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A Solution to the Hard Problem of Soft Law

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A SOLUTION TO THE HARD PROBLEM OF SOFT LAW

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Administrative Agencies often rely on guidance documents to carry out their statutory mandate. Over the past few decades, the Food and Drug Administration (FDA) has been criticized for using soft law guidance documents to exercise powers beyond those authorized by Congress. Since attacks on the use of guidance documents persist and agencies need soft law to respond quickly and flexibly to rapid technological growth, it is essential to develop a solution that preserves this crucial regulatory mechanism and prevents its abuse. The most likely alternative to soft law guidance is formal regulation, which must be developed through the notice-and-comment process. The delays introduced by these formal processes, however, leave innovators uncertain about how to comply in the interim, which slows innovation. Alternatively, agencies may turn toward even less formal mechanisms, which are less expensive. However, these informal mechanisms also present problems, namely vagueness, contradictory rulings, and regulatory accumulation. This Note focuses on how courts can curb the abuse of guidance documents and avoid the pitfalls associated with these two alternatives.

This Note identifies the ends of FDA regulation, the various mechanisms the FDA uses to achieve these ends, and the Agency's and regulated entities' attitudes toward guidance documents. Courts may either treat notice-and-comment rulemaking as necessary to finality and refuse merits review or classify such documents as final and conduct a merits review. This Note endorses the latter solution because it helps courts preserve agency discretion, principally limits discretion, and incentivizes uniformity and predictability. This solution is limited to documents that are practically binding on the agency.

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INTRODUCTION

Agencies are increasingly relying on guidance documents to carry out their statutory mandate.[1] The Food and Drug Administration ("FDA") is the most prolific of the federal agencies when it comes to soft law guidance.[2] The FDA and its predecessors have utilized guidance documents for over a century.[3] However, it was not until the 1990s that the Agency's increased responsibilities and ever-scarce resources led it to use guidance documents as the primary method of policymaking.[4] The FDA uses soft law to solve both narrow technical problems and to set broad, important policies.[5] While the FDA has made clear that these documents do not have the full force of law, they are nevertheless effective in shaping regulated parties' behavior.[6] Over the past few decades the FDA has been criticized for using soft law guidance documents to exercise powers beyond those authorized by congress.[7] As attacks on the FDA's use of guidance documents mount, it becomes increasingly important to develop a process that preserves this crucial regulatory mechanism while preventing its abuse.

The FDA commonly justifies its increased reliance on soft law by citing the need to respond quickly and flexibly to rapid technological growth.[8] The FDA can

1. Clyde Wayne Crews Jr., *An Inventory of Federal Agency Guidance Documents*, FORBES (Mar. 20, 2018), https://www.forbes.com/sites/waynecrews/2018/03/20/an-inventory-of-federal-agency-guidance-documents/#4aa6f5ec5447.

2. Ryan Hagemann et al., Soft Law for Hard Problems: The Governance of Emerging Technologies in an Uncertain Future, 17 COLO. TECH. L.J. 37, 47 (2018); Lars Noah, Guidance Gone Wild?: FDA's Regrettable Retreat from Legislative Rulemaking, 30 LEGAL BACKGROUNDER, no. 2, Oct. 9, 2015, at 1, 2.

3. K.M. Lewis, *Informal Guidelines and the FDA*, 66 FOOD & DRUG L.J. 507, 509 (2011).

4. *Id.* at 520.

5. Noah, *supra* note 2, at 2.

6. Lewis, supra note 3, at 510; Nicholas R. Parrillo, Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries, 36 YALE J. ON REG. 165, 167–68 (2019).

7. Lars Noah, Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority, 1997 WIS. L. REV. 873, 875 (1997).

8. *See generally* Scott Gottlieb, *FDA's Comprehensive Effort to Advance New Innovations: Initiatives to Modernize for Innovation*, U.S. FOOD & DRUG ADMIN. (Aug. 29, 2018), https://www.fda.gov/news-events/fda-voices/fdas-comprehensive-effort-advance-new-innovations-initiatives-modernize-innovation (contemplating an increased role of guidance to spur innovation while ensuring safety and efficacy); Lars

react to attacks on its use of guidance either by implementing more formal mechanisms or by using more informal techniques. While the agency insists that the most likely alternative to guidance is formal regulation, the procedural requirements for formal rulemaking substantially delay the implementation of regulations.[9] During the prolonged notice-and-comment process, innovators are left uncertain about how to comply, which slows innovation. This dearth of regulatory oversight also risks harming the public by delaying the entry of helpful technologies.[10] The availability of faster, more responsive alternatives to rulemaking is essential to promoting innovation through effective regulations.[11]

Instead of embracing formal rulemaking, FDA may respond to efforts to limit their use of soft law by moving toward even less formal mechanisms (e.g. case by case adjudication, and internal management documents).[12] The FDA, like many other agencies, selects informal mechanisms because formal rulemaking continues to be the more expensive route.[13] However, mechanisms that are even less formal than guidance documents also present problems. For instance, case-by-case adjudication is "by its very nature vague and contradictory."[14] Additionally, enforcement manuals, another informal mechanism, that the FDA provides its enforcement personnel to guide their behavior may escape judicial scrutiny.[15] Increased reliance on these kinds of informal actions would make it harder for industry to know how to comply with regulatory requirements. Excessive reliance on informal mechanisms could also contribute to regulatory accumulation, which occurs when "the buildup of more and more regulatory restrictions distorts and deters the business investments that drive innovation and economic growth."[16] Regulatory accumulations increase uncertainty as industry struggles to determine whether the FDA has spoken, which documents

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Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 107, 119 (2014).

9. Administrative Procedure Act, 5 U.S.C. § 553 [hereinafter *APA*].; *Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives*, GOV'T ACCOUNTABILITY OFFICE, 5 (Apr. 2009), https://www.gao.gov/assets/gao-09-205.pdf.

10. *See* Gottlieb, *supra* note 8 ("The agency's role in curating standards for medical technologies can help advance innovation in areas that may lack consensus standards now.").

11. *See* Erica Seiguer and 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, 22 (2005).

12. Stuart Shapiro, *The Role of Guidance Documents in Agency Regulation*, YALE J. REG. ONLINE (May 9, 2019), *https://www.yalejreg.com/nc/the-role-of-guidance-documents-in-agency-regulation-by-stuart-shapiro/*.

13. *Id*.

14. *Id*.

15. Id.

16. Patrick McLaughlin, Regulatory Accumulation: The Problem and Solutions, MERCATUS CTR. (Sept. 27, 2017), https://www.mercatus.org/system/files/mclaughlin_-_policy_spotlight_-_regulatory_accumulation_-_v1.pdf.

apply to its product, and the obligations created by these documents.[17] As such, reliance on mechanisms that are less formal than guidance may harm public health and stifle innovation in much the same way as over-reliance on formal rulemaking.

This Note focuses on how courts can curb the abuse of guidance documents and avoid the pitfalls associated with these two alternatives. One option for courts is to treat notice-and-comment rulemaking as a necessary element of finality. Courts that follow this approach refuse to resolve challenges to guidance documents on the merits because they were not subjected to notice-and-comment procedures. This would leave the permissibility of the decisions and actions outlined by the guidance document unresolved. Alternatively, courts can classify such documents as final. This would allow the court to review the merits of the guidance document and rule on whether the policies it implements are permissible. This merits review would create more uniformity and predictability via a court ruling explaining why the soft law guidance document was a permissible agency action or not.

