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# TOXIC SUBSTANCES CONTROL ACT

## DOCUMENTS

JUN 14 1976

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BEFORE THE

SUBCOMMITTEE ON THE ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE

UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

**S. 776**

TO REGULATE COMMERCE AND PROTECT HUMAN HEALTH  
AND THE ENVIRONMENT BY REQUIRING TESTING AND  
NECESSARY USE RESTRICTIONS ON CERTAIN CHEMICAL  
SUBSTANCES, AND FOR OTHER PURPOSES

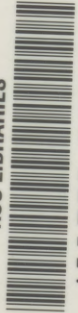
OCTOBER 24, 1975

PART 2

Serial No. 94-24

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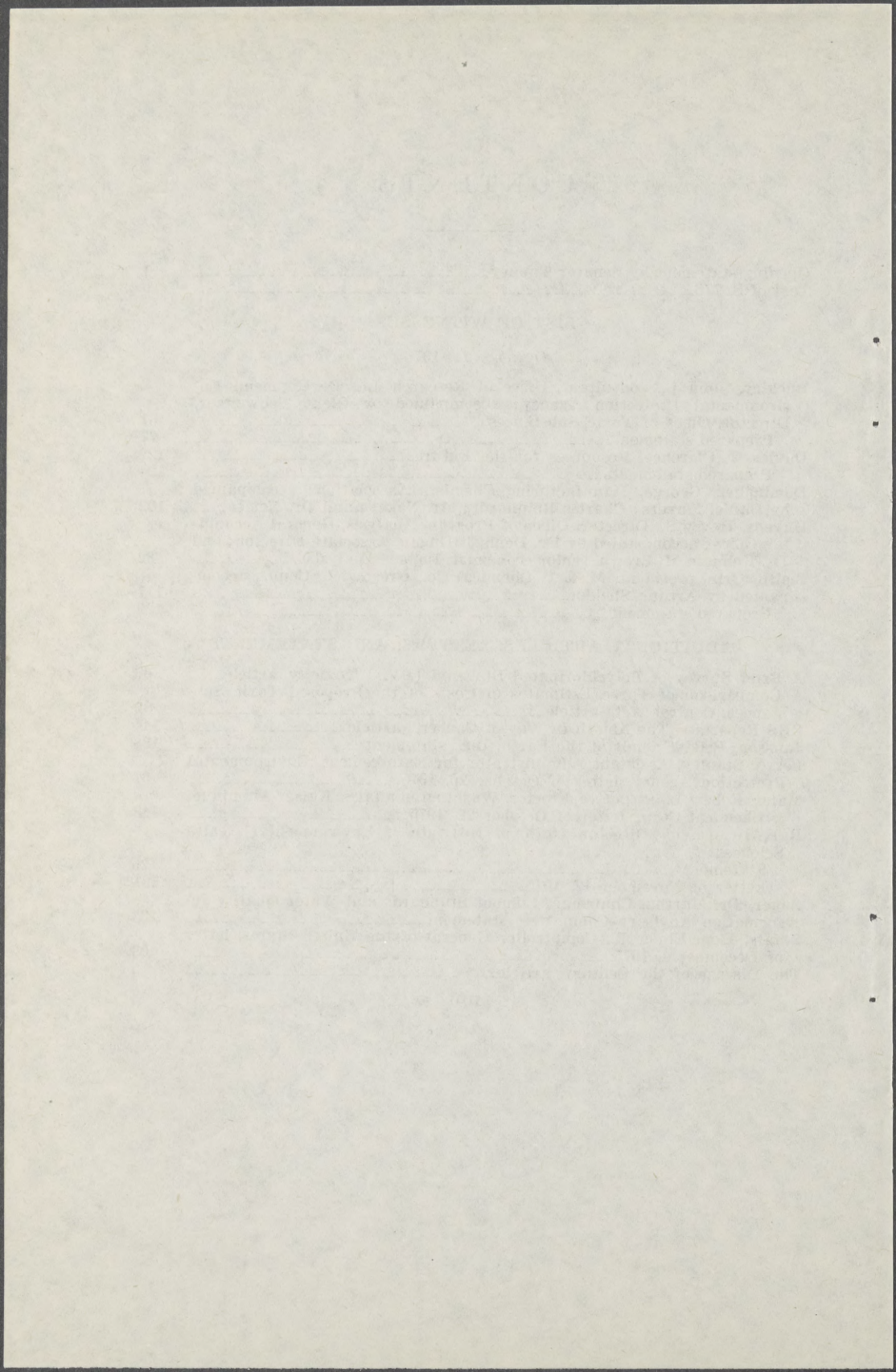
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# TOXIC SUBSTANCES CONTROL ACT

FRIDAY, OCTOBER 24, 1975

U.S. SENATE,  
SUBCOMMITTEE ON THE ENVIRONMENT  
OF THE COMMITTEE ON COMMERCE,  
*Washington, D.C.*

The subcommittee met at 10:08 a.m., pursuant to notice, in room 1318, Dirksen Senate Office Building, Hon. John V. Tunney presiding.

## OPENING STATEMENT BY SENATOR TUNNEY

Senator TUNNEY. Good morning.

This morning the Subcommittee on the Environment will conduct what I hope is its final day of hearings on the Toxic Substances Control Act. Since the introduction of this legislation some 4½ years ago no fewer than 15 days of hearings have been held on toxic substances legislation. The hearings have examined a myriad number of human health effects that are associated with chemical substances.

The list of chemicals which the hearings on this legislation has centered about has grown rapidly: mercury, cadmium, lead, and other heavy metals, PCB's, BCME, nitrosamines and many, many others. In all, some 125 chemicals have been cited in hearings in the Senate and the House over the course of the last 4 years as causing problems capable of solution by the Toxic Substances Control Act.

During the last 4-year period, while this legislation waited on the sidelines, over 1 million people in this country have died of cancer. And Americans are getting cancer at an ever-increasing rate. In fact, the rate of cancer mortality in this country has increased over 20 percent in the past 25 years.

It is clear from the National Cancer Institute studies that cancer is, indeed, a byproduct of an industrialized society. Up to 90 percent are caused by contaminants placed in the environment by man. NCI studies have also shown a high correlation between cancer and industrial centers around the country. From the evidence before us, it is clear that just as technology has brought us tremendous benefits, it has also brought us tragic side effects.

Within the last 10 days two press reports have presented an excellent case for the Toxic Substances Control Act, which is the object of these hearings this morning. The first, entitled "The Disease of the Century," appeared in the October 20 issue of Time magazine. The article deals with the full range of disease associated with environmental contamination including cancer, birth defects, heavy metal poisoning, and respiratory disorders. The article concludes that the best means of preventing new toxic substances from enter-

\*Staff member assigned to this hearing: Michael B. Brownlee.

ing the environment is to screen them out before they are used in products or manufacturing processes.

At this point I will ask that this article appear in the record of these hearings.

[The article follows:]

#### THE DISEASE OF THE CENTURY

Like Thornton Wilder's Mr. Antrobus, man has survived ice ages, more subtle climate changes and, thus far at least, his own inventions. Now his adaptability is facing a new challenge. Industrialization and expanding technology are radically altering the environment and exposing man to growing amounts of harmful pollutants, some of them chemicals that did not exist a century, a decade or even a year or two ago. Result: an increase in many old ailments and the emergence of new ones—all traceable to substances in air, water and food. Says Dr. Irving Selikoff of New York's Mount Sinai School of Medicine: "Environmental disease is becoming the disease of the century."

In other centuries, doctors have known that miners, stone cutters and lens grinders (including the philosopher Spinoza) often developed respiratory disease from inhaling large quantities of dust; hatters suffered brain damage and went mad from absorbing toxic vapors from the mercury used in making felt. A London surgeon named Percivall Pott reported in 1775 that the soot-covered sweepers who cleaned Britain's chimneys had a far higher rate of cancer of the scrotum than the rest of the population.

But in the past 50 years, environmental diseases have spread beyond those in a few specialized trades. Among the most serious:

#### CANCER

The U.S. has one of the world's highest incidences of cancers associated with environmental pollution. A recent National Cancer Institute study (TIME, Aug. 11) shows that the industrialized and highly air-polluted Northeast has a particularly high incidence of lung cancer, as do areas where copper and lead smelters are located. The highest rates of bladder and liver cancers are found in counties with plants producing rubber and chemicals, perfumes and cosmetics, soaps and printing ink. One Ohio community, most of whose workers are employed by chemical plants, had a high rate for all three cancers.

Though cigarette smoking is responsible for at least 80% of all lung cancers, asbestos fibers are also taking an increasing toll. It has long been known that workers exposed to high levels of airborne asbestos fibers developed more lung malignancies than people in other occupations. But doctors have recently suggested that others are also vulnerable: painters or homeowners sanding asbestos-based compounds used for covering rough areas on walls or ceilings; mechanics who work on asbestos-insulated brake linings.

In Russia, researchers have found that workers exposed to chloroprene (the base for several synthetic rubber products) have higher rates of skin and lung cancer than the rest of the population. Vinyl chloride, a colorless gas that is the basic ingredient of the widely used plastic polyvinyl chloride (PVC), has been identified as a cause of angiosarcoma of the liver. Until recently, this cancer was so rare that one Los Angeles hospital found only one case in 52,000 autopsies. Since last year, however, doctors have confirmed 19 cases of the cancer in the U.S. alone, 17 of them in people who worked in plastics plants. There is growing sentiment to ban the use of PVC for containers and plastic wraps for food and drinks; some doctors fear that the compound leaches into the food and could cause cancer.

Even drinking water is suspect. Researchers studying the New Orleans and Cincinnati water supplies found that chlorine, added to water to kill harmful bacteria, can combine with certain pollutants to form compounds that may cause cancer; cancer rates in the New Orleans area, which draws its water from the lowermost—and thus most polluted—part of the Mississippi, are among the highest in the nation. More carcinogens may soon be added to the environment. Studies have shown that the extraction of oil from shale and gas from coal—processes that could eventually be used in a large scale—produces polycyclic hydrocarbons, compounds that can cause cancer in man. Says the National Cancer Institute's Dr. Umberto Saffiotti: "Cancer in the last quarter of the

20th century can be considered a social disease, a disease whose causation and control are rooted in the technology and economy of our society."

#### BIRTH DEFECTS

The Ohio department of health has found that women in three communities with PVC plants—Painesville, Ashtabula and Avon Lake—bore more children with birth defects and other malformations than women in other communities in the state; laboratory research has shown that vinyl chloride can cause chromosomal damage in humans. Anesthetic gases also appear to be teratogenic, or capable of causing birth defects. Russian, Danish and U.S. studies all show a high miscarriage rate among women anesthesiologists and operating-room nurses.

#### HEAVY-METAL POISONING

Once considered largely a problem of the urban slums, where children eat paint flaking off the walls of old buildings, lead poisoning is turning up more frequently in other areas. High levels of lead in the bloodstream have been found in children living near lead smelters in rural Kellogg, Idaho, and El Paso. (Children are metabolically more susceptible to lead poisoning than adults.) Elevated lead levels can also be found in people who live near freeways, where auto exhausts pollute the air. High arsenic levels have been detected in children living near a copper smelter in Ruston, Wash. High levels of lead and other heavy metals, such as arsenic and mercury, are potentially lethal. Mercury poisoning, caused by industrial dumping of toxic compounds into a harbor, killed an estimated 300 people in the area around Minamata, Japan, and crippled almost 1,000 more.

#### RESPIRATORY DISORDERS

Britain had a frightening vision of the future back in 1952, when a combination of pollution and weather produced a killer fog that caused 4,000 deaths, in many cases by aggravating existing respiratory ailments. Communities in the eastern part of the Los Angeles basin have had frequent "smog alerts" during summer months; when an alert is issued, residents with heart or lung problems are warned to avoid unnecessary activity and mothers are told to keep small children indoors. Chicago officials issued warnings 15 times last summer when levels of ozone (a highly active form of oxygen produced, among other ways, by auto engines) rose to the point where they could cause eye and throat irritations. But the prime suspects in the high incidence of respiratory ailments in urban and industrial areas are sulfur dioxide and other pollutants given off by automobile tailpipes or industrial smokestacks. The Environmental Protection Agency's National Environmental Research Center has found that acute bronchitis occurs 20% more frequently among children in communities with high pollution levels than it does among those who breathe cleaner air.

#### STRICT STANDARDS

Action to eliminate or at least reduce environmental pollution has generally been spotty. Enforcement of the federal Clean Air Act, which regulates excessive air pollution, has resulted in some improvement. Installation of pollution-control devices on cars has begun to show some effect in reducing the contaminants in urban air. But despite the tough 1972 amendments to the federal Water Pollution Control Act, a recent study of water supplies in 80 cities showed that most contained contaminants.

The plastics industry has drastically lowered vinyl chloride levels in plants but has challenged federal requirements that they be brought down to one part per million or less, arguing that the costs of full compliance would force many firms out of business and put thousands of employees out of work. Other companies share their concern, pointing out that the costs of combatting pollution will make their products uncompetitively expensive. Part of the hefty jump in auto prices—and the resulting sales slump—stems from the required installation of antipollution devices.

Doctors and environmentalists nonetheless insist that new antipollution laws are essential. "What is an acceptable risk for cancer?" asks Dr. Selikoff. "One out of a hundred? More? Less? With cancer, any risk is too high." To reduce these hazards even further, Selikoff and his colleagues are urging enactment of even stricter new regulations on the manufacture and use of substances known

to be toxic (See under heading "Prescription for Environmental Ills") and better screening to keep those suspected of causing cancer or other illnesses out of the environment.

#### PREScription FOR ENVIRONMENTAL ILLS

What can be done to prevent new toxic substances from entering the environment? Answer: screen out dangerous chemical compounds before they are used in products or manufacturing processes. Easier said than done. Some 2 million chemical compounds are known, and an estimated 25,000 new ones are developed every year. Of the total, about 10,000 have significant commercial uses, and most of them are not dangerous. Even so, to test those that might cause birth defects, cancer or other diseases would be time consuming and costly.

Most of the current testing of new compounds is done by manufacturers. If their record is spotty, it is at least partially due to the difficulty of setting up foolproof test procedures. The tests depend largely on interpreting how results in laboratory animals will apply to man, and they usually fail to take into account synergistic effects (a seemingly benign substance, combined with other compounds in the environment, sometimes becomes hazardous). The chemical industry is moving to correct the situation. Eleven of the biggest companies have pledged \$12 million to start a Chemical Institute of Toxicology to work out better test procedures.

Congress seems ready to go even further. Of four proposed toxic-substances bills now being considered, one is strongly backed by a combination of environmentalists and labor leaders. It would force manufacturers to prove that all their products are safe before they are put on the market, and make the Environmental Protection Agency responsible for screening that proof for "unreasonable risk" to human health and the environment. The chemical industry, claiming that such a measure would duplicate existing laws, favors a weaker bill requiring manufacturers to notify the EPA only about products containing compounds that the agency has listed as dangerous; the EPA then would test the products for safety. What will probably pass Congress is a compromise measure: only potentially hazardous chemicals would have to be tested by industry, with the EPA having final review power. Manufacturers who ignored the agency's decision to keep a product off the market would be subject to criminal prosecution and fines of as much as \$25,000 a day.

Senator TUNNEY. The second was an hour-long broadcast by the CBS television network on Wednesday, October 15, entitled "The American Way of Cancer." In the simplest of terms the program lays out in stark detail the tragedy of unleashing improperly tested chemicals on human beings.

I will ask that a transcript of the program appear in the record of these hearings.<sup>1</sup>

I would also like to announce that there will be a special screening of the program within the next couple weeks for those Senators and Congressmen who might have missed the program the first time around. Details will be announced later.

While environmental toxicants are, indeed, surrounding us apparently at an ever-increasing rate, we need not sit by and idly watch. As correspondent Dan Rather accurately pointed out in his concluding remarks on the CBS program:

The same technological genius that inadvertently produced the "American Way of Cancer" is perfectly capable of reducing the epidemic.

And that is precisely what the Toxic Substances Control Act is all about. While we obviously must consider what legislation like this will cost American industry and what effects it might have on the economy, we must never, never lose sight of the fact that the legislation was

<sup>1</sup> See p. 144.

conceived to protect human beings from environmental disease and that remains its primary goal.

This morning we have 3 hours for this hearing, so we are going to have to keep to a time schedule. I have to catch a plane at National Airport at 1:30, so I have to limit my stay, and I will have to leave at 5 after 1 at the very latest. Hopefully I will be able to leave at 1 o'clock.

[The bill follows:]

94TH CONGRESS  
1ST SESSION

# S. 776

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 20, 1975

Mr. TUNNEY (for himself, Mr. PHILIP A. HART, and Mr. MAGNUSON) introduced the following bill; which was read twice and referred to the Committee on Commerce

---

## A BILL

To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.

- 1 *Be it enacted by the Senate and House of Representa-*  
 2 *tives of the United States of America in Congress assembled,*  
 3 That this act may be cited as the "Toxic Substances Control  
 4 Act".

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1 with respect to their effect on health and the environ-  
2 ment;

3 (2) such testing including the development of test  
4 protocols should be the responsibility of the persons  
5 who manufacture, import, or process such chemical  
6 substances;

7 (3) adequate authority should exist in the Environ-  
8 mental Protection Agency to regulate the distribution  
9 and use of, and to take protective action with respect to  
10 chemical substances which are found to pose an unrea-  
11 sonable risk to human health or the environment; and

12 (4) such authority should be exercised in such a  
13 manner as to assure that technological innovation and  
14 commerce in chemical substances are not unduly impeded  
15 while assuring that the manufacturing or distribution of  
16 such substances do not pose an unreasonable risk to  
17 human health or the environment.

18 DEFINITIONS

19 SEC. 3. As used in this Act, the term—

20 (1) "Administrator" means the Administrator of  
21 the Environmental Protection Agency;

22 (2) "category of chemical substances" means a  
23 group of chemical substances which are similar in  
24 molecular structure, physical or chemical properties,  
25 use, mode of entrance to the human body or the environ-

1        ment, or in some other way suitable for formation of a  
2        group for the purposes of this Act, except that such term  
3        does not mean all new chemical substances within the  
4        meaning of section 5 of this Act;

5            (3) "chemical substance" means (A) any organic  
6        or inorganic substance of a particular molecular identity;  
7        (B) any uncombined radical or element; or (C) any  
8        mixture;

9            (4) "commerce" means trade, traffic, transporta-  
10       tion, or exchange (A) between a place in a State and  
11       any place outside of such State, or (B) which affects  
12       trade, traffic, transportation, or exchange described in  
13       subparagraph (A) of this paragraph;

14           (5) "distribute in commerce" or "distribution in  
15       commerce" means to sell in commerce, to introduce or  
16       deliver for introduction into commerce, or to hold for sale  
17       or distribution after introduction into commerce, includ-  
18       ing use and disposal thereafter, importation, and reim-  
19       portation;

20           (6) "environment" includes man and the human  
21       environment, water, air, land, all living things therein,  
22       and the interrelationships which exist among and be-  
23       tween these;

24           (7) "health and safety data" means any data which  
25       relates to the effects on human health or the environment

1 of a chemical substance, including data developed pur-  
2 suant to health and safety studies. Such data shall in-  
3 clude consumer or other individual correspondence re-  
4 garding alleged adverse effects on human health or the  
5 environment due to a chemical substance, reports of  
6 worker illness or injury allegedly related thereto, and  
7 complaints or other notices of judicial or administrative  
8 proceedings initiated by local, State, or Federal author-  
9 ities relating to injury to human health or the environ-  
10 ment alleged to have been caused by a chemical sub-  
11 stance;

12 (8) "health and safety studies" means any study  
13 of any effects of a chemical substance on human health  
14 or the environment. Such studies shall include epidemio-  
15 logical studies, studies of occupational exposure to a  
16 chemical substance, toxicological studies, clinical studies,  
17 ecological studies, and all tests performed pursuant to  
18 this Act;

19 (9) "includes" and variants thereof should be read  
20 as if the phrase "but is not limited to" were also set  
21 forth;

22 (10) "import" and "reimport" mean to cause a  
23 chemical substance to be transported from a place out-  
24 side the United States to a place within the United  
25 States;



1 (B) the amount of time necessary to complete  
2 a protocol; and

3 (C) the degree to which the protocol con-  
4 forms to or advances the current state of the art of  
5 testing and thereby minimizes costs to ultimate  
6 consumers.

7 (18) "State" means any State, the District of  
8 Columbia, the Commonwealth of Puerto Rico, the Virgin  
9 Islands, Guam, the Canal Zone, or American Samoa;

10 (19) "test protocol" means a specific method or  
11 procedure to be followed in a test or tests to determine  
12 the effects of the manufacture, processing, or distribution  
13 in commerce of a chemical substance;

14 (20) "test results" or "test data" means results or  
15 data obtained from the performance of a test protocol;  
16 and

17 (21) "United States" means all of the States.

18 STANDARDS FOR TEST PROTOCOLS

19 SEC. 4. (a) GENERAL.—If the Administrator deter-  
20 mines that—

21 (1) a chemical substance may present an unreason-  
22 able risk to health or the environment;

23 (2) there is insufficient data upon which to con-  
24 clude that such a risk does in fact exist or not exist; and

1           (3) testing of such substance would assist in mak-  
2           ing such a determination,  
3 then he shall, by rule, prescribe standards for a test protocol  
4 for such substance. Whenever such standards are proscribed,  
5 the Administrator shall require, in accordance with subsec-  
6 tion (b) (3) of this section, that one or more persons formu-  
7 late a test protocol for such substance, in accordance with  
8 such standards, and perform the tests required by such  
9 protocol.

10           (b) STANDARDS.—(1) In prescribing the standards  
11 for test protocols, the Administrator shall require that infor-  
12 mation pertaining to all relevant factors with respect to the  
13 applicable chemical substance be developed. Such factors  
14 include—

15           (A) the effects of such substance on human health,  
16           and the magnitude of human exposure; and

17           (B) the effects of such substance on the environ-  
18           ment, and the magnitude of environmental exposure.

19           (2) Standards for test protocols shall require that such  
20 protocols be formulated in accordance with those standards  
21 and may require that tests be performed, in accordance with  
22 those protocols, for carcinogenicity, mutagenicity, terato-  
23 genicity, acute toxicity, subacute toxicity, chronic toxicity,  
24 cumulative properties, synergistic properties, clinical effects,  
25 epidemiological effects, ecological effects, and any other ef-

1 facts of such substance which might cause unreasonable risk  
2 to human health or the environment.

3 (3) A rule prescribing standards for a test protocol for  
4 a chemical substance shall require that any test contained  
5 in a test protocol for such substance which is formulated in  
6 accordance with such standards shall be performed by any  
7 person or governmental entity which is a manufacturer, proc-  
8 essor, or importer of such chemical substance.

9 (c) PERFORMANCE OF TESTS.—(1) The Administra-  
10 tor may by rule permit two or more persons, who are re-  
11 quired to test under a test protocol formulated in accordance  
12 with standards prescribed by him, to designate one such  
13 person or a qualified and independent third party to perform  
14 such testing pursuant to a cost-sharing arrangement. If the  
15 persons required to test are not able to agree upon a designee  
16 within a reasonable time, or if the agreed-upon designee is  
17 not acceptable to the Administrator, the Administrator may  
18 order one or more of such persons, or may designate a quali-  
19 fied and independent third party, to perform the required  
20 testing. If the Administrator issues such an order, he shall  
21 direct the persons who are thus exempted from the obligation  
22 to perform tests to provide fair and equitable contribution  
23 for the full cost of such testing, and of the cost, if any, of  
24 formulating any test protocol, in an amount determined  
25 under rules of the Administrator.

1           (2) Whenever the Administrator exempts a person  
2 from the obligation to perform tests, he shall, if such exemp-  
3 tion takes effect during the reimbursement period for such  
4 data, order such exempt person to provide reimbursement  
5 in the same manner as if an exemption had been granted  
6 under section 5 (g) of this Act (unless the parties agree on  
7 the amount and method of reimbursement).

8           (3) In any case in which a person provides contribu-  
9 tion or reimbursement in accordance with paragraph (1) or  
10 (2) of this subsection or of section 5 (g) of this Act, sec-  
11 tion 15 of this Act shall not be construed to prevent such  
12 person from having access to any data submitted as a result  
13 of the testing as to which such contribution or reimburse-  
14 ment was provided.

15           (d) REPORTING.—A person required to perform any  
16 test required by an applicable test protocol shall submit the  
17 test data developed pursuant to such test protocol and such  
18 protocol to the Administrator promptly upon completion of  
19 such test. The Administrator may provide for the submission  
20 of preliminary and other reports during the course of such  
21 testing.

22           (f) NOTICE.—Upon the receipt of test protocol and test  
23 data developed pursuant to it under this section, and subject  
24 to section 15 of this Act, the Administrator shall promptly  
25 publish a notice of such receipt in the Federal Register. Each

1 such notice shall (1) identify the chemical substance for  
2 which test data have been received, (2) list the uses or in-  
3 tended uses of such substance, and other information specified  
4 by the Administrator by rule, and (3) describe the nature  
5 of the test performed and the data which were developed.  
6 Such data shall be made available by the Administrator for  
7 examination by any person, except as otherwise provided in  
8 section 15 of this Act.

9 (g) PROCEDURE.—Rules issued under this section (and  
10 amendment thereto or repeals thereof) shall be promulgated  
11 pursuant to section 553 of title 5, United States Code. In  
12 promulgating, amending, or repealing any standard or other  
13 rule under this section, (1) the Administrator shall give  
14 interested persons an opportunity for the oral presentation  
15 of data, views, or arguments, in addition to an opportunity  
16 to make written submissions, and (2) a transcript shall be  
17 made of any oral presentation.

18 PREMARKET SCREENING OF CHEMICAL SUBSTANCES

19 SEC. 5. (a) GENERAL.—Commencing 180 days after  
20 the date of enactment of this Act, a manufacturer or importer  
21 of a new chemical substance (other than a mixture or a  
22 chemical substance covered by subsection (b) of this section)  
23 shall notify the Administrator of the planned manufacture  
24 or importation of such substance at least 90 days in advance  
25 thereof. When providing such notice, such manufacturer or

1 importer shall submit to the Administrator the information  
2 referred to in section 8 of this Act insofar as it pertains to  
3 such substance. If, in the judgment of the Administrator, such  
4 a substance does not present an unreasonable environmental  
5 or human health risk, he may reduce the number of days  
6 after submission of such information during which manu-  
7 facture or importation may not occur. The Administrator  
8 shall give priority attention to a chemical substance with  
9 respect to which information is received indicating that  
10 serious economic or other hardships are likely to result if  
11 there is any unnecessary postponement of manufacture or  
12 importation.

13 (b) SUBMISSION OF DATA.—(1) After the effective  
14 date of test standards issued under section 4 of this Act,  
15 any manufacturer or importer of a new chemical substance  
16 which is covered by such standards, and who first manu-  
17 factures or imports such substance after such date, shall  
18 submit to the Administrator (in lieu of the information  
19 required in subsection (a) of this section), at least 90 days  
20 prior to such manufacture or importation, the test data  
21 developed in accordance with such standards, and the ap-  
22 plicable information referred to in section 8 of this Act which  
23 pertains to the intended use or distribution of such substance.

24 (2) The Administrator shall promptly publish (subject  
25 to section 15 of this Act) in the Federal Register the identity

1 of each such chemical substance, the use or distribution in-  
2 tended, and a statement of the availability of any test data or  
3 other information submitted.

4 (c) RULE.—If warranted by data available to him, or  
5 by the absence of data, the Administrator may propose a rule  
6 under section 6 of this Act with respect to a new chemical  
7 substance. If such rule is proposed prior to the expiration of  
8 the 90-day period referred to in subsection (a) or (b) of  
9 this section, or during the extension provided for in subsec-  
10 tion (d) of this section, such proposed rule shall apply  
11 (pending the outcome of administrative proceedings on such  
12 proposal) to any subsequent manufacture or distribution in  
13 commerce of such new chemical substance as if such proposed  
14 rule were final.

15 (d) EXTENSION.—The Administrator may extend, for  
16 an additional period beyond the 90-day period from the sub-  
17 mission of required information under this section, the date  
18 after which a new chemical substance may be manufactured  
19 or imported for any particular use or distribution. Such addi-  
20 tional period may not exceed 90 days and shall not be granted  
21 except for good cause shown. Notice of any such extension,  
22 and the reasons therefor, shall be published in the Federal  
23 Register. Such an extension shall constitute a final action for  
24 purposes of judicial review.

25 (e) CLEARANCE.—Unless the Administrator proposes a

1 rule with respect to a new chemical substance, under section  
2 6 of this Act, within 90 days after the submission of informa-  
3 tion or data under subsection (a) or (b) (or in the case of  
4 information submitted under subsection (a) within such  
5 shorter period as the Administrator may consider appropri-  
6 ate) or within such period as extended under subsection (e),  
7 manufacture or importation of such new chemical substance  
8 may commence. Nothing herein shall be construed to prohibit  
9 the Administrator from promulgating a rule pursuant to sec-  
10 tion 6 of this Act with respect to any chemical substance  
11 after manufacture or importation has commenced, or from  
12 taking action against any substance which is found to be an  
13 imminent hazard pursuant to section 7 of this Act.

14 (f) EXEMPTION.—(1) The Administrator may exempt  
15 any person from the obligation to submit test data under this  
16 section, if he determines that the submission of test data by  
17 such person would be duplicative of data previously received.  
18 Such an exempt person shall not manufacture or import such  
19 new chemical substance prior to the date of termination of  
20 the premarket screening period for which test data were sub-  
21 mitted under this section. Any chemical substance, or any  
22 manufacturer or importer thereof referred to under the pre-  
23 ceding sentence, shall be subject to all the other provisions of  
24 this Act.

1       (2) If the Administrator, under paragraph (1), ex-  
2       empts any person from submitting data under this section  
3       because of the existence of previously submitted test data, and  
4       if such exemption takes effect during the reimbursement  
5       period for such data (defined in paragraph (3)), then, unless  
6       the parties can agree on the amount and method of reimburse-  
7       ment, the Administrator shall order the person granted the  
8       exemption to provide fair and equitable reimbursement (in  
9       an amount and subject to conditions determined under rules  
10      of the Administrator) —

11           (A) to any person who previously submitted test  
12      data on which the exemption was based, for a portion of  
13      the costs incurred by him in complying with the require-  
14      ment under this section to submit such data, and

15           (B) to any other person who has been required  
16      under this paragraph to contribute with respect to such  
17      data.

18      An order under this paragraph shall be considered final  
19      agency action, for purposes of judicial review.

20       (3) For purposes of paragraph (2), the reimbursement  
21      period for any previously submitted test data is a period—

22           (A) beginning on the earliest date (after submission  
23      of such data) on which a person who previously sub-  
24      mitted test data on which the exemption was based was

1 no longer prohibited from proceeding with the manufac-  
2 ture and distribution in commerce of a chemical sub-  
3 stance to which such data applied, and

4 (B) ending two years after such date (or, if later,  
5 at the expiration of a period after such date equal in  
6 length to the period which the Administrator determines  
7 was necessary to develop the previously submitted test  
8 data).

9 (g) SIGNIFICANT NEW USE.—(1) A chemical sub-  
10 stance may not be manufactured or imported for a use which  
11 is identified by the Administrator in a rule as a significant  
12 new distribution in commerce of such substance, unless, at  
13 least 90 days prior to such manufacture or importation, the  
14 person intending to manufacture or import such substance  
15 for such use submits a notice of his intention to do so to the  
16 Administrator. Any such substance shall be subject to all  
17 other provisions of this section.

18 (2) Any manufacturer or importer who proposes to  
19 distribute in commerce a chemical substance for which notice  
20 may be required under this subsection, shall attempt to ascer-  
21 tain from the person to whom he distributes such substance  
22 (hereafter in this paragraph referred to as "distributee")  
23 whether such distributee proposes to distribute such substance  
24 for a use which would be a significant new use. If the dis-  
25 tributee refuses or is unable to inform such manufacturer or

1 importer whether the proposed use would be a significant  
2 new distribution in commerce, the manufacturer or importer  
3 shall so inform the Administrator and shall inform the dis-  
4 tributee that such substance may be subject to this section.  
5 Such distributee shall thereafter be treated, for purposes of  
6 this section (including this paragraph), as the manufacturer  
7 of such substance.

#### 8 HAZARDOUS CHEMICAL SUBSTANCES

9 SEC. 6. (a) GENERAL.—If the Administrator determines  
10 that a rule with respect to a chemical substance is necessary  
11 to protect against an unreasonable risk to human health or  
12 the environment, he may prescribe such a rule under this  
13 section. Such a rule may consist of one or more of any of the  
14 following types of requirements:

15 (1) Requirements (A) prohibiting the manufac-  
16 ture, processing or distribution in commerce of such  
17 chemical substance or (B) limiting the amount of such  
18 chemical substance which may be manufactured or dis-  
19 tributed in commerce.

20 (2) Requirements (A) prohibiting the manufac-  
21 ture or distribution in commerce of such chemical sub-  
22 stance for a particular use or (B) limiting the amount  
23 of such substance which, or regulating the condition un-  
24 der which such substances, may be manufactured or dis-  
25 tributed in commerce for such uses.

1           (3) Requirements mandating that such chemical  
2 substance, or an article containing such substance, be  
3 marked with or accompanied by clear and adequate  
4 warnings and instructions with respect to its use or dis-  
5 posal, in such form and bearing such content as the  
6 administrator determines to be appropriate.

7           (4) Requirements (A) that persons subject to re-  
8 quirements prescribed under paragraphs (1), (2), or  
9 (3), make and retain records and monitor or conduct  
10 tests necessary to assure their compliance with such  
11 requirements; (B) that manufacturers and processors  
12 of a chemical substances make and retain records of  
13 the processes used to manufacture or process such sub-  
14 stance; and (C) that manufacturers and processors  
15 monitor or conduct tests necessary to determine whether  
16 chemical substances manufactured or processed by them  
17 are adulterated (within the meaning of subsection (e)  
18 (2)), and retain records of such tests. Any records or  
19 data required under this paragraph shall not be con-  
20 sidered research data or process technology for purposes  
21 of section 13 (b) of this Act.

22 The Administrator shall select the least stringent requirement  
23 practicable consistent with the protection of human health  
24 and the environment against unreasonable risks.

1 (b) APPLICABILITY.—(1) The applicability of any rule  
2 issued under this section may be limited to specified geo-  
3 graphic areas.

4 (2) The authority of the Administrator, under subsec-  
5 tion (a) (2) of this section, to prescribe a rule prohibiting  
6 the manufacture, processing, or distribution in commerce of  
7 a chemical substance for a particular use includes the author-  
8 ity to prohibit the distribution in commerce of a chemical  
9 substance for a particular use in a concentration in excess of  
10 a level specified in such rule.

11 (3) Rules limiting the amount of a chemical substance  
12 which may be manufactured, processed or distributed in  
13 commerce or limiting the quantity of such substance which  
14 may be manufactured, processed or distributed for a par-  
15 ticular use, shall provide for assigning production, processing  
16 and distribution quotas to the extent necessary, with respect  
17 to the chemical substance whose manufacture, processing or  
18 distribution is limited thereby. The permissible quota for each  
19 person who applies to manufacture or process such substance  
20 or to engage in its distribution in commerce shall be deter-  
21 mined in accordance with criteria which the Administrator  
22 shall prescribe by rule. Such criteria shall take into account  
23 all relevant factors, including (A) effects on competition,  
24 (B) the market shares, productive capacity, and product

1 and raw material inventories of the precursors of the chemi-  
2 cal substance of persons applying for quotas, (C) emergency  
3 conditions, such as fires or strikes, and (D) effects on tech-  
4 nological innovation.

5 (c) FACTORS.—In promulgating rules under subsection  
6 (a) of this section, the Administrator shall consider all rele-  
7 vant factors, including—

8 (1) the effects of the substance on health and the  
9 magnitude and duration of human exposure to it;

10 (2) the effects of the substance on the environment  
11 and the magnitude and duration of environmental ex-  
12 posure to it; and

13 (3) the benefits of the substance for a given use or  
14 uses and the availability of less hazardous substances for  
15 the same uses.

16 (d) EFFECTIVE DATE.—The Administrator shall spec-  
17 ify the effective date of any rule proposed under subsection  
18 (a) of this section. Such date shall be as soon as feasible.

19 (e) QUALITY CONTROL.—(1) If the Administrator  
20 has good cause to believe that a particular manufacturer,  
21 importer, or processor is manufacturing, importing, or proc-  
22 essing a chemical substance in a manner which permits or  
23 causes the adulteration of such chemical substance.

24 (A) he may require such manufacturer or processor  
25 to submit a description of the relevant quality control

1 procedures followed in the manufacturing or processing  
2 of such chemical substance and he shall take such other  
3 actions as authorized by this Act; and

4 (B) if he thereafter determines by rule that such  
5 quality control procedures are inadequate to prevent  
6 the adulteration of such substance, the Administrator  
7 may order the manufacturer, importer, or processor to  
8 revise such quality control procedures to the extent which  
9 the Administrator finds necessary to remedy such in-  
10 adequacy.

11 (2) For purposes of this subsection, a chemical sub-  
12 stance is adulterated if it or any precursor substance used  
13 or produced in its manufacture or processing bears or con-  
14 tains any other chemical substance or contaminant which  
15 itself or, in combination with the chemical substance, poses or  
16 is likely to pose an unreasonable risk to human health or the  
17 environment.

18 (f) PROCEDURE.—Rules issued under subsection (a)  
19 of this section (and amendments thereto or repeals thereof)  
20 shall be promulgated pursuant to section 553 of title 5 of  
21 the United States Code; except that in promulgating any  
22 such rule, amendment, or repeal (A) the Administrator  
23 shall give interested persons an opportunity for the oral pres-  
24 entation of data, views, or arguments, in addition to an



## REPORTS

1

2       SEC. 8. (a) GENERAL.—(1) The Administrator may,  
3 by rule, require any manufacturer, importer, or processor of  
4 any chemical substance to maintain such records, and to sub-  
5 mit such reports to him annually, and at such more frequent  
6 time as he may reasonably require. Reports which the Ad-  
7 ministrator by rule requires may include the following infor-  
8 mation:

9           (A) the common or trade name, the chemical iden-  
10 tity, and the molecular structure of each chemical sub-  
11 stance for which such report is required, insofar as  
12 known to the person making the report or insofar as  
13 reasonably ascertainable;

14           (B) the categories or proposed categories of use of  
15 each such substance, insofar as known to the person  
16 making the report, or insofar as such are reasonably  
17 ascertainable;

18           (C) reasonable estimates of the amounts of each  
19 substance manufactured, imported, or processed for each  
20 such use; and

21           (D) a description of any byproducts resulting from  
22 the manufacture, processing, distribution in commerce  
23 of each such substance, insofar as known to the person  
24 making the report or insofar as reasonably ascertainable.

1           (2) For purposes of this subsection, the term "byprod-  
2   uct" means a chemical substance which is produced or re-  
3   sults as a consequence of the manufacture, importation,  
4   processing, or distribution in commerce of some other chemi-  
5   cal substance.

6           (b) INVENTORY.—The Administrator shall compile and  
7   publish a listing of each chemical substance which any  
8   manufacturer, processor or importer reports (under this  
9   section) is manufactured, processed or imported into the  
10  United States. A chemical substance shall be included in such  
11  listing as of the earliest date (as determined by the Ad-  
12  ministrator) on which such substance was manufactured in  
13  or imported into the United States.

14          (c) SUBMISSION.—Any test data or other information  
15  required to be developed pursuant to this Act shall be sub-  
16  mitted to the Administrator promptly. The Administrator  
17  may require the submission of preliminary and other reports  
18  during the course of any monitoring or testing.

19          (d) RECORDS.—Any person who manufactures, pro-  
20  cesses, or distributes in commerce any chemical substance  
21  shall maintain records of adverse reactions to human health  
22  or the environment alleged to have been caused by the  
23  chemical substance. Such records may consist of, but not be  
24  limited to, consumer allegations of personal injury or harm  
25  to health, reports of occupational disease or injury, and

1 reports or complaints of injury to the environment submitted  
2 to the manufacturer, processor, or distributor in commerce by  
3 individuals or governmental agencies.

4 (e) HEALTH AND SAFETY STUDIES.—Any person who  
5 manufactures, processes, or distributes in commerce any  
6 chemical substance shall report to the Administrator—

7 (1) all health and safety studies in progress on or  
8 initiated after the date of enactment of this Act, con-  
9 ducted by or for the person; and

10 (2) a list of all health and safety studies conducted  
11 by or for such person 40 years prior to the date of enact-  
12 ment of this Act. Such list shall be submitted to the Ad-  
13 ministrator within 180 days after the date of enactment  
14 of this Act. The Administrator, on the basis of the lists  
15 submitted, may request submission of any study appear-  
16 ing on such list.

17 (f) COMMENTS.—Whenever the Administrator deter-  
18 mines that such action would be necessary to assist him to  
19 carry out his responsibilities and authorities under this Act,  
20 he may, by publishing a notice in the Federal Register, in-  
21 vite and afford all interested persons an opportunity to pro-  
22 vide information and comment in writing respecting the  
23 health or environmental effects of a chemical substance. Such  
24 an invitation and opportunity shall not be deemed a proceed-  
25 ing for purposes of section 15 (a) (2) of this Act.



1 discretion determines the risk associated with such sub-  
2 stance or article may be prevented or reduced to a  
3 sufficient extent under any Federal law administered,  
4 in whole or in part by the Administrator, unless he  
5 finds that the risk associated with such substance or  
6 such article cannot be prevented or reduced as effectively  
7 by his action under such other Federal law;

8 (2) (A) if the entirety of risk to human health and  
9 the environment associated with such substance or  
10 article is designed to be protected against under other  
11 Federal law (other than the National Environmental  
12 Policy Act of 1969) not administered in whole or in  
13 part, by the Administrator; and

14 (B) if the entirety of such risk could be prevented  
15 or reduced to a sufficient extent by action taken under  
16 such other Federal law as determined by the Admin-  
17 istrator in his discretion.

18 (c) NOTICE.—If it appears to the Administrator that  
19 any chemical substance may pose an unreasonable risk to  
20 human health or the environment which could be prevented  
21 or reduced to a sufficient extent by actions taken under other  
22 Federal laws, he shall transmit, and give public notice there-  
23 of, any data received from manufacturers, importers, or proc-  
24 essors, or data otherwise in his possession which is relevant  
25 to such risk to the Federal executive department or agency,

1 independent regulatory agency or other authority of the  
2 Federal Government with authority to take legal action.

3 (d) COORDINATION.—In administering the provisions  
4 of this Act, the Administrator shall consult and coordinate  
5 with the Secretary of Health, Education, and Welfare and  
6 the heads of any other appropriate Federal executive depart-  
7 ment or agency, any relevant independent regulatory agency,  
8 and any applicable instrumentality of the Federal Govern-  
9 ment. The Administrator shall report annually to the Con-  
10 gress on actions taken to coordinate with such other Federal  
11 agencies, and on actions taken to coordinate the authority  
12 under this Act with the authority granted under other Acts  
13 referred to in subsection (b) of this section.

14 OTHER PROVISIONS

15 SEC. 10. (a) ASSISTANT ADMINISTRATOR.—The Presi-  
16 dent, by and with the advice and consent of the Senate, shall  
17 appoint an Assistant Administrator for Toxic Substance to  
18 facilitate administration of this Act from among individuals  
19 who, by reason of their background and experience, are  
20 especially qualified to direct a program concerning the effects  
21 of chemicals on human health and the environment.  
22 Such person shall be be responsible for collection of data,  
23 preparation of studies, and recommendations to the Admin-  
24 istrator for regulatory and other actions to carry out the  
25 purposes of this Act.

