UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE,
5100 Wisconsin Avenue, NW, Suite 400
Washington, DC 20016,

Plaintiff

v.

MARGARET HAMBURG, M.D., COMMISSIONER,
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendant.

Case No.:

COMPLAINT FOR INJUNCTIVE RELIEF

This is an action under the Administrative Procedure Act, 5 U.S.C. § 706, by the Physicians Committee for Responsible Medicine ("PCRM"), seeking injunctive relief ordering the Commissioner of the Food and Drug Administration ("FDA") to provide a substantive response to a petition submitted by PCRM on December 18, 2007. PCRM's petition requested that FDA require a disclosure in the labeling of drugs, such as Avandia, used to manage blood glucose in diabetes treatment. The disclosure would state that a low-fat plant-based diet has an efficacy and safety profile that can be as favorable as, or more favorable than, oral diabetes medications. FDA has failed to provide a substantive response to PCRM's petition in a reasonable time, in violation of the Administrative Procedure Act.

JURISDICTION AND VENUE

1. Pursuant to the Administrative Procedure Act, 5 U.S.C. § 706, and FDA's citizen petition regulation, 21 C.F.R. § 10.30, PCRM has exhausted all administrative remedies and now seeks judicial review. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 706. This court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1361, 2001. Venue lies in this district under 5 U.S.C. § 703.

PARTIES

2. PCRM is a non-profit public health advocacy organization that advocates for preventative medicine through proper nutrition and encourages higher standards for ethics and effectiveness in medical research. PCRM is a national organization representing more than 8,000 physicians and 100,000 other medical professionals, scientists, and lay persons.

3. Defendant Margaret Hamburg, M.D., is Commissioner of Food and Drugs at FDA, a United States agency. FDA regulates matters concerning food or drugs in the United States and is an agency within the meaning of 5 U.S.C. § 552(f)(1).

STATEMENT OF FACTS

4. On December 18, 2007, PCRM submitted a petition pursuant to FDA's citizen petition regulation, 21 C.F.R. § 10.30, requesting that FDA require the labeling of drugs, such as Avandia, in the thiazolidinedione class, i.e., drugs that manage blood glucose in diabetes treatment, to disclose that a low-fat plant-based diet has an efficacy and safety profile that can be as favorable as, or more favorable than, oral medications for managing diabetes.

5. PCRM's petition contrasted the health risks of thiazolidinediones with the benefits of following a low-fat plant-based diet. As set forth in the petition, the side effects of thiazolidinediones include heart failure, myocardial ischemia, and heart problems; fluid retention and swelling; weight gain; shortness of breath or trouble breathing; liver dysfunction; unusual tiredness; and increased incidence of bone fracture. In contrast, the petition provided evidence that a low-fat plant-based diet can be as effective or more effective at lowering blood sugar in diabetic patients; and can have major cardiovascular advantages, including significant improvements in lipid and weight control and demonstrated prevention and reversal of atherosclerotic heart disease. The petition therefore requested that FDA mandate certain disclosures on the labeling of thiazolidinediones to ensure that health care providers and consumers 1) receive full and accurate information about the effects of diet on diabetes and 2) understand that oral medications are not always necessary to manage diabetes.

6. By letter dated June 9, 2008, FDA issued an "interim response" in which it stated that it had been "unable to reach a decision" about PCRM's petition.

7. To date, however, FDA has not provided a substantive response to PCRM's petition.

8. In the two-and-a-half years that have passed since PCRM filed its petition, nearly four million new cases of diabetes have been diagnosed in this country, according to statistics provided by the American Diabetes Association.

9. Meanwhile the risks of thiazolidinediones continue to be a major concern for health experts. As reported on June 11, 2010, by Reuters, a recent analysis by scientists from FDA and the Centers for Medicare & Medicaid Services found that one

thiazolidinedione, Avandia, increased heart risks and deaths compared to a rival drug. A study of more than 227,000 Medicare beneficiaries, led by FDA scientists and researchers found that the use of rosiglitazone (Avandia) was associated with an increased risk of stroke, heart attack, heart failure, and all-cause mortality. The results of that study were recently published in the Journal of the American Medical Association (JAMA). Dr. David Graham of FDA announced the results to Defendant, Commissioner Hamburg, in an email message dated May 28, 2010. Dr. Graham has argued elsewhere that Avandia should be removed from the market.

CLAIM FOR RELIEF

(Failure to timely respond to petition)

10. PCRM realleges and incorporates by reference paragraphs 1-9.

11. According to the Administrative Procedure Act, 5 U.S.C. § 555(b), each agency shall proceed to conclude a matter presented to it within a reasonable time.

12. According to FDA's citizen petition regulation, 21 C.F.R. § 10.30(e)(2), the Commissioner of FDA shall furnish a response within 180 days of receipt of a citizen petition.

13. FDA's failure to provide a substantive response to PCRM's petition in a reasonable time constitutes an unreasonable delay under the Administrative Procedure Act, 5 U.S.C. § 706(1).

14. FDA's failure to provide a substantive response to PCRM's petition in a reasonable time constitutes agency action unlawfully withheld under the Administrative Procedure Act, 5 U.S.C. § 706(1).

RELIEF REQUESTED

WHEREFORE, PCRM respectfully requests that this Court:

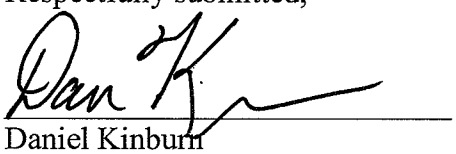
A. Declare that Defendant has violated the Administrative Procedure Act, 5 U.S.C. § 555(b), and FDA's citizen petition regulation, 21 C.F.R. § 10.30(e)(2), by failing to respond to PCRM's petition;

B. Order Defendant to respond to PCRM's petition by a date certain;

C. Award PCRM its reasonable attorney fees and litigation costs incurred in this action; and

D. Grant such other relief as the Court may deem just and proper.

Respectfully submitted,



Daniel Kinburn
PHYSICIANS COMMITTEE FOR
RESPONSIBLE MEDICINE
5100 Wisconsin Avenue, N.W., Suite 400
Washington, D.C. 20016
Attorney for Plaintiff
(202) 686-2210 ext. 380
(202) 527-7480 (fax)

Dated: July 13, 2010