can at times lead to *more* enforcement. Because the enforcement priorities of the agencies differ, DOJ can be more zealous than FDA, pushing it to help pursue enforcement actions it otherwise would not. Sometimes, DOJ pursues cases without consulting FDA at all, or even over FDA's objection. These responses cast doubt on some scholars' claims that DOJ's client agencies "almost certainly will advance a pro-enforcement agenda."[25] Instead, I find DOJ can be a "litigious" lawyer, sometimes favoring more enforcement than its client.

The aim of this Article is to forge a link between the public enforcement literature and the body of work on interagency relationships.[26] Numerous articles address government enforcement policy in which authors tend to conceive of enforcement policy as the product of a single agency, an administration, or the government as a whole.[27] A separate body of work explores the myriad relationships between government agencies.[28] These scholars have shown how agencies exist in varying states of conflict, cooperation, dysfunction, duplication, and reinforcement, in what Jody Freeman and Jim Rossi describe as "shared regulatory space."[29]

What remains underdeveloped, however, is the role of DOJ as the

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23. See *infra* notes 148–153, for a discussion of unlawful promotion practices.
24. *See infra* Section III.D.
25. Devins & Herz, *supra* note 17, at 210.
26. Special thanks to Lawrence Liu for this insight.
27. *See infra* note 90 and accompanying text.
28. *See infra* notes 89–94.
29. Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1144 (2012).

nation's litigator, including how its control of agency litigation shapes its relationships with regulatory agencies, which in turn shapes federal enforcement policy. Likewise, work on FDA enforcement policy largely sets aside the question of how the relationship between DOJ and FDA determines enforcement decisions.[30]

My study reveals that these two areas—public enforcement and relationships between agencies—must be understood together. FDA enforcement policy is the product of neither FDA nor DOJ alone, but rather by the relationship between them. That relationship is shifting and context-dependent, shaped by cooperation, conflict, compromise, and sometimes competing notions of the public interest. The FDA-DOJ enforcement process thus complicates dominant accounts of regulatory overlap and coordination, which tend to see interagency relationships as less fluid than my study suggests.

I argue that the push-and-pull between DOJ and FDA lawyers, when it occurs, reflects divergent policy preferences stemming from their agencies' institutional identities. FDA enforcement policy, then, is made not by a monolithic governing administration, but by multiple agencies with different missions, authorities, expertise, and obligations, overruling and deferring to the other's preferences on a case-by-case basis. By seeing how enforcement policy can result from many individual discretionary decisions, each subject to negotiation, we can better understand both interagency relationships and the process of public enforcement.

This Article proceeds as follows. Part I introduces litigation authority, and presents the arguments for and against DOJ control of agency litigation. It then uses the debate over litigation authority to illustrate the relevance of interagency relationships to enforcement policy and vice versa. Because DOJ control of litigation affects law enforcement, it argues, public enforcement policy must be understood as a product of interagency relationships.

Part II proceeds with the role of litigation at FDA, including how discretionary decisions by FDA and DOJ lawyers determine which enforcement actions are pursued and which are set aside.

Part III presents the findings of the interview study using qualitative analysis to identify themes discussed by former lawyers from each agency. Section III.D explores the most novel finding: that DOJ can sometimes be

30. *See, e.g.*, Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033 (2012); Patrick O'Leary, *Credible Deterrence: FDA and the Park Doctrine in the 21st Century*, 68 FOOD & DRUG L.J. 137 (2013). O'Leary suggests that DOJ control of prosecutions contributes to FDA's conservative approach to criminal enforcement, *id.* at 138, and invites us to consider the benefits of FDA control of those decisions. *Id.* at 175. This Article responds to his invitation.

more aggressive than FDA.

Part IV places the views of the study participants for and against FDA litigation authority in conversation with one another. It then offers and defends a viable option for granting FDA civil litigation authority in light of the study's empirical findings.

Part V comments on the significance of presidential policymaking as a defense of DOJ control, as well as that argument's relative absence from participant responses, and concludes with four implications for enforcement policy and agency independence.

I. LITIGATION AUTHORITY AND ENFORCEMENT POLICY IN THE ADMINISTRATIVE STATE

Regulatory agencies enjoy broad discretion from courts when choosing whether, when, and how to enforce federal law. Public enforcement thus presents a particularly sensitive, consequential, and undertheorized policymaking arena in which to observe the effect of DOJ control of litigation through its relationships with client agencies. By linking the litigation authority debate to broader discussions on interagency administration and regulatory enforcement, this Part shows how the question of who controls litigation implicates foundational issues of regulatory power.

A. Defense and Criticism of DOJ Control of Litigation

Proponents of centralized DOJ control of litigation offer many justifications. Devins and Herz summarize the defense:

> DOJ's status as the government's litigator is justified on the grounds that a single, highly talented "law firm" will ensure quality representation, consistency, efficiency, and responsiveness to presidential preferences. This argument asserts the absolute necessity that the government speak with one voice in the courts, a consistency that can be achieved only by centralizing litigation authority. In addition, because the Attorney General sees the big picture—and sees it with the same eyes as the president—centralization will ensure that representation is consistent with the broader policy concerns of the Administration.[31]

Commentators have cast some doubt on this received wisdom, asking whether DOJ control of agency litigation "interferes with rather than

31. Devins & Herz, *supra* note 4, at 570.

advances" the aims of agency programs.[32] The debate has four components: consistency, expertise, "check" value, and respect for presidential policymaking.

Consistency. Proponents assert that the federal government should "speak with one voice."[33] Consistency, they contend, ensures fairness in the government's dealings with private parties, leads to better outcomes with judges that favor more predictable legal stances, and prevents Agency A from pursuing narrow precedents at the expense of the Agency B.[34]

Critics point out that the federal government already does not present consistent litigating positions.[35] They further contend that there is no evidence DOJ control leads to less inconsistency, and some that it leads to more.[36] Olson points out that DOJ struggles to coordinate the litigation of the many U.S. Attorney's Offices (USAOs)[37]—a finding my study corroborates in the context of FDCA litigation.[38] Finally, critics question whether inconsistency actually hurts the federal government in court, and posit that the supposed need for a single government "voice" may be merely an ideological preference rather than a practical benefit.[39]

Expertise. DOJ litigators, proponents assert, are the best at what they do—litigation—delivering agencies wins in court. Additionally, because much federal government litigation involves common legal issues (Article III standing, *Chevron* deference, and the Freedom of Information Act, for example),[40] it is more efficient to house litigation expertise in one body, rather than duplicating that expertise in individual agencies. Agencies benefit from this concentration of knowledge and experience, as well as the reputation DOJ has developed among the courts as a serious, trusted litigator.

Critics respond that, to the contrary, agency lawyers carry the more relevant expertise—a deep knowledge of the substantive statute specific to their agency and the doctrines associated with it.[41] Furthermore, any discrepancy in expertise between DOJ and agencies is an *acquired* and not

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32. Herz & Devins, *supra* note 15, at 1348; *see* Devins & Herz, *supra* note 4 at 570–94; Olson, *supra* note 3, at 80–83.

33. Guillermo J. Garcia Sanchez, *To Speak with One Voice: The Political Effects of Centralizing the International Legal Defense of the State*, 34 ARIZ. J. INT'L & COMPAR. L. 557, 564–66 (2017).

34. Devins & Herz, *supra* note 4 at 571–74.

35. Devins & Herz, *supra* note 4 at 574 ("[T]he risk of greater inconsistency is nil.").

36. Devins & Herz, *supra* note 4 at 574.

37. Olson, *supra* note 3, at 80–83.

38. *See infra* Section III.C.

39. *See* Devins & Herz, *supra* note 4, at 571–75.

40. *See* Olson, *supra* note 3, at 78–79.

41. Devins & Herz, *supra* note 4, at 585.

an *inherent* characteristic.[42] That is to say: the characteristics of an organization stem from its design and function. If agencies filled the role DOJ now plays, they would have to attract litigators and develop the expertise that DOJ now has. The expertise defense, in the critics' view, is circular because it relies on factors incident to the current arrangement.

"Check" value. Proponents argue that by gatekeeping agencies' access to the courts, DOJ provides a valuable check on zealous agencies eager to bring enforcement actions that DOJ, as a more objective observer, can see are unsupported by evidence or the public interest.[43] By exercising this authority, DOJ bends agencies' enforcement policies to align with national priorities.[44] This view resonates with the accounts of scholars such as Jon D. Michaels, who identifies intra-branch checks and balances that help "[l]egitimiz[e] [a]dministrative [g]overnance,"[45] and Sharon Jacobs's model of "statutory separation of powers," through which Congress divides authority between multiple agencies using checks and balances to prevent factionalism and limit presidential authority.[46] Proponents of the DOJ "check" may prefer a split arrangement of litigation power because it limits agencies' enforcement discretion.

A critic might then respond that the benefits of DOJ's "check" are outweighed by its costs.[47] Even if agencies are more risk-tolerant than DOJ, greater risk may bring greater reward. First, aggressive litigation tactics may yield more victories. Second, even if agencies do lose more often, those outcomes may be consistent with their missions. While DOJ is focused narrowly on choosing winning cases, agencies may care more about their policy agendas, of which formal litigation is only one part. Losing some cases might be consistent with a more robust deterrence-based enforcement strategy. In other words, perhaps the "check" DOJ offers is more burdensome than beneficial, by unduly hindering the implementation of the program Congress assigned to the agency.[48]

Respect for presidential policymaking. This final justification

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42. Devins & Herz, *supra* note 4, at 583–86.

43. Devins & Herz, *supra* note 4, at 586–89.

44. Olson, *supra* note 3, at 79 ("Again and again the claim was made that the Justice Department could and would better represent the 'public interest' or the 'broader governmental interest' beyond one case or one program.").

45. Jon D. Michaels, *An Enduring, Evolving Separation of Powers*, 115 COLUM. L. REV. 515, 551 (2015).

46. Sharon B. Jacobs, *The Statutory Separation of Powers*, 129 YALE L.J. 378 (2019). Notably, Jacobs argues that separating administrative authority may *limit* presidential authority over agency policy. *Id.* at 381. This point cuts against the traditional view that DOJ control of litigation *consolidates* presidential authority.

47. *See* Garcia Sanchez, *supra* note 33, at 565–66 (noting arguments against centralization of litigation).

48. *See supra* notes 15–16 and accompanying text.

considers litigation decisions as a form of agency policymaking.[49] Proponents argue that DOJ's role is to render federal litigation consistent with the Administration's priorities. As articulated by the Office of Legal Counsel, the Attorney General, as the chief federal litigator and a member of the President's cabinet, bears "responsibility to ensure that the interests of the United States as a whole, as articulated by the Executive, are given a paramount position" over the parochial interests of individual agencies.[50]

This argument finds support in models of the administrative state that seek to legitimize agency authority through the Presidency, the only office filled by nationwide election.[51] The dominant account of the administrative state posits that the democratic legitimacy of agency action flows from elected officials. Agency authority is legitimate because Congress has properly delegated the agency such authority,[52] or because its decisions are overseen by the President[53]—officials elected by the public over whom the agency exerts authority. Agency action is likewise subject to control from many sides within our federal system of separated powers. The President, as chief executive, directs agency policymaking, and can appoint and remove agency officials.[54] Congress can express its displeasure by reducing and conditioning funding, convening hearings, or by limiting the agency's statutory authority.[55] Private parties can seek judicial review of agency action under the Administrative Procedure Act (APA).[56] Courts then limit agency action that is arbitrary and capricious,[57] unconstitutional,[58] inconsistent with the agency's substantive statute,[59] or otherwise unlawful.[60] These checks on administrative power thus correspond to the sources of its

49. *See infra* notes 76–82 and accompanying text.

50. Att'y Gen.'s Role as Chief Litigator for the U.S., 6 Op. O.L.C. 47, 54 (1982).

51. *See* Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 485–91 (2003); Thomas O. McGarity, *Presidential Control of Regulatory Agency Decisionmaking*, 36 AM. U. L. REV. 443, 449 (1987).

52. *See* Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1672 (1975) (offering the classic account of regulatory power and the administrative state through the 1970s).

53. *See* Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573, 587 (1984).

54. *See* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001).

55. *See* Brian D. Feinstein, *Congress in the Administrative State*, 95 WASH. U. L. REV. 1187, 1195–98 (2018); TODD GARVEY & DANIEL J. SHEFFNER, CONG. RSCH. SERV., R45442, CONGRESS'S AUTHORITY TO INFLUENCE AND CONTROL EXECUTIVE BRANCH AGENCIES 4–14 (2021).

56. Administrative Procedure Act, 5 U.S.C. §§ 551–559; Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971) (establishing a broad presumption in favor of judicial review of agency action).

57. Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983).

58. Mathews v. Eldridge, 424 U.S. 319 (1976).

59. Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

60. Administrative Procedure Act, 5 U.S.C. § 706(2)(a).

legitimacy: Congress, the President, and the public.

The argument that DOJ should control agency litigation to respect presidential policymaking situates the litigation authority debate within a broader discussion about independent agencies. "Independent" agencies (as opposed to "executive" agencies) can be seen as an attempt by one political branch, Congress, to limit the control of another, the President.[61] Independent agencies tend to share characteristics intended to insulate them from undue political influence—especially from the President.[62] Many have litigation authority, as well as multi-member leadership with set terms and protections against arbitrary removal by the President.[63] By designing independent agencies in ways that restrict Presidential control over agency decision-making, Congress tries to insulate the mission of the agency over the priorities of the President.[64]

Skeptics of independent agencies argue that their design threatens their constitutionality and democratic legitimacy.[65] Independent agencies upset the separation of powers, they contend, by improperly limiting presidential control over the executive branch.[66] Furthermore, independent agencies may be insufficiently accountable to elected officials, and by extension, the public.[67] Litigation authority, as one indicia of independence, can thus be seen as a step in the wrong direction. In this view, the authority to conduct litigation without DOJ oversight presumptively decreases the accountability of the agency to the president and the public.

Critics of DOJ control respond that distancing agency decision-making from the President is the point, because Congress's aim in designing

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61. *See* Marshall J. Breger & Gary J. Edles, *Established by Practice: The Theory and Operation of Independent Federal Agencies*, 52 ADMIN. L. REV. 1111, 1206-09 (2000).

62. There is such wide variation in the characteristics of agencies that Datla and Revesz suggest a spectrum of independence upon which all agencies fall. Datla & Revesz, *supra* note 6; *see also* Jennifer L. Selin, *What Makes an Agency Independent?* (Ctr. for the Study of Democratic Institutions, Working Paper No. 08, 2013) (identifying "50 different structural features of 321 federal agencies").

63. *See* Humphrey's Executor v. United States, 295 U.S. 602 (1935) (upholding removal protections for FTC Commissioners).

64. *See* Lisa Schultz Bressman & Robert B. Thompson, *The Future of Agency Independence*, 63 VAND. L. REV. 599, 611 (2010).

65. *See* Geoffrey P. Miller, *Independent Agencies*, 1986 SUP. CT. REV. 41, 45 (arguing against presidential removal protections on constitutional grounds); Paul R. Verkuil, *The Purposes and Limits of Independent Agencies*, 1988 DUKE L.J. 257.