1 (b) ANNUAL REPORT.—Each January 1st, an annual  
2 report shall be transmitted to Congress by the Administrator  
3 describing his activities under this Act. Such report shall  
4 include detailed short- and long-range plans for future activi-  
5 ties by the Administrator to further the purposes of this Act.

6 (c) CATEGORIES.—Any action which may be taken, by  
7 the Administrator under any provision of this Act, with re-  
8 spect to a chemical substance, may be taken with respect to  
9 a category of chemical substances or to classes of uses of  
10 chemical substances. Whenever the Administrator takes an  
11 action with respect to a category of chemical substances or  
12 to under any provision of this Act, any reference in this Act  
13 to a chemical substance (insofar as such reference relates to  
14 such action) shall be deemed to be a reference to each chem-  
15 ical substance in any such category.

16 RESEARCH, COLLECTION, DISSEMINATION, AND  
17 UTILIZATION OF DATA

18 SEC. 11. (a) AUTHORITY.—The Administrator shall,  
19 in consultation and cooperation with the Secretary of Health,  
20 Education, and Welfare, and other agency or agencies, con-  
21 duct such research and monitoring as is necessary to carry  
22 out the purposes of this Act. Responsibility for conduct of  
23 research shall be assigned to the Environmental Protection  
24 Agency, agencies of the Department of Health, Education,  
25 and Welfare, or such other agencies as would be appropriate,

1 as determined by the Administrator and the Secretary of  
2 Health, Education, and Welfare. The Administrator, in con-  
3 sultation with the Secretary of Health, Education, and Wel-  
4 fare, is authorized to make contracts and grants for research  
5 and monitoring as necessary to carry out the purposes of this  
6 Act.

7 (b) INTERAGENCY COMMITTEE.—(1) The Adminis-  
8 trator shall establish and be responsible for the continuing  
9 activities of an interagency committee which will design and  
10 coordinate an efficient and effective system, within the Envi-  
11 ronmental Protection Agency, for the collection, dissemina-  
12 tion to other Federal agencies, and utilization of data  
13 submitted to the Environmental Protection Agency under  
14 the terms of this Act.

15 (2) The Administrator shall, in consultation with the  
16 Secretary of Health, Education, and Welfare and other ap-  
17 propriate agencies, design and coordinate an efficient and  
18 effective system for the retrieval of toxicological and other  
19 scientific data which could be useful to the Administrator in  
20 carrying out the purposes of this Act. Systematized retrieval  
21 shall be developed for use by all Federal and other agencies  
22 with responsibilities in the area of regulation or study of  
23 toxic substances, including chemicals, on the health of human  
24 beings or the environment.

25 (3) The Administrator is authorized to make contracts

1 and grants for the development of a data renewal system  
2 suitable for carrying out the purposes of this Act, as described  
3 above, in consultation with the Secretary of Health, Educa-  
4 tion, and Welfare.

5 ADMINISTRATIVE INSPECTIONS

6 SEC. 12. The Administrator may authorize any officer,  
7 employee, or agent to enter upon, inspect, and examine at  
8 reasonable times and in a reasonable manner the records  
9 and properties of persons to the extent that such records  
10 and properties relate to the manufacture, processing, or dis-  
11 tribution in commerce of chemical substances subject to this  
12 Act. Any such officer, employee, or agent shall, upon request,  
13 display proper credentials. Unless the owner, operator, or  
14 agent in charge of such records and properties so consents  
15 in writing, no inspection authorized by this section shall  
16 extend to (1) financial data; (2) sales data other than  
17 shipments data; (3) pricing data; (4) personnel data; (5)  
18 research data (other than data required by this Act); or  
19 (6) process technology (other than those data related to  
20 the chemical composition, synthesis information, or the indus-  
21 trial use of a chemical substance).

22 EXPORTS

23 SEC. 13. (a) GENERAL.—This Act shall not apply to  
24 any chemical substance, or to any article containing such  
25 substance, if (1) it can be shown that such substance or

1 article is manufactured, processed, sold, or held for sale for  
2 export from the United States (or that such substance was  
3 imported for export), unless such substance or article is, in  
4 fact, manufactured, processed, or distributed in commerce for  
5 use in the United States, and (2) such chemical substance  
6 or article containing such substance when distributed in com-  
7 merce, or any container in which it is enclosed when so dis-  
8 tributed, bears a stamp or label stating that such chemical  
9 substance or article is intended for export; except that (A)  
10 any manufacturer, processor, or exporter of such chemical  
11 substance who, but for this section, would be subject to sec-  
12 tion 8 of this Act shall be subject to the reporting require-  
13 ments of such section 8; and (B) this subsection shall not  
14 apply to any such substance or article if the Administrator  
15 finds that it will, directly or indirectly, pose an unreasonable  
16 risk to health within the United States or to the environment  
17 of the United States and such chemical shall be subject to  
18 section 5 of this Act.

19 (b) FOREIGN GOVERNMENT.—If the submission of test  
20 data is required for a chemical substance under section 4 or 5  
21 of this Act, or if rules applicable to such substance or an  
22 article containing such substance have been prescribed or  
23 proposed under section 5 or 6 of this Act, the Administrator  
24 shall (except as otherwise provided in section 15 of this Act)  
25 furnish to the governments of the foreign nations to which he

1 knows such chemical substance is exported, or is intended to  
2 be exported, notice of the availability of the data submitted  
3 to the Administrator under section 4 or 5 concerning such  
4 chemical substance and may require warning labels to be  
5 affixed to any package containing such chemical substance;  
6 and shall make available to such government upon request,  
7 notice of any rule applicable to such substance or an article  
8 containing such substance which has been prescribed or pro-  
9 posed by the Administrator under this Act.

10 ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

11 SEC. 14. The Secretary of the Treasury shall refuse  
12 entry into the customs territory of the United States (as  
13 defined in general headnote 2 to the Tariff Schedules of the  
14 United States) of any chemical substances, or any article con-  
15 taining such substance, offered for entry if it fails to conform  
16 with rules in effect under this Act, or if it is otherwise pro-  
17 hibited pursuant to this Act from being distributed in com-  
18 merce. If a chemical substance or article is refused entry,  
19 hereunder, the Secretary of the Treasury shall (1) refuse  
20 delivery to the consignee and (2) cause the disposal or  
21 storage thereof if it is not exported by the consignee within  
22 three months from the date of receipt of notice of such  
23 refusal, under such regulations as the Secretary of the Treas-  
24 ury may prescribe. Notwithstanding the foregoing the Sec-  
25 retary of the Treasury may deliver such substance or article

1 to the consignee pending examination and decision in the  
2 matter, upon execution by the consignee of a bond for  
3 the amount of the full invoice value of such substance or  
4 article, together with the duty thereon, and providing for  
5 forfeiture of the full amount of such bond by the consignee  
6 on refusal to return such substance or article to the custody  
7 of such Secretary, when demanded for any cause, or for  
8 any other purpose. All charges for storage, cartage, and  
9 labor on substances or articles which are refused admis-  
10 sion or delivery under this section shall be paid by the  
11 owner or consignee. In default of payment of such charges,  
12 then shall constitute a lien against any future entry into  
13 the United States made by such owner or consignee. The  
14 Secretary of the Treasury, after consultation with the Ad-  
15 ministrator, shall issue regulations for the administration  
16 and enforcement of subsection (a) of this section.

17

## CONFIDENTIALITY

18       SEC. 15. (a) GENERAL.—All information reported to,  
19 or otherwise obtained by, the Administrator or his represen-  
20 tative under this Act, which contains or relates to a trade  
21 secret or other matter referred to in section 1905 of title 18,  
22 United States Code, shall be considered confidential and shall  
23 not be disclosed; except that such information may be dis-  
24 closed—

25               (1) to officers or employees of the United States;

1           (2) when relevant in any proceeding under this  
2       Act, except that disclosure in such a proceeding shall  
3       be made in such manner as to preserve confidentiality  
4       to the extent practicable without impairing the pro-  
5       ceeding, or

6           (3) to the extent that the Administrator deter-  
7       mines it is necessary to protect health or the environ-  
8       ment.

9       (b) ACCESS BY QUALIFIED SCIENTISTS.—Notwith-  
10     standing any limitations contained in subsection (a) or any  
11     other provision of law, all information reported to or other-  
12     wise obtained by the Administrator or his representative  
13     shall be made available, upon request of qualified scientists  
14     to the extent that release of such information will not result  
15     in significant competitive damage to the originator of the  
16     information.

17       (c) ACCESS BY CONGRESS.—Notwithstanding any  
18     limitation contained in subsection (a) or any other provision  
19     of law, all information reported to or otherwise obtained by  
20     the Administrator or his representative shall be made avail-  
21     able upon request of any duly authorized committee of the  
22     Congress.

23       (d) NAMES OF INDIVIDUALS.—Names of individuals  
24     maintained in records pertaining to health and safety data  
25     shall only be made public after written permission is obtained

1 by the Administrator from the individuals in question. The  
2 confidentiality of medical records shall be maintained insofar  
3 as is reasonable and appropriate for the purposes of this Act.

#### 4 PROHIBITED ACTS

5 SEC. 16. It shall be unlawful for any person to—

6 (1) fail or refuse to comply with any provision of  
7 sections 4, 5, or 6 of this Act, any rule or order pre-  
8 scribed under any of those sections;

9 (2) fail or refuse to comply with section 8 of this  
10 Act or any rule or order under that section;

11 (3) fail or refuse to permit access to or copying  
12 of records, fail or refuse to permit entry or inspection,  
13 or fail to take any other action required under section 12  
14 of this Act;

15 (4) fail or refuse to comply with instructions with  
16 respect to the use or disposal of a chemical substance  
17 where such instructions are required by rule prescribed  
18 under section 6 (a) (3) of this Act; or

19 (5) distribute in commerce or use for commercial  
20 purpose a chemical substance which such person knew  
21 or had reason to know was manufactured or distributed  
22 in commerce in violation of section 5 or 6 of this Act.

#### 23 PENALTIES

24 SEC. 17. (a) CIVIL.—(1) Any person who violates a  
25 provision of section 16 of this Act shall be liable to the United

1 States for a civil penalty. Each day of a continuing viola-  
2 tion is a separate violation for purposes of this subsection.  
3 The amount of such civil penalty shall be assessed by  
4 the Administrator by written notice. In determining the  
5 amount of such penalty, the Administrator shall take into  
6 account the nature, circumstances, extent, and gravity of  
7 the violation or violations and, with respect to the violator,  
8 ability to pay, effect on ability to continue to do business,  
9 any history of prior such violations, the degree of culpability,  
10 and such other matters as justice may require: *Provided,*  
11 That the amount of each penalty shall not exceed \$25,000  
12 for each such violation.

13 (2) Any person who is aggrieved by the assessment  
14 of a civil penalty under this subsection may appeal such  
15 decision of the Administrator by bringing a civil action  
16 against the Administrator for rescission or modification of  
17 such penalty, in the district court of the United States for  
18 the District of Columbia or for any judicial district in which  
19 he resides or transacts business, within 30 days from the  
20 date on which he is notified of such decision by certified  
21 mail. In any such judicial proceeding, the factual findings  
22 of the Administrator shall be sustained if supported by sub-  
23 stantial evidence on the record considered as a whole.

24 (3) The Administrator may, in his discretion, com-  
25 promise, modify, or remit, with or without conditions, any

1 civil penalty imposed or subject to imposition under this  
2 subsection. The amount of such penalty, when finally deter-  
3 mined, or the amount agreed upon in compromise, may be  
4 deducted from any sums owing by the United States to the  
5 person charged.

6 (4) If any person fails to pay an assessment of a civil  
7 penalty after it has become a final and unappealable order, or  
8 after the appropriate court has entered final judgment in  
9 favor of the Administrator, the Attorney General shall re-  
10 cover the amount assessed (plus interest at currently prevail-  
11 ing rates from such date) in any appropriate district court  
12 of the United States. In such action, the validity, amount,  
13 and appropriateness of such penalty shall not be subject to  
14 review.

15 (b) CRIMINAL.—Any person who knowingly or will-  
16 fully violates any provision of section 16 shall, in addition  
17 to or in lieu of a civil penalty imposed under subsection (a)  
18 of this section, be liable, upon conviction, to a fine of not  
19 more than \$25,000 for each day of violation, or to imprison-  
20 ment for not more than one year, or both.

21 (c) The term “knowingly” means (1) having actual  
22 knowledge, or (2) the presumed knowledge based upon  
23 knowledge a reasonable man would have in the circum-  
24 stances, including knowledge obtainable upon the exercise  
25 of due care to ascertain the truth of representations.

## SPECIFIC ENFORCEMENT

1  
2       SEC. 18. (a) INJUNCTIONS.—Upon application by the  
3 Administrator or the Attorney General, the district courts  
4 of the United States shall have jurisdiction to restrain any  
5 violation of section 17 of this Act or to compel the taking  
6 of any action required by this Act or any rule issued there-  
7 under. In any action under this subsection, process may be  
8 served on a defendant in any other judicial district in which  
9 the defendant resides or may be found, and subpoenas for  
10 witnesses may run into any other district.

11       (b) RELIEF AUTHORIZED.—(1) The district court in  
12 which an action under subsection (a) of this section, or  
13 under section 7 of this Act, is filed to grant such temporary  
14 or permanent relief as may be necessary to protect health  
15 or the environment from an unreasonable risk associated  
16 with the substance or article involved in such action. Such  
17 relief may require (in the case of an action under subsection  
18 (a) of this section or under section 7 of this Act a mandatory  
19 order requiring (A) notification of such risk to those pur-  
20 chasers of such substance or article who are known to the  
21 defendant; (B) public notice; (C) recall; and (D) the  
22 replacement or refund of such substance or article. An order  
23 issued under this subsection may require any person who is  
24 a manufacturer, processor, or distributor in commerce of such  
25 substance or article to reimburse any other person for such

1 other person's expenses in connection with carrying out the  
2 order, if the court determines such reimbursement to be in  
3 the public interest.

4 (2) An action under subsection (a) of this section, or  
5 under section 7 of this Act may be brought in the United  
6 States District Court for the District of Columbia or in the  
7 district court of the United States for any judicial district  
8 in which any of the defendants is found, resides, or transacts  
9 business. In any such action, process may be served on a  
10 defendant in any other district in which such defendant re-  
11 sides or may be found. Subpenas requiring attendance of wit-  
12 nesses in such an action may run into any other judicial dis-  
13 trict. The court shall take into account the convenience of  
14 the parties in determining the appropriate judicial district  
15 for an action under this subsection which may otherwise be  
16 brought in more than one judicial district.

17 (c) SEIZURE.—Any chemical substance or article con-  
18 taining such substance which was manufactured or dis-  
19 tributed in commerce in violation of this Act, or which is  
20 the subject of an action under section 7 of this Act, shall  
21 be liable to be proceeded against, by process of libel for the  
22 seizure and condemnation of such substance or such article  
23 in any United States district court within the jurisdiction  
24 of which such substance or article is found. Such proceedings

1 shall conform as nearly as possible to proceedings in rem  
2 in admiralty.

3 COOPERATION OF FEDERAL AGENCIES

4 SEC. 19. Upon request by the Administrator, each Fed-  
5 eral agency is authorized—

6 (1) to make its services, personnel, and facilities  
7 available (with or without reimbursement) to the Ad-  
8 ministrator to assist him in the performance of his func-  
9 tion; and

10 (2) to furnish to the Administrator such informa-  
11 tion, data, estimates, and statistics, and to allow the  
12 Administrator access to all information in its possession  
13 as the Administrator may reasonably determine to be  
14 necessary for the performance of his functions as pro-  
15 vided by this Act.

16 STATE REGULATION

17 SEC. 20. (a) EFFECT ON STATE LAW.—Nothing in  
18 this Act shall affect the authority of any State or local gov-  
19 ernment to regulate any chemical substance, or to establish  
20 and enforce standards for test protocols for chemical sub-  
21 stances to protect health or the environment, except that—

22 (1) if the Administrator prescribes a rule under  
23 section 6 of this Act applicable to a chemical substance,  
24 a State or local government may not, after the effective

1 date of such rule, establish or continue to enforce any  
2 different restriction of its own on manufacture, processing  
3 or distribution in commerce of such substance for pur-  
4 poses similar to those set forth in such rule, other than a  
5 total prohibition on the use or distribution of such sub-  
6 stance within the territorial jurisdiction of such govern-  
7 ment; and

8 (2) if the Administrator prescribes a rule under  
9 section 4 of this Act applicable to a chemical substance,  
10 a State or local government may not, after the effective  
11 date of such rule impose requirements of its own ap-  
12 plicable to such substance for purposes similar to those  
13 set forth in a rule under section 4 of this Act.

14 (b) EXEMPTION.—The Administrator may, by rule,  
15 upon the petition of any State or local government or upon  
16 his own initiative, exempt any State or local government  
17 from a prohibition in subsection (a) of this section with  
18 respect to a chemical substance, if such exemption will not,  
19 through difficulties in marketing, distribution, or other factors,  
20 result in placing an unreasonable burden upon commerce or  
21 lessen the protection accorded human health and the environ-  
22 ment.

23 JUDICIAL REVIEW

24 SEC. 21. (a) GENERAL.—Not later than 60 days fol-  
25 lowing the promulgation of a rule under section 4, 5, or 6

1 of this Act, any person adversely affected by such rule, or  
2 any interested person, may file a petition for judicial review  
3 of such rule with the United States Court of Appeals for  
4 the District of Columbia, or for the circuit in which such  
5 person resides or has his principal place of business. Copies  
6 of the petition shall be forthwith transmitted by the clerk  
7 of such court to the Administrator and to the Attorney  
8 General. The Administrator shall transmit to the Attorney  
9 General, who shall file in the court, the record of the pro-  
10 ceedings on which the Administrator based his rule as  
11 provided in section 2112 of title 28, United States Code,  
12 and shall include the transcript of any oral presentation of  
13 data, views, or arguments required under the applicable  
14 provision of this Act. For purposes of this section, the term  
15 "record" means such rule; any transcript required of any  
16 oral presentation; any written submission of interested  
17 parties; and any other information which the Administrator  
18 considers relevant to such rule.

19 (b) ADDITIONAL DATA.—If the petitioner applies to  
20 the court for leave to adduce additional data, views, or argu-  
21 ments, and shows to the satisfaction of the court that such  
22 additional data, views, or arguments are material and that  
23 there are reasonable grounds for the petitioner's failure to  
24 adduce such data, views, or arguments in the proceeding  
25 before the Administrator, the court may order the Adminis-

1 trator to provide additional opportunity for oral presentation  
2 of data, views, or arguments and for written submissions. The  
3 Administrator may modify his findings, or make new findings  
4 by reason of the additional data, views, or arguments so taken  
5 and shall file such modified or new findings, and his recom-  
6 mendation, if any, for the modification or setting aside of  
7 his original rule, with the return of such additional data,  
8 views, or arguments.

9 (c) **AUTHORITY AND REVIEW STANDARD.**—(1) Upon  
10 the filing of a petition under subsection (a), the court shall  
11 have jurisdiction (i) to review the rule involved, in accord-  
12 ance with chapter 7 of title 5, United States Code, and (ii)  
13 to grant appropriate relief, including interim relief, as pro-  
14 vided in such chapter. Any rule promulgated by the Ad-  
15 ministrator under section 4, 5, or 6 of this Act and reviewed  
16 under this section shall be affirmed, unless the findings re-  
17 quired to be made under the applicable section are not sup-  
18 ported by substantial evidence on the record as required to be  
19 developed in this Act.

20 (2) The judgment of the court affirming or setting  
21 aside, in whole or in part, any rule reviewed in accordance  
22 with this section shall be final, subject to review by the  
23 Supreme Court of the United States upon certiorari or cer-  
24 tification, as provided in section 1254 of title 28, the United  
25 States Code.

## CITIZEN'S CIVIL ACTION

1

2 SEC. 22. (a) GENERAL.—Except as provided in sub-  
3 section (b), any interested person may commence a civil  
4 action for injunctive relief on his own behalf—

5 (1) against any person (including (A) the United  
6 States, and (B) any other governmental instrumentality  
7 or agency to the extent permitted by the eleventh amend-  
8 ment to the Constitution) who is alleged to be in viola-  
9 tion of any rule, order, or restriction prescribed under  
10 section 4, 5, or 6 of this Act, or

11 (2) against the Administrator where there is al-  
12 leged a failure of the Administrator to perform any act  
13 or duty under this Act whether or not discretionary  
14 and a likelihood as determined by the court that such  
15 allegation can be supported by a preponderance of the  
16 evidence in the judicial proceeding.

17 Any action under paragraph (1) shall be brought in the  
18 district court of the United States for the district in which  
19 the alleged violation occurred. Any action brought under  
20 paragraph (2) shall be brought in such district court for  
21 the District of Columbia, or in such district court for the  
22 judicial district in which the plaintiff is domiciled. The district  
23 courts shall have jurisdiction over suits brought under this  
24 section, without regard to the amount in controversy or the  
25 citizenship of the parties.

1 (b) LIMITATION.—No civil action may be com-  
2 menced—

3 (1) under subsection (a) (1)—

4 (A) prior to 60 days after the plaintiff has  
5 given notice of the violation (i) to the Administra-  
6 tor, and (ii) to any alleged violator of the rule, or

7 (B) if the Administrator (or Attorney General  
8 on his behalf) has commenced and is diligently  
9 prosecuting a civil action in a court of the United  
10 States to require compliance with the rule, but if  
11 such action is commenced after the giving of notice  
12 any such person giving such notice may intervene  
13 as a matter of right in such action; or

14 (2) under subsection (a) (2) prior to 60 days  
15 after the plaintiff has given notice of such action to the  
16 Administrator, except that such action may be brought  
17 10 days after such notification in the case of an action  
18 under this section for the failure of the Administrator to  
19 act under section 7 of this Act.

20 Notice under this subsection shall be given in such manner  
21 as the Administrator shall prescribe by rule.

22 (c) GENERAL.—(1) In any action under this section,  
23 the Administrator, if not a party, may intervene as a matter  
24 of right.

25 (2) the court, in issuing any final order in any action

1 brought pursuant to subsection (a), may award reasonable  
2 fees for attorneys and expert witnesses, whenever the court  
3 determines that such an award is appropriate.

4 (3) Nothing in this section shall restrict any right which  
5 any person (or class of persons) may have under any statute  
6 or common law to seek enforcement of any rule or order or  
7 to seek any other relief.

8 (4) For purposes of this section, the term "person"  
9 means an individual, corporation, partnership, association,  
10 State, municipality, or political subdivision of a State.

11 (d) CONSOLIDATION.—When actions brought under  
12 subsection (a) (1) involving the same defendant and the  
13 same issues or violations are pending in two or more juris-  
14 dictions, such pending proceedings, upon application of the  
15 defendant reasonably made to the court of one such jurisdic-  
16 tion, may, if the court in its discretion so decides, be consoli-  
17 dated for trial by order of such court, and tried in (1) any  
18 district selected by the defendant where one of such proceed-  
19 ings is pending; or (2) a district agreed upon by stipulation  
20 between the parties. If no order for consolidation is so made  
21 within a reasonable time, the defendant may apply to the  
22 court of one such jurisdiction, and such court (after giving  
23 all parties reasonable notice and opportunity to be heard)  
24 may by order, unless good cause to the contrary is shown,  
25 specify a district of reasonable proximity to the applicant's

1 principal place of business, in which all such pending pro-  
2 ceedings shall be consolidated for trial and tried. Such  
3 order of consolidation shall not apply so as to require the  
4 removal of any case the date for trial of which has been  
5 fixed. The court granting such order shall give prompt  
6 notification thereof to the other courts having jurisdiction of  
7 the cases covered thereby.

8 NATIONAL DEFENSE WAIVER

9 SEC. 23. The Administrator shall waive compliance  
10 with any provision of this Act upon request of the Secretary  
11 of Defense, and upon a determination by the President  
12 that the requested waiver is necessary in the interest of na-  
13 tional defense. The Administrator shall maintain a written  
14 record of the basis upon which such waiver was granted and  
15 make such record available for in camera examination when  
16 relevant in a judicial proceeding under this Act. Upon the is-  
17 suance of such a waiver, the Administrator shall publish in  
18 the Federal Register a notice that the waiver was granted for  
19 national defense purposes, unless, upon the request of the  
20 Secretary of Defense, the Administrator determines to omit  
21 such publication because the publication itself would be  
22 contrary to the interests of national defense, in which event  
23 the Administrator shall submit notice thereof to the Armed  
24 Services Committees of the Senate and the House of  
25 Representatives.

## EMPLOYEE PROTECTION

1

2       SEC. 24. (a) GENERAL.—No employer may discharge  
3 any employee or otherwise discriminate against any em-  
4 ployee with respect to his compensation, terms, conditions,  
5 or privileges of employment because the employee (or any  
6 person acting pursuant to a request of the employee) has—

7           (1) commenced, caused to be commenced, or is  
8 about to commence or cause to be commenced a pro-  
9 ceeding under this Act;

10          (2) testified or is about to testify in any such pro-  
11 ceeding; or

12          (3) assisted or participated or is about to assist or  
13 participate in any manner in such a proceeding or in any  
14 other action to carry out the purposes of this Act.

15       (b) REMEDY.—(1) Any employee who believes that  
16 he has been discharged or otherwise discriminated against by  
17 any person in violation of subsection (a) of this section may,  
18 within 30 days after such violation occurs, file (or have any  
19 person file on his behalf) a complaint with the Secretary of  
20 Labor (hereinafter in this subsection referred to as the “Sec-  
21 retary”) alleging such discharge or discrimination. Upon  
22 receipt of such a complaint, the Secretary shall notify the  
23 person named in the complaint of the filing of the complaint.

24           (2) (A) Upon receipt of a complaint filed under para-  
25 graph (1), the Secretary shall conduct an investigation of

1 the violation alleged in the complaint. Within 30 days of the  
2 receipt of such complaint, the Secretary shall complete such  
3 investigation and shall notify in writing the complainant (and  
4 any person acting in his behalf) and the person alleged to  
5 have committed such violation of the results of the investiga-  
6 tion conducted pursuant to this paragraph. Within 90 days  
7 of the receipt of such complaint the Secretary shall, unless  
8 the proceeding on the complaint is terminated by the Secre-  
9 tary on the basis of a settlement entered into by the Secre-  
10 tary and the person alleged to have committed such violation,  
11 issue an order either providing the relief prescribed by  
12 subparagraph (B) or denying the complaint. An order of  
13 the Secretary shall be made on the record after notice and  
14 opportunity for agency hearing. The Secretary may not  
15 enter into a settlement terminating a proceeding on a com-  
16 plaint without the participation and consent of the com-  
17 plainant.

18 (B) If in response to a complaint filed under paragraph  
19 (1) the Secretary determines that a violation of subsection  
20 (a) of this section has occurred, the Secretary shall order (i)  
21 the person who committed such violation to take affirmative  
22 action to abate the violation, (ii) such person to reinstate the  
23 complainant to his former position together with the compen-  
24 sation (including back pay), terms, conditions, and priv-  
25 ileges of his employment, (iii) compensatory damages, and

1 (iv) where appropriate, exemplary damages. If such an  
2 order is issued, the Secretary, at the request of the com-  
3 plainant, shall assess against the person against whom the  
4 order is issued a sum equal to the aggregate amount of all  
5 costs and expenses (including attorney's fees) reasonably in-  
6 curred, as determined by the Secretary, by the complainant  
7 for, or in connection with, the bringing of the complainant  
8 upon which the order was issued.

9 (c) REVIEW.—(1) Any person adversely affected or  
10 aggrieved by an order issued under subsection (b) may  
11 obtain review of the order in the United States Court of  
12 Appeals for the circuit in which the violation, with respect  
13 to which the order was issued, allegedly occurred. The peti-  
14 tion for review must be filed within 60 days from the is-  
15 suance of the Secretary's order. Review shall conform to  
16 chapter 7 of title 5 of the United States Code. The com-  
17 mencement of proceedings under this subparagraph shall not,  
18 unless ordered by the court, operate as a stay of the Secre-  
19 tary's order.

20 (2) An order of the Secretary, with respect to which  
21 review could have been obtained under paragraph (1), shall  
22 not be subject to judicial review in any criminal or other  
23 civil proceeding.

24 (d) ENFORCEMENT.—(1) Whenever a person has  
25 failed to comply with an order issued under subsection (b)

1 (2), the Secretary shall file a civil action in the United  
2 States district court for the district in which the violation  
3 was found to occur to enforce such order. In actions brought  
4 under this subsection, the district courts shall have jurisdic-  
5 tion to grant all appropriate relief including, but not limited  
6 to, injunctive relief, compensatory, and exemplary damages.  
7 Civil actions filed under this subsection shall be heard and  
8 decided expeditiously.

9 (2) Any nondiscretionary duty imposed by this section  
10 is enforceable in mandamus proceeding brought under section  
11 1361 of title 28, the United States Code.

12 (e) EXCLUSION.—Subsection (a) of this section shall  
13 not apply with respect to any employee who, acting without  
14 direction from his employer (or the employer's agent), delib-  
15 erately causes a violation of any requirement of this Act.

16 **STUDY**

17 SEC. 25. Notwithstanding the provisions of section 9  
18 of this Act, the Administrator shall, by contract or other  
19 arrangement, commission a study of all Federal laws ad-  
20 ministered by the Environmental Protection Agency for  
21 the purpose of determining whether and under what con-  
22 ditions, if any, indemnification should be accorded any per-  
23 son as a result of any action taken by the Administrator  
24 under any law administered by such agency. This study  
25 shall—

1           (1) be conducted outside of the Environmental  
2           Protection Agency under the direction of a university or  
3           recognized research center by an interdisciplinary group,  
4           none of the members of which may have a financial in-  
5           terest or conflict of interest (other than any fee paid by  
6           the Administrator for serving as a member of such  
7           group) with respect to the findings and conclusions of  
8           such study;

9           (2) include an estimate of the probable cost of any  
10          indemnification programs which may be recommended;

11          (3) include an examination of all viable means of  
12          financing the cost of any recommended indemnification;

13          (4) be completed no less than two years from the  
14          date of enactment of this Act; and

15          (5) be submitted, upon completion, simultaneously  
16          to the Administrator and to the appropriate committees  
17          of the Congress without prior clearance or review by  
18          the executive branch.

19                                    AUTHORIZATION FOR APPROPRIATIONS

20          SEC. 26. (a) There is authorized to be appropriated to  
21          the Administrator, for purposes of carrying out this Act, not  
22          to exceed \$11,100,000 for the fiscal year ending June 30,  
23          1976, not to exceed \$2,600,000 for the transitional quarter

1 ending September 30, 1976, and not to exceed \$10,100,000  
2 for the fiscal year ending September 30, 1977. No part of  
3 the funds so authorized to be appropriated shall be used to  
4 construct any research laboratories.

5 (b) The Administrator may, by rule, require the pay-  
6 ment of a reasonable fee from any person required to submit  
7 test data under sections 4 and 5 of this Act to defray the  
8 cost of administering this Act. Such rules shall not provide  
9 for any fee in excess of \$2,500. In setting such a fee, the  
10 Administrator shall take into account the ability to pay of  
11 the person required to submit the data and the cost of the  
12 Administrator of reviewing such data. Such rules may pro-  
13 vide for sharing such a fee, in any case in which the expenses  
14 of testing are shared under section 4 (d) of this Act.

15 (c) Whenever the Administrator submits, in connec-  
16 tion with this Act, any budget requests, supplemental budget  
17 estimates, legislative recommendations, prepared testi-  
18 mony for congressional hearings, or comments on legisla-  
19 tion to the President or to the Office of Management and  
20 Budget, he shall concurrently transmit a copy thereof to  
21 the Congress. No officer or agency of the United States  
22 shall have any authority to require the Administrator to  
23 submit budget requests or estimates, legislative recommen-  
24 dations, prepared testimony for congressional hearings, or

1 comments on legislation relating to this Act to any officer  
2 or agency of the United States for approval, comments, or  
3 review, prior to the submission of such recommendations,  
4 testimony, or comments to the Congress.

Senator TUNNEY. Our first witness is Dr. John Buckley of the Environmental Protection Agency, accompanied by Mr. Glenn Schweitzer, who directs the Office of Toxic Substances.

**STATEMENT OF DR. JOHN L. BUCKLEY, CONSULTANT, OFFICE OF RESEARCH AND DEVELOPMENT, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY GLENN SCHWEITZER, DIRECTOR, OFFICE OF TOXIC SUBSTANCES**

Dr. BUCKLEY. Mr. Chairman, with your permission I will read the statement that has been presented to you.

Senator TUNNEY. Yes, Doctor; fine.

Dr. BUCKLEY. Mr. Chairman and members of the subcommittee, I am John Buckley, consultant to and former Acting Deputy Assistant Administrator for Program Integration of the Environmental Protection Agency's Office of Research and Development. I am accompanied by Mr. Glenn Schweitzer, Director of EPA's Office of Toxic Substances.

I appreciate the opportunity to discuss for the subcommittee the concern of the Environmental Protection Agency over the recent developments which suggest that environmental contamination by polychlorinated biphenyls (PCBs) is more widespread, and that some concentrations are higher than previously believed. For a number of years I have been directly involved in a broad range of governmental efforts to reduce environmental levels of PCBs.

In 1972 I thought that things were well in hand. The sole U.S. producer had already voluntarily restricted sales except for uses in closed electrical systems. The various agencies of the Federal Government each took actions within their regulatory authority. EPA's part of those efforts was support of the policy permitting use only in closed electrical systems and promulgation of a policy designed to restrict PCBs to very low levels in the aquatic environment. However, while we may have slowed the rate of growth of the problem, I am convinced now that in the absence of legislation authorizing additional governmental action the PCB problem will not be adequately resolved.

I am submitting for the record a copy of our response to the subcommittee's request of October 1, 1975, for information on PCBs. This information is based on industry responses received to date to recent EPA requests for data pursuant to section 114 of the Clean Air Act and section 308 of the Federal Water Pollution Control Act.

[The letter follows:]

U.S. ENVIRONMENTAL PROTECTION AGENCY,  
OFFICE OF ENFORCEMENT,  
Washington, D.C., October 20, 1975.

Hon. JOHN V. TUNNEY,  
U.S. Senate,  
Washington, D.C.

DEAR SENATOR TUNNEY: Mr. Train has asked me to respond to your letter of October 1, 1975, in which you requested a summary of information concerning Polychlorinated Biphenyls (PCBs) contained in responses to letters which the Environmental Protection Agency (EPA) recently sent to a number of companies. In your letter you also asked a number of questions about the distribution and uses of PCBs, and you requested any other information possessed by EPA which might be relevant to the proposed Toxic Substances Control Act.

Enclosed is a copy of a statement delivered by the Director of EPA's Office of Toxic Substances on August 29, 1975. This statement outlines the major ongoing EPA activities directed to PCBs. In addition to these activities, EPA, in cooperation with several other federal agencies, will host a National Conference on PCBs in Chicago on November 19-21. A copy of the press release announcing that conference is enclosed.

On August 16, 1975, EPA sent letters and questionnaires to 84 addressees. Those letters were sent pursuant to section 308 of the Federal Water Pollution Control Act (FWPCA), as amended, and section 114 of the Clean Air Act (CAA). Names of the addressees were obtained from three sources: a customer list provided to EPA by the Monsanto Corporation, the sole domestic producer of PCBs; a list of importers of PCBs, provided to EPA by the U.S. Bureau of Customs; and industry trade lists containing names of manufacturers of capacitors or transformers. Subsequent to August 16, additional letters have been sent to other companies which may be using PCBs. The names of such companies were obtained both from trade lists and from responses to the August 16 letters.

EPA personnel are now processing the information received from the various respondents. At present work has not been completed upon a summary quantification of that data. In responding to your specific questions, however, we have reviewed the responses so that our answers are based upon the information provided to date by the various companies.

Following are answers to your specific questions, numbered to correspond with those questions as they appeared in your letter:

(1) The Monsanto Industrial Chemicals Company is the sole domestic manufacturer of PCBs. Monsanto produces PCBs at its William Krummrich Plant, Sauget, Illinois. EPA does not possess information concerning the importation of PCBs as a part of products.

(2) As indicated above, the U.S. Bureau of Customs has provided EPA with a list of companies which import PCBs in their chemical state, and EPA sent letters to those companies requesting information concerning their uses of PCBs. This list of companies was compiled from information contained in invoices accompanying imported products, and the Bureau of Customs considers this to be confidential or privileged commercial information.

(3) (a) Enclosed is a summary provided to EPA by the Monsanto Company of Monsanto's manufacture and sales of PCBs for the period 1957-1975 (first quarter).

(b) According to the Bureau of Customs information, for the 44-month period from January 1, 1972 to August 30, 1975, the following amounts of PCBs were exported in their chemical state to the United States:

Exporter :	Pounds
France -----	598, 644
Italy -----	147, 895
Japan -----	247, 856
England -----	661
Germany -----	2, 646
Canada -----	6, 525
<b>Total -----</b>	<b>1, 004, 227</b>

Tabulated on a year-by-year basis, PCB imports have been as follows:

Year:	Pounds
1972 -----	281, 275
1973 -----	311, 662
1974 -----	184, 811
1975 (8 months) -----	226, 479
<b>Total -----</b>	<b>1, 004, 227</b>

(4) The principal uses of PCBs that EPA has been able to identify are as follows: dielectric fluids for transformers, capacitors, and radio frequency interference filters; fluids for electromagnets; heat transfer fluids; hydraulic oil; and plasticizers for waxes and adhesives.

(5) (a) With respect to PCBs manufactured in this country, enclosed is the list provided to EPA by the Monsanto Company of Monsanto's PCB customers.

(b) As indicated in (2) above, the list of importers provided to EPA by the Bureau of Customs is considered to be confidential or privileged commercial information. These importers include three companies which use PCBs as heat

transfer fluids and for research and testing purposes; three companies import PCBs for distribution to other companies; and one company imports PCBs for use in mining equipment.

(c) In response to EPA's letters to Monsanto's customers and to importers, EPA has received lists of these companies' own customers (who purchase PCBs either in their chemical state or as incorporated into their products), reclaimers, or disposers. This information is quite detailed, with the lists of customers in some cases numbering into the hundreds. As indicated above, the processing of this information by EPA personnel has not been completed.

(6) EPA has no evidence that the Monsanto Company has violated its voluntary agreement to restrict sales to customers involved in the manufacture of closed electrical systems. On the other hand, there are indications that several of Monsanto's customers are using PCBs for other purposes, such as heat transfer fluids and vacuum pump seal oil in their own manufacturing operations. In addition, evidence suggests that importers are also distributing PCBs for uses other than in closed electrical systems.

(7) (a) While only five spills had previously been reported to EPA Headquarters since 1972, information concerning approximately 15 others has been provided in responses to EPA's recent letters.

(b) In general, disposal of PCBs is primarily as waste in landfills and to a lesser extent by incineration. In addition, responses to EPA's recent inquiries indicate that PCBs are also "disposed of" by the original users through processors who reclaim PCBs for further use ("reclaimers") and oil companies.

(8) Of 106 finished water samples from interstate carrier systems examined by EPA for chlorinated hydrocarbons over the past 18 months, two samples contained PCBs. The finished water of Winnebago, Illinois, contained 3.0 ug/l of Aroclor 1242 and that of Sellersburg, Indiana, contained 0.1 ug/l of Aroclor 1260. Recent responses to EPA's letters have indicated possible contamination of several other drinking water supplies, as well. Three identified to date are Escondido, California (0.4 ug/l), New Bedford, Massachusetts (2.5 ug/l), and Bridgeport, Connecticut (1 ug/l).

(9) The enclosed statement presented at recent hearings held by the Wisconsin Department of Natural Resources details EPA's assessment of the health and environmental hazards associated with the manufacture, use, distribution, and disposal of PCBs. This statement includes a summary of recent health and ecological findings.

With respect to the PCB problem, the pending Toxic Substances Control Act would provide EPA with the critical authority to regulate the manufacture and import of PCBs. Your efforts to promote passage of that legislation are greatly appreciated.

Thank you for your interest in this important matter. You can be assured that EPA is using its statutory authority to take prompt action to identify and control the discharges of PCBs into our environment.

Sincerely yours,

STANLEY W. LEGRO,  
*Assistant Administrator for Enforcement.*

Enclosures.

Dr. BUCKLEY. Also, I am submitting for the record a recent detailed statement by Mr. Schweitzer<sup>1</sup> setting forth the history of the PCB problem, the past efforts of Government and industry to address PCB's, and current EPA activities directed at reducing the problem.

In this statement I plan to highlight very briefly some of our current concerns, and of course we will be pleased to elaborate in detail on those aspects of particular interests to the subcommittee.

We have known for some time that PCB's are a group of chemicals which at certain levels can cause serious toxic effects on man and can adversely affect our ecological resources. During the past several years we have increased our understanding of the extent and nature of the human health threat of PCB's and the extent of the potential adverse effect on fish reproduction of very low levels of PCB's.

<sup>1</sup> See p. 77.

However, we still have much to learn about the full range of toxic effects of PCB's and their movement, persistence and fate in the environment. At the same time industry is working toward finding alternatives to PCB's, which have been particularly important materials in electrical systems.

Recent reports from the Great Lakes area, the Hudson River Valley, and other parts of the country underscore the urgency of the problem. In these areas relatively high levels of PCB's in fish—levels which greatly exceed FDA guidelines—are not only threatening our ecological resources, but are impacting directly on the jobs of local fishermen and on available food supplies. At the same time continuing PCB discharges are adding further to the total environmental burden of these chemicals which degrade very slowly indeed.

PCB's reach man and the environment through many routes: as water effluents, air emissions, and solid waste from manufacturing activities; through leakages from products containing PCB's during their operation, transport, and disposal; and from contamination of raw materials, and products exposed to PCB's. Thus, it has been recognized for a number of years that the most effective way to limit PCB contamination is through the regulation of the manufacture, distribution, use, and disposal of the chemical rather than attempting simply to turn off those individual routes of environmental discharges, one by one, which can be addressed under existing laws.

This approach was strongly recommended in the 1972 interdepartmental task force on PCB's and is embodied in the 1973 decision of the Organization for Economic Cooperation and Development. We understand that Japan has banned the manufacture and import of PCB's. Canada expects to take action against PCB's under pending toxic substances control legislation.

Of course, in the absence of adequate authority to regulate manufacture, distribution, use, or disposal, EPA will continue to address PCB's under existing authorities, and particularly the Federal Water Pollution Control Act, recognizing the inherent limitations in attempting to control the problem through a limited and piecemeal approach.

In view of the severity of the PCB problem and our anticipation that appropriate toxic substances legislation will be enacted along the lines of S. 776, including the amendments proposed by the administration in its June 23, 1975, letter to the chairman of the Senate Committee on Commerce, EPA is in the process of preparing the necessary detailed documentation which would be required for regulatory action under the legislation.

Our aim is to be in a position to propose specific measures when the legislation is enacted. These measures would take into account not only the available information on toxicity and exposure levels, but also the impact of regulatory steps on business, employment, and the economy. A key concern in this regard is the availability of acceptable alternatives to PCB's, which have not been demonstrated for all uses at this time.

An important step in the development of an approach to the PCB problem is a National Conference on PCB's which EPA is sponsoring in cooperation with the Council on Environmental Quality, and the Departments of Agriculture; Health, Education, and Welfare; and Interior. This conference will be held in Chicago from November 19

to 21 of this year, and will cover the entire spectrum of concerns related to PCB's.

We intend to bring together the leading experts on PCB's to insure that the latest and most authoritative information is available for careful consideration in developing a regulatory program. Representatives of Federal and State agencies, industry, environmental groups, universities, and other interested organizations will not only be invited to attend, but will be provided a platform to express their views on practical steps that are needed in the near term, as well as the need for further study and research.