Part I of this Note identifies the ends of FDA regulation, the various mechanisms the FDA uses to achieve these ends, and the Agency's and regulated entities' attitudes toward guidance documents. Also, this section surveys the benefits and risks associated with developing technology and the regulatory dilemma it presents to the FDA: regulate early with little information and risk hampering the development of crucial technology or abstain until more information is available and risk losing the ability to effectively regulate. Part I.B uses nanotechnology as a case study to further develop the consequences accompanying each side of the regulatory dilemma. Part II highlights the importance of judicial review and identifies the two options open to courts determining whether guidance documents that have foregone notice-and-comment requirements are final. Courts may either treat the imposition of notice-and-comment rulemaking as a necessary element of finality and refuse to resolve challenges to guidance documents on the merits, or classify such documents as final and conduct a merits review. Part III advocates for the latter solution because it helps courts preserve agency discretion where appropriate, while principally limiting discretion through a review process that incentivizes uniformity and predictability. This solution is limited to documents that are practically binding on the agency and does not apply to those that purport to bind the regulated. This approach allows the Agency to meet the demands of regulating rapidly developing technology with iterative, flexible, and incremental guidance; and helps courts block agency actions that go beyond Congress' grant of authority.

This essay carves out some middle ground in the larger debate regarding how broadly to read Congress' delegation of power to the FDA in the Food Drug and Cosmetics Act ("FDCA"). It recognizes reasons why courts should read the FDCA broadly as a constitution permitting the FDA to "develop whatever innovative and creative regulatory programs are reasonable and most appropriate to

17. *See infra* notes 140–142 and accompanying text (discussing the merits of clear regulatory expectations for the industry).

achieve the fundamental objectives laid down by Congress."[18] Similarly, it appreciates the main concern motivating a narrower reading of the act: that leaving the FDA's use of guidance under-supervised may permit the Agency to ignore "statutory or constitutional line[s] when necessary to accomplish some valuable end."[19] This essay suggests a form of judicial review that balances the need for accountability and flexibility.[20]

I. FDA REGULATION AND THE CHALLENGES OF RAPIDLY DEVELOPING TECHNOLOGY

The FDA is charged with "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices."[21] It aims to promote public health "by helping to speed innovations that make medical products more effective, safer, and more affordable."[22] The FDA's responsibility to speed innovation can come into tension with its obligation to protect the public from unsafe or ineffective products, such as when terminal patients seek access to unapproved drugs.[23] Additionally, the FDA's efforts to accomplish its substantive mandate must meet procedural requirements.[24] These procedures increase transparency, and are designed to ensure the agency applies its policies uniformly and predictably.[25] However, these procedures also contemplate the need for responsive and flexible administration.[26] Like the FDA's substantive goals, the

18. Peter Barton Hutt, Philosophy of Regulation under the Federal Food, Drug and Cosmetic Act, 50 FOOD & DRUG L.J. 101, 102 (1995).

19. Lars Noah, The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures), 93 CORNELL L. REV. 901, 903 (2008).

20. *See infra* Part III (discussing the value of judicial review in securing both flexibility to the FDA to adapt to changing industry conditions and accountability in adhering to its statutory mandate).

21. *What We Do*, U.S. FOOD & DRUG ADMIN., *https://www.fda.gov/about-fda/what-we-do* (last visited Feb. 27, 2021).

22. *Id.*

23. In such cases, the FDA must decide whether to strictly adhere to the typical approval timeline. If they do not make an exception, they risk withholding potentially safe and effective drugs from people who have run out of medical treatment options. However, making an exception exposes vulnerable patients to unknown risks. *See, e.g.*, Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (seeking the use of an unapproved drug for patients suffering from terminal illnesses); *see also* Suthers v. Amgen, 372 F. Supp. 2d 416 (S.D.N.Y. 2005) (arguing for continued access to a drug after participating in an experimental trial).

24. APA, 5 U.S.C. §§ 551–559.

25. *See* Peter L. Strauss, *Domesticating Guidance*, COLUMBIA LAW SCHOOL SCHOLARSHIP ARCHIVE, at 1 (June 7, 2019), https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3312&context=faculty_scholarship (also available at 49 LEWIS & CLARK ENV'T L. REV. 765 (2019)).

26. U.S. FOOD & DRUG ADMIN., MISSION POSSIBLE: HOW FDA CAN MOVE AT THE SPEED OF SCIENCE 6 (2015), *https://www.fda.gov/media/93524/download*.

procedural ends of responsiveness and uniformity come into conflict. Resolving the competition between these procedural demands is particularly difficult when there is both a pressing need for immediate action and a dearth of information—as is often the case with emerging technology. This section suggests that, in such conditions, the FDA can only fulfill its substantive and procedural obligations by implementing an iterative, incremental, and flexible regulatory approach.[27]

A. FDA Regulatory Mechanisms

Congress delegates authority to the FDA through the FDCA. In these provisions, Congress drafts general standards like "safe and effective" and leaves it to the FDA to resolve smaller, technical issues and outline the content of these standards in greater detail. The FDA carries out its mandate through two broad mechanisms for rulemaking: formal regulations and informal guidance documents.

Formal regulations must be adopted through the notice-and-comment procedures of the Administrative Procedure Act ("APA"). The agency brings enforcement actions under formal, not informal, regulations.[28] This enforcement power is justified by more stringent procedural requirements that facilitate accountability and public participation.[29] First, the government must give notice of proposed rules and state the legal basis and purpose for its actions. After an opportunity for public comments, the government must respond.[30] Final rules might go through multiple public comment periods.[31] After these notice-and-comment periods, the final rule is published in the Federal Register and Codified in the Code of Federal Regulations.[32]

These procedural requirements prevent hard law from keeping pace with rapid technological innovation. For instance, a recent study by the Government Accountability Office showed the APA notice-and-comment requirements take on average four years to turn a proposed rule into its final form.[33] The FDA's

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27. *Cf.* U.S. FOOD & DRUG ADMIN., DRUG PRODUCTS, INCLUDING BIOLOGICAL PRODUCTS, THAT CONTAIN NANOMATERIALS: GUIDANCE FOR INDUSTRY 1–2 (2017), *https://www.fda.gov/media/109910/download* (discussing difficulties in regulation of evolving nanotechnology within the limits of agency procedures).

28. Seiguer & Smith, *supra* note 11, at 18.

29. *See* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 117 (4th ed. 2017).

30. *APA*, 5 U.S.C. § 553(b)–(c).

31. OFF. FED. REG., A GUIDE TO THE RULEMAKING PROCESS 5, *https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf* (last visited Feb. 25, 2021).

