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Interaction of the Drugs Seroquel and Methodone

POGO Letter to FDA Commissioner Hamburg Conc Dangerous Interaction of the Drugs Seroquel and M

July 19, 2011

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The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
White Oak Building
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via: E-mail Margaret.Hamburg@fda.hhs.gov

Dear Commissioner Hamburg:

The Project On Government Oversight is a nonpartisan independe
good government reforms. We take a keen interest in the U.S. Fi
(FDA), which receives around \$4 billion a year in federal taxpaye
almost 25 percent of the U.S. economy.

We are concerned about a letter POGO received this spring from
of the Center for Drug Evaluation and Research (CDER) at the F
disconnect between what Dr. Woodcock told POGO in the letter
FDA.

POGO sent you a letter on October 25, 2010, alerting the FDA to
interaction of the drugs Seroquel (quetiapine) and methadone th
risk.^[2] According to news accounts, these drugs are now widely
veterans with Post-Traumatic Stress Disorder (PTSD).^[3] We rec
the potential drug interaction, and to issue an alert to inform patie

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In her April 15, 2011, response letter, Dr. Woodcock stated that s
interaction was “exceedingly unlikely” and that the FDA would nc
regarding “a revision in labeling that would include new warnings
and professional communications efforts.”

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Less than two months later, in June 2011, the FDA approved cha
note that the drug “should be avoided in combination with other c
Attachment A) In light of this FDA action, the letter from Dr. Woo
frankly makes no sense. It is our understanding that changes to :
months. Given that FDA has to approve label changes, how coul
April that changes would be made in June?

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Again, I remain concerned about the potential for a dangerous in (quetiapine) and methadone that may be putting veterans at risk treat veterans with PTSD. An investigation by *The Military Times* Seroquel almost quadrupled between 2001 and 2009.[4] In a separate study, we found that methadone overdose has caused at least sixty deaths other drug—legal or illegal.[5]

POGO is pleased that the FDA has made progress by requiring it to do so once again that the FDA issue an action alert to inform patients and the public. Given the FDA-approved changes to Seroquel's labeling, we would like to see the natural next step for FDA.

I also request an explanation for the response we received from the FDA regarding the labeling" given the changes to Seroquel's label just two months later.

I appreciate your review of this letter and the attached document. If you have any contact Paul Thacker at thacker@pogo.org or (202) 347-1122.

Sincerely,

Danielle Brian
Executive Director

[Enclosure: 1](#)

cc: Senator Carl Levin, Chairman, Senate Armed Services Committee
Senator John McCain, Ranking Member, Senate Armed Services Committee
Senator Patty Murray, Chairman, Senate Veterans' Affairs Committee
Senator Richard Burr, Ranking Member, Senate Veterans' Affairs Committee
The Honorable Eric K Shinseki, Secretary, Department of Veterans Affairs
Dr. Jonathan Woodson, Assistant Secretary of Defense (Health and Medical Affairs)

[1] Letter to Danielle Brian, Executive Director, Project On Government Reform, October 2011.

[2] [Letter to The Honorable Margaret A. Hamburg](#), Commissioner of Food and Drug Administration, On Government Oversight, October 25, 2010.

[3] For instance, see Andrew Tilghman and Brendan McGarry, "The Military's Spiked; Concerns Surface about Suicide, other Dangers," *Army Times* (September 7, 2010).

[4] "Medicating the Military"

[5] Andrew Tilghman and Brendan McGarry, "Rx for Death: Troops and Veterans," *Navy Times*, September 7, 2010.