In conclusion, PCB's offer an excellent example of the need for the type of regulatory authority similar to that contained in the proposed Toxic Substances Control Act with the amendments to it proposed by the administration in EPA's letter of June 23, 1975. Despite governmental efforts to control the PCB problem, despite voluntary action on the part of the sole U.S. manufacturer of PCB's to sell only to customers who have stated their intention to limit the uses of PCB's, and despite a formal international agreement embodying a multinational commitment to control PCB's, environmental contamination persists. All these factors demonstrate the need for this legislation now.

Mr. Chairman, that concludes my prepared statement. I will be glad to answer any questions the subcommittee may have.

Senator TUNNEY. Thank you. I was interested, Dr. Buckley, in your statement where you indicated—I guess this is the first full sentence:

Thus it has been recognized for a number of years that the most effective way to limit PCB contamination is through the regulation of the manufacture, distribution, use, and disposal of the chemical rather than attempting simply to turn off those individual routes of environmental discharges, one by one, which can be addressed under existing laws.

As you know, one of the arguments that is presented to our committee is that there is existing authority now that is adequate to deal with the problems of toxic substances. They refer to the work of the Pollution Act and other various laws that have been passed to protect the public.

It would seem to me from your statement that that is a very specific reference to the argument that is presently being made, that existing law is adequate, and you are strongly disagreeing with that argument, I understand.

Dr. BUCKLEY. I intended to state that precisely the way I did. I firmly believe that is the situation. This is the best example that I personally am acquainted with in which the best efforts and good will of people inside of the Government and industry attempted but failed to solve a problem.

I think the maximum efforts of the Federal Government in terms of regulatory actions that were coordinated and agreed to among the various departments all took place. Monsanto did its best to limit sales. It worked hard with its customers to find alternatives that might be used. Nonetheless, there is import of PCB's which is not illegal. There continues to be PCB uses which appear to us to be undesirable though in no sense illegal, something over which we have no control; and the fact is that the levels of PCB's, at least in the Great Lakes, in the Hudson River, and in southern California, and in some other locations has not only not declined but in some cases has increased.

I see this as compelling evidence that existing authorities are inadequate to cope with this particular kind of problem.

Senator TUNNEY. Well, it would be helpful, I think, for those of us who are not toxicologists to have a better understanding of what we know about the toxic effects of PCB's and their persistence in the environment, and any other information that you might have that would be illustrative of the hazards associated with this chemical.

Dr. BUCKLEY. Do you wish a statement on this or—

Senator TUNNEY. A short-form statement, yes, but one which outlines, if you would, for the committee and for other members of the committee who are not here but who are going to be involved in the markup of the toxic substance bill in another few days or weeks, what the impact of PCB's are on human health.

You said the existing law is not adequate to control their dispersal throughout the environment.

Now, I would like to know what is the impact of PCB's upon human health and what is their persistence in the environment?

Dr. BUCKLEY. I will submit a short statement on health effects and offer a few additional remarks now. I would point out that at the PCB conference in November there will be a series of sessions during the 3 days, one of which will address the question of health effects and current information on the effects of PCB's on man, rather an update of what we did in 1972. There will be a similar session that deals with movement in the environment and another dealing with the effects on organisms in the environment.

[The following information was subsequently received for the record:]

#### A BRIEF SURVEY OF POLYCHLORINATED BIPHENYL (PCB) TOXICITY

(By Kenneth P. Cantor, Health Effects Division, Environmental Protection Agency)

Several characteristics of polychlorinated biphenyls (PCBs) contribute to their toxicity. PCBs are but slightly soluble in water and highly soluble in fat. This, plus the fact that they are chemically stable and are refractory to most metabolic breakdown reactions, leads them to accumulate in fatty tissue, and to increase in concentration as they move up the food chain. A "single" commercial PCB is in fact a mixture of several chlorinated organics (isomers), all having the same basic molecular structure, but with different degrees of chlorination. The various isomers within a commercial PCB mixture have different toxic, bio-accumulation, and tissue storage characteristics. PCBs readily pass through the placenta to the fetus. Furthermore, they concentrate in the fatty portion of mother's milk. In general, PCBs with fewer than four chlorine atoms have higher acute toxicity and are not as readily stored as those with more chlorines. The acute toxicity of PCBs is low relative to many other compounds, but certain contaminants sometimes found in commercial PCBs (chlorinated dioxins and chlorinated dibenzo furans) have a high acute toxicity. Chronic toxicity of PCBs is of major concern.

Our knowledge of PCB toxicity is based on experimentation with laboratory animals, scattered reports of industrial exposures to workers, and an accidental exposure in 1968 of over 1,000 Japanese to PCBs which had inadvertently contaminated a shipment of rice oil (the "Yusho" incident). In addition, some information has been drawn from incidents of accidental animal feed contamination.

Toxic effects of PCBs of concern from a public health standpoint derive primarily from long-term, low-level ingestion. High-level acute exposures to PCBs, such as occurred in Yusho, Japan, also pose a threat to health and therefore should be carefully monitored. Possible effects resulting from chronic ingestion include alteration of reproductive function, induction of cancer, production of

liver abnormalities, and possible immuno-suppressant activity, which results in a lowering of the body's defenses to infection. Ingestion of large doses of PCBs in a short time period may lead to some of the same effects as chronic low-level doses, and in addition can cause acute dermatitis and damage to the peripheral nervous system.

The more detailed information on PCBs which follows represents a small selection of available data chosen for its relevance to human exposures arising from environmental contamination. There is a continuing need for more information, especially on the effects of low-level PCB exposures.

Reproductive effects have been observed in several species, including non-human primates, minks, rats, and numerous avian species. With a diet containing 2.5 and 5.0 parts per million (ppm) Aroclor 1248, rhesus monkeys showed abnormalities in menstrual cycles after four months. Monkeys were mated after seven months of PCB ingestion. In the 5.0 ppm group, and to a lesser extent in the 2.5 ppm group, there was a resorption and spontaneous abortion of fetuses, stillbirths, and infertility. Of eight mated animals in the 5.0 ppm group, one had a normal birth, while all twelve of a control group fed no PCBs had normal births. Minks fed 5.0 ppm of Aroclor 1254 in their diet had severely affected reproduction.

PCBs have been shown to be liver carcinogens in rats fed 100 ppm of Aroclor 1260 in their diet over a 21-month period. Twenty-six of 184 test animals had hepato-cellular carcinoma, 146/184 had neoplastic nodules in the liver, and 182/184 had areas of hepato-cellular alteration. The 174 surviving control group animals showed one carcinoma, no neoplastic nodules, and 28 areas of hepato-cellular alteration. 100 ppm Aroclor 1260 in the diet for 21 months thus induced a statistically significant number of liver tumors.

Possible liver carcinogenicity has also been demonstrated in mice fed 300 ppm Aroclor 1254 for six and eleven months. This feeding regime resulted in induction of hepatomas which are potentially malignant growths. None of the controls, one of 24 mice fed PCBs for six months, and nine of 22 mice fed for eleven months developed hepatomas.

These exposures are far above any to which humans are likely to be exposed through a normal diet. Concern is warranted, however, since there is great uncertainty when extrapolating to the effects on humans of low-level exposures to identified animal carcinogens, and exposure to PCBs is widespread throughout the U.S. population.

Ingestion of PCBs results in morphologic and biochemical alterations in the liver. Rats, at 20 ppm of Aroclor 1256 and 1265 in their diet, show pronounced liver changes after eight months of ingestion, including an increase in liver weight and size, enlarged liver cells, and abnormal inclusions in liver cell cytoplasm. Transplacental transport of PCBs results in an increase in the liver to body weight ratio of rat pups born to mothers exposed during pregnancy to 5 ppm or more of Aroclor 1254. Certain strains of experimental rates show this effect in weanling males born after dietary exposure of the pregnant mother to a PCB level of 1 ppm.

At higher levels of dietary intake, 100 ppm for two to four months, PCBs (Aroclor 1254) induced in rats a severe metabolic abnormality in liver function called porphyria. This defect is manifested by urinary excretion of porphyrin (a precursor in heme synthesis), dermal photosensitivity, and mechanical fragility of the skin. These effects are related to an increase in activity of a specific enzyme. The effects of lower levels of PCB ingestion on this enzyme are presently under investigation.

Several reports have indicated that PCBs may alter immune response in animals. Ducklings fed diets containing Aroclor 1254 show lower resistance to infection with duck hepatitis virus than ducklings receiving a normal diet. Rabbits fed PCBs show an atrophy of the thymus gland and a decrease in total white blood count, lowering their resistance to infection.

PCBs are stored in body tissue, and the length of storage may exceed that of persistent pesticides. When male weanling rats were fed 100 ppm of dietary Aroclor 1254 for 58 days, their adipose tissue contained 500 ppm PCB, liver had 12 ppm, and brain tissue 2-4 ppm. Seventy-one days after the PCB had been removed from the diet, adipose tissue still had 400 ppm PCB, liver 4.7 ppm, and brain 2 ppm.

After feeding rats dietary DDT at 100 ppm for two years, their adipose tissue contained 95 ppm of the pesticide. When Aroclor 1254, at 100 ppm in the diet, was fed to the same strain of rats for 240 days, the PCB level in adipose tissue was

about 1,000 ppm, indicating a much slower elimination of this compound than DDT.

Ingestion of large doses of PCBs can lead to chloracne, a dermatitis which can be caused by several other chlorinated hydrocarbons as well. Symptoms of chloracne have appeared after accidental exposures in industrial situations. Chloracne was a common complaint of the Japanese who ingested PCBs during the Yusho incident.

The "Yusho" (oil disease) incident in Japan deserves special attention, since it is one of the few examples of extensive human exposure to PCBs. Leakage of PCBs from a heat exchange unit in a rice oil plant in early 1968 resulted in contamination of oil with 2,000 ppm of Kanechlor 400, a chlorobiphenyl containing 48 percent chlorine. Over 1,000 persons, including a few pregnant women, were affected during the epidemic, which was most severe in the summer of 1968. The average total PCB intake of affected individuals was estimated as 2 grams, and the minimum intake was approximately 0.5 grams. Younger people were affected more severely than older persons with the same intake of oil. Symptoms varied considerably. It was shown that most PCB components were stored for long periods in the adipose tissue, and in the pregnant women PCBs passed through the placenta into the fetus. In one study of 100 female and 89 male Yusho patients, the following were the most common symptoms experienced by over half of the study group:

[In percent]		
Symptom	Male	Female
Sébum (gum secretion in eyes).....	89	83
Acnelike skin eruption (chloracne).....	88	82
Blackening of nails.....	83	75
Change in skin color.....	75	72
Swelling of upper eyelids.....	72	74
Black spots in all pores.....	64	56
Sense of weakness.....	58	52
Temporary failure of eyesight.....	56	55
Pigmentation of mucous membranes.....	56	47

Of 12 births of Yusho patients, two were stillborn. Nine of the ten liveborn children had unusually greyish, dark brown stained skin. Most of the babies were smaller than the national standards at birth. As they grew older, symptoms gradually disappeared over a three-month period. When the symptoms reported by 159 patients, in 1970 were compared with their symptoms a year earlier, it was observed that half the patients had improved clinically, while the remaining half showed no improvement and more than 10 percent had become worse.

Neural effects of PCBs were also reported during the Yusho incident. Seven of 21 patients admitted for treatment of severe chloracne from PCBs also complained of numbness or pain in their extremities and five showed reduced sensitivity to pain and/or to heat. Nerve conduction velocity was slowed in a number of these individuals.

#### POLYCHLORINATED BIPHENYLS—A BRIEF BIBLIOGRAPHY

The following references contain much of the existing toxicologic and epidemiologic data on polychlorinated biphenyls.

Kimbrough, R. D., The Toxicity of Polychlorinated Polycyclic Compounds and Related Chemicals. *Critical Reviews in Toxicology*, Vol. 2, Issue 4, pp. 445-498, 1974.

Environmental Health Perspectives, Experimental Issue Number One, April 1972. Entire issue devoted to articles on PCBs.

Kimbrough, R. D., et al. Induction of Liver Tumors in Rats by Polychlorinated Biphenyl Aroclor 1260. *Journal of the National Cancer Institute* (in press), 1975.

Polychlorinated Biphenyls—Environmental Impact. A Review by the Panel on Hazardous Trace Substances. *Environmental Research* 5, pp. 249-362, 1972.

Dr. BUCKLEY. It would be premature to speak to some of the conference findings but, as in 1972, we are aware of one incident in Japan in which there had been a clearcut case of disease caused by leakage of PCB's into rice oil, a very heavy contamination, which did in fact

result in considerable human suffering. Babies that were born had dark skins. There were an unusually large number of miscarriages among the pregnant women exposed to this. There were an assortment of other symptoms.

I do not pretend to be an authority on health effects and I would prefer that these questions, other than what I provide for the record, be handled by someone else.

As to the persistence, I suspect that certainly they are less persistent in the environment than the heavy metals but my own judgment is that they probably are more persistent than almost any other of the synthetic organic chemicals. They probably metabolize very slowly, and apparently are broken down by physical processes in the environment very slowly.

It is at least possible that the increased levels that we find now in the environment result from not an increase of material added to the environment but simply the continued accumulation, leakage into the environment, if you will, of materials that have been used widely for the past 40 or 50 years.

It is clear to me that one would talk about the duration and persistence in the environment in terms of probably decades rather than months or even years.

As to the effects on living organisms other than man, there is reasonably clear evidence of impairing of reproduction in some fish species which can be demonstrated in the laboratory and is believed to have been observed in the field.

It is clear that in the case of mink, captive mink at any rate, that relatively low levels in the diet, a few parts per million, is enough to completely eliminate or greatly reduce reproduction of mink.

This was discovered first because when some fish were considered unfit for human consumption, they were fed to mink, as a cheap source of food. When the mink stopped reproducing, it became clear that the contaminated food was really very expensive.

There are other kinds of effects on other organisms and I guess I would suggest that—to generalize, which is always a little risky—I think PCB's have a greater reproductive effect on mammals than on birds and organisms lower in the food chain.

Senator TUNNEY. Is there evidence that they are carcinogenic?

Dr. BUCKLEY. There is evidence submitted for publication that they produce tumors in rats.

Senator TUNNEY. At what part per million feeding level?

Dr. BUCKLEY. I am sorry. I didn't hear.

Senator TUNNEY. At what level has it been determined that they are carcinogenic?

Dr. BUCKLEY. I am sorry, I don't have that information here.

Senator TUNNEY. Do you have it?

Dr. BUCKLEY. I will provide it for you.

Mr. SCHWEITZER. No; I don't have it.

[The following information was subsequently received for the record:]

Senator Tunney asked at what feeding level PCBs have been determined to be carcinogenic to rats. The levels in the study referred to were 100 parts per million in the diet. The following citation and summary of the study performed by Dr. R. D. Kimbrough, to be published in the Journal of the National Cancer Institute, may be helpful to the Committee:

"Kimbrough, R. D.; Squire, R. A.; Linder, R. E.; Strandberg, J. D.; Montaili, R. J. and Burse, V. W.; 'Induction of Liver Tumors in Rats by Polychlorinated Biphenyl Aroclor (R) 1260' *J. Natl. Cancer Inst.* (in press 1975).

"200 Sherman Strain female rats were fed 100 ppm of a polychlorinated biphenyl (Aroclor (R) 1260) for approximately 21 months, and 200 female rats were kept as controls. The rats were sacrificed when 23 months old. Twenty-six of 184 experimental rats and 1/173 control rats examined had hepatocellular carcinomas. None of the controls, but 146/184 experimental rats had neoplastic nodules in their liver. Areas of hepatocellular alteration were noted in 28/173 controls and 182/184 experimental rats. It was concluded that the polychlorinated biphenyl Aroclor (R) 1260 had a hepatocarcinogenic effect in female Sherman Strain rats when fed in the diet. The incidence of tumors in other organs did not differ appreciably between the experimental and control groups."

Senator TUNNEY. Is there evidence that PCB's are found in the environment in the United States in levels that are in excess of what toxicologists, the authorities, feel is safe?

Dr. BUCKLEY. I think that if we take the FDA guideline for allowable amounts in fish at 5 parts per million, it is clear that there are numbers of fish which exceed that concentration by a very considerable amount, a factor of several times—not all fish in all places—but there have been levels in fish found in the range of 40, 50, maybe even 150 p/m. So it is not just a modest amount over the levels which are thought to be acceptable.

Senator TUNNEY. Well, now, I received a letter the other day from Stanley W. Legro, Assistant Administrator for Enforcement, EPA, and the letter is dated October 20.

Have you seen this letter?

Dr. BUCKLEY. Yes; I have. In fact, I referred to a copy of it in my statement and said that I would submit it for the record.

Senator TUNNEY. As I read this letter, it says we have information that the EPA has gathered information that reveals that far from having PCB's under control by voluntary agreement of the sole American manufacturer, Monsanto, the problem of PCB's is far from solved, and he goes on to say there are a number of importers of PCB's—I think the number is 12—who are not a party to the Monsanto agreement. Their importation has amounted to over 1 million pounds of PCB's in the course of the last 3½ years. And also that the importers are using PCB for other than the closed system usage which apparently results in their release and disposition into the environment.

As I read the letter, it is further indicated that there are certain indications that several of Monsanto's customers are using PCB's as heat transfer fluids and as vacuum pump seal oil, neither of which are closed system uses.

Apparently PCB's have been found in five municipal water systems, and apparently it represents a far more serious toxic threat than we had initially anticipated.

It is indicated that, as you have indicated, that Japan, one of the most highly industrialized countries in the world, has managed to do without PCB's for some time.

Now, the question I suppose is—again, talking as a complete layman who doesn't really understand the molecular makeup of PCB's but who does understand cancer very well, having gone through a number of cancer wards in my life and having a number of relatives and friends die from cancer—I just wonder if we could do without PCB's?

Dr. BUCKLEY. Well, this is one of the questions which we will address at the conference in November. As I pointed out in the statement, I think there are uses of PCB's for which I personally have not yet seen evidence of entirely satisfactory substitutes.

It may well be that there are substitutes and in that case there are things of which I am unaware. It is not clear to me that one necessarily would have to ban all uses of PCB's. They are extraordinarily valuable compounds for certain purposes and it is not evident either that those uses which we agreed to in 1972 result in substantial amounts reaching the environment. It may well be that its other uses over which we apparently have no means of control today, are resulting in continued pollution of the environment by PCB's.

Senator TUNNEY. Well, you say that EPA had no evidence that the Monsanto Co. has violated its agreement to restrict sales, and you go on to say that they have been used in ways that will be beyond the agreement, not by Monsanto but by the customers of Monsanto and by the importers. And you say that while only 5 spills have previously been reported to EPA headquarters from 1972, information indicating approximately 15 others are indicated in recent situations. You say, in general, disposal of PCB's is primarily in landfills and wastes and less by incineration. This indicates that these were disposed of through processors who reclaim PCB's for further use, and that you indicate, as I say, that you have taken water samples from interstate carrier systems and that you have identified certain levels of PCB's in Illinois, Indiana, Escondido, Calif., Bridgeport, Conn., and Bellevue, Mass.

Now, was the level in any of those water systems of the PCB's in excess of what the FDA advises it should be?

Dr. BUCKLEY. Senator Tunney—

Senator TUNNEY. Above the safe level?

Dr. BUCKLEY. The FDA has authority over water insofar as it is a food additive but predominantly drinking water is an EPA responsibility.

As to the safety, there is no published standard or criteria for PCB's in drinking water. We have asked the National Academy of Sciences, which is conducting the study for us in implementation of the new Safe Drinking Water Act, to give special attention to this question. I would point out, however, that the levels that are found in these five samples of water out of a great many samples that have been looked at, are at very low levels. They are most of them in fractions of a part per billion and at the highest, a few parts per billion.

This is a factor of 1,000 less than the amounts which are regularly found in some fish, fish which are used as food. On the face of it, if I were to worry about health in relation to PCB's I would be much more inclined to worry about food as a source of PCB's rather than drinking water. Nevertheless, EPA will pay attention to this in its publication of standards.

Senator TUNNEY. Because of that tendency of toxic substances to concentrate in ever-increasing amounts the higher experience in the food chain, is that basically the thought? Plankton has a certain level—water has a certain level and plankton higher, and fish a higher level.

Dr. BUCKLEY. In many cases there is a direct uptake by the fish from the water, not accumulation through the food chain. PCB's are

taken in both through the body surface and the gills, and with food, and the result is accumulation. Differences in levels resulting from accumulation may be as much as 100,000 between the amount present in the water and the amount present in the fish in that water.

The other point I would like to comment on if I may, you noted that even though Monsanto had these restrictions, other sources seem to be using PCB's in other ways.

I am not totally knowledgeable about the Monsanto operation and what controls they have over their customers and how closely they can police those people to whom they sell PCB's. I suppose it is conceivable that EPA could ask through letters who buys it and then in turn could visit each one of these companies and check out in detail how they are used, but there is no violation of law in the use those companies make of it. It may be inappropriate according to what we in Government and Monsanto agreed were proper things to do. But it is not illegal for them to use that chemical in the ways causing problems.

Senator TUNNEY. That is because of the lack of regulatory authority?

Dr. BUCKLEY. Yes, sir. There is no authority to regulate the use.

Senator TUNNEY. And which lack of regulatory authority could be corrected by the Toxic Substances Control Act passage?

Dr. BUCKLEY. That is my opinion.

Senator TUNNEY. I note in your letter you say that EPA—not your letter but EPA's letter to me—says that EPA does not possess information concerning the importation of PCB's as opposed to the chemical state. Do you have an idea of the magnitude of this problem, the importation of PCB's?

Dr. BUCKLEY. To my knowledge we have no indication of the scale of it. Certainly what we had in mind in the letter is the importation of electrical equipment or other things of this sort, which may well include PCB's but we have no information on those sorts of importations.

Senator TUNNEY. According to Mr. Schweitzer's statement accompanying your testimony, the fish in southern California have been found to have concentrations of PCB's of 6.6 parts per million, up to 350 p/m in the Hudson River.

What has been the effect of finding these levels on commercial and sport fishing in these waters? Has it had any impact on it? Has there been any control over ingestion of those fish by the sports fishermen? Has there been any warning to sports fishermen in those areas?

Dr. BUCKLEY. Excuse me, I don't know about the State of California. In those States surrounding the Great Lakes, particularly around Lake Michigan, there have been for several years warnings to sports fishermen to eat not more than one meal a week of fish taken from these waters. This has been a standing admonition from the health departments. It doesn't apply to all fish in those waters but the large fish, particularly the trout and salmon.

There is a considerable ferment in the State of New York about fish in the Hudson River. In addition to recreational aspects there have been seizures of fish moving in interstate commerce which have been taken in Michigan and shipped to Oregon or Washington.

Senator TUNNEY. Well, if in fact fish in the Hudson River have been found with 350 p/m of PCB's and if the FDA says that 5 parts per

million is a safe level, we are talking about a very large order of magnitude in excess of FDA's safe level. And what is being done to notify the sports fisherman in and around the Hudson as it relates to PCB's and what could happen to them if they ate those fish containing these high levels.

Dr. BUCKLEY. May I ask Mr. Glenn Schweitzer to respond.

Senator TUNNEY. Yes.

Mr. SCHWEITZER. The State of New York is taking steps to bring the situation under better control. I do not have the precise dates with me but there have been hearings and there are hearings scheduled and organized by EPA and by the State of New York directed specifically to the problems in the Hudson River and also to other problems in other rivers of New York. The New York authorities are indeed very concerned with the problem.

Similarly, the adjacent New England States are concerned. We have had inquiries from your congressional colleagues reflecting this concern.

Senator TUNNEY. Not to be an alarmist, but information is made available by some cancer experts that a single exposure to a carcinogen may cause cancer. That may or may not be true, but that is what we hear from time to time.

But if in fact that is true, I am just wondering, just one meal of fish containing 350 parts per million PCB could cause cancer.

Do you have any comment on that, Dr. Buckley?

Dr. BUCKLEY. Well, Senator Tunney, as an ecologist rather than a health scientist I would be wise to not respond.

Senator TUNNEY. I know that there is a difference between the two disciplines, but I am not quite sure I understand what the difference is as it relates to that question. I mean, you must—

Dr. BUCKLEY. I will respond as an individual and how I would treat that according to my own personal feeling. I would certainly prefer not to eat fish which contain 350 parts per million of PCB's. I think there certainly is evidence that in some cases single exposures of carcinogens in experimental animals have resulted in tumors. That is reasonably clear.

I think there is also evidence of other carcinogens of which continued intake at moderate levels has not resulted in tumors. I think until we in the scientific community as a whole understand the mechanisms better than we do now, there will continue to be a debate as to whether a single exposure can cause cancer in man or whether a continuous low exposure is necessary; and whether there is or is not a threshold below which there would be no cancer.

Senator TUNNEY. Is it possible, Dr. Buckley, for you to, the EPA, determine the major contributions of PCB, environmental contaminants, where they come from?

Dr. BUCKLEY. I am sorry, I did not understand the question.

Senator TUNNEY. Are you able or is the Environmental Protection Agency able to discern where the major contributions of PCB's come from to the environment?

Dr. BUCKLEY. I guess the only thing I could say is that we are working at it. I think probably they reach the aquatic environment mostly through point-source discharges, through sewage treatment plants or industrial manufacturing facilities.

There is also some evidence that they come from diffuse sources; there have been samples of snow taken, for example, which have contained very low but measurable quantities of PCB's which would eventually flow into the aquatic environment. By and large I expect we can prove the major sources will be domestic waste sources and manufacturing facilities. Yes, it is possible to answer that but it takes an enormous amount of sampling and a great deal of time. Those things are underway, they have been for 5 or more years, and we know more about it now than we did then but there are some things we do not know.

Senator TUNNEY. Have you made available to the committee in the various statements that you have given to us, or collation of data, have you given us a summary of your investigation to date in any of those submissions?

Mr. SCHWEITZER. No, I do not believe we have given you a complete summary. Our goal is to have all the information available and put in a usable form by the November conference. We have, for example, a great deal of monitoring information which has been collected by many Federal agencies, by States, by private institutions. Assembling that, putting it into a format in which it is useful has been quite a job. Our target is to have that data laid out for the Congress in mid-November. So I would say that we think we will be in an excellent position in about a month to provide you and other interested parties with a rather complete picture of what is known about PCBs.

Of course, if the schedule is such that you need input sooner than that we would be happy to give you what we have.

Senator TUNNEY. It would be helpful to get what you have simply because the committee is going to start marking up the toxic substance bill sometime in the next few weeks. Now that we have gotten our energy conservation measures pretty well taken care of I think we will be able to address ourselves to the toxic substance bill and so what information you have would be helpful.

Mr. SCHWEITZER. Certainly, we will be happy to work with your staff. I think rather than just send up piles of documents we should be somewhat selective and we will talk with you again. We will be happy to give you what we have. I think in the monitoring area we can be helpful because we have devoted a great deal of effort in pulling together what is known from all sources.

Senator TUNNEY. Fine. One last question before I turn it over to Senator Ford; if a PCB is a carcinogen, what is the impact of the Delaney clause of the FDC Act in making it illegal to have any residues of a carcinogen?

Dr. BUCKLEY. I will venture an opinion, though you recognize that the responsibility lies with the FDA, not EPA. It is my understanding, however, that the Delaney clause refers explicitly to deliberate food additives and PCBs do not fall in that category.

Senator TUNNEY. They are nonfood additives?

Dr. BUCKLEY. PCBs are a non-deliberate additive. So the law itself would not explicitly apply.

Senator TUNNEY. Senator Ford?

Senator FORD. Thank you, Mr. Chairman.

Doctor, let me ask you a question or two. This legislation primarily is directed, I think, at the large volume producer. We have a large number of chemical manufacturers. They have a wide line of low-

volume products sold for specific applications. It is not unusual for the majority of such products to be sold in volumes of less than 100 pounds per year as opposed to a commercial producer of high volume products of millions of pounds annually.

Should these small specialty producers have the total bill imposed upon them or could there be a way they could carry out their procedure now up to the point that would be satisfactory to your operation?

Dr. BUCKLEY. I would like to respond very briefly and then I would like to ask Mr. Schweitzer if he would like to comment, Senator Ford.

It is my personal view that one can't make a judgment solely on the basis of volume. There are some substances which are sufficiently toxic or which have sufficiently unpleasant, unacceptable, undesirable characteristics which would make it wrong to put a flat prohibition or restriction within the law which specifies some fixed amount below which the substances were not covered.

On the other hand, it is clear to me that EPA and any sensible regulatory agency will wish to do first things first and deal with those things that are severe and difficult problems. So the matter of priorities would tend to direct one towards higher volume chemicals. With that I would like to ask Mr. Schweitzer to comment.

Mr. SCHWEITZER. I believe that answer reflects my views also.

Senator FORD. I didn't understand you.

Mr. SCHWEITZER. That answer reflects my views also.

Senator FORD. Sometimes the bureaucratic system is not sensible though so I hope that your agency is sensible.

In this day of energy shortage, the chairman and I have just finished working on a piece of legislation that we hope will be helpful to the people of this country. Is there any way we can be involved in this area as far as liquefaction and gasification of coal?

Mr. SCHWEITZER. Well, I think there is the concern of possible contaminants that might be involved and once again I think one would examine the possibility of contaminants very selectively. There is a concern that the new sources of energy could inadvertently result in contaminants coming into the environment which are of concern.

Senator FORD. Of course, the liquefaction and gasification of coal needs a great deal of water and normally, not normally, I think it is a must that these pilot demonstration plants and, hopefully, leading to commercial operation, they will be located in an area where water is sufficient. You are saying to me then that we could get involved under this legislation in gasification and liquefaction of coal?

Dr. BUCKLEY. May I suggest, and again I am no authority on the ins and outs and details of the legislation, but it is clear to me that the intent of the legislation is to deal with chemicals which enter into commerce. To the extent that there are chemicals which are used in the coal gasification or liquefaction processes of this sort, clearly they could fall under the Toxic Substances Act as proposed.

The products, I would suspect, would not necessarily fall under this.

Senator FORD. Say that again; you would not think that this type of operation would fall under this legislation, is that what you are saying?

Dr. BUCKLEY. I would say the chemicals used in the process of liquefaction or gasification are likely to fall under the proposed toxic substances bill. The product of the process to the extent it is an oil or gas-

oline or gas, would be subject to existing authorities in the same way as any natural product of this sort.

Senator FORD. Are you aware of a study that has been completed by the EPA in the field of liquefaction and gasification?

Dr. BUCKLEY. Well, what sort of a study, Senator?

Senator FORD. Well, about possible problems with the environment and contamination of water, and so forth.

Dr. BUCKLEY. Yes, I am sure there have been a number of such studies. I cannot at the moment recite them.

Senator FORD. Well, in the paper today, an unpublished report is credited with having said that the liquefaction and gasification of coal have some very strong possibilities of harmful products both for water and for air.

If that report has been leaked without being published, I think it is extremely unfortunate, and I would be very hopeful that you could forthwith see that this committee receives a copy of that report so that we might be able to look at it maybe in an area in which we might get ourselves involved. But it seems very unfortunate to me to those States working very hard on liquefaction and gasification plants when EPA comes out with a study that it is very harmful, at least first leakage of the report to the news media indicates that there is a problem associated with that.

[The following information was subsequently received for the record:]

Senator Ford requested a report, which he believed was written by this Agency, concerning the effects of coal liquefaction and gasification on water and air. He referred to a news report in the October 24, 1975 Louisville (Ky.) Courier-Journal.

The report referred to in the article is the environmental impact statement portion of a draft report prepared by the National Synthetic Fuels Commercialization Program, an Executive Branch inter-agency task force, for the Office of Management and Budget. The report is still under internal review; we will provide a copy as soon as it is available for release.

The news article referred to quotes from testimony given by EPA Deputy Administrator Quarles on October 22, 1975 concerning legislation providing for energy research assistance. A copy is attached. We have also enclosed an EPA study titled "Potentially Hazardous Emissions from the Extraction and Processing of Coal and Oil."<sup>1</sup>

Dr. BUCKLEY. I have been associated with Government for quite a long time and I am aware that things leak which one might have never wished—

Senator FORD. Sometimes they make sure it is leaked. That is part of the process and part of the agency. You know, it is a little unfortunate. I am a little upset about it because I represent the largest coal reserves in the State and Nation. We have a liquefaction plant under construction, \$100 million, and several million dollars of our taxpayers' money is involved. We have already spent, I suspect, between \$2½ and \$3 million for environmental impact studies that are required and now we are in the application for a gasification plant which will ultimately cost \$1 billion.

After we are led down the primrose path we are finding ourselves in jeopardy now by a study that is leaked and not published. I wonder how long the study has been completed and if it is under print and it

<sup>1</sup> The study is in the committee files.

would be helpful if you two gentlemen would see that we get a copy of that.

Dr. BUCKLEY. I do not know of that study in particular, but I will see that you get a copy of that study if I can.

Senator FORD. You understand my feelings though, on that.

Dr. BUCKLEY. I certainly can.

Senator TUNNEY. In answer to your question whether or not this act would apply to liquefaction and gasification of coal, it would apply if the air and water laws are not as effective as the administrator feels they should be to handle them, to deal with it; and if the EPA includes a natural mixture in its regulatory scheme so that it is conceivable that it would have application to the issue of gasification.

Senator FORD. I think it will. But we will look into it. But we need that information.

Senator TUNNEY. Yes; we need that information.

I want to thank you very much for being here. We appreciate your being here.

Dr. BUCKLEY. Thank you, Mr. Chairman.

[The statement referred to follows:]

STATEMENT OF GLENN E. SCHWEITZER, DIRECTOR, OFFICE OF TOXIC SUBSTANCES,  
ENVIRONMENTAL PROTECTION AGENCY

I greatly appreciate the opportunity to present the views of the Environmental Protection Agency concerning the environmental problems associated with the manufacture, use, distribution, and disposal of polychlorinated biphenyls (PCBs). Since its initial days the Agency has been concerned with practical steps that could be taken to clarify and reduce the environmental risks attendant to commercial applications of PCBs. More recently the Agency has intensified its efforts to help insure that unnecessary hazards are effectively curtailed. Thus, we fully share your concerns, and we will continue to work with the State Governments and other interested organizations in seeking feasible solutions to this problem.

In view of the background papers that are available and the detailed statements being presented by specialists participating in these hearings, I will limit my comments to a brief summary of the history of the PCB problem, recent developments that have heightened interest in PCBs, and the current spread of EPA activities directed to PCBs. I will then comment on several aspects of particular interest to the State of Wisconsin.

1972 FINDINGS OF INTERDEPARTMENTAL TASK FORCE AND ENSUING ACTIONS

In May 1972, the interdepartmental Task Force concluded that PCBs were highly persistent, could be found in all parts of the environment, could bioaccumulate in fish by a factor of up to 75,000, and could have serious adverse effects on human health. The Task Force urged discontinuance of all uses of PCBs except uses in closed electrical systems and called for enactment of the Toxic Substances Control Act to provide a needed regulatory mechanism to deal with PCBs and other problems of this type.

Largely as a result of the activities of the Task Force, the Monsanto Company, the sole U.S. producer of PCBs at that time, voluntarily limited its sales to manufacturers of closed electrical systems. Also, EPA promptly announced that it would begin restricting the discharges of industrial effluents so that the levels of PCBs in rivers or lakes do not exceed 10 ppt. FDA took steps to establish PCB tolerances for several types of food (from .2 ppm in baby food to 5 ppm in fish) and to limit PCB contamination in food packaging and in food plants.

As further follow-up to the Task Force recommendations, the General Services Administration amended its procurement specifications to ban PCBs in paper, and the Department of Interior prohibited future use of PCBs in off-shore oil operations. The American National Standards Institute issued guidelines for industry on the use, disposal, and labelling of PCBs.

Internationally, a decision of the Organization for Economic Cooperation and Development (OECD) provides that PCBs shall not be used for industrial or

commercial purposes except in certain closed systems. However, even with respect to the excepted uses, the OECD Council (a) decided that PCBs should only be used when adequate environmental controls are exercised and when benefits outweigh the risks, and (b) recommended that countries work toward the elimination of PCBs in small capacitors. The Decision leaves it to Member countries to go beyond the Council agreements and, in effect, invites governments to phase out PCB uses wherever possible. Japan, in the wake of PCB contamination of rice oil that adversely affected 1,000 people, banned future production or import of PCBs. More recently the Canadians have begun to collect necessary data for restricting PCBs pursuant to a new Environmental Contaminants Act which should be enacted this year.

#### DEVELOPMENTS SINCE THE TASK FORCE REPORT

##### *Health and ecological effects*

Recent research results have heightened concern over the toxicity of PCBs previously documented in the Report of the Interdepartmental Task Force. Concentrations as low as 2.5 and 5 ppm have produced serious adverse health effects in monkeys, including loss of hair, acneform lesions, loss of weight, increased secretion of total urinary ketosteroids, irregularities in menstrual cycles, impaired ability to maintain pregnancy, and undersized offspring. A still unpublished report indicates malignant liver tumors in rats exposed to one grade PCB at levels of 100 ppm. Several superficial reports of chloracne among workers exposed to PCBs have been received. Also, concentrations of 5 ppm in fish eggs have resulted in fry mortality.

In considering these effects it is important to remember that there are eight commercial grades of PCBs, and their toxicity characteristics may vary to some degree. However, there is no basis for assuming that any one of the grades is not a potential hazard.

##### *Monitoring and exposure data*

As a result of the FDA actions described above, the PCB levels in foods have been steadily declining. At the same time, however, the levels detected in fish and wildlife appear to have increased. Available monitoring data for PCBs in the ambient air, water, sediment, soil, or human tissues do not provide a good basis for estimating national environmental trends. For example, analyses of water samples have seldom extended into the parts per trillion range, and thus only rarely have PCBs been detected. Limited adipose tissue samples for FY 1972 and 1973 indicate a slight downward trend with levels in excess of 3 ppm being observed. Usually high levels of PCBs have been detected in recent months in the fish in Lake Michigan (up to 165 ppm), Lake Pepin (up to 40 ppm), the Hudson River (up to 350 ppm), and Southern California (up to 6.6 ppm), although the average levels are significantly lower than these upper limits. PCBs have been detected in sludge from sewage treatment plants as well as in the effluents from these plants. PCBs have been identified in only two drinking water supplies during the past year. There have been five water spills involving PCB leakage from transformers during the past year, and currently there are tens of thousands of capacitors, each containing several gallons of PCBs, awaiting disposal.

##### *Production, imports, and uses*

While Monsanto is believed to be limiting its sales to manufacturers of closed electrical systems, information has been received by EPA indicating that PCB reproducers may be selling PCBs for other uses. It is believed that most of the PCB imports (which exceed 375,000 pounds in 1974) are not used in closed electrical systems. Among the PCB uses which are known to persist in the U.S. at present are applications in investment casting processes, heat exchange fluids, and hydraulic fluids. There are a variety of other potential uses of PCBs although firm evidence of such current uses is not in hand.

With regard to substitutes, Dow Chemical has developed a product for use in large power capacitors, and Dow Corning has a product which can substitute for PCBs in certain transformer applications. At least one of these substitutes is reportedly being introduced at the present time in Japan.

##### *Recent regulatory actions*

In 1973, Water Quality Criteria were proposed to limit PCBs to 2 ppt in ambient waters. Also, a national effluent standard for PCBs was proposed under Section 307(a) of FWPCA. PCBs were included in the advanced proposal of a

hazardous substances list under Section 311 of the FWPCA in 1974. Finally, NPDES permits that limit the discharge of PCBs have been issued for at least six facilities; preliminary reports indicate that approximately 10-15 other discharge permits may contain effluent limitations for PCBs. In addition, the effluent guidelines promulgated for the steam electric power generating category contain limitations requiring no discharge of PCBs. A significant percentage of the permits issued for this category to date contain these limitations.

As you know, several states are currently considering imposing limitations on PCBs.

#### ONGOING ACTIVITIES OF EPA

The following EPA activities to assess and control the PCB problem have been underway for some time:

1. A water quality criteria level of 1 ppt will soon undergo interagency review prior to final promulgation. The originally proposed level of 2 ppt has been reduced in view of the recent ecological effects data.
2. Detailed documentation necessary to support a national standard for water effluent discharges under Section 307(a) is being assembled with issuance of a revised proposed standard scheduled in the near future.
3. Proposed levels of harmful quantities of PCBs accidentally released into navigable waters and rates of penalties for such spills are currently being developed pursuant to Section 311 of the FWPCA.
4. A laboratory demonstration program is underway to develop and test control technology for treatment of PCB manufacturing wastes, including the aqueous effluent from PCB users and the discharge from leaks from transformers and capacitors.
5. The scientific literature concerning the health and ecological effects of PCBs is being reviewed. Further, a continuing research program is investigating the metabolism and effects of PCBs. As part of this program, several studies have examined the effects of PCBs in rats after long-term feeding regimes, especially effects on reproduction, liver function, carcinogenesis, and hemoglobin metabolism.
6. Collection and analysis of adipose tissues are continuing.
7. Several laboratories have been conducting research on the ecological effects and environmental fate of PCBs.
8. Studies of the behavior of PCBs in soil, with particular attention to possible ground water contamination following a spill, are underway.
9. Analyses of the technological and cost aspects of using substitutes for PCBs in closed electrical systems are underway.
10. Technical assistance is routinely provided on the storage and disposal of PCB-containing wastes. In addition test burns of capacitors containing such wastes in a high temperature incinerator are planned for early 1976.

#### NEWLY INITIATED ACTIVITIES OF EPA

In view of the new evidence concerning the toxicity of PCBs and the recent reports of high environmental levels in several areas of the country, EPA has accelerated its efforts directed to PCBs. These activities, being carried out in cooperation with other Federal and State agencies, include:

1. The National Academy of Sciences is being requested to give special attention to whether a drinking water standard for PCBs is needed. Meanwhile, monitoring for PCBs in drinking water supplies is being expanded.
2. Information concerning the best sampling and analysis techniques for PCBs in different media is being assembled and reviewed to provide guidance to the Regions, states, contractors, and other organizations involved in monitoring.
3. A limited number of ambient air, water, sediment, soil, and fish samples are being collected and analyzed from throughout the country. This data, together with existing data, will provide an up-to-date overview of the current level of environmental contamination by PCBs.
4. In response to local concerns, several Regions will be measuring PCB levels in effluent streams from industrial and municipal sources, receiving waters, and associated fish populations to assist in relating specific discharges to environmental levels of particular concern.
5. Information concerning the use and distribution of PCBs and the levels of PCBs in effluent discharges has been requested from 84 companies which are believed to handle PCB compounds or mixtures in their operations. These requests for information have been made pursuant to EPA's authority under Section 308 of FWPCA and Section 114 of the Clean Air Act.

6. A special review of past and recent data to assess the carcinogenic potential of PCBs is underway.

7. Test data on the chemical properties and potential bioactivity of substitutes for PCBs have been requested from Dow Chemical and Dow Corning.

8. Imported PCBs and polychlorinated terphenyls (PCTs), are being analyzed to identify possible contaminants. In addition, the techniques for detecting PCBs, PCTs, and polybrominated biphenyls (PBBs) are being examined to determine whether interference among the substances prevent reliable analysis for any one of them.

9. General guidance for proper disposal of wastes containing PCBs will be developed.

10. The Department of Defense, the General Services Administration, and other agencies will be requested to review and to amend as appropriate their procurement specifications and those of their contractors concerning the purchase of PCBs and materials containing PCBs.

11. Consultations with the Japanese Government are being initiated concerning their experience in implementing a ban on the production and import of PCBs.

12. Consultations with OECD Governments are continuing in an effort to determine the effectiveness of the 1973 Decision in reducing the PCB problem on a worldwide basis and to encourage expeditious carrying out of the provisions of the 1973 agreement.

