Agency Adherence to Legislative History

Laura E Dolbow*

Abstract

Every year, Congress gives hundreds of specific directions to agencies through legislative history. Amidst debates about how agencies use legislative history as an interpretive tool to implement directives contained in statutory text, little work has been done about how agencies respond to directives contained in the legislative history itself. How agencies respond to directives in legislative history, such as committee reports, provides important information about interactions between agencies and Congress. This Article explores how congressional committees leverage legislative history to direct agency action by studying instructions to the Food and Drug Administration (FDA) in appropriations committee reports. Based on this study, I suggest that agencies follow appropriations committee report instructions with high fidelity, though they retain flexibility in their responses. Moreover, appropriations committees use legislative history to monitor details about the substance of agency action. The influence of congressional committees over the content of agency action affects negotiating dynamics between Congress and agencies, which has important implications for understanding the relationship between Congress and agencies. Congressional oversight through legislative history can promote efficient oversight, public participation, and political accountability in agency actions, particularly in the guidance document development process. However, delegating such

* J.D., Vanderbilt Law School; B.A., Vanderbilt University. I thank Professor Kevin Stack, Professor Owen Jones, Hannah Frank, Christopher Hanson, Jessica Haushalter, Ezra Marcus, Clayton Masterman, and Ben Raker for helpful conversations and comments. I also thank the members of the *Administrative Law Review* who provided feedback and edited this Article.

oversight to the committee level sparks concerns about committee bias and interest group capture, emphasizing the need for transparency.

Table of Contents

INTRODUCTION

After decades of exercising enforcement discretion, the FDA released a draft guidance document in October 2014 announcing its plans to begin regulating Laboratory-Developed Tests as medical devices.[1] Industry protested, arguing that this change in policy would impose enormous costs, would hinder innovation, and must, therefore, be implemented through notice-and-comment rulemaking or statutory amendment.[2] Congress then weighed in on the debate—but it did so using legislative history. In a committee report, the House Appropriations Committee directed the FDA to stop efforts to finalize the guidance and to instead work with Congress to pass new legislation to develop a regulatory framework.[3] Language in legislative history is not binding, yet every year committee reports accompanying the appropriations bill contain hundreds of detailed provisions targeted at all administrative agencies. For fiscal year 2017, the House and Senate committee reports contained 104 provisions directed at the FDA

---

[1] *See* FOOD & DRUG ADMIN., FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTS) (2014) https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf.

[2] PAUL D. CLEMENT & LAURENCE H. TRIBE, LABORATORY TESTING SERVICES, AS THE PRACTICE OF MEDICINE, CANNOT BE REGULATED AS MEDICAL DEVICES (2015) http://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf; Shannon Haymond, *Should the FDA Oversee All Lab-developed Tests?*, THE HILL (Nov. 19, 2015 06:30 AM) http://thehill.com/blogs/congress-blog/healthcare/260594-should-the-fda-oversee-all-lab-developed-tests.

[3] H. REP. NO. 114-531, at 73 (2016). Ultimately, the Food and Drug Administration (FDA) announced it would not finalize the guidance document, stating it would continue to work with stakeholders, the next executive administration, and Congress. Christopher Hanson, *Obama Administration Will Not Finalize LDT Framework Guidance*, Inside Medical Devices (Nov. 20, 2016), https://www.insidemedicaldevices.com/2016/11/obama-administration-will-not-finalize-ldt-framework-guidance/.

alone.[4] Targeted at a wide array of federal agency actions, the prevalence of these non-statutory instructions brings up questions: If agencies are not required to follow committee instructions, do they do so anyway? Should they?

Agencies are the main users of legislative history. Recent scholarly debate has shifted away from the role of legislative history in the courts, to the role of legislative history in agencies. Yet little attention has been paid to whether agencies actually *are* following legislative history guidance in practice.[5] In response to calls for more empirical work about how agencies interpret statutes, a recent study by Professor Christopher Walker found that agencies do consider legislative history, particularly committee and conference reports, to be an important source when interpreting statutes,.[6] This Article builds on the Walker study by exploring whether agencies actually implement specific instructions within legislative history. The influence that congressional committees exert over agency action through legislative history provides important insights about how Congress oversees agencies.

Legislative history plays an especially important role in the appropriations context. Scholars suggest that agencies pay close attention to committee report language in appropriations bills because the Appropriations Committee controls their budgets, and these budgets must be

---

[4] H. REP. 114-531, at 65–80 (2016); S. REP. 114-259, at 81–93 (2016).
[5] Robert A. Katzmann, *Madison Lecture: Statutes*, 87 N.Y.U. L. REV. 637, 660 (2012) ("Although there has been some thoughtful writing on agency construction of statutes, there is a dearth of empirical knowledge about the methodology of agency interpretation. I would urge a full empirical inquiry across agencies."); Jerry Mashaw, *Norms, Practices, and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation*, 57 ADMIN. L. REV. 501, 537 (2005); Peter L. Strauss, *When the Judge Is Not the Primary Official With Responsibility to Read: Agency Interpretation and the Problem of Legislative History*, 66 CHI.-KENT L. REV. 321, 329 (1990).
[6] Christopher J. Walker, *Inside Agency Statutory Interpretation*, 67 STAN. L. REV. 999, 1005 (2015).

renewed on a yearly basis.[7] However, the study scholars rely on for this proposition is based on outdated data from decades ago when committee reports contained around thirty provisions per report.[8] With the expansion of the modern administrative state, appropriations committee reports today contain hundreds of provisions. Given the increased stakes, updated research is needed to determine whether agencies continue to follow appropriations committee report instructions with such fidelity. This Article seeks to fill that gap by studying how appropriations committee report language from fiscal years 2011-2016 impacted FDA actions.

Congressional committee oversight has particularly significant implications in the guidance document development process. The modern administrative state increasingly regulates through informal guidance documents. But guidance documents provide no formal procedures for public participation and are insulated from political oversight. Thus, this study focuses on committee report instructions related to guidance documents in particular to evaluate whether this oversight can address concerns about inadequate public participation and insufficient political accountability.

Based on this study, I suggest that agencies do pay close attention to congressional instructions in legislative history. The FDA issued a new guidance document in response to a majority of committee report instructions to do so. The high rate of compliance indicates that legislative history in the appropriations context exerts a powerful influence over how agencies administer statutes. Therefore, committee reports function as an avenue for congressional involvement in how agencies execute statutes.

---

[7] Abbe R. Gluck & Lisa Schultz Bresssman, *Statutory Interpretation From the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 980 (2013); Katzmann, *supra* note 5, at 649–50; ALLEN SCHICK, THE FEDERAL BUDGET: POLITICS, POLICY, PROCESS 271 (3d. 2007).

[8] MICHAEL W. KIRST, GOVERNMENT WITHOUT PASSING LAWS (1969).

Yet congressional committee involvement in agency implementation of statutes implicitly provokes several separation of powers questions about the relationship between Congress and agencies generally. Committee reports may provide an effective means to increase legislative oversight, public participation, and political accountability. However, committee oversight, rather than oversight by Congress at large, sparks concerns about committee bias and interest group capture. Therefore, transparency about the dialogue between congressional committees and agencies is important.

Part I discusses the relationship between Congress and administrative agencies, surveying existing literature about the role of legislative history in agency actions and congressional oversight. Part II explains the choice to focus on guidance documents at the FDA, then presents the findings of the study to suggest that legislative history instructions do influence agency action in practice. Part II then evaluates how the Appropriations Committee employed legislative history instructions to direct agency action and how the FDA responded. Part III discusses several implications of congressional committee influence over informal agency actions for larger debates about the relationship between Congress and agencies.

I. THE RELATIONSHIP BETWEEN CONGRESS AND THE ADMINISTRATIVE STATE

Though much scholarly attention has focused on the relationship between the President and administrative agencies, less work has been done on the relationship between Congress and agencies.[9] This Article addresses the under-explored interactions between Congress and agencies by focusing on how congressional committees invoke legislative history to direct agency actions. Section A begins with an overview of the role of legislative history in the administrative state, considering both existing literature on how agencies use legislative history

[9] *See, e.g.*, Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2255 (2001).

and normative arguments about whether agencies should consult legislative history. Section B then discusses the role of congressional oversight in the modern administrative state, with a particular focus on the appropriations context.

A. The Role of Legislative History

Amidst longstanding debates between textualists and purposivists about whether courts should consider legislative history when interpreting statutes, scholarly debate recently turned to how much weight agencies should give legislative history when interpreting statutes.[10] Legislative history plays a different role in the agency context than in courts. This Section discusses the debate over the proper role of legislative history when agencies interpret statutes, then considers potential concerns when Congress delegates to committees the authority to oversee agencies through legislative history.

1. Agency Statutory Interpretation

Though judges frequently read legislative history to interpret statutes, agencies are often the first, and primary, interpreters of statutes.[11] Administrative agencies interpret statutes more frequently than courts, and many agency interpretations are final because courts often do not review agency actions.[12] Moreover, Congress considers agencies as the key audience for legislative history.[13] A study by Professors Abbe Gluck and Lisa Bressman suggested Congress views legislative history as a tool to influence how agencies implement statutes.[14] This indicates

---

[10] *See* Gluck & Bressman, *supra* note 7, at 929; Katzmann, *supra* note 4, at 655; Kevin M. Stack, *Purposivism in the Executive Branch: How Agencies Interpret Statutes*, 109 N.W. L. REV. 871, 882–83 (2015); Strauss, *supra* note 4, at 321; Walker, *supra* note 6, at 1009–11.
[11] Katzmann, *supra* note 5, at 656; Walker, *supra* note 6, at 1006.
[12] Kevin M. Stack, *Purposivism in the Executive Branch: How Agencies Interpret Statutes*, 109 N.W. L. REV. 871, 883 (2015).
[13] Gluck & Bressman, *supra* note 7, at 972
[14] *Id.* (finding 94% of congressional drafters surveyed considered shaping the way agencies interpret statutes as a purpose of legislative history); *see also* Katzmann, *supra* note 5, at 655.

that congressmen intend to use legislative history directions to oversee and direct agency action. Thus, the relationship between Congress and agencies, rather than the relationship between Congress and courts, is particularly significant when it comes to statutory interpretation and the use of legislative history.[15]

Textualists caution against using legislative history in courts primarily because legislative history may not provide reliable evidence of statutory meaning and has not gone through the full legislative process.[16] Institutional differences between agencies and courts, however, mitigate some of these concerns in the context of agency statutory interpretation. Unlike courts, agencies interpret statutes as part of ongoing activity to implement the statute, have continuing interactions with committees, and sometimes even play a role in drafting legislative history.[17] Thus, scholars have argued that agencies are uniquely capable of evaluating the reliability of different sources of legislative history.[18] Moreover, it is widely accepted that politics plays a legitimate role in agency statutory interpretation.[19] In this sense, legislative history may be a beneficial tool for political oversight, as informal mechanisms of political oversight are considered acceptable, and even desirable, to ensure agencies comply with congressional intent when executing the law. Therefore, formal legislative process may not be as crucial in the

---

[15] Walker, *supra* note 6, at 1006 (noting that as scholars gain more insight into how federal agencies interpret statutes, the relationship between Congress and agencies should improve, as should the judicial branch's ability to monitor and faithfully constrain lawmaking by regulation).
[16] Gluck & Bressman, *supra* note 14, at 965.
[17] Stack, *supra* note 12, at 906–08; Strauss, *supra* note 5, at 334.
[18] Nicholas R. Parrillo, *Leviathan and Interpretive Revolution: The Administrative State, the Judiciary, and the Rise of Legislative History, 1980-1950*, 123 YALE L.J. 266, 282–84 (2013); Strauss, *supra* note 5, at 321, 334; Stack, *supra* note 12, at 906–08 (2015).
[19] Stack, *supra* note 12, at 882; Strauss, *supra* note 5, at 335; Walker, *supra* note 6. Some scholars, however, have acknowledged that not all political influences are legitimate. Nina A. Mendelson, *Disclosing "Political" Oversight of Agency Decision Making*, 108 MICH. L. REV. 1127, 1140-46 (2010); Kathryn A. Watts, *Proposing a Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 56 (2009).

agency context where agencies are capable of evaluating the reliability of different types of legislative history; political oversight plays a legitimate role; and agencies are expected to act as faithful agents of Congress. Thus, concerns about courts using legislative history may not translate into the agency context.

2. Congressional Delegation to Committees

While the use of legislative history may not present the same concerns in the agency context as in courts, extensive agency reliance on legislative history may still cause other concerns. For example, Dean John Manning has argued that delegating interpretive authority to congressional committees creates a separation of powers concern.[20] Under the nondelegation doctrine, Congress is not allowed to delegate its lawmaking power—and this includes delegating to subgroups within Congress.[21] Manning asserts that through legislative history, Congress implicitly delegates authority to interpret the law to the specific committee or sponsors.[22] Congressional delegations to subgroups within the legislature pose a different set of problems than delegations to agencies and courts. When Congress delegates to agencies and courts, it incurs agency costs, which helps maintain the constitutional structure.[23] Congress does not directly control the agencies or courts that interpret ambiguities in the law, which gives Congress an incentive to make the law clear. But when Congress delegates to subgroups within the legislature, these agency costs are not present.[24] If legislative history plays an authoritative role, issues left unresolved in statutes can be clarified by actors under congressional control, but without going through bicameralism and presentment. Because of these concerns, Manning

---

[20] John F. Manning, *Textualism as a Nondelegation Doctrine*, 97 COLUM. L. REV. 673, 673 (1997).
[21] *Id.*
[22] *Id.*
[23] *See id.* at 706–07, 715–25.
[24] *See id.*

suggests that Supreme Court separation of powers cases typically uphold broad delegations of authority to agencies and courts, but are more skeptical when the legislature self-delegates to subgroups of the legislature.[25] Therefore, if legislative history plays too powerful of a role in influencing agency action, it may pose a separation of powers problem by vesting legislative power within a subgroup of Congress.

Because legislative history does not interpret the law in a binding way, however, statutory interpretations in committee reports likely do not formally violate the nondelegation doctrine. Yet delegating influential oversight authority to a subset of Congress also sparks policy concerns that underlie the separation of powers concerns. Powerful influence at the committee level creates potential for committee bias and interest group capture.[26] If agencies frequently follow legislative history instructions, these concerns warrant attention. Potential issues created by delegation to subgroups within Congress underscore the importance of studying how congressional committees use legislative history to influence agency action and how agencies respond in practice.

