

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

September 2, 2015

Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Ostroff:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is seeking information from U.S. Food and Drug Administration (FDA) concerning the safety of the widely-prescribed blood thinner drug, Coumadin, or its generic version, warfarin.

A recently published ProPublica analysis found that from 2011 to 2014, at least 165 nursing home residents were hospitalized or died after errors involving Coumadin or warfarin.¹ According to ProPublica, there are thousands more injuries every year that are never investigated by the government. These findings demonstrate how important it is that the drug be carefully calibrated. In too large a dose, the drug can cause the patient to bleed uncontrollably. If the dose is too small, the patient can develop life-threatening clots.

The ProPublica report noted that the dangers of Coumadin have drawn relatively little scrutiny. Further, the article stated that the Department of Health and Human Services (HHS) identified Coumadin and other anti-coagulants as one of the drug categories most frequently implicated in adverse drug events. However, the article did not explicitly discuss the FDA's role in the HHS review or other reviews mentioned. While the committee recognizes that FDA has no role in overseeing the safety and health requirements for nursing homes, or the practice of medicine, the problems identified in the ProPublica report have prompted the committee to consider whether there are any further actions FDA could take to decrease the incidence and severity of adverse events related to the use of Coumadin and/or warfarin.

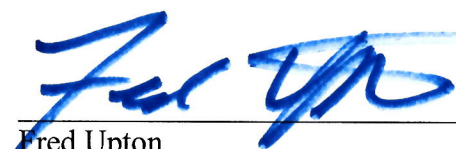
Given the public health interests in assuring the safety of Coumadin and/or warfarin, the committee seeks the FDA's assistance in providing the following by September 16, 2015:

¹ Washington Post, Aug. 4, 2015, p. 3.

1. Summaries of adverse events associated with Coumadin and/or warfarin by calendar year, starting with calendar year 2010. Please also provide any further information the agency has regarding the trends in adverse events associated with the use of Coumadin and/or warfarin, in particular whether the incidence of adverse events has been increasing.
2. If FDA conducted any safety activities relating to the safety of Coumadin and/or warfarin since January 1, 2010, please provide a description of these activities, the dates of these activities, and the offices involved.
3. If FDA conducted any analyses of safety issues associated with Coumadin and/or warfarin, please provide all documents relating to these analyses (including analyses of medication errors) since January 1, 2010.
4. Was FDA involved in the HHS review that identified Coumadin and other anti-coagulants as one of the drug categories most frequently implicated in adverse drug events? If so, please explain FDA's role in this effort related to Coumadin. If not, why not?
5. What steps, if any, is FDA taking to address safety and/or medical error issues related Coumadin and/or warfarin?
6. Safety labeling changes for Coumadin were last approved by FDA in January 2010. Has FDA considered any changes to the safety labeling or black box warning of Coumadin and/or warfarin in light of the recent issues related to the use of the product in nursing homes?

An attachment to this letter provides additional information about how to respond to the committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the majority committee staff at (202) 225-2927 and Una Lee with the minority committee staff at (202) 225-3641.

Sincerely,




Fred Upton
Chairman



Frank Pallone, Jr.
Ranking Member



Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations



Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Attachment