66. *See* Steven G. Calabresi & Saikrishna B. Prakash, *The President's Power to Execute the Laws*, 104 YALE L.J. 541 (1994); Breger & Edles, *supra* note 61, at 1206–09.

67. *See* Bressman, *supra* note 51, at 482 (discussing the relationship between accountability and agency independence). Proponents of agency independence may assert that Congress has merely replaced the short-term priorities of future presidential administrations with the long-term aims of the current legislature. Since both are elected officials, there is no accountability deficit. Skeptics may respond that the President can embody a coherent political ideology and oversee agencies with a decisiveness that Congress cannot as a matter of institutional capacity, making the presidency uniquely accountable to the public. *See* Kagan, *supra* note 54, at 2246.

independent agencies with litigation authority is to insulate them from external political pressure.[68] This may be considered especially appropriate for agencies like FDA, which rely heavily on scientific expertise.[69] Finally, they point out that all agencies, even independent ones, are led by Presidential appointees more likely sympathetic to the administration's views.[70]

B. Interagency Enforcement

Having now introduced the debate over litigation authority, I proceed in this section to situate DOJ control of agency litigation against the backdrop of two scholarly discussions: enforcement policy and interagency administration. I offer FDA-DOJ litigation as an example of interagency policymaking, where FDA enforcement policy results from a complex relationship between two agencies. This framing complicates dominant understandings of how regulators make enforcement decisions and offers a new model for how federal agencies can exist in more fluid, context-dependent states of bilateral cooperation and conflict.

A potent way DOJ can influence substantive agency programs is by gatekeeping an agency's ability to sue enforcement targets. Agencies engage in two general types of litigation: enforcement actions (the agency sues a private party) and defensive litigation (the agency itself is the defendant).[71] This Article focuses on the former, because it provides the clearest insight into how DOJ control of litigation shapes agency decision-making. FDA, for example, uses its discretion when deciding when to sue, shaping enforcement policy that aims to promote public health. DOJ, by controlling these decisions, cabins FDA's discretion. By contrast, defensive litigation is more case specific and irregular. It depends on when the FDA is sued, rather than the other way around. For this reason, the exact effect of DOJ control in defensive cases is harder to determine, and the consequences of litigation authority are harder to predict.

Federal agencies enjoy broad latitude from courts when deciding when to bring an enforcement action. Unlike other agency actions, such as rulemakings and adjudications, which are presumptively subject to judicial review under the APA, enforcement decisions are "committed to agency

68. Litigation authority is among the "set of tools [Congress] can use to make the agency more or less independent from the President." Datla & Revesz, *supra* note 6, at 773.

69. *See* Daniel Carpenter, *Strengthen and Stabilize the FDA*, 485 NATURE 169 (2012).

70. *See* Devins & Herz, *supra* note 4, at 576; Neal Devins & David E. Lewis, *Not-So Independent Agencies: Party Polarization and the Limits of Institutional Design*, 88 B.U. L. REV. 459, 468 (2008).

71. *See* JARED P. COLE, CONG. RSCH. SERV., R44699, AN INTRODUCTION TO JUDICIAL REVIEW OF FEDERAL AGENCY ACTION 10–12 (2016).

discretion" unless Congress provides otherwise.[72] Agencies do not have to provide public rationales for individual enforcement decisions.[73] Congress and the President have shown little interest in the day-to-day enforcement decisions of federal agencies when compared with other forms of agency action. Margaret Lemos describes congressional oversight of enforcement as "spotty [to] non-existent,"[74] while Kate Andrias describes presidential involvement in regulatory enforcement matters as "sporadic, crisis-driven, and opaque."[75]

Despite the lack of formal oversight, public enforcement is undeniably a form of agency policymaking.[76] Increasingly, scholars frame enforcement discretion "as systemic policymaking, rather than an accumulation of myriad inscrutable, individual judgments."[77] This move reflects the reality that the sum of many discrete enforcement decisions, executed with policy aims in mind, can carry the same power to shape private conduct as rules and adjudications.[78] Indeed, many of FDA's programs are "organized

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72. Heckler v. Chaney, 470 U.S. 821 (1985) (citing Administrative Procedure Act, 5 U.S.C. § 701(a)(2)) (holding FDA's refusal to take enforcement action is not subject to judicial review).

73. Margaret H. Lemos, *Democratic Enforcement? Accountability and Independence for the Litigation State*, 102 CORNELL L. REV. 929, 932 (2017).

74. *Id.* at 975.

75. Kate Andrias, *The President's Enforcement Power*, 88 N.Y.U. L. REV. 1031, 1035 (2013). The President's rare involvement in day-to-day agency enforcement policy reflects the view that "law enforcement policy should be driven by nonpolitical experts." *Id.* at 1050.

76. "Enforcement policy affects, for example, the amount of pollution that firms generate, the extent of compliance with the income tax code, and the incidence of theft, robbery, and other crimes." A. Mitchell Polinksy & Steven Shavell, *The Economic Theory of Public Enforcement of Law*, 38 J. ECON. LIT. 45, 45 (2000). A recent high-profile example of enforcement-discretion-as-policymaking is the Deferred Action for Childhood Arrivals (DACA) policy, in which the Obama Administration categorically offered forbearance of removal to undocumented immigrants brought to the U.S. as children. *See* Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 140 S. Ct. 1891, 1901 (2020); Benjamin Eidelson, *Reasoned Explanation and Political Accountability in the Roberts Court*, 130 YALE L.J. 1748, 1752–53 (2021) (arguing that the *Regents* Court sought to "ensure that the Trump Administration could not rescind DACA without paying the appropriate political price" for the agency's "policy choice"). The principle of agency enforcement discretion closely aligns with the judgment-laden notion of prosecutorial discretion—that prosecutors carry special obligations to "seek justice" and act in the public interest when deciding whom to charge and how to seek a penalty. *See* Bruce A. Green, *Must Government Lawyers "Seek Justice" in Civil Litigation?*, 9 WIDENER J. PUB. L. 235, 236 (2000); *see also* Freeport-McMoRan Oil & Gas Co. v. FERC, 962 F.2d 45 (D.C. Cir. 1992) (holding that agency counsel has special obligation to seek justice, and to refrain from unfair litigation).

77. ADAM B. COX & CRISTINA M. RODRÍGUEZ, THE PRESIDENT AND IMMIGRATION LAW 232 (2020); *see also id.* at 196 (describing "policymaking through enforcement" as a "thinly understood dimension of executive power"); David M. Uhlmann, *Prosecutorial Discretion and Environmental Crime*, 38 HARV. ENV'T L. REV. 159 (2014) (describing patterns in the investigation and prosecution of environmental crimes by EPA and DOJ); GREGORY A. HUBER, THE CRAFT OF BUREAUCRATIC NEUTRALITY: INTERESTS AND INFLUENCE IN GOVERNMENTAL REGULATION OF OCCUPATIONAL SAFETY 70–83 (2007) (describing the Occupational Safety and Health Administration's enforcement policy of "strategic neutrality").

78. *See* Lemos, *supra* note 73, at 946–49; Gillian E. Metzger, *The Constitutional Duty to Supervise*, 124 YALE L.J. 1836, 1840 (2015) ("Agencies not only adjudicate individual cases, take

explicitly around the systematic exercise of enforcement discretion."[79] A vast literature on public enforcement explores the strategies available to regulators exercising this discretion.[80] Different models prioritize compliance, deterrence, preventing agency capture, or promoting cooperation between regulator and industry.[81] Other scholars focus on the design of the enforcing agency itself as a way to improve enforcement policy through accountability mechanisms.[82]

Given the broad enforcement discretion enjoyed by federal agencies, disagreement inevitably results between the agencies that must coordinate enforcement. I have thus far referred to DOJ as the agency's "lawyer," perhaps implying that DOJ must generally defer to its "client" agency's preferences.[83] But the analogy is imperfect (albeit common), and points to unresolved questions about the nature of government representation.[84] DOJ indeed represents the agency. But the question "Who is the client?" is tricky for any government lawyer to answer.[85] There is no consensus; government lawyers might serve the "public interest," the President, the office of the Presidency, the federal government as a whole, or the agency that employs

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specific enforcement actions, or issue discrete rules. They do all these activities on a massive scale as part of a broader project of law implementation that requires coordination, investigation, and prioritization.").

79. Lewis A. Grossman, *Enforcement Discretion Under Attack: Implications for FDA*, 41 ADMIN. & REGUL. L. NEWS 24, 24 (2016).

80. *See, e.g.*, IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 4, 35 (1992) (arguing that "by working more creatively with the interplay between private and public regulation, government and citizens can design better policy solutions" and offering an "enforcement pyramid" of options ranging from persuasion to license revocation); Polinsky & Shavell, *supra* note 76; Neil Gunningham, *Compliance, Enforcement, and Regulatory Excellence* (Sch. Regul. & Glob. Governance, Research Paper No. 124, 2017); Neil Gunningham, *Enforcing Environmental Regulation*, 23 J. ENV'T L. 169 (2011); Robert A. Kagan, *Editor's Introduction: Understanding Regulatory Enforcement*, 11 L. & POL'Y 89, 92 (1989) (identifying two poles of public enforcement: one "conciliatory" model focused on compliance and cooperation, and another, harsher, "legalistic" model focused on deterrence and coercion).

81. *See* Jodi L. Short, *The Politics of Regulatory Enforcement and Compliance: Theorizing and Operationalizing Political Influences*, 15 REGUL. & GOVERNANCE 653, 655–59 (2021) (recounting the dominant economic and political theories of regulatory enforcement).

82. *See* Kent Barnett, *Towards Optimal Enforcement*, 72 VAND. L. REV. 127 (2019); Rachel E. Barkow, *Overseeing Agency Enforcement*, 84 GEO. WASH. L. REV. 1129 (2016) (offering strategies for redesigning and overseeing agency enforcement regimes to make them more accountable, especially in criminal cases).

83. *See* Griffin B. Bell, *The Attorney General: The Federal Government's Chief Lawyer and Chief Litigator, or One Among Many?* 46 FORDHAM L. REV. 1049, 1061 (1978) (presenting the expectation that DOJ lawyers "take care not to interfere with the policy prerogatives of our agency clients").

84. *See, e.g.*, Att'y Gen.'s Role as Chief Litigator for the U.S., 6 Op. O.L.C. 47, 47 (1982) (referring to the "other departments or agencies of the United States" as "'clients' in the particular litigation").

85. *See* Mark B. Stern & Alisa B. Klein, *The Government's Litigator: Taking Clients Seriously*, 52 ADMIN. L. REV. 1409, 1409–10 (2000).

them.[86] The uncertainty expands for lawyers who work at DOJ and represent outside agencies.[87] For example, suppose that DOJ and the agency it represents hold different views of what the "public interest" requires, or that the interests of the agency's "client" conflict with DOJ's "client." In such cases, DOJ has the option to defer to or overrule the agency's preference. The fact that DOJ has this authority creates fertile ground for policy disputes that further strain the lawyer-client analogy, and are discussed in the context of FDA-DOJ litigation in Part III.

Whether or not DOJ has "client" agencies is not mere semantics; the nature of that relationship may determine federal policy.[88] Work on "interagency administration" urges us to consider government policy as the product of relationships between agencies,[89] unlike the literature on public enforcement, which tends to consider regulators as singular agencies, administrations, or governments.[90] For example, Farber and O'Connell investigate adversarial relationships between agencies, creating a taxonomy of hierarchies.[91] In their brief discussion of the DOJ-agency relationship in litigation matters, they classify it as a "hard hierarchy" because DOJ

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86. *See* REPORT BY THE DISTRICT OF COLUMBIA BAR SPECIAL COMMITTEE ON GOVERNMENT LAWYERS AND THE MODEL RULES OF PROFESSIONAL CONDUCT, *reprinted in* WASH. LAW., Sept.–Oct. 1988, at 53, 55 (1988) (settling on an "employing agency as client" model); James R. Harvey III, *Loyalty in Government Litigation: Department of Justice Representation of Agency Clients*, 37 WM. & MARY L. REV. 1569, 1597–1612 (1996) (describing the public interest, agency, and executive model of representation and collecting sources in support of each); *see also Government Counsel and Their Obligations*, 121 HARV. L. REV. 1409, 1412–15 (2008).

87. *See* Harvey, *supra* note 86.

88. *See* Stern & Klein, *supra* note 85, at 1409 (noting that "the identity of the client matters a great deal" to DOJ lawyers, because "the client's wishes and interests in large part define the lawyer's objectives and litigation strategy").

89. *See* Jason Marisam, *Interagency Administration*, 45 ARIZ. ST. L.J. 183, 185–86 (defining interagency administration as "the emerging system of governance created by agencies' increasingly complex relationships with each other"); Todd S. Aagaard, *Regulatory Overlap, Overlapping Legal Fields, and Statutory Discontinuities*, 29 VA. ENV'T L.J. 237 (2011); Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201; Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181 (2011); Rachel E. Sachs, *Encouraging Interagency Collaboration: Learning from COVID-19*, 4 J.L. & INNOVATION 71 (2021); Catherine M. Sharkey, *Agency Coordination in Consumer Protection*, 2013 U. CHI. LEGAL F. 329 (2013); Freeman & Rossi, *supra* note 29; Jacobs, *supra* note 46.

90. Lisa Barkow, for example, considers the singular "agency" when discussing agency design and enforcement policy. Barkow, *supra* note 82, at 1130–34. *See also* Ashutosh Bhagwat, *Modes of Regulatory Enforcement and the Problem of Administrative Discretion*, 50 HASTINGS L.J. 1275, 1295 (considering "how an agency enforces its rules"); Barnett, *supra* note 82, at 134 (discussing "state regulators" and "federal regulators"); Gunningham, *Compliance*, *supra* note 80 (considering "the regulator"); Andrias, *supra* note 75, at 1031 (addressing "agency enforcement activity"); Kagan, *supra* note 80, at 92 (referring to "agencies" and "agency officials"); AYRES & BRAITHWAITE, *supra* note 80, at 8–12 (describing regulatory enforcement under the "Reagan administration" and "Thatcher government").

91. *See* Daniel A. Farber & Anne Joseph O'Connell, *Agencies as Adversaries*, 105 CALIF. L. REV. 1375 (2017).

exercises ultimate control over all litigation decisions.[92] Freeman and Rossi offer a similar typology of interagency coordination, including "interacting jurisdictional assignments," in which agencies with different missions must cooperate, and "delegations requiring concurrence," in which multiple agencies have veto power over the same action.[93] Applying the lens of interagency relationships to the enforcement context, Kate Andrias offers "interagency enforcement" as a framework to understand how agency enforcement efforts can complement one another (for example, multiple overlapping workplace safety regimes), or conflict with one another (for example, labor and immigration law).[94]

The relationship between DOJ and FDA does not fit within any of these existing categories, suggesting either that the relationship is relatively unique, or, more likely, that the categories may fail to capture certain nuances that inform the inter-operation of the administrative state. In practice, the FDA-DOJ dynamic appears context-dependent—sometimes deferential and sometimes contentious.[95] As a formal matter, Farber and O'Connell's hierarchical characterization of the agency-DOJ relationship in litigation sets aside that agency lawyers are not subordinates of DOJ lawyers.[96] It is fairer to say FDA is DOJ's "client" than its subordinate (keeping in mind the limits of the lawyer-client analogy). Their authority does not "overlap" (because FDA cannot pursue litigation without DOJ), nor do their missions truly conflict (because both agencies seek to enforce the FDCA).[97] Instead, both agencies bring different perspectives and priorities to bear on the same statute, which they must cooperate to enforce effectively.[98]

C. Agencies with Independent Litigation Authority

Congress occasionally deviates from the default of DOJ control of

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92. *Id.* at 1389–91 (defining "hard hierarchy" as one in which "one actor is formally subordinate to the other").