B. Congressional Oversight of Administration

Beyond debates about the proper role of legislative history in agency statutory interpretation, the use of legislative history also has implications for understanding how Congress oversees agency action. When Congress delegates to agencies, agencies are charged with implementing the law. Agencies do not, however, have constitutional authority to make law.[27] Congressional supervision of agency action is therefore important to ensure that agencies

---

[25] Parts III.A.2 and III.A.3 *infra* provide an in-depth discussion of Supreme Court separation of powers cases, such as *Chadha*, *Bowsher,* and *MWAA*.
[26] Manning, *supra* note 21, at 688.
[27] Kagan, *supra* note 9, at 2255.

are implementing statutes consistent with legislative intent, rather than impermissibly exercising lawmaking power.[28] In the modern administrative state, Congress often gives broad delegations of authority to agencies.[29] Yet whether Congress is able to effectively monitor how agencies implement these broad delegations is unclear. This Section addresses debates about whether Congress does in fact retain control over agency statutory implementation, then turns to the appropriations context in particular.

1. Congressional Control

When Congress delegates broad authority to agencies, it creates a principal-agent problem.[30] Under the principal-agent model, the relationship between elected officials and administrative agencies is characterized as a principal-agent relationship.[31] Broad delegations to the agent create a problem, because Congress would like for agencies to carry out its wishes faithfully. However, ensuring agency fidelity may be costly, if not, impossible—creating a need for the principal to find ways to monitor the agent to assure the agent adheres to the principal's wishes.[32] Political scientists have noted that Congress experiences difficulties in overseeing its bureaucratic agents due to information asymmetries, expertise, and differing preferences between Congress and agencies.[33] The delegation to agencies comes with a "built-in problem of control"

---

[28] *See id.*
[29] *See* Gary Lawson, *The Rise and Rise of the Administrative State*, 107 HARV. L. REV. 1231, 1237–41 (1994).
[30] McCubbins et al., *Administrative Procedures as Instruments of Political Control*, 244 J. OF L. ECON. & ORG. 243, 247 (1987); Strauss, *supra* note 5, at 336.
[31] McCubbins, *supra* note 30, at 247.; Strauss, *supra* note 5, at 336. The principal-agent model may be an overly simplistic model for assessing agency "fidelity" in a larger sense because agencies also have relationships with interest groups, the public, and the executive. Walker, *supra* note 6, at 1002–03. This Article, however, focuses on the relationship between agencies and Congress and thus uses this model as a mechanism to describe that relationship.
[32] Strauss, *supra* note 5, at 336; Walker, *supra* note 6, at 1001.
[33] McCubbins et al., *supra* note 31, at 244, 246–48; Walker, *supra* note 6, at 1001 (2015). There is also the dual principal problem, which notes that agencies are subject to oversight by both the

because agencies have expertise and other information, "about [their] own diligence and aptitude, for example, or [their] actual behavior on the job," that that is largely unavailable to Congress.[34] The resulting information asymmetry makes it difficult for Congress to ensure its own interests are being faithfully pursued by agencies.

Congress may attempt to solve this information asymmetry issue through oversight. Previously, scholars thought that when Congress made broad delegations to agencies, it did not continue to effectively exercise control over regulatory policymaking.[35] However, over time, scholars have argued that Congress is more involved in agency action than previously thought, exploring various formal and informal oversight mechanisms.[36] One theory is that Congress monitors agency action through "fire alarm" oversight—where Congress sanctions agencies in response to reports from citizens and interest groups, placing primary monitoring duties on these non-government entities.[37] Alternatively, Congress also engages in "police patrol" monitoring of agency actions through reporting requirements and oversight hearings.[38] Increased congressional involvement may help address concerns that broad delegations create a principal-agent problem. Moreover, congressional involvement has implications for judicial doctrines, particularly for separation of powers issues.[39] For example, Professor John Beermann has argued that detailed congressional involvement in agency policymaking helps justify a more lenient nondelegation

---

legislative and the executive branches. The competing tensions between legislative and executive oversight, however, are outside the scope of this Article.

[34] Terry M. Moe, *Political Control and the Power of the Agent*, 22 J.L. ECON & ORG. 1, 3 (2006).

[35] Kagan, *supra* note 28, at 2256.

[36] *Id.* at 2257–58; Jack Beermann, *Congressional Administration*, 43 SAN DIEGO L. REV. 61, 65–66 (2006).

[37] Kagan, *supra* note 28, at 2258; Matthew D. McCubbins & Thomas Schwartz, *Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms*, 28 AM. J. POL. SCI. 165, 171 (1984).

[38] Beerman, *supra* note 36, at 66–67.

[39] *Id.* at 144–48.

doctrine.[40] Thus, exploring how committees invoke legislative history and how agencies respond will help further understand Congress's role in overseeing agency action.

2. Annual Appropriations as a Monitoring Tool

Legislative history plays a particularly powerful role in the appropriations context. The Appropriations Committee is in a unique position to oversee agency activity because the committee reviews agency behavior through reports on a yearly basis, and it can influence policy through the power of the purse.[41] In this special oversight role, the Appropriations Committee employs legislative history as a tool to direct agency action. Professors Abbe Gluck and Lisa Bressman recently found that in appropriations bills, unlike in other bills, congressional drafters consider the purpose of committee reports as essentially to legislate by directing where the appropriated money will go.[42] Every year, appropriations committee reports include detailed provisions commenting on agency actions and guiding future agency action. Yet this language is not legally binding on agencies, and courts give little credence to legislative history in appropriations bills.[43] Thus, appropriations committee report language retains its force not

---

[40] *Id.* at 146.

[41] Katzmann, *supra* note 5, at 649–50 (2012); ALLEN SCHICK, THE FEDERAL BUDGET: POLITICS, POLICY, PROCESS 271 (3d. 2007). For a discussion of how appropriations committee oversight differs from other congressional committee oversight, see LAWRENCE C. DODD & RICHARD L. SCHOTT, CONGRESS AND THE ADMINISTRATIVE STATE 157–62, 222–25 (2d ed. 1986); CHRISTOPHER H. FOREMAN, SIGNALS FROM THE HILL 98 (1988) ("[Reports] become just as compelling [as the bill] because these are the guys that give us the money.")

[42] The study also found that legislative counsel help draft committee reports in the appropriations context, but not in other contexts, reinforcing the special role of appropriations committee legislative history. Gluck & Bressman, *supra* note 14, at 980.

[43] Tennessee Valley Authority v. Hill, 437 U.S. 153, 189, 191 (1978) ("Expressions of committees dealing with requests for appropriations cannot be equated with statutes enacted by Congress."); *see also* Hein v. Freedom from Religion Found., 551 U.S. 587, 608 n. 7 (2007) (plurality opinion). Though some scholars have suggested courts should accord more deference to appropriations committee legislative history given its unique context, others have suggested it is optimal for courts not to strictly enforce statements in appropriations committee reports

through legal status, but through practical realities that the appropriations committee reviews agencies on a yearly basis and controls their budgets.[44]

Based on these practical realities, scholars suggest that agencies do in fact take appropriations committee report language seriously.[45] In 1969, Professor Michael Kirst conducted an in-depth study of the use of non-statutory controls in the appropriations context based on six committee reports, records of hearings before the subcommittees, debates on appropriations bills in the *Congressional Record*, and interviews with appropriations committee members.[46] Professor Kirst found that agencies rarely disregard non-statutory language in committee reports.[47] In his study, the prevalent attitude of administrators with regard to non-statutory directives was that "we just have to live with them."[48] Based on this study, scholars have viewed non-statutory controls by the Appropriations Committee as an effective oversight technique.[49] Therefore, since scholars suggest agencies pay careful attention to legislative history in the appropriations context in particular, it is a good place to begin research into the overall role legislative history plays in modern agency statutory interpretation in practice.

II. THE DIALOGUE BETWEEN THE APPROPRIATIONS COMMITTEE AND AGENCIES

The Appropriations Committee regularly gives detailed, non-statutory instructions to agencies through legislative history. This Part suggests that non-statutory instructions continue to exert a similarly powerful influence over agency action in the modern administrative state as

---

because Congress may have intended for agencies to maintain flexibility. Gluck & Bressman, *supra* note 14, at 982 n.282.

[44] SCHICK, *supra* note 41, at 271.

[45] DODD & SCHOTT, *supra* note 41, at 243–44; SCHICK, *supra* note 41, at 271.

[46] KIRST, *supra* note 8 (defining non-statutory controls as including hearings, committee reports, floor debates, and informal meetings).

[47] *Id.* at 73 ("The interview responses were so uniform and emphatic that it was not necessary to explore the extent of noncompliance through a detailed enumeration of the printed record.").

[48] *Id.*

[49] *See, e.g.*, SCHICK, *supra* note 41, at 223.

they did in the 1960s. Based on the study, I conclude that the FDA followed most, but not all, committee report instructions to issue new guidance documents. Section A describes the choice to study legislative history directions about guidance documents at the FDA specifically. Section B analyzes how the FDA responded to committee report instructions, then discusses how the FDA leveraged its expertise to resist some committee report directives. Section C evaluates the various ways the Appropriations Committee sought to direct agency action, considering the implications these different uses could have for effective oversight and public participation in the guidance development process.

A. Study Design: Guidance Documents

In recent years, the administrative state shifted toward policymaking through more informal means, particularly guidance documents.[50] Informal procedures are less expensive and allow more regulatory flexibility.[51] For example, a 2005 study found the FDA issued twice as many guidance documents as rules—and the FDA issued guidance documents at a four-hundred percent greater rate in the 1990s than the 1980s.[52] Though guidance documents are technically not legally binding, they often prompt regulated entities to change behavior and have a de facto binding effect in practice.[53] The widespread practical impact of informal guidance documents

---

[50] Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 90–91 (2014); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 165–66 (2000).

[51] Nina A. Mendelson, *Regulatory Beneficiaries & Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 400, 408 (2007).

[52] Erica Seigur & John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD & DRUG L.J. 17, 25 (2005); Rakoff, *supra* note 50, at 168; *see also* K.M. Lewis, *Informal Guidance at the FDA*, 66 FOOD & DRUG L.J. 507, 550 (Appendix A (2011)) (finding the FDA issued around 100 guidance documents per year since 2000).

[53] Mendelson, *supra* note 51, at 408; Noah, *supra* note 50, at 92; Rakoff, *supra* note 52, at 165–67.

makes oversight and public participation especially important, yet the lack of procedural requirements for guidance documents casts doubts about whether effective oversight can happen and whether the public can adequately participate. The increasing use of guidance documents as an administrative policymaking tool makes these concerns about congressional oversight and public participation more urgent. To observe how Congress oversees guidance documents, and whether such oversight contributes to increased public participation, I chose to focus on guidance documents. This Part discusses how the trend toward regulating through guidance documents creates challenges for political oversight and for public participation, then explains the choice to focus on the FDA.

1. Political Oversight

Procedural requirements provide a mechanism for the executive and legislative branches to monitor agency action.[54] Yet when a federal agency issues a guidance document, the Administrative Procedure Act (APA) does not require any specific procedures.[55] The lack of procedural requirements, therefore, brings up concerns that guidance documents may be subject to insufficient political oversight.

Executive and legislative oversight of guidance documents is limited. The executive branch reviews significant guidance documents through the Office of Management and Budget

---

[54] Lisa Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749, 1758 (2007) (noting procedures also serve values of public accountability and rule of law); Harold H. Bruff & Ernest Gellhorn, *Congressional Control of Administrative Regulation: A Study of Legislative Vetoes*, 90 HARV. L. REV. 1369, 1376–77 (1977); McCubbins et al., *supra* note 31, at 244.

[55] Administrative Procedure Act, 5 U.S.C. § 553. This stands in contrast to notice-and-comment rules, which the Administrative Procedure Act (APA) requires agencies to publish on the *Federal Register*, provide an opportunity for public comment, respond to these comments, and include a statement of basis and purpose.

(OMB).[56] Moreover, through the Final Bulletin for Agency Good Guidance Practices, the executive branch directs agencies to develop written procedures for the process of issuing guidance documents.[57] Written procedures could promote more procedural regularity and facilitate oversight, though a recent Government Accountability Office (GAO) study suggests not all agencies have complied.[58] Congressional oversight of guidance documents, on the other hand, is generally ad hoc. Guidance documents are not subject to the Congressional Review Act, which requires federal agencies to submit reports to Congress about new regulations.[59] Thus, congressional oversight of guidance documents, in contrast to oversight of regulations, occurs without an organized framework. No formal mechanisms are in place for Congress to oversee development of guidance documents.

2. Public Participation

Beyond concerns that regulating through guidance documents decreases the ability of other government branches to oversee agency action, the informal guidance process also raises concerns about public participation in agency actions. In particular, the lack of required procedures and insulation from judicial review question whether the public can adequately participate in the guidance development process.

---

[56] The Bush Administration issued an Executive Order to allow the Office of Management and Budget (OMB) to require consultation with an agency before the agency issued a significant guidance document. *See* E.O. 13422, 72 Fed. Reg. 2763 (Jan. 23, 2007). Though President Obama revoked this executive order, the Obama Administration continued OMB review of significant guidance documents. *See* Peter R. Orszag, Director, OMB, Memorandum for the Heads and Acting Heads of Exec. Dep'ts & Agencies, Guidance for Regulatory Review (Mar. 4, 2009). *But see* Mendelson, *supra* note 53, at 411 (questioning whether the OMB would exercise this oversight frequently).

[57] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).

[58] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-368, REGULATORY GUIDANCE PROCESSES: SELECTED DEPARTMENTS COULD STRENGTHEN INTERNAL CONTROL AND DISSEMINATION PRACTICES at 49 (2015).

[59] Mendelson, *supra* note 53, at 411.