32. Seiguer & Smith, *supra* note 11, at 18.

33. U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-205, FEDERAL RULEMAKING: IMPROVEMENTS NEEDED TO MONITORING AND EVALUATION OF RULES DEVELOPMENT AS WELL AS TO THE TRANSPARENCY OF OMB REGULATORY REVIEWS 5-6 (2009), https://www.gao.gov/new.items/d09205.pdf ("Based on the limited information available at the time of our review, the average time

rulemaking process for dietary supplements and physician labeling requirements took more than twice as long, clocking in at ten and fourteen years, respectively.[34] These procedures cost both time and money. If the FDA is limited to formal mechanisms, the proliferation of idiosyncratic technologies that require individualized consideration will increase the overall number of rules. The cost of trying to keep pace would be staggering.

Given these costs and the speed at which technology develops, the FDA has increasingly relied on guidance documents.[35] Guidance takes many forms. Occasionally the FDA will send letters to industry entities.[36] Other times the guidance document takes the form of a policy statement or interpretation published in the federal register.[37] The FDA uses the documents to set agency policy about enforcement priorities and standards of conduct for its staff[38] as well as to inform the regulated about which approaches meet the FDA's standards. The Agency also communicates its interpretation of ambiguous statutes or regulations through guidance.[39] When regulated entities adhere to guidance documents, it would be unfair for the Agency to accuse them of non-compliance after they relied on the position the Agency outlined in the guidance document.[40]

Throughout its history the FDA has refined its guidance practices.[41] To try to maintain industry confidence in the certainty of guidance documents, the FDA drafted regulations outlining "Good Guidance Practices."[42] Passed as part of the Food and Drug Administration Modernization Act in 1992, the FDA's Good Guidance Practices announced that the agency would not consider guidance documents to be binding on the agency.[43] Additionally, the FDA renewed its promise to apply statutes and regulations consistently and took steps to ensure greater

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needed to complete a rulemaking across our 16 case-study rules was about 4 years, with a range from about 1 year to nearly 14 years, but there was considerable variation among agencies and rules.").

34. *Id.* at 18.

35. Gottlieb, *supra* note 8.

36. *Letters to Industry*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry (last visited Dec. 4, 2019); Henley v. Food & Drug Admin., 873 F. Supp. 777, 782–83 (E.D.N.Y. 1995) (discussing a volley of letters sent by the FDA that both adjudicates a citizen's petition challenging labeling requirements and communicates guidance regarding labeling requirements).

37. 21 C.F.R. § 10.115(g) (2011).

38. Strauss, *supra* note 25, at 2–3.

39. *Id.* at 2.

40. *See id.* at 3.

41. *See* 40 Fed. Reg. 40682, 40683 (Sept. 3, 1975).

42. *See* Good Guidance Practices, 21 C.F.R. § 10.115 (2011) (these GGPs were then codified in the Food and Drug Administration Modernization Act, 21 USC §§ 101–405(1997)).

43. 57 Fed. Reg. 47314, 47314 (Oct. 15, 1992).

participation and transparency.[44] Though one intended results of the Good Guidance Practices was to render all forms of informal guidance non-binding upon the agency, courts frequently find the FDA is bound to follow guidance documents.[45]

The APA identifies "general statements of policy" and "interpretative rules" as two types of guidance, but the Act subjects them both to the same procedures.[46] Unlike formal regulations, guidance does not undergo robust notice-and-comment rulemaking under the APA.[47] Instead, guidance documents go through one of two processes depending on whether they are classified as level 1 or level 2.[48] Level 1 guidance documents provide interpretations of statutes or regulations, set forth policy changes that are more than minor, include complex scientific information, or otherwise "cover highly controversial issues."[49] Procedural demands on level 1 guidance are less robust than notice and comment, but more substantial than those imposed on level 2 documents.[50] Level 2 guidance documents cover "less consequential matters."[51] Importantly, neither process requires the agency respond to the comments it receives.[52] As it is fairly difficult to determine in practice when a guidance document is sufficiently serious to warrant classification as Level 1,[53] the agency can avoid more robust procedural requirements by characterizing guidance as level 2 or by leaving documents in draft form.[54] Whereas level 1 requires the agency to publish notice of the guidance document in both the Federal Register and online and to implement the document immediately, notice of level 2 guidance documents need only be posted online (not in the Federal Register), and the FDA can delay the implementation of level 2 guidance documents. [55]

The attitudes of the FDA and industry toward guidance converge and diverge in interesting ways. For one, regulated parties often feel a large amount of pressure to follow guidance documents.[56] Sometimes this drives them to seek

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44. 62 Fed. Reg. 8963, 8963 (Feb. 27, 1997).

45. 57 Fed. Reg. 47314, 47315 (Oct. 15, 1992); Lewis, *supra* note 3, at 523–24.

46. Strauss, *supra* note 25, at 4; Ronald Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 320 (2018).

47. *APA*, 5 U.S.C. § 553(b)(3)(A).

48. 21 C.F.R. §§ 10.115(c)(1)–(2) (2011).

49. 21 C.F.R. § 10.115(c)(1) (2011).

50. 21 C.F.R. § 10.115(g) (2011).

51. Noah, *supra* note 8, at 100.

52. Lewis, *supra* note 3, at 522.

53. *Id.*

54. *See* Noah, *supra* note 8, at 101-02; *See e.g.*, Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 28–30 (D.D.C. 1995) (providing an example of the FDA seeking to avoid judicial review of a policy statement by keeping it as a draft rather than final agency action).

55. 21 C.F.R. §§ 10.115(g)(1)–(4) (2011).

56. Parrillo, *supra* note 6, at 174.

individual variances or exemptions, but it is hard to predict whether an agency will grant such a request. The agency's decisions is largely influenced by a particular official's fears about the potential wide spread effects of her decision.[57] FDA officials often feel strong pressures from various stakeholders to behave consistently and predictably, so the agency is reticent to grant variances and exceptions.[58] Moreover, since the multitude of a party's regulatory obligations make non-compliance fairly likely, regulated entities often seek to develop a strong relationship with the FDA.[59] Industry players hope to earn points for compliance with regulations and guidance wherever possible to help convince the FDA to be lenient when they fail to comply. The FDA's role in dispensing valuable incentives (e.g. market approval and exclusivity), increases the pressure to appease the agency through compliance.[60] To avoid wasting their substantial investment in the pre-market approval process, industry entities follow even draft guidance closely because approval decisions are largely discretionary.[61]

From the FDA's perspective, the ability to ensure compliance without having to spend resources on notice-and-comment procedures is one reason guidance documents are particularly valuable.[62] Another reason is that agencies can argue, often successfully, that guidance documents are typically not ripe for judicial review because the guidance does not constitute final agency action.[63] So, the agency has a lot of control over whether and when its actions are subject to challenge in court.[64] Guidance fills gaps left by formal rules and helps reduce uncertainty, thereby preventing the applicant from "investing in protocols that will not meet with approval."[65] Guidance also conserves enforcement resources, as regulated parties have the perception that repeated violation of guidance documents carries the threat of closer surveillance by the agency.[66] The FDA has to use discretion in when and how to enforce its regulations to best use its scarce resources.

In light of its responsibility and the difficult regulatory challenges it faces, the FDA often toes the line between creative problem-solving and abuse of discretion. That said, the harms caused by agency overreach, both to the regulated entity and the broader public, are severe. Additionally, the FDA leverages its power

57. *Id.* at 240.

58. *Id.* at 174.

