

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

AMERICAN FUND FOR ALTERNATIVES )  
TO ANIMAL RESEARCH, )  
333 Washington Street )  
Boston, Massachusetts 02108, )

BRITISH UNION FOR THE ABOLITION )  
OF VIVISECTION, )  
16a Crane Grove )  
London, England N7 8NN, )

IN DEFENSE OF ANIMALS, )  
3010 Kerner Blvd. )  
San Rafael, California 94901 )  
(415) 448-0048, )

NEW ENGLAND ANTI-VIVISECTION )  
SOCIETY, )  
333 Washington Street )  
Suite 850 )  
Boston, Massachusetts 02108 )  
(617) 523-6020, )

Plaintiffs, )

v. )

MARGARET HAMBURG, M.D. )  
COMMISSIONER, )  
Food and Drug Administration )  
10903 New Hampshire Ave. )  
Silver Spring, Maryland 20993, )

Defendant. )

Case: 1:10-cv-00552  
Assigned To : Roberts, Richard W.  
Assign. Date : 4/6/2010  
Description: Admin. Agency Review

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

1. This is a complaint for declaratory and injunctive relief to require the federal Food and Drug Administration ("FDA") to provide a substantive response to a petition for rule-

making that was submitted to the agency on November 14, 2007. The petition requests the FDA to promulgate regulations to require pharmaceutical companies, medical device manufacturers, and other entities regulated by the FDA to utilize non-animal testing methods to comply with their obligations to demonstrate that their products are safe and effective, whenever such scientifically satisfactory non-animal testing methods are available. Promulgation of such regulations would bring the United States in line with the European Union, which for over twenty-three years has required that experiments not be performed on animals “if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available,” and it would help curtail the unnecessary, costly, ineffective, and painful experimentation that is done on millions of animals each year in this country. The petition was submitted by the plaintiff organizations as part of a coalition called “The Mandatory Alternatives Petition Coalition” (hereinafter “the MAP Coalition”).

2. Although the Administrative Procedure Act (“APA”), 5 U.S.C. § 555(b), requires all federal agencies to provide a response to a rule-making petition “within a reasonable” period of time, the FDA has failed to abide by this command with respect to the MAP Coalition’s petition. Accordingly, plaintiffs seek a declaration that the agency has violated its mandatory duty under the APA, and an order compelling the agency to provide plaintiffs with a substantive response to their November 14, 2007 petition.

### **JURISDICTION**

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1361, and 2201.

## PARTIES

4. Plaintiff American Fund for Alternatives to Animal Research is a private foundation dedicated to promoting and assisting research in, and development of, alternatives to animal use in science.

5. Plaintiff British Union for the Abolition of Vivisection is one of the world's leading organizations advocating the abolition of animals used in experiments, and coordinates an international network of scientists, lawyers, campaigners, investigators, researchers, and other supporters in this effort. It is widely respected as an authoritative voice on animal testing issues and is frequently called upon by governments, media, corporations and official bodies for its advice or expert opinion.

6. Plaintiff In Defense of Animals is an 80,000-member international animal protection organization dedicated to ending the exploitation and abuse of animals by raising the status of animals beyond that of mere property and by defending their rights, welfare and habitat.

7. Plaintiff New England Anti-Vivisection Society is a national organization of 25,000 supporters that works to replace animal experiments in laboratories and classrooms with ethically and scientifically responsible modern research methods. Its board of directors and advisory board include physicians, veterinarians, psychologists, and other scientists.

8. Defendant Margaret Hamburg is the Commissioner of the FDA – the federal agency that regulates matters concerning food, drugs, cosmetics, and medical devices in the United States. The FDA is responsible for providing plaintiffs with a substantive response to their November 14, 2007 rule-making petition.

## FACTS GIVING RISE TO PLAINTIFFS' REQUEST FOR RELIEF

9. Pursuant to requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355 and § 360e, manufacturers of certain drugs and medical devices must demonstrate to the FDA that their products are both "safe" and "effective," before those products can be lawfully marketed to the public. In an effort to comply with these requirements, these regulated entities typically conduct experimentation on animals, including e.g., rodents, dogs, rabbits, and non-human primates. These experiments, which in the aggregate cost tens of millions of dollars, often do not produce valid or otherwise usable data for the purpose of demonstrating the safety and efficacy of the drug or device for use in humans, yet they inflict excruciating pain and suffering on their animal subjects.