Procedural requirements give the public opportunities to participate directly in agency policymaking. In the notice-and-comment process for regulations, federal agencies must provide the public an opportunity to comment, must respond to comments, and must disclose data relied upon.[60] Yet again, the APA requires no such procedures for guidance documents. The Good Guidance Practices referenced in the previous Subsection aim to combat some concerns about the lack of public participation in guidance development.[61] For "significant" guidance documents, these practices require agencies to set up a means for public comment electronically, make guidance documents accessible on the Internet, clearly label guidance documents, and publish economically significant guidance documents in the *Federal Register*.[62] However, the Good Guidance Practices do not solve all problems for public accessibility because they do not require agencies to respond to the comments, as agencies must do in notice-and-comment procedures. Moreover, the Good Guidance Practices only apply to "significant" guidance documents. Furthermore, the Good Guidance Practices create no right to judicial review to enforce the use of such procedures. The lack of judicial review is problematic because a recent GAO study suggests not all agencies are following the Good Guidance Practices.[63] The benefits from these increased procedures may be limited in practice if they are not enforced. Therefore, the minimal, and possibly unenforced, procedural requirements for guidance documents cast doubt on the public's ability to participate in the guidance development process.

---

[60] 5 U.S.C. § 553; *see also* Am. Radio Relay League v. FCC, 524 F.3d 227, 236–40 (2d Cir. 2008); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 252–53 (2d Cir. 1977).
[61] The FDA originally adopted these practices in a regulation, then Congress wrote them into the FDA statute. Outside the FDA, the executive branch expanded procedures to all federal agencies through the Final Bulletin for Agency Good Guidance Practices.
[62] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).
[63] U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 58, at 10.

Insulation from judicial review poses another threat to public participation in guidance development. Parties discontent with agency action sometimes seek recourse through judicial review. Guidance documents, however, may avoid judicial review because courts only review final agency actions and only consider disputes that are ripe for adjudication. Since guidance documents are not legally binding, a court may not consider it a "final" agency action.[64] Moreover, even if the guidance document is a final agency action, courts may not consider guidance documents "ripe" for review because the documents are technically not legally binding. Courts rarely find the practical effect of guidance documents as a basis for finding ripeness, but rather more frequently decline to review the documents.[65] Professor Nina Mendelson noted that the concerns about inadequate participation are particularly grave for regulatory beneficiaries because regulatory beneficiaries have less political clout, which hinders involvement in the development process.[66] Moreover, regulatory beneficiaries have fewer opportunities than regulated entities to challenge the reasoning in court, since beneficiaries are not subject to enforcement proceedings.[67]

3. The FDA

Studying the FDA is particularly useful because the Good Guidance Practices originated within the FDA and the agency follows them pursuant to its organic statute.[68] Thus, FDA actions provide an opportunity to study whether the practices promote congressional oversight and public participation. Moreover, the FDA issues on average around one hundred guidance documents per year, so it provides a good example to study how Congress chooses to employ ad

---

[64] Mendelson, *supra* note 53, at 411. *See, e.g.*, Ass'n of Flight Attendants v. Huerta, 785 F.3d 710, 713 (D.C. Cir. 2015) (finding a guidance document not a "final" agency action).
[65] Mendelson, *supra* note 53, at 411.
[66] *Id.* at 430–31.
[67] *Id.* at 421–22; 430–31.
[68] *See* 21 U.S.C. §371; Lewis, *supra* note 52, at 521.

hoc oversight of guidance documents.[69] Therefore, I chose to focus on committee report instructions that were directed to the FDA specifically.

To study whether agencies faithfully follow appropriations committee directives, I studied the committee report provisions directed at FDA guidance on specific topics from fiscal years 2011 through 2016. I tracked committee report provisions from the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (the Subcommittee) in both the House and the Senate that commented on an existing guidance document or the need for a specific guidance document.[70] Every year, when the FDA submits its budget justification, it includes a provision-by-provision response to all of the items in the appropriations committee reports. So I used the FDA budget justifications to track the FDA's responses to each committee report directive.[71] I also checked the FDA website to search for guidance documents to track whether the FDA issued a guidance document in response to the congressional directive.[72]

During fiscal years 2011 through 2016, the FDA issued 738 guidance documents.[73] In the committee reports, the Subcommittee commented on thirty-seven of those guidance

---

[69] *See* Lewis, *supra* note 52, at 549; Noah, *supra* note 50, at 102–03.

[70] I did not include general comments, such as the need for transparency in guidance development, or comments asking the FDA to develop "clear guidelines," "performance standards," or "advisories." I did this because I wanted to focus on issuance of guidance documents to be able to track in a binary way whether the FDA issued a guidance document or not and to focus on the influence on guidance document development in particular.

[71] I focused my study on FY2011-2016, because FY2011 was the earliest committee report that the FDA published responses to appropriations committee reports on its website with its budget justifications.

[72] The website to search for FDA guidance documents is available at https://www.fda.gov/Regulatoryinformation/Guidances/.

[73] To measure this, I tracked all guidance documents published on the FDA website from October 1, 2010 through September 30, 2016.

documents—only 0.5% of the total guidance the FDA issued during that timeframe, as shown in Figure 1 below.

Figure 1: Total Guidance Issued by FDA Organization (FY2011-2016)

FDA Organization	Total Guidance Documents FDA Issued	Total Guidance Documents Congress Commented On	% of Guidance Congress Commented On
Center for Drug Evaluation and Research	267	23	9%
Center for Biologics Evaluation and Research	40	2	5%
Center for Devices and Radiological Health	114	1	1%
Center for Food Safety and Applied Nutrition	53	4	8%
Center for Veterinary Medicine	50	3	6%
Office of Regulatory Affairs	101	0	0%
Office of the Commissioner	16	0	0%
Joint Organizations	83	2	2%
None	14	2	14%
TOTAL	738	37	5%

Nevertheless, the commentary spread across subject areas relatively evenly as shown in Figure 2 below. The only exception was that the Subcommittee commented on a disproportionately high percentage of guidance documents issued by the Center for Drug Evaluation and Research compared to the percentage of total guidance documents issued out of that center.[74]

Figure 2: Percentage of Guidance Issued by FDA Organization Compared to Percentage of Congressional Commentary (FY2011-2016)

FDA Organization	% of Total Guidance FDA Issued	% of Total Congressional Commentary
Center for Drug Evaluation and Research	36%	62%
Center for Biologics Evaluation and Research	5%	5%
Center for Devices and Radiological Health	15%	3%
Center for Food Safety and Applied Nutrition	7%	11%
Center for Veterinary Medicine	7%	8%
Office of Regulatory Affairs	14%	0%
Office of the Commissioner	2%	0%
Joint Organizations	11%	5%
None	2%	5%

[74] To approximate the subject area, I tracked the percentage of guidance documents issued from the different centers within the FDA.

In total, the committee reports contained thirty-seven provisions with comments about guidance documents on specific subjects. The following Section analyzes the type of directives included in these provisions and how the FDA responded.

B. Congressional Instructions to Issue New Guidance Documents

Most committee report instructions directed the FDA to issue finalize, or revise a specific guidance document. Overall, when committee report provisions directed the FDA to issue a particular guidance document, the FDA usually issued new guidance documents, though the FDA retained flexibility to disagree and sometimes followed through at a delay. In particular, the FDA used expertise when it resisted legislative history instructions. This Section provides a detailed description of committee report instructions and FDA responses.

1. Followed Directions

Generally, the FDA followed the Subcommittee's instructions articulated in the committee reports. To analyze the types of directions the Subcommittee provided to the FDA, I recorded the specific directives within each committee report provision. Some provisions had multiple directives. For example, the 2013 Senate report provision relating to "antimicrobial resistance" directed the FDA to finalize an existing draft guidance document and to provide a report about implementation of a second guidance document, so I coded these as two separate directives.[75]

Most directives instructed the FDA to issue a new guidance document in some form. The Subcommittee also included directives to collaborate with stakeholders when developing guidance, to ensure the FDA implemented guidance consistently, and to publish reports about

[75] *See* S. REP. 112-163, at 77-78 (2012).

implementation of guidance documents.[76] The reports included thirty-nine total directives—twenty-eight directives to issue a new guidance document, seven directives to consult with stakeholders, and four directives related to implementation of guidance documents. Because of the low frequency of non-statutory provisions related to consulting stakeholders and implementing guidance, I did not code these provisions. Instead, I discuss these directives and FDA responses in the descriptive analysis in the following Section. Moreover, a complete summary of the total committee report instructions is listed in Figure 5 at the end of this Section.

After tracking the total non-statutory directives, I sorted the committee report instructions to issue a new guidance document into four general categories. The directives to issue a new guidance document took four general forms as instructions to either: (1) develop a new guidance document, (2) finalize an existing draft guidance document, (3) revise and re-issue an existing draft document, or (4) provide a report about plans to develop guidance. The FDA issued a new guidance document in response to a majority of each type of these directives, as shown in Figure 3 below. To test whether the FDA followed the directives to issue new guidance documents, I then tracked whether the FDA issued a new guidance document in response to each congressional directive at some point. I determined whether the FDA issued a guidance document based on the FDA's explanation in its budget justification, which explicitly responded to each committee report provision from the preceding year. I also searched the FDA website for guidance documents to track whether the FDA issued a guidance document on the topic mentioned in the committee report instruction.

---

[76] The Subcommittee also commented favorably on issued guidance seven times. I did not code these as directives because they did not direct the FDA to take any action. All of these comments were in subject areas where report language elsewhere contained some form of a direction.

Figure 3: Congressional Directives to Issue New Guidance Documents FY2011-2016

Type of Directive	Number of Directives in Committee Reports	Number of Directives that Resulted in New Guidance Document	% of Directives that Resulted in New Guidance Document
Issue a new guidance document	11	8	73%
Finalize an existing guidance document	8	7	88%
Revise and re-issue an existing guidance document	3	3	100%
Provide a report about plans to develop guidance	6	5	83%
TOTAL	28	23	82%

Overall, the FDA issued a new guidance document at some point in response to eighty-two percent of the non-statutory provisions. Moreover, the FDA issued a new guidance document more frequently when the Subcommittee asked the agency to finalize or to revise an existing guidance document than when the Subcommittee asked the agency to develop a totally new guidance document or to provide a report about plans to develop guidance. These findings suggest that non-statutory controls from the appropriations committee exert a powerful influence over agency action.

Yet the FDA did not comply with *all* directives. When the FDA disagreed with the Subcommittee in its responses in its budget justifications, it relied on its scientific or procedural policymaking expertise, which is discussed below. The failure to issue a guidance document in response to all committee report instructions suggests that agencies still retain flexibility to resist committee directives even though these instructions exert considerable influence.

2. Repeated Instructions

The raw number of congressional directives and guidance documents published by the FDA do not tell the whole story. Sometimes the Subcommittee repeated language about the same guidance document over multiple years or in both the House and Senate reports. Therefore, I also coded the Subcommittee directives and FDA responses by topic. In total, the

Subcommittee commented on eighteen specific substantive areas, and the dialogue contained at least one directive to issue a new guidance document for each topic. The FDA ultimately issued a new guidance document in fifteen out of the eighteen subject areas. Sorting by subject area therefore further shows that the FDA issued new guidance documents in response to most committee report instructions.

The various subject areas and the FDA's responses are listed in Figure 4. In this Figure, each shaded box represents a committee instruction. The gray boxes show instructions to issue a guidance document contained in committee reports. The black boxes show instructions contained in the actual appropriations statute, which are discussed below. When the FDA ultimately issued a guidance document, there is an "X" in the last column. In a few areas, the Subcommittee commented on multiple guidance documents, so the separate guidance documents are listed as #1 and #2.

Figure 4: Congressional Directives by Subject Area

Topic	**Congressional Directives**			**Guidance Document Issued**
Artificial Pancreas				X
Sunscreen				X
Honey				X
Menu Labeling				X
Botanical Dietary Supplements				
Regenerative Medicine				X
Biosimilars				X
Fixed Dose Combination Products				X
Antimicrobial Resistance #1				X
Antimicrobial Resistance #2				X
Abuse-Deterrent Opioids #1				X
Abuse-Deterrent Opioids #2				X
Blood Product Policies				X
New Dietary Ingredients				X
Special Protocol Assessment				X
Duchenne Muscular Dystrophy				X
Off Label Guidance				
Antibiotic Development				X
Nutrition Ratings Systems				
Compounding Drugs #1				X
Compounding Drugs #2				X

Overall, the FDA published at least one new guidance document in eighty-three percent of the substantive areas. Moreover, Figure 4 highlights that the Subcommittee at times repeated instructions. In five subject areas, the Subcommittee repeated an instruction to issue a guidance document before the FDA ultimately issued a new document.[77] In one additional subject area—Botanical Dietary Supplements—the Subcommittee repeated an instruction to issue a new guidance document three times, but the FDA did not issue a new guidance document.

Notably, in two of these subject areas—menu labeling and abuse-deterrent opioids—the Subcommittee followed up with *statutory* directives to issue a new guidance document when the FDA did not initially publish a new document in response to a non-statutory directions.[78] For menu labeling, a House committee report provision requested the FDA provide guidance for newly regulated entities, such as local grocery store chains, about new menu labeling regulations. After the FDA did not publish a guidance document in response, the Subcommittee included bill language the following year that prevented the FDA from using funds to implement the final rule until at least one year after it published a guidance document.[79] Additionally, in response to concerns about rising opioid addiction, the Subcommittee instructed the FDA to finalize

---

[77] In the subject areas of Honey, Antimicrobial Resistance, and New Dietary Ingredients, the Subcommittee repeated the instruction over multiple years before the FDA issued a guidance document. With Biosimilars and Special Protocol Assessment, the instruction was repeated in both the House and Senate reports in the same year.

[78] When the committee report provisions for these two topics merely stated that the Subcommittee included bill language conditioning funding on these actions, I did not code the instructions as "non-statutory instructions" in the previous Subsection because these were in fact statutory instructions. However, I am including them in the discussion of repeated instructions to illustrate the overall dialogue between the Subcommittee and the FDA.