59. *Id.* at 177.

60. *Id.* at 184–85.

61. *See id.* at 186 (noting how the FDA can threaten to delay approval to promote compliance).

62. *See id.* at 199.

63. Noah, *supra* note 7, at 887.

64. *Id.* at 874.

65. Parrillo, *supra* note 6, at 187.

66. *Id.* at 199 (suggesting that this fear is overblown as reviewers in charge of pre-approval rarely learn of enforcement-related disputes).

over regulated industries to stifle challenges to its actions that would reveal instances of overreach. These features of our system make it important to ensure judicial review is accessible, particularly in the case of innovators producing rapidly developing technology, as most of these innovators' obligations are defined in guidance documents.

B. Rapidly Developing Technology and the Collingridge Dilemma

Rapidly developing technology presents tremendous benefits and disastrous risks. This creates a Scylla and Charybdis which the FDA must navigate: overregulation may delay or prevent the entry of useful technology,[67] but under-regulation may endanger public health by allowing the continued use of unsafe or ineffective technologies.[68] As uncertainty regarding benefits and risks associated with nanotechnology is particularly acute, and formal mechanisms cannot keep pace with the development of nanotechnology, it provides a good case study to explore how the FDA can use guidance documents to regulate effectively without exceeding its statutory authority.[69]

Nanotechnology is implemented in every field that the FDA regulates. The agency defines nanotechnology as (1) a product "engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1nm to 100nm)" or (2) if its dimensions fall outside that range, a product "engineered to exhibit properties or phenomena…that are attributable to its dimensions."[70] Nanotechnology has exceptional promise for treating various diseases. For instance, nanotechnology is used to target cells more accurately. The increased accuracy in the delivery of cancer treating drugs increases their efficacy by avoiding under and over-dosing—both of which frequently cause damage to healthy cells in

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67. *See* Kenneth A. Young, *Of Poops and Parasites: Unethical FDA Overregulation*, 69 FOOD & DRUG L.J. 555, 555 (2014); Henry I. Miller, Editorial, *Overregulation is an Unnecessary Hindrance to Human Gene Therapy*, 6 HUM. GENE THERAPY 1361, 1361 (1995) ("Eliminating unnecessary layers of gene therapy regulation would be a win-win proposition" that would allow money to be funneled toward research rather than meeting regulatory requirements.).

68. *See* Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 757–58 (discussing the FDA's contribution to the opioid crisis through under-regulation); Robin Marantz Henig, *The Dalkon Shield Disaster*, WASH POST (Nov. 17, 1985), https://www.washingtonpost.com/archive/entertainment/books/1985/11/17/the-dalkon-shield-disaster/6c58f354-fa50-46e5-877a-10d96e1de610/. Bara Fintel et al., *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation*, HELIX (July 28, 2009), https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation.

69. Hagemann et al., *supra* note 2.

70. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY CONSIDERING WHETHER AN FDA-REGULATED PRODUCT INVOLVES THE APPLICATION OF NANOTECHNOLOGY 3 (2014), https://www.fda.gov/media/88423/download.

the body.[71] Nanotechnology also has diagnostic applications. Researchers have developed a targeted gold nanoparticle that acts as a contrast agent in screening for early-stage cancer.[72] Earlier detection often improves the efficacy of subsequent treatments and a patient's chance of recovery.[73]

Despite these clear benefits, nanomaterials may be harmful.[74] Toxic nanotechnology used in drugs can injure organs where nanomaterial resides for unknown amounts of time.[75] The effects nanoparticles have on particular organs is difficult to track because nanoparticles go through unique changes as they pass through various biological barriers.[76] Passing through these barriers may alter their composition and their impact on the human body.[77] The ability of nanotechnology to cross the blood-brain barrier is particularly concerning.[78] As a result, some governments have adopted a cautious approach until more research uncovers the features and bugs of this new technology.[79]

The regulatory difficulties associated with nanotechnology are one instance of the Collingridge Dilemma. This dilemma forces agencies to choose between either accepting the consequences that come with regulating a new technology early in its development or bearing the costs associated with waiting until there is more information about the technology.[80] Earlier intervention is easier, but more likely to mitigate the impact of the technology (both positive and negative); later intervention struggles to mitigate the potential harms of technology, but better understands the particular regulatory demands created by the innovation.[81] In the context of rapidly

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71. Frank Alexis et al, *New Frontiers in Nanotechnology for Cancer Treatment*, 26 UROLOGIC ONCOLOGY: SEMINARS & ORIGINAL INVESTIGATIONS 74, 77 (2008).

72. A. Agarwal et al., *Targeted Gold Nano Rod Contrast Agent for Prostate Cancer Detection by Photo Acoustic Imaging*, 102 J. APPLIED PHYSICS 064701, 064701–1 (2007).

73. *Cancer*, WORLD HEALTH ORGANIZATION, https://www.who.int/cancer/detection/en/ (last visited Dec. 20, 2019).

74. MARGIE PATLAK & CHRISTINE MICHEEL, NANOTECHNOLOGY AND ONCOLOGY WORKSHOP SUMMARY 42 (2011), https://www.nap.edu/read/13037/chapter/1.

75. *Health Risks of Nanotechnology: How Nanoparticles Can Cause Lung Damage, And How The Damage Can Be Blocked*, SCIENCEDAILY (June 11, 2009), https://www.sciencedaily.com/releases/2009/06/090610192431.htm.

76. Marziyeh Ajdary et al., *Health Concerns of Various Nanoparticles: A Review of Their in Vitro and in Vivo Toxicity*, 8 NANOMATERIALS, August 21, 2018, at 1, 4.

77. Patlak & Micheel, *supra* note 74; Paul FA Wright, *Perspectives: Potential Risks and Benefits of Nanotechnology: Perception of Risks in Sunscreens*, 204 MED. J. AUSTL. 369, 369–370 (2016).

78. Jordan Paradise, *Regulating Nanomedicine at the Food and Drug Administration*, 21 AM. MED. ASS'N J. ETHICS 347 (2019).

79. Catharine Paddock, *Nanotechnology in Medicine: Huge Potential, But What Are The Risks?,* MED. NEWS TODAY (May 4, 2012), *https://www.medicalnewstoday.com/articles/244972.php#1.*

80. DAVID COLLINGRIDGE, THE SOCIAL CONTROL OF TECHNOLOGY 11 (1980).

81. *Id.*

developing technology, the FDA must decide whether to implement informal guidelines—that can take effect relatively immediately—or to initiate the notice-and-comment rulemaking procedure which often takes years to complete.[82]

Many scholars adopt a precautionary principle in response to the Collingridge dilemma.[83] They recommend early intervention that simultaneously avoids limiting innovation to the greatest extent possible.[84] As more information about the risks, rewards, and trajectory of regulated technology becomes available, the informal regulations can be formalized without fear of stifling innovation or threatening public health.[85] Only informal guidance documents can regulate rapidly developing technology in a way that balances the benefits of innovation and the importance of public health. If we embrace these technologies and the precautionary principle,[86] then we should also embrace informal guidance documents. This entails committing to reforming, rather than replacing, guidance documents. Reforms should reduce the burden guidance documents place on the regulated while maintaining the documents' efficacy. The next section examines whether guidance documents can promote uniformity, achieve predictable enforcement, and principally limit agency discretion.