93. Freeman & Rossi, *supra* note 29, at 1148–49.

94. Andrias, *supra* note 75, at 1078–83. *See also* Joseph Daval, *The Problem with Public Charge*, 130 YALE L.J. 998, 1038–46 (2021) (describing the asymmetrical, zero-sum conflict between immigration agencies tasked with enforcing the public charge exclusion and the agencies tasked with providing public benefits to eligible beneficiaries).

95. *See infra* Part III.

96. FDA exists within the Department of Health and Human Services—not the DOJ. As such, FDA lawyers answer to the FDA Commissioner (under the Secretary of Health and Human Services), not the Attorney General. *FDA Overview Organization Chart*, U.S. FOOD & DRUG ADMIN. (Feb. 17, 2022) https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart [https://perma.cc/AR7L-LLEJ].

97. *See infra* Part II.

98. *See infra* Part III.

agency litigation, but it follows no clear pattern as to when or why.[99] Most agencies with litigation authority are considered "independent" agencies, although not all.[100] Congress has broad discretion to tailor agencies' enabling legislation; it could amend the FDCA to give FDA all, any, or none of the characteristics of independent agencies.[101] If it chose, it could single out litigation authority to grant or withhold. Furthermore, litigation authority itself is not a simple binary. Congress could give FDA authority to litigate all actions arising under the FDCA, only some, or none.

The Federal Trade Commission (FTC), for example, has been granted partial litigation authority.[102] Like FDA, FTC is a small, powerful agency with the authority to regulate large portions of the economy.[103] FTC's Office of General Counsel, like FDA's Office of Chief Counsel, has a litigation division.[104] But unlike FDA, FTC litigators represent the agency in court, rather than sitting "second-chair" at DOJ's discretion.[105] FTC attorneys themselves can bring injunctions and civil penalties under the Federal Trade Commission Act and antitrust statutes.[106]

But FTC is not completely untethered. It must refer all criminal matters to DOJ, and must give DOJ the first chance at pursuing civil penalty cases.[107] FTC officials argued in 2008 in favor of even greater authority,

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99. Herz & Devins, *supra* note 15, at 1347 ("search[ing] in vain for an organizing principle" for which agencies have litigation authority).

100. Datla & Revesz, *supra* note 6, at 799–801.

101. Datla & Revesz, *supra* note 6, at 773.

102. Trans-Alaska Oil Pipeline Authorization Act, Pub. L. No. 93-153, § 408, 87 Stat. 576, 591–92 (1973); Federal Trade Commission Improvement Act, Pub. L. No. 93-637, § 204, 88 Stat. 2183, 2199 (1975); *see* Neal Devins, *Unitariness and Independence: Solicitor General Control over Independent Agency Litigation*, 82 CALIF. L. REV. 255, 271 (1994).

103. *See* Alden F. Abbott, Gen. Couns., Fed. Trade Comm'n, Protecting Consumers and Competition at the New FTC, Remarks Before the Free State Foundation's Policy Seminar, 2–5 (June 28, 2018) [https://perma.cc/YA2E-BXQB].

104. *Office of the General Counsel*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc/bureaus-offices/office-general-counsel [https://perma.cc/7SQ7-QH78].

105. Abbott, *supra* note 103, at 3-4.

106. 15 U.S.C. § 56(a)–(c). Both FTC and DOJ wield authority to seek injunctions preventing mergers under federal antitrust law. *See* William E. Kovacic, *Downsizing Antitrust: Is It Time to End Dual Federal Enforcement?*, 41 ANTITRUST BULL. 505, 508–21 (1996). It is difficult to present a head-to-head comparison of DOJ and FTC performance in litigation, in part because the agencies pursue different enforcement strategies. BILL BAER ET AL., RESTORING COMPETITION IN THE UNITED STATES: A VISION FOR ANTITRUST ENFORCEMENT FOR THE NEXT ADMINISTRATION AND CONGRESS 26 (Nov. 2020) https://equitablegrowth.org/research-paper/restoring-competition-in-the-united-states/ [https://perma.cc /8D59-CWVF]; *see also* Malcolm B. Coate, *Merger Analysis in the Courts* 2 (Fed. Trade Comm'n, Working Paper No. 207, 1994) (finding that DOJ is "less likely to prevail on the merits than either the FTC or private plaintiffs") [https://perma.cc/RY67-7Z4N].

107. *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N apps. A & B (May 2021), https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority [https://perma.cc/2ES7-CS9T]; *Prepared Statement of the Federal Trade Commission Before the S. Comm. on Com., Sci., & Transp.*, 110th Cong. 9 (2008) [https://perma.cc/H2QQ-QBVK].

getting rid of DOJ's "first bite" option for civil penalties and allowing FTC to decide DOJ's role in *all* litigation matters.[108] They relied on the argument that the FTC lawyers, with the most subject-matter expertise and experience with the statute, should be in charge of deciding when to seek out DOJ's expertise.[109] They were unsuccessful.

Additional examples illustrate that litigation authority is not always, or even usually, all-or-nothing. The Environmental Protection Agency (EPA) too, for a time, retained the partial authority to bring certain enforcement actions by itself if DOJ declined.[110] As Herz and Devins describe, this arrangement gave the EPA "more leverage and greater autonomy than most executive agencies," because the EPA could "disagree with DOJ" openly, backed by the plausible threat of bringing the case itself if it chose.[111] The Federal Communications Commission (FCC) likewise has partial litigation authority.[112] Devins writes that "[p]olicy disputes between [FCC and DOJ] occur frequently," and the agencies sometimes openly disagree over enforcement priorities and statutory interpretation.[113] Other agencies, like the Federal Energy Regulatory Commission (FERC), have near-complete litigation authority.[114] I note here the general assumption of these scholars that the agencies will favor *more* enforcement, across the board, than DOJ.[115] As I discuss in Part III, this is not true for FDA with regard to certain types of cases. Part II continues by mapping the role of litigation in FDA enforcement.

II. FDA ENFORCEMENT VIA LITIGATION

FDA regulates over $2.7 trillion per year—about a fifth of U.S. consumer spending.[116] Over many products, such as new drugs, FDA has arguably the most formidable pre-market authority of any regulatory body

108. *Prepared Statement*, *supra* note 107, at 12-15.

109. *Id.*

110. Herz & Devins, *supra* note 15, at 1351.

111. Herz & Devins, *supra* note 15, at 1351.

112. Neal Devins, *Political Will and the Unitary Executive: What Makes an Independent Agency Independent?*, 15 CARDOZO L. REV. 273, 299 (1993).

113. *See id.* at 279.

114. I offer FERC's enabling legislation as a model for FDA litigation authority, *infra* text accompanying notes 282 286. FERC attorneys "may appear for, and represent the [FERC] in[] any civil action brought in connection with any function carried out by [FERC.]" 42 U.S.C. § 7171(i).

115. *See, e.g.*, Devins & Herz, *supra* note 17, at 210; Olson, *supra* note 3, at 74 ("[T]he agencies wish to concentrate power in the interest of their regulatory missions, while the Justice Department seeks to supervise and thus temper that power.").

116. *FDA at a Glance*, U.S. FOOD & DRUG ADMIN. OFF. OF THE COMM'R (Nov. 2021) https://www.fda.gov/media/154548/download [https://perma.cc/WL85-H9PD].

in the world.[117] This authority takes the form of a requirement that manufacturers prove to the FDA that their products have sufficient safety and efficacy before marketing.[118] The resulting regulatory regime aims to incentivize innovative products while promoting the public health.[119] To enforce this comprehensive scheme, FDA can conduct warrantless inspections, and revoke its approval of violative products, effectively removing them from the market.[120] All told, FDA wields astonishing power over the American economy.

Notwithstanding FDA's power, noncompliance is widespread in FDA-regulated industries. For example, drug companies regularly violate the FDCA by unlawfully promoting or distributing their products, concealing study findings, and maintaining substandard manufacturing practices.[121] These firms fold hefty fines into their operating costs, along with fines for violations of other federal laws, such as the False Claims Act and antitrust statutes.[122] The $40 billion per year dietary supplement industry is similarly rife with adulterated products that the FDA seemingly will not, or perhaps cannot, effectively regulate.[123]

FDA treats enforcement via litigation as a last resort. The agency prefers to first seek compliance by sending firms warning letters that threaten future enforcement action.[124] Many consider these letters tantamount to an

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117. *See* CARPENTER, *supra* note 11, at 10; *see also* Bhagwat, *supra* note 90, at 1277–79 (distinguishing "ex post" regulatory regimes, which address violations after they occur, from "ex ante" regulatory regimes, such as FDA market approval for drugs and medical devices, which require pre-approval to engage in certain activities).

118. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1756–57 (1996).

119. Wyeth v. Levine, 555 U.S. 555, 566–67 (2009) (describing the development of FDA's pre-market regulatory authority in response to public health threats).

120. Scott Bass & William McConagha, *FDA Enforcement Powers*, *in* FOOD AND DRUG LAW AND REGULATION 745–48 (3d ed. 2015).

121. *See* SAMMY ALMASHAT & SIDNEY WOLFE, PUB. CITIZEN, PHARMACEUTICAL INDUSTRY CRIMINAL AND CIVIL PENALTIES: AN UPDATE 44–50 (2012) [https://perma.cc/2VFQ-KTNT]. *See also* GRAHAM DUKES, JOHN BRAITHWAITE & J.P. MOLONEY , PHARMACEUTICALS, CORPORATE CRIME AND PUBLIC HEALTH 310 (2014) ("[T]here is a massive corporate crime problem here that causes more harm than all the crime problems currently dealt with by the police.").

122. *See* Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms?*, 70 FOOD & DRUG L.J. 435, 435–37 (2015).

123. Of 746 known adulterated supplements from 2007–2016, none resulted in mandatory recalls and only one led to a DOJ press release. *See* Jenna Tucker, Tessa Fischer, Laurence Upjohn, David Mazzera & Madhur Kumar, *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food and Drug Administration Warnings*, JAMA NETWORK OPEN (Oct. 12, 2018) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2706496 [https://perma.cc/EZG9-HPRF]; Pieter A. Cohen & Scott Bass, *Injecting Safety into Supplements—Modernizing the Dietary Supplement Law*, 381 NEW ENG. J. MED. 2387, 2388 (2019).

124. For example, in 2017, FDA sent 15,318 warning letters and pursued 12 injunctions and 3 seizures. *FDA Enforcement Statistics Summary Fiscal Year 2017*, U.S. FOOD & DRUG ADMIN. (Jan. 17, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compli

enforcement action.[125] True enforcement action by initiating litigation is rare in comparison, and is generally reserved for serious situations, such as an immediate public danger,[126] or when the firm is a repeat offender.[127]

A. The 1972 Bill to Grant FDA Litigation Authority

While FDA has always depended on DOJ for representation in litigation, Congress has considered granting FDA litigation authority. Historically, FDA has never had a perfectly smooth relationship with DOJ, as evidenced by archived oral history interviews with former FDA attorneys. One former Chief Counsel stated "I remember being very frustrated as Chief Counsels generally have been by the unwillingness of Assistant U.S. Attorneys to bring our cases."[128] Another described how FDA "didn't have very much luck" convincing DOJ to help it regulate misleading advertising in the 1960s.[129] Arthur Levine, Deputy Chief Counsel for Litigation from 1970–1991, described "frequent negotiations" between FDA and DOJ over enforcement referrals.[130] "Nothing was taken at face value" when DOJ reviewed FDA cases.[131]

The bill Congress considered in 1972 would have granted FDA independent litigation authority. It was part of a broader effort to reform FDA, including making the FDA Commissioner an "Administrator," appointed to five-year terms.[132] The bill authorized the new Administrator, "[u]pon the failure of [DOJ] within a reasonable time" to file requested

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ance-actions-and-activities/enforcement-activity [https://perma.cc/Q8DC-AKUZ].

125. O'Leary, *supra* note 30, at 155–56.

126. Heckler v. Chaney, 470 U.S. 821, 824–25 (1985) (quoting the statement of the FDA Commissioner that "[g]enerally, enforcement proceedings . . . are initiated only when there is a serious danger to the public health or a blatant scheme to defraud").

127. Telephone Interview with Participant 3, DOJ (Apr. 27, 2021); Telephone Interview with Participant 5, DOJ (Mar. 31, 2021); Telephone Interview with Participant 17, FDA (Apr. 15, 2021); Telephone Interview with Participant 19, FDA (Apr. 21, 2021). Study participants are referred to by randomly assigned number and former agency affiliation.

128. Oral History Interview by Catherine Copp with Nancy Buc, Chief Couns., Food & Drug Admin. Off. of Gen. Couns., in White Oak, Md., at 138 (Aug. 12, 2015) [https://perma.cc/29Z6-H4R9].

129. Oral History Interview by Robert G. Porter & Fred L. Lofsvold with Ronald T. Ottes, Dir., Food & Drug Admin. Off. of Reg'l Operations, in Rockville, Md., at 96 (May 16, 1986) [https://perma.cc/9BV6-QX9A].

130. Oral History Interview by Catherine Copp with Arthur N. Levine, Deputy Chief Couns. for Litig., Food & Drug Admin. Office of Chief Couns., in White Oak, Md., at 96 (Dec. 6, 2016) [https://perma.cc/Y4S3-S33A].

131. *Id.* at 94.

132. *Hearing Before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce: H.R. 15315, A Bill to Strengthen the Food and Drug Administration, and for Other Purposes*, 92d Cong. (1972) (testimony of Peter Barton Hutt, FDA General Counsel). The bill would have replaced the FDA Commissioner with an administrator appointed for five-year terms, granted rulemaking authority, and granted the authority to issue subpoenas. *Id.* at 2–5.

litigation, to "take such action through his own legal representative, and . . . direct the course of all litigation involving the [FDA]."[133] Speaking in favor of this arrangement in hearing testimony, FDA General Counsel Peter Hutt pointed to a 30–35% rate at which DOJ would decline criminal cases—cases FDA presumptively would have brought but for DOJ control of its docket.[134]

Strikingly, the bill would have granted FDA *criminal prosecution* authority.[135] This would have been a radical departure from the status quo, since without exception, DOJ controls all federal criminal litigation as the nation's source of federal prosecutorial authority.[136] The bill also invited workability problems with its overbroad language. It is unclear whether FDA or DOJ would have had the final word in disagreements over matters of litigation strategy (appeals, brief-writing, conducting oral argument). Would FDA have been bound by DOJ's decisions, or would DOJ have been obligated to take literally "any action at the Administrator's request" to enforce the FDCA?[137] The complexity of the enforcement process described in Section II.C underscores the need for clear delegations of authority.