[79] Consolidated Appropriations Act of 2016, Pub. L. No. 114-113 (https://www.congress.gov/114/plaws/publ113/PLAW-114publ113.pdf); H.R. REP. NO. 113-468, at 56–57 (2014); H.R. REP. NO. 114-205, at 70 (2015).

guidance for approval of opioid drugs with abuse-deterrent properties.[80] When the FDA did not finalize a guidance document in response to the committee report provision, the Subcommittee followed up the next year with bill language that conditioned funding on whether the FDA finalized the guidance.[81] If the FDA did not finalize a guidance document by a certain deadline, $20,000,000 of discretionary funds allocated to the Office of the Commissioner would be moved to the Office of Criminal Investigation instead to assist in preventing opioid drug abuse.[82] In both of these situations, the FDA responded to the statutory directives by issuing a new guidance document.[83]

This shows that when agencies do not follow non-statutory instructions that are important to the Committee, the Committee conditions funding in the statute to elicit agency action. Moreover, the fact that the Subcommittee at times resorted to statutory instructions suggests that when the Subcommittee chooses to instruct through a non-statutory provision, the Subcommittee intends to allow the agency flexibility in determining how to follow the congressional commentary.[84] Thus, even though the non-statutory controls have a powerful influence over agency action, they still leave room for agency discretion.

---

[80] H.R. REP. NO. 113-116, at 57 (2013).
[81] *See* Consolidated and Further Continuing Appropriations Act 2015, Pub. L. No. 113-235 (https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf).
[82] *Id.*; H.R. REP. NO. 113-468, at 63 (2014); S. REP. 113-164, at 81 (2014).
[83] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 242–43 (2015); DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2017 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 271 (2016). For menu labeling, it also delayed implementation of the rule, met with industry stakeholders, and agreed to provide educational assistance as well as to work cooperatively and flexibly with those who made a good faith effort to comply.
[84] Additionally, Professor Kirst suggested the Appropriations Committee also chooses to convey various levels of flexibility based on the exact wording of the non-statutory directive. He found that when a subcommittee wishes to bind an agency, it used the verbs "directs" or "instructs," yet subcommittees used the terms "expect" or "urge" to allow more flexibility, with weaker verbs

Figure 5 below summarizes the types of comments the Subcommittee made on each subject area and provides the names of the ultimate guidance documents the FDA issued. The number in parentheses following a congressional instruction indicates the number of times the Subcommittee repeated that instruction. Overall, this Figure shows that most committee report instructions included an instruction to issue a new guidance document, and the FDA issued a new guidance document in response to most directives.

Figure 5: Congressional Directives and FDA Responses

Topic	Congressional Directives	Guidance Documents Issued
Artificial Pancreas	Finalize guidance (1) Consider stakeholders (2) General approval (3) Implementation (2)	*The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems* (Final, November 2012, CDRH)
Sunscreen	Issue guidance (1)	*Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data* (Final, November 2016, CDER)
Honey	Issue guidance (2)	*Proper Labeling of Honey and Honey Products* (Final, February 2018, CFSAN)
Menu Labeling	Issue guidance (1) [followed by a statutory directive]	*A Labeling Guidance for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II* (Final, April 2016, CFSAN)
Botanical Dietary Supplements	Issue guidance (3)	
Regenerative Medicine	Issue guidance (1) Consider stakeholders (1)	*Expedited Programs for Regenerative Medicine Therapies for Serious Conditions* (Draft, November 2017, CBER)
Biosimilars	Issue guidance (1) Provide a report (1)	*Labeling for Biosimilar Products Guidance for Industry* (Draft, March 2016, CDER)
Fixed Dose Combination Products	Finalize guidance (1)	*New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products* (Final, October 2014, CDER)
Antimicrobial Resistance	Finalize guidance #1 (2) Provide report on guidance #2 (1) General approval (2) Implementation (2)	Guidance #1: *New Animal Drugs and New Animal Drug Combination Products Administered In or On Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* (Final, December 2013, CVM) Guidance #2: *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (Final, April 2012, CVM)
Abuse-Deterrent Opioids	Finalize guidance #1 (1) [followed by a statutory directive] Issue guidance #2 (1)	Guidance #1: *Abuse-Deterrent Opioids—Evaluation and Labeling* (Final, April 2015, CDER) Guidance #2: *General Principles for Evaluating the Abuse Deterrence of Generic Opioid Drug Products* (Final, November 2017, CDER)

like "desires" or "feels" suggesting the agency could ignore the instruction. KIRST, *supra* note 8, at 36–38.

Blood Product Policies	Finalize guidance (1)	*Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion* (Draft, March 2016, CBER)
New Dietary Ingredients	Revise and re-issue guidance (1) Provide report (1)	*Dietary Supplements: New Dietary Ingredient Notifications and Related Issues* (Draft, August 2016, CFSAN)
Special Protocol Agreement	Revise and re-issue guidance (2)	*Special Protocol Agreement* (Final, April 2018, CDER)
Duchenne Muscular Dystrophy	Provide report (1) Consider stakeholders (2) General approval (2)	*Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment* (Final, February 2018, CDER)
Off Label Guidance	Finalize guidance (1)	
Antibiotic Development	Provide report (1)	*Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment* (Draft, May 2014, CDER) *Community-Acquired Bacterial Pneumonia—Developing Drugs for Treatment* (Draft, January 2014, CDER) *Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment* (Final, October 2013, CDER)
Nutrition Ratings Systems	Provide report (1)	
Compounding Drugs	Finalize guidance #1 (1) Issue guidance #2 (1) Consult stakeholders (2)	Guidance #1: *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* (Final, January 2018, CDER) Guidance #2: *Prescription Requirement under 503A of the Federal Food, Drug, and Cosmetic Act* (Final, December 2016, CDER)

3. Agency Resistance Through Expertise

Expertise is often used as a justification for giving agencies discretion. When agencies resist non-statutory instructions, relying upon their expertise can be an effective way to defend their disagreement with Congress over the need for a particular action. In fact, Professor Kirst's work in the 1960s suggested agencies were aware they could use technical expertise as a tool to resist non-statutory directions.[85] In an interview with the Corps of Engineers, a corps member stated, "We can back [the subcommittees] down with technical information showing the

[85] KIRST, *supra* note 8, at 58.

unfortunate effects of obeying their instructions."[86] This Article suggests agencies can use not only substantive expertise, but also expertise regarding policymaking tools to resist committee instructions. This Subsection describes a few examples from the FDA to illustrate how agencies may rely upon substantive expertise or policymaking expertise to disagree with congressional commentary.

i. Substantive Expertise

The FDA's substantive expertise relates to its scientific expertise regarding food, drugs, and medical devices. The FDA used its scientific expertise to disagree with the need for guidance documents by pointing out that science in certain areas was rapidly evolving, which would make articulating specific guidelines potentially counterproductive at such an early stage. For example, in the 2016 House report, the Subcommittee urged the FDA to issue guidance on the use of specific data checkpoints in clinical trials to accelerate approval of regenerative medicine pharmaceuticals.[87] The FDA disagreed on the need for guidance. The FDA explained that since regenerative medicine was a rapidly evolving field, identifying specific data points for approval could risk prematurely defining the field and limiting exploration of innovative treatments.[88] Although the FDA ultimately issued a new guidance document after the 2017 House report repeated a similar instruction and Congress passed a new statute related to

---

[86] *Id.*

[87] H.R REP. NO. 114-205, at 74 (2015). Thus far, the FDA has not issued a guidance document on this topic, though the 2017 House report again "urged" the FDA to issue guidance and to consult with appropriate stakeholders. H.R. REP. NO. 114-531, at 80 (2016).

[88] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2017 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 279 (2016).

regenerative medicine, the FDA's decision to delay issuing guidance demonstrated resistance based on its substantive expertise.[89]

The FDA also relied on its scientific expertise to express disagreement on the topic of abuse-deterrent drugs. To combat rising problems with narcotic addiction, the Subcommittee commented on the need to develop new drugs with abuse-deterrent properties. In the 2015 House report, the Subcommittee expressed concerns that the FDA approved a new, powerful narcotic that did not have an abuse-deterrent formulation.[90] The Subcommittee worried that approving this drug presented a public health danger and may stifle innovation.[91] Based on these concerns, the Subcommittee instructed the FDA to finalize existing draft guidance by June 30, 2015.[92] Though the FDA agreed on the concerns about opioid addiction and ultimately issued a new guidance document, it relied on scientific expertise to defend its approval of the narcotic without any abuse-deterrent properties. The FDA explained that for the specific narcotic, it determined the benefits outweighed its risks despite the lack of abuse-deterrent properties.[93] The narcotic

---

[89] In particular, the FDA noted that "The [new] legislation recognizes that these early meetings between FDA and sponsors of RMAT-designated products may be a suitable time to discuss whether accelerated approval would be appropriate based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites." DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2018 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 282–83 (2017). This suggests that its decision to issue a guidance document may have been based more on the new statute than on the legislative history instruction, which reinforces that the FDA used its substantive expertise to resist the Subcomittee's nonstatutory directive. *See* H.R. REP. 114-531 at 80 (2016).

[90] H.R. REP. NO. 113-468, at 63 (2014).

[91] *Id.* (noting this seemed in conflict with FDA statements that prevention of opioid abuse was highest priority).

[92] *Id.* The Senate report echoed concerns about the need for guidance. *See* S. REP. NO. 113-164, at 81 (2014).

[93] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 242–43 (2015).

was the first long-acting hydrocodone product and decreased liver toxicity risks.[94] Thus, even though the FDA agreed on the need for a guidance document, it used scientific expertise to defend its autonomy over specific drug approvals. Overall, scientific expertise bolstered the FDA's ability to maintain discretion over how it administered statutes.

ii. Policymaking Expertise

Beyond subject matter expertise, agencies can also use their expertise about available policymaking tools to resist committee report instructions. At times, when the Subcommittee directed the FDA to issue a new guidance document, the FDA pointed to other available policymaking tools that could achieve the desired goals. For example, the Subcommittee encouraged the FDA to issue a guidance document regarding methods of manufacturing plant-derived dietary supplements to ensure that such supplements were not contaminated.[95] The FDA responded that it currently met with stakeholders about best practices and engaged in research, opining that the current publications and meetings with stakeholders provided adequate guidance for the industry.[96] So far, the FDA has not issued any guidance documents on botanical dietary supplements.[97]

---

[94] *Îd.* Moreover, for its latest approved product, the FDA required the pharmaceutical company to study the product's abuse-deterrent properties on actual abuse as a condition of approval, providing an opportunity for the FDA to build more scientific expertise by acquiring more information. The FDA also employed its policymaking expertise to resist the Subcommittee's instructions here, as described in the following Subsection.

[95] S. REP. NO. 112-73, at 81 (2011); S. REP. NO. 112-163, at 78–79 (2012); S. REP. NO. 113-46, at 79–80 (2013).

[96] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2013 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 586 (2012); *see also* DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 181 (2014) (noting that research with its Center for Excellence at the University of Mississippi would inform next steps).

[97] I could not locate any guidance documents on this topic on the FDA website. Also, the committee reports from the past three years did not repeat these instructions, suggesting the Subcommittee dropped the issue. The FDA issued a guidance document about Botanical Drug

The FDA also invoked policymaking expertise to disagree with the Subcommittee about best methods for issuing guidance. In the 2015 Senate report, the Subcommittee expressed concern that the FDA was not meeting with stakeholders before releasing guidance about drug compounding for public comment. The Subcommittee then directed the FDA to meet with stakeholders to help inform implementation of the Compounding Quality Act.[98] The FDA responded that meeting with stakeholders before issuing draft guidance documents for comment would unnecessarily delay issuance of guidance documents necessary to achieve the public health goals of the statute. The FDA further opined that stakeholders can provide more meaningful input on a topic after they see the FDA's proposed approach in a draft guidance or proposed regulation.[99] Thus, the FDA stated it would continue to issue draft guidance documents for public comment in compliance with its Good Guidance Practices, which do not require the FDA to meet with stakeholders *before* issuing draft guidance. Additionally, the FDA noted that it had already met with many key stakeholders, told them it was willing to entertain written submissions, and was considering public comments when finalizing guidance documents.[100]

The FDA also used its procedural expertise to cast doubt about whether finalizing a guidance document would make a practical difference on policy implementation. For example,

---

Development in 2016. *See* FDA, BOTANICAL DRUG DEVELOPMENT (December 2016). Although that document references botanical dietary supplements, it is mainly directed towards drugs and does not address methods and standards to verify source plants and ingredients in the supplements as the committee reports requested.

[98] S. REP. NO. 113-164, at 81 (2014).

[99] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 246–47 (2015).

[100] *Id.* The FDA held a fifty-state meeting, met with federal agencies that handle or reimburse for compounded drugs, and held listening sessions with over forty stakeholder organizations, including pharmacy groups, hospital associations, consumer groups, and medical practice groups.

the Subcommittee directed the FDA to finalize its guidance document on developing abuse-deterrent drugs, as discussed in the previous Subsection.[101] In response, the FDA noted that though a final version would be helpful, the fact that the guidance was not finalized had not and would not prevent the FDA from evaluating proposals to include abuse-deterrence language in product labeling.[102] Though the FDA finalized the guidance document, it employed expertise to note that the distinction between draft and final guidance may have a limited practical impact on the actual approval of drugs with abuse-deterrent properties.[103] Therefore, agency expertise about available tools to implement policies provides another route to resist non-statutory instructions.

C. Oversight Uses of Committee Commentary on Guidance Documents

The findings in the previous Part show the Appropriations Committee comments regularly on agency action through non-statutory controls, and those comments significantly influence agency actions. It is therefore important to look at the ways the Appropriation Committee leverages these committee reports directives to influence agency actions. This Section describes three major ways the Subcommittee used committee report instructions to influence guidance document development: to encourage the FDA to consider input from

---

[101] *See supra* Part II.B.3.i.

[102] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 242–43 (2015)

[103] FDA, ABUSE-DETERRENT OPIOIDS—EVALUATION AND LABELING (April 2015). The FDA also used its policymaking expertise in the regenerative medicine example described in the previous Subsection. The FDA commented that there were a variety of other regulatory tools available to facilitate development and review of regenerative medicine products, such as considering proposals on a case-by-case basis, meeting with sponsors individually, and holding educational sessions, workshops, and advisory committee discussions. It also noted that other existing guidance documents could apply to this area and provide guidance. DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2017 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 279 (2016).

stakeholders, to monitor whether the FDA implemented statutes consistent with legislative intent, and to develop clear guidelines for industry. This Part provides descriptive examples to illustrate how the Appropriations Committee may leverage legislative history to monitor agencies.[104] These oversight uses have implications for concerns that guidance documents are not subject to organized congressional review nor do they contain formal procedures for public input. Thus, this Section also considers how committee directives may increase effective oversight and public participation in guidance development generally.

