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Nathan Cortez
Southern Methodist University, Dedman School of Law

Jacob S. Sherkow
Illinois College of Law

Author ORCID Identifier:

Nathan Cortez:  <https://orcid.org/0000-0002-2536-1297>

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PRESIDENTIAL ADMINISTRATION AND FDA GUIDANCE: A NEW HOPE

Nathan Cortez*
Jacob S. Sherkow**

Assessments of a President's first 100 days in office typically focus on legislative priorities and executive orders. Less attention is paid to early victories achieved via guidance and other informal acts of "presidential administration." The COVID-19 pandemic has opened a window for the Biden Administration to effectuate critical public health policies through guidance issued by the Food and Drug Administration. This brief essay highlights the power—and pitfalls—of effectuating public health policy this way, and discusses the lasting power of guidance for any new administration.

A President's first 100 days in office is often marked by the Chief's major executive orders and legislative priorities. Less attention is typically devoted to a different type of policymaking—administrative guidance, an important instrument of regulatory policy that details an agency's "thinking" on a specific subject.¹ Guidances are especially important for the U.S. Food and Drug Administration (FDA), as they constitute "the agency's primary mode of policymaking."² In President Biden's first 100 days, FDA has issued nine guidances, all final, meaning that they largely reiterated the work of the previous administration.³ The lack of new draft guidance belies the critical importance of guidances to FDA's work—and as an instrument of executive policy. In an age where the Agency is routinely placed under the vise of

* Callejo Endowed Professor of Law, Gerald J. Ford Research Fellow, Southern Methodist University, Dedman School of Law.

** Professor of Law, College of Law, and Affiliate, Carl R. Woese Institute for Genomic Biology, University of Illinois at Urbana-Champaign; Permanent Visiting Professor, Center for Advanced Studies in Biomedical Innovation Law, University of Copenhagen Faculty of Law.

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1. E.g., *Guidances*, FDA (Feb. 10, 2021), <https://www.fda.gov/industry/fda-basics-industry/guidances> [<https://perma.cc/H7R9-CWMS>] ("Guidance documents represent FDA's current thinking on a topic.").

2. Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 212 (2014).

3. *Search for FDA Guidance Documents*, FDA, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> (last visited Apr. 11, 2021) [<https://perma.cc/S8S3-DNW5>].

political pressure, and perhaps neglect by a gridlocked Congress,⁴ the President has the authority to free FDA to pursue policy experiments via guidance.⁵ We argue he should do so.

FDA is an important agency. It is the nation's steward for public health, which it largely advances by interacting with—and enforcing its interpretation of—highly technical legal and scientific matters.⁶ Ideally, agencies like FDA craft new policies via legislative enactments or rulemaking. But the previous administration's management of the Agency, combined with political stalemate in Congress, has made that difficult.⁷ By contrast, guidances, according to FDA staffers, “provide for quicker communication, [are] more flexible, [and] allow[FDA] to communicate in a way that . . . is helpful and timely.”⁸ Guidance can relieve some pressure from congressional gridlock and may be used as an institutional marker to resist future political pressure, especially when such pressure runs counter to scientific evidence.⁹ Guidance thus can be a key tool of “presidential administration,” a president's “public assertion of ownership of agency action” that persists long after the next administration has moved in.¹⁰

So far, President Biden has done a good job of elevating science back to its proper, superlative place in policy discourse, including making the Office of Science and Technology Policy a cabinet-level office.¹¹ But, at the time of this writing, Biden has yet to nominate a new FDA Commissioner, leaving potential gaps in the exercise of the Agency's full power.¹² Yet Congress, especially as of late, seems inert on matters of technical, scientific policy.¹³ Guidance, then,

4. See Jacob S. Sherkow, *Regulatory Sandboxes and the Public Health*, 2022 UNIV. ILL. L. REV. (forthcoming 2022) (manuscript at 39–41), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3792217 [<https://perma.cc/Q5WX-3MUV>].

5. Cf. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2353 (2001) (describing agencies' “need to incorporate in administrative decisionmaking the scientific, technical, and other kinds of professional knowledge and experience that agency officials possess” as a form of “experimentalism and information sharing”).

6. See, e.g., *Advisory Committee Research Reports, and Announcements*, FDA (Mar. 27, 2018) <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm165313.htm> [<https://perma.cc/5N89-RZYZ>] (“The U.S. Food and Drug Administration, to assist in its mission to protect and promote the public health, uses 50 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.”).