B. Prohibited Acts and Remedies Under the FDCA

The FDCA grants FDA extremely broad enforcement authority to prevent the adulteration and misbranding of consumer products.[138] The Act prohibits the interstate manufacture, sale, or purchase of adulterated or misbranded products, as well as the sale of certain products, such as drugs, that lack FDA approval.[139] It backs up these prohibitions with civil and criminal liability, which often overlap.[140] Any person who violates a long list of prohibited acts is subject to fines and imprisonment.[141] Remarkably, this is true regardless of what they knew or intended, because the Supreme

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133. *Id.* at 7–8.

134. *See id.* at 40.

135. *Id.* at 7–8 (providing "[u]pon the failure of the Attorney General [to] prosecute . . . the Administrator may take such action").

136. Devins & Herz, *supra* note 4, at 561.

137. *Hearing*, *supra* note 132, at 8.

138. *See* Bass & McConagha *supra* note 120, at 742; KATHRYN B. ARMSTRONG & JENNIFER A. STAMAN, CONG. RSCH. SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 7 (2018) [https://perma.cc/UM8E-SH7S]; John R. Fleder, *Who Decides Your Fate in FDA Enforcement Matters?*, FOOD & DRUG L. INST. UPDATE MAG. 38 (May/June 2007) [https://perma.cc/WXV8-RRMD].

139. 21 U.S.C. § 331.

140. Nancy W. Mathewson, *Prohibited Acts and Enforcement Tools*, 65 FOOD & DRUG L.J. 545, 552–54 (2010) (offering a concise overview of acts prohibited by the FDCA, penalties, and legal actions available to FDA).

141. 21 U.S.C. § 333.

Court has found that the FDCA imposes strict criminal liability under the "Responsible Corporate Officer," or *Park*, doctrine.[142]

Most FDCA enforcement litigation responds to violations in two categories: quality and safety, and promotional activities. To ensure product quality, FDA sets standards for manufacturers called Good Manufacturing Practices (GMPs).[143] A drug made by a company violating GMPs is, by law, "adulterated."[144] Two civil remedies, seizures and injunctions, grant FDA the power to control products and the conduct of corporations through court orders. Via seizure, FDA can seek to hold, fix, or destroy goods that are adulterated or misbranded.[145] Via injunction, FDA can seek to "restrain" an individual or corporation from violating the FDCA.[146] Products that threaten health and safety can thus quickly be addressed, although the power of these tools is blunted somewhat by DOJ, which can delay or refuse to file the actions.[147]

Off-label promotion of drugs, and related violations, comprises the other major category. When a drug manufacturer actively promotes a drug for an unapproved use, FDA considers the drug "misbranded."[148] While doctors may lawfully prescribe approved drugs for unapproved indications, manufacturers' promotion of drugs for off-label uses is presumptively unlawful and presents significant public health concerns.[149] Prosecutions of manufacturers for unlawful promotion are often joined to violations of the False Claims Act (FCA), under the theory that the defendant has committed fraud against the federal government by promoting non-FDA-approved uses of drugs paid for by Medicare and other public payors.[150] Under the FCA's *qui tam* provisions, private whistleblowers may sue other private parties,

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142. *See* United States v. Park, 421 U.S. 658 (1975); United States v. Dotterweich, 320 U.S. 277 (1943); O'Leary, *supra* note 30, at 141–44 (recounting the doctrine's development).

143. *See* Merrill, *supra* note 118, at 1786–87.

144. *See* Merrill, *supra* note 118, at 1786–87.

145. 21 U.S.C. § 334.

146. 21 U.S.C. § 332.

147. *See infra* Section III.A.

148. *See* Aaron S. Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225, 227 (2011). The future of off-label prosecutions is uncertain. *See* United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012) (holding that prohibiting truthful off-label promotion violates the First Amendment).

149. *See* Regulations Regarding "Intended Uses," 86 Fed. Reg. 41,383, 41,391 (Aug. 2, 2021) (to be codified at 21 C.F.R. pts. 201, 801) ("The categorical exclusion of all truthful speech from regulatory review would undermine FDA's ability to promote and protect the public health through premarket review of medical products . . . ."); Jerry Avorn, Ameet Sarpatwari & Aaron S. Kesselheim, *Forbidden and Permitted Statements About Medications — Loosening the Rules*, 373 NEW ENG. J. MED. 967 (2015).

150. *See* Aaron S. Kesselheim et al., *False Claims Act Prosecution Did Not Deter Off-Label Drug Use in the Case of Neurontin*, 30 HEALTH AFFS. 2318, 2318–19 (2011).

alleging fraud on behalf of the government, for a portion of the recovery.[151] The results of this enforcement regime are headline-grabbing settlements with DOJ, regularly reaching hundreds of millions of dollars.[152] Off-label drug promotion cases have dominated FDA's enforcement docket in the past few decades, making up the biggest source of FCA recoveries by DOJ.[153]

Tracking FDA enforcement policy proves challenging. As former FDA General Counsel Peter Barton Hutt writes, "[t]he raw enforcement data easily show that formal court enforcement actions have decreased. But that does not translate to a reduction in total FDA enforcement or in industry compliance."[154] For example, from 2013 to 2020, DOJ filed between five and fifteen FDCA injunctions per year.[155] A year with fewer cases might indicate either high rates of compliance or lax enforcement policy. Likewise, more cases might indicate either low rates of compliance or aggressive enforcement policy. In other instances, enforcement policy appears driven by external factors such as legal developments, rather than agency policy. For example, DOJ actions against manufacturers for off-label promotion dropped after the Second Circuit case *Caronia* in 2012 found that truthful off-label promotion was protected speech under the First Amendment.[156]

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151. *See* Aaron S. Kesselheim, David M. Studdert & Michelle M. Mello, *Whistle-Blowers' Experiences in Fraud Litigation Against Pharmaceutical Companies*, 362 NEW ENGL. J. MED. 1832, 1832 (2010); David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 NW. U. L. REV. 1689, 1707 (2013).

152. Press Release, U.S. Dep't of Just., Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 ("$2.6 billion relates to matters that involved the health care industry, including drug and medical device manufacturers . . . .") [https://perma.cc/R7NM-6Q9U].

153. *See* ALMASHAT & WOLFE, *supra* note 121, at 13; *Pharma Biggest Source of DOJ False Claims Act Recoveries*, PHARMA LETTER (Jan. 15, 2021), https://www.thepharmaletter.com/article/pharma-biggest-source-of-doj-false-claims-act-recoveries [https://perma.cc/L6YF-F5QL].

154. Peter Barton Hutt, *Historical Themes and Developments at FDA Over the Past Fifty Years*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 17, 24 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015) (citation omitted).

155. Beth Weinman, Josh Oyster & Jessica Bond, *Deconstructing the Consent Decree: A Primer and Recent Trends for FDCA Injunctions*, FOOD & DRUG L. INST. UPDATE MAG. (Winter 2020), https://www.fdli.org/2020/11/deconstructing-the-consent-decree-a-primer-and-recent-trends-for-fdca-injunctions/#_edn3 [https://perma.cc/JL5F-P95L].

156. Sheng Liu, Michelle M. Mello & Aaron S. Kesselheim, *Prospects for Enforcing Prohibitions on Off-Label Drug Promotion after* United States v. Caronia*: An Analysis of Litigated Cases*, 46 J. HEALTH POL., POL'Y & L. 487, 490–91 (2021). *See* United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012).

C. FDA's Enforcement Process Through Litigation

FDA enforcement actions follow a complex web of referrals before landing in court.[157] When FDA seeks to pursue an enforcement action through DOJ, it has two options.[158] It can reach out to the Consumer Protection Branch (CPB) at DOJ headquarters in Washington D.C., which oversees all FDA litigation. Or, it can call the U.S. Attorney's Office (USAO) in the district where the alleged violation occurred.[159] If the case is referred to a USAO, the USAO must "notify and consult" with CPB upon opening any investigation.[160] This requirement is often flouted, as discussed in Section III.A.

The FDA's Office of Chief Counsel (OCC) is divided into two legal functions: counsel and litigation.[161] OCC counselors consult with FDA officials on substantive policy.[162] Litigators, by contrast, support the agency's litigation efforts, in coordination with DOJ.[163] "Litigator" is somewhat misleading, because FDA litigators do not technically have the authority to litigate. Instead, they work with the other parts of FDA to prepare enforcement referrals for DOJ, and support DOJ in litigating the FDA's position.[164] Like DOJ, FDA has a central office supported by a body of field agents spread across the country. An FDA field office may refer a matter to FDA headquarters before it goes to CPB, but it also may refer a case directly to the local USAO.[165]

In a typical enforcement referral, an FDA inspector discovers a violation and reports it to the relevant center, which forwards it to FDA OCC.[166] OCC then prepares the case for review by DOJ. After review, discussion, and

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157. *See generally* Fleder, *supra* note 2, (describing these formal pathways).

158. *The FDCA Case Referral Process*, U.S. DEP'T OF JUST. CONSUMER PROT. BRANCH (Nov. 17, 2021), https://www.justice.gov/civil/consumer-protection-branch-29 [https://perma.cc/X42M-F5VE].

159. *Id.*

160. U.S. Dep't of Just., Just. Manual § 4-8.200 (2020), https://www.justice.gov/jm/jm-4-8000-consumer-protection [https://perma.cc/BFB8-F84L].

161. *Office of the Chief Counsel*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2019), https://www.fda.gov/about-fda/office-commissioner/office-chief-counsel [https://perma.cc/XS4W-7D9X].

162. *Id.*

163. *Id.*

164. U.S. Food & Drug Admin., Regul. Procs. Manual § 6-2-9(D) (2020) ("OCC will participate in concurrent review and provide legal review, prepare pleadings and other legal documents, and provide legal assistance necessary for presentation of the action, including direct assistance to [CPB] and/or the [USAO] and the compliance staff.").

165. *See* KATHRYN B. ARMSTRONG & JENNIFER STAMAN, CONG. RSCH. SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 4-5 (2018).

166. *See* John R. Fleder, *Administrative Inspections by the Food and Drug Administration: The Role of the Department of Justice*, 44 FOOD, DRUG, COSM. L.J. 297, 301 (1989).

acceptance by DOJ, a DOJ attorney files a complaint and the litigation commences. The one enforcement action that FDA has the authority to levy without relying on DOJ, at least initially, is a civil monetary penalty.[167] However, FDA ultimately requires DOJ representation if the target challenges the penalty or refuses to pay. In such cases, an administrative hearing commences, followed by an appeal to the Department of Health and Human Service's Departmental Appeals Board, which can then be challenged in federal court.[168]

By law, the FDA Commissioner is "responsible for executing" the FDCA.[169] Thus, in theory, all FDCA civil enforcement actions originate within FDA, while criminal cases can arise in either DOJ or FDA. DOJ has the authority to bring criminal prosecutions without any particular agency as its "client."[170] However, FDA is often involved in criminal investigations and prosecutions. Agents at FDA's dedicated law enforcement office, the Office of Criminal Investigations (OCI), work closely with DOJ to develop cases into prosecutions.[171] The decision of a USAO to bring the prosecution depends less on taking or declining a one-time referral, and more on a back-and-forth in which the OCI agent, sometimes with OCC's support, seeks to persuade the USAO to expend its limited resources on a particular case.[172]

While the procedural contours of this enforcement regime are relatively clear, the published literature is silent on how DOJ control of litigation affects implementation of the FDCA, and how the agencies' policy priorities shape enforcement decisions. The following Part addresses these questions with qualitative analysis of firsthand accounts from former agency lawyers.

III. STUDY DESIGN AND FINDINGS

With so much uncertainty in the literature about how the FDA-DOJ relationship affects FDA enforcement policy, I developed a semi-structured interview study of twenty former government attorneys.[173] My interview

167. 21 C.F.R. § 17.1–17.54 (2018).

168. 21 C.F.R. § 17.47 (2018).

169. 21 U.S.C. § 393(d)(2).

170. 28 U.S.C. § 547; U.S. Dep't of Just., Just. Manual § 9-2.001 (2020).

171. KATHRYN B. ARMSTRONG & JENNIFER A. STAMAN, CONG. RSCH. SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 17–18 (2018) [https://perma.cc/UM8E-SH7S]. For more on the Office of Criminal Investigations, see *About OCI*, U.S. FOOD & DRUG ADMIN. (Mar. 12, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/about-oci#OCIagents [https://perma.cc/V9SW-R92R].

172. Telephone Interview with Participant 11, FDA (May 4, 2021); Telephone Interview with Participant 16, FDA (Apr. 14, 2021).

173. My goal was to include former government attorneys who were employed by DOJ or FDA

guide[174] aimed to uncover a) how often DOJ declines FDA enforcement referrals and under what circumstances, b) how the priorities of the agency decisionmakers affect FDA enforcement policy, c) how enforcement might change if FDA were granted litigation authority, and d) the mechanics of FDA enforcement referrals, as well as e) the participants' views on the question of independent litigation authority for the FDA, which I take up in Part IV.

Ten participants were former litigators at FDA's Office of Chief Counsel. The other ten were former lawyers at the Department of Justice who had substantial firsthand experience with litigation arising under the FDCA, including four at USAOs and six at CPB or one of its predecessor offices.[175] One participant was a former litigator at both FDA and DOJ.[176] Because the relationship between DOJ and FDA is a professionally sensitive topic, I offered anonymity and non-recording to promote candor, which all participants accepted.[177] Some participants declined to be quoted even anonymously. Participants agreed to be identified only by their former agency affiliation (FDA or DOJ).[178]

I used qualitative content analysis to arrange participant responses into themes, using a mixed approach of deductive and inductive data analysis.[179]

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and had substantial experience with FDCA litigation. I identified forty-three potential participants from the literature, web searches, and referral from early interviewees and reached out to them via a single email. Twenty consented to participate, one declined, and twenty-two did not respond (participation rate: forty-seven percent). I conducted a total of twenty-two hours and twenty-four minutes of phone interviews, with an average interview time of one hour and seven minutes.

174. *See* Qualitative Interview Guide, Appendix A.

175. Though my results may not be generalizable to all former lawyers involved in FDCA litigation, sequential interviewing is a widely used qualitative research technique that can be used to draw logical inferences. *See generally* Mario Luis Small, *'How Many Cases Do I Need?' On Science and the Logic of Case Selection in Field-Based Research*, 10 ETHNOGRAPHY 5 (2009). For example, most participants who were former DOJ lawyers spoke against FDA litigation authority, while most former FDA lawyers spoke in favor of it. I conclude, therefore, that pervasive (though not necessarily exclusive) sentiment exists for greater FDA litigation authority among former FDA lawyers, and against it among former DOJ lawyers.

176. This participant agreed to this wording of their affiliations.

177. For another anonymized interview study in legal scholarship, see Jonathan S. Gould, *Law Within Congress*, 129 YALE L.J. 1946, 1955 n.23 (2020) ("Interviewees were granted anonymity to promote candor. Citations refer to institutional affiliation only, defined loosely to prevent identification given the small number of people who have held the relevant positions.").