13. Consultations are being conducted with the Canadian Government to inform them of our information and activities concerning PCB users in Canada and to coordinate future actions.

#### REDUCING CONTAMINATION LEVELS IN THE AQUATIC ENVIRONMENT

EPA considers that a PCB concentration of 1 ppt in the ambient water environment represents an appropriate goal for the nation. This conclusion is reflected in the Water Quality Criteria which are currently undergoing final review prior to promulgation. We would suggest that this goal serve as very broad guidance in developing strategies on a nationwide basis and locally to control discharges of PCBs into our waterways.

However, we are not prepared at this time to provide more specific guidance on the control strategies that should be adopted nationally or locally concerning the regulation of individual dischargers. We are developing a nationwide strategy with a significant component of our approach to be reflected in a toxic effluent standard for PCBs scheduled for proposal early next year. At the same time, we recognize that a nationwide standard might not be adequate in addressing local problems in some areas, and the control strategies adopted locally may of necessity require an elaboration of the national approach.

In any event, we believe that better information is needed concerning the specific facilities discharging into the aquatic environment before reaching a final judgement on a national standard. Also, it is important to clarify the portion of the PCB contamination problem which can be attributed to specific dischargers and the practical feasibility of reducing the discharges. As a key step in this regard, on August 16, we requested from 84 companies detailed information concerning their activities involving PCBs including details on their uses of PCBs and monitoring data in the effluent stream and in the receiving waters. With this information in hand, we believe we will be in a much better position to develop meaningful regulatory approaches which take into account the realities of current industrial activities.

#### THE ROLE OF THE TOXIC SUBSTANCES CONTROL ACT

As I have indicated, EPA is currently utilizing or preparing to utilize authorities under the Federal Water Pollution Control Act which address the problems of effluents and spills containing PCBs in an effort to reduce the environmental levels of PCBs. Additional authorities may also be used if warranted by further information concerning levels of PCBs in drinking water or even possibly in air. However, each of these available authorities has a limited focus and none provides the most critically needed authority—to limit selected uses and distribution of PCBs. Indeed, even with the cooperation of Monsanto to limit production as well as the use of existing authorities, it seems clear that the PCB problem will continue to persist in some form.

Under the pending Toxic Substances Control Act, however, EPA would have the needed authority and could deal with the problem in a far more effective manner. In addition to authority to restrict the production and use of PCBs, the legislation would, if necessary, enable EPA to require testing concerning the health and ecological effects of the proposed substitutes for PCBs.

With regard to the limitations that might be considered under this legislation, the 1972 Task Force Report concluded that there were appropriate substitutes, presumably at reasonable cost, for all non-electrical uses of PCBs. We have no information which would contradict this conclusion. However, we currently are carefully analyzing each PCB use and the technological, environmental, and cost aspects of possible substitutes to insure the soundness of the conclusion. Also, we are carefully reviewing the recent developments concerning substitutes for PCBs in closed electrical systems before reaching our final conclusions concerning the extent and character of limitations that would be appropriate under this authority. We are optimistic that we will have this authority within a few months, but as you know, further movement in this regard rests with Congress.

Finally, one key aspect of the Toxic Substances Control Act should be emphasized: the authority to review new chemicals before they are marketed and if appropriate require testing or take steps to limit the production or use if there is reason to believe a hazard to human health or the environment might ensue. This preventive or "front-end" approach to the control of chemical hazards would provide a more reasonable and cost-effective approach than current efforts to correct problems after the damage has been done. Not only would the public benefit from the environmental point of view but also the economic costs to industry would be minimized by taking actions prior to the time major investments would be made. It is clear that the past policies of allowing uncontrolled proliferation of chemicals such as PCBs in the environment, chemicals which have proven to be both persistent as well as hazardous, can no longer be tolerated.

#### EXPERIENCE IN JAPAN

The most relevant foreign experience in regulating PCBs has probably been the recent efforts in Japan where PCBs have been under governmental regulation since 1972. The Japanese Government has recently provided us with some preliminary insights as to their experience. The following comments are based on the initial reports we have received, and we plan to obtain more definitive information in the near future.

According to information provided by the Japanese Government, there has been practically no production, import, or export of PCBs in Japan since 1972. The only two companies which had been producing PCBs in Japan stopped production and suspended sales in early 1972. One exception has been the production of PCBs for railroad transformers which was discontinued in September 1973. Use of existing stocks of railroad transformers and condensers, but no new equipment, using PCBs is permitted. Even this limited use is subject to the restriction that no discharge of PCBs to the environment may occur. Beginning in 1976, paper plants will be prohibited from accepting PCB contaminated paper for recycling and such plants will be required to build treatment plants which will meet general discharge standards.

Further, we understand that the import of equipment using PCBs has also been virtually eliminated as of September 1972, and for those few products which are permitted into the country, importers must cooperate with the ultimate users to ensure that the components containing PCBs are recovered and properly disposed. Disposal is regulated by the Waste Disposal and Public Cleaning Control Law which was amended in February 1975 to include PCBs. Currently there are no regulations for labelling or handling PCBs.

The present limitations on the use, import, and export of PCB are based on Article 3 of the Chemical Substances Control Law which went into effect on June 10, 1974. Any manufacturer who wishes to produce PCBs in the future must apply to the Ministry of International Trade and Industry, although approval of such a request is regarded as highly unlikely. The Japanese Government projects that a total ban on PCBs will take effect in approximately six to ten years, when the current stock on equipment containing PCBs is exhausted.

The Japanese Government has established PCB contamination limits for fish and shellfish of 3 ppm for near-shore varieties and 0.5 ppm for ocean varieties. These limits are derived from a basic limitation for human intake of 5 mg/kg of

body weight per day. Guidelines first set in 1973 for water quality and bottom sediment were revised in February 1975 to "not detectable" (less than 0.5 ppb) for ambient water and 10 ppm for bottom sediment. These standards are not necessarily permanent standards, since they were set with current monitoring capabilities in mind. Under the Water Quality Control Law, the authority used in setting these standards, penalties are imposed for exceeding authorized limits. Monitoring of the water quality and bottom sediment by each prefecture is required by this Law.

We have only very sketchy information concerning effluent limitations. According to the reports we have received, the Japanese Prime Minister's Office Ordinance based on Article 3 of the Water Quality Control Law sets the maximum permissible PCB concentration in effluents at the point of discharge into rivers or lakes at 3 ppm. Coupled with this limitation is a provision authorizing a penalty for exceeding the effluent limit.

The environmental levels of PCBs in Japan have subsided in the last two years and are expected to continue to diminish. In a 1974 survey of bottom sediment including 1789 samples, 14 samples had PCB concentrations of over 50 ppm, 37 had concentrations of 10 to 50 ppm, and 21 had concentrations of 5 to 10 ppm. In the previous year, some PCB levels had exceeded 10,000 ppm; no such peaks were found in 1974. Concentrations of PCBs in the milk of mothers were down over the previous two years, although 25 percent of the samples were contaminated in excess of the prescribed level.

The Japanese Association for Disposal of PCBs is responsible along with local Governments for the collection and temporary storage of household electric appliances and other electrical equipment containing PCBs. The Association will develop PCB treatment technology and treatment plants for disposal, although the latter effort has been delayed by public opposition to the selection of proposed treatment plant sites.

Substitutes for PCBs that are currently in use in Japan include (1) for carbonless carbon paper, alkyl naphthalene, alkyl phenylethane, (2) for heat transfer, diphenyl, diphenylether, alkyl diphenyl, alkyl naphthalene, alkyl benzene, and mineral oil, and (3) for transformers and capacitors, mineral oil and silicone oil.

#### CONCLUSION

In conclusion, I would like to stress that EPA intends to continue to give high priority to the problems associated with PCBs. The recent data on toxicity and levels of environmental contamination have heightened our concerns and have stimulated considerable new activity.

Much is known about PCBs, and much more will be known in a few months as our current data collection efforts are brought to fruition. In recognition of the national interest in the PCB problem, and particularly the interest in the Great Lakes area, I am pleased to announce that in late fall EPA, in cooperation with other Federal agencies, will sponsor a national symposium in Chicago to further clarify selected aspects of the PCB problem. The State of Wisconsin herewith receives our first invitation to participate.

Senator TUNNEY. Next we are going to have Mr. Harry S. Havens, Director, Office of Program Analysis, U.S. General Accounting Office, accompanied by Dr. Kenneth Brown.

#### **STATEMENT OF HARRY S. HAVENS, DIRECTOR, OFFICE OF PROGRAM ANALYSIS, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY DR. DENIS J. DUGAN, ASSOCIATE DIRECTOR; AND DR. KENNETH M. BROWN, SENIOR ECONOMIST, IMPACT ANALYSIS**

Mr. HAVENS. Thank you, Mr. Chairman. I would also like to introduce another of my associates. Chief Economist, Mr. Dugan, also in the Office of Program Analysis, General Counsel.

With your permission I would like to read the prepared statement which has been submitted for the record.

Senator TUNNEY. Yes, fine.

Mr. HAVENS. Mr. Chairman, and members of the committee, thank you for the opportunity to testify before your committee concerning our review of three studies of the costs to industry of the proposed Toxic Substances Control Act.

The three studies we have reviewed are:

1. Draft Economic Impact Assessment for the Proposed Toxic Substances Control Act, S. 776, U.S. Environmental Protection Agency, June 1975.
2. Study of the Potential Economic Impacts of the Proposed Toxic Substances Control Act as illustrated by Senate Bill S. 776 (February 20, 1975), Manufacturing Chemists Association, June 1975.
3. Statement on S. 776 and the Toxic Substances Legislative Issue, Dow Chemical USA, April 1975.

Our work has been done in response to an earlier request from the committee staff and a more recent request from Senator Hart to review the three studies. Because we had only a few weeks for this work, we confined our analysis to the information contained in the three studies. We did not have time and, therefore, have not attempted to verify the accuracy of basic technical data, such as the cost of performing a certain chemical test. Nor did we discuss the results of our analysis with the organizations which prepared the studies. Our comments deal mainly with the methodology of the studies—whether they use the data properly to estimate costs.

A draft of our staff paper was provided previously to your staff and the final version is now submitted for the record.

In this study, we present an overview of the studies and then compare the estimates of each element of cost, so the committee can see where the studies agree and where they disagree. In several instances, we point out certain shortcomings in the studies, and finally we try to arrive at some judgment as to a reasonable range of cost figures. We have also tried to give a general perspective of how costs faced by industry fit into the broader picture of total costs and benefits that might be expected to result from this act.

One of the main goals of the proposed act is to make sure that information is provided on the potential dangers to people and the environment of new and existing chemical substances so that appropriate steps can be taken to guard against these dangers. Inevitably, producing such information involves costs. The crucial question is whether these costs are justified by the potential benefits. The three studies that we have reviewed addressed only a part of the whole problem—the costs to industry. The possible benefits to society are discussed only in passing, and no attempt is made to measure the costs to the rest of society.

An example of costs to society that the proposed legislation would bring about is the inevitable delay in the marketing of new chemicals which are ultimately determined to be safe, but must first be tested. The studies which we have reviewed attempt to measure the costs to industry, in terms of delayed profits, but they do not measure the costs to consumers, who are prevented from using potentially valuable new chemicals during the testing period.

At this early date, all cost estimates are extremely uncertain. This is demonstrated by the studies themselves. For example, the EPA study gives a range of cost estimates. The high end is about double the low

end. In the Manufacturing Chemists report the high end of the range is more than three times the low end. The estimate of cost in the Dow Chemical study is 25 times the lowest EPA estimate.

In making our comparisons, however, we found that there was reasonably close agreement between the EPA and the Manufacturing Chemists reports on the cost per test of new chemical substances. The main source of difference between the two studies lies in the assumptions they make about the number of new chemical substances which will require testing. This, in turn, appears to stem from a significant difference in interpretation of the requirements of the proposed act.

As difficult as it is to predict the number of new chemical substances that will be produced, it is even more difficult to say in advance how many of them will have to be subjected to testing and how thorough the testing will have to be. Our reading of the proposed legislation, however, leads us to believe that the EPA interpretation is closer than the industry studies to an accurate picture of what the legislation will entail. The two industry studies seem to interpret the legislation as calling for testing of many chemicals when in fact screening and reporting is all that may be necessary.

Screening and reporting entail notifying EPA of a firm's intention to produce a chemical, the intended uses, the composition of the chemical, and other fairly straightforward information. Laboratory testing, which can be very costly, is not automatically required; it is up to the administrator, who must decide in each case whether the testing appears to be necessary. It is possible that this difference in interpretation between the EPA and MCA studies results from the Manufacturing Chemists' report being based on the February 20, 1975, version of the bill. The June 6 working draft narrowed the definition of "chemical substance" and was more explicit than the earlier version in indicating when testing may be required.

Although there was some agreement upon the cost per test for new chemical substances, the studies varied markedly in their assumptions about the costs of testing existing chemical substances, which is covered in section 4 of the act. The EPA study assumes that costs per test of existing chemicals will be about the same as the costs per test of new chemicals. We believe, on the other hand, there is some merit in the assumption (implicit in the other two studies) that the average cost of testing existing chemicals may exceed that of new chemicals. With new chemicals, the industry may choose at any time to drop the item if the testing becomes too expensive or the outlook for success begins to look too bleak. The situation is somewhat different, however, with existing chemical substances which the administrator puts on the list of "highest priority candidates for the establishment of criteria for data development" (Sec. 4(c)). In these cases, the industry will already have made an investment in production facilities, inventories, sales efforts, and so forth. There will be a strong incentive to follow through with tests in order to protect this investment, even if the testing becomes very costly, rather than discontinuing production.

Our review also led us to conclude that the Dow study, which gives by far the highest cost figure, is the least reliable. It is based upon an interpretation of the act which seems to greatly overstate the amount of testing that would be required. In addition, it extrapolates from seemingly rough estimates for Dow Chemical to cost figures for the

industry as a whole. Dow's sales are only about four percent of industry sales, and Dow's costs are not necessarily representative of the industry as a whole. In view of these factors, we consider the \$2 billion cost estimate in the Dow study to be highly questionable.

The highest cost estimate by the Manufacturing Chemists' study is about \$1.3 billion. Half of this figure is a cost referred to as "maintenance of innovation." It seems to be meant to represent the extra cost necessary to maintain the same rate of output of marketable new chemicals, given the assumption that many new chemicals would be kept off the market because they could not meet the new safety standards. In examining the rationale for this component of cost, we came to the conclusion that it was not justified and should not be included as a cost. The MCA survey questionnaire, on which the study was largely based, did not appear to provide a basis for the estimate. In addition, it was not clear to us why a firm would behave in such a way as to incur these costs. If these costs are excluded from the MCA estimate, it would bring the EPA and Manufacturing Chemists' cost figures much closer together.

The Manufacturing Chemists' study includes a section on the economywide effects of the act. The study infers that the various testing and reporting requirements of the act would increase the costs of producing chemical substances which in turn would have an impact upon employment and the rate of inflation. There may be some repercussions or ripples in the U.S. economy due to increased costs in the chemical industry, but we believe that there are other factors that offset these potential effects, such as increased spending on testing itself. Furthermore, if as we believe, the cost figures presented in the Manufacturing Chemists' study are too high to begin with, the impact will be significantly less even without taking account of offsetting factors. Finally, any effort to make economic impact assessments of this sort this far into the future is automatically subject to a high degree of uncertainty.

With all of our caveats about the uncertainty of predictions in this area, and based only on the data available in the three studies which we reviewed, we believe the costs to industry will most likely fall within a range that includes the EPA high estimate and went somewhat higher than that to take account of the likelihood that EPA has underestimated the costs of testing existing chemicals. This would yield estimates of cost in the range of \$100 to \$200 million per year.

Again, we would point out that none of the studies have considered the potential benefits of the legislation. Whatever the costs might be, the benefits to society might still exceed these costs. It is particularly true of the costs in banning chemicals that are shown to be dangerous. The bill, as it would stand if the staff amendments were accepted, would require that EPA consider the costs and benefits of each chemical individually before reaching a decision on whether or not that particular substance should be banned or restricted. Assuming that this provision is implemented wisely and carefully, it is reasonable to conclude that the result would be to ban only those chemicals where the dangers were sufficiently great to warrant the costs resulting from the action.

To the extent that there is uncertainty about the costs and benefits of the process which would be established by this bill, it is primarily in

connection with screening and testing new chemical substances. Until there has been more experience with this or a similar process, it does not appear possible to predict the costs with any high degree of confidence, nor to predict confidently the numbers of dangerous substances which would otherwise be permitted to go into general use.

Mr. Chairman, this completes my prepared statement. We would be pleased to answer questions.

Senator TUNNEY. Well, I want to thank you, Mr. Havens, for your testimony and for having done the analysis which you did. I know it was time consuming.

I think that it is important that the discrepancies between various cost estimates be precisely identified. This is certainly one of the arguments that is made against the bill by opponents of it.

I would like to go through them with you in some detail.

You indicate that the Dow study is not acceptable and that we ought to focus on the MCA and the EPA study. Would you agree with that?

Mr. HAVENS. I would agree, sir.

Senator TUNNEY. As I understand your testimony it is that the Dow study is incredible.

Mr. HAVENS. It seems to us that the Dow results are beyond the range of what seems probable.

I would not—

Senator TUNNEY. That is a statistician for you.

Mr. HAVENS. It seems highly unlikely to us that it would cost that much.

Senator TUNNEY. Isn't it nice to be—even like politicians—to be so precise and absolutely definite in answers to questions?

Senator FORD. Goes to prove you can ask questions in four-letter words and get answers in nine-letter words and still it is pretty hard to come up with a precise answer.

Senator TUNNEY. Well, I would like to ask Mr. Havens this question; maintenance of innovation costs is about 50 percent of the higher MCA estimate. Would you explain for us more fully precisely why you say it is not a valid cost?

Mr. HAVENS. To begin with we had some questions about how it was derived in the MCA study. The survey itself did not appear to provide a basis for the assumption, which was made in the estimate, that in order to maintain a given rate of product innovation there would have to be a 30-percent increase in R. & D. effort. The \$600 million appears to be derived as a 30-percent increase in R. & D. which is based on a base of \$2 billion a year. Therefore, I question the methodology.

Second, we find it very unlikely, based on what little we as economists know about the subject, that firms would, in fact, perform in such a way as to incur these costs.

The effect of the increased cost would be in the long run to reduce the return to R. & D. and innovation because the costs of innovation would be greater; therefore, it would appear to us that there would be less effort to innovate rather than more effort to innovate. But the net result would be reduced expenditures for innovation, rather than increased expenditures for innovation. What innovation there is may well be oriented toward reducing the costs of testing or to innovation in areas that are likely to be able to avoid testing because of known safe chemical substances being involved.

Therefore, we conclude that what efforts there are will be directed toward avoiding the cost of testing and to consider that these costs are partly the cost of the bill, would be double counting them with the testing cost.

Senator TUNNEY. You seem to indicate that it is not very important to accurately estimate the costs of regulation since these costs must be carefully weighed against the benefits. That would indicate you feel that we should focus our attention on the testing rather than on costs of regulation.

Mr. HAVENS. That would be our conclusion. The bill as we read it would require that EPA make an appraisal prior to reaching a decision to restrict or ban the use of a particular chemical substance, and that this process would involve necessarily weighing costs and benefits of that particular decision on that particular substance. The costs of testing are less well known at this point, as we indicated.

The estimates necessarily are imprecise, as we indicated. But they are, in fact, the area in which enactment of the bill, per se, would have the most possibility of errors in cost versus benefits.

For this reason we suggest that since the benefits cannot be known in advance, the costs can be known only with a range of accuracy, and not quite precisely; that the legislation might well include a process of evaluation subsequently so that we can come back 2 years from now and know whether, in fact, the process yielded benefits in excess of costs.

Senator TUNNEY. Well, I think that's right. We are considering amendments to the legislation which I am sure you are familiar with, they have been offered already publicly to the committee, although there has not been any acceptance of any of them yet, but in which we will require the agency to weigh the costs to the industry of providing this information as contrasted with the benefits that would be obtained by the agency having that information.

As I understand your testimony, in general what you are saying is that that is an important part of the decision made?

Mr. HAVENS. Yes.

Senator TUNNEY. Now the estimates of screening new chemicals differ in the two studies by a factor of 10 to 20. What is the basis for this difference?

Mr. HAVENS. Basically it comes down to the question of how firms are likely to behave or how we would conjecture they may behave when faced with a requirement of testing a new chemical versus testing of a chemical which they have in production. A firm with a chemical in production has a substantial investment in that chemical. They are producing it, selling it, and the profit stream derives from that manufacture and sale.

Our belief would be that the firm would go to greater lengths to protect its investment on a chemical substance which is in production and, therefore, would be willing to undertake very thorough testing in the hope that it would lead them to determining that it was a safe chemical.

When a new chemical substance is involved, on the other hand, there is much less of an investment by the firm in that chemical, in its production and sale, and, therefore, if the process of testing becomes very expensive or it appears likely that it will not lead to demonstration of safety, then the firm is more likely to drop the substance and simply not go into production. Therefore, in our view the average cost per

chemical with respect to new substances should logically be less than with respect to the other.

Senator TUNNEY. One thing I am not clear about, and that is, could you distinguish between extensive testing which a company might undertake voluntarily to protect its investment, its capital, and the kind of testing that would be required by the EPA mandatorily?

Mr. HAVENS. I guess I would have to plead ignorance in this area, Mr. Chairman.

We have not examined the possibility of firms actively doing testing beyond that required by EPA.

Senator TUNNEY. Well, in other words, you are assuming they just wouldn't do any testing other than that required by the EPA insofar as your analysis goes?

Mr. HAVENS. Insofar as our analysis was concerned we did not, to the best of my knowledge, make assumptions with respect to independent testing.

Senator TUNNEY. Or voluntary?

Mr. HAVENS. Or voluntary testing and evaluation, no, sir.

Senator TUNNEY. How would differences in the number of new chemicals tested and the extent of testing existing chemicals affect the estimated costs in the two studies?

Mr. HAVENS. Differences in the estimates of the number of substances to be tested apart from the maintenance and innovation issue. The principal difference between the MCA and EPA studies are those. They do represent in our view probably a difference in interpretation of the act and do account for the bulk of the difference.

Senator TUNNEY. And your interpretation of the act is purely the interpretation that EPA gives to the act or does that—is that done independent of the EPA and the evaluation that they may have made?

Mr. HAVENS. Our conclusion that EPA was closer to estimating the likely impact of the act in terms of the number of substances to be tested is based on really two factors: One, EPA would be administering the act and, therefore, would be in the best position at this point, we believe, to indicate how it would intend to administer the act.

And, second, EPA's estimates were based—were said to be based at least—on very intensive research as to previous experience in this area. I believe we refer to that at one point in the study.

Yes, if I could quote from the staff study, "the estimates are said to be based on 2 years of intensive staff work, 4 years of legislative history, experience with other environmental laws, and consultations with experts in the field."

We do go on to point out that the sources are not, in fact, cited, the work done has not been, in fact, documented in the staff study, but we are prepared to take EPA's word on the fact that they did base their study on that work.

Senator TUNNEY. As I understand it, in the question of cost in dealing with these two basic areas, the number of chemicals to be tested and the extent to which they will be tested—

Mr. HAVENS. That together with the maintenance and innovation issue, yes, the extent to which firms will expand their R. & D. effort to do this.

Senator TUNNEY. I see.

And could you just summarize again—I know you have already said it, but I would like to have it as an estimate that can be quoted easily—can you tell us where you feel the greatest discrepancies are between the two studies dealing with the variables that you mentioned?

Mr. HAVENS. Certainly.

The primary discrepancies between the two studies are, one, the assumed increased cost for innovation in the MCA study which accounts for about \$600 million in their \$1.3 billion estimate; two, the number of chemical substances to be tested where it appears to us that MCA has overestimated based on an overly rigorous application of the law; and, three, the difference in cost of testing new chemical substances versus existing chemical substances where we believe EPA has underestimated costs with respect to existing substances.

Senator TUNNEY. Do you feel that the legislation contains such provisions to make sure that EPA action does not impose inordinate costs on the industry?

Mr. HAVENS. We believe the requirement with respect to regulation that a chemical substance not be banned or restricted from use until and unless EPA has gone through a process of determining cost versus benefits is a sufficient protection to assure that the proper factors are taken into account in making those regulatory decisions.

With respect to the costs of testing itself, we believe that it is not possible at this point to know with any degree of certainty whether the costs are excessive or not. That is why we think it would be appropriate to have evaluation of the testing requirement process itself at some point down the road.

Senator TUNNEY. Does the legislation provide adequately for evaluation later on as to how well it is doing the job—EPA is doing the job?

Mr. HAVENS. The legislation requires EPA to submit an annual report, requiring certain things in connection with that report. We do not believe the report requirement as it is now drafted is sufficient to require the sort of rigorous evaluation that we believe ought to be applied to this procedure. We would be happy to work with the committee staff to draft such language if you wish.

Senator TUNNEY. Yes, I would.

Now just one last question, Mr. Havens. I would like to have you describe to the committee the expertise that you bring personally into an evaluation with the various cost data that have been made available by the two studies, EPA and MCA data, which would give us some degree of confidence that you have experience in the area of being able to evaluate these cost estimates as it relates to chemical testing as opposed to some other kind of testing, and could you just give us some idea of your degree of expertise in that area?

Mr. HAVENS. Well, I think probably my personal expertise is less important than the expertise of the individuals who worked on the study. Dr. Kenneth Brown has a Ph. D. in economics from the Johns Hopkins University. Dr. Dennis Dugan has a Ph. D. in economics from Brown University. Both have taught at leading universities and have extensive research experience.

The estimates are not based on our expertise as chemists or as toxicologists or on any of the hard science disciplines. My expertise is that of bureaucrat looking at a set of numbers and trying to figure

out why they are different. In attempting to do this study, we relied primarily on economic analyses. We did not go below the data that was provided in the studies themselves. We did not attempt to validate the estimates of costs of testing; for example, in terms of how much it costs to test a particular substance for a particular form of toxicity.

We took the studies at face value and simply compared them. We attempted to identify differences between them and figure out whether from the standpoint of economists whether or not the studies make sense; whether the logic of the study—or the data presented in the study supports the conclusions of that particular study.

We did not, as I would repeat, attempt to estimate the costs of testing concerning a particular substance. There was no time for it and frankly we would not have the expertise for that. We analyzed the studies, again taking them at face value.

Senator TUNNEY. I see.

Now, taking the MCA study at face value, you found that there were inaccuracies in their interpretation of the data. Is that correct?

Mr. HAVENS. We found that MCA's basis for its estimate of the cost of maintenance and innovation was not logically sound. We found that they had assumed a volume of testing which seemed to us to be excessive based on EPA's stated experience.

I think it is probably better not to call it inaccuracy so much as serious reservations about the methodology of the study.

Senator TUNNEY. And the area that you found reservations about the methodology of the EPA was—

Mr. HAVENS. Was with the cost of testing existing chemical substances.

Senator TUNNEY. Senator Ford?

Senator FORD. Thank you, Mr. Chairman.

Mr. Havens, I would like to preface my questions with a statement from your testimony and you say the critical question is whether these costs are justified by the potential benefits. Also in the next paragraph you say the cost to society of the proposed legislation and the delay in ability of the consumer to have use of these chemicals, which would be delayed during the testing period.

You have also said that there are inaccuracies in MCA's statement in the way they adjust their figures. Would you say it is inaccurate in MCA's statement that a typical chemical will be increased by approximately 10 percent as a result of this legislation?

Mr. HAVENS. Senator Ford, I think we would conclude that the costs of testing should not increase the cost of producing a chemical substance by anything approaching 10 percent.

Senator FORD. Well, the cost of production and the testing, the two items are an expense to the manufacturer.

Mr. HAVENS. Yes, sir.

Senator FORD. He would have to include that in his sales price.

Mr. HAVENS. Yes, sir.

Senator FORD. So I am not trying to juggle figures, but if you produce a product, there is certain cost in getting to that point of production?

Mr. HAVENS. Yes, sir.

Senator FORD. And if this testing is a part of that chemical getting into production, where production means it is a salable item, it appears to me that that would be an additional cost.

Mr. HAVENS. There is no question that that is correct, Senator.

I perhaps misinterpreted your question. There is no question that the cost of testing would increase—would have an inflationary impact.

Senator FORD. Well, we will just leave it at that. Regardless of the percentage, we will say that it will increase it  $x$  number of cents.

Mr. HAVENS. It will have a marginal impact on the price of the commodity.

Senator FORD. In your good judgment, would you say that it would cost more percentagewise for a small manufacturer to do this testing than it would for a volume producer of chemicals?

Mr. HAVENS. I would not conclude that there was necessarily a connection between volume of production and percentage cost required for testing.

Senator FORD. What about a specialty producer of chemicals?

Mr. HAVENS. It would be possible that a particular small volume producer, if he produced only one chemical, for example, or a very small range of chemicals, and because of the nature of those chemicals all of them were determined by EPA to have potentially toxic effects, that he might be in a position of incurring very substantial testing costs.

There is no question about that. And it could be greater in the case of a particular small manufacturer than of a large volume manufacturer.

Senator FORD. A small businessman, I could see where volume and percentage of cost as to volume would be reduced considerably. For a small volume producer, he would have to have the same testing of his chemical as the volume producer and, therefore, it would increase his cost proportionately.

What I am driving at is in this legislation there are certain areas of request in part of the study—it is hard to keep up with all the legislation that is going on, I thought I had it here—but there are certain testings required under this particular legislation.

Would you say that all of those tests need to be applied to every chemical or could it be up to a point and then EPA makes a decision as to additional tests that would be required?

What I am trying to get to is the question that Senator Tunney asked a few moment ago and I think he was asking if this legislation, I think, contained sufficient provisions to make sure that EPA action does not impose additional cost or any more than necessary in the form of cost on the chemical industry.

What I am trying to get to, do you feel that a small specialty operator or volume operator could go down the first four or five sections of it and at that time EPA would make a decision as to whether they need further testing or not, and that would probably curtail or retard the cost to the industry?

Mr. HAVENS. I would say that whether the manufacturer in question is a large or small company, Senator, the EPA should require no more testing than is necessary to determine the degree of danger.

Senator FORD. This is what I am getting to. This is something which could prevent additional cost or a smaller percentage of additional cost to the consumer and it might expedite or eliminate your fear in that it would delay use of a valuable chemical to the consumer.

Mr. HAVENS. That is correct, sir. I would not pretend to be completely familiar in every detail with the bill as it is drafted. I believe that there is a provision in the bill or in amendments under consideration which would require EPA to determine what tests are necessary in order to—

Senator FORD. I think the staff has technical amendments to the bill which I think are very good.

I appreciate your frankness and I appreciate your answering my questions. I have no more questions, Mr. Chairman.

Senator TUNNEY. Thank you very much.

I want to thank you, Mr. Havens and the members of your staff, for the excellent work you did on really quite short notice in making your analysis and study available to us. I know that it has been difficult for you to do, but it is deeply appreciated by the committee and I want to thank you also for your excellent testimony, Mr. Havens, in response to our requests.

Mr. HAVENS. Thank you, Mr. Chairman, and I appreciate the compliment.

Senator TUNNEY. Thank you.

[The following information was subsequently received for the record:]

#### A COMPARISON OF THREE ESTIMATES OF COSTS OF THE PROPOSED TOXIC SUBSTANCES CONTROL ACT

(By Economic Analysis Staff Members of the Office of Program Analysis of the U.S. General Accounting Office)

The purpose of this paper is to review three studies that estimate the costs to industry of the proposed Toxic Substances Control Act. The three studies we have reviewed are:

1. Draft Economic Impact Assessment for the Proposed Toxic Substances Control Act, S.776, U.S. Environmental Protection Agency, June 1975 ("EPA study");
2. Study of the Potential Economic Impacts of the Proposed Toxic Substances Control Act as Illustrated by Senate Bill S.776 (February 20, 1975), Manufacturing Chemists Association, June 1975 ("MCA study");
3. Statement on S.776 and the Toxic Substances Legislative Issue, Dow Chemical U.S.A., April 1975 ("Dow study").

The three estimates vary considerably. In this paper, the component costs of each estimate are set against each other in Table 1, so the reader can see the reasons for the differences. We then examine the economic rationale behind the estimates and attempt to determine which is most reasonable. Our analysis is confined almost entirely to the information contained in the three studies. We did not attempt to verify the accuracy of the basic technical data, such as the cost of performing a certain test for toxicity. Our criticism deals mainly with the economic methodology of the studies—whether they use the data properly to estimate costs.

Toxic substances are potentially dangerous to people and the environment during each stage of their existence—manufacture, use, and disposal. The main goal of the proposed Toxic Substances Control Act (TSCA) is to insure that information is provided on the toxicity of new and existing chemical substances so that appropriate steps can be taken to guard against their dangers. Unquestionably, there are certain costs of producing such information. The economic question is whether these costs are justified by the benefits. The objective of the three studies is to estimate the magnitude of the costs that the TSCA would impose upon the technical industry. The MCA study also considers the impact upon related industries. Benefits are scarcely discussed, and costs to the rest of society are not mentioned. Because these studies are confined to only part of the problem, none of them is sufficient to determine whether the TSCA should be passed or not.

Going beyond the simple question of benefits versus costs, one could ask the more difficult question of how strict the testing requirements should be, i.e., at

what level of strictness of testing requirements do marginal testing costs start to exceed the marginal benefits of the information generated. The MCA study does not address this question directly, but it does give some insight into the manner in which testing costs increase as the thoroughness of testing and product coverage is increased. This is an important point because while it is obviously true that *some* testing should be required, it is also possible to require testing far in excess of what is necessary.

#### OVERVIEW OF THE THREE STUDIES

*The EPA Report.*—The EPA study is said to be based upon two years of intensive staff work, four years of legislative history, experience with other environmental laws, and consultations with experts in the field. On this basis, it would appear to be realistic in specifying the number of chemicals that would have to be screened and tested under the Act. This, in turn, would appear to make the estimates relatively reliable. However, very few sources are cited in support of specific assumptions and statements. In other words, the study is not documented well enough to allow the reader to check the basis for all of the assumptions.

For each component cost, it gives a range of figures; the totals then add up to "low" and "high" figures of \$79 million and \$141.5 million. In order to keep the comparisons simple, we will generally refer to the "high" figures, even though this may somewhat misrepresent the main thrust of the EPA report. Both "high" and "low" figures are reported in Table 1.

*The Dow Study.*—The Dow Study gives the highest cost figure—\$2 billion per year—and uses a relatively unsophisticated approach. Its estimate of costs for the industry is based solely upon its estimate of what Dow Chemical's costs would be. The method is to multiply Dow costs by the ratio of industry sales to Dow sales, which is about 24 to 1. In other words, the study makes projections from a 4 percent *non-random sample*. If Dow Chemical is unrepresentative of the industry in such crucial (and varying) factors as new products per dollar of sales, or in fraction of products that have to be tested, then the total figure is biased. The smallness of the "sample" assures that this bias can be a large dollar amount.

This study's high cost estimate derives from assuming that it will cost \$1 million per test of existing chemicals. This figure far exceeds that of the other studies. The number of existing chemicals assumed to be tested also exceeds that of the other studies by a significant amount.

*The MCA Study.*—This study is by far the most ambitious in data collection. It attempts to estimate costs from data collected in a survey of chemical firms. Some of these data are not available elsewhere and give valuable insight into the composition of output of the chemical industry. Unfortunately, the study has several important defects:

1. It makes what seems to be an excessively broad interpretation of the screening and testing requirements of the Act.
2. Its "maintenance of innovation scenario", which gives large cost estimates, purports to be based upon sound economic theory and upon the results of the survey. In fact, it is based upon neither. In fairness to the study, the apparently bogus figure of \$600 million for "maintenance of innovation" is used in only one scenario. It is this scenario, however, that seems to find its way into various references to the report. This point is discussed later in this study.
3. Too much is made of the supposed "economic impact" on the rest of the economy. As is discussed below, the MCA study uses questionable methodology to arrive at the large negative impacts.

The cost estimates range between \$360 million and \$1.3 billion per year, plus over \$100 million "start-up" costs.

Thus, we see how widely the estimates vary. The EPA study gives a range of cost estimates that differ, from high to low, by a ratio of almost two to one. The Manufacturing Chemists' report shows a range, from high to low, of more than three to one. The ratio of the lowest EPA estimate to the Dow Chemical estimate is 25 to one, though it must be said that the high Dow estimate is probably the least reliable of all the figures.

#### COMPONENT COSTS OF TSCA

In the simplest terms, what would the TSCA require? Firms would have to give advance notice and brief descriptions of new chemical substances that they

plan to produce. Some of these, as well as some existing chemicals, would have to be tested. Depending upon the results of the tests, some chemicals would be banned or restricted in use.

The costs of this process would be as follows:

1. Direct costs of screening and testing,
2. Associated costs of administration and reporting,
3. Delays in the introduction of beneficial products,
4. Costs associated with developing products that are later shown to be dangerous and are therefore banned or restricted.
5. All other indirect costs to the firm associated with testing requirements.

The studies' estimates of these costs are shown in Table 1. Each of these costs is discussed below, and each study's method of estimation is compared. Each number is taken as it appears in the studies, even though some rounding is in order, so that the reader can more easily find each number in the original study.

TABLE 1.—COMPARISON OF TSCA COST ESTIMATES

	EPA (low)	EPA (high)	MCA No. 4 (lowest)	MCA No. 1 (highest)	Dow
1. Screening and testing:					
(a) Screening:					
Number of chemicals.....	1,000	1,000	(1)	(1)	(1)
Cost per chemical.....	\$3,300	\$5,500	(1)	(1)	(1)
Total (millions).....	\$3.5	\$5.5	(1)	(1)	(1)
(b) Testing new chemicals:					
Number of chemicals.....	150	150	1,230	7,900	916
Cost per chemical.....	\$20,000	\$40,000	\$51,900	\$33,700	\$382,000
Total (millions).....	\$3	\$6	\$63.8	\$266.5	\$350
(c) Testing existing chemicals:					
Number of chemicals.....	200	200	65	100	482
Cost per chemical.....	\$22,500	\$42,500	\$465,000	\$411,000	\$1,000,000
Total (millions).....	\$4.5	\$8.5	\$30.2	\$41.1	\$482
Total (millions).....	\$11	\$20	<sup>2</sup> \$79.0	<sup>1</sup> \$292.6	<sup>3</sup> 712
2. Administration and reporting (millions).....	\$19.5	\$41.5	\$64	\$82.0	\$133
3. Delays (millions).....	10.0	19.5	24	86.0	145
4. Bans or restrictions (millions).....	37.5	60.0	165	195.0	965
5. All other (millions).....	.5	.5	26	669.4	-----
Total cost (millions).....	78.5	141.5	358	1,325.0	2,000

<sup>1</sup> Included in testing.

<sup>2</sup> Net of \$15,000,000 for current testing.

<sup>3</sup> Net of \$120,000,000 for current testing.

*Direct Costs of Screening and Testing.*—These costs depend upon the testing cost per chemical and the number of chemicals that have to be tested. Here the three studies vary considerably, not only in these two aspects but also in their interpretation of what the TSCA would require in the way of reporting.

The EPA views the process as screening (or simply reporting upon) about 1,000 chemicals per year at low cost, and testing 150 of them plus 200 existing chemicals at a cost of about \$40,000 each. The MCA study, however, assumes that all new chemical substances (defined so as to number up to 7,900) will be subject to some fairly costly testing in the early stages. The Dow study assumes that about 900 new chemicals per year will be tested.

The MCA study shows how widely costs of testing can vary depending upon how stringent they are; the most thorough testing would cost \$800,000 per test. The averages presented in Table 1 do not reflect this variation, but merely show the general magnitudes involved. MCA Scenario #4 assumes that fewer tests are required, with the least costly ones dropping out. Thus, costs per test are higher.

The EPA and MCA studies are in near agreement about the cost per test of new substances; it is the number of tests that accounts for the large differences in total cost. The EPA figure, based on extensive low-cost reporting and selective testing, seems most consistent with the TSCA requirements.

Significant differences appear among the studies in their treatment of testing existing chemicals. The EPA uses a cost near \$40,000, the MCA figure is ten times higher, and the Dow figure is more than double that figure—\$1 million per test. The Dow study assumes 482 tests per year, far more than the other studies.

It would appear that the two industry reports have a valid point here. Testing costs of other substances thought to be dangerous have been quite high. The MCA report lists the costs of a whole battery of tests, the (high) costs of which are fairly well known. If testing is required for a given product, then there is a presumption that the product could be dangerous in some uses, even though it had passed some of the preliminary, less costly, tests. The industry would then be in a position of having to prove the absence of danger, which naturally would require thorough testing. Firms would be more likely to have a vested interest in an existing product than in a new one, and they would therefore, go to greater expense to exonerate an existing product before deciding not to produce it. Perhaps a figure of \$30-40 million would be appropriate here; this is the MCA estimate. (Note, however, that the EPA assumes 200 existing products per year would be tested, while the MCA figures are 65 to 100.)

Another possibility for reconciling the two studies would be to use EPA's number of tests and MCA's cost per test. Using the lowest figures in each case would give a cost for testing existing chemicals of \$82.2 million. This, however, would probably be an overestimate; the MCA figures imply a decreasing marginal cost of testing as the number of chemicals tested increases. (The reasons for this are logical but need not be elaborated here.) Taking decreasing costs into account would give a cost figure of around \$60-65 million, depending upon the assumptions made. Given the contents of the studies, a case could be made for any of these figures. Our point here is to show the wide range of plausible estimates that exists.

*Administration and Reporting.*—The EPA figures range between \$19 million and \$41.5 million, which includes annual reports, recordkeeping, and preparation of a bibliography of health and safety studies. Pre-market screening is called an "administrative cost" but we have included it in Table 1 under Screening and Testing. MCA's figures range from \$64 million to \$82 million. The two studies appear to be referring to costs for the same administrative activities, so there is no way to account for the difference except to realize that this type of cost is impossible to forecast accurately. As might have been expected, the government estimate of administrative costs is lower than the industry's estimate; unfortunately, this does not tell us whether one (or both, or neither) is biased.

The Dow study estimate of administrative and reporting costs is \$133 million, far above the other two. According to the study, this figure is the low side, since it does not figure in the possibility that progress reports on each test-mouse and test-rat might have to be sent to Washington. The Dow study estimate appears to be little more than a guess, especially when extrapolated to the entire industry; the other two studies appear more plausible.

*Delays.*—The TSCA will cause delays in marketing chemicals. The 90-day waiting period could be relatively minor, especially if the required reporting is done early enough so that the 90 days are spent on other necessary product development. Much more important costs would be incurred for chemicals for which extensive testing is required. Assuming that the chemical ultimately reaches the market, the firm will have incurred the cost of having to wait longer for the beginning of the stream of income from selling the product.

Example: A product costs \$500,000 to develop and, starting in one year, it will produce a net income of \$50,000 per year forever. This is a rate of return of 10% and is the same as depositing \$500,000 in a bank that pays 10% compounded annually. If the income stream does not start until two years from now, then the firm has lost next year's \$50,000. The discounted value of this loss is \$50,000 divided by  $(1 + \text{the interest rate})$ , or \$45,454.

This method is used by both the EPA and MCA studies, except that in the above example they would simply multiply \$500,000 by 10%, for a "cost" of \$50,000. This is a slight overestimate, but it pales in comparison to the other uncertainties and can therefore be overlooked.

Using the same method the two studies come up with somewhat different figures for the cost of delay: \$19.5 million for the EPA, and \$24 million to \$82 million for the MCA. The MCA study uses lower discount rates and assumed capital investment per product. If it had used the EPA figures on discount rates and investment, its "high" estimate would have been over \$280 million, instead of \$82 million. The higher MCA estimate, therefore, is attributable to its

assumption that thousands of products will be delayed, not just 750 as EPA assumes.