1. Encouraging the Agency to Consider Input from Stakeholders

The Appropriations Committee may influence agency action by instructing agencies to consult with stakeholders when developing guidance documents. In this study, the Subcommittee directed the FDA to consult with two major constituencies when developing guidance documents: regulated entities and regulatory beneficiaries. Using committee oversight to encourage agencies to meet with stakeholders provides an avenue to increase public participation in guidance development.

i. Regulated Entities

Regulated entities include the members of industry directly regulated through agency rules and enforcement actions. In committee reports, the Subcommittee instructed the FDA to meet with and to consider input from entities that would be directly regulated by new guidance documents. For example, in the 2013 House report, the Subcommittee expressed concern that the FDA was using a guidance document about dietary supplement ingredients to inform enforcement activities even though the guidance document was only in draft form.[105] Therefore,

[104] These various uses of oversight often overlap. The illustrative examples in each Section often had implications for the other uses of oversight as well.
[105] H. REP. NO. 112-542, at 47–48 (2012).

the Subcommittee urged the FDA to withdraw the draft guidance and re-engage with the dietary supplement community to develop a new guidance document about what constitutes a "new dietary ingredient."[106] The FDA ultimately held meetings with dietary supplement trade associations to discuss issues of concern, then eventually published a revised draft guidance document.[107] Thus, the committee report directives encouraged the FDA to meet with regulated entities to revise a guidance document that influenced regulation of their industry.

This suggests committee oversight could be used to encourage agencies to meet with regulated entities during guidance development. Promoting meetings with stakeholders when the agency is developing guidance may help address some concerns about the lack of public participation in guidance development due to the lack of formal procedures.[108] The dialogue between the committee and the agency also promotes transparency when the agency responds with information about which entities the agency met with regarding the guidance document. Overall, even when a committee encourages agencies to meet with regulated entities that already have relationships with the agency and are already providing input directly to the agency, the committee oversight can provide a mechanism to reinforce public participation and to monitor which stakeholders the agencies are consulting during guidance development.

ii. Regulatory Beneficiaries

Beyond encouraging meetings with regulated entities, the Subcommittee also used committee report provisions to encourage the FDA to meet with regulatory beneficiaries to

---

[106] *Id.* The next year, the Subcommittee followed up on these concerns, and directed the FDA to report back with a timeline for plans to re-engage the dietary supplement community. *See* H. REP. NO. 113-116, at 54 (2013).

[107] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 171 (2014); FDA, DIETARY SUPPLEMENTS: NEW DIETARY INGREDIENT NOTIFICATIONS AND RELATED ISSUES: GUIDANCE FOR INDUSTRY 1 (August 2016).

[108] *See supra* Part II.A.2.

develop guidance. Regulatory beneficiaries include entities that are not directly regulated from agency action but benefit from the effects of agency regulation. The Subcommittee encouraged the FDA to meet with regulatory beneficiaries about guidance in two subject areas—the artificial pancreas and Duchenne Muscular Dystrophy. To encourage development of artificial pancreas systems for diabetes patients, the Subcommittee encouraged the FDA to collaborate with stakeholders in committee reports over three years.[109] The FDA issued new guidance documents, considered public comments, and met with stakeholders.[110] This process helped a regulatory beneficiary, the Juvenile Diabetes Research Foundation (JDRF), play a particularly important role in the guidance development and implementation process. JDRF proposed draft guidance to the FDA, conducted an extensive campaign, and provided comments on the draft guidance.[111] Moreover, the FDA co-sponsored a public workshop with the National Institutes of Health and the JDRF.[112]

With respect to Duchenne Muscular Dystrophy guidance, the Subcommittee commended the FDA for collaborating with patient groups. The Subcommittee encouraged the FDA to continue its collaborative approach to evaluate the needs of the rare disease community.[113] The rare disease community included a regulatory beneficiary, the Parent Project Muscular

---

[109] S. REP. NO. 112-73, at 80 (2011); S. REP. NO. 112-163, at 78 (2012); S. REP. NO. 113-116, at 57 (2013).
[110] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2014 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 446 (2013); DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 178, 180 (2014).
[111] William Soresnsen, Final FDA Artificial Pancreas Guidance a Milestone for People with Type 1 Diabetes, http://advocacy.jdrf.org/wp-content/uploads/sites/111/2012/09/11-13-12-AP-Final-Guidance-JDRF-Statement-FINAL-docx3.pdf.
[112] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 178, 180 (2014).
[113] H. REP. NO. 113-468, at 59 (2014); H. REP. NO. 114-205, at 59 (2015); S. REP. NO. 114-82, at 85 (2015).

Dystrophy organization (PPMD). PPMD exerted significant influence over the guidance development. PPMD submitted a sample draft guidance to the FDA.[114] The FDA then sought public comment on PPMD's proposed guidance and used that input to write the draft guidance document it ultimately issued in 2015.[115] Thus, both the artificial pancreas guidance and the Duchenne Muscular Dystrophy guidance represent examples where the Subcommittee encouraged and reinforced FDA collaborations with regulatory beneficiaries when developing guidance documents.

Similar to encouraging agencies to consult with regulated entities, encouraging agencies to consult with regulatory beneficiaries furthers public participation. Providing access to regulatory beneficiaries is particularly important though because of concerns that regulatory beneficiaries may lose opportunities for input through the shift toward regulating via guidance documents.[116] Regulatory beneficiaries do not get a chance to challenge agency reasoning to guidance documents in enforcement proceedings, and often have less political clout or relationships with agencies to provide input during early stages of guidance development.[117] Thus, using committee report language to encourage agencies to consult with regulatory

---

[114] FDA Draft Guidance on Duchenne, ENDDUCHENNE.ORG, http://www.parentprojectmd.org/site/PageServer?pagename=Advocate_fdaguidance

[115] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 233 (2015) (noting that it "appreciate[d] the hard work of the Parent Project Muscular Dystrophy"). The purpose of this guidance is to encourage development of drugs to treat diseases like X-linked DMD. DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2017 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 265–66 (2016). The FDA has since finalized the guidance document. FDA, DUCHENNE MUSCULAR DYSTROPHY AND RELATED DYSTROPHINOPATHIES: DEVELOPING DRUGS FOR TREATMENT GUIDANCE FOR INDUSTRY (Feb. 2018).

[116] Mendelson, *supra* note 53, at 430–31.

[117] *Id.* at 420–33.

beneficiaries could be an especially useful way to promote public participation in guidance development.

2. Monitoring the Agency's Statutory Interpretation

Another way the Appropriations Committee may influence agency action is to monitor whether agency implementation of policies comports with legislative intent behind the statutes granting authority to agencies. In this study, the Subcommittee utilized committee report provisions to monitor whether FDA action complied with legislative intent in a couple of ways. First, the Subcommittee expressed its view about how to interpret ambiguous statutory provisions and directed the FDA to issue guidance clarifying its interpretation of the statute. Second, the Subcommittee directed the FDA to ensure it followed clear statutory directives, like meeting a deadline to issue a new document. Both of these uses provide an avenue to increase congressional oversight of informal policymaking despite the lack of organized legislative oversight of guidance documents.

i. Interpretation of Ambiguous Statutes

The Subcommittee used committee reports to weigh in on the FDA's statutory interpretation of ambiguous statutes. For example, on the topic of special protocol assessments, the Subcommittee provided its interpretation of a statute in a committee report and directed the FDA to issue guidance.[118] A Special Protocol Assessment (SPA) is an advanced declaration from the FDA that a clinical trial design is acceptable for FDA approval. This allows a company to use its designed clinical trial to test a potential pharmaceutical product without concerns that the FDA will object to the trial design if the company ultimately applies for approval of the product it is testing. A statute grants the FDA authority to rescind a SPA if the FDA identifies a

[118] H. REP. NO. 113-468, at 59 (2014); S. REP. NO. 113-164, at 86 (2014).

new scientific issue that questions the product's safety or efficacy.[119] After the FDA rescinded approval of a specific product, the Subcommittee commented that it interpreted the statute to require the FDA to give notice to the sponsors when new scientific issues came to the agency's attention.[120] The Subcommittee then instructed the FDA to issue a new guidance document clarifying its statutory authority to rescind SPAs.[121] The FDA responded that it made decisions based on a careful review of statutory standards and published a revised draft guidance.[122]

The Subcommittee also commented on legislative intent in the area of drug compounding, expressing concern that the FDA interpreted sections of the Drug Quality and Security Act in a manner inconsistent with legislative intent.[123] The FDA interpreted § 503A to prohibit a practice known as "office-use compounding." The Subcommittee, however, stated that the statute did not intend to prohibit this practice.[124] The Subcommittee then directed the FDA to issue a guidance document on how pharmacists could continue to engage in office-use compounding.[125] The FDA responded with its own statutory interpretation, explaining that though office-use compounding is important, it poses health risks as the drugs used are not approved by the FDA

---

[119] § 505(b)(5)(C)(ii) of the Food, Drug, and Cosmetic Act
[120] H. REP. NO. 113-468, at 59 (2014); S. REP. NO. 113-164, at 86 (2014).
[121] H. REP. NO. 113-468, at 59 (2014); S. REP. NO. 113-164, at 86 (2014). The Subcommittee also commented that though the FDA had statutory authority to rescind SPAs, public policy and fairness required sufficient notice to the companies.
[122] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 233 (2015). The FDA has since finalized the guidance document. FDA, SPECIAL PROTOCOL ASSESSMENT GUIDANCE FOR INDUSTRY (April 2018).
[123] H. REP. NO. 114-531, at 67 (2015). The Subcommittee also noted that this interpretation was inconsistent with the agency's own prior interpretations. The 2017 House report again directed the FDA to issue a final guidance document that provided for "office-use" drug compounding in appropriate circumstances. H. REP. NO. 114-205, at 69 (2016).
[124] H. REP. NO. 114-531, at 67 (2015).
[125] *Id*.

and recently led to incidents of contamination.[126] The FDA thus concluded that § 503A intended to place conditions on the practice.[127] The FDA ultimately issued a guidance document that described how pharmacists could engage in office-use compounding permissibly under the statute.[128]

Leveraging non-statutory instructions to monitor whether agency actions comply with legislative intent helps Congress monitor whether the agency is executing laws consistent with legislative intent. In the guidance context in particular, the Appropriations Committee can provide an avenue for regular, organized oversight since congressional oversight of guidance currently occurs ad hoc without an organized framework.[129] However, leaving this oversight to the Appropriations Committee, or even to just the Subcommittee who drafts the committee report, highlights concerns that the "legislative intent" as defined by the small group of elected officials may not reflect the true legislative intent of Congress as a whole.[130] This is particularly

---

[126] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2017 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 263–64 (2016).
[127] *Id.* To establish policies on office use compounding, the FDA intended to consider public health issues as well as the statutory language and the need to provide a clear line between permissible compounding and impermissible manufacture of unapproved drugs.
[128] FDA, PRESCRIPTION REQUIREMENT UNDER 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (April 2016). Interestingly, the 2017 House report commented on the draft guidance and directed the FDA to finalize the guidance document, with specific instructions to allow office-use compounding before receipt of a prescription. H.R. Rep. 114-531, at 68–69 (2016). The FDA finalized the document, but responded that the statute does not allow for office-use compounding before the compounder receives a prescription for an individual patient and explained the importance of the prescription requirement. DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2018 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 250–51 (2017). In the 2018 House report, the Subcommittee reiterated that the statute intended to allow compounding in anticipation of receiving a prescription. H.R. Rep. 115-232, at 69 (2017). The report went on to instruct the FDA to rescind the guidance document and publish a proposed rule that is consistent with congressional intent "as stated in both Appropriations Reports and the DQSA." *Id.*
[129] *See supra* Part II.A.1.
[130] *See* Manning, *supra* note 21, at 688.

problematic for older statutes. In the examples above, the drug compounding statute was passed in November 2013, and the Subcommittee provided its commentary in 2015.[131] Thus, members of the Subcommittee could have been involved in passing that legislation and were likely familiar with the legislative process behind that statute. For SPAs, however, the relevant statute passed in 1997 and the Subcommittee provided its commentary in 2014, many years later.[132] The passage of time creates a greater disconnect between the enacting Congress and the interpreting Congress. Thus, though committee interpretation of ambiguous statutes can provide a useful mechanism to monitor agency implementation of statutes, the potential for bias warrants attention and reinforces the need for agencies to retain flexibility in their responses to committee report instructions.[133]

ii. Implementation of Clear Statutory Directives

The Subcommittee also used committee reports to monitor whether the FDA complied with less ambiguous statutory provisions, such as deadlines for the FDA to issue certain documents. For example, the Sunscreen Innovation Act included a deadline for the FDA to publish four guidance documents.[134] In the 2016 House report, the Subcommittee directed the FDA to meet its statutory deadline to publish guidance regarding safety and efficacy standards

---

[131] 21 U.S.C. § 353a; H. REP. NO. 114-531, at 67 (2015).
[132] Pub. Law No. 105-115 (1997), codified at 21 U.S.C. § 355; H. REP. NO. 113-468, at 59 (2014); S. REP. NO. 113-164, at 86 (2014).
[133] Here, the FDA appeared to maintain its flexibility. Though it ultimately issued a guidance document for drug compounding, it employed its substantive expertise to defend its own statutory interpretation in response to the Subcommittee oversight, as described previously. This helps combat some of the concerns about vesting too much influence in a committee.
[134] Sunscreen Innovation Act, Pub. Law No. 113-195.

for sunscreen active ingredients.[135] The FDA then issued the guidance document six days before the deadline.[136]

Again, Appropriations Committee commentary can provide a way to increase congressional oversight of informal agency actions. Moreover, unlike with ambiguous statutes, concerns about committee bias are lower when the statute articulates a clear directive, such as a specific deadline. Using non-statutory controls to monitor statutory deadlines is especially significant because of recent concerns about regulatory delay. A recent study found federal agencies missed nearly half of the deadlines Congress set in statutes.[137] Since agencies frequently miss statutory deadlines, employing appropriations committee oversight to ensure agencies meet these deadlines could increase efficiency of statutory schemes. As the Appropriations Committee reviews agencies on yearly basis, its oversight provides a way for Congress to monitor when agencies miss deadlines and to prompt agencies to act quickly in the event of a missed deadline.