7. Sherkow, *supra* note 4, at 35–41.

8. Erica Seiguer & 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, 23 (2005).

9. See Kagan, *supra* note 5, at 2344 (suggesting that presidential oversight over rulemaking can relieve “political gridlock”); Sherkow, *supra* note 4, at 39–41 (noting this in the context of FDA emergency use authorizations).

10. Kagan, *supra* note 5, at 2299.

11. *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*, WHITE HOUSE (Jan. 27, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/> [<https://perma.cc/79HP-FN48>].

12. See Michael R. Taylor, *Protecting FDA's Ability to Protect Public Health*, 61 FOOD & DRUG L.J. 805, 808 (2006) (linking congressional oversight of FDA policy to periods of “interregnum between commissioners”).

13. Martha Kinsella, *Congressional Science and Technology Capacity Must Be Revitalized*, JUST SEC. (Feb. 10, 2020), <https://www.justsecurity.org/68404/congressional-science-and-technology-capacity-must-be-revitalized/> [<https://perma.cc/3B84-6UKH>].

seems like a good opportunity both to address emerging problems and experiment while also putting down public and rhetorical stakes to Biden's presidency.¹⁴

This would be true even in some parallel universe where the country's only major scientific policy problems were political; where a deadly pandemic was not sweeping the nation and claiming hundreds of thousands of lives. The pandemic and a slowly unfurling economic crisis are some of the best excuses for FDA to be aggressive in promulgating policies through guidance. COVID-19 therapeutics and vaccines are coming online, as set against a rapidly changing technological landscape.¹⁵ There is not necessarily time to build a robust rulemaking record for every decision FDA may encounter.¹⁶ And the Agency is already endowed with flexibility and discretionary authority through its Emergency Use Authorization program.¹⁷ Even for guidances that skirt the line of the Agency's legal authority, industry, it seems, welcomes them; regulated firms need signals about what to expect from FDA.¹⁸ Given the speed of the pandemic, the absence of a Senate-confirmed Commissioner, and a less responsive Congress, FDA's most frequent customers seem to recognize that such policies are not going to be enacted through traditional legislation or rulemaking.¹⁹

But guidance can be useful beyond merely immediate and short-term ends. Guidance can effectively bind future administrations, particularly if the guidance is later codified into statute. This is not unusual; FDA policies that were first floated in guidance documents find their way into the U.S. Statutes at Large with some frequency.²⁰ Seen this way, guidances can be a vehicle for policy experimentation, subject to further refinement through experience.²¹ Particularly for dynamic technologies, guidance can be a way for FDA to test potential paradigm shifts in regulation.²² In 2017, for example, FDA announced plans to

14. Kagan, *supra* note 5, at 2299.

15. Sherkow, *supra* note 4, at 21–26.

16. *See, e.g., id.* at 23 (“For COVID-19, for example, waiting for the full completion of an ‘average’ vaccine clinical trial would result, at current case fatality rates, in the deaths of a staggering 20.8 million people.”).

17. *Id.* at 28–33.

18. Cortez, *supra* note 2, at 215 n.268.

19. *Cf.* Richard Moscicki, *Lessons Learned from COVID-19: The Way We Develop New Medicines Is Changing*, CATALYST (Feb. 10, 2021), <https://catalyst.phrma.org/lessons-learned-from-covid-19-the-way-we-develop-new-medicines-is-changing> [<https://perma.cc/4MNE-EQXL>] (noting industry participating with FDA in crafting guidances during the pandemic).

20. With acknowledgement of the irony, after FDA first published a guidance document declaring several “Good Guidance Practices,” including notice-and-comment type procedures, Congress later codified FDA's approach via statute. *See* Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314 (Oct. 15, 1992); The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997); Food and Drug Administration Modernization and Accountability Act of 1997 (FDAMA), Pub. L. No. 105-115 § 405, 111 Stat. 2296, 2368–69 (codified at 21 U.S.C. § 371(h)); *see also* Cortez, *supra* note 2, at 213.

21. *See, e.g.,* Nathan Cortez, *Digital Health and Regulatory Experimentation at the FDA*, 21 YALE J. L. & TECH. (SPECIAL ISSUE) 4 (2019).

