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Seven Former FDA Commissioners: The FDA Should Be An Independent Federal Agency

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ABSTRACT Seven former commissioners of the Food and Drug Administration (FDA) from both sides of the political aisle recommend that the FDA be moved out of the Department of Health and Human Services and reconfigured as an independent federal agency. We believe that such a reengineering would promote reliance on consistent science-based regulation and ensure that the American public has access to the best that science and industry can offer.

In the years since the Pure Food and Drug Act of 1906 became law, giving birth to the Food and Drug Administration (FDA) and the modern consumer safety net, the complexity and breadth of the FDA's tasks have grown exponentially.

The agency now oversees more than \$2.5 trillion in products, which account for twenty cents of every dollar spent in the US.¹ That includes 75 percent of the nation's food supply, among it a vast array of products that come from all over the world. Nineteen thousand FDA-regulated prescription drugs are on the market, and the agency oversees 6,000 categories of medical devices and 12 percent of all imported goods. Tobacco was added to the FDA's packed plate in 2009, requiring that the agency oversee more than 85,000 tobacco products. The agency's wide-ranging responsibilities also include over-the-counter medical products, cosmetics, radiological health, veterinary and livestock products, vital aspects of the emergency response system, and blood-related products.

With its expanding portfolio come more opportunities to promote and protect the health of the public. But to fully realize those opportunities, the FDA needs to operate within a structure that accommodates efficient, science-based decision making. The regulatory history of the Food Safety Modernization Act of 2011 suggests the limits of the current configuration. Signed into law with broad bipartisan and industry support,

the act creates a significantly more sophisticated and proactive approach to food safety regulation. But it took the FDA more than five years after the act's passage to put implementing rules in place, and full implementation and enforcement are still years away.²

While the agency has recently been able to move more rapidly in some regulatory areas (notably tobacco and food labeling), the costs, risks, and lost opportunities associated with delays are too great to forsake opportunities to bake enduring efficiencies into the FDA's structure. In a world of rapidly advancing scientific knowledge, emerging and persistent health threats, and intense global competition, it is essential that the agency leverage science to advance the public health as swiftly as possible.

Toward that goal, the seven authors of this article—all former FDA commissioners, with a combined tenure of more than thirty years—recommend that the FDA be moved out of the Department of Health and Human Services (HHS) and reconfigured as an independent federal agency.

As physician-scientists who collectively have served in both Republican and Democratic administrations, we remain deeply committed to the FDA's mission. Over an eighteen-month period, under the auspices of the Health, Medicine, and Society Program of the Aspen Institute, we examined the FDA's position within the federal government, its reporting relationships and re-

quired layers of executive-branch review, the economic and health consequences of delayed decision making, the growing responsibilities that have been placed on the FDA, and the structure of other federal agencies. (A report with a fuller discussion of the detailed evidence that informed our conclusions is available on the Aspen Institute's Health, Medicine, and Society Program website.)³

That information gathering, coupled with our own experiences over more than three decades, has persuaded us that the current structure, which has the agency buried within HHS, can produce administrative bottlenecks. We believe that the national interest would be best served by a strategy that would enable the FDA to act without the delays inherent in multiple levels of clearance, protect its integrity, promote reliance on consistent science-based regulation, and ensure that the American public has access to the best that science and industry can offer.

Objectives Of Independence

Our ideas for reengineering the process by which FDA regulations, guidance documents, and an array of other communications flow from proposal to final form have ten overarching objectives: (1) promote and protect the public health; (2) ensure predictable decision making, firmly grounded in scientific evidence, that allows safe and effective products to reach the market in a timely fashion; (3) speed the development of biomedical innovations; (4) enhance the transparency of the agency and sustain public confidence; (5) ensure the safety of FDA-regulated imports, including food and cosmetics; (6) foster the development and availability of medical products that respond to deliberate and naturally emerging public health threats; (7) promote the agency's capacity to act swiftly in an emergency; (8) design a legal and enforcement framework that is efficient and accountable; (9) improve access to external scientific advice from a wide range of sources; and (10) ensure that stakeholders—including patients, health professional groups, consumer groups, and industry—have ample opportunity to inform FDA decision making.

