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SPECIAL SUPPLEMENT TO VOLUME 45:4 • WINTER 2017

Symposium Articles

SYMPOSIUM

Blueprint for Transparency at the U.S. Food and Drug Administration

Guest edited by Anna L. Davis, James Dabney Miller, Joshua M. Sharfstein, and Aaron S. Kesselheim

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BACKGROUND

The U.S. Food and Drug Administration (FDA) traditionally has kept confidential significant amounts of information relevant to the approval or non-approval of specific drugs, devices, and biologics and about the regulatory status of such medical products in FDA's pipeline.

OBJECTIVE

To develop practical recommendations for FDA to improve its transparency to the public that FDA could implement by rulemaking or other regulatory processes without further congressional authorization. These recommendations would build on the work of FDA's Transparency Task Force in 2010.

METHODS

In 2016-2017, we convened a team of academic faculty from Harvard Medical School, Brigham and Women's Hospital, Yale Medical School, Yale Law School, and Johns Hopkins Bloomberg School of Public Health to develop recommendations through an iterative process of reviewing FDA's practices, considering the legal and policy constraints on FDA in expanding transparency, and obtaining insights from independent observers of FDA.

RESULTS

The team developed 18 specific recommendations for improving FDA's transparency to the public. FDA could adopt all these recommendations without further congressional action.

FUNDING

The development of the *Blueprint for Transparency at the U.S. Food and Drug Administration* was funded by the Laura and John Arnold Foundation.

Given the profound public health and economic ramifications of decisions made by the U.S. Food and Drug Administration, the degree to which FDA activities should reflect an approach founded on complete transparency versus one focused on preserving confidentiality of information deserves public discussion. On one hand, reasonable requirements for transparency are critical to stimulating effective innovation, knowledge dissemination, and good business practice. On the other, ensuring the vitality of the medical products industry requires protecting legitimately proprietary information. With current standards reflecting a lengthy accumulation of legal, regulatory, and practical precedent, recent significant changes in the environment in which the FDA operates should prompt a critical examination of current practices. In this article, I comment on Sharfstein and colleagues' "Blueprint for Transparency," which calls for multiple specific actions to increase transparency at the agency across five key areas, including interactions between FDA and industry, public disclosure of internal FDA analyses, deliberations concerning generics and biosimilars, expanded access to raw study data, and approaches to countering misleading information in the public sphere. I evaluate these recommendations in light of my experience as a clinician, researcher, and former FDA Commissioner, and reflect on possible outcomes that could result from enacting these practices.

Transparency requires more than disclosure of data. It requires a mechanism and policy for conveying information to the public. In order for the aims of the excellent report of the FDA Transparency Working Group to be realized, a publicity initiative will need to accompany the plan of action. The FDA will need to actively convey information about the evidence concerning benefit-risk profiles of drugs, sometimes pointing out misleading claims by manufacturers or sponsors. In other cases, the FDA will need to make available its procedures, including possible conflicts of interest, not only in drug approval, but also in guidance documents and in rulemaking. Transparency as a process of letting the public see into the agency should be accompanied by a proactive strategy of distributing information about the products regulated by the agency.

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