178. Participants emphasized that the professional world of FDA litigation is small and sometimes contentious. Confidentiality therefore extended, per their requests, to any nonessential identifying features, including their current employment status (private practice, retired, etc.), areas of practice, position at the agency, and years of government employment.

179. Qualitative content analysis is "a set of techniques for the systematic analysis of texts of many kinds addressing not only manifest content but also the themes and core ideas found in texts as primary content." JAMES W. DRISKO & TINA MASCHI, *Qualitative Content Analysis*, *in* CONTENT ANALYSIS 81, 85 (2015). Qualitative content analysis declines to use statistical assertions, aiming instead to "descri[be] patterns or regularities" in the data. *Id.* at 86. This makes it an "ideal approach" for the

After the completion of all interviews, interview notes were reviewed to derive coding categories using frequently mentioned themes.[180] Some themes were predetermined by the interview guide (e.g., effects of DOJ control on FDA enforcement), while others emerged from the interviews themselves (e.g., times when DOJ favors more enforcement than FDA).[181] Participants' responses were coded, and representative statements were selected. Each participant then reviewed, edited, and confirmed the representative quotes and assertions as they appear here.

Themes were grouped into three general descriptive findings (Sections III.A–C), responding to three questions: A) Does DOJ control or limit FDA's policy preferences, and if so how?; B) Do the agencies' enforcement priorities differ, and in what ways?; C) How do those priorities affect enforcement policy, beyond limiting FDA's preferences?

A. DOJ Control of Litigation Impedes FDA's Preferred Implementation of the FDCA

One primary theme among the responses was that DOJ makes use of its authority to shape FDA enforcement and direct key decision-making in litigation, limiting FDA's preferred implementation of the FDCA. DOJ sometimes uses its gatekeeping authority to decline and delay filing cases FDA seeks to bring, and to make strategic decisions in court over the disagreement of FDA. While participants described mutual respect, cooperation, and compromise, they also described significant tension between the agencies over enforcement decisions.

The character of the working relationship between FDA and DOJ shifted depending on who told it. FDA lawyers described "tons of dysfunction" and "lots of frustration" between the offices,[182] including heated discussions about what ought to be the role of FDA in litigation.[183] One stated that "the

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descriptive qualitative research undertaken here, given the complexity of the research questions and the scarcity of empirical work in this area. *Id.* at 87. *See also* Dennis G. Willms et al., *A Systematic Approach for Using Qualitative Methods in Primary Prevention Research*, 4 MED. ANTHROPOLOGY Q. 391 (1990).

180. *See* Frequency of Participant Responses Coded by Theme, Appendix B. For an example of a semi-structured phone interview study using qualitative content analysis to generate themes, present findings, and offer policy recommendations, see Ameet Sarpatwari et al., *Patient and Caregiver Experiences with and Perceptions of Risk Evaluation and Mitigation Strategy Programs with Elements to Assure Safe Use*, JAMA NETWORK OPEN (Jan. 2022).

181. *See generally* Ji Young Cho & Eun-Hee Lee, *Reducing Confusion About Grounded Theory and Qualitative Content Analysis: Similarities and Differences*, 19 QUALITATIVE REP., no. 32, Aug. 11, 2014, at 1 (describing a mixed approach of deductive and inductive data analysis in qualitative content analysis).

182. Telephone Interview with Participant 15, FDA (Apr. 6, 2021).

183. Participant 16, *supra* note 172.

FDA view was resentment: Why do I need you?"[184] DOJ denials "rubbed FDA wrong, [because] they thought they should make the decision."[185]

DOJ lawyers, meanwhile, emphasized the "culture of deference" and "close relationship" with FDA.[186] One said that the agencies "aim to reach agreement. DOJ wants to get FDA's blessing," adding that "[d]efensive litigation tends to be very collaborative, although occasionally contentious."[187] Another DOJ lawyer conceded: "The arrangement was not smooth. There were plenty of battles about who would argue a case, who would write the brief, who had the final say in what the brief would say, what arguments would be made."[188]

Participants confirmed that DOJ in fact declines enforcement referrals, albeit rarely.[189] One former FDA attorney estimated that DOJ declined cases 30% of the time, and outright refused to consider them fewer than 10% of the time.[190] Another noted that the rate of DOJ declining cases varied over time, and often depended on politics.[191]

But while DOJ formally declined few FDA referrals, the expectation of DOJ review appeared to shape the cases FDA referred in the first place. Participants described a system in which FDA does not "waste time on cases that were not likely to be brought, and [DOJ] could focus on cases that are high priority."[192] Because FDA lawyers know that any enforcement action FDA seeks to bring will require DOJ sign-off, they are unlikely to pursue cases they think DOJ will not bring.[193] This follows from the referral process, which is usually a collaborative back-and-forth between the agencies, rather than a single referral from FDA that DOJ either declines or accepts without further discussion.[194]

More often than declining cases, FDA lawyers described how DOJ delayed filing them.[195] One stated:

"One point of contention between FDA and DOJ is how long to wait

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184. Participant 17, *supra* note 127.

185. Telephone Interview with Participant 6, DOJ (Apr. 1, 2021).

186. Participant 5, *supra* note 127.

187. *Id.*

188. Telephone Interview with Participant 7, DOJ (Apr. 5, 2021).

189. Participant 6, *supra* note 185.

190. Participant 15, *supra* note 182.

191. Participant 19, *supra* note 127.

192. Participant 7, *supra* note 188.

193. One described it as "collaborative, with the recognition of both DOJ and FDA that if there's a debate [the] DOJ attorney makes the final decision." Participant 6, *supra* note 185.

194. The referral process is an "iterative back and forth, where FDA is checking in with DOJ," rather than a "simple referral where you work up the entire file and DOJ rejects it." Participant 17, *supra* note 127; Participant 5, *supra* note 127.

195. Telephone Interview with Participant 12, FDA (May 12, 2021).

before filing a lawsuit. We told the firm they had X days, but on X day the FDA lawyer had no power to file the case. [This] could last from days to months without filing the case."[196]

While some delay is inevitable when two offices must coordinate, DOJ's delays appeared to some FDA lawyers to be strategic decisions to prevent the filing of cases DOJ thought unmeritorious.[197] FDA lawyers also expressed frustration at DOJ's reluctance to pursue other judicial action—in particular, contempt actions (to punish failure to comply with a court order) and applications for search warrants (for inspections of facilities).[198]

After a case has been filed, DOJ maintains ultimate control over all aspects of litigation.[199] This includes strategic decisions about what arguments to make and when to appeal. As one participant said: "While FDA has input, and often sit at counsel table, DOJ controls the pen, controls the lectern, decides what happens in the briefs and what arguments are made at court. FDA gets input, but DOJ has plenary authority."[200] FDA at times disagrees with DOJ's decisions. An FDA attorney noted that DOJ sometimes makes decisions against FDA's express recommendation, describing "regular disagreement about how to present things, [and] how to respond," adding, "appeals is a particularly sensitive area."[201]

This control often took the form of deciding what arguments the agency should make on appeal. One DOJ lawyer stated: "There were arguments that we forced FDA to make that they didn't want to make."[202] Participants discussed how FDA and DOJ preferred different kinds of arguments. While FDA may have preferred to rely on its interpretation of the statute or the Constitution, DOJ would have had FDA make procedural arguments instead (standing, ripeness, exhaustion of administrative remedies).[203] For example, one participant described a case in which FDA wanted to argue a First Amendment claim on the merits, while DOJ wanted to argue that the First Amendment did not apply.[204]

As many DOJ lawyers pointed out, DOJ control of these decisions may

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196. Participant 19, *supra* note 127. Another echoed the point: "You more often see delay, or stalling, than decline. A formal declination is rare. Instead, dragging feet, to the point where it's almost impossible to bring it, is more common." Telephone Interview with Participant 14, FDA (June 1, 2021).

197. "[There were] definitely times FDA wanted to file and DOJ was holding out." Participant 19, *supra* note 127.

198. *Id.* Warrants, in particular, were described as "incredibly hard" to get through DOJ and into court. *Id.*

199. *See generally* Devins & Herz, *supra* note 4.

200. Telephone Interview with Participant 10, DOJ/FDA (Mar. 24, 2021).

201. Participant 14, *supra* note 196.

202. Participant 7, *supra* note 188.

203. *Id.*

204. Participant 17, *supra* note 127.

be a good thing. In their view, DOJ's reliance on procedural arguments delivered FDA some big wins. According to a former DOJ attorney, it was DOJ that forced FDA to rely on prosecutorial discretion—the dispositive argument—in *Heckler v. Chaney*.[205] Participants emphasized DOJ's mission is to look out for the interests of the federal government as a whole: "DOJ is interested in the development of the law, [and] worried that bad precedent would affect them in other areas."[206] Like declining potentially weak cases, DOJ may have been better equipped to recognize a losing argument.

B. FDA's Priority Is Public Health; DOJ's Is Preventing Fraud

Another frequently discussed theme was that the agencies have different enforcement priorities.[207] FDA's overriding aim is protecting public health by enforcing safety, quality, and labeling requirements.[208] DOJ, on the other hand, is concerned with fraud—enforcing the FDCA to prevent economic injury, discourage false advertising, and recover unlawfully obtained money.[209] Participants characterized DOJ attorneys' preference as seeking big settlements against large firms for promotional offenses. Most notably, this includes FCA cases for off-label promotion.[210]

Many participants brought up that DOJ is incentivized by publicity and financial recoveries, an observation supported by other empirical research.[211] One FDA lawyer lamented that in the past ten to fifteen years, FDCA enforcement has been overly focused on revenue generation from promotional activities—because regulators can seek huge settlements—rather than safety and quality.[212] Another FDA lawyer said that when considering which cases will yield settlements, "[DOJ] is looking for big

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205. Participant 7, *supra* note 188; Heckler v. Chaney, 470 U.S. 821 (1985) (establishing the presumptive unreviewability of agency enforcement decisions).

206. Telephone Interview with Participant 20, FDA (Mar. 31, 2021).

207. One participant described DOJ's interest in recovering "large financial awards, restoring money to the public fisc. FDA is less focused on money, more focused on the public health impact. FDA is more focused on its public health mission, DOJ more focused on law enforcement mission." Participant 10, *supra* note 200. Another participant noted that "FDA's principal concerns are public health, harm to consumers and patients, harmful classes of products, and evidence of harm," whereas "DOJ thinks hard about likelihood of success, [and] financial significance for industry." Participant 15, *supra* note 182.

208. Telephone Interview with Participant 1, DOJ (Apr. 21, 2021).

209. Telephone Interview with Participant 13, FDA (May 14, 2021).

210. Participant 16, *supra* note 172.

211. Jonas Heese, Ranjani Krishnan & Hari Ramasubramanian, *The Department of Justice as a Gatekeeper in Whistleblower-Initiated Corporate Fraud Enforcement: Drivers and Consequences*, 71 J. ACCT. & ECON., Feb. 2021, at 2 (finding that DOJ enforcement decisions are driven by monetary recoveries and likelihood of success).

212. Participant 16, *supra* note 172.

dollar signs to justify their budget."[213] Another noted how Assistant U.S. Attorneys "love to have a big case that makes a big splash, they like a big press release, and that's part of the incentive," while "FDA's thinking about how these enforcement actions are going to affect public health."[214] Similarly, others described DOJ preference for felony prosecutions, rather than the misdemeanors that the FDCA authorizes.[215]

A common point was that "FDA would," in fact, "make different decisions if it could."[216] Some respondents predicted that, if FDA were granted litigation authority, its enforcement policy would become more aggressive in some (perhaps most) areas, but less aggressive in others.[217] One stated that FDA "would want to bring more things generally, but on some things, like off-label, it might be less aggressive,"[218] while others said that, in most cases, FDA would be far more aggressive, and bring far more total cases, than DOJ.[219] One FDA lawyer said that "at least double the enforcement cases" the FDA brings in a year "would be brought and resolved," largely due to the time saved by cutting out DOJ.[220] Another echoed this point, predicting more cases across the board due to cases being faster to file and litigate without the added layer of DOJ review.[221]

Most participants' predictions about *how* FDA enforcement policy would change followed the agency priorities described above. Without DOJ's focus on promotional cases, FDA would pivot toward quality and safety. Participants thought that "smaller cases" like seizures and injunctions would increase,[222] that FDA would prioritize the "quality of supply chains, manufacturing issues, [and] product safety, rather than revenue generation,"[223] and that FDA might be more aggressive in regulating dietary supplements.[224] "FDA would push maybe 20%" of the off-label and False Claims Act cases it brings now, "without DOJ," said one.[225]

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213. Participant 15, *supra* note 182.
214. Participant 20, *supra* note 206.
215. Participant 7, *supra* note 188.
216. Participant 16, *supra* note 172.
217. Participant 1, *supra* note 208; Telephone Interview with Participant 4, DOJ (Apr. 29, 2021); Participant 15, *supra* note 182.
218. Participant 19, *supra* note 127. Similarly, "[t]he types of cases brought would be different; in some areas more aggressive than DOJ, in others less aggressive." Participant 20, *supra* note 206.
219. Participant 1, *supra* note 208; Participant 4, *supra* note 217; Participant 15, *supra* note 182.
220. Participant 14, *supra* note 196.
221. Participant 12, *supra* note 195.
222. Participant 4, *supra* note 217.
223. Participant 16, *supra* note 172.
224. Participant 20, *supra* note 206.
225. Participant 15, *supra* note 182.

C. DOJ Can Be More Aggressive than FDA

Finally, participants described how, due to their differing priorities, DOJ has sometimes been *more* willing than FDA to enforce certain types of cases. One FDA lawyer stated that when it came to bringing cases, "FDA is often the bottleneck, not DOJ."[226] This sometimes takes the form of DOJ encouraging FDA to pursue an action that it otherwise would not undertake. Another FDA lawyer explained, "Main Justice was always pushing FDA OCC to bring cases. Sometimes FDA is more aggressive, and at other times DOJ."[227]

Multiple participants cited as a "huge problem" instances of DOJ (primarily USAOs) bringing FDCA cases without notifying FDA.[228] This resulted from the overlap between criminal prosecutions, which DOJ can initiate without FDA, and civil enforcement, which requires FDA sign-off. FDA lawyers felt that as the "client" agency, FDA should at least know when DOJ brought an action under the FDCA.[229]

Most commonly, FDA lawyers described USAOs bringing criminal prosecutions that involved FDCA violations—usually off-label promotion or falsified records cases—without informing FDA.[230] Sometimes, FDA attorneys instructed USAOs to drop these cases.[231] Multiple participants noted that DOJ prosecutors would add FDCA charges to existing criminal fraud cases, almost as an afterthought. One participant described:

> [This] happened regularly. Often, a [USAO] would be bringing harsher penalties, for example for wire fraud or mail fraud, and at the end they would throw in some FDCA charges as an add-on. FDA would become aware at the last minute, or as it was filed, as they're walking into the grand jury.[232]

Although USAOs are required to inform CPB at Main Justice when they are pursuing FDCA claims,[233] they sometimes do not.[234]

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226. Participant 13, *supra* note 209.