II. JUDICIAL REVIEW: TO DISMISS FOR PROCEDURAL DEFICIENCIES OR ADJUDICATE THE MERITS

As briefly mentioned in the introduction, soft law mechanisms and guidance documents are often subjected to criticism. To a large extent, criticisms leveled by scholars[87] have been picked up by courts and politicians. Since 1984, agencies have enjoyed significant deference from the judiciary when interpreting

82. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 33, at 5.

83. WENDELL WALLACH, A DANGEROUS MASTER: HOW TO KEEP TECHNOLOGY FROM SLIPPING BEYOND OUR CONTROL 73 (2015); Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 179–80 (2014); Timothy B. Lee, *The way we regulate self-driving cars is broken—here's how to fix it*, ARS TECHNICA (Apr. 10, 2018) *https://arstechnica.com/cars/2018/04/the-way-we-regulate-self-driving-cars-is-broken-heres-how-to-fix-it/* (technology is changing so fast that any regulations written today are likely to be obsolete in a few years).

84. *See, e.g.*, Cortez, *supra* note 83, at 201–02.

85. *Cf.* David A. Super, *Against Flexibility*, 96 CORNELL L. REV. 1375, 1411 (2011) (describing the costs of information-rich decision environments).

86. Scholars like Jean Warshaw have suggested that agencies do embrace a precautionary principle. Jean Warshaw, *The Trend Towards Implementing the Precautionary Principle in US Regulation of Nanomaterials*, 10 DOSE-RESPONSE 384, 384 (2012) ("Recent developments in the regulation of nanomaterials that are not drugs or pesticides have demonstrated a trend towards application of the precautionary principle.").

87. *See generally* Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, 16 GEO. J.L. & PUB. POL'Y 103, 103 (2018) (seeking "to help judges, legislators, litigants, and scholars focus their calls for reforming how courts review agency interpretations of law" by surveying key arguments in favor of and against deference to agencies).

statutes that are ambiguous under the *Chevron* doctrine;[88] however, *Chevron* deference has begun to receive challenges, notably from Justice Gorsuch and Justice Kavanaugh.[89] Many of these challenges build on earlier judicial efforts to narrow *Chevron*'s scope and limit or eliminate *Skidmore* and *Auer* deference.[90] Determining the legal effect of guidance documents will help identify which complaints about the use of guidance are well-founded and thereby shape potential solutions.

Agencies' use of guidance documents to circumvent accountability requirements and issue regulations without public input is one primary cause for concern.[91] This use of guidance documents escapes the general administrative practice of imposing more process on agencies when they seek greater coercive power.[92] Moreover, the capture of the FDA by partisan and industry interests could undermine public participation in the development of soft law:[93] captured officials circumvent procedural mechanisms by failing to give public comments due consideration. This part focuses on the lack of judicial accountability and how courts might increase accountability by reviewing the merits of informal agency actions.

A. The Three Paths Available to Courts Confronted with Guidance Documents

Courts reviewing challenges to guidance documents typically take themselves to have two options: dismiss the petition for lack of jurisdiction because the document is not final, or vacate the guidance on the merits because it "*is* a final regulation but was promulgated in violation of the APA."[94] However, courts have a

88. *See* Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

89. *See generally* Heather Elliott, *Gorsuch v. the Administrative State*, 70 ALA. L. REV. 703 (2019); Kristin E. Hickman, *To Repudiate or Merely Curtail? Justice Gorsuch and* Chevron *Deference*, 70 ALA. L. REV. 733 (2019); Matthew C. Turk & Karen E. Woody, *Justice Kavanaugh*, Lorenzo v. SEC, *and the Post-Kennedy Supreme Court*, 71 ADMIN. L. REV. 193 (2019).

90. Talk Am., Inc. v. Mich. Bell Tel. Co., 564 U.S. 50, 66–69 (2011) (Scalia, J., concurring). Gorsuch recently wrote a concurrence advocating for the elimination of *Auer* deference. Kisor v. Wilkie, 139 S. Ct. 2400, 2425 (2019) (Gorsuch, J., concurring in the judgment). He was joined by Thomas, Kavanaugh, and Alito, and Chief Justice Roberts suggested that "the distance between the majority and Justice Gorsuch is not as great as it may initially appear." *Id.* at 2424 (Roberts, C.J., concurring in part).

91. Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 408 (2007) (explaining the ways in which guidance documents are subject to lesser public input and congressional and executive oversight).

92. *APA*, 5 U.S.C. § 553.

93. A captured official "uses his or her position to advance the interests of the powerful, rather than to create policy that is responsive or good." Alexander A. Guerrero, *Against Elections: The Lottocratic Alternative*, 42 PHIL. & PUB. AFFS. 135, 142 (2014). *See generally* Tummino v. Hamburg, 936 F. Supp. 2d 162 (E.D.N.Y. 2013) (criticizing the FDA and the Secretary of Health and Human Services for refusing to approve Plan-B for over the counter use during an election year for fear of political repercussions).

94. Cement Kiln Recycling Coal. v. EPA, 493 F.3d 207, 226 (D.C. Cir. 2007). The court may stay the effect of the rule before it is used in an enforcement action by the agency or "permit the agency to supplement the record for its review, remand the rule to the agency, and vacate the rule." LELAND E. BECK, AGENCY PRACTICES AND JUDICIAL REVIEW OF ADMINISTRATIVE RECORDS IN INFORMAL RULEMAKING 76 (2013),

third option. They can find the document was final and conduct a full review of the merits even when documents failed to comply with notice-and-comment requirements.[95] On this approach the court looks beyond procedural shortcomings to determine whether the agency document's interpretation or policy is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[96]

Federal courts have jurisdiction over final regulations.[97] Courts deploy the test formulated in *Bennet v. Spear* to determine whether an agency action is final: "First, the action must mark the 'consummation' of the agency's decisionmaking process….[a]nd second, the action must be one by which 'rights or obligations have been determined," or from which "legal consequences will flow.'"[98] With regard to the first prong, an agency action that is not "tentative or interlocutory in nature" marks the consummation of its decision making process.[99] The inclusion of "final" in the document's title constitutes strong evidence of finality.[100] A document can even be final if it contains a disclaimer indicating that "[t]he policies set forth in this paper are intended solely as guidance, *do not represent final Agency action*, and cannot be relied upon to create any rights enforceable by any party."[101] In *Appalachian Power Company v. Environmental Protection Agency*, the DC Circuit reasoned that this was boilerplate and the surrounding language strongly suggested that the document was binding.

Unfortunately, courts often avoid determining the legitimacy of informal guidance documents on the merits. A few factors stymie judicial review. For one, the FDA seeks to prevent courts from weighing in on the effect of documents (i.e. whether they are final) by construing compliance as "voluntary."[102] Lars Noah calls the practice of using leverage to impose illegitimate requirements through documents that purport to be voluntary "arm-twisting."[103] Distinguishing between permissible

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https://www.acus.gov/sites/default/files/documents/Agency%20Practices%20and%20Judicial%20Review%20of%20Administrative%20Records%20in%20Informal%20Rulemaking.pdf.

