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Senate Republicans Press Food and Drug Association on Draft Guidances

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On May 6, 2014, four of the ten Republicans on the **United States Senate's Committee on Health, Education, Labor, and Pensions** (HELP) sent a letter (recently posted by Hyman Phelps) to **FDA** Commissioner Margaret Hamburg expressing "significant concern" about FDA's penchant for using draft guidances to make "substantive policy changes." In addition to the Committee's Ranking Member Senator Lamar Alexander (R-TN), Senators Richard Burr (R-NC), Johnny Isakson (R-GA), and Orrin Hatch (R-UT) brought attention to the increasing trend of draft guidances "becoming default FDA policy and position," even though draft guidances are purportedly distributed only for comment purposes. In particular, the Republicans outlined four chief concerns about this practice involving draft guidances:

- FDA's website does not differentiate between draft and final guidances. As a result, it appears that FDA is giving the two document categories "equal weight" and failing to emphasize the comment period afforded to draft guidances after their publication.
- FDA is not revising, finalizing, or withdrawing draft guidances in a timely manner based on public comments.
- Even though draft guidances are "distributed for comment purposes only," FDA often fails to issue final guidance at all. Thus, the draft guidances are the only information that FDA review staff, patients, clinicians, and regulated entities have to rely on to understand FDA's "most current thinking."
- Finally, FDA guidances do not "take into account, or may even conflict with, the scientific community."

With regards to this final concern, the Senators cite a January 7, 2014 draft guidance on the use of blood glucose monitoring (BGM) systems in patient care settings. In that particular guidance, FDA decided not to follow the international scientific community's recommendation on accuracy standards for BGM systems, but instead chose to apply a more rigorous accuracy standard — which many in the industry have claimed may be scientifically unachievable.

Finally, the Republican Senators conclude their letter by posing five questions to FDA related to the issuance of draft guidances, including the following: “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?” Only time will tell whether the Senators’ letter prompts FDA to become more proactive and timely in updating and finalizing draft guidance documents.

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