UNITED STATES DISTRICT COURT

for the

DISTRICT OF COLORADO

Civil Action No. 00-D-1090

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, a non-profit corporation, THE PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE, a non-profit corporation, and DORIS DAY ANIMAL LEAGUE, a non-profit corporation,

Plaintiffs,

vs.

CAROL M. BROWNER, Administrator of the United States Environmental Protection Agency,

Defendant.

COMPLAINT

INTRODUCTION

1. This is an action under the Toxic Substances Control Act, 15 U.S.C. Sec. 2601, *et seq.* ("TSCA" or "the Act"). Plaintiffs seek an order of this Court directing Defendant to initiate proceedings for the issuance of new rules under the Act. Such rules would require manufacturers, processors and distributors of certain chemical substances or mixtures to submit certain reports of data concerning the environmental and health effects of such substances or mixtures.

2. Under 15 U.S.C. Sec. 2620(a), any person may petition the Administrator to initiate a proceeding for the issuance of a rule under 15 U.S.C. Sec. 2607. On December 27, 1999, Plaintiffs petitioned Defendant under 15 U.S.C. Sec. 2620(a), in accordance with the procedures set forth in 15 U.S.C. Sec. 2620(b), to initiate proceedings for issuance of rules under 15 U.S.C. Sec. 2607, Subsecs. (a) and (d). Defendant denied that petition by decision dated March 30, 2000.

JURISDICTION

3. TSCA provides, in 15 U.S.C. Sec. 2620(b)(4)(A), that if a citizen petition under 15 U.S.C. Sec. 2620(a) is denied by the Administrator, the petitioner may commence a civil action in a U.S. district court to compel the Administrator of the Act to initiate a rulemaking proceeding as requested in the petition. That remedy is in addition to other remedies provided by law. 15 U.S.C. Sec. 2620(b)(5). Therefore this Court has federal question jurisdiction of this action under 28 U.S.C. Sec. 1331.

PARTIES

4. Plaintiffs People for the Ethical Treatment of Animals, The Physicians Committee for Responsible Medicine and Doris Day Animal League, all are organizations dedicated to, *inter alia*, promoting safe, effective and relevant chemical screening and testing methods that do not rely on the use of animals. Collectively the three organizations have over 1 million individual members. All three organizations were signatory to the above-described citizens' petition for rulemaking and therefore have standing to bring this action under 15 U.S.C. Sec. 2620(b)(4)(A).

5. Defendant Carol M. Browner is Administrator of the Environmental Protection Agency ("EPA"). TSCA provides that the term "administrator" as used therein means the Administrator of the EPA. 15 U.S.C. Sec. 2602(1). Defendant is sued in her official capacity as Administrator of the EPA.

STATUTORY PROVISIONS GOVERNING JUDICIAL CONSIDERATION OF ACTIONS TO COMPEL ISSUANCE OF NEW RULES UNDER TSCA

6. The Act provides that in an action such as this under 15 U.S.C. Sec. 2620(b)(4)(A), respecting a petition to initiate a proceeding to issue a rule under 15 U.S.C. Sec. 2607, the plaintiff shall be provided an opportunity to have such petition considered by the court in a *de novo* proceeding. 15 U.S.C. Sec. 2620(b)(4)(B). If the plaintiff demonstrates to the satisfaction of the court by a preponderance of the evidence that there is a reasonable basis to conclude that the issuance of the requested new rule is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, the court shall order the Administrator to initiate the action requested by the petitioner. 15 U.S.C. Sec. 2620(b)(4)(B)(ii).

BACKGROUND OF THE CASE

PURPOSES OF TSCA

7. Congress enacted the Toxic Substances Control Act in 1976 after five years of public hearings and debate on a legislative proposal developed by the President's Council on Environmental Quality in 1971. That proposal was made in response to a growing public fear that some toxic chemicals may present risks to health and the environment.

8. In adopting the Act, Congress declared it U.S. policy that (1) "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment" (15 U.S.C. Sec. 2602(b)(1)), and (2) "adequate authority should exist to regulate chemical substances and mixtures that present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards." 15 U.S.C. Sec. 2602(b)(2).

PERTINENT TOXICITY AND EXPOSURE REPORTING REQUIREMENTS AND RULEMAKING PROVISIONS OF TSCA

9. In order to achieve its stated purposes, the Act provides that "If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule" regulate the use of such substance or mixture "to the extent necessary to protect adequately against such risk." 15 U.S.C. Sec. 2605.

10. To enable the Administrator to make the determination as to whether or not to regulate the use of a chemical substance or mixture, the Act also provides that in the case of chemical substances or mixtures for which the Administrator finds that there is an insufficiency of data and experience relevant to a determination that the manufacture, distribution, processing, use, and/or disposal of such substance or mixture does or does not present an unreasonable risk of injury to health or the environment, the Administrator shall by rule require that testing be conducted on such substances or mixtures to develop data with respect to health and environmental effects. 15 U.S.C. Sec. 2603.