Because, as was noted earlier, the EPA study seems to take a more plausible view of the number of chemicals that would have to be tested, it would appear that its estimates of delay costs are more believable.

The Dow study gives \$133 million as the cost of delays, but does not present much support for this figure. Our previous comment on the Dow study's extrapolation method still applies.

Because all of the studies deal only with cost to the chemical industry, they ignore a very important aspect of delay costs—the costs to the consumer. Just as the firm's profits are postponed, so too are the benefits to the consumer, i.e., the difference between the value to the consumer and what he pays for the product. The cost of delay to the consumer could very well equal the cost of delay to the industry.

This concept requires further explanation. "Consumer surplus" is the benefit that a consumer receives from being able to buy a certain good. It is the difference between the value of the good to the consumer and the amount of money that he has to pay for it. A textbook example: A thirsty man buys a drink for \$1 but would have been willing to pay as much as \$5. His consumer surplus is \$4. Depriving him of the opportunity to buy the drink would impose a cost of \$4 in lost benefits.

Economists have attempted to measure consumer surplus in many specific cases, such as the introduction of a new good. More to the present point, there have been attempts to measure the cost of delays in introducing new goods. Sam Pelzman's study of the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetics Act (*Journal of Political Economy*, Sept./Oct. 1973, pp. 1049-91) found that benefits foregone on effective new drugs were substantial. Although Pelzman's actual cost estimates, as well as his measures of cost avoided by preventing the use of harmful drugs, may be questioned, his study does indicate that delay can be a significant cost to the consumer.

*Bans and Restrictions.*—As with the costs of delay, the cost estimates differ considerably. Here, however, the EPA and MCA studies are roughly in agreement over the number of chemicals expected to be banned or limited in use, but they differ on the cost per banned chemical. The same methodology is used as with delays: Not being allowed to produce a chemical eliminates the return to invested capital. The difference between the two estimates appears to be due mainly to a "multiplier" of 2.5 by which the MCA study multiplies the cost of banning a major substance. Though not fully explained, it appears to be an estimate of the cost to industries that formerly used the banned product but which no longer can do so. As such, it appears to be an attempt to capture the lost "consumer surplus" that was discussed in the previous section. In our view, this is a legitimate procedure, though the accuracy of this particular estimate is in doubt.

The EPA study is no clearer than the other studies as to the costs of bans and restrictions. Although the EPA study presents two pages of numbers with detailed assumptions about such quantities as "R & D investment for each chemical at time of ban" and "percentage of R & D investment recoverable", not a single number is documented. The reader is given no information as to where the numbers came from or why they are what they are rather than something else. We therefore have no great confidence that the range of cost figures is likely to include the actual cost that the Act would incur due to bans and restrictions.

In a larger sense, it is possible to take the view that this type of cost need not be estimated very accurately for the purpose of deciding whether or not to enact the proposed legislation. If it is assumed that chemicals will be banned or restricted only if it is determined that the benefits of the ban exceed the costs, then we could be sure that this part of the Act's costs would indeed be canceled out by benefits.

*Other Costs.*—A. Maintenance of Innovation: The MCA Scenario #1 ascribes a cost of \$600 million to what it refers to as "maintenance of innovation." It appears to be an estimate of the extra cost required to maintain the same rate of innovation as before the imposition of testing requirements. As will be discussed, it is not clear why the firm would want to do this. Neither is it clear how the study arrived at the number, because the innovation questions on the survey do not seem to get at this at all.

From the point of view of economic theory, there are two ways in which the TSCA might affect the rate of spending on research and development:

1. Testing costs would tend to reduce the rate of return to the discovery of new products, and this would reduce the optimal level of R & D spending.

Assuming that firms would want to maintain the rate of innovation implies that firms do not pay attention to the rate of return on R & D spending and, therefore, do not try to maximize profits.

2. It is possible that some R & D would be undertaken to find new ways of reducing the cost of testing, either by discovering cheaper tests or new products that would not have to be tested. If successful, such spending would reduce testing costs by an amount at least equal to its cost. Therefore, if such increases are counted as costs, the cost of testing should be reduced. Or, if testing costs are estimated in full, then it is double-counting to add in this type of R & D cost.

It follows from this that the \$600 million figure should not be counted as a cost. MCA omitted it from Scenario #4.

## B. Economic Impacts

The MCA study considers the effects of the Act on GNP, employment, and international trade. The value of this analysis is questionable. In the first place, no information is given about the models that were used, so we don't know the magnitudes of such crucial parameters as the elasticity of demand for chemical products or the elasticity of demand for exports. The values of these parameters are subject to some difference of opinion among economists and differ from model to model.

Second, the economic process that is assumed to take place is not realistic. Costs of testing would result in higher prices which decrease the demand for chemical products. So far, so good (except that the original estimates of testing costs may be too high, which would overstate the consequent price increases). The next and final step, however, appears to be that this decrease in output by the chemical industry reduces sales by other industries to the chemical industry, and so affect GNP by means of a reverse multiplier. The estimate in the study has GNP decreasing by as much as \$1.6 billion. This reasoning ignores the possibility that if less money is spent on chemicals more will be spent in other sectors, perhaps enough to cancel out the decrease in demand for chemicals. The testing industry will certainly expand by the amount of the testing costs. Consumers who previously bought chemical products will divert their spending to other goods. We therefore conclude that these estimates should not be considered in the evaluation. Although there will be an economic impact on other industries, we do not believe that the studies so far have managed to quantify that impact very successfully. The crucial question at this point is the estimation of direct costs to the chemical industry.

## CONCLUSIONS

Cost estimates for the TSCA entail many analytical steps and many assumptions about how the Act would work in practice. It is hazardous to generalize about the studies because so many separate elements are involved. Nevertheless, on the basis of our discussion, some general impressions emerge:

1. Despite the efforts that have been made so far, the costs to industry due to the Toxic Substances Control Act are, at this stage, quite uncertain.

2. The Dow study is the least plausible of the three.

3. The differences between the EPA study and the MCA study exist mainly because the MCA study assumes many more tests would be required. Only with the cost of delays does the EPA study assume a higher cost per delay, but that is partly because the MCA study assumes many more small delays, which bring down the average.

4. If it is assumed that the EPA study is based upon more accurate knowledge of the scope of the TSCA's requirements, then one would conclude that the EPA figures are more accurate, with the following exceptions:

(a) For tests of existing chemicals, the MCA figures seem more plausible. Substituting the MCA #1 figure of \$41.1 million for the EPA (high) figure of \$8.5 million would add \$32.6 million to the EPA cost estimate. (See page 8)

(b) Because all of the studies consider costs to industry, but not cost to consumers, no figures are given for the costs of delays to consumers. These costs could be substantial. (See page 11)

With all of our caveats about the uncertainty of predictions in this area, but faced with the necessity of stating some cost figure, we would feel least uncomfortable with a range that included the EPA high estimate and went somewhat higher than that to take account of the point about costs of testing existing chemi-

calcs. This would include estimates of cost that may range of \$100 to \$200 million per year.

Again we would point out that none of the studies has considered benefits and that, whatever costs might be, the benefits might still exceed costs. This is particularly true of the costs of banning chemicals that are shown to be dangerous; whatever the costs to society, we would assume that these costs would be considered for each chemical and weighed against the potential dangers. It is with the costs of screening and testing new chemical substances where most of the uncertainty lies.

COMPTROLLER GENERAL OF THE UNITED STATES,  
Washington, D.C., December 4, 1975.

Hon. JOHN V. TUNNEY,  
United States Senate.

DEAR SENATOR TUNNEY: On October 24, Mr. Harry Havens (Director, Office of Program Analysis) testified before the Subcommittee on the Environment. His testimony was based upon our staff paper "A Comparison of Three Estimates of Costs of the Proposed Toxic Substances Control Act" (OPA-76-6). In order to resolve the apparent differences between our testimony and the testimony of the Manufacturing Chemists Association (MCA), you asked us, in your letter of November 7, 1975, to study some of the issues further. Part of our original testimony dealt with the MCA "Study of the Potential Economic Impacts of the Proposed Toxic Substances Control Act as Illustrated by Senate Bill S. 776 (February 20, 1975)," and we found that several of the statements in that study were not well documented. In order to see if these statements could be substantiated by information not included in the MCA study, we met with representatives of the MCA and discussed their background information and our points of disagreement.

The cost estimates presented in the MCA study were significantly higher than those made by the Environmental Protection Agency (EPA) in its "Draft Economic Impact Assessment for the Proposed Toxic Substances Control Act S. 776," dated June 1975.

We believe that the basic issues are: 1. Estimates of the number of chemicals to be tested and the testing costs per chemical; 2. The "maintenance of innovation" cost; 3. The methods of data collection for the MCA report; and 4. The economic impact estimates.

Each of these will be discussed in turn.

1. *Estimates of the Number of Chemicals to be Tested and the Testing Costs Per Chemical*

In our staff study, we pointed out that the three studies of the TSCA differed substantially in their estimates of costs of testing. We said that the EPA cost figures were based on assumptions that seemed to be the most consistent with the TSCA requirements, but we also pointed out areas where the industry studies made seemingly valid points. In our subsequent discussions, representatives of the MCA expressed their concern that the TSCA would require testing costs substantially greater in scope than what is envisioned by the EPA. In particular, they cited their findings that thorough toxicity testing of a chemical substance could total as much as \$800,000, as compared to the range of \$200,000 to \$400,000 assumed in the EPA report.

At this point, we are unable to add to our earlier analysis of this issue, which continues to be the area of greatest uncertainty in the cost estimates. We understand that the Subcommittee has obtained other expert testimony which has shed more light on this question. In addition, we have suggested that the Subcommittee consider including in the proposed legislation more specific requirements for later evaluation of the testing requirements and economic impacts of the Act as a whole, so that modifications of the legislation can be considered on the basis of more substantial information than is now available.

2. *"Maintenance of Innovation"*

In the MCA study, one of the costs listed is "maintenance of innovation." This appears to be an estimate of the cost required to maintain the same rate of successful product innovation as before the imposition of testing requirements and restrictions on production. Maintenance of innovation costs appear in only two of the study's four scenarios. The other scenarios assume "displacement of innovation," whereby the firms do not attempt to maintain their former rates of new product introduction. In the two scenarios where this cost is included, it is

estimated at \$600 million and \$300 million, depending on whether "extensive testing" or "low level testing" is assumed. Scenario #4, which is the lowest in total cost, does not include maintenance of innovation as a cost.

We have raised three basic objections. First, in our judgment, firms would not necessarily behave in such a way as to incur these extra costs. Second, even if they do incur these costs, we do not believe these should be counted as costs of the TSCA. Third, even if these "maintenance of innovation" costs were conceptually valid, we do not believe that the MCA study has estimated them accurately. We now consider each of these objections.

(a). Firms will probably not increase their research and development spending.

The TSCA would have two basic economic effects. The additional testing costs are likely to be passed on in higher prices. This would tend to lower the demand for chemical products. Furthermore, whatever restrictions are placed on chemicals shown to be dangerous would tend to make it more difficult to introduce commercially successful products. These two factors would tend to reduce the rate of return on investment in research and development (R & D), which would mean that profit-maximizing firms would spend less, not more, on R & D. (As we noted in our staff paper, firms might spend more on R & D meant to reduce or partially avoid testing or restrictions. They might invest in research on more efficient testing techniques and on developing products that would not require much testing. But this type of spending, if successful, would pay for itself in reduced costs of testing and restrictions. Therefore, it would be double-counting to count it as a cost.)

It must be said, however, that economic theory is not clear on precisely what determines a firm's R & D spending. If a firm is motivated by efforts to maintain the same rate of new product introduction, then it would have to increase its R & D spending. Although such behavior would not be in accord with the goal of maximizing profits, we cannot prove that firms would not act in this manner. There is a large body of economic literature on the goals of the firm, in which sales maximizing and attempting to achieve a target rate of return are analyzed, but very little has been found to indicate that firms actually do behave in these ways.

(b) Such costs, if they occur, are not costs of the TSCA.

The costs of testing and of restrictions are estimated in another section of the MCA study. In particular, an attempt is made to estimate the losses to the industry that would occur when a product (which was costly to develop) cannot be freely marketed. If a firm decides to increase its R & D to develop additional new products, then it must believe that these costs will be justified by the results, whether the results be greater profits, a greater market share, or some other effect. We do not believe it is correct to count in as a cost something which, one would assume, is offset by benefits to the firm.

(c) We do not believe that the MCA study has accurately estimated changes in R & D spending that might result from the TSCA.

The maintenance of innovation cost estimates were obtained from data compiled from questionnaires and interviews with fifteen firms. The information obtained was the basis for the \$600 million and \$300 million estimates of maintenance of innovation costs. In order to establish that the process of obtaining these estimates was reliable, several questions must be answered.

(i) Was the hypothetical new situation (the enforcement of the provisions of a Toxic Substances Control Act) described accurately to the firms being surveyed?

The consequences of the TSCA were depicted in brief statements (MCA study, pages 88-89 and 250-251). These statements present a fairly strict interpretation of the Act, certainly one that would require more testing than EPA envisions. There is, of course, considerable disagreement and uncertainty on this point. These brief statements, however, are far too short to do justice to the complexities and subtleties of the proposed Act. We do not know how the provisions of the TSCA were further depicted by the interviewers.

Our second criticism on this point is that logic of the incentive to maintain innovation is not related to the questions or the responses. The firms were simply asked for the percentages by which research costs, number of products launched, and overall sales volume would change. They were not asked how much more they would have to spend in order to maintain the same rate of innovation. Yet, on page 88, the study describes the findings as "Extra R & D Expenditures Needed to Maintain Current Levels of Innovation Besides Costs of TSCA Compliance" and "Maintenance of Present Budget For Innovation : Percent Decrease in Number

of New Products Launched Without Extra Expenditures." It is not explained how these results could have been obtained from the relatively simple questions asked.

(ii) Were the firms able to respond accurately? That is, could they be expected to predict their response to the new situation?

Aside from the fact that the TSCA was not fully described, there is a question as to whether the firms could accurately predict their own responses to the proposed legislation. Analysis of surveys of firms' plans for investment in plant and equipment have shown that there can be significant differences between firms' plans and their subsequent actions.

In addition, there is some question as to whether the firms would accurately reveal their actual plans, however uncertain. In general, the industry believes that the TSCA would be very costly. If they were to misrepresent their intentions, the obvious incentive would be to respond in such a way as to make the TSCA appear more costly. We were told by the MCA that the firms did not know how their responses would be used, and we had no reason to question that statement. Nevertheless, if a firm wished to tailor its response to denigrating the TSCA, it clearly would lean to the side of responding with higher costs and lower numbers of new products launched. This bias, if it exists, would apply only to the innovation questions; it would not apply to the questions on numbers of products, etc., in the "Survey on New Product Areas."

(iii) Were the estimates (the \$600 million and the \$300 million) derived correctly from the survey?

It appears to us that these estimates were not derived correctly from the survey data. The \$600 million was arrived at by multiplying a \$2 billion (estimated) R & D expenditure by a 30 percent increase. We do not question the \$2 billion for existing R & D; it is the 30 percent figure that appears to be a significant overestimate. According to the MCA study (page 95), there was a considerable range of responses. In our discussions, an MCA representative said that some of the firms reported that they would reduce their R & D spending. We believe that with this type of data the researchers should have estimated the industry's mean percentage change in R & D expenditures and provided confidence limits for that estimate. We conjecture that with this wide range of responses from such a small sample of firms the confidence limits would be far apart. That is, no great credibility could be attached to the estimate. In fact, neither the sample mean nor the sample standard deviation are reported. In fact, the 30 percent seems to be the *highest* of the *range* of effects, rather than an average. The 30 percent figure is, therefore, substantially larger than whatever the average figure might be, and it does not represent any kind of typical industry behavior. The 15 percent figure, which yields the \$300 million cost, does not seem to be justified either; it is meant to apply to a lower level of testing. But, again, it does not appear to represent an estimate of average industry response.

In summary, we maintain the position we took in our staff study—"the \$600 million figure should not be counted as a cost." Nor should the \$300 million figure be counted.

### 3. *Methods of Data Collection for the MCA Report*

Some questions about the confidentiality of MCA data were raised in conjunction with the MCA testimony on September 21, 1975. Although it is true that the MCA has promised the respondent firms that information from individual questionnaires will not be divulged, we do not believe that this presents a serious problem in resolving the differences among the various cost studies. The study presents the aggregate figures derived from the questionnaires, and that is the important source of information on such questions as the number of new chemical products developed.

On certain questions, we have disputed the MCA figures. On the question of "maintenance of innovation," we do not believe that the estimates were accurately derived from the survey. On the question of economic impact, we do not agree that the data support all of the conclusions. Our analysis of these problems was not hindered by the confidentiality of the individual questionnaires.

### 4. *Economic Impact Estimates*

We have a number of reservations about the approach taken in the MCA study to obtain estimates of the impact of the TSCA upon gross national product, employment, prices, and international trade.

The MCA study used the INFORUM model to generate its economic impact estimates. While we have no particular criticism of the model itself, it should be

realized that there are a number of possibilities for error when it, or any other complex econometric model, is used for a specific purpose. The results depend upon what information is fed into the model.

In general, we agree that the TSCA would increase costs of production in the chemical industry and that most of these costs would be passed on to the consumer. Because chemicals are used as inputs to other manufacturing processes, the impact is likely to spread through the economy. We question the magnitude of the effects estimated in the MCA study.

Before we discuss the specifics, it should be pointed out that we believe that the MCA's "broad model" gives economic impacts that are at least twice as high as they should be. The reason is that the "maintenance of innovation" costs, which we believe should not be counted, account for about half of the costs in that model. All of the economic impacts are roughly proportional to the magnitudes of the original costs estimates. For example, if the highest cost estimate made by the Environmental Protection Agency (\$141.5 million) were used as the basis for the economic impact modeling work, the economic impacts would be about one-ninth of the magnitude of the MCA figures.

#### EFFECT ON PRICES

In the MCA "broad model," it is assumed that industry costs would be passed on in the form of higher prices. This gives a 1.28 percent increase in the price of chemical industry products, which is plausible if one accepts the MCA cost estimates. Lower cost estimates, which we believe to be more accurate, would give proportionately smaller price increases. The impact on the Consumer Price Index, which measures the price of all consumer goods, is estimated as one-half of one percentage point. This figure seems much too large; it would represent a significant fraction of all inflation. The MCA cost figure of \$1.3 billion is less than one-tenth of one percent of GNP, and so a similar figure for increase in the CPI would be more plausible. We are unable to explain why the MCA figure is so large. Again, if one accepts a lower cost figure, the impact on the CPI would be proportionately smaller.

In the MCA "selective model," it is assumed that none of the costs would be passed through in higher prices. We disagree with that assumption.

In summary, we believe that an accurate estimate of TSCA costs would yield estimates of price increases significantly lower than those of the MCA study.

#### IMPACT ON GROSS NATIONAL PRODUCT

There are two ways in which the TSCA could affect GNP. One has to do with the workings of the domestic economy and the other with international trade. In the domestic economy, higher prices of chemicals would reduce the demand for chemical products. However, there would be an increase in the demand for testing services and for administration personnel which would be nearly as large, in dollar terms, as the decrease in the output of chemicals. In the MCA study, the "domestic effect" is quite small, and most of the impact on GNP comes from the effects on imports and exports.

Increased prices for chemical exports would reduce the demand for exports, and this tends to reduce GNP. Again, we agree that some effect of this kind could be expected, but we believe that the MCA report greatly overstates the magnitude of this effect.

First of all, it is not certain that firms would increase the price of exports in proportion to increased testing costs. As far as most exports are concerned, testing costs will have already been incurred; they are fixed costs, not variable costs. In order to meet competition in foreign markets, they may well absorb most of the costs due to the TSCA.

Second, the MCA study appears to have assumed that export prices would increase by more than the 1.28 percent estimate for prices of chemicals produced domestically. The information is not presented in the report. MCA gave us the data that was used for six categories of chemical exports and imports, and all of these figures significantly exceeded 1.28 percent. The resulting bias appears to be an overstatement of the negative impact on both the balance of trade and gross national product.

The study presents estimates of the changes in the balance of trade in chemicals, but only on page 212 does it show the estimated impact on imports separately. No information is presented on exports separately. The impact on imports

is far larger than what would be consistent with the earlier assumptions about price increases and demand elasticities. If this inconsistency also occurs in the export estimates, it would mean that the estimate of the balance of trade impact is too large by several orders of magnitude.

Nowhere in the report has it been taken into account that increased testing is of some value to consumers—they can feel more confident that the chemical they purchase is safe. This has the effect of increasing the demand for chemicals, which would act to partially offset the decrease in demand caused by higher prices. We have not attempted to estimate the magnitude of this effect, but we point out that it would tend to offset the negative effects on exports and on GNP.

In summary, we believe that the TSCA would have some effect upon GNP, but the MCA report greatly exaggerates that effect.

#### CONCLUSIONS

Our discussions of the MCA report with representatives of MCA have not caused us to change the conclusions of our staff study. We continue to maintain that the MCA report, in several instances, overestimates the costs to industry of the proposed TSCA. In our judgment, a major source of overestimation is the "maintenance of innovation" cost.

Our staff study listed several other points upon which we disagreed with the approach taken by the MCA report and the EPA study as well. To put these points in their proper perspective, however, it should be emphasized that the main problem in estimating cost is to determine the extent of testing required.

Sincerely yours,

ELMER B. STAATS,

*Comptroller General of the United States.*

Senator TUNNEY. There has been in the past complaints by various members of industry that they did not have a chance to testify until after the press had left. So we are going to give to the industry an opportunity to testify now while the press is still here.

I am going to call first Mr. George Dominguez, Manufacturing Chemists Association, accompanied by Mr. Daniel Mayers, Dr. Charles Reinhardt, Mr. Negey, and Dr. Nemeč. Then we will call Mr. Orin Smith, president of the M. & T. Chemical Co., and then back to Dr. Rall.

Mr. Dominguez.

#### STATEMENT OF GEORGE DOMINGUEZ, MANUFACTURING CHEMISTS ASSOCIATION; ACCOMPANIED BY DANIEL MAYERS; CHARLES REINHARDT; MR. NAGEY; AND DR. NEMEC

Mr. DOMINGUEZ. I am George S. Dominguez. I appear today in behalf of the Manufacturing Chemists Association, Inc. (MCA), a nonprofit trade association having 186 U.S. company members representing more than 90 percent of the production capacity of basic industrial chemicals within this country. I have had nearly 20 years of professional experience as an industrial marketing analyst and business management educator.

With me today are Dr. Charles Reinhardt, associate director of research, E. I. du Pont; Dr. Joseph Nemeč, vice president of Foster D. Snell; and Steve Nagey, research director and project manager of the MCA study, and also with Foster D. Snell; and Mr. Dan Mayers of Wilmer, Cutler & Pickering, counsel for MCA.

Since testifying before this subcommittee on March 5 of this year on S. 776 as then written, MCA engaged a study of the economic impact of this legislation by Foster D. Snell, Inc., a division of Booz-

Allen & Hamilton, to clarify the earlier conflicting and widely differing estimates of the annual cost of the proposed toxic substances control legislation—from a Government figure of \$45 million to a company's estimate of \$2 billion. Our testimony today deals chiefly with the findings of this report.

The study was based on S. 776 in its original form, inasmuch as it was the only one then extant, but the 4-year legislative history made it seem likely that the same cost factors would apply to other anticipated bills, such as subsequently introduced in the House and the June 6 revision of S. 776, albeit in different degrees.

The Snell analysis was based on 45 companies with annual sales ranging from \$100 million to more than \$1 billion. These represent about 23 percent of total industry sales of chemicals and allied products, which last year came to \$86.8 billion.

While the identities of these companies, and the information each contributed, were and are held in confidence, the magnitude of their sales volumes as reported by categories, indicates that they do, collectively, represent the chemical industry. Thus, there is sound justification for extrapolating the information so gathered to reflect the entire industry.

Our testimony will illustrate the impact of S. 776 and of related bills. Details and supporting data are contained in the complete report which we offer for the record.<sup>1</sup>

Using the provisions of S. 776 and 1975 cost figures, the survey documents annual economic dollar impacts on the industry ranging from a conservative \$358.0 million for the "selective" model to \$1.3 billion for the "broad" model. (In this context, "selective" means the exercise of thoroughly justified and careful discrimination by EPA; "broad" means very little selectivity in EPA's activities however within the limits of the ultimate law.)

This does not include one-time, nonrecurring preparation expenses estimated at from \$78.2 to \$114.5 million. Even to an industry as large as ours, these figures are not insignificant, but more significant is the impact of these increased costs on the Nation's economy in terms of inflationary effects, jobs and the balance of trade.

The models cover requirements in the proposed legislation, the broader the restraints, the higher the costs. We hasten to note, however, that the overall economic effect of S. 776 (Rev.) could be even greater than for the S. 776 broad model. The reason is the sweeping, discretionary powers given the Administrator including his mandate to list "not less than 300 chemical substances (other than new chemical substances)" with the highest priority for testing.

The June 6, 1975 staff working draft of S. 776 also could increase costs substantially for other reasons. This would depend on the number of mixtures to be tested and the proportion of longer term, more costly tests required to prove or disprove preliminary indications of the "potential to induce cancer."

Some likely economic impacts remain unquantified. For example: Company failures and/or increased industry concentration through acquisition or merger of smaller firms; higher risk and more conserva-

<sup>1</sup> The study is in the committee files.

tive return-on-investment criteria; the "wasting" of patent time during testing, and various Toxic Substances Control Act compliance phases which would become evident only as implementation developed.

#### RESULTS BY CATEGORY

If EPA were to impose relatively unselective S. 776 (Rev.) demands, the yearly cost to the chemical industry would be \$1.3 billion not including startup, nonrecurring costs. Broken down, costs would be—and may I interrupt to indicate that we have a prepared chart from which it might be a little bit easier to illustrate and follow the discussion.

These costs would be:

##### 1. Start-up \$114.5 million

These nonrecurring preparation expenses involve administrative organization, establishment of recordkeeping and reporting systems and submission of in-progress health and safety studies. The latter encompass new and existing substance reports including 40-year bibliographies of 50,000 or more chemical compounds.

##### 2. Institutional \$1.125 billion

Included are: (a) \$82 million to administer the program, to interpret regulatory developments and to consult with EPA on testing protocols and all other responsibilities including record maintenance for reporting adverse effects.

(b) \$600 million in additional research and development funds to overcome a projected 30-percent reduction in the introduction of new products to the marketplace due to restraints and thus maintain the status quo. The industry's current level of R. & D. funding is \$2 billion a year.

(c) \$41 million for formulating protocols and testing existing substances plus reporting results to EPA. This evaluation excludes testing existing products which might be on the proposed list of 300 substances. If they were added, costs would range from \$90 million to \$120 million as the Administrator would be required to perpetuate the list.

Short- and long-term environmental tests, as well as sub-acute and chronic animal testing, would be included since the compounds would have suspected significant hazard-potential or would be classified as having unreasonable risks.

(d) \$22.6 million for premarket screening of 6,500 new and modified products that reach the marketplace each year.

(e) \$35.9 million for premarket screening of significant new applications of some 450 older products.

(f) \$86 million annually in lost income due to delays of four or more years in the introduction of new products.

(g) \$50.5 million in added manufacturing costs as a result of tighter quality control tests, new test protocols, labeling and other in-house recordkeeping.

(h) \$19.4 million for all other incidental costs such as fees to EPA for submitting test data; judicial action, if required; and defense of third party civil suits.

### 3. Extraordinary \$195 million.

These costs cover those products which could be banned from or restricted in the marketplace, without adequate justification and thus preventing maximum utilization of productive capacity.

#### INTERPRETATION

Cost levels for each factor and totals may be visualized readily in this table for the "broad" and most "selective" models:

ECONOMIC IMPACT		
[In millions of dollars]		
Cost factor	Selective	Broad
Nonrecurring preparation expenses.....	78.2	114.5
RECURRING ANNUAL INSTITUTIONAL EXPENSES		
Administration.....	64.0	82.0
Maintenance of innovation.....		600.0
Testing of existing substances.....	30.2	41.1
Premarket screening (new substances).....	60.3	225.6
Premarket screening (new application).....	3.5	40.9
Less testing without act.....	(15.0)	(15.0)
Delays (time costs of completed R/D testing).....	24.0	86.0
Product labeling QC monitoring.....	21.7	50.5
Application/legal fees.....	4.3	18.9
Subtotal.....	193.0	1,130.0
Extraordinary costs limiting and banning.....	165.0	195.0
Total continuing cost.....	358.0	1,324.0

To better understand the magnitude of difference between the models, let us examine one factor, premarket screening. If the Administrator's authority were limited to selective testing only those substances he finds pose an unreasonable risk to health and environment, the estimated annual cost would be \$63.4 million, the sum of screening new substances and new applications.

If his authority covered the broad model and he exercised more speculation than firm justification in requiring testing of as many as 6,500 new and modified products marketed yearly, then the cost would be \$261.5 million.

What we have here as another illustration on the total testing costs related to the number of substances and adding mixtures allowing for the fact that mixtures may not be included, the costs will result therefrom is a direct incremental cost associated with the number of products and/or mixtures as one would expect.

This scaling process between the broad and most selective models is applicable to any of the proposed bills.

Obviously, total testing costs would depend on the number of substances to be tested and the testing costs per substance. In the four calculated models shown in the full report, mixtures are omitted.

Provision for such testing, however, clearly is included in S. 776 (Rev.). According to the Snell survey, there are some 10,000 significant new mixtures and more than 350,000 minor formulation changes each year. Conservatively, inclusions of mixtures readily could double the number of products to be tested.

Of even greater economic impact significance is the current language of S. 776 (Rev.) that would require tests which could show " \* \* \* the

potential to induce cancer \* \* \*". The costs would be far higher because of the need for vastly more extensive validating tests.

Clearly the Administrator's discretion bears heavily on economic impact, and in this respect, the Snell figures again are most conservative.

#### TOXICOLOGICAL TESTING COSTS

The Snell study also surveyed toxicological testing laboratories to determine current test costs on mamalian, wildlife and aquatic species. To adequately evaluate the chronic, metabolic and reproductive effects of a single chemical substance, costs already run \$800,000 and may escalate further.

Much less costly techniques are being developed to indicate mutagenic and teratogenic effects, with some foundation for extrapolation to carcinogenicity. These, however, are still screening tests, not always applicable to broad classes of substances, and that the present state of the art inevitably require validation by much longer term and far more costly testing protocols. It follows that the Administrator's action based on screening level or preliminary test data could be unjustified and could, in fact, be contraindicated by results of the ultimately necessary long term tests.

These factors are at the heart of MCA's emphasis that the Administrator explicitly determine the economic impacts of his final rulemaking activities.

#### OTHER RELATED FACTORS

In addition to these direct costs, there were other limiting factors examined in the Snell study.

One of these is the ability of the toxicology testing industry to respond to the obviously increased demands to which it would be subjected. The level of demand will depend upon the criteria finally expressed in the law.

As stated earlier, we believe the level of action in S. 776 (Rev.) would be even greater than stringent interpretation and enforcement of the original S. 776. Our figures forecast doubling of the present \$350 million testing business in 5 years. The number of toxicologists could not be doubled in this time. Consequently, major changes would be required in the administration and work force of testing facilities, probably with some adverse effects on quality and/or quantity of output.

These facilities, especially the larger laboratories, are strained to capacity now. This reflects industry's continual shift to a more responsible level of testing employing more sophisticated protocols. At stake is the setting of a precise standard for a more responsible level of testing in good balance with the real need.

#### A FORWARD-LOOKING ANALYSIS OF PRODUCTION LIMITATION

To substantiate forecasts on costs of limiting production, an analysis was made of the possible prohibition of markets for polychlorinated biphenyls, "PCB's." These are highly stable synthetic liquids now used solely as dielectric fluids in highly restricted applications.

For this one closely related group of compounds, costs are estimated at a one-time expense of \$13.7 million and annually at \$110

million for 20 to 30 years, based on the life cycle of involved end-use products.

These figures confirm the very conservative basis of the forecasted levels for this type of restrictive action, which seems highly probable.

#### CHEMICAL PROCESS INDUSTRIES

An area of this legislation which has received little attention but which warrants serious consideration is its effect on the chemical process industries (CPI), as opposed to the primary chemical producers.

The CPI includes elements from 14 major SIC groups such as paper and allied products, petroleum refining, et cetera, all of which could be affected by reporting requirements and testing provisions. Because these effects are so diffused, no attempt was made to quantify them. Their exclusion adds to the conservative nature of this report's estimates.

#### MACROECONOMIC EFFECTS

To this point, we have noted only those economic effects relating to the chemical industry. However, costs in economic sectors are inter-related and affect others. Obviously, the more basic the industry and the larger its product contribution to base line industry, the greater its impact as incremental costs flow through the total economic matrix.

The U.S. chemical industry is one of the economy's most basic. What happens elsewhere when it is adversely affected can best be determined by employing widely accepted principles through computerized economic models. This technique is generally recognized as valid and is used by EPA in many of its macroeconomic effect analyses. See, for example, "The Macroeconomic Impacts of Federal Pollution Control Programs," by Chase Econometric Associates, Inc., for EPA and CEQ, January 1975.

While such analysis is designed to determine various effects, most significant are the impacts on inflation, unemployment, foreign trade, and economic growth.

These have been analyzed in our study employing the macroeconomic input/output model developed by the University of Maryland—popularly known as the Maryland "Inforum" Model. We believe that this is a useful model. We recognize that there are other modes equally suitable, to wit, the Chase Econometric Model, and in the interest of improving accuracy, we invite those interested to make their own additional analyses of these important economic impacts.

[The chart follows:]

#### MACROECONOMIC EFFECTS

Factor (per year)	Base	Selective	Effect	Broad	Effect
	forecast	model		model	
Gross national product.....	\$1,603.33B	\$1,603.07B	-\$0.26B (1972).....	\$1,601.76B	-\$1.6B (1972).
Inflationary impact:					
Wholesale Price Index (1967=100).....	201.50	201.50	No effect.....	202.42	+0.5 percent or \$11.89B fewer (1985 dollars).
Unemployment (per- cent).	4.45	4.52	80 000 fewer jobs not created.	4.47	200,00 fewer jobs because 54 000 jobs will be created.
Favorable Export-Import balance for 1972.	4.26B	\$4.48B	Trade balance appears to grow since exports are un- affected.	\$3.12B	-25 percent trade balance.

Mr. DOMINGUEZ. As you see in this chart, in the context of GNP, we see a base forecast of \$1,603,353, in selective model \$1.603, the net effect is a reduction of  $-.26$  billion in 1972 dollars, and in the broad model we see \$1.601, or a reduction of  $-1.6$  1972 dollars.

In terms of inflationary impact based on changes in wholesale price index we go from 201.550 with essentially no effect in the selective model to a 202.42, or, in other words, inflationary effect of  $+.5$  percent on WPI, which would translate into 11.89 billion fewer dollars per annum in 1985.

In terms of unemployment, our base forecast is 4.5 percent which in the legislative model increases to 4.52, meaning there are 80,000 fewer jobs; in the broad model it increases to 4.47, reflecting 20,000 fewer jobs because 54,000 jobs will be preserved in the sector.

In terms of export-import balance, the base forecast is \$4.26 billion, which is altered to \$4.48 billion in the selective model, a light growth, to a decrease to \$3.12 billion in the broad model in terms of percentages being  $-.25$  percent.

SUMMARY OF ECONOMIC IMPACT OF PROPOSED TOXIC SUBSTANCES CONTROL LEGISLATION

*Capital Investment.*—While fixed assets would remain, there would be a reduction in capital investment in the chemical industry.

For example: Unanticipated additional R. & D. expenditures of \$600 million per year to maintain present rate of innovation will reduce available capital for investment.

Expansion or improvement of existing facilities and construction of new facilities would be hampered and restricted.

The birth of new chemical companies would be greatly reduced because little if any risk or venture capital would be allocated to so severely regulated an industry plagued with product marketing uncertainties.

*Employment.*—The U.S. chemical industry directly employed about 1 million people in 1972. Indirect employment, in the chemical process and regulated and dependent industries, was estimated at 12 million in 1970. Unemployment effects, therefore, must be considered on both direct and indirect bases. Elements which would contribute to unemployment include:

(1) Direct: (a) Curtailed expansion and limited formation of new companies due to scarce capital and high risk would have a negative effect on new employment.

(b) The unjustified banning or restricting of existing products also would have a negative effect.

(c) Plant closings, a particularly logical conclusion as related to small- and medium-sized companies, would result in short- and long-term employment.

(2) Indirect: The relationship to dependent industries, integrated both forward and backward, would create a "ripple" effect resulting in two types of unemployment: direct as a consequence of immediate forestallment or curtailment of activities, and indirect through no new hiring.

Should legislation such as S.776 (Rev.) be enacted in 1975, the number of jobs not created could reach 80,000 in 1985, according to the selective model.

In the chemical industry, there are losses of about 20,000 and 9,000 jobs in the productive sector under the "selective" and "broad" models, respectively. Under the latter model, this loss is more than offset by an increase in service-sector jobs attributed to the chemical industry.

*Contribution to GNP.*—An analysis of GNP often is considered of major economic significance. The inflated value of goods produced, due to added costs, would appear to be a positive contribution to the GNP. However, these are nonproductive costs and make no real addition to the GNP. In fact, the survey's broad model forecasts a decrease in the GNP of \$1.6 billion a year, based on the 1972 dollar.

*Imports-Exports.*—The chemical industry is a massive contributor to a favorable balance of trade. This would change as increased costs would place us at an economic disadvantage to foreign producers subject to less or no regulation. Furthermore, there would be a strong tendency toward ever greater U.S. chemical production abroad.

Both factors would combine to affect adversely the export of U.S. chemical production and negatively influence the industry in two ways: (1) a direct loss of sales and volume, and (2) a fostering of development of the foreign chemical industry.

While the selective model indicates a slightly favorable effect, the net economic effect of the broad model projects a reduction in the trade balance of 25 percent, or \$1.14 billion, an amount this Nation can ill afford.

*Research and Development.*—While a world leader, the U.S. chemical industry has no corner on scientific breakthroughs. Even the position now held would be threatened because there undoubtedly would be a reduction in the industry's research and development investment and activity. The entire complex of R. & D.-related questions would require the most serious evaluation.

*Inflation.*—While the selective model indicates no significant effect on the wholesale price index, the broad model indicates that a substantial inflationary impact would flow from this legislation. Our figures show a 0.5-percent increase in the wholesale price index or close to \$12 billion by 1985. This would be felt in direct additional costs as well as in the "additive" costs incurred as products flow through the manufacturing, processing, distribution, and marketing channels.

Another factor, difficult to quantify but which must be considered, would be the effect on discretionary spending. This is a very sensitive economic indicator. Additional expenses incurred in the purchase of any given entity adversely affect the availability of money for discretionary spending, thus helping to disrupt and distort the economy. The consumer ultimately pays all these costs.

In another area, excessive costs could force small producers to close and lead to further chemical industry consolidation. Larger companies, able to absorb such costs, might grow even larger, generating undesirable effects on normal marketing competition.

*Effects on Dependent Industries.*—While the input/output analysis looks to quantification of direct economic effects, there would be many indirect effects on dependent industries. Dependent industries are those that produce and sell goods to the chemical, chemical process and allied industries, as well as those that are dependent upon goods produced by the chemical process and allied industries.

Logic dictates that any negative forces affecting the chemical in-

dustry would "ripple" through these dependent industries. This would further affect employment in all sectors of the economy.

*Industrial Transfer.*—There would be considerable emphasis towards the redirection and growth of chemical process industries abroad. Multinational firms would seriously reconsider their positions with a strong emphasis on foreign investment. Foreign producers, taking advantage of the U.S. situation, undoubtedly would increase capital, R. & D. and related investment in their home countries thus effecting a further transfer of chemical industry growth as well as dominance from the United States.

*Benefits of Toxic Substances Control Legislation.*—Preventive and corrective benefits for the chemical industry and the total economy are possible in a toxic substances control law designed to provide effectiveness in acceptable balance with cost.

Premarket screening cannot be an entirely reliable indicator of long-term effects which may require decades to be manifested. It would, however, reduce risk to workers, consumers, and to the environment. The data base provided by this and other requirements ultimately should provide helpful analytical comparisons with later epidemiological studies and so improve our understanding of the true relationship between chemical substances and health and the environment.

This information—continually augmented and improved by reporting, inspection and adulteration provisions—also should help reduce the frequency of voluntary produce discontinuations by industry and regulatory actions by EPA. Further, through the Inter Agency Coordinating Committee and other communication routes among all concerned Federal agencies, the information could provide a sound basis for regulations related to any substance.

Many sectors of the chemical industry already are exercising risk-management actions of the types mandated by S. 776 (Rev.), but a law based on this bill could make performance more uniform and reduce the probability of extreme aberrations.

It has been impossible to quantify the potential benefits of this legislation in terms of "dollars saved" principally because benefits most likely would be diffused throughout the entire economy and no analytical techniques have been established to relate them to gross health and environmental expenditures.

*Conclusions and recommendations.*—In closing, there is an additional subject area to consider. Our comments have been confined to toxic substances control legislation. To our knowledge, no one has addressed the problem of multiple economic effects—micro and macro—of all major legislation and the totality of the cumulative effect on industry, the public, the United States and world economics.

This is a factor recently identified and elaborated upon by M. L. Weidenbaum in "Government Mandated Price Increases," American Enterprise Institute for Public Policy Research, Washington, D.C., February 1975. In addition, there are the ever-increasing, nonlegislated cost burdens under which industry and the public must function.

We could not undertake the enormous project needed to quantify and interrelate all pertinent material. We do, however, respectfully call the committee's attention to this matter. Of particular importance is the need to appreciate the direct and indirect increasing economic cost factors under which industry, the public and the economy now

and in the future will operate in respect to : energy, crude oil feedstocks, pollution control, occupation safety and health, labor, and social benefits programs.

From the foregoing, it is not to be surmised that the chemical industry does not have a profound concern for human life and safety. Where decisions involving human life and safety are at issue, it is obvious that numerous factors come into play requiring carefully reasoned judgments and cost is only one of them.

Examined objectively and on balance, however, it always is necessary to evaluate consequences as well as benefits associated with any action. Therefore, we respectfully submit that the impact of the proposed legislation must be understood and carefully assessed.

Specifically we recommend that :

1. The economic effects of toxic substances control legislation—not on the chemical industry alone but on the United States and world economies—be carefully analyzed and weighed ;
2. Steps be taken to more clearly delineate toxic substances control legislation needs and the Administrator's authority to act under any such legislation, and
3. Provision be made for a specific requirement that the Administrator include an economic impact analysis in any of his final rule-making procedures.

We thank the subcommittee for its time and appreciate the opportunity to present this analysis and our viewpoints.

Senator TUNNEY. Thank you.

I would, unfortunately, not be able to question you because of the fact it is now 12:15 and your reading the statement took about 45 minutes so I—although I have questions—I will have to defer at this time.

I do have one question, however, as it relates to data. That is, in your statement you indicated that the data baseline which you have, the base-line data that you have is being posed in confidence. I understand the problems of proprietary interest but can you just mask the company's name and provide us with the data itself so that we could make that evaluation? Just mask the company's name or give it to us in a form that it would not be recognizable, in a form in which we could have an opportunity to exercise an independent evaluation of the data and do it in a way that could protect the proprietary interest of the companies.

Mr. DOMINGUEZ. Since the study was conducted by Snell and done by them in their relationship with the participants, I would defer the answer to Dr. Nemeec.

Senator TUNNEY. Fine.

Dr. NEMEEC. Senator, let me read to you from the letter that went out with the questionnaire which we sent to the responding companies.