227. Participant 17, *supra* note 127.

228. Participant 15, *supra* note 182. For frequency of assertions generally, see Appendix B.

229. "[Sometimes] DOJ would just start pursuing without FDA, without treating FDA like a client that should be coordinated with, and FDA was either skeptical or brought into the loop later, and FDA thought they shouldn't be pursuing [it]." Participant 20, *supra* note 206.

230. Telephone Interview with Participant 9, DOJ (Apr. 7, 2021); Participant 13, *supra* note 209. "The use of FDA authority by USAOs was always an issue. USAOs would be investigating and we might not know about it." Participant 17, *supra* note 127.

231. Participant 17, *supra* note 127. The legal authority of FDA to require that DOJ desist from prosecution is unclear.

232. Participant 19, *supra* note 127.

233. U.S. Dep't of Just., Just. Manual § 4-8.200 (2020).

234. Participant 7, *supra* note 188; Participant 20, *supra* note 206.

Most DOJ lawyers gave different answers than most FDA lawyers when asked about whether DOJ brings cases without consulting FDA. DOJ lawyers answered that they "can't imagine that happening" and it would be "incredibly unusual,"[235] while FDA lawyers described it as regular and problematic. One FDA lawyer noted that FDA was unlikely to know the full scope of cases brought without its knowledge.[236]

Some participants described these prosecutions as a threat to FDA's enforcement policy. Five participants mentioned *United States v. Farinella* when asked about instances when DOJ ignored FDA.[237] In this prosecution, an Assistant U.S. Attorney conflated the "sell-by" date on bottles of salad dressing with the "expiration" date, leading to a misbranding conviction unsupported by law or public health practice.[238] In a blistering opinion, Seventh Circuit Judge Richard Posner overturned the conviction and held that the DOJ prosecutor engaged in prosecutorial misconduct.[239] Participants pointed to *Farinella* as "Exhibit A" of the dangers of DOJ proceeding without consulting FDA.[240]

Participants also described rare, serious instances in which DOJ undermined FDA policy by threatening to prosecute companies for violations that FDA had already decided not to pursue.[241] DOJ's actions, according to FDA lawyers' accounts, endangered public health and eroded the value of industry consulting with FDA and receiving opinions on the appropriateness of planned business practices. An FDA lawyer recalled how "FDA discovered manufacturing flaws, told the company to continue for public health reasons, declined to take action, then DOJ comes in and opens up a criminal investigation. The company relied on assurances by FDA, then DOJ undercut them, creating a fear of prosecution, [and] risk to public health."[242] Another explained how "FDA gave assurance to a company for a technical violation with no public health implications, and DOJ pursues it because they see dollar signs, leading to unfairness, waste of resources, [and] bad law."[243] In both cases, FDA convinced DOJ not to prosecute

235. Participant 6, *supra* note 185.

236. Participant 12, *supra* note 195.

237. Telephone interview with Participant 8, DOJ (Apr. 7, 2021); Participant 10, *supra* note 200; Participant 12, *supra* note 195; Participant 15, *supra* note 182; Participant 20, *supra* note 206. *See generally* United States v. Farinella, 558 F.3d 695 (7th Cir. 2009).

238. *Farinella*, 558 F.3d at 697.

239. *Id.* at 701.

240. "FDA told DOJ 'don't pursue this' and that played out in court, where they lost bad." Participant 20, *supra* note 206. "DOJ should've listened." Participant 10, *supra* note 200.

241. Participant 15, *supra* note 182; Participant 20, *supra* note 206.

242. Participant 20, *supra* note 206.

243. Participant 15, *supra* note 182.

companies that followed FDA's instructions.[244]

D. Understanding Divergent Enforcement Priorities: The Litigious Lawyer

My findings provide important evidence on how DOJ control of litigation shapes agency policy by limiting enforcement.[245] But the interviews also uncovered the seemingly novel finding that DOJ can at times be a *more* zealous enforcer than its client agencies.[246]

Past scholarship has viewed the DOJ-agency relationship in litigation as between a gatekeeper and an oft-stymied policymaker, or as between a law firm and client.[247] While there is truth to these accounts, the relationship sometimes assumes a third form. DOJ at times seeks to bring cases that FDA does not see as worth bringing. DOJ pursues and prosecutes FDCA violations over FDA objection, and often pushes and encourages FDA to take on cases that it otherwise would not. DOJ, in these instances, does not act as either a mere representative or a risk-averse gatekeeper, but as a litigious lawyer.

This dynamic results from the differences in DOJ and FDA's enforcement priorities, because each agency uses its substantive mission as a lens through which to interpret the same statutory prohibitions. This explains why DOJ sometimes pursues law enforcement actions that public health does not require, while FDA will let violations stand if they do not threaten public health.[248]

The enforcement priorities of the agencies correspond to their structure, function, and missions. The prevention of fraud is central to the identity of DOJ as a law enforcement agency.[249] DOJ's budget and reputation depends

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244. Participant 20, *supra* note 206; Participant 15, *supra* note 182.

245. Specifically, they support the suggestions that DOJ control "might reduce the scope and effectiveness of agency enforcement," and that DOJ might "directly influenc[e] or interfer[e] with the agencies' substantive decisions." Herz & Devins, *supra* note 15, at 1346.

246. This confirms O'Leary's observation, "Each [USAO] has the independent authority to pursue food- and drug-related cases *without or in spite of* FDA input." Patrick O'Leary, *Recalibrating Enforcement in the Biomedical Industry: Deterrence and the Primacy of Protecting the Public Health*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 162, 170 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015) (emphasis added).

247. *See supra* Section I.A.

248. *See* O'Leary, *supra* note 246, at 171 (noting that "strategic FDA-related enforcement decisions are routinely made by lawyers at the DOJ, which, unlike FDA or HHS, has no statutory obligation to prioritize public health").

249. Heese et al., *supra* note 211, at 2; *see also* Pamela H. Bucy, *Trends in Corporate Criminal Prosecutions*, 44 AM. CRIM. L. REV. 1287, 1292 (2007) (graphing DOJ corporate fraud enforcement from 2002 to 2005).

on its percentage of courtroom wins and financial recoveries.[250] FDA, by contrast, is at its core a public health agency.[251] Its leadership is comprised predominantly of public health experts who think in terms of preventing harm and ensuring public confidence in regulated products.[252]

These differences lead to two interpretations of the underlying prohibitions on "adulteration" and "misbranding."[253] Recall the regulatory violations that DOJ pursued after FDA offered assurance to the contrary.[254] The two agencies, looking at the same situation, reached radically divergent conclusions—criminal prosecution or non-enforcement—by considering the violations in light of their underlying missions. Something similar happened in *Farinella* (the "salad dressing case"). FDA saw an insignificant misrepresentation that did not threaten public health; DOJ saw fraud. FDA sees the prohibitions against "misbranding" and "adulteration" primarily as tools to better protect the health of patients and consumers. DOJ looks at the same language and sees an extension of its existing authority to discourage fraud through criminal prosecution.[255]

To be sure, the fact that the agencies have distinct enforcement priorities does not mean those priorities are inherently at odds. For example, the regulation of off-label promotion favored by DOJ may yield substantial public health benefits.[256] Indeed, FDA might support these prosecutions, but prefer to prioritize different cases given limited resources.[257]

IV. LITIGATING AUTHORITY FOR THE FDA

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250. Heese et al., *supra* note 211, at 5.

251. *See generally* Hamburg & Sharfstein, *supra* note 12.

252. *See* CARPENTER, *supra* note 11, at 10–11; *FDA Overview Organization Chart*, *supra* note 96.

253. *See* 21 U.S.C. § 331(b).

254. *See supra* text accompanying notes 241–244.

255. *See* U.S. Dep't of Just., Just. Manual §§ 9-41.000 to 9-47.000 (2020) (describing DOJ's authority to prosecute bankruptcy fraud, fraud against the government, mail fraud, wire fraud, health care fraud, program fraud, bribery, and crimes under the Foreign Corrupt Practices Act of 1977).

256. *See* Liu et al., *supra* note 156, at 488 (highlighting the "substantial public health risks of off-label prescribing").

257. Some may argue that DOJ's apparent role in limiting FDA enforcement priorities is merely the result of its current role in allocating finite resources. In other words, because DOJ shoulders much of the burden of litigation and has the final say over litigation decisions, it must allocate its limited capacity more carefully than FDA. If FDA had to shoulder that burden, it may end up pursuing cases at a similar rate. Predictions about FDA's increased litigation docket if granted litigation authority may therefore fail to consider that FDA would face resource constraints that are not currently salient.

While time and resource constraints undoubtedly affect DOJ's decisions, a few factors limit the explanatory power of this argument. First, FDA also presumably faces resource constraints due to its continued involvement in litigation after a referral. *See supra* notes 200–205 and accompanying text. Second, litigation authority would reduce the coordination costs that FDA lawyers pointed to as a major barrier to more forceful enforcement. *See supra* notes 216–222 and accompanying text. Finally, while

In this Part, I place the arguments of the participants for and against litigation authority in conversation. Then I propose and briefly defend a viable option for granting civil litigation authority to FDA. Unlike the findings of the previous Part, which were based on participants' descriptive responses to the semi-structured interview's factual inquiries, this Part discusses their opinions. The views of these agency attorneys are valuable for two reasons. First, the attorneys alone understand firsthand how the FDCA litigation process actually works, allowing them to speak from experience rather than mere speculation or ideological preference. Second, they wield the authority to set federal policy through their enforcement decisions. Their views thus add needed weight and depth to the debate over DOJ control over agency litigation.

A. Participants' Views for and Against Litigation Authority

The former FDA lawyers were broadly supportive of independent litigation authority, while DOJ lawyers almost uniformly disagreed. DOJ attorneys' support for DOJ oversight was strong. They argued government should "speak with one voice" and that DOJ has superior litigation expertise.[258] One said that although it was a "close call," DOJ lawyers' familiarity with courts and judges tips the balance.[259] The following response epitomizes the argument for DOJ control:

> In most instances, DOJ can litigate FDA cases more effectively than the agency can on its own. DOJ attorneys have the perspective and experience to effectively present complex subject matter to lay judges. That's what DOJ does—for agencies across the federal government. DOJ attorneys are more apt to see the whole forest and its attorneys are less prone to the tunnel vision and groupthink that can sometimes entrap agency attorneys. While FDA attorneys are undoubtedly skilled and provide valuable expertise, they can also get bogged down in extraneous technical detail or programmatic arcana, and their singular perspective and narrow focus can be an impediment to effective advocacy. The litigation skill and outside perspective that DOJ brings to the table adds value in most instances and results in a

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former DOJ lawyers mentioned resource constraints, they emphasized the substantive legal value of DOJ review—preventing cases that are weak, or not in the public interest. *See infra* text accompanying note 261. This suggests that, even with unlimited resources, DOJ would decline some number of FDA referrals on grounds of insufficient merit.

258. Participant 1, *supra* note 208; Telephone Interview with Participant 2, DOJ (Apr. 26, 2021); Participant 5, *supra* note 127; Participant 9, *supra* note 230; Participant 10, *supra* note 200.

259. Participant 10, *supra* note 200.

> more persuasive presentation of the agency's case than the agency would likely muster on its own.[260]

A recurring concern was that "FDA might be overzealous" in bringing cases, leading to courtroom losses, wasted resources, and bad legal precedent that might hurt the FDA or other agencies in the future.[261] DOJ, one participant argued, "has a broader perspective" allowing it to "act in the interest of the U.S. as a whole."[262] Even a former FDA lawyer conceded "DOJ plays an important role, [an] important constraint. I wouldn't take DOJ out of the equation."[263]

Those in favor of FDA litigation authority, only FDA lawyers, argued that relying on DOJ is inefficient[264] and leads to an uneven enforcement regime that fails to create effective deterrence for FDCA violations.[265] They were skeptical that DOJ helps the government "speak with one voice" or that DOJ's litigation expertise actually helps FDA much in court.[266] One former FDA lawyer addressed the arguments about consistency and DOJ "checking" an over-zealous FDA:

> I don't see the consistency argument [for DOJ control]. Independent litigation authority would lead to more consistency, because the current system of de facto concurrence means there are two bosses, two places where industry can go to seek different answers . . . . FDA doesn't need an independent check; the courts are the independent check. If they bring an unmeritorious case, the courts will let them know.[267]

Litigation authority would improve democratic accountability, some argued, because it would place full responsibility for enforcement decisions on one entity—FDA.[268] "FDA would benefit from being emboldened and empowered, held accountable for bringing those actions."[269]

While the above arguments represent the two dominant camps, some views fell in between. These participants preferred a compromise position

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260. Participant 5, *supra* note 127.
261. Participant 1, *supra* note 208.
262. Participant 6, *supra* note 185.
263. Participant 20, *supra* note 206.
264. Participant 13, *supra* note 209; Participant 17, *supra* note 127.
265. Participant 15, *supra* note 182; Participant 19, *supra* note 127.
266. Participant 13, *supra* note 209.
267. Participant 17, *supra* note 127.
268. *Id.*
269. Participant 13, *supra* note 209. This argument about increasing accountability appears to cut against a typical justification for independent litigation authority—*independence* from political control. One way to square these views is using Bressman's distinction between promoting political accountability and preventing agency arbitrariness. *See* Bressman, *supra* note 51, at 462–63.

with shared litigation authority, consultation requirements,[270] and veto powers.[271] "Both should be involved," said a former attorney of both FDA and DOJ; "Both agencies should participate in both decision-making and [the] process of litigation."[272] A former DOJ attorney voiced a similar preference for DOJ maintaining veto authority.[273]

In line with these compromise positions, some participants drew a useful distinction: grant FDA independent litigation authority for some types of cases, but not others. For small-claims cases, one former FDA lawyer suggested, let FDA bring cases without DOJ; for big promotional cases with massive fines, the decision stays with DOJ but FDA can veto.[274] Another supported "having DOJ prosecute and investigate under the FCA, leaving FDA to focus on stuff that is not generating revenues, but protecting public health."[275]

B. Proposal: Civil Litigation Authority

One viable path forward would be for Congress to grant FDA independent litigation authority over all civil cases, but not criminal prosecutions. It has already granted such authority to the Federal Energy Regulatory Commission (FERC), offering a potential model for FDA.[276] Control of appeals would follow from the type of case—civil appeals would stay with FDA, and criminal with DOJ.[277] For cases in which FDA is the defendant, Congress could create a consultation requirement requiring that FDA hear DOJ input. But control of such defensive litigation, which is civil, would ultimately lie with FDA.

Granting FDA civil litigation authority would free up FDA to quickly remedy time-sensitive public health threats while allowing DOJ to retain

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270. Participant 10, *supra* note 200; Participant 20, *supra* note 206.

271. Participant 7, *supra* note 188; Participant 19, *supra* note 127.

272. Participant 10, *supra* note 200.

273. Participant 6, *supra* note 185 (suggesting "a situation where DOJ would maintain a veto option. DOJ get[s] the first shot to bring or defend the case. If it declines, it might veto or say you're on your own").

274. Participant 15, *supra* note 182. This participant also suggested a monetary threshold above which DOJ needs to have input, but below which FDA has sole litigation authority. *Id.*

275. Participant 16, *supra* note 172.

276. *See infra* notes 283–287 and accompanying text.