Essential Attributes

We have concluded that no single model for an independent federal agency could be adopted in its entirety, although a number of agencies have features that could serve as models. These include the Environmental Protection Agency, Federal Trade Commission, Securities and Exchange Commission, and Social Security Admin-

istration. In our view, four specific attributes of an independent agency would safeguard and strengthen the sound, science-based decision making and transparency that are essential to the FDA's mission.

First, the agency should be led by one person, appointed by the president and confirmed by the Senate. Second, the agency should have rule-making authority in accordance with congressional enabling legislation and intent, and with appropriate and judicious input from the executive branch. Third, oversight of the agency by the Office of Management and Budget (OMB) should be limited to significant regulations and policy development, with transparency embedded and limitations clearly defined. Finally, the agency should have litigation authority, in coordination with the Department of Justice.

Recommended Interim Steps

Recognizing that achieving such independence is an ambitious goal that would require federal legislation, we also urge HHS to take interim steps to ensure the FDA's capacity to keep pace with rapidly evolving knowledge. The HHS secretary could promote a more responsive FDA by acting on the following five recommendations: (1) identify, in consultation with the commissioner, opportunities to streamline the current system of multilayered, executive-branch oversight of FDA decision making; (2) formalize more-direct communication between the HHS secretary and the commissioner so that timely decisions can be made on high-priority issues; (3) define the criteria for determining which regulations would be subject to OMB review and discontinue OMB review of guidance documents and communications with Congress; (4) allow the FDA full recruitment and hiring authority; and (5) enhance the independence and robustness of the scientific advisory system.

This two-step recommendation—immediate action to foster greater efficiency within HHS and a longer-term effort to enact legislation that would give the FDA the status of an independent federal agency—would not abjure accountability. The FDA would still be subject to appropriate external oversight, and the benefits of regulations would still have to outweigh their costs. But acting on the recommendation would better enable the agency to operate within a structure that roots action more firmly in science, safeguards the agency's contributions to the nation's health and economy in a competitive global environment, and builds on its remarkable track record of success.

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Conclusion

FDA policies and actions are not driven by partisan politics: The scientific foundation for its decision making is guided by legislation that almost invariably has strong bipartisan support. We believe that our recommendations fit square-

ly within that bipartisan tradition of keeping the agency as up-to-date and effective as possible. Carrying out these reforms would enable the FDA to better fulfill its increasingly complex, challenging, and critical mission to promote and protect the health of the public. ■

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Dehoney, vice president of policy and advocacy. William Hubbard, policy adviser to numerous FDA commissioners, and David Vladeck, an expert in administrative law at Georgetown Law School, provided content expertise. The commissioners attest that they received no financial support for participating in this project and that they have no conflicts of interest regarding the conclusions and

recommendations contained in the article. Many of the commissioners have financial relationships in the private sector, including with the pharmaceutical industry, and serve on various corporate and professional association boards. Further disclosures can be found at <http://aspeninstitute.org/authorfinancialdisclosures>.

NOTES

- 1 Food and Drug Administration. Fact sheet: FDA at a glance [Internet]. Silver Spring (MD): FDA; 2018 Aug [cited 2018 Nov 25]. Available from: <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm553038.htm>
- 2 Food and Drug Administration. FSMA rules and guidance for in-

dustry [Internet]. Silver Spring (MD): FDA; [last updated 2018 Nov 5; cited 2018 Nov 25]. Available from: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#rules>

- 3 Health, Medicine, and Society Program of the Aspen Institute on behalf of the FDA Commissioners. Seven

former FDA commissioners recommend: FDA should be an independent federal agency [Internet]. Washington (DC): Aspen Institute; 2019 Jan [cited 2019 Jan 7]. Available from: <http://www.aspeninstitute.org/FDAIndependence>