It is on page 231 of the Snell MCA study. I will pick up in the middle of the letter :

Confidentiality. Our report will aggregate the data and will not identify any data sources nor attribute any to any of your companies. We have also tried to organize the questionnaire so as to aggregate the inputs and ask specific product data. Nevertheless we recognize that some confidential information might leak through.

We have therefore established the following precautions: One, the questionnaire will be utilized by the Snell Corporation. MCA will have no access to it.

Two, the last page is split into two parts, the lower half is the only place that calls for company identification. We would like to have this while we are working on our project in case we have to go back to you for clarification or for further questions. This identification segment, however, will be kept in a locked file to which only two people will have access. This identification will be destroyed at the time the report is completed.

The actual questionnaire will be destroyed as soon as MCA gives approval.

Senator, we have considered carefully this question because we knew it would come up. I really have no way of—I can't think of any way to respond to your question without violating the confidentiality commitment I have made to the people that responded.

Senator TUNNEY. I had not seen this statement before that you read from but what you have done, I assume, is to destroy the names.

Dr. NEMEC. Yes, sir, we have followed those instructions.

Senator TUNNEY. Why is it not possible to at some point, when you are dealing with a congressional committee, to treat us as adults? Why can't you give us data that is not screened by somebody else who is going to interpret it, and give us the privilege of looking at the raw data ourselves and, all right, take out the name of the company, I don't have any objection to that whatsoever, take out the name of the company so that the proprietary interest is protected, but why do we have to get the results of a study based upon the interpretation of the trade association or the industry or the—in your case—Snell, why can't we have the basic data?

I mean, are we perceived as being incapable of making that interpretation?

Mr. MAYERS. Senator, I would like to answer that. I think there are basically two answers. One, as you, yourself, understand from your question, this is not an MCA study.

Senator TUNNEY. I might tell you this in all frankness, I didn't know what the answer would be because the question was prepared by a member of the staff. So I asked the question and then—now, for the first time I saw the statement here when it was read. I read it for the first time when he began to read it.

We have not had the opportunity to go over this in advance of the hearing and so I believe it was not what I call a setup arranged by me. Maybe it was by members of the staff who knew what the answer was but now that I understand the issue, it makes me even angrier, because I think that is the sort of thing that we ought to have available to us.

I can't understand why we are considered as members of this committee working on legislation, incapable of evaluating data from industry as well as we are capable of evaluating data from EPA. I will tell you now one of the great fights we are having in the Congress is making sure that the administration supplies the information that the Congress feels is necessary to make decisions on regulations and legislation.

You know of the confrontation that now exists on the other side of the Congress between a House investigative committee and a department of this Government and where an important member of the Cabinet is going to perhaps be held in contempt of Congress for not making data available to the Congress.

So we are not just singling out industry. Congress is trying to get the information from the executive branch as well as from industry and I don't know why something that—this bill has been before us

for 5 or 6 years now. I have worked on part of it for 4 years. This is a loaded issue. So you come forward and tell us you have a study but that you destroyed the data.

Mr. MAYERS. Senator, I would like to reply to the question.

Senator TUNNEY. Well, please answer it. Answer it, please answer it, I am waiting for your answer.

Mr. MAYERS. I have not had an opportunity yet to do so. First of all, Senator, as you understand, this was not an MCA study. MCA asked a prominent independent economic analysis firm to undertake a study of the consequences of the proposed toxic substances legislation.

I am, however, an antitrust lawyer, I am very much aware of the problems within a trade association of gathering data. It was not—although I must say we did not participate in this—it was not at all unusual for Snell to ask for that data under the terms of confidentiality that have been read to you and it is done all the time. It is done primarily to insure—and I have to add it is subject of personal concern to you as a Senator, I know—to insure that this data is not misused through industry efforts.

The insinuation, the insinuation that there was any interest whatsoever in not having that data available to the Senate or this committee is really unwarranted. I did not hear today, I did not hear today any similar question for the witness that preceded MCA for the data underlying their study.

Now, secondly—

Senator TUNNEY. You mean the EPA?

Mr. MAYERS. That is right.

Senator TUNNEY. Or the GAO?

Mr. MAYERS. The GAO?

Second, there is no dispute as to the data. This is a point which I think Mr. Dominguez should discuss.

The estimates on testing are almost identical. The dispute is to the amount of testing required, the amount of premarket screening required. There is very little dispute as to data itself. But we want to be heard very loud and clear as to any insinuation that there was any interest whatever in keeping this data from this committee. We have been involved in this for 5 years, too, Senator. We have attended all 14 days of hearings, and we have not had one morning devoted to the issue which you mentioned this morning, a detailed analysis of why existing Federal legislation does not cover more of the problems that you yourself raised. I could discuss for 15 minutes how the PCB problem and to what extent it can be handled under seven or eight statutes. We are running out of time this morning and we have never addressed that in any open hearing that I am aware of.

Senator TUNNEY. The GAO indicated to Mr. Havens that they have accepted the data on its face. There was no reason to go behind their statement because they said that the statements on their face were accepted as being accurate. The only thing that they were looking at was the method only to see if there was logical inconsistency. That is one of the reasons we did not ask the GAO for any information beyond their statement. I think that is a very important difference.

Now, I was not aware of it until 5 minutes ago about this issue of the questionnaire being sent out and then having the results of the questionnaire destroyed, and if I had been aware of it longer than

5 minutes ago I would have said something about it before we got to the hearing because I think that one of the things that we are doing here is we are trying to at least find out what the costs are. That is a very important factor. We have had testimony now from Havens, the GAO, and he says there is logical inconsistency in the MCA study and their methodology was wrong. You were sitting in the room, you heard it.

Mr. MAYERS. He did not question the data, sir.

Senator TUNNEY. He did not question the data because he did not know about it. He said that he accepted the MCA study on its face and assumed that the data was accurate. That is what he said and he did the same thing with regard to the EPA analysis. He accepted it on its face. Now whether the things that—one of the things that we have to try and determine and I cannot do it personally, I do not have the expertise but I do remind my staff and this committee to help me in these judgments as do other members of the committee, and I would like to believe that the members of the staff are objective and are trying to do the right thing.

Mr. MAYERS. I think they are.

Senator TUNNEY. And I must say that I am deeply concerned about a situation where when we ask to determine what the accuracy of the underlying data in order that we might verify it, we are told that the information has been destroyed and we will have to rely on the interpretation that has been made by the company that was hired to do the analysis.

Mr. MAYERS. Your staff will tell you, Senator, that both EPA and the Snell study largely agreed on the underlying data base and Mr. Dominguez stands here ready to explain that to you. The question is not as to data. Your staff and you personally, Senator, have had this study. I am sorry you did not have a chance to see it, but you have had it for over 2 months. We did not do this in specific response to a congressional request. We did it to determine as best we could without mandating the result in any way what an independent economic concern thought the economic effects would be.

Now, I think you should hear from Mr. Dominguez as to lack of any real dispute as to the data base. I think EPA would agree with that. It just is not an issue.

Senator TUNNEY. Go ahead, Mr. Dominguez.

Mr. DOMINGUEZ. I think I would amplify Mr. Nemeč's comments. What we heard earlier from GAO, I must agree it dealt primarily with the question of the number of products involved in testing; the level of testing involved; and certain other assumptions, if you will, and use of the baseline data.

To that extent it would appear that the assembled data which was developed by Snell and which provides the basis for general methodology applications, it would appear that it is those methodology applications that are more at issue than are the baseline numbers. We heard this morning as a case in point, that indeed GAO agrees with our statement of average cost of testing. If anything they feel our average cost of testing indicates for new products is a more accurate one than that provided by EPA.

So I can only concur with Mr. Mayers' indications that it would be more profitable and more desirable to explore these difficulties

rather than to reiterate and go into questions as they might address the mere assembling and collation of the baseline data which is in fact what Snell did.

To the extent we are discussing methodology, once again I would have to concur with what Mr. Mayers said, that the study was conducted independently by Snell for MCA and, therefore, we relied on Snell's judgment in terms of the methodology to be applied in the conduct of the study. So that when we get into the discussion of these specifics we intentionally brought with us Mr. Nemeec and Mr. Negy so we could discuss in depth the methodology developed and applied by them.

Senator TUNNEY. Well, it is my understanding that there is agreement on the testing cost between EPA and MCA, but that only—that the issue of maintenance and innovation information, there is a reliance, almost entirely reliance of company input. We are talking about now R. & D. expenditures; new products introduced; and so forth.

The companies were the ones that had this information and the Snell study presumably had some of that information available to it which they will not provide us; is that correct?

Mr. NEMEEC. I am afraid I did not hear the last part of the question.

Senator TUNNEY. That the Snell study had this information on the maintenance—on R. & D. expenditures, new products introduced, and so forth, and that Snell interpreted it in the report that we have available to us now.

Mr. NEMEEC. There is data available to us in our files, that is secondary data primarily from the Bureau of Census, R. & D. in the NSF. When we looked at the data publicly available, the level of detail required to do analysis was not there. Consequently, we had to go to the survey of companies that are in that business to ascertain the number of products.

Senator TUNNEY. How does Snell check the accuracy of the reports?

Mr. NEMEEC. By going through the questionnaires with the companies, close checking the proportion of a given company's responses to the known U.S. capacity in that given sector looking at available statistics as to import and export and correlating it on that basis.

Senator TUNNEY. Well, is it not true, Mr. Mayers, that the maintenance of innovation information is exclusively the company's preserve and that the EPA must get that information from the companies?

Mr. MAYERS. Well, Senator, to answer that I think I will only recall what I heard from Dr. Buckley this morning. And point out the conclusions do not depend on that so much as one's own inference is. Excuse me, I am talking about Mr. Havens, not Dr. Buckley. My mistake.

Mr. Havens very clearly stated that a basic postulate of their study was the companies would rather not do R. & D. on new products than to do the onerous testing associated with such new products under the bill.

That is very broad economic assumption.

Second, I noticed this morning that he said that he thought industry exaggerated the amount of testing because under section 4 in his words "EPA will only request that testing which is necessary."

Well, I really hope that Mr. Havens did not use that assumption because as you know, and as Mr. Brownlee knows, this is the very amendment sought by industry. S. 776 does not provide only for testing which is "necessary".

Senator TUNNEY. So——

Mr. MAYERS. So in short the problem is nonexistent.

Mr. NEMEC. May I add something to that?

I would like to point out that in attempting to predict behavior 5 to 10 years into the future against a set of unknowns resulting from a proposed bill, the best way that we know of to estimate the impact, to illustrate to the legislative decisionmakers the potential effect of the legislation, is to use the scenario approach which effectively attempts to bracket or range the possible behavior of the economy and of the companies. Consequently, the first scenario which assumes the maintenance of innovation is just that. We have another assumption that there would be no additional expenditures to maintain innovation.

In our judgment the most probable course of events in the future assuming the legislation is passed as written, as we analyzed it, would be someplace in between but it is not possible to accurately predict the behavior of a large number of institutions operating under various conditions. This is why we have used the scenario approach to bracket the two conditions.

Senator TUNNEY. All right.

Mr. DOMINGUEZ. I would like to comment. Senator, that that intentionally was done in terms of structuring these evaluations so that a range of possible events could be covered. I think that in the analysis that we heard earlier this morning there was a failure to acknowledge that indeed we had attempted to develop four sets of operational conditions, one of which, as Dr. Nemeec has just indicated, totally excluded the \$600 million factor for maintenance of innovation. So in point of fact, boundary conditions reflecting four sets of alternative conditions were applied and developed and while we seem to talk always to the point of the \$600 million it certainly is not valid to say we did not analyze the opposite extreme alternative of no application.

Senator TUNNEY. Let me read from Havens' statement to us. He said:

The highest cost estimate by the MCA study is about \$1.3 billion. Half of this figure is the cost referred to as maintenance of innovation. It is meant to represent the extra cost necessary to maintain the same rate of output of marketable chemicals given the assumption that many new chemicals would be kept off the market because they could not meet the new safety standards. In examining the rationale of this component of cost we came to the conclusion that it was not justified and should not be included as a cost. The MCA survey questionnaire, on which the study was largely based, did not appear to provide a basis for the estimate. In addition, it was not clear to us why a firm would behave in such a way as to incur these costs. If these costs are excluded from the MCA estimate, it would bring the EPA and Manufacturing Chemists' cost figures much closer together.

That is why the question was asked, that is why it is important. That is why we were interested in getting underlying data because the GAO said they were going to exclude it in their presentation but they did not think it was justified. That is the whole basis for the question of the Chair as to why that information is necessary because the GAO said that it was necessary and they have a much better understanding of this than I do.

I am not an expert in this area but I have to rely on experts the way every other member of this committee does. We are told now that the information cannot be made available to us or to the GAO because it has been destroyed.

All right, you can destroy it, you did not have to have the study, you do not have to make information available to us but we can draw our own conclusions thereupon.

Mr. NEMEC. Senator, May I add the following comments; in the report that was submitted to MCA is a transcription of the methodology used to obtain responses from companies, from the member companies of MCA as to the probable effect on their R. & D. expenditures. And that provides a summary of the reasons why companies would feel more invaded for increasing the R. & D. expenditures.

I believe that MCA's position is that we would be more than happy for us to meet with GAO to go over the technical details.

Senator TUNNEY. I would like to have you do that. I think it would be important. We will speak with Mr. Havens. I think it is important that you meet and discuss the study because their testimony to us is that they feel we ought to just exclude that component of cost and I think it is important that we get the best information that we can have in order to make a decision.

There are a lot of people on this committee that have not made their minds up how they will vote on this bill and the purpose of the hearing is to give people an opportunity to testify and bring facts forward and to give the committee a chance to test those facts as they are brought forward so that the other members of the committee can make their decisions based upon the very best information that is available. I think it is important that in as much as the GAO sees that we have to exclude one of the major cost components of your study, that there try to be some reationalization of the methodology that was used by your study and that we have some better information available to us as to why there are those differences between your approach and the GAO approach.

I am going to have to call Mr. Smith now. Everyone else is from Washington so I guess we will have to have another day of hearings to give the people from Washington a chance to testify.

We will see what can be done with respect to the others from the Washington area, whether they submit statements and then submit to questions based on the statement or whether we can get another day of hearings. We will have to check the schedule of the committee staff as well as my schedule.

I want to thank you for being here to testify and it is a very detailed analysis that MCA made of cost based on the Snell study. I know a lot of time went into preparation of it. We are glad to have it and glad to have given you the opportunity to testify today.

Mr. Orin Smith, president, M. & T. Chemical Co., Greenwich, Conn., accompanied by Arthur Sheldon. Mr. Smith please.

**STATEMENT OF ORIN SMITH, PRESIDENT, M. & T. CHEMICAL CO.,  
GREENWICH, CONN.; ACCOMPANIED BY ARTHUR SHELDON**

Mr. SMITH. Yes, Senator, with your permission I will not read the statement that was submitted. I will try and be brief and simply summarize some of the points that we have attempted to make.

I am Orin Smith, president of the M. & T. Chemical Co., Inc. We are a specialty chemical producer. We are similar to that type of company that Senator Ford talked about earlier.

We do support the basic concept of this legislation, Senator. We do not believe that unreasonable risks should be taken to health and environmental areas. We accept the concept of premarket testing. We do it today and we do it prior not only to marketing, but prior to manufacturing as well.

I would like to concentrate on the specialty area. I guess to do that, I had better define what I mean by "specialty chemicals." It is a product designed to perform a certain task in a specific application, normally using a small volume (a few PPM's added to a larger product). Hence the total pounds of it sold is usually small. It is also typically designed to optimize a given company's product and is very often made for one company.

It is also normally unique to the manufacturer. If another supplier expects to solve the same problem, they will generally come up with another molecule. So there are not very many pounds to spread the testing cost over. That is really the heart of our problem.

We are a relatively large company in the specialty field. We employ over 2,300 people in 24 manufacturing locations and research locations in the United States and the world. We have come up with about 130 new products per year, only five of which are sold in large volume. Large volume is when you get to 800,000 or 900,000 pounds per year. The typical product is well below 100,000 pounds per year volume.

Of these 130 new products 60 tend to be new entities. This is an average over the last 5 years. Seventy tend to be mixtures and blends not containing a new chemical entity.

Our estimates of the initial screening and testing that would be required under the legislation would show a cost of about \$20,000 per screening. This would be \$1.2 million per year in cost. It has been estimated by EPA that 10 percent of the products tested would go on to extensive testing and they have estimated the cost per test to be \$200,000. That would be \$1.2 million of additional cost to M. & T.

Our experience shows that the cost of extensive testing is far more than \$200,000 a year, and some of the data submitted by MCA tend to support that. So the total cost to us (M & T) could easily be over 4 million a year, (assuming rigorous enforcement by EPA). If blends and formulations were also included under the act, as I understand they may be, the cost could be much higher. For one small company could approach \$6 million per year.

Hence, we see the threat that the average price increase on our products would be way over the 10 percent MCA talked about. We fear that some safe new products would not reach the market. We fear that in some cases a lot of development and testing marketing would be done overseas, so the commercial success of a product would be determined before essential testing had to be done.

In light of all this we have come up with a number of recommendations. First, we do endorse and encourage you to consider the recommendations of MCA and F. D. Snell.

Second, we would request that the legislation be limited to what we term high-risk chemicals. That would mean that simple mixtures or

formulations would be excluded. It would mean that minor modifications of existing products would be excluded, and it would also mean that intermediates, (products consumed internally never reaching the market) would be excluded as well as very small volume products and chemicals.

We would also request that some definitions be included in the bill which would define the economics that the EPA Administrator is supposed to consider, such as if 100,000 pounds of a product is the maximum to be used and the use were defined, and restricted, that the testing would by definition be limited to such things as the appropriate acute toxicity studies.

We would also request a strict protection on trade secrets. We would request that the chemical formulation, the molecular structure, proposed use and amount sold not be made available for all to see. I am particularly concerned about the effect overseas in some nations where companies are not bound by patents or agreements.

We would request also that the present submission of data only be required if the item is known or suspected to be hazardous. Otherwise, the data should be retained by the company and available for the periodic inspection by the appropriate agency.

In sum and substance we favor the intent of the legislation, but we would ask that the cost effects on the specialty chemicals, small volume products, be considered and that some assurances be provided that the Administrator will be reasonable in his interpretation of the act.

Thank you.

Senator TUNNEY. Well, thank you, Mr. Smith. I just would ask you, have you had an opportunity to speak personally—or have any members of your company—had an opportunity to speak with representatives of the EPA as to what their interpretation of the law is as to what they anticipate costs to be?

Mr. SMITH. Yes, Senator, we have. One case—I guess it was rather frightening to us. In one case we were told that a specific individual who would be primarily in charge of this was a reasonable man—we agree he is—and then one week later he was transferred. That kind of thing, you know.

That is what upsets us and with the uncertainties in the legislation, and in talking to members of the committee staff they had indicated that certainly if the Administrator was not reasonable, we would have recourse in court.

Our problem is since we can't afford to do the testing we can't afford to go to court either. So again our whole slant here is directed at the potential effect of this legislation on relatively small volume products as differentiated from commodities.

We felt that most of the data and information that had been supplied to the committee quite properly was directed at the large volume products.

Senator TUNNEY. I think the points you make with respect to the small volume producers are very good and I know that Senator Ford feels very strongly about this, too. He and I have talked about it. We have talked about it as it relates to the legislation's chances of passage in the Congress, or of the Commerce Committee.

We have gotten assurances from the Environmental Protection Agency that they plan to take into consideration the size of a business,

and the legislation provides, I think, the possibility for them to take into consideration the size of the company in its testing.

But I would say that your coming down here and making your views known as a small company which could be put out of business if the testing requirements were too severe—

Mr. SMITH. And the effect on our company would be far less than on many smaller companies, but the principle is the same.

As was stated earlier, why should it cost more for specialty companies to test? It won't cost more per product. The problem is there are less pounds of a given product to spread the cost over. It is that simple. That doesn't say that a 100,000-pound product can't be extremely toxic and shouldn't be tested.

Senator TUNNEY. That's right, I was about to say that. A small company can put out a product just as toxic and can have just as much impact. It may not be disseminated as far throughout the environment, but it can be just as damaging to the health of the public as a large company's product.

Mr. SMITH. Certainly when a product is designed for a given function, the environmental aspects are far less, more confined and, hence, the environmental testing should be far smaller.

Senator TUNNEY. Well, I want to thank you for your statement.

Mr. SMITH. I appreciate your time.

Senator TUNNEY. I know that Senator Ford wanted to have you know that he welcomes you here.

Mr. SMITH. We appreciate his invitation.

Senator TUNNEY. Thank you.

[The statement follows:]

#### STATEMENT OF M&T CHEMICALS, INC.

##### INTRODUCTION

M&T Chemicals is a manufacturer of specialty chemicals and products. We employ over 2,300 people in 24 manufacturing and research locations in the United States and overseas. We support the basic concept of Senate Bill 776 and are concerned that unreasonable risks to health and environment be avoided. We believe and support the concept of pre-market testing prior to sales that is proposed by this Bill and we presently conduct pre-market testing. Moreover, we currently screen all new products before manufacturing. It is our intent to continue to take all reasonable measures to insure the safety of our employees and customers.

##### THE EFFECT ON THE SPECIALTY CHEMICALS INDUSTRY

You have already heard many major chemical manufacturers review the effects of this legislation. Most of these remarks are directed at large volume commodity chemicals. The effect of S. 776 on the specialty chemical company would be even more dramatic.

A specialty chemical manufacturer typically has a wide line of low volume products sold for specific applications. It is not unusual for the majority of such products to be sold in volumes of less than 100,000 pounds per year, as opposed to the commodity chemical producer's high volume products of millions of pounds annually. The specialty chemical manufacturer's products are also proprietary in nature. They are normally unique chemical entities which are different from another manufacturer's product. Consequently, these products would have to be tested and paid for individually by each manufacturer. There would be no other producer to share the cost.

M&T strives to produce new chemicals to outperform old products and for new uses. We develop an average of 130 new products per year. From this massive research effort, typically only five are sold in large volumes. Another 60 are new

chemical entities and/or mixtures thereof sold in small volumes. The remaining products are normally different mixtures of existing chemical entities.

We estimate that initial acute and environmental testing required by this legislation would cost about \$20,000 for each product. If we were only required to test our new chemical entities and/or mixtures thereof, the cost would be over \$1.2 million per year. The EPA estimated that 10% of new products would require extensive testing at \$200,000 per individual product. This would add another \$1.2 million. However, our experience indicates that extensive testing would cost at least \$500,000 per product. Thus, the total cost to M&T for testing under this legislation would be in excess of \$4 million per year. If acute and environmental testing were required for new formulations and minor modifications of existing products, our costs would be even higher.

The Manufacturing Chemists Association (MCA) says that this legislation will raise the price of a typical chemical by 9.5%. This, of course, would result in large consumer price increases. The price increases for small volume specialty chemicals will be much higher—on the order of 20 to 25%. This will not only cause price increases to our customers' products, but will inhibit our ability to compete on the international market. Over a third of our volume is typically sold overseas.

Expenses of this size would definitely prevent many new and safe products from reaching the market. Some companies could be expected to move their research, development and test marketing operations overseas to avoid testing restrictions until market success is assured.

#### RECOMMENDATIONS

1. We fully endorse the recommendations regarding S. 776 proposed by the Manufacturing Chemists Association (MCA) and the Synthetic Organic Chemical Manufacturers Association (SOCMA). We encourage the Senate Commerce Committee to consider these recommendations when reviewing this legislation. Additionally, we implore you to consider the economic implications for the specialty chemical manufacturer.
2. Legislation should be limited to high risk chemicals. Chemical mixtures, formulations, minor modifications of existing products, non-commercial chemicals and intermediates (those produced and consumed internally) and research chemicals should be exempted.
3. A manufacturer of small volume specialty chemicals (those products designed to perform a special function and selling less than 100,000 pounds per year) should be required to perform only the five major acute toxicity studies normally utilized, assuming no problems are revealed by these studies.
4. Toxic Substances Control Legislation should provide for coordination among the existing Federal Agencies, OSHA, NIOSH, EPA, FDA, etc. and the more than 25 laws in this area. Overlapping jurisdiction and duplication of effort should be eliminated. Legislation should focus on areas where there is no adequate coverage by existing regulatory agencies.
5. Legislation should offer strict control of manufacturers' trade secrets. The chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see and use. Similarly, disclosure of detailed information on formulations, that is, a mixture of materials, should be avoided. Disclosure of all such information can have particularly severe competitive repercussions abroad, in those foreign countries whose manufacturers are not or do not feel restricted by patents and other agreements.
6. Submission of data for all new products to the EPA three to six months in advance of sale causes unnecessary expense. Required data should be retained by the manufacturer and be made available for periodic inspection by the appropriate agency. Submission prior to marketing should only be required if the product is known or suspected to be hazardous.
7. Extensive testing should not be required unless the product demonstrates an unreasonable risk in the particular use or application. When potentially harmful products are used in a manner that will not expose workers or consumers to harmful effects, extensive testing should not be automatically required.

#### CONCLUSION

The socio-economic impact of this legislation should be fully explored and considered. This is particularly important to the specialty chemical industry

which is characterized by many unique, small volume products often manufactured by small chemical firms. S. 776 in its current form will place thousands of jobs in jeopardy and greatly limit innovation in the specialty chemical industry. We fear that these negative effects far outweigh the advantages of the proposed legislation in its current form.

Senator TUNNEY. I am going to ask Dr. Rall, Director of the National Institute of Environmental Health Sciences, to come up.

We have about 10 minutes, Dr. Rall, for your testimony.

Did Dr. Rall leave?

[No response.]

Senator TUNNEY. Well, we have about 10 minutes. Why don't we hear from Dr. Clarence Davies, if he is here.

#### STATEMENT OF J. CLARENCE DAVIES, RESOURCES FOR THE FUTURE, WASHINGTON, D.C.

Dr. DAVIES. Thank you, Senator. I appreciate the opportunity to be here.

Let me try very briefly to highlight some of my testimony. The complete statement has been submitted for the record.

Senator TUNNEY. Yes; it will be incorporated in the record.

Dr. DAVIES. Would you like to have me dispense with reading the statement altogether?

Senator TUNNEY. Yes; and I would like to have you comment—do you have a short comment to make as you sat through the hearing here? Did anything come to your mind as you heard the others? If not, I will ask you some questions.

Dr. DAVIES. Senator, I guess I would simply say that there seems to be general agreement on the need for this legislation and, therefore, it is not really necessary to dwell on that. An exception was the statement made by the gentleman from MCA, who said that he thought that PCB's and other similar problems could be handled without the legislation. I very much question that, and I would support the statement of Dr. Buckley on the need for this kind of authority.

The other big problem, of course, is the degree of discretion left in the hands of the Administrator. I would agree that there is considerable discretion involved in the bill, but I see no real way around that. I think that is inherent in the nature of the situation, as I say in my statement and as the committee of the National Academy of Sciences that I chaired concluded. Discretion is inevitable in this area, but you can hedge the degree of freedom of the Administrator through various kinds of legal provisions. I think the bill does an excellent job of steering a middle course between the necessary degree of flexibility and making sure that the decision the Administrator makes is soundly based.

Senator TUNNEY. As you know, we will be offering amendments that relate to economic costs weighed against social benefits.

Dr. DAVIES. Right.

Senator TUNNEY. I personally think that is a new course, an important middle course.

Dr. DAVIES. I strongly endorse staff amendment number one. I think that is essential and I strongly endorse it.

Senator TUNNEY. Is there anything novel in the proposed Toxic Substances Act in giving discretionary authority? For example, the Pesticides Act and Toxic Substances Act, is there a comparison?

Dr. DAVIES. I would say that the degree of discretion left to the Administrator is about the same. I think the toxic substances bill, S. 776, does a somewhat better job than the Federal Insecticide, Fungicide, and Rodenticide Act in terms of spelling out the kinds of considerations which the Administrator has to take into account in arriving at decisions for various regulatory actions.

I think that the requirement for a statement of justification at the time that the decision is proposed is an excellent innovation. I think that the requirement should be spelled out further than it is in the current version of the bill, but it is something which, for example, is not in the Federal Insecticide, Fungicide, and Rodenticide Act and which helps to describe the basis for the decision to be sure that the decision is reasonable.

Senator TUNNEY. Have you had an opportunity to speak to members of our staff with respect to language that you think should be included in the legislation at this point?

Dr. DAVIES. I have not proposed or suggested specific language, but I would be glad to talk that over with the staff.

Senator TUNNEY. I wish you would. I certainly wish that you would. Do you feel that the EPA Administrator is sufficiently constrained by the language of the legislation? I mean, I can well understand the fear some people in the industry have that they may be regulated out of existence by what is essentially an irresponsible judgment on the part of an Administrator and occasionally we have irresponsibility demonstrated by officials in any walk of life.

But what are your views with respect to the constraints in that respect?

Dr. DAVIES. My own opinion is that the constraints really are adequate and appropriate and that further constraints would probably be counterproductive in terms of the intent of the bill. It seems to me that in terms of legal reviewability in the courts of the decisions made by the Administrator, as well as other types of review, that provisions in the bill are adequate and consistent with similar types of regulatory authority.

I think it may be possible in the future to specify in more detail the kinds of criteria and information which the Administrator takes into account in reaching his decisions. But I think that can't be done at this point, at least I couldn't suggest any points at which that could be done. Such further specifications will have to be arrived at out of experience with the legislation.

Senator TUNNEY. Well, I appreciate, Dr. Davies, your testimony and we may have a couple of questions that we will submit to you in writing.

Dr. DAVIES. All right.

Senator TUNNEY. But I want to express my apologies to Dr. Martha Sager for not having time to listen to her. I am going to ask staff to meet with her and also with Dr. Rall, to see if we can work out some satisfactory arrangement either through submission of the statements plus questions; or if it can be worked out, to come forth with the

schedules that witnesses have as well as the Senators. Maybe we can have another day of hearing or another morning of hearing.

Be that as it may, I wish to express my apology for not having had a chance to hear them.

Thank you very much, Dr. Davies.

Dr. DAVIES. Thank you.

[The statement follows:]

#### STATEMENT OF J. CLARENCE DAVIES III

Mr. Chairman, I very much appreciate the opportunity to appear before the committee. My name is J. Clarence Davies, III. I am currently with Resources for the Future, Inc., an independent non-profit research organization in Washington, D.C. However, the views that I will express here today are strictly my own and in no way represent the views of Resources for the Future.

I was invited to testify because I recently served as chairman of a committee of the National Academy of Sciences. The report of the committee, entitled "Decision Making for Regulating Chemicals in the Environment," was published by the National Academy last month. However, here again I must enter a caveat. My testimony today should not be taken to represent the views of either the National Academy of Sciences or the Academy's Committee on Principles of Decision Making for Regulating Chemicals in the Environment. Although I shall draw heavily on the committee's report, the committee did not take any position directly on the Toxic Substances bill. I shall suggest changes in the bill which I think follow from the recommendations of the committee report, but the juxtaposition of the report and the bill is purely my own.

#### THE NAS REPORT

The NAS Committee on Principles of Decision Making for Regulating Chemicals in the Environment was convened pursuant to a contract between the National Academy and EPA's Office of Toxic Substances. We held a two-day planning seminar in September 1974. In February of this year we convened about 60 people in New Orleans for a five-day working session. The participants in this session represented a wide diversity of disciplines and backgrounds, but almost all of them were people with extensive experience in the problems of chemical regulation. Mike Brownlee of your staff attended the session as an observer. Dr. David Rall, whom you heard from earlier this morning, was a member of the committee.

The participants in the New Orleans meeting were divided into eight working panels, and at the end of the five days each panel produced a report. After the meeting, I took the eight panel reports and synthesized them into a draft final report. This draft was then reviewed several times by the committee and, after making various changes, the committee approved the final report. The report was then further reviewed and approved by the Environmental Studies Board and the Natural Resources Commission of the NRC and by an outside review committee of the NAS.

The report contains a total of 34 recommendations. I shall not attempt to describe all of them but will concentrate only on those that are most relevant to your committee's consideration of S. 776. The recommendations are divided into the four major aspects of the regulatory decision-making process that we considered to be of most importance. These are: (1) the statutory and organizational basis for regulation; (2) openness and access to the decision-making process; (3) the availability of adequate and reliable information; and (4) the proper use of analysis. In each of these areas the committee reached conclusions which I believe to be important with respect to the toxic substances legislation.

#### STATUTORY AND ORGANIZATIONAL BASIS

The first two recommendations of the report deal with the question of who should have the burden of providing the harm or safety of a chemical. This is absolutely the most fundamental question in the regulatory statutes, but the existing statutes are rarely clear on the matter and the answer to who has the burden of proof usually has evolved only after a long series of court cases.

Our first recommendation states that, "As a general principle the burden of proof that society will obtain a benefit from a new use of a chemical should rest with those proposing such use." The second recommendation states that, "Once

the government has made a reasonable case that the challenged use of an existing chemical creates an excessive hazard to human health or to the environment, the burden of producing evidence should shift to the proponent of use, who must then make an appropriate showing that the continued use is desirable."

From my layman's reading of S. 776, I would say that the bill does not square with these principles, although I am not clear to what extent section 13(e) affects section 6 and the other relevant sections. In any case, I do not want to pursue this matter because it is so highly charged that I doubt very much that my views or the views of the National Academy will have much impact on your deliberations respecting burden of proof. I would simply urge that the language of the bill be made as clear as possible on this point because it is so central.

The report's third recommendation is also relevant to the Toxic Substances bill. It states that, "Statutory provisions should not preclude consideration of any relevant factors in the decision-making process." In other words, regulatory decisions should not be based exclusively on health considerations or economic considerations or any other type of considerations but should involve a careful weighing of all the important anticipated impacts of the decision. S. 776 is quite good in this respect, although I would strongly endorse amendment #1 as a way of insuring and reinforcing the legislative mandate that all relevant factors are taken into account in the decision-making process.

#### OPENNESS AND ACCESS

The NAS committee felt that the decision-making process should be as open as possible to outside participation. We believed this to be essential not only because of the democratic norms of our society but also for two more pragmatic reasons. First, openness in the decision-making process is likely to improve the quantity of the information used to make the decision. New sources of information can be tapped and the available information can be subject to critical scrutiny by a variety of groups and individuals. Second, implementation and acceptance of the decision is likely to be facilitated by an open decision-making process. There will be less likelihood that the decision will be questioned in the courts or subjected to other forms of criticism and delay.

The report recommends a number of steps that can be taken to insure an open and accessible process of reaching decisions. The most important, in my opinion, is the recommendation that states: "The essential elements of decision making should be part of the public record. The agency should publish a 'white paper' for each important regulatory action undertaken. The paper should include the key details of the economic, legal, scientific, and other considerations taken into account in reaching the decision. It should be issued when the agency decides to take some action but sufficiently in advance of a final decision to permit considered response. An important decision to take no regulatory action, or to defer such action, should also be accompanied by a 'white paper.'"

I am very aware of all the difficulties that have been caused by the requirement for environmental impact statements contained in the National Environmental Policy Act. But we now also have a presidential requirement for inflationary impact statements, and proposals have been made for requiring energy impact statements and other types of statements as well. It is time that we stopped trying to tackle the problem piecemeal and recognize that requiring an explicit public justification of important decisions is healthy and beneficial not only for the public but for the decision makers as well.

The white paper that we envision in the report does not have to be a large, cumbersome document. It should not entail the collection of any information that has not already been collected for the purpose of making the decision. The basic criterion for judging the adequacy of such papers should be simply whether a reasonably intelligent person on the basis of the information contained in the white paper can understand how and why the agency arrived at the decision that it did. The white paper should lay the basis for understanding the decision and should also serve to focus the areas of doubt or controversy about the proposed decision.

In the specific context of S. 776, the statement of purpose and justification required under section 14(f) has at least the potential for satisfying our idea of a white paper. However, I think that to insure that the statement is not simply a pro forma document, the requirement should be elaborated on both in the bill and in your committee report.

One other recommendation regarding openness is worth calling to your attention. It states, "The early and open exchange of information and opinions on a

proposed decision should be encouraged to reduce the current dependence on subsequent judicial challenge. The EPA Administrator should hold public hearings at the earliest feasible stages of the decision process. He also should facilitate prehearing exchange of information among parties (for example, through depositions, interrogatories, and other discovery procedures)." I believe that the current version of S. 776 is satisfactory in this respect. However, your committee might want to consider adding to the policy statement in section 2(b) of the bill or in the committee report a statement along the general lines of the NAS recommendation.

#### ADEQUATE AND RELIABLE INFORMATION

It is clear that adequate and reliable information is fundamental to making sound decisions. The quantity and quality of all types of information used for regulating chemicals need to be greatly improved. The information available to the decision maker will never be perfect and is often not satisfactory, but a number of steps can be taken to provide more adequate information.

One such step is to provide a regular process for external scientific review of the technical data base presented to the decision maker. Experience indicates that many mistakes can be avoided and the credibility of the decision can be greatly increased if the scientific data used to make the decision has been reviewed by competent experts outside the agency. With respect to the Toxic Substances bill, if the requirement for a white paper is incorporated then one function of the paper should be to indicate the extent to which non-government experts have been consulted. The provision in the legislation requiring an annual report from EPA might also be amended to require that the annual report include an account of the use of outside experts to review the data used in making decisions on toxic substances.

One means by which outside experts can be brought into the decision-making process is through the public hearings. This is not the only or even the most satisfactory way of bringing such expertise to bear on the information employed in the decision, but it is useful nonetheless. Section 6(d) of the Federal Insecticide, Fungicide, and Rodenticide Act allows the EPA Administrator, acting through the Hearing Examiner, to subpoena expert witnesses to appear at the public hearing called to consider cancellation of a pesticide. As I read it, section 14(b) of the Toxic Substances bill provides similar authority and this is one way of obtaining and utilizing the knowledge of non-government experts.

The NAS report recommends that, "The Department of Health, Education, and Welfare, in conjunction with EPA, should attempt to develop a hazard rating system, placing particular emphasis on evaluation of use patterns." The rating system would be based on both the intrinsic toxicity of the chemical and on its use. The development of such a system is possible and could be accomplished within a fairly short time if there were sufficient incentive to do so. Your committee might want to consider requiring EPA to use such a system either in conjunction with or instead of the list of 300 chemicals required under section 4(c)(1) of the committee's bill.

A very important but neglected aspect of improving the information base for regulatory decisions is the ability to learn from experience. Neither current legislation nor administrative practice encourage the development of an "institutional memory" within the bureaucracy. Our report recommends that, "For optimal regulatory decision making, a procedure to conduct retrospective analyses of the impact of given decisions should be adopted. This should emphasize evaluation of the accuracy of the predictive models for health, economics, and environmental sciences in the original decision-making process." In short, there should be feedback on the actual impact of past decisions.

The annual report requirement in S. 776 provides a good vehicle for getting EPA to do such retrospective analyses. I would suggest that a provision be added to section 16 of the bill requiring the annual report to include an evaluation of the impact of major decisions two or three years after the decision has been made.

#### PROPER USE OF ANALYSIS

The NAS committee carefully reviewed the available techniques of cost-benefit analysis and decision theory. Our conclusion was that there is not now and probably never will be an objective scientific way of making regulatory decisions. The methods of cost-benefit analysis as they have been developed by economists and decision theorists are useful for collecting and organizing data and for

presenting it to the decision maker, but they are of little or no use in actually deciding what standard to set or what course of action to follow.

Very briefly, there are four reasons why formal cost-benefit analysis cannot be used to make regulatory decisions. First, and most fundamental, such decisions always entail values on which there is no agreement. I value human life differently from Evil Kneivel. The Dow Chemical Company places a different value on encouraging innovation in the chemical industry than does EPA. The most important elements in the decision are likely to be values about which there is widespread disagreement and no objective way to deciding what the "right" value is. Second, even apart from the lack of agreement on values, there is usually no way to quantify the important factors in the decision in such a way that they can be added or subtracted. Even if we agree on their value or importance, we would be hard-put to assign dollar values to human life or maintaining industry competition or other important elements in a decision. Third, there are the problems of distribution, the question of whose costs and whose benefits. The difficulties of occupying with the geographical, social, and temporal distribution of the impacts of a decision are immense: the distributional questions are highly salient for the decision-maker; and yet there are no good analytical techniques for dealing with these problems. Fourth, there is the uncertainty of the data used in the analysis. It may be a waste of time and can be highly deceptive to use refined analytical techniques if the key questions in a decision are validity of the data used. Greater use of probability theory does provide a method for dealing with problems of uncertainty, and such theory should be employed more frequently. But if the decision hinges on whether or not a substance is carcinogenic, no amount of number manipulation is going to get around that central question.

Given that there is no scientific way to make regulatory decisions, ultimate reliance must be placed on the judgment of an informed decision maker. The recommendations in our report were framed with this in mind. I attach particular importance to the white paper concept in this regard because it is a way of keeping the decision maker "honest," of forcing him to publicly explain the basis for his decision. It is important that the white paper and the other documents supporting a decision deal explicitly with the value judgments that have entered into the decision. Every effort should be made by the regulating agency to avoid concealing such judgments in supposedly objective data. Your committee report may want to address this problem directly.

#### CONCLUSION

My own opinion is that the Toxic Substances bill is of vital importance. The marketing of new chemicals and the use of chemicals already being produced are areas where governmental regulation is absolutely essential. Existing legal authorities are clearly inadequate to accomplish this.

It has been almost five years now since the first toxic substances bill was considered by the Congress. The vacillation by the Executive Branch and the inability of Congress to reach agreement on a bill has been dismaying. But the delay has had the advantage of allowing a greater opportunity to learn from regulatory experience in other areas and to apply that experience to the writing of the toxic substances legislation. The recommendations contained in the NAS report are based on what we have learned about regulating chemicals, and I hope that they are useful to you in your consideration of what I hope will become the Toxic Substances Control Act.

Senator TUNNEY. The hearing is adjourned.

[Whereupon, at 1 p.m. the subcommittee adjourned, to reconvene at the call of the Chair.]



## ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

STATEMENT OF DR. DAVID RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Mr. Chairman and members of the subcommittee, it gives me great pleasure to appear before you once again to testify in support of the toxic substances legislation. Previously, on March 10 of this year, I testified before your Committee on behalf of the Department of Health, Education, and Welfare. Our position then was in support of the concept of toxic substance legislation, and our position is the same today.

Although this legislation has been debated pro and con for over three and one-half years, we feel some basic issues involved must be reemphasized or brought into the spotlight for public consideration.

We need a Toxic Substances Control Act. Today, it is entirely possible for a company to produce and distribute throughout our nation highly toxic chemicals, and many thousands of citizens could be exposed to such chemicals during the production and distribution cycle. Once a disease process has begun, in many cases, it can become progressively worse and may lead to disability, even without further exposure to the toxic substance. We believe cancer, for instance, can develop from a single exposure to a carcinogenic substance.

One of the major themes of this year's forward Plan for Health is preventive medicine. Toxic substances control legislation which prevents the exposure of segments of the population to disease producing substances is a key element of preventive medicine.

We need, therefore, legislation to control the production and distribution of those few agents that pose an unreasonable risk for damage to the public health.

Many representatives of the chemical manufacturing industry agree with the need to control toxic substances, but feel strongly that the industry is responsible and can control itself. I must say that we too are confident that many chemical manufacturing companies do feel that responsibility and do effectively exert self-control. They do test their products and market only those that are safe. But we are dealing here with human nature. There are some—a minority—who do not exert such self-control. Because of the potential seriousness of the problem, we believe legislation is needed.

We must emphasize that the design and implementation of toxic substances control legislation is a very difficult and challenging task. Such legislation must not be so restrictive as to stifle chemical innovation. It must not submerge the chemical industry with acres of paperwork. It must not deprive society of essential chemicals on the basis of whims and fantasies. It must, however, seek to identify those few substances that do pose unreasonable risks to health. Can this be done? We believe it can.

