

Quantifying the FDA's rulemaking delays highlights the need for transparency

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In a study published in *Health Affairs* on February 3, 2014, Aaron Kesselheim, MD, JD, MPH, and co-authors, quantify how long it takes the FDA to enact a formal rule affecting drugs, medical devices and other health-related products.

The FDA frequently uses rulemaking to establish or modify the way it regulates the medical product marketplace. Rulemaking may also be required by Congress or be needed to correct a public health problem. The FDA's rulemaking is controversial because of its perceived complexity, lack of transparency and lengthy duration. To shed light on the FDA's rulemaking process, the authors examined the evolution of the most important rules that the agency published during 2000-12.

The authors write, "We found that the rules' median time to finalization was 7.3 years, with the pre-rule phase and post review deliberation." Rules that involve cost-benefit analysis were associated with additional delays. The authors recommend, "The FDA's rulemaking could be improved by allocating additional resources to improve efficiency and by embarking on initiatives to promote transparency by the FDA and other parts of the executive branch."

Provided by Brigham and Women's Hospital

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