3. Developing Clear Guidelines for Industry

Congressional committees may influence agency action by prompting agencies to develop clear guidelines for industry. In this case study, the Subcommittee encouraged the FDA to develop clear guidelines for industry in two major ways: (1) to regulate behaviors and (2) to encourage development of new products. Using non-statutory instructions to develop new guidance documents can provide a mechanism for Congress to increase oversight and public participation in informal policymaking procedures.

---

[135] H. REP. NO. 114-205, at 74 (2015).
[136] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 278 (2016).
[137] Kevin R. Koser, *Federal Agencies Missed 1,4000 Regulatory Deadlines*, ROLL CALL (Aug. 5, 2015), http://www.rollcall.com/news/home/federal-agencies-missed-1400-regulatory-deadlines-commentary.

i. Regulating Behavior and Monitoring Compliance

The Subcommittee included committee report provisions that directed the FDA to issue guidance documents to regulate specific industry behaviors. For example, the Subcommittee instructed the FDA to issue guidance about the proper labeling of honey to protect consumers from misbranded and adulterated honey products that were entering the U.S. market.[138] The FDA responded by publishing a draft guidance document.[139]

The Subcommittee also used directions to provide guidelines for industry as a tool to monitor industry compliance. For example, antibiotic-resistance developing from human consumption of animals that had taken antibiotic drugs posed a rising public health problem. In response to this public health concern, the Subcommittee directed the FDA to issue guidance to provide pharmaceutical companies with guidelines on how they could modify antimicrobial drugs for animals to decrease potential antibiotic resistance in humans.[140] Moreover, the Subcommittee asked for a report about new drugs approved and a list of industry members who voluntarily complied with the guidance.[141] The FDA issued new guidance documents and published a list to its website with information about the approved drugs and sponsors voluntarily participating.[142]

---

[138] S. REP. NO. 112-163, at 79 (2012); S. REP. NO. 113-46, at 81 (2013).
[139] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 183 (2014). The FDA has since finalized the guidance document. FDA, GUIDANCE FOR INDUSTRY: PROPER LABELING OF HONEY AND HONEY PRODUCTS at 2 (February 2018).
[140] S. REP. NO. 112-73, at 80 (2011).
[141] S. REP. NO. 112-163, at 78 (2012); H. REP. NO. 113-116, at 53 (2013).
[142] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2015 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 168 (2014); FDA, NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 1 (Dec. 2013); FDA, THE

These instructions to develop clear guidelines can help promote public participation and congressional oversight in guidance development. The instructions can increase public participation when the committee passes along requests from the public for a guidance document. In the honey example, manufacturers had previously submitted a citizen petition requesting guidance from the FDA, and the FDA did not respond.[143] A specific instruction in the committee report then finally elicited a response from the FDA. Thus, the appropriations committee report bolstered public participation in the guidance development process. Additionally, these instructions can provide a framework for congressional oversight. In the antibiotic-resistant drugs example, the Appropriations Committee leveraged the new guidance to collect information about whether industry complied and developed new drugs. This information-gathering mechanism could allow Congress to monitor whether new legislation is needed to address public health concerns. Again, the Appropriations Committee is in a good position to facilitate information gathering as it reviews agency actions on a yearly basis and is familiar with the details of agency action.

ii. Encouraging Development of New Products

Committees can also instruct agencies to provide clear guidelines to incentivize regulated entities to develop new products. The Subcommittee used committee reports to direct the FDA to issue guidance documents that would encourage industry actors to develop new products. For example, the Subcommittee requested guidance to promote development of new products in the areas of fixed-combination drugs and antibacterial drugs.[144] The 2015 Senate report applauded FDA's draft guidance to promote development of fixed combination for drugs for diseases like

---

JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS at 3 (April 2012).

[143] S. REP. NO. 111-221, at 97 (2010).

[144] S. REP. NO. 113-164, at 82 (2014).

cancer, HIV, malaria, tuberculosis, and drug-resistant infections. The report then encouraged the FDA to finalize the guidance by the end of the calendar year to facilitate development of new treatments for these diseases.[145] The FDA responded by publishing a final guidance document.[146] Moreover, to promote antibiotic development to treat diseases like bacterial pneumonia and skin infections, the Subcommittee instructed the FDA to issue guidance about unresolved scientific issues in clinical development.[147] Since then, the FDA has issued three draft guidance documents relating to these topics.[148] These examples show how the Subcommittee leveraged legislative history to encourage new guidance documents aimed at promoting the development of new drugs.

Committee instructions that prompt agencies to publish guidance to spark development of specific products provide another example of how appropriations committee oversight can provide an avenue to increase congressional oversight in informal agency policymaking. Similar to the oversight about industry behaviors, appropriations committee oversight gives the committee an opportunity to monitor whether desired progress is being made on a yearly basis and to evaluate the need for future legislation to provide statutory incentives to develop products. Additionally, if the committee report instructions reflect requests from constituents contacting congressmen about the desire for clear guidance, it can serve to reinforce public participation.

---

[145] *Id.*

[146] DEP'T HEALTH & HUMAN SERVS., FDA FISCAL YEAR 2016 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, at 248–49 (2015).

[147] S. REP. NO. 111-221, at 93–94 (2010). The Subcommittee also asked for a report to include efforts to work with other governmental entities and interested parties to identify ways to incentivize development and/or appropriate use of anti-bacterial drugs in humans.

[148] FDA, HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA AND VENTILATOR-ASSOCIATED BACTERIAL PNEUMONIA: DEVELOPING DRUGS FOR TREATMENT (May 2014); FDA, COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA: DEVELOPING DRUGS FOR TREATMENT (Jan. 2014); FDA, ACUTE-BACTERIAL SKIN AND SKIN-STRUCTURE INFECTIONS: DEVELOPING DRUGS FOR TREATMENT (Oct. 2013).

Overall, this Part suggests that Congress, and particularly the Appropriations Committee, plays an influential role in agency policymaking. In the guidance document context specifically, appropriations committee oversight can provide opportunities for more consistent legislative oversight and more public participation. This study showed that the Subcommittee used legislative history to prompt the FDA to consult with stakeholders, to monitor how the FDA interpreted statutes, and to publish new industry guidelines. The FDA followed most non-statutory instructions to develop new guidance documents, though it occasionally leveraged its expertise to resist. On balance, the committee report instructions and FDA responses demonstrate that Congress may play a more significant role in overseeing informal agency actions than previously recognized. The next Part discusses implications of this congressional involvement in agency action for larger debates about the relationship between agencies and Congress.

III. IMPLICATIONS

This Article suggests agencies pay close attention to non-statutory instructions, and congressional committees can leverage these non-statutory instructions for a variety of oversight uses. When agencies faithfully follow legislative history instructions, it provides an increased role for Congress in regulatory policymaking. This Part evaluates how these findings affect debates about interactions between Congress and agencies. Congressional oversight through appropriations committee reports implicates several separation of powers issues, particularly with respect to the nondelegation doctrine, the legislative veto, and encroachment on the executive. This Part argues that though appropriations committee oversight through legislative history does not formally violate separation of powers, the separation of powers issues warn about the dangers of unchecked congressional involvement in agency actions. Such strong influence at the committee level brings up policy concerns about public participation and

political accountability. These concerns underscore the importance of transparency in interactions between committees and agencies.

A. Separation of Powers Issues

A fundamental premise underlying the American constitutional system is that separation of the judicial, executive, and legislative powers is necessary to preserve liberty.[149] Congressional involvement in the details of agency actions, therefore, raises separation of powers concerns about whether the legislative and executive branches are truly operating separately. This Section analyzes three major separation of powers issues—the nondelegation doctrine, the legislative veto, and legislative encroachment on the executive. On balance, committee oversight can provide an effective means to help police the nondelegation doctrine. Moreover, committee oversight does not amount to an unconstitutional violation separation of powers because the directives are nonbinding and agencies retain flexibility in their responses. Yet while not formally violating the Constitution, appropriations committee oversight may alter negotiating dynamics between Congress and agencies, shifting the balance of power toward Congress. This shift in the balance of power brings up policy concerns that underlie the separation of powers issues. In particular, the fact that such oversight occurs at the committee level, rather than from Congress as a whole, may risk committee bias or interest group capture. This Section therefore also evaluates implications of the separation of powers issues for political accountability and public participation, highlighting the importance of transparency in committee-agency interactions.

---

[149] Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 635 (1952) (Jackson, J., concurring); The Federalist No. 47, p. 325 (J. Cooke ed. 1961).

1. The Nondelegation Doctrine

A separation of powers concern arises if agencies act in a *legislative* capacity. The nondelegation doctrine states that under the Constitution, the legislative branch cannot delegate lawmaking authority to another branch.[150] So for a delegation of authority to be constitutional, Congress must provide an "intelligible principle" to guide agency discretion.[151] Yet the Supreme Court has expansively interpreted "intelligible principle," permitting broad delegations of authority to the administrative state.[152] In fact, in its entire history, the Supreme Court has only found two statutes lacked an intelligible principle.[153] Therefore, in the modern administrative state, the "intelligible principle" standard is not closely policed.[154] Rather, broad delegations are the norm. It is, thus, important for agencies to implement law consistent with congressional intent.[155] The constitutional legitimacy of these broad delegations of lawmaking authority to unelected regulators may hinge on whether regulators act as faithful agents of Congress.[156]

Appropriations committee oversight may help reinforce the nondelegation doctrine because it provides an effective tool for Congress to monitor whether agencies are faithfully

---

[150] U.S. Const. art. I, § 1.
[151] Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457 (2001); J.W. Hampton, Jr. & Co. v. United States, 276 U.S. 394 (1928).
[152] Whitman, 531 U.S. at 486 (finding "requisite to protect public health" a sufficient intelligible principle).
[153] *Id.* at 474.
[154] *See* Lawson, *supra* note 29, at 1237–41 (describing the "death" of the nondelegation doctrine).
[155] Watts, *supra* note 19, at 45 ("It is a well-accepted rule of administrative law that federal administrative agencies, which act pursuant to congressional delegations of power, must act consistent with congressional intent and must consider only factors that Congress intended the agency to consider.")
[156] Walker, *supra* note 6, at 1002–03; *see also* Mashaw, *supra* note 5, at 505 ("In some sense, the position of agencies as 'faithful agents' of the legislature has a constitutional clarity that exceeds that of the judiciary.").

implementing statutes.[157] The Appropriations Committee is in a good position to monitor agency actions since subcommittees meet with agencies within their jurisdictions on a regular basis and issue committee reports yearly. As shown in the previous Part, the appropriations committee reports are able to annually comment on and monitor specific agency actions at a detailed level. For example, when the FDA did not finalize a guidance document regarding abuse-deterrent opioid drugs, the Subcommittee followed up the next year with a statutory directive.[158] The FDA then finalized the guidance document. Moreover, appropriations committee oversight can help address information asymmetry problems for Congress in monitoring whether agencies implement statutes consistent with legislative intent. For example, the Subcommittee asked the FDA to elaborate on its interpretation of the SPA statute and used the opportunity to provide its own interpretation of the law.[159] Moreover, through its responses in budget justifications, the FDA frequently provided Congress with its statutory interpretation as well as insights from its expertise.[160] Therefore, appropriations committee oversight could help ensure agencies are acting as faithful agents to execute the law. This could serve to support the constitutional legitimacy of the administrative state by bolstering the nondelegation doctrine.

Leaving oversight to the Appropriations Committee, rather than to Congress as a whole, however, sparks concerns about committee bias and interest group capture. If the purpose of oversight is to ensure agencies faithfully implement the wishes of the principal, one committee may not truly be the "principal." The committee only consists of a subset of the total members

---

[157] It is widely accepted that the administrative state makes policy decisions. However, the constitutional foundations of the branches of government underscore the importance of congressional oversight of these policy decisions.
[158] *See supra* notes 65–67 and accompanying text.
[159] *See supra* Part II.C.2.i.
[160] *See supra* Part II.B.3 and II.C.2.

of Congress, and individual committee members' views of legislative intent may not align with the views of the collective Congress, particularly if the committee interprets statutes that were passed years ago by prior congresses.[161] For example, in the SPA statute, the Subcommittee interpreted a statute passed seventeen years earlier.[162] Moreover, individual committee member bias could cloud the oversight activities, as subcommittee members tend to be proponents of the programs whose budgets they review.[163] Though previously scholars viewed appropriations committee members as neutral guardians of the budget who were attracted to the committee position based on prestige, more recent studies show appropriations committee members are likely to seek to benefit their congressional districts.[164] Professor Adler found the Agriculture Subcommittee in particular was likely to be disproportionately comprised of representatives from rural farming districts, and such membership results in increased outlays for agriculture funding.[165] Moreover, since the subcommittees writing the reports consist of just a handful of elected officials each, there is potential for interest group capture. Lobbying organizations and powerful constituents can form relationships with the specific individuals on the subcommittees,

---

[161] Professor Kirst, however, noted that these committee report provisions can still be subject to oversight by Congress at large. KIRST, *supra* note 8, at 138–52.
[162] *See supra* Part II.C.2.i.
[163] JOSEPH HARRIS, CONGRESSIONAL CONTROL OF ADMINISTRATION 101-03 (1964); *see also* William N. Eskridge, Jr., *Legislative History Values*, 66 CHI.-KENT L. REV. 365, 383–84 (1990).
[164] E. SCOTT ADLER, WHY CONGRESSIONAL REFORMS FAIL 54-71 (2002); *see also* SCHICK, *supra* note 32, 220–21 (describing how the appropriations process has become enmeshed in party politics).
[165] ADLER, *supra* note 164, at 70–71, 97. This Article does not look at oversight of the Subcommittee to the USDA, which would more accurately illustrate potential bias for agriculture districts. However, these results show the concerns about capture and bias within the Subcommittee. The findings presented in Part II.A.3 that the Subcommittee comments on a disproportionately high percentage of drug-related guidance documents, for example, suggests bias is still a concern in the food and drug context of the Subcommittee's oversight also.

giving them an ability to influence the subcommittees.[166] In this case study, the Subcommittee directed the FDA to consult with specific organizations on multiple occasions.[167] This suggests particular organizations, especially those with political clout, may be able to disproportionately impact how the Appropriations Committee exercises oversight.

