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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

May 6, 2014

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

We write today to express significant concern about the U.S. Food and Drug Administration's (FDA) use of draft guidances to make substantive policy changes.

According to the FDA website, "Level 1 guidances set forth the agency's initial interpretations of new significant regulatory requirements; describe substantial changes in FDA's earlier interpretation or policy; and deal with complex scientific or highly controversial issues."

Stakeholders tell us that draft guidances are increasingly becoming default FDA policy and position. Draft guidances state that the "guidance document is being distributed for comment purposes only." However, in the absence of finalized guidance, drafts are the only information that FDA review staff, patients, clinicians, and FDA-regulated entities have on the agency's most current thinking on important issues.

One major concern is that the agency's website does not differentiate between draft and final guidances, making it seem that the documents have equal weight, and undercutting the important purpose of soliciting public comment on draft guidances.

A second concern is that these draft guidances are not being revised, finalized, or withdrawn in a timely manner. We believe that public comment from FDA-regulated entities, health care providers, consumers, and patients not only will help shed light on any unintended consequences of the agency's draft guidance, but better inform and, ultimately, improve that guidance. It is integral that those improvements are reflected in updated guidance documents and the guidance is being appropriately and consistently applied by product reviewers.

Third, we are concerned that, although the agency's draft guidances state that the "guidance document is being distributed for comment purposes only," in the absence of finalized guidance these drafts are the only information that FDA review staff, patients, clinicians, and FDA-regulated entities have on the agency's most current thinking on important issues and feel compelled to follow draft guidances as if they were final.

For example, at the Health, Education, Labor and Pensions Committee Hearing on Thursday, March 13th, there was a discussion on the guidance on abuse-deterrent formulations and you said that “the guidance is very important and lays out how we’re thinking about it”, yet that guidance is still in draft form and states “Not for implementation.”

Another example: draft guidance, published in June 2013 on cyclosporine emulsion bioequivalence, is still available in draft form even after doctors and patients, including the American Academy of Ophthalmology and American Glaucoma Society, submitted comments expressing concerns regarding the safety and reasoning behind the guidance. Because that draft is still available, and is FDA’s only public statement, FDA application reviewers, drug manufacturers, doctors, and patients may believe that it is the Agency’s current thinking. If that draft guidance is not FDA’s current thinking, or FDA’s current thinking has changed due to the concerns raised in the comments, it would be best to withdraw, revise, or finalize the draft guidance.

In addition, according the President’s Council of Advisors on Science and Technology in the *Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation*, drug manufacturers require greater clarity about how innovative products are regulated. The report states that “the development of rapid, clear, and thorough guidance documents that reflect the consensus of the scientific community on new and emerging areas of scientific innovation could help address this need.”

Our fourth concern is that, despite those findings, FDA issues guidance that seemingly does not take into account, or may even conflict with, the scientific community. For example, FDA recently issued a draft guidance on the use of blood glucose monitoring systems in patient care settings, and chose not to follow the international scientific community’s recommendation on regulatory standards.

To help us better understand the FDA’s use of guidances to effectively communicate with FDA-regulated entities seeking advice on how to bring life-saving medical products to patients, we respectfully request that you provide information and answers to following questions:

1. A list of all Level 1 Draft Guidances, including the date issued, and the timeline with which you plan to withdraw, revise, or finalize each guidance.
2. An update on Agency-wide activities to implement the “best practices” to make the finalization of guidance more efficient and expeditious, as discussed in the 2011 report *Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency*.
3. Have you implemented the President’s Council of Advisors on Science and Technology recommendation to rely more on the biomedical community in help developing and revising guidances, and if so, could you provide examples of specific guidances?

4. For the guidances still in draft form, how do you ensure your staff does not follow the guidance in the absence of any other policy or final guidance?
5. What is the average amount of time in calendar days that the FDA has taken to finalize draft guidances in the last five years? What is the range?

Thank you for your consideration of this request. If you have any questions, please have your staff reach out to Ranking Member Alexander's staff Grace Stuntz at (202)224-6770.

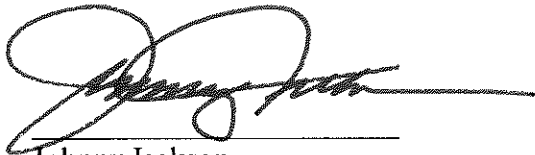
Sincerely,




Lamar Alexander
Ranking Member



Richard Burr
U.S. Senator



Johnny Isakson
U.S. Senator



Orrin G. Hatch
U.S. Senator