The science or discipline of toxicology which seeks to identify and understand the damaging or hazardous effects of chemicals on living matter, including man, is young—but vigorously growing. The burden toxic substances control legislation will place upon toxicology is severe. It is a difficult task to study a chemical compound in a research laboratory and then to predict its effects on a population of 210 million people.

Recent developments in the area of rapid, simplified test systems, particularly for mutagenesis and carcinogenesis will be the keystone of this effort.

In Dr. de Serres testimony of March 10, he described the development of rapid, inexpensive tests for chemical mutagenicity and probably also for carcinogenicity. We think it is important to describe the development of the tests for mutagenesis because this demonstrates the need for the effective coupling of basic research and toxicology.

A mutation is a change—chemical in nature—in the DNA (desoxyribonucleic acid) which is the genetic material that transmits the information from parent to child that determines form and function. Such mutations occur in germinal cells—the precursors of female ova or eggs and male sperm. If a mutation occurs in a general body cell, it is called a somatic mutation and can cause a change in hair color for instance, or transform a normal cell into the precursor of a neoplastic or cancer producing cell. Many if not most human cancers are thought to begin with such a chemically induced somatic mutation. Therefore, accurate tests for

mutational activity will serve to predict for the possibility that a chemical can cause genetic damage and also can cause cancer.

These tests are based on two concepts that have developed from basic biomedical research in the last 5-10 years. The first is the beginning understanding of the chemical basis for genetics and for the development of genetic mistakes or mutations. This permitted the development of sensitive reproducible and simple unicellular systems for easily testing genetic damage. The second is the beginning understanding of the process by which the body handles foreign organic chemicals. It is now known that most such chemicals are metabolized by enzyme systems in the body to different, though closely related chemicals which the body can get rid of more easily. It is often the metabolized chemical—the metabolite, that is the toxic agent—the chemical that reacts with normal body chemicals to cause the damage. These enzyme systems can be extracted from such tissues as rat liver and added with the chemical under test to the genetic test system. This mimics in a test tube or petri dish what happens in the body.

These tests cost hundreds of dollars instead of hundreds of thousands of dollars that the classic two year, two species, two sex chronic animal exposure tests cost, and they take days instead of years. Currently, Dr. Ames at the University of California, Berkeley, has shown that with his test—which is one of perhaps a dozen promising tests—only about 10% of known carcinogens are missed—false negatives, and a similar 10% of chemicals shown to be non-carcinogenic in classic test systems are positive—false positives. In surveying over 100 common chemicals, only 1/2% were positive.

Although emphasis has been placed on using these tests to predict for carcinogenicity, genetic disease itself is a major cause of human disability and death. Serious diseases or abnormalities due to genetic damage are present in between 1/2% of newborn babies. Genetic damage which becomes apparent later in life is responsible for 5% of the hospital admissions to the pediatric wards of major teaching hospitals. Diseases which have a strong genetic component—but one not solely due to mutations—represent about 30% of such hospital admissions.

One interesting new hypothesis is that atheromatous plaques—which are the basic lesion in many forms of cardiovascular disease—are small benign tumors resulting from a somatic mutation, probably induced by an environmental chemical, in the lining of the blood vessel. And as you remember from the earlier hearings, vinyl chloride as well as other industrial and environmental chemicals are mutagenic in laboratory test systems.

Before I close let me indicate what general features I believe are essential to an effective and fair toxic substances control law.

First, premarket notification of proposed production of new chemicals, and of major new uses of an existing chemical, must be required. Where feasible, information on chemical and physical properties, health and safety data and anticipated volume and use should be included. This information, excluding trade secrets, should be published so that the scientific community can have the opportunity to present any pertinent data.

Second, it is not necessary to require premarket testing on all substances. Rather, the government must establish criteria of unreasonable risks relating to new or old chemicals. If it is determined that these criteria apply, then there should be a requirement for industrial testing and control distribution, if needed.

Third, ideally, manufacturers should voluntarily make available pertinent health and safety data they have generated or are aware of. If they do not, then legislation should require the disclosure of these data while protecting proprietary trade information.

As I said earlier, administration of this Act will be difficult and challenging. We of DHEW pledge to the Congress and to EPA our wholehearted cooperation. We fully support EPA's testimony before your Subcommittee on March 10, detailing selective changes to S. 776. But the science of predictive toxicology is not perfect. It seems to me likely that even with the best of science and of intentions, judgments will be made which on the basis of later and better knowledge will be shown to be less than perfect. We must recognize and live with this problem.

Thank you for the opportunity to discuss our views with you. I would be happy to answer any questions you might have.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
PUBLIC HEALTH SERVICE,  
NATIONAL INSTITUTES OF HEALTH,  
Bethesda, Md., November 17, 1975.

Hon. JOHN V. TUNNEY,  
U.S. Senate,  
Washington, D.C.

DEAR SENATOR TUNNEY: Thank you for the opportunity to reply to the questions posed in your letter of October 31, 1975.

My responses to your questions are enclosed.

In summary, I would like to state again that legislation in the area of toxic substances can make a significant contribution to the solution of the national problem of identifying the extent of health hazards associated with new and existing chemical substances and protecting our citizens from exposure to them.

If I may be of further assistance to the Committee, please call on me.

Sincerely yours,

DAVID P. RALL, M.D., Ph.D.

Enclosure.

*Question 1.* What factors are most important for ranking the potential hazards posed to human health and the environment by untested or inadequately tested chemicals?

Answer. The following are the key factors which must be taken into account in attempting to rank the potential hazard of untested or inadequately tested compounds.

- A. Amount produced.
- B. Distribution through various media such as air or water.
- C. Use and exposure pattern: food additive, drug, industrial, etc.
- D. Nature of population exposed: age, sex, general health, occupational groups, etc.
- E. Persistence—both environmental and biological.
- F. At what concentrations is chemical biologically significant.
- G. Available data regarding biological activity.
- H. Are alternative chemicals available.

*Question 2.* What is the status of efforts to apply these hazard considerations to the development of a list of chemicals which would be high-priority candidates for testing?

Answer. These considerations have been taken into account by two studies carried out on contract by the Stanford Research Institute to come up with lists of chemicals and with priority ratings on the basis of general health hazards and carcinogenic risks. While there are some limitations in these studies, at present, we are optimistic that they will greatly improve our ability to estimate the hazard of new chemicals.

*Question 3.* Given a chemical with a certain hazard rating, and given the requirement that the potential benefits of test data generated should be commensurate with the cost of generating such data, would there be reasonable consensus among competent toxicologists as to the types of tests that should be performed for a particular chemical?

Answer. Yes, there would be reasonable consensus among competent toxicologists regarding the types of tests that have to be performed *first*. While toxicologists will differ on how much additional testing is required to reach a level of certainty regarding the possible toxicity of a chemical, it should be generally possible for them to reach a consensus.

*Question 4.* In the EPA and MCA cost estimates of implementing S. 776, there is agreement as to the clustering of batteries of toxicological and environmental tests in the (a) \$10,000–\$20,000 range and (b) in the \$200,000–\$400,000 range. However, MCA also includes a battery of tests costing approximately \$800,000. What types of chemicals would appropriately be tested at the \$800,000 level?

Answer. Very few chemicals will be tested on the \$800,000 level. Those which are would include those which show red flags at the level of less expensive tests, especially if they involve things like carcinogenesis, teratogenesis, or mutagenesis. In addition, chemicals which have a significant benefit factor, are very persistent and likely to be widespread in our environment and should have more complete testing with a variety of tests.

*Question 5.* How many (a) new and (b) existing chemicals would be appropriately tested at the \$800,000 level each year?

Answer. Very few chemicals require testing at the \$800,000 level. This applies both to new and existing chemicals.

*Question 6.* How many (a) new and (b) existing chemicals would be appropriately tested at the \$200,000–\$400,000 level each year?

Answer. There would possibly be half a dozen existing chemicals that deserve testing in the \$200,000–\$400,000 level cluster and fewer new chemicals would be tested on that level, due to the increasing effectiveness of the cheaper screens and tests.

*Question 7.* How many (a) new and (b) existing chemicals would be appropriately tested at the \$10,000–\$20,000 level each year?

Answer. Hundreds of new and existing chemicals will be tested each year at this level except that the cost of these tests will be less than the \$10,000–\$20,000 level. The reason for the decrease in cost is not that things are getting cheaper or bound to get cheaper but with the development of new test methods this level of testing will be less expensive.

Among these new tests would be the rapid, inexpensive tests for chemical mutagenicity that appear to be effective for determining the carcinogenicity of most chemicals.

These tests are designed to affirm positive results at the prescreen level and to provide an indication of the type of genetic damage (point mutations or chromosomal effects) induced.

Particular tests to be used include:

Mammalian cells in culture:

1. point mutations
2. *in vitro* cytogenetics

Whole animal tests:

1. dominant lethal type
2. *in vivo* cytogenetics
  - (a) somatic cell
  - (b) germ cell

Currently, Dr. Ames at the University of California, Berkeley, has shown that with his test—which is one of perhaps a dozen promising tests—only about 10 percent of known carcinogens are missed (false negatives) and a similar 10 percent of chemicals shown to be non-carcinogenic in classic test systems are positive (false positives).

The Ames test, and also the DNA repair and the *in vivo* and *in vitro* carcinogenicity test of De Paulo and others, bring us close to the time when we will be able to detect within a few days compounds which have a high likelihood of being either carcinogenic or mutagenic. In addition, they are far less expensive—about \$2,000. The short time and the low cost required are critical because there is no way we could test for carcinogenicity by the classic two species, two sex, two year studies, the hundreds of compounds will have to in the future.

These new tests are not perfect. They are not good at picking up heavy metals, and they fall down completely with such substances as asbestos fibers and fiberglass fibers. But they do appear to be about 90 percent accurate in terms of predicting true positives. Thus, they seem to be an important development in our testing, and offer promise of being able to take their place in our testing programs in a year or a little more.

*Question 8.* Would you comment on whatever you perceive to be the reasons for any discrepancies between your answers to questions (5), (6) and (7) and the estimates presented in the EPA and MCA studies?

Answer. In the absence of clear information regarding how the estimates were derived in the MCA sponsored study, it is difficult to comment meaningfully. However, in general the MCA sponsored study assumes that EPA will require far more stringent testing than EPA says it will. My view is that more testing will be required at the lowest level than either the EPA or MCA estimates, while I do not believe as much testing will be required at the higher levels as either of those organizations will estimate.

*Question 9.* Would it be feasible for EPA to develop categories of chemicals to serve as guidelines such that a manufacturer could reasonably anticipate the level of testing, if any, that would be required for a new chemical?

Answer. With regard to mutagenicity and carcinogenicity, it is possible to develop categories of such compounds which would be useful though not all inclusive. With regard to teratogenicity, it is clearly not possible to develop such categories at this time. However, various categories of tests can be developed and carried out in proper sequence and after each test cluster, an assessment can be made whether additional testing will be necessary. With regard to new chemicals, it may well be that an exhaustive first test cluster will be all that is necessary to establish whether the compound is to be developed or set aside.

*Question 10.* There is a large body of toxicological data in other agencies, much of which would appear to be pertinent to the administration of a Toxic Substances Act by EPA. Would you briefly report on the efforts of the Toxicology Coordinating Committee to make the data banks of the various agencies useable to one another?

Answer. In February 1974, the Toxicology Information Subcommittee of the DHEW Committee to Coordinate Toxicology and Related Programs was established to deal with the "collection, storage and dissemination of appropriate data and information with respect to toxicological and related activities within the Department". The managerial and operational control of toxicology activities are lodged in the Toxicology Information Program (TIP) of the National Library of Medicine.

The Subcommittee has primarily engaged in two areas of activity: (1) creating new toxicology information bases and services of identifiable importance to various health agencies and to the scientific community; and (2) establishing interagency communication channels that will keep each participating agency informed of the others' information activities in toxicology.

#### POTENTIALLY HAZARDOUS COMPOUNDS OF INTEREST TO AGENCIES

In the course of selecting compounds for inclusion in Toxicology Information Programs on-line Toxicology Data Bank (TDB), it became apparent that lists of "hazardous" substances are maintained by various agencies for differing purposes. Thus, NIOSH and OSHA have lists of compounds that are potential occupational hazards, while the Coast Guard keeps lists of compounds that may represent hazards during transport.

In collaboration with the Subcommittee, the TIP is now collecting as many of these lists and their "sponsoring" agencies as possible. A "master list" containing some 2,800 compound names was reduced through a duplicate elimination process to a list of 1,200 unique compounds. TIP has developed a computer program producing table that show the name of the compounds, the Chemical Abstracts Service Registry Numbers, and codes for the agencies having expressed interest in any given compound.

*Question 11.* Would you indicate the current status of health effects arising from PCB's?

Answer. At this point I would like to submit a document prepared by the National Institute for Occupational Safety and Health. This paper provides a most useful overview of current knowledge concerning industrial uses and toxicity of the PCB's.

Beyond what has occurred in the past with regard to this compound, we are extremely concerned that although Monsanto voluntarily restricted sales of PCB's in 1971, the PCB concentrations have greatly increased in the Hudson River, the Great Lakes and other areas.

This increase in environmental occurrences coupled with new information regarding carcinogenicity in rodents and reproductive toxicity in primates is disturbing.

#### STATEMENT OF DR. MARTHA SAGER, CHAIRMAN, EFFLUENT STANDARDS AND WATER QUALITY INFORMATION ADVISORY COMMITTEE

The Effluent Standards and Water Quality Information Advisory Committee (ES&WQIAC), a statutory committee mandated under Section 515 of PL 92-500 has advisory functions for Sections 304(b), 306 and 307 (Toxic Substances) of that Act. ES&WQIAC has, therefore, followed the development of toxic industrial point source limitations by EPA under Sec. 307 pursuant to its mandated responsibilities.

The difficulties experienced by the Environmental Protection Agency in fulfilling its mandated authorities under Sec. 307 of PL 92-500 have caused concerns both to the Agency and this Committee. When still another toxic control bill was proposed which would also fall within the authority of the Agency, members of ES&WQIAC undertook an extensive analysis of the scientific and technical sections of both current and proposed toxics legislation and regulations in relation to EPA's burden of responsibilities for carrying out these statutory mandates.

As a result of this effort and additional information acquired, I will address three questions today:

- (1) What coverage is provided by current Toxic Substances Legislation and Regulations?
- (2) Is additional Toxic Substances Control Legislation needed?

(3) If needed how can the implementation of this new legislation be structured to adequately reflect the intent of Congress?

*Question.* What coverage is provided by current toxic substances legislation and regulations?

*Answer.* Our study of legislation and regulations covered the following:

Current:

- PL 92-500—Federal Water Pollution Control Act—Sec. 307
- PL 92-532—Ocean Dumping Act
- PL 93-523—Safe Drinking Water Act
- PL 92-516—Federal Environmental Pesticide Control Act
- PL 91-596—Occupational Safety and Health Act
- PL 75-717—Federal Food, Drug and Cosmetic Act
- PL 86-613—Federal Hazardous Substance Act

Proposed:

- H.R. 7664—McCollister
- H.R. 7458—Brodhead—versions of the new and proposed Toxic Substance Control Act
- H.R. 7229—Eckhardt
- S. 776 —Tunney

Details of the results of the ES&WQIAC study are contained in the Appendix. The results can be summarized as follows. Analysis of current legislation on toxic substance control reveals that the chemicals are NOW regulated:

- (1) In the market place by Acts through labeling which is permitted only after extensive testing;
- (2) In the work place by Occupational, Health and Safety Act through required handling parameters which are developed after intensive examination of the testing required in FIFRA, etc. (List);
- (3) In the intimate environment (on the person) by the Food, Drug and Cosmetic Act through permits which are provided only after extensive testing has proven them safe for human use;
- (4) At the source of industrial production and use in the effluent discharges of industrial point-sources by PL 92-500, section 307;
- (5) In the drinking water which serves the Nation by the Safe Drinking Water Act which specifies permissible amounts denied after extensive testing has proven the materials in specific amounts safe for human consumption;
- (6) In the ocean wastes by the Ocean Dumping Act through permits which are issued after extensive testing has determined amounts of toxic materials which can be removed by the ocean without harm to either the biotic or a-biotic systems;
- (7) In the air by the Clean Air Act through standards which limit the amounts of toxic and noxious materials in the troposphere after extensive testing demonstrated tolerable limits of such toxic materials by amounts, vegetation and man in the ocean environment.

*Question.* Is new toxic substances control legislation needed?

*Answer.* Based on the previous analysis and additional information on the results of current toxics legislation the following can be concluded:

Protection of the physical/chemical factors of the environment is absent from the current toxic substance control acts. Accordingly, there exists a need for the inclusion of such protection of the a-biotic systems (air, water and land) from toxic and hazardous materials abuse to insure the continuance of these life-support systems.

The proposed Toxic Substance Control Bills do include this specific protection of a-biotic systems in the phrase "water, air, land, all living things and the inter-relationship which exists among these", and, therefore, fill a previous void in toxic legislation. However, the bills do not require a suggested mechanism which should be comparable to an environmental impact statement which would necessitate consideration of conditions of economics and other factors.

The proposed bill does suggest use of multi-interest groups or persons during the evaluation procedure, filling a void which presently exists but stops short of providing some authority for these groups to which EPA would have to be responsive.

The proposed bill contains a formal statement with reference to not impeding technological development; but mechanisms for implementation are not suggested. This statement, therefore, provides more lip service than substance to the concept.

More guidance is needed on the following: research chemicals and their uses; management of exceptions, exemptions, or variances; specific methodologies and

protocols for selecting materials for the list; methodologies to be used for economic evaluative procedures; methods to be used for assessing environmental effects of prohibitions and/or exceptions to the ordinances.

While such details are normally developed in ensuing regulations, the potential impact of this bill is such that further clarification must be made explicit in the legislation. Specifically, generalizations are made with reference to extensive toxicological testing. These should be expanded to suggest accepted current protocols. Carcinogenic tests are now required, by the proposed bill yet medical science has not yet fathomed the actual natural causes for cancer; it is well known that almost anything can become a carcinogen dependent upon its use. By what standard, then should new chemicals thought to be hazardous be evaluated? This same principle can be applied to the terms teratogenic, mutagenic, behavioral aberration, biological transformation, biological accumulation. None of the bio-responses can be predicted on a statistical scale.

At the same time, the proposed bill would exempt tobacco from being classified as a toxic material although tobacco—out of all of the thousands of organic substances suspected of being carcinogenic—has been proven to be carcinogenic to human beings both those who smoke and those who are exposed. (Is this a logical scientific approach?)

The character of the kinds of controls to be imposed on research and laboratory use chemicals is not clearly defined but is covered instead by the blanket statement that the bill is not intended to impede technological innovation.

Recently, the American Chemical Society published a detailed document titled "Chemistry and the Environment". Both pros and cons of our societal dependence on these materials was elaborately documented. (It is well recognized that toxic substances have beneficial and vital uses irrespective of their hazard.)

The hazards of restricting creativity in any area also need not be documented.

Restricting production of new chemicals at the very period in history when resource scarcities are becoming obvious and when resource recovery is the slogan of the political economist and environmentalist alike would appear to be in disharmony with the National concert. For example: new technological conversion of resources such as gasification or liquefaction of coal; conversion of raw sewage to methane; utilization of land based waste water treatment systems; production of vast quantities of radioactive materials (classed now as wastes which might later be resources) may reveal some toxic materials during production which should not be prohibited from production or from commercial utilization in this time of acute National energy sensitivity.

*Question. How can the new bill be implemented?*

Answer. The new proposed Toxic Substance Act imposes great responsibility and authority on the Administrator of EPA in regulation development, exemptions, exceptions and variances—which will have a tremendous impact on the Nation.

The strengthening of the proposed bill to handle specific directions for testing mechanisms can be easily remedied.

The clarification of the kinds of regulations to be imposed on research and laboratory chemicals can also be quickly corrected.

A number of administrative procedures could be mandated in the Act: short of total reorganization of EPA, a Peer Review Board, external to EPA, could materially assist the Agency and immeasurably improve confidence of the non-Federal sector. (See example in Appendix.) Such a Board would be involved in every phase of the regulations and standards development process, and in decision making with responsibilities for exemptions and exceptions.

The comprehensive coverage of the proposed legislation and the potential impact of the legislation in the Nation necessitate extremely careful attention to clarification of key technical and administrative issues.

It should be apparent that the Congress, in proposing this additional control on chemical materials in a fundamentally industrial and technological society, must be certain that such additional legislation is indeed a necessity: that it will not preclude further advances for mankind through strict manipulation of the chemical environment; and, finally, that the planned implementation of such a serious regulatory effort will indeed be structured to reflect the intent of the Congress, rather than result only in the creation of a super Federal agency empowered through regulatory mandates to control the entire gross National material product of this country.

## APPENDIX

### HANDLER CALLS FOR PANEL APPROACH FOR PEER REVIEW

Dr. Philip Handler, president of the National Academy of Sciences, has proposed that the National Science Foundation shift from its present use of individual reviewers to the systematic use of convened panels to evaluate research proposals. Indeed, such a shift, in Handler's view, is the "most important single step" NSF can take to improve its evaluative procedures for research proposals and to meet criticisms of the present arrangement.

Convened panels offer a number of unique advantages over *ex parte* criticisms by individual reviewers, Handler says in testimony submitted at press time to the House Subcommittee on Science, Research & Development, which held hearings on peer review this summer. For example, Handler says, the convened panel arrangement avoids the possibility of personal arbitrariness on the part of program managers. And it minimizes the possibility of undue influence or bias by individual reviewers in giving preference to particular institutions or schools of scientific thought. Further, from panel discussions, a coherent strategic approach to research in a particular area can emerge. This approach, in effect, becomes agency policy.

The best means for securing competent judgments and freedom from irrelevant considerations, in Handler's view, is to select the advisers from a national pool of scientists in a discipline, avoiding undue regional and institutional concentration. Further, membership on the panels should be on a relatively short-term basis.

Commenting on other areas of the peer review controversy—particularly those aired at the House hearings (C&EN, July 28, page 6)—Handler observes that, among other things, "on the whole, the NSF program staff has been quite competent, witness . . . the NSF reputation for supporting research of the highest quality." He "completely agrees" with a National Science Board decision requiring NSF to provide principal investigators with verbatim copies of reviews. And he hopes that NSB will maintain that policy "in the interest of encouraging candid reviews and participation by the most qualified reviewers. Departure from this policy could seriously undermine the usefulness of this type of peer review." On the other hand, if NSF switched to convened panels, confidentiality of reviewers wouldn't be an issue.

Finally, Handler says that institutionalization of the panel review in place of the individual review process at NSF does not require legislative action. (Indeed, there is virtually no evidence that Congress does intend to change peer review legislatively.) It can be changed by administrative action.

### DETAILED DISCUSSION OF THE ANALYSIS OF THE TOXIC SUBSTANCES LEGISLATION AND REGULATIONS

Analysis of the legislation and regulations in ES&WQIAC's study, illustrated in Figure I, indicated the following:

1. The toxic legislation is divided toward two major areas:
  1. The effects of toxic materials on man, the consumer, the worker.
  2. The effects of toxic materials on the natural environment.

Those Acts concerned either exclusively or predominately with man are:

- (a) Safe Drinking Water Act (PL 93-523)
- (b) Occupational Safety and Health Act (PL 91-596)
- (c) Federal Food, Drug and Cosmetic Act (PL 75-717)
- (d) Federal Hazardous Substance Act (PL 86-613)

Concern for the effects of toxic materials on the natural environment are found in:

- (a) Water Pollution Control Act (PL 92-500)
- (b) Marine Protection Research and Sanctuaries Act (PL 92-532) (Ocean Dumping Act)
- (c) Federal Environmental Pesticides Control Act (PL 92-516)
- (d) Toxic Substances Control Bills

2. Definitions: Only the Federal Hazardous Substance Act defines hazardous toxic and highly toxic substances.

The Water Pollution Control Act (PL 92-500) and the Federal Hazardous Substance Act have the only definitions of "toxic pollutant" among the eight Acts.

PL 92-500's definition is compatible with the Guidelines for Registering Pesticides in the United States (containing extensive test protocols) under the Federal Environmental Pesticides Control Act (FIFRA).

3. Selection criteria: Of the four Acts with natural resource protection provisions from toxic/hazardous substances, only FIFRA (PL 92-576 Pesticide Act) has promulgated Regulations and Guidelines which provide criteria for selecting those chemicals which are potentially hazardous to the aquatic environment.

4. Test Protocols: Of the four Acts seeking to control toxic and hazardous materials in the natural environment only under FIFRA have test protocols been promulgated for developing data used in evaluating hazards in the use of a chemical/pesticide.

5. Standards: The analyses of existing standards revealed that of the three existing laws concerned with the protection of aquatic organisms, only the Ocean Dumping Act has as yet promulgated standards. These standards are in the form of trace contaminant concentrations of mg/kg (both solid and liquid) for Mercury, Cadmium and Organohalogenes.

Toxicity levels (standard in mg/l) under acute and chronic conditions were initially proposed for ten toxic and hazardous substances under PL 92-500 in EPA's Advance Notice of Proposed Rule-Making for Toxic Pollutant Effluent Standards, December 1974. However, these standards were deemed unsubstantiated in a hearing and new standards have not as yet been proposed. Proposed interim standards were promulgated in March 1975 setting maximum contaminant levels in mg/l for inorganic and organic chemicals, and pesticides under the Safe Drinking Water Act. The same toxic pollutants in water which affect man, as he drinks the water, may have an entirely different affect on aquatic organisms. Thus it is difficult to compare standards in the Safe Drinking Water Act and standards developed for the protection of aquatic organisms as in PL 92-500. (Assuming that PL 92-500 is primarily concerned with aquatic organisms.)

Cadmium, Toxaphene and a few Organic Compounds have standards in both PL 92-500 (307) (proposed) and Ocean Dumping (existing). Again, it is difficult to compare standards because proposed standards for Section 307 are for freshwater organisms and existing standards for Ocean Dumping apply to marine organisms only.

6. Agency Authority: In all four Acts dealing with the control of toxic/hazardous materials in the natural environment, EPA has the overall, overview authority, with the power to set criteria standards in cooperation with the States and other applicable Federal agencies. For example, the administering of the Ocean Dumping Law involves: EPA, Army Corps of Engineers (issuance of permits for disposing of dredged material) NOAA (research and monitoring) and the Coast Guard (surveillance and compliance monitoring) and may involve others such as HEW if research and studies of toxic affects are involved.

Federal agencies which have responsibilities in the control of toxic/hazardous substances are:

Agency and Role:

EPA—Administration, Regulation, Enforcement and Research

Labor—Administration, Regulation and Enforcement

Health, Education and Welfare—Administration, Regulation, Enforcement and Research

Consumer Product Safety Commission—Administration, Regulation and Enforcement

Agriculture—Research, Information

National Oceanic and Atmospheric Admin.—Surveillance and Monitoring

Geological Survey—Surveillance and Monitoring

Coast Guard—Surveillance and Monitoring

7. Prohibition Mechanisms: The authority to prohibit toxic pollutant discharges is provided in all four Acts seeking to protect the natural environment although only FIFRA has exercised this authority successfully.

Under FIFRA, Aldrin, Dieldrin and DDT have gone through cancellation proceedings and manufacture has been suspended, with a very few exceptions. Imminent hazard has been declared by EPA again under FIFRA for Chlorine Heptachlor and suspension and cancellation hearings are proceeding.

## STATEMENT OF THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION, INC.

This statement is submitted on behalf of The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), a national trade association of the cosmetic industry, representing 186 manufacturers of cosmetic products as well as 200 manufacturers and distributors of cosmetic product ingredients and supplies. Member companies of CTFA manufacture approximately 90% of the cosmetic products distributed in the United States. Approximately 6 billion units of cosmetic products are sold in this country, accounting for an annual retail sales volume of approximately \$6 billion.

S. 776 does not presently provide an exemption for cosmetic products, but does exempt food and drugs.

The CTFA urges that the Senate not place cosmetics within the scope of this proposed legislation. Cosmetics are and have been for nearly 40 years regulated by the Food and Drug Administration (FDA) under the authority of the Federal Food, Drug and Cosmetic Act. There is no legislative or administrative gain from the standpoint of efficiency or regulatory authority to transfer jurisdiction over cosmetics to a new agency (Environmental Protection Agency) or to divide that jurisdiction between agencies.

Moreover, the Health Subcommittee of the Labor and Public Welfare Committee is presently considering additional cosmetic legislation. In the 93rd Congress, Senator Eagleton introduced S. 863, a cosmetic safety bill, and in 1974 held extensive hearings on that bill. Earlier this year, Senator Eagleton introduced a revised cosmetic bill (S. 1681), cosponsored by Senators Leahy, Gravel and McGovern. In June, 1975, hearings were held before the Health Subcommittee. This legislation would maintain authority over cosmetics with the FDA.

Accordingly, CTFA urges that cosmetics be exempted from S. 776. We propose that section 9(a)(2) [page 26, lines 9 through 18] be revised to include an additional exclusion for cosmetics and to read as follows: *cosmetics (as such term is defined in section 201(i) of the Federal Food, Drug and Cosmetic Act)*, drugs (as such term is defined in section 201(g) of the Federal Food, Drug and Cosmetic Act) and food as defined in section 201(f) of the Federal Food, Drug and Cosmetic Act, including poultry and poultry products (as defined in section 4 (e) and (f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act) and egg and egg products (as defined in section 4 of the Egg Products Inspection Act).

## STATEMENT OF ERIK JANSSON FOR FRIENDS OF THE EARTH, INC.

I am Erik Jansson, a research associate for Friends of the Earth, which is an environmental lobby of 29,000 members in the United States with sister groups in 14 foreign countries. Our Washington, D.C. office is located at 620 C Street, S.E.

## SUMMARY OF PRESENTATION

1. The need for the pre-screening of chemicals before they are marketed is nowhere better illustrated than by the rapid increase in concentrations of polychlorinated hydrocarbons such as PCB's and PCT's in the environment and in human tissues, blood and mother's milk.

2. Friends of the Earth strongly supports a screening program as has been proposed in Toxic Substances Control Acts drafted by a number of Congressmen.

## The Case of PCB's (Polychlorinated Biphenyls)

3. PCB's, polychlorinated biphenyls, are presently used in the United States for electrical transformers and capacitors after having been banned in 1972 for all other uses such as food container cardboards and boat paints because of evidence of widespread environmental contamination.

4. Japan has banned PCB's for all uses after a very large number of persons were exposed to toxic levels of the chemical due to an industrial spill which contaminated rice oil. If Japan, one of the primary producers of electronic equipment and appliances, can prosper without the use of PCB's, one wonders how American users can claim that it is not possible to discontinue the use of PCB's.

5. A continuing series of industrial spills, chemical plant emissions, and evidence that PCB's can be released into the home and work environment through

the burnout of transformers has led many to suggest that a rapid phaseout of PCB's would be in the best interest of the public.

6. Numerous studies find PCB levels in human blood, tissues, and mother's milk to have reached concentrations equal and often in excess of those characterizing DDT prior to its removal from the marketplace. Like DDT, it is believed that PCB' may pose a cancer risk. In addition, very serious embryo abnormalities in offspring, abortions, changes in child growth rates, and metabolic disturbances have been found to be caused by relatively low exposures to PCB's, indeed by exposures quite close to levels found routinely in fish from numerous American water bodies.

7. A study of urban and rural dwellers in the United States finds PCB levels in the blood of Americans to equal a significant percent of that of the Yusho victims in Japan. Yusho disease, named after these victims, is a very serious skin disease caused by PCB exposure, and is generally associated with changes in the liver function. The rice oil contamination in Japan in 1968 was paralleled by a similar event in 1971 in the United States when PCB's leaking from cooling equipment contaminated feed for chickens. The Food and Drug Administration was unable to locate 60,000 eggs which were sold in Washington, D.C. A follow-up of ill effects was apparently not possible.

8. Gross contamination of fish in the Hudson River, in Pensacola Bay, in Lake Ontario, Lake Michigan, Milwaukee and Ohio River is a matter of great concern because levels found in fish from these rivers exceed concentrations that have caused serious genetic breaks and miscarriages in laboratory monkeys. Contamination of birds, fish and other animals in the remotest part of the earth, such as the arctic, makes PCB distribution similar to that of DDT.

#### CONCLUSION

9. It would have been easy to screen PCB's prior to market introduction. Animal tests would have revealed the substantial genetic and birth problems associated with the chemicals. Friends of the Earth believes strongly that a pre-screening program as proposed in the Toxic Substances Control Act is a matter of common sense and wisdom.

10. The very substantial problems with the PCB's and gross environmental contamination and high levels in human blood, tissues, and mother's milk would recommend a quick phasing out of the chemicals. If Japan, which is a primary producer of electrical products, can ban the use of PCB, this can also be accomplished in the United States.

11. Industry arguments that varying compounds of PCB's have differing stabilities and toxicities present only a half-truth, as will be noted in the following presentaion. The differences among PCB mixtures are not substantial enough to warrant continued use. PCB is not indispensable.

#### PRESENTATION

Gentlemen of the Senate Commerce Committee: The wisdom of legislation requiring pre-screening of new chemical substances before they are marketed, as the Toxic Substances Control Act proposes, is nowhere better demonstrated than by the history of PCB's use as an industrial and consumer chemical and concentration in the environment and in the human.

PCB's are presently banned in Japan, where massive poisonings have occurred, and banned in the United States for any use not self-enclosed. While once used in a wide variety of consumer uses such as paint for boats, carbonless duplicating paper, lubricants, cardboard used in food containers and elsewhere, present uses are primarily electrical transformers and capacitors where the fire resistance of the PCB's and their electrical insulating properties are cited as important values.

But these chemical mixtures are not indispensable. If Japan, a major force in world electronics, can operate without PCB's then any nation can do likewise.

Large scale leakages from transformers, chemical plants, urban dumps, burning transformers and other sources has led to gross contamination of some American waterways, a number of serious poisoning incidents, and very high levels in human blood, tissues, and mother's milk in the United States and elsewhere.

#### PLASMA LEVELS IN UNITED STATES OFTEN EXCEED JAPANESE YUSHO PATIENTS

In 1968, more than 1,000 people in Japan suffered an epidemic of a disfiguring skin disease called Yusho Disease, that was traced to rice oil heavily contaminated with PCB's. The victims also suffered disturbances in liver function

and abdominal pain. As a result of this incident and high levels of PCB found in Japanese residents, Japan banned all PCB use.

Finlea in 1972 reported measurements he had completed of PCB levels in 616 Americans, apparently healthy, from widely differing backgrounds. It was found, as in Table 1, that PCB levels in the blood plasma of Americans can exceed the levels of Yusho patients in Japan by 5 times. (Apparently, the Japanese measurements were made some time after acute exposure, but the comparison of levels is disconcerting particularly in view of animal experiments showing childbirth and embryo problems at levels measured in the United States.)

TABLE 1.—COMPARISON OF FINLEA'S 1972 MEASUREMENTS OF PCB LEVELS IN AMERICAN BLOOD PLASMA WITH BLOOD LEVELS IN JAPANESE YUSHO PATIENTS AND TOKYO RESIDENTS. (ALSO COMPARISON WITH DDT, DDE AND PCT LEVELS)

	Blood levels in parts per billion			
	PCB	pp DDT	pp DDE	PCT
<b>Japanese levels:</b>				
37 Yusho patients (see Poguchi)-----	6.0	NA	NA	NA
27 blood samples in Tokyo, 1974 (no occupational exposures):				
Mean-----	3.2	NA	11.2	5.0
Maximum-----	5.8	NA	19.6	19.6
<b>Blood plasma levels in parts per billion</b>				
<b>American levels (see Finlea):</b>				
107 to 139 rural blacks:				
Mean-----	.3	8.8	10.5	NA
Maximum-----	20.6	28.2	43.5	NA
151 to 175 urban blacks:				
Mean-----	1.9	5.4	6.2	NA
Maximum-----	29.0	62.7	18.5	NA
166 to 199 urban whites:				
Mean-----	2.3	1.7	2.6	NA
Maximum-----	22.0	6.6	7.4	NA
192 to 210 rural whites:				
Mean-----	3.1	1.5	3.4	NA
Maximum-----	16.6	6.0	9.7	NA

The levels found in some American blood plasma are believed by some to be sufficient to cause poisoning. For example, Hesselberg studied the blood levels of PCB in wasting patients (mostly with cancers) in Missouri. As fat is released by the body, the high levels of DDT and PCB are released into the blood. A 47 parts per billion level was found for 9 such patients, with a range of 10 to 100 ppb. It was suggested that such levels may have poisoned the patients.

#### PCB LEVELS IN MOTHER'S MILK AND GENETIC AND CHILDBIRTH PROBLEMS

Wisconsin's Primate Research Center found that rhesus monkeys, after only a few months of diets containing as little as 2.5 parts per million of PCB's suffered loss of hair, general metabolic disturbance and severe stomachache.

These PCB levels are typical of fish caught in a number of waterways including Lake Ontario, the Hudson River, and Pensacola Bay and river serving it. Recent samples of fish from Lake Michigan averaged 5.6 ppm in bloater chubbs, 22.9 ppm in large lake trout and 10.5 ppm in coho salmon. PCB levels in the edible portions of the fish exceeded 5 ppm, the present F.D.A. limit for food. Fish in the Escambia River near Pensacola were found to contain 4 ppm of PCB with a range of .29 to 20 ppm.

At Wisconsin, low levels of PCB's in monkeys caused abortions and sickly offspring. Similar embryo abnormalities were found in chickens hatching in eggs with high PCB levels.

A series of studies of mother's milk in a number of countries found high levels of PCB, which can be passed on to nursing children with effects on child growth during the early period of life.

#### (1) Milk levels of PCB found to equal or exceed DDT levels before it was banned

The impact of PCB's and DDT upon nursing young has been a matter of concern among scientists. A Swedish study, for example, simulated PCB and DDT levels in milk found in wild mice in Sweden to determine the impact upon the young.

It was found that nursing young mice exposed to PCB and DDT levels in their mothers' milk similar to those present in Sweden grew much faster than control mice on a milk diet free of these contaminants. The young mice were weaned at the age of 21 days. In the following days, the control mice started to grow faster, and at the age of 33 days no difference in weight could be demonstrated.

Interference with natural growth patterns in the very young may have dangerous effects, a possibility for human children in view of the high levels of PCB and DDT that have been measured in mother's milk.

Table 2 presents some of the findings of Swedish, Japanese, and American scientists, with the dramatic finding that PCB levels now equal or exceed DDT levels ten years ago, before that pesticide was banned.

TABLE 2.—SOME MEASURED LEVELS OF PCB'S AND DDT AND DERIVATIVE DDE IN MOTHER'S MILK

	Whole milk—human parts per million		
	PCB	ppDDT	ppDDE
Japan:			
Fukucka prefecture, 1972.....	0.03	NA	NA
Ishigahi prefecture, 1972.....	.03	NA	NA
United States:			
Fort Collins, Colo., 1972 (instrument incapable of detecting less than .04 ppm).....	( <sup>1</sup> ) NA	( <sup>1</sup> ) 0.67	( <sup>1</sup> ) 0.09
1960 to 1961.....	NA	.03	.029
Published 1969.....	NA	.023	.084
Published 1971.....			
Canada:			
Nova Scotia.....	.022	.013	.035
Province of New Brunswick.....	.018	.006	.019
Sweden:			
1967.....	NA	.04	.065
1968 to 1969.....	NA	.03	.052
1971 to 1972.....	>.04	.02	.059

<sup>1</sup> 6 samples found with 0.04 to 0.1 ppm out of 39 samples.

Levels of PCB are quite similar to those of DDT 5 to 10 years ago, as can be seen. DDT levels have shown a 50 percent reduction in Sweden, but DDE levels have remained unchanged as DDT is metabolized in the body to DDE and as fish supply additional amounts.

It should be noted that some researchers have found PCB, DDT, DDE, and dieldrin to interact to magnify the toxicity involved. Maki found that DDT at .3 and .5 ppb increased the toxicity of Aroclor 1254 by 2 times, and 12 ppb of PCB increased the toxicity of DDT by an average of 20 percent to *Daphnia Magna* Strauss.

#### HIGH LEVELS FOUND IN WILDLIFE IN REMOTE AREAS

PCB's resemble DDT in their high stability in the soil and body fat, long half-lives and capacity of biomagnification by aquatic animals and birds in particular.

Table 3 summarizes some of the findings about PCB and DDT levels in wildlife around the world.

TABLE 3.—Measured PCB, DDE Levels in Wildlife in Remote Areas

Melquist et al, 1975:

Idaho Osprey Eggs: DDE levels found to average 8.53 ppm with significant failure of eggs at 7.1 ppm; and PCB levels were 1.2 ppm.

Braestrup et al, 1974:

Birds sampled in Greenland: DDE levels found to average (fat) .8 ppm in Common Eider (a low); 10.3 in Cormorant; and, 13.9 in Raven (a high). PCB levels were found to average (fat) 2.0 ppm in Common Eider; 26.3 in Cormorant; and 37.1 in Raven.

Clausen et al, 1974:

Arctic Mammals in west Greenland: Porpoise, 6.7 ppm PCB in fat; Polar Bear, 1.3 ppm DDE in fat; Common Porpoise, .32 ppm DDE in fat, Bearded Seal, 47 ppm DDE in fat; and .053 ppm lindane in fat.

Thompson et al, 1974:

Turtle Eggs in Ascension Island, South Atlantic Ocean (Aroclor 1241 found and DDE).

Gingston, 1974:

Reykjavik, Iceland, DDT and PCB found in specimens in N.E. Iceland.

## CONCLUSION

Had the PCB's received a rigorous laboratory testing before commercial introduction, many of their harmful characteristics would have been discovered.

It would have been found that potential abortions and sickly offspring can arise in animals due to relatively low food exposures, that liver problems and liver cancer are a possible result of exposure.

It would have been discovered that many of the PCB mixtures are contaminated with other compounds, also carcinogenic. The persistence of the chemical might have been discovered, as well as the problem of biological magnification due to the affinity of PCB's for fat.

It would have been known that it would not be wise to consider PCB for cardboards used in food packaging.

Evidence today indicates that it would be a matter of wisdom that PCB's are expeditiously removed from the marketplace, particularly considering the great spread of the PCB mixtures across the globe and concentration into dangerous levels in the environment and in human tissue, milk and blood.

*(1) New PCB Compounds Are Not Sufficiently Different to Warrant Marketing*

It has been maintained that the biodegradability of varying PCB mixtures may permit continued use in transformers and other closed system uses. Unfortunately, the stability of even the most biodegradable PCB mixtures is not sufficiently different to warrant this conclusion.

Other problems also present themselves. Contamination of PCB mixtures seems almost unavoidable. Webb and McCall (1971) for example, identified 16, 32, 42, and 26 chlorinated components in Aroclor 1232, 1242, 1248 and 1254. Two PCB compounds have been found to contain dibenzofurans, which are embryotoxic. Cecil suggests that some of these contaminants may be one reason that PCB residues in chicken eggs caused  $\frac{1}{3}$  to  $\frac{1}{2}$  of embryos to die from abnormalities in some experiments.

Furthermore, the affinity of PCB mixtures for animal fat presents problems, for persistence and stability increases in fat as opposed to the general environment. Biomagnification is generally a result of stable chemicals that is attracted to fat.

*(2) Enclosed and Self-Contained Uses Contribute Gross Contamination of Riverways and Environment*

The partial ban of PCB's to only self-contained uses as transformers was wise in view of scientific findings that PCB's were entering the food chain through food packaging and the environment through all other uses such as paint and carbonless paper. Stanovick et al (1973), for example, found that treated paperboard containing PCB's resulted in migration through various liner papers into the food. In ready to eat cereals, PCB levels were measured at less than .1 to 4.3 ppm. Cereal grains were also contaminated up to 1.8 ppm of PCB.

