

For Immediate Release

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Health Committee Republicans Request Details on FDA's Promotion of the New Health Care Law

Send letter to FDA Commissioner asking "why and under what authority" the agency is using time and resources to enroll Americans in the new insurance exchanges

***"While our nation suffers from numerous drug shortages and patients are waiting for drugs and medical device approvals, the FDA should not be using resources designated for these purposes to fund an effort unrelated to your agency's mission."*– Letter to FDA commissioner**

Washington, D.C., June 19 – All Republican members of the Senate health committee today sent a letter to U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg requesting details on the agency's promotion of the new health care law, saying, "The upcoming enrollment period and coverage availability under PPACA appear to be outside of your agency's mission to approve and regulate lifesaving medical products in a timely manner and keeping our food supply safe."

Senator Lamar Alexander (R-Tenn.), the committee's lead Republican, along with Senators Mike Enzi (R-Wyo.), Richard Burr (R-N.C.), Johnny Isakson (R-Ga.), Rand Paul (R-Ky.), Orrin Hatch (R-Utah), Pat Roberts (R-Kan.), Lisa Murkowski (R-Alaska), Mark Kirk (R-Ill.), and Tim Scott (R-S.C.) sent the letter in response to an email alert issued through the FDA's public email distribution system that promoted open enrollment in the new health insurance exchanges—offering links to a free webinar and promoting the benefits of the law to four different groups: families, individuals,

small businesses and clinicians. For example, for clinicians the email detailed “the top 5 ways you and your practice benefit from the Affordable Care Act.”

The senators wrote: “We are writing to ask why and under what authority the Food and Drug Administration (FDA) is using its time and resources to enroll Americans in health insurance marketplaces created by the new health care law. On June 3, 2013, the FDA sent a notice to families, individuals, small businesses and clinicians promoting insurance market changes in the new health care law. The e-mail alerts your agency sends to the public should reflect your agency’s actual statutory mission to assure the safety of food, drugs, and medical devices. The upcoming enrollment period and insurance coverage availability under the new law appear to be outside of your agency’s mission to approve and regulate lifesaving medical products in a timely manner and keeping our food supply safe.”

They added: “In light of the current fiscal environment and recent sequestration, it is especially important to focus scarce resources on FDA’s actual mission. You have said publicly that under the sequester, ‘Clearly we will be able to provide less of the oversight functions and we won’t be able to broaden our reach to new facilities either, so inevitably that increases risk.’”

They continued: “While our nation suffers from numerous drug shortages and patients are waiting for drugs and medical device approvals, the FDA should not be using resources designated for these purposes to fund an effort unrelated to your agency’s mission of ‘assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.’ We are also concerned that this is another attempt by the Department of Health and Human Services to avoid congressional limitations on implementation expenditures for the new health care law.”

The full text of the letter is below:

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

Dear Commissioner Hamburg:

We are writing to ask why and under what authority the Food and Drug Administration (FDA) is using its time and resources to enroll Americans in health insurance marketplaces created by the new health care law. On June 3, 2013, the FDA sent a notice to families, individuals, small

businesses and clinicians promoting insurance market changes in the new health care law. The e-mail alerts your agency sends to the public should reflect your agency's actual statutory mission to assure the safety of food, drugs, and medical devices. The upcoming enrollment period and insurance coverage availability under the new law appear to be outside of your agency's mission to approve and regulate lifesaving medical products in a timely manner and keeping our food supply safe.

In light of the current fiscal environment and recent sequestration, it is especially important to focus scarce resources on FDA's actual mission. You have said publicly that under the sequester, "Clearly we will be able to provide less of the oversight functions and we won't be able to broaden our reach to new facilities either, so inevitably that increases risk."^[1]

While our nation suffers from numerous drug shortages and patients are waiting for drugs and medical device approvals, the FDA should not be using resources designated for these purposes to fund an effort unrelated to your agency's mission of "assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation." We are also concerned that this is another attempt by the Department of Health and Human Services to avoid congressional limitations on implementation expenditures for the new health care law.

For these reasons, we would like to know:

1. Under what legal authority is your agency promoting implementation of the new health care law and/or insurance coverage?
2. How do your activities further the mission of the Food and Drug Administration?
3. In addition to the attached email, what additional activities is FDA undertaking to support implementation of the new healthcare law?
4. What appropriations account is FDA charging for its costs in supporting implementation of the new healthcare law?
5. What are the total costs to date and what is the amount allocated for the fiscal year for these activities?

Please respond in writing no later than June 26, 2013.

Sincerely,

Lamar Alexander, Ranking Member

Mike Enzi

Richard Burr

Johnny Isakson

Rand Paul

Orrin Hatch

Pat Roberts

Lisa Murkowski

Mark Kirk

Tim Scott

cc: The Honorable Daniel Levinson, Inspector General
The Honorable Gene Dodaro, Comptroller General