277. Currently, FDA's Office of the Chief Counsel is also the Food and Drug Division of the Department of Health and Human Services Office of the General Counsel. *Office of the Chief Counsel*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2019), https://www.fda.gov/about-fda/office-commissioner/office-chief-counsel [https://perma.cc/XS4W-7D9X]. Because FDA's legal function is housed within the Department of Health and Human Services, assigning litigating authority to FDA alone without also removing it from within that Department presents questions about how to reconcile that overlapping authority, which I do not address here.

control over slower-moving criminal prosecutions, including off-label promotion cases. Civil enforcement authority, including seizures, injunctions, and civil monetary penalties, provides FDA with sufficient tools to regulate for the public health on its own, while leaving prosecutorial authority with DOJ, the institution best suited to make criminal enforcement decisions.[278] It would also improve efficiency. DOJ participants noted how the agencies often duplicate labor, with the back-and-forth of the referral process taking up time and resources better spent elsewhere.[279]

The civil/criminal allocation plays to the institutional strengths of each agency by allowing for the robust enforcement of both safety violations that immediately threaten public health *and* high-profile white-collar cases for promotional offenses. FDA is a public health agency, tasked with ensuring the safety and efficacy of products.[280] It should have the power to seek judicial injunctions and seizures immediately in the name of public safety, rather than waiting months for backup from DOJ. With this authority, FDA can develop more consistent enforcement norms and promote effective deterrence. A substantial part of DOJ, meanwhile, is dedicated to prosecuting criminal fraud.[281] Leaving prosecutorial authority with DOJ puts the discretion to pursue criminal cases in the most experienced hands. Because the FDCA imposes criminal liability for misbranding and adulteration, DOJ will be free to prosecute misconduct as it chooses. For this reason, granting FDA civil litigation authority will not limit DOJ's enforcement of promotional violations.

Congress has done this before in the realm of energy regulation. FERC's enabling legislation grants the agency litigation authority over "any civil action" while leaving to DOJ the authority to prosecute criminal violations.[282] FERC, an independent agency charged with regulating the

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278. As one participant explained:

> Just results are better obtained when prosecution decisions are made by experienced prosecutors who are familiar with many different types of criminal cases, rather than by narrow agency specialists who 1) may lack sufficient trial experience to prosecute tough cases against experienced, skilled defense counsel, 2) may wear blinders about the importance of their cases, and 3) because they work for the investigating agency, may not be able to serve as a check on the investigating agency to ensure that the Justice Manual/Principles of Federal Prosecution are satisfied for each defendant in each case.

Participant 2, *supra* note 258.

279. Participant 20, *supra* note 206.

280. *See generally* Hamburg & Sharfstein, *supra* note 12.

281. *See* U.S. Dep't of Just., *supra* note 255.

282. 42 U.S.C. § 7171(i) ("Except as provided in section 518 of title 28, relating to litigation before the Supreme Court, attorneys designated by the Chairman of the Commission may appear for, and represent the Commission in, any civil action brought in connection with any function carried out by the Commission pursuant to this chapter or as otherwise authorized by law.").

U.S. energy supply, has had this authority since its creation in 1977.[283] Congress expanded FERC's enforcement tools with the Energy Policy Act of 2005, widening the scope of sanctionable conduct and increasing penalties for violations.[284] In the same Act, Congress granted DOJ authority to seek higher fines and longer prison sentences for criminal violations of federal energy law.[285] Thus, Congress has allocated litigation authority between FERC and DOJ by enforcement action type (civil/criminal), creating a bifurcated enforcement regime in a particularly consequential market.[286]

The viability of this approach for FDA depends on further changes. First, dividing litigation authority between FDA and DOJ will create regulatory overlap.[287] Because many FDCA offenses carry both civil and criminal penalties, each agency would have the discretion to sanction the same prohibited conduct. This sort of overlap has precedent, in the FTC and DOJ's dual enforcement of federal antitrust law.[288] Even so, it would be wise for FDA and DOJ to coordinate their enforcement policy through regular communication to avoid unfairness. To encourage this coordination, Congress could impose clear notification requirements on both DOJ and FDA to inform the other of any litigation it pursues under the FDCA.[289] In addition, FDA will need to expand its litigation team significantly if it is to take over civil cases.[290] Many participants agreed that the litigation department in OCC is not currently prepared to lead all civil enforcement and defensive cases on its own.[291] To make civil litigation authority a reality,

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283. *See* Department of Energy Organization Act of 1977, 42 U.S.C. §§ 7131, 7171(i).

284. *See* Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005); Allison Murphy, Todd Hettenbach & Thomas Olson, *The FERC Enforcement Process*, 35 ENERGY L.J. 283, 288–89 (2014).

285. *See* Energy Policy Act of 2005 §§ 314(a), 1284(d).

286. A full assessment of FERC's enforcement policy is beyond the scope of this paper. For criticism and defense of FERC enforcement practices, *compare* William S. Scherman, Brandon C. Johnson & Jason J. Fleischer, *The FERC Enforcement Process: Time for Structural Due Process and Substantive Reforms*, 35 ENERGY L.J. 101 (2014) (critiquing the enforcement regime), *with* Murphy et al., *supra* note 284 (offering a defense of FERC's enforcement policies). FERC enforcement actions generally follow an internal adjudication process, and very few result in federal litigation. *See* Todd Mullins & Chris McEachran, *Adjudication of FERC Enforcement Cases: "See You in Court?"*, 36 ENERGY L.J. 261 (2015) (arguing that FERC enforcement cases should start in federal court, not at the Commission).

287. Some scholars have addressed the benefits and costs of jurisdictional overlap, as well as strategies to address it through agency design. *See supra* note 89.

288. *See supra* note 106.

289. This suggestion adds content to the recommendation of seven former FDA Commissioners that Congress grant FDA litigation authority "in coordination with" DOJ. *See Seven Former FDA Commissioners Recommend*, *supra* note 7, at 15.

290. Multiple participants pointed to this. Participant 9, *supra* note 230; Participant 13, *supra* note 209; Participant 14, *supra* note 196.

291. *Id.*

Congress will have to appropriate the necessary funds for OCC to expand its litigation department.

C. A Defense Against Arguments for DOJ Control

In this Section, I subject my proposal to the arguments for DOJ control of litigation outlined in Section I.A: consistency, expertise, "check" value, and respect for Presidential policymaking. Guided by the empirical findings of Part III and the views of the study participants, I anchor the theoretical arguments about DOJ control of litigation to the case of FDA litigation.

Consistency. This argument comes in two variants—one practical, and one more abstract.[292] The abstract argument—that "the United States is a single entity and as such should not be at odds with itself"[293]—can be easily dealt with. The government already does not "speak with one voice," in federal litigation generally[294] and in FDCA litigation in particular.[295] FDCA enforcement consists of many actors pursuing different objectives. USAOs bring cases without consulting CPB or FDA. Participants described instances in which FDA and DOJ sometimes landed on different sides of the same case.[296] Others pointed out that if industry enforcement targets do not like the answer of one agency, they can try for a second answer with the other.[297] Thus, if consistent argumentation is the aim of DOJ centralization, it has largely failed.[298]

The practical argument, however, is quite serious: What if FDA, by pursuing its own agenda in court, argues a case in a way that hurts other agencies through binding legal precedent? Much federal litigation is trans-substantive.[299] Any agency, including FDA, has the power to hurt the programs of other agencies, or the federal government as a whole, through single-minded litigation in pursuit of its own mission. Centralizing control of litigation in DOJ, they suggested, mitigates the risk of this "friendly fire" in administrative law.[300]

Although this concern has merit, a few factors lessen its weight. First,

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292. *See* Devins & Herz, *supra* note 4, at 572–77.

293. *Id.* at 572.

294. *Id.* at 570–71.

295. *See supra* Sections III.0& III.0

296. *See supra* text accompanying notes 241–245.

297. Participant 17, *supra* note 127.

298. This assumes, further, that "speaking with one voice" is even a worthy goal in domestic enforcement matters. As Devins and Herz have pointed out, this assumption may be emptier than is commonly believed. *See* Devins & Herz, *supra* note 4, at 571–75.

299. *See* David Marcus, *Trans-Substantivity and the Processes of American Law*, 2013 BYU L. REV. 1191, 1194 (2013).

300. *See supra* text accompanying notes 261-263.

because the risk of harmful precedent is primarily limited to appeals, it can be mitigated through consultation requirements for appellate litigation, giving DOJ the chance to talk FDA away from setting a truly harmful precedent from federal appellate courts.[301] Second, some scholars suggest that administrative law tends to be agency-specific. As Robert Glicksman and Richard Levy argue, "judicial precedents tend to rely most heavily on other cases involving the agency under review, even for generally applicable administrative law principles."[302] This limits agency cross-fire, and further suggests that there may be substantial benefit to agency-specific expertise in the courtroom. Third, arguments before the Supreme Court on behalf of the United States are, in practice, presented almost exclusively by the Office of the Solicitor General in DOJ.[303] Even when an agency, such as FTC, has the authority to appear before the Court on its own, the Court has expressed a preference for hearing arguments by the Solicitor General instead.[304] FDA is thus insulated from the Court, even with civil litigation authority, through the Court's discretionary review and preference for familiar practitioners, assuaging fears that an unbridled FDA will lead the Court to set a harmful precedent.

Finally, as noted above, the consistency argument likely cuts the other way as applied to FDA enforcement policy, with litigation authority rendering federal policy *more* consistent, not less. DOJ's ability to decline and delay FDA cases may inhibit the predictability necessary for enforcement to lead to effective deterrence. This argument bleeds into broader concerns participants raised about capacity: "FDA regulates twenty-odd cents on the dollar. But it's only forty litigators, bringing single-digit enforcement actions a year . . . . It's kind of a drop in the bucket, and industry is not afraid of FDA enforcement, because it happens so rarely."[305] Eliminating the delay resulting from coordination between the offices would allow FDA to decisively pursue enforcement actions with the consistency necessary to effectively deter violations.

Expertise. Perhaps the most commonly invoked justification for DOJ centralization, former DOJ attorneys argued that DOJ houses valuable

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301. This recommendation accords with the compromise positions of some participants. *See supra* notes 271–273.

302. Richard E. Levy & Robert L. Glicksman, *Agency-Specific Precedents*, 89 TEX. L. REV. 499, 500 (2011).

303. *See* LINCOLN CAPLAN, THE TENTH JUSTICE: THE SOLICITOR GENERAL AND THE RULE OF LAW 19–50 (1987).

304. *See* Karr, *supra* note 16, at 1097 ("By actively seeking out the Solicitor General's opinions in these cases, the Court demonstrates a desire for the Solicitor General to retain control over as much of the litigation before the Supreme Court on behalf of the federal government as possible.").

305. Participant 19, *supra* note 127.

expertise on judges, courts, and the substantive elements of federal litigation.[306] Without DOJ guidance when crafting arguments and choosing where to file, FDA would simply lose more cases, harming its policy aims and reputation.[307]

The weight of this argument depends on whether one sees litigation expertise as an *acquired* or an *inherent* characteristic of an agency.[308] I argue that it is largely acquired—that is to say, FDA could gain much of the necessary expertise over time. Currently, FDA is not ultimately responsible for its own decisions in litigation. If it were, it would likely acquire some of the characteristics that DOJ now holds, including knowledge of what arguments are likely winners, and which judges are most favorable to FDA's position. FDA could hire experienced litigators and develop the institutional memory that currently exists in DOJ. Nor would FDA have to do so alone. FDA would effectively determine DOJ's role in civil litigation, allowing it to consult with DOJ for expertise when needed. For example, FDA may choose to let DOJ take the lead on complex cases while it builds an office of litigators.

When the "expertise" argument is understood as an aversion to risk of loss, the debate reduces to choosing between multiple reasonable litigation strategies. For example, DOJ's preference for winning cases on procedural grounds may limit the development of FDA's statutory authority. By forcing FDA to push the prosecutorial discretion argument in *Heckler v. Chaney*, DOJ prevented the agency from pursing the statutory interpretation argument it first sought to make.[309] By arguing more cases on the merits, FDA risks losing on questions about its core authority, but opens the possibility of winning them as well. Indeed, a higher tolerance for courtroom losses may be consistent with FDA's overall enforcement policy (though not DOJ's). FDA may prefer to have a clearer understanding of the limits of its power, and the tools available to it when faced with regulatory violations.

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306. Participant 10, *supra* note 200.

307. *See* in-text quote accompanying note 261.

308. Devins & Herz, *supra* note 4, at 583–86.

309. One participant described how in *Heckler v. Chaney*, FDA wanted to make a statutory argument—that it lacked the authority to regulate lethal injection drugs on the basis that they were not "held for sale" in interstate commerce. *See* Participant 7, *supra* note 188. DOJ forced it to lean instead on prosecutorial discretion—that it had the authority to choose when to *not* enforce the FDCA. Then-judge Antonin Scalia, siding with FDA in dissent, decided on the basis of the argument FDA did not make: "that FDA lacked jurisdiction because the drugs were not 'held for sale' in interstate commerce." Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions, 43 OP. O.L.C. 1, 20 (2019) (quoting Chaney v. Heckler, 718 F.2d 1174, 1199–1200 (D.C. Cir. 1983), *rev'd*, 470 U.S. 821 (1985)). "Because FDA did not press the point, neither opinion addressed whether . . . drugs intended for use in lethal injection are subject to regulation under the FDCA." *Id.*

"Check" Value. A common view expressed by participants against litigation authority was that DOJ, when it turns down or delays filing cases, is acting as a valuable "check" on FDA. Without this check, FDA would be overzealous, bringing losing cases more often.[310] This, participants asserted, would hurt FDA's reputation in the eyes of courts and the public, waste time and money, and be unfair to its enforcement targets.[311]

These concerns have some merit, but do not overwhelm. First, there is good reason to believe that FDA would litigate thoughtfully. Throughout its history, as Daniel Carpenter argues, FDA has strategically cultivated its reputation through restraint and compromise in diverse policy arenas.[312] It would be remarkable, then, if FDA became suddenly and recklessly litigious once granted the authority to bring civil cases.[313]

Second, as a matter of institutional design, we may prefer to trust FDA with policy-laden matters involving public health and safety. Admittedly, an untethered FDA may not always pursue wise cases; it may make mistakes DOJ could have prevented. But in matters of public health, inaction carries risk as well. On balance, it is not obvious that DOJ's understanding of the public interest deserves deference over FDA's in such cases. Evidence suggests DOJ's litigation decision-making tends to be driven by large monetary recoveries and the likelihood of success.[314] At the very least, we should view with some concern the dynamic whereby DOJ, an agency comprised of professional litigators, prevents FDA, an agency of public health experts, from bringing enforcement actions to promote public health.

Third, even if FDA were more aggressive in bringing questionable cases than DOJ, they may win more too. As noted above, FDA may find courtroom losses more tolerable than DOJ, and DOJ's risk-averse litigation strategy may not always produce the most wins for FDA's policy priorities.[315] Risk can bring reward, and FDA might be in the best position to weigh the costs to its reputation against the potential benefits for its policy goals.

Finally, if the aim of DOJ oversight is to prevent unfairness against enforcement targets, DOJ largely duplicates an existing check—the courts. Courts have the authority to dismiss meritless cases and address unlawful

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310. *See supra* notes 259-263 and accompanying text.