95. Strauss, *supra* note 25, at 9; William Funk, *Final Agency Action After* Hawks, 11 N.Y.U. J.L. & Liberty 285, 304 (2017).

96. *APA*, 5 U.S.C. § 706(2)(A).

97. 42 U.S.C. § 6976 (working in accordance with provisions 5 U.S.C. §§ 701–706 determining forum, venue, and when the petitioner must first seek relief from the agency).

98. Bennett v. Spear, 520 U.S. 154, 177–78 (1997).

99. Appalachian Power Co. v. EPA, 208 F.3d 1015, 1022 (D.C. Cir. 2000).

100. *Id.*

101. *Id.* at 1023 (emphasis added) (quoting EPA, PERIODIC MONITORING GUIDANCE FOR TITLE V OPERATING PERMITS PROGRAMS 19 (1998)).

102. Noah, *supra* note 8, at 123 (identifying various ways in which the FDA utilizes arm-twisting strategies to extend its power).

103. *Id.*

guidance practices and arm-twisting is largely up to courts.[104] Accordingly, the FDA has attempted to shield its arm-twisting efforts from judicial review by keeping guidance documents in the draft stage rather than finalizing them.[105] *Washington Legal Foundation v. Kessler* presents one example of such an effort: a public-interest group advocating on behalf of doctors targeted an FDA policy prohibiting manufacturers of medical products from distributing information relating to off-label use.[106] The FDA responded that its policy was not final and as such the issue was unripe.[107] In this case the FDA's efforts failed: the court rejected the FDA's argument, finding that the policy was appropriate for review because it had the practical effect of binding the regulated party.[108]

Guidance documents are also rarely litigated, and when they are "their treatment is contentious and confused."[109] Determining finality is difficult. Courts struggle to determine whether compliance with a document is accurately characterized as voluntary.[110] In *Bennet* the court provides a sufficient test for finality, but a guidance document may be final even if it does not actually determine legal rights or obligations, so long as it is practically binding.[111] Agency documents are binding in practice when they appear to bind either the agency, the regulated parties, or both.[112] When it comes to determining whether compliance is mandatory, industry actors are often as confused as courts. This is demonstrated by a multitude of instances where parties ask for permission to deviate from guidance documents which are not supposed to be binding on anyone but the agency.[113] Despite these difficulties, there are good reasons for courts to characterize guidance documents that bind the government, but not the regulated, as final and to subsequently review the merits of

104. *See* Hale Melnick, *Guidance Documents and Rules: Increasing Executive Accountability in the Regulatory World*, 44 B.C. ENV'T AFF. L. REV. 357, 367 (2017) (discussing the obstacles to effective judicial review of guidance documents).

105. *Id.*

106. Wash. Legal Found v. Kessler, 880 F. Supp. 26, 28 (D.D.C. 1995).

107. *Id.* at 33.

108. *Id.* at 36.

109. Strauss, *supra* note 25, at 3.

110. Hagemann et al., *supra* note 2, at 115.

111. *See* Funk, *supra* note 95, at 288–89 (analyzing the court's decision in U.S. Army Corps of Eng'rs v. Hawkes Co., 520 U.S. 154, 177–78 (2016)).

112. Strauss, *supra* note 25, at 6.

113. *See* Lars Noah, BDSM in Administrative Procedure: Using Agency Guidance for Bondage and Discipline 3 (Jan. 27, 2020) (unpublished manuscript), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3391569*; *see also* Parrillo, *supra* note 6, at 232–237 (discussing reasons firms might seek approval to depart from requirements outlined in guidance, and why other regulated entities often oppose these requests).

these documents—even when they did not undergo the notice-and-comment procedure.[114]

B. After Finality

After a reviewing court determines a guidance document is final, it can do one of two things: vacate it for failure to comply with the APA's notice-and-comment procedures, or determine whether the agency action is arbitrary and capricious. The D.C. Circuit followed the first approach in its treatment of an FDA guidance document in *Community Nutrition Institute v. Young*.[115] The Community Nutrition Institute challenged the FDA's guidance establishing "action levels" that set the allowable levels of unavoidable contaminants in foods, like corn.[116] The court vacated the agency's guidance because it determined the rights and obligations of the plaintiff without subjecting the document to notice-and-comment requirements.[117]

The D.C. Circuit followed the second approach in *Appalachian Power Company v. Environmental Protection Agency*.[118] In *Appalachian Power*, the EPA published guidance documents imposing periodic monitoring requirements on power companies and the chemical and petroleum industry.[119] In determining whether the guidance document was final, the court looked to the agency's attitude toward the document.[120] It sought to determine whether the agency acted as if the document was controlling, treated the document as if it were a legislative rule, or based enforcement on policies or interpretations included in the document. If the agency did, then the guidance document was binding "for all practical purposes."[121]

Subsequent jurists have taken the court's reasoning to indicate that compliance with notice-and-comment procedures is a necessary element of finality.[122] Despite this popular use of *Appalachian Power*, the D.C. Circuit actually went on to find the guidance at issue was reviewable on the merits and determined that the guidance document was an unreasonable reading of the regulation it was meant to interpret.[123] Accordingly, the reasoning courts and commentators often rely on is

114. Strauss, *supra* note 25, at 14–15.

115. 818 F.2d 943, 945 (D.C. Cir. 1987).

116. *Id.*

117. *Id.* at 946–47, 950.

118. 208 F.3d 1015, 1021 (D.C. Cir. 2000).

119. *Id.* at 1015–18.

120. *Id.* at 1021.

121. *Id.* at 1022.

122. Strauss, *supra* note 25, at 14.

123. 208 F.3d at 1023.

merely dictum. In some cases, notice-and-comment is sufficient, but not necessary for finality.[124]

Courts rarely exercise their power to review practically binding documents on the merits.[125] This power is an important tool, as many of the benefits achieved through notice-and-comment procedures can be adequately promoted by allowing judicial review.[126] This tool may be the best alternative available for regulating rapidly developing technology, as allowing unchecked agency discretion or completely replacing informal regulation with formal rules exposes the public to substantial risk and chills innovation.[127] By reviewing the substantive merits of guidance documents, courts can prevent the FDA from abusing guidance documents while affording the agency the flexibility it needs to fulfill its statutory mandate. I now turn to the merits of this approach.

III. SECURING THE LEGITIMACY OF GUIDANCE

When judges assess whether guidance documents hue sufficiently closely to the relevant regulation or statute, they enable guidance documents to promote uniformity and predictability. This effectively limits the FDA's discretion and preserves the flexibility the FDA needs to deal with unique regulatory demands created by the new technologies. Whenever the Agency wishes to change its policy, it could likely withdraw the guidance document and implement new regulatory requirements through notice-and-comment procedures—provided that the court reviewing the initial guidance document found it was one of multiple permissible interpretations of the FDCA rather than the only permissible interpretation.[128] After showing the practical effects test obtains these advantages when it is applied to guidance documents that purport to bind the agency, I give some reasons to prefer judicial reform to legislative action. Crucially, this approach is permitted by the language of the APA, which exempts actions from notice-and-comment requirements when "the agency for good cause finds . . . that notice and public procedure thereon

124. Funk, *supra* note 95, at 285.

125. *See generally* David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Shortcut*, 120 YALE L.J. 276 (2010) (explaining why judges wisely resist taking the shortcut of asking whether an agency used notice-and-comment procedures to determine whether an action was final).

