More transparency at FDA needed, researchers say

March 13 2017

As the new administration considers the future direction of the Food and Drug Administration, a group of leading researchers has created a Blueprint for Transparency at the agency to advance the development of safe and effective new products.

The researchers include senior faculty from the Johns Hopkins Bloomberg School of Public Health, Harvard Medical School/Brigham and Women's Hospital, Yale Medical School, and Yale Law School. The project was organized by Joshua Sharfstein, MD, Professor of the Practice at the Bloomberg School.

Sharfstein and Michael Stebbins, PhD, of the Laura and John Arnold Foundation, have authored an overview of the Blueprint in *JAMA*, released online March 13. The full report, Blueprint for Transparency at the U.S. Food and Drug Administration, is being released simultaneously online at http://www.jhsph.edu/blueprintFDA.

"FDA is more than an agency that makes regulatory decisions," says Sharfstein, a former FDA Principal Deputy Commissioner. "It is also a repository for scientific analysis and data that, if more widely available, would improve understanding of existing therapies, the pharmaceutical pipeline and opportunities for innovative product development."

The report makes 18 recommendations in five principal areas:

- **The FDA should disclose more information about key milestones in the application process.**

  Today FDA does not disclose when a drug is being evaluated; transparency at key steps could help shed light on progress through the therapeutic pipeline for a wide range of medications, informing patients, doctors and researchers.

- **The FDA should disclose more of its own analysis and decision-making.**

  Today FDA does not explain why products are not approved, and companies often leave out important reasons in their public communications. Greater disclosure would help guide drug development to more promising areas.

- **The FDA should disclose more about the application and review process for generic drugs and follow-on biologics.**

  Disclosing which products are in the generic pipeline can help more companies make decisions to enter the market and lower prices for consumers. At a congressional hearing last year, an FDA official was asked whether there had been any applications filed for products to compete with EpiPen. Members of Congress appeared shocked when the official could not answer because of confidentiality rules.

- **The FDA should correct misleading information in the market.**

  In some cases, manufacturers have released information the FDA knew to be false or misleading but the agency waited months to correct the record. When there is potential for confusion about

the safety or efficacy of a medical product for both approved and unapproved uses, the FDA should help to clarify matters.

- **The FDA should disclose data from scientific studies to enhance understanding of medical products.**

  When manufacturers have not already done so, the agency should make de-identified data from all clinical trials used to approve or reject a drug available for other researchers.

All of the Blueprint's recommendations can be implemented by FDA without new legislation from Congress, and all respect legal protections for trade secrets.

Provided by Johns Hopkins University Bloomberg School of Public Health