11. In order to assure that the Administrator of the Act can and will develop the information necessary to assess the risk of harm to health or the environment from specific chemical substance or mixtures so that she can decide whether to order testing under 15 U.S.C. Sec. 2603 and/or regulate their use under 15 U.S.C. Sec. 2605, the Act includes, in 15 U.S.C. Sec. 2607, a comprehensive set of rulemaking mandates and data record-keeping and disclosure requirements. These TSCA provisions address both (a) the possible toxic effects of particular chemicals and (b) the degree of exposure of health and the environment to such possible toxic effects from manufacture, processing or consumer use of such chemicals.

12. Specifically, 15 U.S.C. Sec. 2607(a)(1) requires the Administrator to "promulgate rules under which - (A) each person (other than a small manufacturer or processor) who manufactures

or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the to the Administrator such reports as the Administrator may reasonably require." Subparagraph (2) of 15 U.S.C. Sec. 2607 details the kinds of information as to which the Administrator may require maintenance of records and reporting. Such information includes, *inter alia*, "(E) All existing data concerning the environmental and health effects of such substance or mixture" and "(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure."

13. Further, in 15 U.S.C. Sec. 2607(b)(1), the Act directs its Administrator to compile, keep current and publish a list of each chemical substance manufactured or processed in the United States, excluding substances manufactured or processed only in "small quantities" for specified, limited purposes. Substances on such list commonly are referred to as "high production volume" ("HPV") chemicals.

14. Further, in 15 U.S.C. Sec. 2607(c), the Act mandates that "Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated

representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records."

15. Next, in 15 U.S.C. Sec. 2607(d), the Act provides that "The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes or distributes in commerce, or who proposes to manufacture, process or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator – (1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies is unnecessary to carry out the purposes of this Act; and (2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person."

16. Finally, in 15 U.S.C. Sec. 2607(e), the Act, recognizing the importance of prompt disclosure of substantial risks to health and the environment by those in the best position to know of such risks at the earliest stage, provides that "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who maintains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

POSSIBLE GAPS IN TOXICITY DATA

17. In 1997, the Environmental Defense Fund ("EDF") issued a report asserting that basic toxicity data was lacking for 75% of a random sample of some 2800 chemicals on the EPA's published HPV list. The EPA thereafter issued its own report detailing the extent to which it

appeared that data was lacking. Shortly thereafter, Vice President Gore called on government, industry and the environmental community to develop a plan to rapidly fill the data gaps. In October 1998 the EPA announced the immediate launch of a massive, expedited chemical testing program (the "Program").

18. The crash Program, dubbed The HPV Voluntary Challenge Program, called for development of data on approximately 2,800 HPV chemicals by the year 2004 because, the EPA asserted, for those chemicals it appeared that data on possible risks was lacking. The Program contemplated that testing be done by chemical companies, and the EPA solicited the voluntary participation of chemical companies. As an inducement to voluntary participation in the Program, the EPA agreed not to issue formal, more onerous rules requiring testing of those chemicals that participant companies voluntarily tested. Many chemical companies signed up for the Program, and the testing industry geared up for an influx of work.

EPA MODIFIES HPV VOLUNTARY CHALLENGE PROGRAM

19. As a result of concerns raised by animal protection organizations, including plaintiffs herein, and the general public, the EPA agreed to modify the Program to try to improve the process for obtaining the missing data on the toxic effects of HPV chemicals. Rather than begin with broadside, time-consuming *de novo* testing of HPV chemicals on animals, the EPA agreed to concentrate more on steps to obtain existing data from chemical companies and evaluate that data before further testing, and to allow for development of alternative effective testing methods that do not require time-consuming tests on animals.

20. The Program modifications implicitly recognized that risks of injury to health and the environment could be identified and addressed by the EPA earlier if unnecessary further testing were eliminated and the energies of the Agency and the chemical companies were focused on chemicals as to which there truly was a lack of data as to their toxicity and the extent, if any, of harmful exposure of health and the environment to those chemicals.

INADEQUACY OF PROGRAM TO FULFILL ADMINISTRATOR'S TCSA RESPONSIBILITY

21. The Program still falls short of what is required to fulfill the Administrator's responsibility under TSCA.

22. First, the Program remains entirely voluntary. Approximately 400 U.S. companies that manufacture, process or distribute HPV chemicals are not participating. Therefore, existing toxicity and exposure data known to those companies remain outside the reach of the Program.

23. Second, the Program addresses only toxicity data, not exposure data. Without exposure data, the Administrator cannot assess the risk of harm to health or the environment arising from chemicals, whatever the degree and nature of the possible toxic effects.