126. *See* Strauss, *supra* note 25, at 15.

127. *See supra* notes 67–68, 80–85 and accompanying text (discussing the Collingridge dilemma and the harms of under- and over-regulation).

128. *Cf.* Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 984–85 (2005) (holding that an agency could adopt a regulation that deviates from a previous regulation upheld by a court only if it the previous court found the statutory language was unambiguous); *see also* Kisor v. Wilkie, 139 S. Ct. 2400, 2415 (2019) (refusing to overturn *Auer*, which defines the deference courts must afford to agency interpretations of regulations).

are impracticable, unnecessary, or contrary to the public interest."[129] I close by addressing two counterarguments: (1) permitting broader and more searching judicial review risks encouraging litigation which is costly to the FDA; and (2) if judicial deference to agencies is eroded or eliminated, the approach I outline will inhibit the permissible use of guidance documents by making these documents more likely to be vacated on the merits.

Encouraging judicial review of the merits of agency actions that are practically binding—even when they have not gone through notice-and-comment procedures—helps secure the benefits of both Agency discretion and the rule of law. This solution provides the agency the discretion it needs to flexibly respond to the specific concerns raised by the many rapidly developing technologies in each of the regulatory classes under the FDA's control.[130] With regard to predictability and uniformity, a more permissive conception of reviewability conforms with the APA's recognition that guidance plays a key role in ensuring predictability and public knowledge of its policies.[131] As illustrated above, agency guidance need not go through notice-and-comment rulemaking to make agency action more predictable.[132] The litigation costs this imposes on the agency are worth tolerating, since the alternative is to leave agencies unstructured discretion in regulating rapidly developing technology.[133]

The possibility of judicial review provides sufficient oversight to prevent the agency from abusing its discretion. For instance, it discourages the FDA from arguing that the guidance document cannot be reviewed because it is not a final agency action, like it did in *Washington Legal Foundation v. Kessler*,[134] because the possibility of having the document struck down on the merits provides a stronger disincentive than just setting aside the guidance document or dismissing the challenge. Invalidation on the merits can foreclose a substantive regulatory route, while vacating a guidance document leaves similar strategies more open in the future—as does requesting that the agency further develop the administrative record.[135] The worst-case scenario under judicial review escalates from having to invest in notice-and-comment rulemaking to having a substantive regulatory path foreclosed.

While judicial review will allow some documents to be struck down on the merits, it will also allow some to be upheld. This is a sweetener for the FDA because

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129. 5 U.S.C. § 553(b)(3)(B).

130. See Hagemann et al., *supra* note 2, at 67.

131. *See id.* at 64–65; *see also* 5 U.S.C. §§ 551–559.

132. *See supra* notes 53–58 and accompanying text (discussing industry entities' desire for draft guidance as it clarifies their obligations).

133. Strauss, *supra* note 25, at 15.

134. Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 29 (D.D.C. 1995).

135. Strauss, *supra* note 25, at 16.

it provides validation of their substantive policies without the agency having to invest extensive time and money into notice-and-comment requirements or relying on Congress to legislatively adopt the guidance document.[136] Accordingly, it will cost the agency less to bind its own agents, facilitating uniform regulatory practices. This provides a substantial incentive for the FDA to make clear which guidance documents it takes more seriously. More merits review disincentives arm-twisting and provides a source of authorization without requiring notice-and-comment rulemaking or explicit congressional action.

Judicial review also permits the agency to more flexibly tailor its regulatory approach to the specific features of the technology. Importantly, the agency retains some control over when a guidance document becomes reviewable.[137] For instance, the agency can avoid indicating that it takes the guidance document particularly seriously to try to shelter it from judicial review as it irons out the details of its policy. The best way the agency can protect guidance is by clearly indicating to industry that the guidance is not meant to be practically binding.[138] If the agency convinces the court its document was not meant to be binding on the agency itself, it will be able to resolve the case before the court reaches the merits—where litigation costs really start to pile up. Then, once the Agency feels confident the document is effective and adheres to the relevant regulation or statute, it can transition from development into implementation. This iterative process can be repeated as more information about the technology becomes available. The agency can build on more solid a foundation when past iterations have been upheld in court. Since litigation is expensive and the FDA already has very limited resources, allowing the FDA to retain some control over when to litigate is crucial.[139]

Moreover, merits review provides substantial benefits to the regulated. For one, it prevents the morass of active FDA documents from chilling innovation.[140] This problem is particularly acute for innovators producing rapidly developing technology and other fields that the FDA regulates almost exclusively through guidance.[141] An unequivocal indication of which guidance the FDA takes particularly seriously makes it easier for industry to identify and adhere to its obligations. Additionally, this approach provides incentives for plaintiffs challenging FDA

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136. Noah, *supra* note 7, at 923 (concluding that the FDA could effectively regulate industry without ever designating a policy "final").

137. *See* Strauss, *supra* note 25, at 6.

138. *See supra* notes 111–114 and accompanying text.

139. *See infra* note 150 and accompanying (discussing the FDA's efforts to make good use of its scarce resources).

140. *See* McLaughlin, *supra* note 16.

141. *See, e.g.*, U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications*.

guidance. Plaintiffs that challenge the FDA's guidance might convince the court to foreclose the substantive policies as an unreasonable interpretation or construction of the statute. This is a more lasting victory than vacating the document for inadequate procedure. Accordingly, industry players will be more likely to file a suit when the FDA failed to adequately protect their interest—though this litigation may be made more difficult by the absence of the factual record ordinarily developed by notice-and-comment rulemaking.[142] These suits also help cut through the existing regulatory morass and clarify the FDA's expectations. The public stands to benefit from the novel medical technology made possible by a system that fosters scientific progress by giving innovators a clear sense of which regulatory requirements apply.

Allocating some responsibility to the judiciary to curb the FDA's discretion comes with important advantages. For one, Congress may have too much on its plate to legislate minor details in a fine-grained way. The fact that Congress will invite, invalidate, or adopt guidance documents suggests Congress recognizes its own inability to keep up with the pacing problem of rapidly developing technology.[143] Indeed, a pattern has emerged where the FDA will try to regulate in a way that exceeds its statutory authority, then Congress will endorse the FDA's action by explicitly extending its statutory authority.[144] Thus, while it is helpful when Congress clarifies their views regarding the reasonableness of various guidance documents, it cannot be counted on to serve this function for each guidance document that an agency decides to make binding on itself.

Moreover, the question of a guidance document's permissibility will often be a fact-specific inquiry that hinges on technical aspects of the technology. This is in part driven by the difficulty of developing a regulatory scheme from scratch because the FDA opts to regulate by analogy. This has been the FDA's approach with nanotechnology. The agency has extended its existing authority over pre-market review and post-market monitoring, for instance over new drugs and biologics, to cover nanotechnology and advised consulting the FDA where it lacks authority.[145] The FDA's current approach to nanotechnology deploys premarket review authority where it exists and encourages nanotechnology developers to frequently consult the FDA throughout stages of development.[146] The agency notes that nanotechnology can be used in a "broad array of FDA-regulated products," but the regulatory scheme

142. Strauss, *supra* note 25, at 17.

143. Indeed, if administrative officials with more expertise addressing a narrower range of problems struggle to keep pace, it should come as no surprise that it would be even more difficult for Congress to consistently check agency discretion. *See* Hagemann et al., *supra* note 2, at 83.