22. *Id.* at 14–19 (explaining how experiments with digital health regulation introduced under former FDA Commissioner Scott Gottlieb represented important departures from longstanding FDA oversight of medical products such as drugs and traditional devices); Tim Wu, *Agency Threats*, 60 DUKE L.J. 1841 (2011).

experiment with digital health regulation, including outsourcing review from FDA to third parties, shifting most review from the pre-market to post-market phase, and focusing on firm-level indicators of quality rather than product-level indicators.²³ Each represents an important departure from traditional medical product regulation.²⁴ And none were previously contemplated by statute.²⁵

Of course, guidance presents its own problems. One is that initial postures announced via guidance can become de facto rules that are never reexamined, updated, or codified.²⁶ For example, the late 1980s, in response to deaths caused by radiation machines, FDA published draft guidances for regulating medical device software.²⁷ But the drafts were never finalized or codified, and FDA withdrew them without comment 18 years later.²⁸ Thus, during a revolution in computerized medicine, when software became critical to patient care, FDA offered only tentative guidance, and then—nothing.²⁹ The guidance became stale and perhaps even counterproductive. It was not until 2012 that Congress asked FDA to recommend a risk-based framework for regulating software.³⁰ Failed guidance experiments sometimes endure.³¹

And sometimes guidance can be *too* durable—used not as a pilot or precursor to lawmaking, but as a substitute. By the 1990s, FDA had become notable for relying more on guidance than rulemaking to advance policy, eventually issuing twice as many guidances as rules.³² Yet, despite being hailed as more “flexible” than rulemaking,³³ guidances are actually updated less frequently.³⁴ Eventually, backlash against FDA’s use and abuse of guidance led the agency to adopt its own “Good Guidance Practices,” committing itself to

23. Scott Gottlieb, *Fostering Medical Innovation: A Plan for Digital Health Devices*, FDA (Jun. 15, 2017), <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612019.htm> [<https://perma.cc/B4WA-L6YV>].

24. Cortez, *supra* note 21, at 14–19.

25. *Id.* at 25; Letter from Elizabeth Warren, Patty Murray, & Tina Smith, U.S. Sens., to Scott Gottlieb, Comm’r, FDA & Jeffrey Shuren, Dir., Ctr. for Devices & Radiological Health, FDA (Oct. 10, 2018) 3–4, <https://www.warren.senate.gov/imo/media/doc/2018.10.10%20Letter%20to%20FDA%20on%20regulation%20of%20software%20as%20medical%20device.pdf> [<https://perma.cc/SD3L-FBFY>].

26. Cortez, *supra* note 2, at 216.

27. Draft Policy for Regulation of Computer Products, 52 Fed. Reg. 36,104 (Sep. 25, 1987); FDA Draft Policy for the Regulation of Computer Products (proposed Nov. 13, 1989) (on file with author); Cortez, *supra* note 2, at 191–96.

28. Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 70 Fed. Reg. 824,890 (Jan. 5, 2005).

29. Cortez, *supra* note 2, at 191–96.

30. Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) § 618, Pub. L. No. 112-144, 126 Stat. 993 (2012).

31. Nathan Cortez, *Analog Agency in a Digital World*, in *FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES* 438 (Holly Fernandez Lynch & I. Glenn Cohen eds. 2015).

32. See Seiguer & Smith, *supra* note 8, at 25–26; Todd D. Rakoff, *The Choice Between Formal and Informal Models of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000); K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507, 520 (2011).

33. Wu, *supra* note 22, at 1843–48.

34. Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 818–19 (2010).

follow notice-and-comment-like procedures akin to rulemaking.³⁵ This episode presaged heavy use of guidance by other federal agencies, which led to similar “Good Guidance Practices” imposed on executive agencies by the Office of Management and Budget (OMB).³⁶ FDA’s guidance practice in this way became not so much a stamp of executive authority but a tattoo.

Still: given the concurrent crises now facing the country, guidance presents the Biden Administration with a convenient but powerful tool to right the Agency. Guidance, if used as a tool of policy experimentation—particularly as a true precursor to rulemaking or legislation—can be an important executive tool for protecting public health. But making guidance work—and avoiding established pitfalls—requires being sensitive to guidance’s past failures, following FDA’s Good Guidance Practices, and ventilating policies before they are considered for rulemaking or legislation—whether in an administration’s first 100 days or its last.

35. Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314 (Oct. 15, 1992); The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997); 5 U.S.C. § 553.

36. Final Bulletin on Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).