24. Third, the Program is focused more on new testing than on disclosure of data that already exist. This is a major deficiency, preventing industry and the EPA from devoting all available resources to prompt identification and regulation of injurious chemicals, and results in an unreasonable risk of injury to health and the environment, for the following reasons:

a. Much undisclosed data already exist concerning many of the 2800 HPV chemicals covered by the Program, including critical data concerning both possible toxicity of particular chemicals and the risk of harmful exposure of health and the environment to such chemicals. Such data, lodged in the records of or known and accessible to private companies (both companies that have volunteered for the Program and companies that have not done so), may be in the form of results of past testing conducted by or on behalf of chemical companies or by research under the auspices of unaffiliated institutions, or it may take the form of real-world feedback received by chemical companies from field usage of their products, including data on the effects of chemical on humans, whether consumers, employees or others.

b. As evidenced by the EPA's offer in the program as modified to grant amnesty to companies volunteering for the program, some of such existing, undisclosed data probably incriminates particular substances or mixtures as injurious to health or the environment. Indeed, the history of products liability litigation in the United States has revealed repeatedly that manufacturers, processors and distributors of products or components of products often are loathe to reveal, if not wont to conceal, evidence that their products cause injury. In cases of chemicals already shown by existing undisclosed data to be injurious, delay while the chemicals are re-tested creates an unreasonable risk of injury to health and the environment.

c. On the other hand, much of the undisclosed data concerning many of the HPV chemicals probably are exculpatory, showing that the substances or mixtures are not injurious to health or the environment. As to such data, the manufacturers, processors and distributors of chemicals have, in the past, had no incentive to undertake the work necessary to disclose the data to the EPA, since such data is not covered by the statutory disclosure mandates. Exculpatory data showing that particular chemicals are not toxic, or that health and the environment are not exposed to risk of injury from them, also contribute materially to the overriding objective of determining as quickly as possible which chemicals, if any, should be tested further and which of those, if any, should be regulated. In the case of chemicals already tested and shown to be harmless, further testing is simply a waste of time and resources, of both chemical companies and the EPA, that could be focused instead on those chemicals as to which there is no existing data one way or the other.

PLAINTIFFS' PETITION SEEKS MANDATORY DISCLOSURE RULES TO SUPPLEMENT PROGRAM

25. Plaintiffs petitioned the Administrator to exercise her existing authority under TSCA to commence proceedings leading to issuance of rules requiring immediate disclosure of existing

data not reached by the Program. They sought rules that would apply to all companies that manufacture, process or distribute HPV chemicals, not merely those that volunteered. Those rules would unearth data both as to toxicity and as to exposure, and both exculpatory or incriminatory of particular chemicals.

26. Specifically, plaintiffs petitioned the Administrator under 15 USC Sec. 2620(a) to initiate proceedings with respect to all chemical substances or mixtures included on the HPV Challenge Program list (1) for the issuance of a Preliminary Assessment Information Rule under 15 USC Sec. 2607(a) requiring all persons who manufacture or process any substance or mixture to submit a Preliminary Assessment Information Manufacturer's Report (EPA Form 77100-35) with respect to each such substance or mixture, and (2) for the issuance of a Health and Safety Data Reporting Rule under 15 USC Sec. 2607(d) requiring all persons who manufacture, process or distribute any covered substance or mixture to report unpublished health and safety data in accordance with the guidelines provided in the Federal Register of September 15, 1986 (51 FR 32720). Plaintiffs asked that such rules apply to all companies that manufacture, process, or, in the case of a Health and Safety Data Reporting Rule, distribute HPV chemicals, not merely those that have volunteered to participate in the Challenge Program, and that the rules include all HPV chemicals, not merely those that a volunteer participant has offered to test.

27. That petition was consistent with the purpose and thrust of the Program as modified. Indeed, issuance of the rules sought by Plaintiffs in their petition, and in this action, would contribute directly to achievement of the Program's stated objective of early identification of injurious chemicals.

28. In denying Plaintiffs' petition for commencement of proceedings to initiate the requested information-gathering rules as authorized by the Act, the Administrator abdicated her responsibility and authority under the Act. Mandatory disclosure rules should be issued in order to avoid the pointless delays and dilution of the Agency's progress in fulfilling its mandate to

gather, evaluate and act on information as to the risks of chemicals as well as to prevent the needless suffering of uncounted animals in laboratories.

29. The disclosure rules sought in the petition, and in this action, would expedite materially the process of identification and regulation of chemicals that threaten injury to health or the environment. Failure to take those steps that would allow industry and the Agency to devote all available resources to prompt identification and regulation of injurious chemicals results in an unreasonable risk of injury to health and the environment. Thus the disclosure rules sought by plaintiffs are necessary to protect health and the environment against unreasonable risk of injury.

WHEREFORE, Plaintiffs respectfully request that this Court: (1) conduct a *de novo* hearing to take evidence on the merits of Plaintiffs' contention that there is a reasonable basis to conclude that an unreasonable risk of injury to health or the environment can be prevented only by issuance of the requested rules as set forth in paragraph 26 hereof; (2) decide that the issuance of the requested rules is necessary to protect health and the environment against an unreasonable risk of injury; and (3) issue its order that the Administrator institute the action requested in the petition as set forth in paragraph 26 of this complaint.

RESPECTFULLY SUBMITTED,

May 30, 2000

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