Japan has banned all uses of PCB's, which seems wise in view of what is known. If Japan, a primary leader in electrical equipment, can operate without PCB's, then the substance is not essential.

The potential for contamination even by enclosed system use was illustrated by Carnes' 1973 study of PCB in solid waste, finding contamination in widely separate city incinerators and compost piles.

Even the home and office is open to contamination by closed use PCB's. Staff (1974) showed how heating of fluorescent ballasts due to burnout on fire releases significant levels of PCB in the room involved. At nose height, a high of .166 mg/M3 of PCB was found 1 meter from a burnt out ballast with a persistence after 3 days of .004 mg/m3.

Transformer spills have led to crisis situations. In October of 1974, one hundred gallons of PCB's were spilled accidentally from a transformer dropped on a pier. The spilled PCB's fluid entered the Duwamish River. It was noted that one hundred gallons of PCB's would pollute 10 trillion gallons of water, since marine life is able to concentrate PCB from water with concentrations as low as 3 parts per billion.

Industrial spills have had a dramatic impact upon the Pensacola Sound, where marine concentrations of spilled PCB's are astonishingly high. Large segments of American waterways have been found to contain fish, sediment, and marine life with high levels of PCB's. The public is advised to not eat the fish from the Hudson River, Lake Ontario, Lake Michigan, the Milwaukee and Ohio Rivers, where gross contamination with PCB's has been measured.

How far do we have to go towards closing all of America's waterways before PCB's are finally removed from the marketplace? A pre-screening program would have prevented the problem from its inception.

Friends of the Earth strongly supports the Toxic Substances Control Act procedure as common sense, as well as supporting a most rapid and urgent reduction and removal of PCB's from the marketplace in the nation, to follow the wise course of Japan which has proven as a major power in electrical equipment that PCB's are not essential to national prosperity and that a nation can do without them without a loss of prosperity.

When food concentrations and human blood plasma levels of PCB's rise to the point where laboratory animals are showing embryo abnormalities, miscarriages, sickly offspring, and liver upsets and cancer, an imminent health hazard can be said to exist. In the United States, food concentrations and body content have indeed reached such levels for PCB's.

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KAISER ALUMINUM & CHEMICAL CORP.,  
Washington, D.C., October 22, 1975.

HON. WARREN G. MAGNUSON,  
Chairman, Senate Committee on Commerce,  
Washington, D.C.

DEAR SENATOR MAGNUSON: We are taking this opportunity to submit the following comments on S. 776, the "Toxic Substances Control Act" of 1975, which we understand will be the subject of hearings before your committee on October 24. It would be appreciated if you would have this made part of the Record for these hearings.

Kaiser Aluminum & Chemical Corporation opposes passage of S. 776 in its present form because it would, in many instances, duplicate existing Federal regulation of production and usage of chemical substances, and because it would slow down and discourage further development and production of a variety of specialty chemicals upon which the U.S. industrial machine depends.

Kaiser Chemicals, a division of the corporation, manufacturers and sells commodity chemicals for the aluminum process, and specialty chemicals for numerous industrial applications. Kaiser Chemicals will not be affected in any major way by S. 776. However, the bill does affect many small specialty chemical suppliers to our operations, such as suppliers metal lubricants, defoamers, water treatment chemicals, coatings, corrosion inhibitors, etc. The blanket requirement to premarket screen all their products—which often are produced in small volume but which are quite diverse in chemical nature—will be expensive to them and eventually will discourage them from further product development and improvement.

The language in S. 776 is too broad and inclusive and thereby will lead to administrative nightmares if enacted. Four examples will illustrate this point:

1. New revisions to the bill try to define "unreasonable risk to health or the environment," when only a case-by-case examination can determine the effects of a certain chemical substance. Each chemical substance is distinct and its effect on health and environment only can be determined by reports and case histories evaluated by the EPA Administrator.

2. The definition of chemicals which will require a premarket screening has not been narrowed down to high risk chemicals. The existing all-inclusive definition will lead to needless and expensive paperwork, extensive EPA involvement at taxpayers' expense, long delays in getting new products to the market and—worst of all—disincentives to produce useful chemical products.

3. Testing and clearance of new minor variations of existing chemicals will be required, further adding unnecessary expense and administrative burdens.

4. The bill has been drafted without consideration of its language overlapping existing Federal law governing chemical substances. Nor has any qualification been written in the bill to coordinate its application to industry with the application of OSHA and environmental control laws.

The projected economic impact of S. 776 to the chemical industry is staggering as the Manufacturing Chemists Association reported earlier this year to Congress. This group commissioned an independent economic impact report which concluded that S. 776 could cost the U.S. chemical industry more than \$1.3 billion annually. The costs come from required premarket screening of new products and new applications of existing products; the delays in introducing

products in the marketplace; controls and record-keeping requirements stemming from the law; and the potential increased research and development costs coming from cutbacks in new product innovation.

The report also concluded that legislation such as S. 776 will lead to a \$12 billion or .5 percent inflationary impact on the economy by 1985—during the next decade when the nation will have to keep inflation in control. The consumer will suffer as a result of such impact while his variety of constructive chemical products could decline.

A final economic reason for our opposition to S. 776 is that this overly-restrictive legislation would give foreign-developed chemicals a competitive advantage and create a further substantial reduction in the U.S. balance of payments.

Kaiser Aluminum & Chemical Corporation supports public efforts to insure our health and environment be protected from harmful effects of toxic substances produced and used in industry. But, we believe this Toxic Substance Control Act is not the way to approach the question in the light of existing laws and the extensive precautions and screening being conducted by the vast majority of chemical manufacturing companies. There are ways to protect the public from toxic substances without resorting to S. 776 which would cripple the nation's chemical industry, would further enhance the regulatory confusion and expense which emanates from our nation's Capitol, and would render questionable benefits to the general public since it does little to pinpoint the true problem areas.

Very truly yours,

ROBERT L. MAIER.

[The following information was referred to on p. 4:]

CBS REPORTS<sup>1</sup>—"THE AMERICAN WAY OF CANCER"

(BROADCAST OVER THE CBS TELEVISION NETWORK, WEDNESDAY, OCTOBER 15, 1975, 10 P.M., TO 11 P.M., EDT., WITH CBS NEWS CORRESPONDENT DAN RATHER)

ANNOUNCER. CBS Reports—with Correspondent Dan Rather.

DAN RATHER. The news tonight is that the United States is number one in cancer. The National Cancer Institute estimates that if you're living in America your chances of getting cancer are higher than anywhere else in the world. Evidence indicates a link between rising cancer rates and industrialization, and we have led the world in both. This year, two-thirds of a million Americans will get cancer; a third of a million Americans will die from cancer. In the past 25 years, the cancer mortality rate has increased over twenty percent.

Cancer doesn't only attack the old. It's the number-one disease killer of children under fifteen, and of women between the ages of 25 and 64. It is estimated that 85% of all cancer is caused by smoking, by chemicals in the air we breathe, the food we eat, the water we drink and substances we are exposed to at work. We have spent billions of dollars in this country looking for cancer cures, but evidence now indicates that the way to lick cancer may be to prevent it. This is what tonight's CBS REPORTS will discuss—"The American Way of Cancer."

ANNOUNCER: CBS REPORTS: "The American Way of Cancer"—with Correspondent Dan Rather.

[Announcements.]

DAN RATHER. Cincinnati, Ohio.

NICOLE CAPPEL. I'm ready to jump!

DAN RATHER. Nicole Cappel, 15 months old. Nicole doesn't have cancer, but like the rest of us, she's already been exposed to cancer-causing agents in the air she breathes, in the water she drinks, in the food she eats. By the time Nicole is two-and-a-half, she'll have been inoculated against measles, mumps and other diseases. But the only protection against cancer for Nicole or for any of us is to cut down unnecessary exposures to cancer-causing substances. We used the Cappel family as stand-ins for us all. We went along shopping with them while they bought the normal things that a family in their circumstances would buy for their table.

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Now, there's a Federal law—the Delaney Amendment—that prohibits the addition of any known cancer-causing substance to food. The FDA is charged with seeing that the law is obeyed. But there are loopholes to the enforcement of that law, and cancer-causing chemicals (called carcinogens) slip through those loopholes. We wanted to know whether the Cappels had bought any of those carcinogens along with their food—if so, how the chemicals got there, and in what amounts. So we took samples of their meat and dairy products, packed them in dry ice, and sent them to the University of California for scientific analysis.

What we were looking for were small amounts of some pesticides that have been banned as cancer-causing agents—DDT, aldrin and dieldrin. We've been told that they are regularly turning up in food, and that all of us are storing these chemicals in our fatty tissues. The question is whether the natural defenses of the body can take care of small amounts of these carcinogens. This is a basic scientific issue. Richard Ronk, the Food and Drug Administration's expert on additives, says that man may have a built-in defense against certain amounts of lethal chemicals.

RICHARD RONK. I find that most people, when they are candid with you, feel that man is—is—has evolved in a way that he is able to handle small doses of just about anything, that this liver that sits in—in the middle of our body here is an— an amazing chemical plant and that it—it apparently is able to handle low-dosage exposures to many things. I think it's evolved to do that. The question becomes, as in the last 4,000 years, as we move materials around in our environment, whether this amazing chemical plant, our liver, can continue to handle these types of—insults. There is some—some indication that it does.

Mr. RATHER. Dr. Marvin Schneiderman of the National Cancer Institute says that, while only small amounts may slip through, cancer starts small.

Dr. MARVIN SCHNEIDERMAN. It's certainly possible that minute amounts can be dangerous. If we think of cancer as an illness that starts with one small change in one cell, and the cell is so modified that the normal control mechanisms—mechanisms of the body don't kill it, don't knock it off, don't—don't get it away from us, then that cell can multiply and multiply and multiply, and that can become a cancerous cell. The possibility that one change of this kind can cause cancer is certainly a real possibility.

Mr. RATHER. When the lab tests came back, we found that there were trace amounts of cancer-causing agents in the Cappels' hot dogs, hamburgers, milk, butter and cheese. Everything that came from livestock showed traces of DDT or dieldrin. Three years ago, after a suit brought by the Environmental Defense Fund, the Government outlawed DDT; but so much had been used it's still in the soil. Aldrin and dieldrin are chemically related to DDT. Again, the Environmental Defense Fund sued, and again these pesticides were banned as cancer-causing agents, although farmers were allowed to use up existing stock. There's another related pesticide, chlordane. Evidence indicates that it, too, causes cancer. The Government is now holding hearings to determine if it should also be banned.

These chemical bug killers are persistent pesticides. They travel from the soil into plants, into the animals who eat the plants, into the families who eat the animals and their products. The amounts we are talking about may seem small, but as Dr. Schneiderman said, cancer can start small.

Not all pesticides cause cancer, but DDT, aldrin and dieldrin were widely used before they were tested for cancer, and it's likely they will continue to turn up in food for the next decade or more. In spite of the evidence, there are those in agriculture and industry who don't believe these pesticides are dangerous. They're fighting the ban.

Because the Cappels didn't buy beef liver, we couldn't run a test for the most controversial chemical being used in animal husbandry—DES. There's a controversy over DES involving billions of dollars. DES is a synthetic hormone that comes in pellets, used to put weight on cattle cheaply and quickly and hold down the price of beef.

Robert Huelsebusch—DES manufacturer.

Mr. ROBERT HUELSEBUSCH. Well, it's used because it helps to produce beef more efficiently and economically. It saves something like 81 pounds of grain for every hundred pounds of beef put on a steer. And if you can save the grain produced from a million-and-a-half acres and use it, then you have to say that there's value in the feeding of DES. America is the greatest food producer in the world, and certainly the chemical industry has—has been a big part in this fine production of foods that are admired by other people in other lands.

Mr. RATHER. There's no doubt that DES saves millions of bushels of grain. These farmers who are selling beef for export must sign affidavits that say they have not used DES. Canada, Germany, France—32 countries in all—have banned the use of DES in feed. Many call it a cancer-causing agent. Our own Government's Food and Drug Administration tried to ban DES, but the ban was overturned on legal technicalities. What's the trouble with DES? Well, in the 1940's and fifties, it was given to women to prevent miscarriages. This year several of those women testified before a Senate subcommittee. Mrs. John Malloy took DES before the birth of two of her daughters.

Mrs. JOHN MALLOY. In December of 1956, I had a—Christmas Day—I had a baby girl. When she was 14, I was reading the morning paper and the morning paper had an article written by Dr. Herbst describing the dangers of DES and stating that several daughters of mothers who had taken DES had vaginal cancer. And of course I became alarmed, and I called my doctor immediately; and during the course of examination, Marilyn was found to have cancer of the vagina. Three weeks later she had vaginal surgery in New York City. She was four weeks in the hospital. The doctors told me they had gotten all of it, there was no problem, everything was taken care of, that the cancer had rarely ever spread beyond the female organs.

Mr. RATHER. Mrs. Malloy's daughter died at age 17. She is one of over 200 women who took DES whose daughters developed cancer. Some experts say taking large doses of DES as medicine is different from getting an occasional tiny amount in meat. They point out that DES has only been found in beef liver, that only one in fifty of those livers tested has been contaminated, and that the amount found is thousands of times less than that taken for medical purposes. Nevertheless, many scientists insist even small amounts of DES are potentially dangerous.

We know the Cappels have eaten small quantities of pesticides. It's possible they have also absorbed DES. And that hot dog Nichole's eating contains sodium nitrite, which is used to preserve meat. Sodium nitrite can also turn into a cancer-causing agent.

Dr. JACQUELINE VERRETT, FDA scientist. Well, sodium nitrite reacts with other chemicals to give compounds that produce cancer. For example, you may eat a hot dog this morning or this afternoon for lunch, and you may take a Contact pill because you're getting a cold. And Contact contains amines, and those two will react in your stomach, in the acidity of the stomach, to form nitrosamines. Amines additionally are found in beer and wine, in fish, in tea, in cigarette smoke, any numbers of foods and drinks; and it is these nitrosamines which have been found to cause cancer in just about every species of laboratory animal that have been tested, ranging from mice, on up to monkeys. And in some cases only a single dose, a single administration, was sufficient to induce cancer several months later in the animal population.

Mr. RATHER. It is said, however, that if we don't use sodium nitrite, meats cannot be preserved as well as they are now, and then we'll be in danger of botulism.

Dr. VERRETT. Well, that's not entirely true. Preserved meats can be preserved in a way that nitrites would not be necessary. It is done in some cases. You know, many times, this type of additive is used to make up for poor manufacturing techniques. In other words, if meat is heated to the right temperature for the proper length of time, and then refrigerated properly, there will be no growth of bacteria.

Mr. RICHARD RONK. If we're going to have these products, we have to have nitrite. If we're going to eat these products safely—quote "safe"—the first hazard that we're going to have to face is that real hazard of botulism. It isn't a theoretical hazard, or theoretical risk. If I look at that risk, it's very real, very known. We know that people will die from botulism if we—if we allow it without that. If one wants to eat bacon, then I believe that it's better that the nitrite is there. If one wants no risk, if one wants to eliminate or reduce the risk that they have been exposed to for some—some centuries that we've used these products, then one probably could make the decision not to consume these products.

Mr. RATHER. Then there's the question of what makes the hot dog red. A red hot ought to be red, of course, and one of the ways you can color it up is by adding a substance known as Red Dye Number Two. In 1907, the Government gave Red Dye Number Two provisional approval. Almost 70 years later, the Government still hasn't given a final ruling. We colored \$10-billion worth of food last year just to make it look pretty.

Dr. VERRETT. It's used in white icing to enhance the color. It's used in chocolate cake to intensify the chocolate look.

Mr. RATHER. Excuse me? Red Dye is used in white icing and in chocolate cake?

Dr. VERRETT. Yes, in those two extremes. I thought you'd find that interesting, because it is not only in foods that are obviously colored red. It is in those too, of course. The labeling requirements are such that the manufacturer does not have to reveal a specific dye. He only has to say that there is artificial coloring. So there is no way to really know whether Red Two is present or not, and this is the problem.

Mr. RATHER. You've taken a position that Red Dye Number Two should not be used as a food coloring. Why?

Dr. VERRETT. Well, there have been a number of happenings over the last several years which have indicated that Red Two may not be entirely safe. First of all, there was a study many years ago in about 1951 done right here at Food and Drug, and which was to test whether or not Red Two could cause cancer. At the time, that experiment was interpreted as showing no effect, that there was no cancer. A more recent evaluation of that study indicates it may indeed have had some carcinogenic effects in it. The most important thing is that in the late sixties the Russians did some studies, and they found Red Two to be carcinogenic, to cause cancer in rats. On the basis of their studies, they banned Red Two.

Mr. RATHER. Why haven't we banned it?

Dr. VERRETT. Well, that's a good question. I think the answer is probably more economics and politics than science.

Mr. RATHER. There is serious debate over whether Red Dye Number Two causes cancer. The current FDA position is that it doesn't. The data is inconclusive. A test begun by the FDA several years ago to settle the issue was botched.

Because tests for cancer-causing agents can take at least 18 months, it may be years before anyone can say whether Red Dye Number Two is safe or not. Most hot dogs contain sodium nitrite. Many contain sodium nitrite and Red Dye Number Two. There may be some that contain sodium nitrite, Red Dye Number Two and vinyl chloride.

It's hard to imagine an American supermarket without polyvinyl chloride, but it could happen. All plastic isn't polyvinyl chloride, of course, but most of us can't tell which is which. Last July the Health Research Group announced that small amounts of vinyl chloride leach into food from hard vinyl bottles and cartons. Two months later, the FDA proposed banning them. Some scientists also worry about these soft vinyl wrappings. They're as American as the hamburgers they wrap. No one knows whether they are dangerous or not. There hasn't been adequate testing.

Dr. SCHNEIDERMAN. Well, obviously, nobody is intentionally putting cancer-causing materials into the food. I think our food industry in this country is very good, and I think perhaps one of the reasons why we've had a substantial decrease in stomach cancer is the way we handle foods in this country, the way we store food—refrigeration—has helped reduce stomach cancer in the United States. So fungal products and things of that sort—the molds that might grow on foods if they weren't well-stored—are controlled by refrigeration. As for other materials going into the foods, that are being put in for reasons—making the food look pretty or making it last a little longer, shelf—increasing its shelf life, I think these certainly all need to be tested to see if they are carcinogens and potential carcinogens.

Mr. RATHER. Everything doesn't cause cancer. The list of cancer-causing agents or suspected agents is short. The trouble seems to be that we discover them too late. But for every one of the cancer-causing chemicals we have mentioned, there's probably a substitute that doesn't cause cancer. The reluctance to change may come more from economics than science. Meanwhile, in industrial cities across the country, chemically polluted air and chemically polluted water add to our cancer rates. Food, air and water can be cleaned up. The youngest may be the most vulnerable.

What about this potential combination in terms of what its effect may be on that 15-month-old baby, Nicole Cappel?

Dr. SCHNEIDERMAN. I wish I knew. I'm afraid that the combination, particular combinations of things we don't even know anything about now, may multiply and may put that child at much higher risk than my children, for example, who are well past the age of 15 months and who perhaps grew up in an environment with fewer chemicals in it and with less risk. But I think the problem is containable.

If we really thought that all cancer came to us because of our genetics, our inheritance (my father developed cancer; I'm going to develop cancer)—then we'd be in a terrible situation. There's nothing you can do about your inheritance. My father is my father, and I can't change him. And I'm the father to my children, and they can't change me. But knowing that a great deal of cancer is derived from the environment, we can then say "What do we have to do to the environment? What do we have to do to see to it that these things which cause cancer in the environment are reduced or eliminated?"

I think if we can discover more of these things, control them, get their levels down to zero, if possible; and if these are extremely important things that we must have in our society, get them down to the lowest possible level that our technology is able to get them down to, we'll be in a position of reducing cancer in this country and continuing to reduce it.

Mr. RATHER. In the meantime, there are things individuals can do to cut down exposure. Dr. Schneiderman says your chances are better if your diet has less animal fat in it, if you cut out preserved meats, and if you stop smoking. Your chances are even better if we can get agriculture and the food industry to stop using that short list of chemicals that are known to cause cancer. Meanwhile, the slow epidemic goes on, and most of the people who get cancer will never know what caused it.

There are specific cases of cancer that can be directly traced to specific exposures. We'll look at these in a moment.

[Announcements.]

Mr. RATHER. This is the American way of cancer illustrated in maps. Look for your community. This map shows cancer deaths of American males from 1950 to 1969. As you can see, they are concentrated in the Northeast, along the Great Lakes, and along the Gulf Coast. For women, there are high-risk areas scattered through Ohio, Illinois, Pennsylvania and throughout New England. The maps have been compiled from the National Cancer Institute's county-by-county study. They may be an important clue to what specific things cause what specific cancers.

That's why we went to New Jersey. New Jersey leads the country on a per capita basis in some types of cancer. Breast cancer, lung cancer, bladder cancer, intestinal cancer and rectal cancer are all abnormally high. New Jersey is also the most highly industrialized state in the country. And there seems to be an association between some kinds of industry and cancer.

[Church bells at funeral.]

William Contrini, 60 years old. Contrini died of lung cancer. The cause of his cancer is now known. On his death certificate the cancer is legally linked to asbestos. It's been said that we are suffering a cancer epidemic in slow-motion.

PRIEST. Hail Mary, full of Grace . . .

Mr. RATHER. Because the disease usually takes fifteen to thirty years to develop, most cancers people are dying from today reflect substances they were exposed to years ago. So, we went back almost 25 years to look at a plant in Paterson, New Jersey.

This is where it happened—Contrini hired on here in 1951 for just a few months. Today this plant manufactures paint, but up until 20 years ago it manufactured asbestos. There were over 900 men who worked in that asbestos plant. A group of medical detectives now is tracking down what's happened to all those 900 and their families.

Mr. PERRONE, detective. Back in December, and I wonder whether you think we could get him in, together with his brother.

CHUCK. Has he been examined before?

Mr. PERRONE. He was, but back in 1973, and it's two-and-a-half years now.

CHUCK. Oh, he's—he's due—he's due again, yes.

Mr. RATHER. If careful records and statistics can prove anything, they have bitterly proved there is a link between asbestos and cancer. The Paterson Asbestos Control Program records that link.

Dr. HENRY ANDERSON. We're finding one-in-five are dying from lung cancer; one-in-fifteen from mesothelioma; about one-in-ten from gastro-intestinal cancers.

Mr. RATHER. Mesothelioma—a form of cancer so rare most surgeons never see it. But those who take care of asbestos workers know it well.

Dr. MAXWELL BOROW. This is a lung, the upper lobe and the lower lobe of the lung, and this white tissue is the malignancy, which is arising from the chest wall and compressing and covering the lung just like a glove on a finger. And here you see the tissue growing between the lobes. It's not in the lung—

Mr. RATHER. This is the actual cancer?

Dr. BOROW. This is the actual cancer. It remains in the cavity where it starts, and just gets larger and larger in bulk and mass, and eventually compresses the lung and diminishes the patient's ability to breathe.

Mr. RATHER. Now, that's a case in the lung. How about in the intestine?

Dr. BOROW. This is a— a cross-section of the abdomen. Here are intestines, and this whole white mass is the mesothelioma, which has completely filled the free space in the abdominal cavity and is compressing the intestines, as you see here in cross-section.

Mr. RATHER. What are the chances of you being able to save him?

Dr. BOROW. Our mortality's been a hundred percent. We have no therapy which is effective in the treatment of this disease.

Mr. RATHER. Asbestos inhaled at this plant 20 to 30 years ago caused the deaths of a third of those who worked here. Asbestos has caused the deaths of tens of thousands of workers all around the country. For years asbestos was considered an occupational hazard, but in Paterson there is almost certain evidence that asbestos has reached beyond the plant.

Isabelle Van Zile, the records show, died at 37 of cancer caused by asbestos. Her only known exposure came when, as a child, she washed her father's work clothes.

[Children shout in swimming pool.]

Manville, New Jersey. Johns Manville has been making asbestos here for 63 years. In the old days, this plant, like most asbestos plants, was dusty, the air heavy. Workers often couldn't see each other across the aisles. When they complained, they were told it was nuisance dust. Almost a hundred workers in this plant died of mesothelioma. Two died the week we were here.

Today, this plant meets government standards, and workers and management are safety conscious; but that doesn't mean that this plant, or any other asbestos plant in the country, is safe. Current regulations allow a few asbestos fibers in the air, but the Government now says these few may be too many. New evidence indicates low levels may also cause cancer. Just proposed—standards ten times stricter than those in effect. There is even less protection for over a million workers exposed to asbestos in hundreds of other jobs, where even existing regulations are not enforced. That's the pattern: the enforcement of questionable regulations one place, no enforcement in another.

And asbestos is just one substance, a mineral. Most cancer-causing agents are chemicals. The chemical industry is everywhere in New Jersey, and chemical leftovers spill out into the air and water. In some places you don't need elaborate scientific proof that there are foul substances in the air. In Paterson, almost every man we saw emerging from this plant was using a handkerchief.

Maybe the most shocking thing we found in New Jersey is that cancer rates are so high some people have come to accept the unacceptable.

EDIE DESHAZO. I am not afraid of cancer. It falls into the category of non-worry, like the atomic bomb.

Mr. RATHER. Edie DeShazo has lost a breast to cancer. She also lost these relatives to the disease.

Mrs. DESHAZO. Died of cancer—my mother and my father, my husband, many, many aunts and cousins, my—one of my grandmothers; and one of my grandfathers, I'm sure, had cancer, although they didn't call it that. They didn't diagnose it as that. And when I was in my teens and early twenties, I worked in Camden, a very chemical atmosphere, pretty much, and my father had, and my husband had. Whether this had anything to do with it—all of our cancers or not, I wouldn't be able to say, or my mother's. But, I mean, I certainly can't help believe that some of the chemicals that are in the air and that we're ingesting have got to—I mean, why would you have a sudden tremendous rise in it?

Mr. RATHER. Salem, New Jersey. It looks like a nice rural place, but it leads the country in bladder cancer. The County is over the average in leukemia, breast cancer, lung cancer, cancer of the intestine, prostate and rectum. In Salem County, just opposite Wilmington, is one of the largest chemical plants in the country—DuPont's sprawling Chambers Works. It is an efficient, well-run operation. Over the years, DuPont has produced thousands of chemical products and, by their own admission, produced cancer.

Paul Humanick, plant manager.

PAUL HUMANICK. In 1932, there was a significant development which indicated that cancer was being developed in the form of bladder tumors among our employees here. The actions that were taken by the management of that era were to try to contain the equipment, develop closed systems, and to protect the personnel.

Mr. RATHER. More than 40 years later, DuPont workers are still developing bladder cancer. Over 300 cases of bladder cancer have turned up among men who worked with dye chemicals right here. The slow epidemic continues, even though DuPont has long since stopped using the two chemicals that directly caused the cancer.

In New Jersey, 334 men exposed to benzidine and beta-naphthylamine at the DuPont plant have developed bladder cancer. Is this an isolated incident?

Dr. JOSEPH WAGONER, National Institute of Occupational Safety & Health. Not in the least bit. We entered into five or six or seven major facilities throughout the United States that were producing benzidine and beta-naphthylamine, two agents which, by the way, have been either voluntarily withdrawn or banned in every other civilized country throughout the world: England, Switzerland, Japan, Italy. Yet, we were producing it in the United States. We actually went into one facility where beta-naphthylamine was produced, and we saw men standing hip-deep in slurry tanks covered with beta-naphthylamine. We've entered into a facility in the Buffalo area of New York where, out of 365 employees at that facility, over 110 are known to have developed bladder cancer. It—it's not an isolated occurrence. It's nothing other than a—a pure tragedy.

Mr. RATHER. The pattern with these chemicals was the same as with asbestos. We were slow to acknowledge them as cancer-causing agents. Eventually, under pressure from public interest groups and labor, plants were cleaned up, safety measures were taken. But the Government list of cancer-causing chemicals in the work place is fifteen—only fifteen—and there are 50,000 chemicals in daily use in the United States. Almost all of those 50,000 chemicals in use have not been tested for cancer. Scientists tell us that among the untested there are probably killers as deadly as asbestos, benzidine and beta-naphthylamine.

The danger to workers from these untested chemicals is obvious. More subtle is the hazard to those who live around the plant. But the hazard is there. The bladder cancer rates for men in Salem County are the highest in the country, but the rates are also high for women, none of whom worked for DuPont. And Salem is not unique. The National Cancer Institute studied 139 counties where the chemical industry is most concentrated. They found high rates of bladder cancer, liver cancer and lung cancer. But even if you live far from a chemical history, the products and by-products of modern chemistry stretch across America. Tighter Federal controls and pre-testing have been proposed, but industry is wary of over-regulation.

Mr. RUSSELL TRAIN, EPA Administrator. It is not practical to believe industry will police itself, and I—and that is not to be critical. Many elements of industry are very responsible, but industry is a very big name. This would be like saying: Do you think it's reasonable to expect society full—fully to police itself? The answer is no. We do need in this field a good, effective, balanced toxic substances control act that imposes reasonable burdens and responsibilities on industry to test and to produce the data that can assure the public that the public interest is being safeguarded in his regard.

Mr. RATHER. President Ford has taken the position that, while he considers environmental problems as serious, that he is not going to allow environmental measures to endanger the economy. Is it possible to be protective and economically supportive at the same time?

Mr. TRAIN. Absolutely. In fact, unless we protect the environment, we're not going to have any economy at all. Jobs aren't going to do an awful lot of good for people if their children are getting sick. We do need jobs. We do need industrial activity and good healthy economy. And at the same time we do need a good healthy society, and we have to do both.

[Announcements.]

Mr. RATHER. Tacoma, Washington. In one corner of Tacoma there's a small community, Ruston, dominated by an enormous copper smelter. Everywhere you go in Ruston the smokestack's there. The smokestack is at the heart of this problem. There are doctors who say it threatens everyone in the town—the workers and their children. The company ASARCO, doesn't agree.

Charles Melton, 55 years old. He worked at ASARCO until last winter, when he became ill.

Mr. Melton, how long did you work at the smelter?

CHARLES MELTON. I worked at the copper smelter for approximately fifteen-and-a-half years.

Mr. RATHER. ASARCO's Tacoma smelter. About 1,000 people work here. It's one of the largest smelters in the country. It was built at the turn of the century, and that's part of the problem. Over the years working conditions have been

improved, but processing copper remains a hot and dangerous business. The air is often thick with fumes..

Mr. MELTON. You have a choked-up feeling most of the day. Your head runs a lot, your nose, and your—inside your throat. You're always spitting up something. We've tried to sneak instruments in to test those fumes to see what they were and what effect they'd have on us, but we never had no success with it yet.

Mr. RATHER. Among the substances that Mr. Melton and everyone else who has worked here has been exposed to is arsenic. Arsenic is a byproduct of making copper. This ASARCO plant is the largest producer of arsenic in the United States. Arsenic is used in insecticides, in paint, and in making glass. The Government estimates one-and-a-half million American workers are exposed to arsenic. This is where it's produced.

This is what's known in the vernacular of the plant as the arsenic kitchen. In general, what happens here is that arsenic is turned from a gas into a dust. There's arsenic cooking on either side of these walls. Now, for the men who work in this room, it's fair to say that nobody in the plant has to face a higher concentration of arsenic dust. To give you some idea of what the dust looks like, let's—well, you can see it's a—that's just a light switch, dust coming off there. Arsenic is a white powder—Well, on the pipes, perhaps, see along here. Accumulations of dust are here on the floor. This room has been cleaned up, partially for our benefit, I would assume. But nonetheless, this is what the dust looks like.

Mr. RANDY ROLAND, smelter worker. When you come down to take a break or something, you have to blow your clothes off, and of course the dust billows out like that. You can tell that you've been working in the dust. Yeah, there's no doubt about it.

Mr. RATHER. There's no doubt in your mind this is a dangerous line of work?

Mr. ROLAND. Well, dangerous in the sense that it—it's bad for you. It's rat poison, right? It's what they spray to kill insects, and insects can just about survive anything. A good example of it is—You see these?

Mr. RATHER. I was just going to ask you.

Mr. ROLAND. Well, those are arsenic sores, and what happened there is my glove got a little bit of a build-up in it of arsenic, and so then it creates sores. And it doesn't take much of anybody to tell that if it'll do that to your tough old skin, that if you breathe the stuff or eat it, that it's going to really goof up your insides, you know.

Mr. RATHER. For hundreds of years we have known that arsenic is a deadly poison. A 1948 study indicated that arsenic might cause cancer. But in 1963, ASARCO's company doctor, Sherman Pinto, reported there was no evidence that arsenic was a cause of cancer. Coming from the leading doctor of the largest arsenic plant in America, Pinto's paper was widely accepted—until two years ago. Then his facts were questioned.

Dr. SAMUEL MILHAM, Washington State Dept. of Health. I did a count from our death records in Washington State of—I looked at lung cancer deaths in Pierce County in men, and I came up with more lung cancer deaths than that paper reported for the analogous time period. So I was concerned, and especially in light of the fact that a—that a number of the—the deaths that they—they signed out to other causes were—were probably lung cancers. So, I went up with the death certificates in hand, and I visited Dr. Pinto. We compared them, one by one, and these six were the ones which I—I counted to lung cancer and which—which I think, according to international death certificate coding rules, are unequivocally primary carcinomas of the lung. He'd coded to—to other causes.

Mr. RATHER. What company doctor Pinto did was note that the primary cause of death on the certificate was bronchopneumonia. But the bronchial condition was due to carcinoma—cancer of the lung. The company counted it a pneumonia death, not a cancer death.

Dr. MILHAM. It's pretty hard for me to understand how these—that these certificates were not counted in the lung cancer pile, pure and simple. I just don't understand how.

Mr. RATHER. Well, how was it that a company doctor and the company were allowed to investigate the company anyway? And then have it accepted by both industry and the Government as the definitive work?

Dr. MILHAM. Well, that's the way it is. I mean, this is—this isn't unique. I mean, tomorrow there'll be a hearing, and the company will be represented by a hired physician, you know, somebody who's paid by them to—to represent their position. Now I—I work for the citizens of the State of Washington, and I, you know, I—I'm unholding what I think is their—their benefit and working for them. I guess Dr. Pinto worked for the smelter, and they paid his salary.

Mr. RATHER. Last spring at Department of Labor hearing in Washington, D.C., Dr. Pinto admitted that there was too much lung cancer at the plant.

Dr. SHERMAN PINTO, ASARCO company doctor. For the causes of death shown, a statistically significant excess was observed only for respiratory cancer. This is clearly related to the arsenic exposure index.

Mr. RATHER. ASARCO finally admitted the link between arsenic and cancer. The Government proposed arsenic dust be reduced 100 times lower than that found in certain parts of the plant. ASARCO flatly said it couldn't meet those standards.

ARMAND LABBE, Plant manager. The conclusion that we've drawn, that we can't meet these standards, is the fact that the plant is a unique one; this particular plant is unique. And in handling, processing, these materials in such large facilities, it is extremely difficult to corral arsenic or other heavy metals to the degree required by the proposed standard.

Mr. RATHER. The company says it has a unique problem, but the workers at the plant, according to Dr. Milham, now have a cancer rate five times higher than he would have anticipated. The company suggested a compromise—put workers into respirators in areas where arsenic dust is too high. Respirators have been used here since the forties. These homemade contraptions were designed to keep large particles from burning a worker's nose. Whether they filter cancer-causing dust is a matter of debate. Whether everyone who should wear a respirator does wear one is another question.

Mr. MELTON, did you wear a respirator?

Mr. MELTON. No, I don't wear respirators there on—that job. They said it wasn't necessary.

Mr. RATHER. Shortly after the company's announcement that it couldn't meet the Government's suggested standards, it was rumored that ASARCO might even shut down the Tacoma plant. At the local union hall, a meeting was called after the day shift. It went on for hours. The workers were split between concern over medical safety and the possibility of losing their jobs. During the meeting our microphones were barred, but minutes later the debate spilled out before us.

WORKER 1. Now, there are not a lot of jobs in this area, and if this one down here is eliminated, I don't know where I'd go. Do you realize that the State would probably end up providing for my family until I could get relocated.

WORKER 2. I think if they don't clean that place up, I don't want to really work down there.

Mr. RATHER. The working hands are split on this issue, aren't they?

WORKER 2. Yeah, people don't want to lose their jobs, and I agree with that. I—I really wouldn't want to lose mine. It pays good money. I have a house, a wife, and a whole bunch of responsibilities I have to pay for. But if it's going to kill me, I'm not going to be around to worry about it or pay for them any way.

WORKER 3. I live in fear that every day that the environmentalists are going to end up shutting down the plant. Every day I hear this.

MAN. We know that, unless there is pressures put on, there'll be no changes made. And we are fortunate, I think, that we have new allies. In the old days who cared what happened inside of a smelter, what happened to the pollution? Now we have people, environmentalists, people who have not been in the smelter, who also show concern about environment and don't want to live in garbage cans. So labor inadvertently has gotten a new ally, and this new strength has, I think, changed the whole mores of thinking in America. And so, the working person, working in this isolated smelter in Tacoma, now finds he's got a lot more political clout to do something about his conditions of work.

Mr. RATHER. Despite the evidence, many workers find it hard to believe that a small amount of dust inhaled today may cause cancer twenty years from now. Some in management say they also have doubts.

Are you convinced that there is a relationship between—a direct relationship—between arsenic and lung cancer?

Mr. ARMAND LABBE. No, I'm not, even though I've seen many—many works on this. I'm not truly convinced that it is a carcinogenic by itself.

Mr. RATHER. Despite the testimony of the doctors?

Mr. LABBE. That is correct.

Mr. RATHER. Well, let—let's talk about that for a moment, if we may. On what do you base that?

Mr. LABBE. Well, we have a—We have made surveys here on people as to their smoking habits, and we find that we have a great deal of employees, over

the average, who are heavy smokers. And this question of the effect of smoking and in conjunction with, say, arsenic oxide still is debatable in my mind.

Mr. RATHER. Do you personally know of—of any smelter workers who currently have lung cancer?

Mr. LABBE. No, I do not.

Mr. CHARLES MELTON. So I told the boss I was going up to get chest x-ray to see what was wrong and see if he could find out. So I went up, and I got the results of—I got the x-ray and everything, and went back. I tried contacting the doctor. He was out.

Mr. RATHER. This was the company doctor?

Mr. MELTON. Company doctor. Dr. Pinto, and he was out that day.

Mr. RATHER. Excuse me? He gave the x-ray?

Mr. MELTON. He gave the X-ray himself. So, over the weekend it kept getting a little more severe and hurting more, and I—I started getting weak. So I went to see my family doctor, and took the cardiogram and so forth, and then he says, "There's nothing there. We'll take a chest x-ray." So in five minutes he came back, and he told me I had serious trouble. And he said he was sending me up for more tests, and he was taking me out of the smelter until further notice.

Mr. RATHER. Plant manager Armand Labbe says that he knows of no one on the payroll who has cancer. We asked Mr. Melton, "Do the bosses know about you?"

Mr. MELTON. I'm positive of it. The personnel manager knows it, and he's the closest to the plant manager; so he'd have to know it. There's no way. The doctor knows it, because my report goes in every two weeks—don't it?—to collect my sick leave. We send in a report filled out by Dr. Dille, and he's got the diagnosis on it and everything.

Mr. RATHER. If arsenic causes cancer, the danger may not stop at the plant gates. One hundred six tons of arsenic fell on Ruston last year. The Health Department has warned parents to wash their children's hands and faces carefully, because there may be high quantities of arsenic in the dirt. And in this school, which hangs over the plant, the children have abnormally high arsenic counts in their urine. Many registered levels as high as their fathers, who work below in the smelter.

Dr. J. G. KATTERHAGEN, cancer specialist. What this will mean in regards to their future health, I don't know, but the thing you've got to keep in mind is that you don't breathe arsenic in today and develop a lung cancer six months from now. Often there's a lag time of 10, 15 or 20 years from the point of contamination until the point of developing the malignancy. If I had children in that school, which I don't, I would move them to another school.

Mr. RATHER. Town doctors and ASARCO disagree as to whether the amount of arsenic falling on Ruston is dangerous. But the National Cancer Institute has declared that communities surrounding smelters have high rates of cancer; and the local air pollution agency demanded that ASARCO reduce the fallout. The agency called a hearing. The company flew in people from all over the country to defend its position. In excerpts, we present the company's argument.

KENNETH NELSON, ASARCO Vice President. Certainly we want to protect health, but before we go to extremes, we must be sure we have a health problem. Dr. CHARLES HINE. We do not think there is any data to show that low exposures to arsenic create any problems.

*Question.* Are you prepared to give a medical opinion as to the level at which arsenic found in the air has an effect on the human body?

Dr. S. A. PEOPLES. To try to say what—what actual level would be the—the top—the critical one, I can't say.

Mr. RON THOMPSON, smelter worker. I've lived in Ruston—up on the hill—for 40 years. I've raised six wonderful children, all healthy, and I can't see anything wrong with the air out there. I mean, it's—it's bad, but it's not that bad, and Mr. Labbe is doing a wonderful job of cleaning it up.

Mr. ARMAND LABBE, Plant Manager. In fact, ASARCO simply cannot at this time undertake the programs sought by the staff. The staff recommendations are unrealistic.

Mr. RATHER. We presented only the company's point of view because those people who gave evidence that ASARCO was dangerously polluting the air carried the vote.

MAYOR. And therefore, I move that we deny this variance.

MAN. Second.

CLERK. Having heard the motion, all those in favor, signify aye.

ALL. Aye.

CLERK. Opposed? [Silence.]

[Applause . . . gavel.]

Mr. RATHER. Well, knowing what you know about yourself right now, what your own condition is, how do you feel about all this?

Mr. MELTON. Well, now, I felt kind of bitter for a while, but I seem to get over it a little as I go along now. I was kind of bitter to begin with. [Stops to drink] I think the reason I was so bitter to begin with, when I first got the news—that I couldn't do more at the time that I should have been doing, more to help the problem, you know, kind of clear up the air and so forth. I thought I was doing all I could, but I—I think now I could have done a little bit more.

Mr. RATHER. Are you bitter toward the company at all, Mr. Melton?

Mr. MELTON. Oh, not really, not really. There's ways, yeah, there's ways I'm bitter to the company, but they're all human beings, too, like everyone else. They have their problems, we have ours.

Mr. RATHER. Late in August, Charles Melton died of lung cancer. In September, a lower court suspended the fines levied by the Puget Sound Air Pollution Control Board. A long court battle lies ahead. Meanwhile, arsenic dust still falls on Ruston.

When Charles Melton was first exposed to arsenic, no one knew it caused cancer. When William Contrini and all the thousands of asbestos workers who died were first exposed, again no one understood that asbestos caused cancer. But we understand now. We now understand the potential danger to the little girl in Cincinnati, to all of us, of cancer-causing substances, even in small amounts, in our food, air and water. If, as scientists say, 85% of all cancer can be traced to substances in the environment, then the majority of cancers can be prevented. So, cancer turns out to be a social disease, in large part a by-product of our way of life. But the same technological genius that inadvertently produced the American way of cancer is perfectly capable of reducing the epidemic.

What can we do? We can identify cancer-causing agents before they are added to food. We can pre-test chemicals before exposing workers and dumping the leftovers into the air and water. We can prevent great numbers of cancers. If we do not, our children will certainly suffer even higher rates of cancer than we do.

Dan Rather for CBS REPORTS. Good night.

[ANNOUNCEMENTS]

ANNOUNCER. Tonight Dr. Verrett clarified her statement on mixing hot dogs and Contac. She points out that many other cold remedies as well contain these same amines and create the same chemical reactions she described.