These concerns about committee bias and interest group capture may present different risks in the different ways the committee leverages legislative history. For example, concerns about committee bias are low when the committee is merely directing the agency to meet a clear statutory deadline, as it did with the Sunscreen Innovation Act.[168] Actions that seek to benefit specific regulated entities, on the other hand, may be more suspicious. Thus, to guard against these concerns, transparency is important. Transparency not only allows the public to hold the committee accountable, but also allows other members of Congress to be more informed of how the committee is exercising oversight.[169] Detailing directives to agencies in legislative history, rather than engaging in informal conversations, promotes transparency by creating a written record. Thus, the detailed provisions in the committee reports help mitigate concerns about committee bias.

2. The Legislative Veto

A distinct separation of powers concern arises when Congress acts in a legislative capacity without following the full constitutional procedures. The "legislative veto" cases illustrate this concern. For half a century and increasingly in the 1970s, Congress passed statutes

---

[166] ROGER H. DAVIDSON & WALTER J. OLESZEK, CONGRESS & ITS MEMBERS, 383–84 (9th ed. 2004).

[167] In particular, the Subcommittee directed the FDA to consult with the dietary supplement industry, the Juvenile Diabetes Research Foundation (JDRF), and the Parent Project Muscular Dystrophy organization (PPMD). *See supra* Part II.C.1.ii.

[168] *See supra* Part II.C.2.ii.

[169] DAVIDSON, *supra* note 166, at 382 (noting that countervailing forces like citizen groups and aggressive journalists have helped decrease the power of interest groups over committees).

that included veto provisions for Congress to invalidate executive actions.[170] These provisions allowed two-house vetoes, one-house vetoes, and committee vetoes—all of which did not submit the actions to the President for his signature or veto.[171] In *INS v. Chadha*, the Supreme Court found the legislative veto unconstitutional, holding that Congress cannot engage in legislative actions without going through bicameralism and presentment.[172] The opinion emphasized that efficiency benefits do not make a government action constitutional.[173] Instead, to determine whether action is legislative, and thus subject to the bicameralism and presentment requirements, the Court instructed that one must look to whether the action is essentially legislative in character and effect. The Court explained that legislative actions alter the "legal rights, duties, and relations" of persons outside the legislative branch.[174]

Therefore, since committee reports do not go through bicameralism and presentment, appropriations committee report directives could present a separation of powers problem if the instructions are considered legislative actions. The previous Part showed that these committee report instructions often had the de facto effect of vetoing or prompting FDA action. For example, when the Appropriations Committee directed the FDA to issue guidance on antibiotic resistance in drugs, the FDA followed suit.[175] Moreover, the FDA rescinded and revised its draft

---

[170] James Abourezk, *The Congressional Veto: A Contemporary Response to Executive Encroachment on Legislative Prerogatives*, 52 IND. L.J. 323, 324 (1977); JESSICA KORN, THE POWER OF SEPARATION 31 (1996).
[171] Louis Fisher, Cong. Research Serv., Legislative Vetoes after *Chadha* 1 (2005).
[172] INS v. Chadha, 462 U.S. 919, 956–59 (1983). All legislative vetoes violated presentment because they were not submitted to the President, and one-house and committee vetoes violated the bicameralism requirement.
[173] *Id.* at 944.
[174] *Id.* at 952.
[175] *See supra* Part II.C.3.i.

guidance on dietary supplement ingredients in response to a committee report instruction.[176] Yet these non-statutory instructions are not likely to qualify as the type of legislative action that would violate the Constitution.

Scholars have noted that informal and non-statutory controls have continued in the present day, and such informal oversight mechanisms do not run afoul of *Chadha*.[177] Moreover, courts (including the *Chadha* Court itself) have found statutes that require an agency to report to Congress about actions but do not give Congress the power to actually veto an executive action are still constitutional.[178] Such reporting provisions allow Congress to analyze executive action and to "badger an agency with extensive questions or threats if the proposed action is somehow unsatisfactory"—but these provisions do not give Congress power to overturn agency action through a process that shortcuts the full legislative process.[179] Moreover, in reviewing a statute with a reporting provision, the U.S. Court of Appeals for the Federal Circuit explained that there is nothing unconstitutional about an agency's decision to defer to a committee's opinion. Instead, the Federal Circuit noted that informal cooperation is necessary within the separation of

---

[176] *See supra* Part II.C.1.i.

[177] Louis Fisher, *supra* note 171, at 2–4; *see also* KORN, *supra* note 170, at 33, 42–43 (arguing that the legislative veto was not as essential to government functions as some suggest due to Congress's other tools for oversight).

[178] Rather than unilaterally vetoing executive action, such statutes give Congress the opportunity to review agency action and assess the need for more legislation. If Congress objects to the executive action, it can pass new legislation before the executive action becomes effective. City of Alexandria v. United States, 737 F.2d 1022, 1026 (Fed. Cir. 1984); INS v. Chadha, 462 U.S. 919, 935 n.9 (1983); Fisher, *supra* note 171, at 6. *But see* Hechinger v. Metro. Wash. Airports Auth., 36 F.3d 97 (D.C. Cir. 1994), cert. denied, 513 U.S. 1126 (1995) (invalidating a statutory provision that required reporting and allowed a board, acting as an agent of Congress, to make recommendations when it had a coercive effect on agency action in context because the delays effectively nullified the time-sensitive agency action and the board had discretion over which actions to review).

[179] KORN, *supra* note 170, at 35.

powers system.[180] Thus, congressional oversight mechanisms that rely solely on informal political pressures or on a threat to re-engage in the full legislative process are constitutional even after *Chadha*.[181] The fact that in practice these informal oversight tools may amount to legislative vetoes because agencies follow committee instructions does not make them unconstitutional.

Committee report directives are more akin to these constitutionally sound report-and-wait provisions than to actual legislative vetoes. Though the non-statutory instructions encourage agencies to take certain actions, and provide a tool for the committee to oversee and "badger" agencies about particular actions, they do not legally require the agency to follow the committee report provisions.[182] Instead, agencies still retain flexibility to disagree with the committee report instruction or to implement the directives at their own pace. For example, the FDA did not issue a guidance document about botanical dietary supplements despite committee report directions to do so.[183] Moreover, on five substantive topics, the Subcommittee repeated its non-statutory instructions before the FDA actually issued a new guidance document.[184] Thus, appropriations committee oversight is likely not an unconstitutional exercise of legislative power.

---

[180] City of Alexandria v. United States, 737 F.2d, at 1026 ("Committees do not need even the type of 'report and wait' provision we have here to develop enormous influence over executive branch doings.").

[181] KORN, *supra* note 170, at 35. Moreover, as a practical matter, appropriations committee report directives will continue. OMB Director, James Miller, during the Reagan administration announced to agency heads they did not need to follow appropriations committee report directives because they were not voted on by both houses of Congress nor presented to the President. The appropriations committee responded that it would just tie agencies hands with stricter, statutory directives, which agencies did not want. Afterwards, Miller ended up rescinding his statement. *Id.* at 37.

[182] *See* KORN, *supra* note 170, at 35.

[183] *See supra* notes 75–77 and accompanying text.

[184] *See supra* note **Error! Bookmark not defined.**.

Yet these committee report provisions often have the practical effect of prompting executive agencies to engage in specific actions, as shown in the previous Part. The FDA issued a new guidance document in response to eighty-two percent of appropriations committee report instructions to do so. The reality that the Appropriations Committee can influence agencies to take action, therefore, brings up policy concerns associated with the legislative veto, particularly related to the negotiating dynamics between agencies and Congress. In fact, before the legislative veto was declared unconstitutional, the actual veto power was not used very often by Congress.[185] Instead, a study by Professors Harold Bruff and Ernest Gellhorn found that the primary effect of the legislative veto power was to alter negotiating dynamics between Congress and agencies.[186] The existence of the veto power caused agencies to negotiate with Congress, primarily with oversight committees, over the substance of policy to avoid invoking a formal veto. Therefore, the veto operated to increase Congress's bargaining power, and prompted more negotiations between Congress and agencies over the substance of agency action.[187] The actual impact on the negotiation process varied by agency, as Bruff and Gellhorn found that different agencies had different bargaining power with respect to Congress.[188] However, despite varying

---

[185] Clark Norton, Cong. Research Serv., Interim Report on the Exercise of Congressional Review, Deferral and Disapproval Authority Over Proposed Executive Actions, 1960-1973 11 (1976).
[186] Bruff & Gellhorn, *supra* note 54, at 1420.
[187] *Id.* at 1420–23.
[188] Factors such as pressure from courts, expertise in technical areas, and popular pressure could increase an agency's relative bargaining power, while congressional self-interest in particular agency actions, such as election regulations, could decrease agency bargaining power. Moreover, yearly review may make agencies more likely to compromise with Congress as part of ongoing interactions, like the yearly appropriations process, rather than singular review of a specific agency action. *Id.* at 1411.

levels of agency bargaining power, the negotiation process between committees and agencies always resulted in some form of compromise.[189]

Appropriations committee oversight may operate in a similar way. The threat of a potential legislative veto is similar to the threat of taking away funding in the appropriations context. Agencies may be motivated to negotiate with the Appropriations Committee to avoid reductions in funding in subsequent years. Thus, the ability of the Appropriations Committee to reduce agency funding in yearly appropriations bills could work to increase the bargaining power of the committee. This increased bargaining power may then prompt negotiations between agencies and the committee over the substance of agency action. As shown in the previous Part, the interactions between the Subcommittee in its committee reports and the FDA in its responses in yearly budget proposals reveal such a negotiation. The Subcommittee and the FDA exchanged detailed dialogue about the substance of specific guidance documents. Moreover, similar to the Gellhorn and Bruff study about the impact of the legislative veto, the negotiations between the Subcommittee and the FDA usually resulted in a compromise—the FDA ultimately issued a guidance document in response to the Subcommittee's requests in eighty-three percent of the substantive areas, and the Subcommittee resorted to statutory directives in only two situations.[190] Therefore, committee report instructions may alter the working relationship between Congress and agencies.

Thus, appropriations committee oversight brings up policy concerns similar to those brought up by legislative veto provisions—namely, concerns about public participation and political accountability. The previous Part discussed how congressional oversight might provide

---

[189] *Id.*
[190] *See supra* Figure 4.

opportunities to increase public participation in guidance development. The heightened bargaining power of congressional committees, however, may work to reduce the value of public participation in procedures before the agency. The power of the committee in negotiations may shift agencies' focus from currently required public procedures, like those in the Good Guidance Practices, to congressional review procedures.[191] Formulation of rules or guidance documents during negotiations with Congress may displace the agency's consideration of public comment when drafting the document, making the document harder to change during the public comment process.[192] Here, interest groups that lobby Congress may be able to impact the substance of ultimate rules or guidance outside of the public comment process, or in addition to the public comment process.[193] However, the initial drafting of an agency rule or guidance document remains a critical stage in formulating policy, so public participation at the initial stage may help displace some of these concerns.[194] Moreover, a record of public comments from the earlier stages of drafting the document can help the agency resist congressional pressures, bolstering the agency's bargaining power.[195] Yet Bruff and Gellhorn found that when legislative vetoes existed in the rulemaking context, agencies sometimes drafted rules in anticipation of the interest groups to avoid unfavorable review by Congress.[196]

In this study, the FDA responses do not indicate these threats to public participation. In two situations, the committee report provisions directed the FDA to consult with specific

---

[191] *See* Bruff & Gellhorn, *supra* note 54, at 1378–79; *see also* OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (2007).
[192] Bruff & Gellhorn, *supra* note 54, at 1382, 1413.
[193] *Id.* at 1413.
[194] *Id.* at 1412–13.
[195] *Id.* at 1413. Bruff and Gellhorn noted this could shift emphasis from reasoned debate over policy to a showing of political strength meant to impress both the agency and Congress.
[196] *Id.*

stakeholders who submitted draft guidance. However, both of these were regulatory beneficiaries, which are groups that are traditionally considered to have less political clout and relationships with agencies.[197] The appropriations committee oversight, therefore, served to reinforce public participation. Moreover, when the Appropriations Committee encouraged the FDA to consult with industry stakeholders before issuing draft guidance relating to drug compounding, the FDA refused. Instead, the FDA maintained it would receive public comments after it issued draft guidance.[198] Thus, the FDA responses to appropriations committee oversight do not appear to pose threats for public participation. However, the concerns highlighted by Bruff and Gellhorn may be a concern in other contexts, warranting attention.

Another justification for congressional oversight is that it could increase political accountability of agency actions.[199] However, the increased bargaining power of a specific committee, rather than Congress as a whole, may cast doubts about political accountability.[200] As discussed in the previous Section, the composition of a committee is narrower than Congress as a whole, and oversight committees are often stacked with members of Congress who have interests favorable to the agencies they regulate.[201] Moreover, committee negotiations typically do not receive national publicity, so Congress may not truly be held accountable by the public for actions taken by one committee. This calls into question the idea of national responsibility to a national constituency that underlies the value of political accountability.[202] The risk that action will escape national attention is particularly high when the change prompted by a committee

---

[197] *See supra* Part II.C.1.ii; Mendelson, *supra* note 53, at 420–33.
[198] *See supra* notes 98–100 and accompanying text.
[199] Jamelle Sharpe, *Judging Congressional Oversight*, 65 ADMIN. L. REV. 183, 205, 220 (2013).
[200] Bruff & Gellhorn, *supra* note 54, at 1379, 1417.
[201] *Id.* at 1418; *see* ADLER, *supra* note 164, at 70–71, 97; DAVIDSON & OLESZEK, *supra* note 166, at 383–84; HARRIS, *supra* note 163, at 101–03.
[202] Bruff & Gellhorn, *supra* note 54, at 1418.

under the influence of an interest group has only a diffuse impact on the public at large, as then it is less likely to evoke public scrutiny.[203]

Overall, these potentially negative implications for public participation and political accountability highlight the need for transparency. Yet by their nature, agency contacts with congressional committees are likely to be confidential or undisclosed on the administrative record.[204] Thus, negotiations between committees and agencies over the substance of agency actions pose a threat to transparency if they occur off the record. Therefore, the public disclosure of appropriations committee reports and FDA responses in its budget justifications help guard against these concerns.