144. Noah, *supra* note 8, 135 n.203.

145. *FDA's Approach to Regulation of Nanotechnology Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products (last visited Feb. 27, 2021).

146. *Id.*

utilized for dietary supplements differs significantly from that used for medical devices which in turn varies from the FDA's approach to regulating drugs.[147] As the FDA's characterization of the technology greatly impacts which regulatory regime will be enforced, this merits inquiry would be a fact specific one examining the way the technology functions and how it interacts with various systems in the human body.

This inquiry would be easier to conduct inside a courtroom than outside of one. We frequently trust judges with this kind of task. For instance, patent litigation regarding whether an alleged innovation is sufficiently different from prior literature depends on a deep understanding of the science supporting the technology.[148] Judges often have to know enough about the inner workings of various drugs to determine when it is appropriate to defer to the FDA's conclusion regarding what constitutes compliance with a statute. For instance, courts readily assess whether the new drug is similar enough to apply the Abbreviated New Drug Application mechanisms, for drugs that perform similarly to already approved drugs, rather than requiring approval under the New Drug Application provisions, which are subjected to heightened safety and efficacy standards.[149] Indeed, cases against the FDA are frequently brought in D.C. District court where judges have expertise relevant to the intricate, technically complex questions the FDA must resolve.

Despite these benefits, some may worry that this approach does too much to encourage litigation, which is costly to the FDA. This concern is heightened by the fact that money spent litigating is money not spent on other important regulatory functions, as the FDA has meager resources.[150] This criticism lands if the amount the FDA spends on litigation exceeds that spent on complying with notice-and-comment in the long run. I have two responses. First, this criticism may overestimate two likelihoods: (1) the likelihood of challenges to guidance documents that purport to bind the FDA; and (2) the likelihood of the FDA losing these challenges. Regarding these likelihoods, the approach I have described preserves judicial deference. This deference provides the FDA a noteworthy advantage at the merits stage. This makes it less likely for the FDA to lose than this objection might assume, and as a result reduces the likelihood of a challenge. Second, money spent litigating claims might

147. *Id.*

148. *See, e.g.*, Bayer AG v. Biovail Corp., 279 F.3d 1340, 1346–50 (Fed. Cir. 2002).

149. *See, e.g.*, Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1420 (Fed. Cir. 1994); *see also* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355(b),(j).

150. *See* Parrillo, *supra* note 6, at 197 (discussing discretion not only about whether to pursue enforcement but also what form of proceedings to adopt). While Congress could also increase the FDA's budget (and has done so fairly consistently) the fact that these increases are insufficient is supported by the accompanying increase in user fees the FDA has charged to try to bridge the gap. *See* AGATA DABROWSKA & VICTORIA R. GREEN, CONG. RESEARCH SERV., R44576, THE FOOD AND DRUG ADMINISTRATION (FDA) BUDGET: FACT SHEET 1-3 (2020), *https://crsreports.congress.gov/product/pdf/R/R44576#:~:text=Between%20FY2016%20and%20FY2020%2C%20FDA's,fee%20revenue%20increased%20by%2033%25*.

result in a court order upholding the guidance document. Notice-and-comment is one way of validating a policy approach, merits review allows litigation to serve as another. Litigation can be seen as an investment in viability of the measures in the guidance document and may cost less than notice-and-comment rulemaking more often than not.

Another concern is that the viability of the approach I have outlined depends on courts continuing to defer to agencies. This concern is validated by the recent reform efforts to eliminate or reduce guidance. One effort by law makers, The Separation of Powers Restoration Act, was introduced in the Senate in March of 2019.[151] The Act proposes amending the APA to eliminate *Chevron* deference.[152] A similar provision could be developed to eliminate *Auer* and *Skidmore* deference. While some are skeptical about the likelihood these efforts will prevail,[153] they should be taken seriously. Reducing or eliminating judicial deference undermines the incentive structure of the merits review outlined above. A weaker, more pliable deference doctrine undercuts advantages of merits review by making the outcome of these cases harder to predict. This may encourage the FDA to move to even less formal, less accountable mechanisms like informal adjudication through enforcement actions.[154] It also risks increasing the cost of litigation by making it harder for the Agency to determine which suits it should settle. This makes it more difficult for the agency to allocate its scarce resources wisely by making it less obvious which cases are clear winners that warrant full litigation and which to abandon before the court makes a merits determination. Eliminating or reducing deference would likely mean that more guidance documents would be struck down as arbitrary and capricious.

However, there is some reason to doubt eliminating deference would lead to an increase in litigation at least in regulatory areas where the FDA has pre-market approval authority. The cost of obtaining pre-market approval creates some incentive for companies to litigate guidance documents in hopes of achieving easier approval standards that cost less to comply with. That said, even after the elimination of deference, regulated entities would still be concerned the FDA would be less inclined to grant premarket approval after defending against these firms' efforts to lower premarket approval costs in court. Under my approach, the FDA would retain substantial discretion regarding which applications to approve and when. This ameliorates some concerns about the frequency with which regulated entities would file drug suits. In response to the second criticism, then, it is worth recognizing that

151. Separation of Powers Restoration Act, S. 909, 116th Cong. (2019).

152. "[T]he court shall not interpret that gap or ambiguity as an implicit delegation to the agency of legislative rulemaking authority and shall not rely on the gap or ambiguity as a justification for interpreting agency authority expansively or for deferring to the agency's interpretation on the question of law." *Id.* § 2(2)(B).

153. Hagemann et al., *supra* note 2, at 120.

154. *Supra* notes 13–18 and accompanying text.

the approach I propose will likely be adversely impacted if reform proposals seeking to weaken or eliminate deference are successful.

IV. CONCLUSION

Rapidly developing technologies have forced the FDA—a small, over-extended agency—to develop increasingly creative regulatory strategies. The FDA relies primarily on informal guidance documents to fulfill its statutory mandate and use its scarce resources economically. These informal guidance strategies are particularly well-suited to rapidly developing technologies that demand an iterative, incremental, and flexible regulatory approach. That said, discretionary use of guidance that goes unchecked threatens to exceed the authority delegated to the agency by Congress. Guidance documents that contravene the Agency's statutory mandate to promote public health chill innovation, delay the entry of helpful products, or allow the use of harmful technologies. This essay advocates for a broader conception of finality for the purposes of determining the reviewability of an agency action. Rather than set aside the guidance document as invalid for procedural failures (i.e. non-compliance with APA notice-and-comment provisions), courts ought to adjudicate the merits. This approach is limited to guidance documents that purport to bind the agency because only those guidance documents limit agency discretion, and promote uniformity and predictable regulation. Allowing courts to proceed to merits review will preserve the discretion the FDA needs to respond to the challenges of rapidly developing technology.