10. There are alternative non-animal testing methods that can be used to generate some of the data that are needed to fulfill the statutory requirements of the FDCA, and more such methods are being developed.

11. The FDA has the authority to issue regulations that govern the kind of testing that is done by regulated entities to meet the requirements of the FDCA. This includes the authority to mandate that, where feasible, manufacturers of drugs and medical devices use non-animal testing to fulfill these requirements.

12. In 1986 the European Union issued a Directive that provides that "an experiment shall not be performed [on an animal], if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available." This requirement is legally binding on all European Union member states, including e.g., Austria, Belgium, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands,

Poland, Portugal, Spain, Sweden, the United Kingdom.

13. On November 14, 2007, pursuant to the APA, and the FDA's own regulations, 21 C.F.R. § 10.30, and in an effort to bring the United States in line with the European Union on this issue, the MAP Coalition hand-delivered to the FDA a 60-page petition for rule-making, requesting the agency to promulgate regulations that would require regulated entities in meeting their statutory obligations to demonstrate safety and efficacy for new drugs or devices to use and rely upon non-animal testing methods, unless there is no scientifically satisfactory non-animal testing method available to obtain the necessary data. In furtherance of this objective, the petition further requested that the agency "designate as 'scientifically satisfactory' any and all methods validated as acceptable alternatives to one or more animal tests currently in use;" "develop and implement standardized procedures requiring that [the agency's] drug and device application reviewers accept as valid and sufficient any and all data submitted using scientifically satisfactory alternatives to animal test methods;" "use the strongest possible language in [the agency's] industry guidances regarding the acceptability and sufficiency of scientifically satisfactory non-animal alternatives;" and "support efforts to obtain adequate funding directed specifically toward the development and utilization of its extensive human drug database as particularly effective method for improving preclinical and clinical drug testing and public safety, informing FDA decisions regarding content of new drug or device applications, and replacing animal test methods with scientifically satisfactory non-animal alternative methods."

14. The MAP Coalition's petition was supported by several additional animal welfare and protection groups, including The Humane Society of the United States, the Association of Veterinarians for Animal Rights, and the Animal Protection Institute; and it was also supported

by dozens of physicians, scientists, veterinarians, professors, and other individuals interested in reducing as much as possible unnecessary testing on animals.

15. Since the petition was submitted over two and a half years ago, the petitioners have made several attempts to obtain a substantive response from the FDA. However, to date, the agency has failed to provide such a response.

**PLAINTIFFS' CLAIMS FOR RELIEF**

16. The APA requires an agency to provide a substantive response to a rule-making petition within "a reasonable time," 5 U.S.C. 555(b), and the FDA's own regulations provide that it will provide such a response within 180 days of the submission of a petition, 21 C.F.R. § 10.30(e)(2).


17. The FDA has failed to comply with these requirements of applicable law, to the detriment of the plaintiff organizations which are entitled to a timely response to their petition. Accordingly, this Court may compel a timely substantive response to the plaintiffs' petition pursuant to the APA, 5 U.S.C. § 706(1), which provides that the court may compel agency action that has been "unreasonably delayed."

**WHEREFORE**, the plaintiffs request that the Court enter an Order:

1. Declaring that defendant's delay in providing plaintiffs a substantive response to the MAP Coalition's petition is unreasonable;
2. Requiring the defendant to provide plaintiffs with a substantive response to their petition;

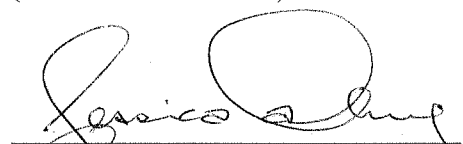
3. Awarding the plaintiffs their reasonable attorneys' fees and costs for this action;
- and
4. Granting plaintiffs such other and further relief as may be just and proper.

Respectfully submitted,



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Katherine A. Meyer  
(D.C. Bar No. 244301)



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Date: April 6, 2010