311. *Id.*

312. *See* CARPENTER, *supra* note 11, at 1–32.

313. *See* Sharon B. Jacobs, *The Administrative State's Passive Virtues*, 66 ADMIN. L. REV. 565, 565 (2014) (arguing that "agencies sometimes use restraint strategically . . . to avoid unnecessary conflict with other institutional actors").

314. *See* Heese et al., *supra* note 211, at 5.

315. *See* text accompanying notes 47–48.

agency action.[316] This division of judicial and executive functions is a core design element of our system of government.[317] Descriptions by participants of DOJ review of enforcement actions were consistent with the view that DOJ largely tries to duplicate judicial review, by predicting likelihood of success in court.[318] While it is true that FDA could, in theory, harass firms with meritless litigation, various factors weigh against this in practice; courts can discipline agencies for misconduct through contempt findings and sanctions,[319] and agencies have resource incentives to choose their enforcement actions carefully.[320]

V. RESPECT FOR PRESIDENTIAL POLICYMAKING AND THE POLITICS OF ENFORCEMENT

Notably rare in interview responses was mention of the President or agency leadership—the dominant players in contemporary accounts of the administrative state.[321] This is perhaps surprising; scholarly debates about independent agencies and litigation authority tend to center on the hierarchical nature of the executive branch and debate the extent to which decisionmakers should be insulated from top-down political control.[322] But the debate among the agency lawyers had little to do with Presidential preferences, political accountability, or susceptibility of FDA decision-making to Presidential control.[323] This suggests that discussions of agency independence and litigation authority might benefit from another framing, one focused less on formal hierarchy and politics and more on interagency relationships.

When participants mentioned politics at all, it was rarely as an argument for or against FDA litigation authority. Two participants mentioned political accountability in *favor* of granting FDA litigating authority, with the aim of

316. *See supra* notes 56–60 and accompanying text.

317. *See supra* notes 52–60 and accompanying text.

318. *See supra* notes 260-263 and accompanying text.

319. *See* Nicholas R. Parrillo, *The Endgame of Administrative Law: Governmental Disobedience and the Judicial Contempt Power*, 131 HARV. L. REV. 685, 686 (2018).

320. *See* Amitai Aviram, *Allocating Regulatory Resources*, 37 J. CORP. L. 739, 742-44 (2012) (discussing how resource allocation shapes enforcement decisions).

321. *See* Peter Barton Hutt, *Historical Themes and Developments at FDA Over the Past Fifty Years*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 17, 20–21 (Holly Fernandez Lynch & I. Glenn Cohen, eds., 2015) (describing how "the close supervision and decisional authority of the [FDA] commissioner eroded" in the second half of the 20th century).

322. *See supra* notes 61–70 and accompanying text; Olson, *supra* note 3, at 78–79 (noting the argument that DOJ "is where the President's policy and the courts 'interface.' Centralizing litigation authority improves the public's ability to know whom to praise or blame for the positions taken.").

323. *See* Frequency of Participant Responses Coded by Theme, Appendix B.

forcing FDA to "own" its litigation decisions.[324] More generally, the view of political influence on the agencies was divided; three participants stated that FDA was more subject to political pressure than DOJ,[325] one stated the opposite,[326] and another said they were roughly the same.[327]

Rather than make arguments for or against political control of agency decision-making, participants based their views predominantly on the institutional characteristics of the agencies themselves. They discussed their colleagues and counterparts, the expertise of the offices, the resource constraints that bound their decisions, the institutional cultures of the agencies that employed them, and the norms of professional conduct that guided their interactions.[328] The relationship between the agencies themselves, not the existence or absence of centralized political control, appeared to form the core of the discussion.

The relative absence of the Presidential policymaking argument from participant responses leads to four implications:

First, it points to the significance of institutional characteristics in driving agency decision-making. Agency policy is indelibly shaped by agency culture, which is itself a product of an agency's structure, function, mission, and legal authority, as well as the agency's interactions with other agencies. This cyclical development does not exist independent of politics, but narratives that insist on centering political actors may fail to tell the whole truth.[329]

Second, as an argument in favor of DOJ control of litigation, respect for presidential policymaking is, at most, a latent advantage (assuming it is an advantage at all).[330] Presumably, if an enforcement action garnered sufficient public attention, the President could intervene through the Attorney General to bring the action into line with the administration's priorities.[331] The President would lose this opportunity if FDA had civil

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324. *See supra* notes 268–269.

325. Participant 3, *supra* note 127; Participant 15, *supra* note 182. "Politicians were more able to pressure FDA than DOJ, so enforcement benefitted from that independence." Participant 7, *supra* note 188.

326. Participant 10, *supra* note 200.

327. Participant 5, *supra* note 127. "There's political leadership at both places and neither agency is fully immune from political pressures or considerations." *Id.*

328. *See supra* Part III–Section IV.A.

329. *See* Jennifer Nou, *Subdelegating Powers*, 117 COLUM. L. REV. 473, 473 (2017) (describing as "incomplete" the "traditional portrait of the administrative state [with] the politically-appointed agency head at its center").

330. *See supra* notes 61–70 and accompanying text for arguments for and against agency independence.

331. Something like this arguably occurred when HHS Secretary Kathleen Sebelius prevented FDA from increasing access to over-the-counter Plan B contraception in 2011, the year preceding President Obama's re-election. *See* Tummino v. Hamburg, 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013)

litigation authority. FDA control of FDCA litigation might also complicate a President-driven categorical enforcement policy, like DACA, in relation to FDA-regulated industries.[332] But these examples are speculative; recent political interference in FDA policy notwithstanding,[333] examples of overt political influence on individual FDA *enforcement* matters seem rare.

Third, to the extent this hands-off approach indicates a lack of political influence on individual enforcement decisions, it represents a victory for the separation of prosecutorial authority from political power. For those who argue that government attorneys serve the public interest, there are compelling reasons to separate and insulate prosecutors from political actors.[334] At the federal level, this includes preventing prosecutors from becoming mere tools of the President to bludgeon political rivals.[335]

Finally, it underscores the importance of career civil servants—especially agency lawyers—as policymakers. Participant responses evoked a relatively autonomous vision of the American civil service. The legal offices were not entirely divorced from politics, but operated primarily with their agency's mission in mind, not the particular views or policy preferences of the Attorney General, FDA Commissioner, Secretary of Health and Human Services, or President. This may present a challenge to a President- or election-based view of agency accountability in a representative democracy.[336]

One response to this apparent democratic deficit is to separate agency accountability for arbitrary decision-making from agency accountability via executive control.[337] As Jack Goldsmith argues, an agency "can be partially

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(concluding "[t]he decisions of the Secretary were . . . arbitrary, capricious, and unreasonable"); *see also Eastern District of New York Rejects FDA Limitations on Plan B Emergency Contraception as Arbitrary and Capricious* – Tummino v. Hamburg, 936 F. Supp. 2d 162 (E.D.N.Y. 2013), 127 HARV. L. REV. 1196 (2014); *see also* Jeffrey M. Drazen, Michael F. Greene, & Alastair J.J. Wood, *The FDA, Politics, and Plan B*, 350 NEW ENG. J. MED. 1561, 1561 (2004) (arguing that FDA's earlier decision "to postpone a decision on the proposal to switch [Plan B contraception] to over-the-counter status suggests that the FDA's decision-making process is being influenced by political considerations").

332. FDA relies heavily on non-binding Guidance documents to share its enforcement policies with industry. *See* Simon F. Haeder & Susan Webb Yackee, *Policies that Bind? The Use of Guidance Documents by Federal Agencies*, 43 J. HEALTH & HUM. SERV. ADMIN. 87 (2020) (surveying FDA guidance documents).

333. *See generally* Adashi et al., *supra* note 8.

334. *See* Bruce A. Green & Rebecca Roiphe, *May Federal Prosecutors Take Direction from the President?*, 87 FORDHAM L. REV. 1817, 1822–27 (2019); Rachel Barkow, *Separation of Powers and the Criminal Law*, 58 STAN. L. REV. 989 (2006); Leslie B. Arffa, Note, *Separation of Prosecutors*, 128 YALE L.J. 1078 (2019).

335. *See* Bruce A. Green & Rebecca Roiphe, *Can the President Control the Department of Justice*, 70 ALA. L. REV. 1, 4 (2018) ("identif[ying] and analyz[ing] the flaws in the argument that the President controls federal prosecutors").

336. *See supra* notes 51–64 and accompanying text.

337. *See* Bressman, *supra* note 51, at 461.

independent of the President and yet deeply accountable at the same time."[338] Courts, for example, can prevent agencies from exercising authority without meaningful reason-giving.[339]

Another response is to look to Congress, rather than the President, as the dominant legitimizing force behind agency authority.[340] Congress created FDA to fulfill an objective—to protect the public health[341]—and DOJ to fulfill another—to represent the interests of the United States in litigation.[342] The notion that Congress creates mission-bound agencies that dutifully carry out the purposes of their statutes may today sound simplistic or naïve.[343] But this view of agency legitimacy finds support in participants' responses, which above all reflected a steadfast commitment to serving the missions of their agencies and the interests of the public.

CONCLUSION

Enforcement of federal food and drug laws today requires the cooperation of two agencies—one Congress has charged with enforcing federal law, and another it has charged with representing the first in court. Each case filed is the product of a push-and-pull between agencies vying for their vision of what the public interest requires. The resulting enforcement policy can therefore only be understood in light of the complex relationship that produced it.

Interagency enforcement of the FDCA reframes old questions about agency independence. Does "independence" mean insulation from political control, or also independence from the constraining authority of other agencies? Who bears responsibility for squaring the divergent priorities of agencies with different missions? These questions implicate the very legitimacy of the most coercive tools in our national bureaucracy—civil and

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338. *See* Jack Goldsmith, *Independence and Accountability at the Department of Justice*, LAWFARE (Jan. 30, 2018, 2:16 PM), https://www.lawfareblog.com/independence-and-accountability-department-justice [https://perma.cc/P3U9-BNR3], (discussing the FBI and DOJ).

339. *See* Jodi L. Short, *The Political Turn in American Administrative Law: Power, Rationality, and Reasons*, 61 DUKE L.J. 1811, 1811 (2012) ("Reason giving is central to U.S. administrative law and practice.").

340. *See* Rebecca Ingber, *Congressional Administration of Foreign Affairs*, 106 VA. L. REV. 395, 401 (2020) (defining Congressional administration as "the management and manipulation of internal executive branch decision-making processes for the purpose of advancing a substantive agenda").

341. *See generally* Hamburg & Sharfstein, *supra* note 12.

342. *About DOJ*, DEP'T OF JUST., https://www.justice.gov/about [https://perma.cc/4C8W-A5WP].

343. *See* Bressman, *supra* note 51, at 470 (describing the early "transmission belt" model of "agencies as merely implementing clear legislative directives"); *see also* Stewart, *supra* note 52, at 1671–81 (describing how the problem of discretion arising from vague statutory commands eroded the viability of this model).

criminal enforcement suits filed in federal court against private parties on behalf of the United States.

More tangibly, who should wield these coercive tools? This Article has responded by centering on the practitioners whose experiences and choices constitute our federal FDCA enforcement policy. A truly informed discussion must begin with the public servants who have spent their careers navigating the pathways of authority Congress created. Only then can scholars, lawmakers, and policymakers begin to grapple with agency independence, litigation authority, and their relation to the legitimacy of regulatory power.

APPENDIX A: QUALITATIVE INTERVIEW GUIDE

Background: I am conducting a study on litigation authority and the relationship between the Food and Drug Administration (FDA) and the Department of Justice (DOJ). My questions aim primarily to assess the extent to which DOJ control of litigation arising under the Federal Food, Drug, and Cosmetics Act (FDCA) affects the substantive implementation of the FDCA, including enforcement referrals and defense against challenges to FDA actions.

Questions:

Walk me through the process of a typical enforcement referral.

- What kinds of factors does FDA consider when preparing enforcement referrals?
- What kinds of factors does DOJ consider when deciding whether to take a referral?

How often does DOJ decline FDA referrals? Why, and in what kinds of cases (civil, criminal)?

- Can you provide me with any particular cases? In whatever level of detail you find appropriate.

Does DOJ tend to favor certain types of enforcement actions?

Walk me through a typical defensive litigation case, *e.g.*, if someone challenges an FDA rule.

- What role do FDA lawyers typically play?

Does DOJ ever refuse to represent FDA? *E.g.*, refuse to recover civil penalties, or defend against challenges to FDA action?

- Can you provide me with specific cases? In whatever level of detail you find appropriate.

Would FDA conduct defensive litigation differently than DOJ does (*e.g.*, use different arguments in APA challenges)?

- Does DOJ use arguments or pursue cases that the FDA disagrees with? Examples? In whatever level of detail you find appropriate.
- Does FDA ever ask DOJ to stop/change? Examples? In whatever level of detail you find appropriate.

Does DOJ ever prosecute/litigate under the FDCA without asking FDA first?

- In what kinds of cases? Examples? In whatever level of detail you find appropriate.

What kind of institutional/budgetary changes would be necessary for FDA to litigate on its own?

Would you support FDA gaining independent litigation authority?

- Why/Why not?
- For certain kinds of cases but not others? In whatever level of detail you find appropriate.

Do you think the FDA would be more or less aggressive than DOJ in enforcing in specific areas?

- Specifically: 1) off-label promotion cases, 2) *Park* prosecutions, 3) adulterated supplements?

What's the relationship between central DOJ and U.S. Attorneys' offices regarding referrals for FDCA cases?

How does the referral-to-DOJ enforcement process affect the substantive enforcement of the FDCA?

APPENDIX B: FREQUENCY OF PARTICIPANT RESPONSES CODED BY THEME

Themes	**Number of Responses**
DOJ Declines Cases	14
Tension Between FDA and DOJ over Litigation Decisions	14
DOJ Makes the Final Decision, but FDA is Consistently Involved	10
DOJ Rarely if Ever Declines Cases Outright	9
The Agencies' Enforcement Priorities Differ: Public Health v. Law Enforcement/Press/Settlement Awards	9
Do Not Support FDA Litigation Authority	8
Litigation Authority Would Change Enforcement Policy	8
DOJ Litigates Without Asking FDA, or over FDA Protest	8
DOJ Does not Generally Litigate Without Asking FDA	7
Agencies Share Similar Enforcement Priorities	7
Support for FDA Litigation Authority	6
Preference for Compromise Position/Cooperation	6
FDA Would be More Aggressive in Some Areas but not Others	5
FDA Would be More Aggressive Generally	5
U.S. v. Farinella ("Salad Dressing Case")	5
Coordination Problems Between USAOs and Main Justice; FDA Bringing Cases to USAOs Without Telling Main Justice	5
Culture of Deference and Cooperation Between the Agencies	4
DOJ Delays Filing Cases	3
FDA is More Politicized than DOJ	3
DOJ Undercuts FDA's Strategic Non-Enforcement Decisions	2
FDA Understands the FDCA Better than DOJ	2
DOJ is More Politicized than FDA	1
FDA and DOJ Are About Equally Politicized	1