3. Encroachment on the Executive

The legislative veto issue highlights concerns that arise when Congress can circumvent the full legislative process to engage in legislative actions. A separation of powers concern also arises when Congress engages in *executive* actions. The American constitutional system emphasizes a separation of the judicial, executive, and legislative powers to preserve liberty.[205] For example, the Incompatibility Clause prevents Congress members from holding appointed office in either the executive or judicial branch.[206] Moreover, the Supreme Court has interpreted separation of powers more broadly to require that legislative officials cannot engage in executive actions, prohibiting legislative action that encroaches on the executive branch.

---

[203] *Id.* at 1419.
[204] *Id.* at 1377–78, 1413.
[205] Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 635 (1952) (Jackson, J., concurring); The Federalist No. 47 325 (Jacob E. Cooke ed., 1961).
[206] U.S. Const. art. I, § 6.

In *Bowsher v. Synar*,[207] the Court invalidated a statute that allowed a legislative official to retain ultimate authority over spending reductions for budget deficit reductions. The statute required the President to issue sequestration orders as mandated by the Comptroller General.[208] Such actions fell within the purview of "executive" action because the Comptroller General had to exercise judgment about facts that affect application of the law and interpreted the law.[209] The Court reasoned, "Interpreting a law enacted by Congress to implement the legislative mandate is the very essence of 'execution' of the law."[210] The Comptroller General was a legislative official because he worked for the Government Accounting Office, which is a legislative branch agency, and was removable by Congress.[211] The Court emphasized that "[t]he structure of the Constitution does not permit Congress to execute the laws."[212] Thus, *Bowsher* limits the ability of Congress to retain non-legislative, post-enactment involvement in the administration of federal law.[213]

Moreover, in *Metropolitan Washington Airports Authority v. Citizens for the Abatement of Aircraft Noise, Inc*. (*MWAA*), the Court invalidated a statute that established a Board of Review for National and Dulles Airports, which consisted of nine congressmen serving in their "individual capacities as representatives of users of the airports."[214] This Board would oversee the Metropolitan Washington Airports Authority. Even though members were serving in their individual capacities, the Court found that situations like this would impermissibly allow

---

[207] 478 U.S. 714 (1986).
[208] *Id.* at 718.
[209] *Id.* at 732–33.
[210] *Id.* at 733.
[211] *Id.* at 727–31.
[212] *Id.* at 726.
[213] Sharpe, *supra* note 199, at 193.
[214] 501 U.S. 252, 267 (1991).

Congress to retain control outside the ordinary legislative process of administration of the laws.[215] The Court quoted James Madison to reiterate that when power is of an "encroaching nature," it must be "restrained from passing the limits assigned to it."[216]

Thus, appropriations committee directions to agencies could violate separation of powers if the Committee encroached on executive actions when it interpreted laws or retained control over statutory administration. For example, the Subcommittee could be said to be engaging in executive actions when it directed the FDA to consult with certain stakeholders when developing guidance or directed the FDA to issue guidance and publish certain information on its website.[217] One could argue these attempts to micromanage how the agencies implement statutes amount to encroachment since the FDA followed non-statutory instructions at such a high rate. However, unlike in *Bowsher*, the appropriations committee members do not retain ultimate authority over agency action, and agencies are not obligated to carry out committee instructions without variation. Moreover, unlike *MWAA*, the committee members are not serving on a review board as part of the agency itself. Overall, agencies can resist legislative history directives, as shown in the drug compounding example where the FDA refused to begin meeting with stakeholders before publishing draft guidance.[218] Additionally, courts have recognized that some congressional control and oversight of agencies is permissible.[219] Therefore, appropriations

---

[215] *Id.* at 277.
[216] *Id.* at 273.
[217] *See supra* Part II.C.1 and Part II.C.3.ii.
[218] *See supra* notes 98–100 and accompanying text.
[219] INS v. Chadha, 462 U.S. 919, 955 n.19 (1983); *see also* Ameron, Inc. v. U.S. Corps of Eng'rs, 809 F.2d 979, 990 (3d Cir. 1986) (finding that the mere fact that a non-executive government official interprets a law does not necessarily mean the action encroaches on the executive).

committee oversight is likely not an example of unconstitutional encroachment on the executive.[220]

Indeed, some scholars have argued that congressional involvement in execution of the law is actually beneficial to increase political accountability of agency action.[221] Presidential oversight is often viewed as the central tool to ensure political accountability of agencies, and congressional oversight may reinforce political accountability as well.[222] Professor Jamelle Sharpe has argued that presidents dedicate insufficient resources to check most agency policymaking, so congressional oversight is needed to supplement presidential oversight.[223] Moreover, Congress uses oversight to respond to complaints brought by constituents.[224] However, as discussed in the previous Subsection, leaving oversight to a committee brings up concerns about committee bias and interest group capture.[225] The Appropriations Committee on its own may not respond to democratic preferences of the nation as a whole as perhaps the President or Congress at large may. Rather, the committee may focus on the interests of the

---

[220] Additionally, in *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009), the Court acknowledged that Congress and committees routinely influence agency officials. In a plurality opinion, Justice Scalia noted "the precise policy change at issue here was spurred by significant political pressure from Congress." *Id.* at 523. A majority upheld the agency adjudication because the agency provided a sufficient explanation, signaling that the fact that congressional influence was one factor in the agency's decisionmaking did not invalidate the action. The dissent emphasized that political preferences *alone* are insufficient to justify agency action though.

[221] Sharpe, *supra* note 199, at 220–27; Mendelson, *supra* note 19, at 1131, 1137; Watts, *supra* note 19, at 13, 42–45.

[222] Sharpe, *supra* note 199, at 204–06, 211–14; Mendelson, *supra* note 19, at 1137; Watts, *supra* note 19, at 35–37.

[223] Sharpe, *supra* note 199, at 205–06.

[224] McCubbins & Schwartz, *supra* note 37, at 165–66; Watts, *supra* note 19, at 36–37.

[225] See ADLER, *supra* note 164, at 70–71, 97; DAVIDSON & OLESZEK, *supra* note 166, at 383–84; HARRIS, *supra* note 163, at 101–03. This is one reason presidential oversight may be preferable to congressional oversight—the President represents a national constituency and thus has an incentive to take more of a national perspective and be more responsive to voter preferences than Congress. Mendelson, *supra* note 19, at 1137–38.

constituents the specific committee members serve, questioning whether the oversight is truly serving the value of political accountability.

Again, transparency is important to ensure congressional involvement does not exert influence distorted by committee bias. Professor Nina Mendelson and Professor Kathryn Watts have argued that requiring agencies to disclose how political oversight impacted their decisionmaking can increase accountability to other political actors and to constituents.[226] Moreover, they argue that disclosing political influences on agency action can help determine when agencies are influenced by legitimate versus illegitimate factors.[227] Thus, the following Section provides suggestions for increasing transparency in committee-agency dialogues.

B. Suggestions for Transparency and Public Participation

Appropriations committee oversight can provide an effective mechanism to monitor whether agencies are implementing statutes consistent with legislative intent. Yet as the power of the purse gives the Appropriations Committee increased bargaining power in substantive negotiations with agencies, concerns about committee bias and interest group capture arise. These concerns pose a potential threat to public participation and political accountability. Thus, transparency is crucial to balance efficient oversight and political accountability with potential for committee biases and abuses. Moreover, public participation is important for public accountability and reinforcing administrative law values. This Section provides suggestions for how Congress and agencies can increase transparency about the dialogue between committees and agencies as well as increase public participation in the regulatory process.

---

[226] Mendelson, *supra* note 19, at 1131; Watts, *supra* note 19, at 42–45.
[227] Mendelson, *supra* note 19, at 1131, 1140–46; Watts, *supra* note 19, at 53–57.

Agency transparency about their responses to appropriations committee report directives is particularly important to promote political accountability. Public disclosure of agency responses would demonstrate to both the public and to Congress how the committee influences agency action.[228] Appropriations committee reports are published, which makes the committee report instructions more transparent than off-the-record conversations and other forms of informal oversight. Through these published reports, stakeholders and other congressmen can monitor how the Appropriations Committee is instructing agencies. However, currently, many agencies do not publish specific responses to appropriations committee report instructions in their budget justifications. Easily accessible, published responses from agencies to appropriations committee reports would provide information to both the public and to Congress how the committee is influencing agency action. Therefore, to increase political accountability and to help combat concerns about committee bias, other agencies should consider including provision-by-provision responses to appropriations committee report provisions in their budget justifications that they publish on their websites, as the FDA currently does. With clear, public explanations of how agencies responded to each appropriations committee report instruction, interested parties can monitor how the Appropriations Committee's influence impacts particular agencies. Clear, publicly available responses will make oversight easier for the Appropriations Committee and Congress at large as well.[229]

Moreover, agency transparency about their own actions generally, outside responses to specific appropriations committee reports, would help mitigate concerns about a lack of public participation and political accountability in informal policymaking procedures. With respect to

---

[228] Mendelson, *supra* note 19, at 1131, 1140–46; Watts, *supra* note 14, at 53–57.
[229] *See* Watts, *supra* note 19, at 42.

guidance documents in particular, agencies could promote transparency by maintaining clear, online databases of their current guidance documents. A recent study by the GAO found that some agencies are not complying with the Good Guidance Practices from the executive order.[230] Complying with these practices would promote public participation and transparency, which would give stakeholders more avenues to communicate directly with the agency rather than appealing to Congress. Further, organized, online databases would provide information to Congress that could assist with more effective oversight.

Additionally, administrative law values public participation in the regulatory process, and the Section above described how influential committee oversight might threaten public participation in favor of specific interest groups. One mechanism to promote public participation could be to increase opportunities for constituents to access agencies directly, particularly in the guidance development process. For example, though the Good Guidance Practices in the FDA statute provide that agencies should provide an opportunity for public comment, they do not require agencies to respond to these comments. Congress could require the FDA to respond to public comments by including a statement of basis and purpose in significant guidance documents. Moreover, Congress has not extended the Good Guidance Practices to other agencies by statute. Instead, these Good Guidance Practices are extended to other agencies through an OMB Bulletin, which is not well enforced.[231] Providing a formal mechanism for public comment on guidance documents from other agencies would increase avenues for constituents to communicate with agencies directly during the guidance document development

---

[230] *Id.*; *see also* ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, ACUS REC 2014-3, GUIDANCE IN THE RULEMAKING PROCESS 3–4 (2014).

[231] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-368, REGULATORY GUIDANCE PROCESSES: SELECTED DEPARTMENTS COULD STRENGTHEN INTERNAL CONTROL AND DISSEMINATION PRACTICES (2015).

process. Increasing avenues for constituents to engage with agencies directly may decrease some of the need for Congress to micromanage substantive details of regulatory policy.

Lastly, stakeholders seeking to access regulatory actions should consider appropriations committee members in their advocacy efforts. Regulatory beneficiaries or stakeholders who feel they do not have adequate opportunities to participate in informal policymaking directly with agencies, in particular, may consider congressional advocacy to gain access to the guidance document development process. Stakeholders can read appropriations committee report directives to monitor how the committee is exerting oversight, and they can inquire with agencies if their responses are not publicly available. Moreover, to promote political accountability, congressmen advocating for specific agency actions could collaborate with the relevant appropriations subcommittee members to push for committee report provisions to prompt desired agency actions.

Overall, congressional oversight through committee report provisions is an effective way to gain information about agency action, to hold agencies accountable to legislative intent, and to promote public accountability in the administrative state. Yet to protect values of public participation and political accountability, transparency in how committees exercise oversight and how agencies respond is of utmost importance.

Moreover, further research about how committees leverage legislative history would help promote transparency and an understanding about the influence of congressional committees over agency actions. Monitoring appropriations committee report directives and agency responses would be a good topic for a GAO study. It particular, it would be useful to explore how the Appropriations Committee exercises oversight over other agencies, how the Appropriations Committee oversees other types of agency actions beyond guidance documents,

and how other agencies respond to appropriations committee reports in practice. This Article focused on *whether* agencies followed non-statutory instructions and *how* the appropriations committee used those instructions to influence agency action. It did not address *why* agencies followed these directives. To explore scholarly suggestions that agencies pay particular attention to appropriations committee reports because of the power of the purse, future research should consider whether agency funding decreased in response to lack of compliance with non-statutory instructions and whether compliance rates are as high for agencies that are self-funded. If funding did not change or there is little difference for self-funded agencies, perhaps aspects of the agency-committee relationship other than the power of the purse is increasing the committee's bargaining power to leverage agency action.

Additionally, this Article focused on how the *legislative* branch exercises oversight. The administrative state is subject to oversight by both the legislative branch and the executive branch, so it would be interesting to look into how agencies respond when they receive differing instructions from the legislative and executive branches through informal, non-binding mechanisms of oversight. If agencies follow executive instructions when they conflict, the influence of congressional committees may not be as powerful. Moreover, concerns about committee bias and interest group capture may not be as grave. More information about which branch exerts a stronger influence over agency action would help inform scholarly debates about the relationship between Congress and agencies.

CONCLUSION

Agencies are the first, and primary, interpreters of statutes. As scholars have begun focusing attention on whether agencies consult legislative history to interpret statutes, little work has been done on whether agencies actually follow congressional instructions in legislative history. How agencies use non-statutory instructions to implement policy has important

implications for the relationship between Congress and agencies, providing insight into how congressional committees direct agency action outside of the full legislative process. Congressional oversight of agency action is particularly important in the guidance context, as agencies are increasingly regulating through informal guidance documents with little organized framework for oversight and decreased formal opportunities for public participation.

To investigate the influence of congressional committee reports, I studied appropriations committee report instructions to the FDA regarding guidance documents. The findings indicate that the FDA followed a majority of appropriations committee report instructions to issue new guidance documents. Yet the FDA maintained flexibility in its responses and used its expertise as a tool to resist committee instructions at times, which protects against separation of powers concerns.

Though this study only began the inquiry into the ongoing dialogue between Congress and agencies, it illuminates how congressional committees leverage legislative history to influence agency action. The high rate of agency compliance with non-statutory instructions suggests that agencies pay close attention to instructions in legislative history, and congressional committees retain influential bargaining power in negotiations with agencies over the details of regulatory policy. Congressional oversight can be a powerful tool to increase public participation in agency policymaking and to promote political accountability. Yet transparency about the dialogue between committees and agencies is important to guard against concerns surrounding committee bias and interest group capture.