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GOVERNMENT

COSMETIC SAFETY AMENDMENTS, 1975

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HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON LABOR AND PUBLIC WELFARE UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

S. 1681

TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC
ACT WITH RESPECT TO COSMETIC SAFETY

JUNE 12, 1975



Printed for the use of the Committee on Labor and Public Welfare

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COSMETIC SAFETY AMENDMENTS, 1975

THURSDAY, JUNE 12, 1975

U.S. SENATE,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:45 a.m., in room 6226, Dirksen Senate Office Building, Senator Thomas F. Eagleton presiding pro tempore.

Present: Senators Eagleton, Nelson, Javits, and Stafford.

Senator EAGLETON. Good morning, ladies and gentlemen.

The Subcommittee on Health of the Senate Labor and Public Welfare Committee is now in session.

I would like to take just a moment to express my appreciation to Senator Kennedy, the chairman of the Health Subcommittee, for scheduling today's hearing. His attention to this long-neglected area of cosmetic regulation will, I hope, lead to effective action being taken by this subcommittee and by Congress to protect the health of the many million Americans who make up the consuming public.

As those of you who have followed the subcommittee's investigation into the problem of cosmetic safety are aware, I introduced a cosmetic safety bill, S. 863, in February 1973, along with Senators Mondale, Nelson, and Burdick. This subcommittee held 2 days of hearings on that bill in 1974.

Now, once again on May 7, 1975, I introduced S. 1681, the Cosmetic Safety Amendments of 1975, which has the same basic thrust as the earlier bill—to assure the safety of all cosmetic products offered for sale.

The need for this legislation has become increasingly apparent. Estimates of annual injuries presented in hearings held on my bill last year range from 60,000 by the Commission on Product Safety, to 29,000 by Mrs. Virginia Knauer, Special Assistant to the President for Consumer Affairs, to 9,700 by the director of applied research for Chesebrough-Ponds. Regardless of the precise figure, it is clear that a substantial number of persons suffer injuries associated with cosmetic use.

Questions regarding the safety of cosmetics continue to be raised by authoritative sources. A recent report by a Food and Drug Administration advisory review panel charged with studying and evaluating the safety and effectiveness of over-the-counter [OTC] antimicrobial drug products which are used on a daily basis has found some ingredients that are used in both cosmetics and OTC drugs are not generally recognized as safe. The review panel concluded that these ingredients should not be used in drugs until evidence to substantiate their safety

is developed. However, as the panel also noted, in the absence of adequate regulatory authority with respect to cosmetics, there is nothing to prevent the incorporation of these ingredients of questionable safety in cosmetic products used daily by millions of Americans.

Other disturbing reports include the recent account of laboratory studies by Dr. Bruce Ames, a biochemist at the University of California, which raised the possibility that hair dyes may cause cancer and birth defects. In addition, a New York Times article of March 18, 1975, reported that a New York internist has noted that an unusually high percentage of his patients who developed breast cancer had been regular users of hair dyes. Both studies, while not purporting to be definitive statements on the safety of the products involved, do point to the existence of potential hazards to consumers of cosmetics.

Nearly every American family uses cosmetic products of one kind or another, since the term includes everything from lipstick and mascara to toothpaste and shaving cream. Most consumers purchase this wide range of products under the mistaken assumption that they are free from potential health hazards because of Food and Drug Administration supervision under the Federal Food, Drug, and Cosmetic Act of 1938.

However, that law does not now provide any such protection to consumers. The present authority of the FDA over cosmetics is extremely limited. It can only require that all cosmetic products indicate the net weight contents of a package and the name and address of the manufacturer. It contains no provisions regarding ingredient labeling, that is, the kind of labeling which is most important to the consumer to allow him or her to avoid certain ingredients about which safety questions have been raised or which are known to cause allergic reaction. The FDA has promulgated regulations requiring ingredient labeling, but under the authority of a different statute.

The existing law also gives the FDA authority to act against cosmetics which are adulterated—that is filthy, putrid, or decomposed. Should a cosmetic be determined to be either misbranded or adulterated, the FDA has the authority to seize the product. However, this after-the-fact approach permits potentially injurious products to be sold and leaves totally unprotected those who have already purchased the product and continue to use it.

Although the FDA regulations incorporate the principle that every cosmetic manufacturer has a duty to substantiate the safety of his products, the agency acknowledges that such regulations will be very difficult to enforce, and one of questionable legality under the existing authority.

S. 1681 leaves no question that the FDA has the authority, and indeed the responsibility, to see that manufacturers substantiate the safety of their products. Title I of the bill sets forth procedures for the safety substantiation of cosmetics and cosmetic ingredients, placing the burden on manufacturers of thoroughly testing their products for safety before offering them to the public. There is no requirement that the manufacturer submit this data indicating the safety of his product prior to sale as there was in the prior legislation I introduced. However, the FDA is given that authority to require the submission of safety data if it feels that so doing would better protect the public health and safety.

In addition, the FDA is given the authority to require premarket submission of safety test data for any cosmetic containing an ingredient or any class of cosmetic which the Secretary has determined presents a significant risk of injury.

Let me emphasize that this is not a blanket authority for premarket submission. Dr. Alexander Schmidt, Commissioner of the Food and Drug Administration, testified last year that such submission or reporting would in fact be the same thing as preclearance. Therefore, this bill would only require presubmission of safety data in those instances where there is a risk associated with a particular product, ingredient, or classification of products. If the Secretary finds that action is necessary to assure the safety of cosmetics, he may require additional labeling, prohibit or limit use of a particular ingredient, require additional testing, or ban a cosmetic.

Title II requires manufacturers to register with the FDA, to submit a list of each cosmetic product manufactured, and a list of ingredients in each cosmetic. In addition, it requires that manufacturers submit consumer complaints about adverse reactions to the FDA every 3 months. For the most part, this title would codify and make mandatory the FDA's "voluntary compliance program" launched in 1972. Further, title II would require every manufacturer to notify the FDA of any product which he discontinues, and of any new product. It also expands FDA's inspection authority and authorizes administrative detention and seizure.

Title III provides for ingredient, cautionary, and informational labeling of cosmetics. Although these provisions are largely compatible with the ingredient labeling regulations FDA has promulgated under the Fair Packaging and Labeling Act (FPLA), they allow the FDA to use the authority of the Federal Food, Drug, and Cosmetic Act rather than the unduly restrictive and sometimes ambiguous authority of FPLA.

Title IV contains general provisions relating to cosmetic regulation. First, a system through poison control centers to make information available when there has been ingestion of a cosmetic is established; second, the Secretary is required to cooperate with the Small Business Administration in recommending loans to small cosmetic manufacturers to assist them in complying with the safety substantiation and good manufacturing provisions; third, preemption of State law with respect to labeling is provided; fourth, the FDA is given substantive rulemaking power and procedures for issuing regulations and judicial review of the regulations are set forth; and fifth, the appointment of advisory committees to make recommendations to the Secretary regarding all aspects of assuring the safety of cosmetics is authorized.

I look forward to the additional testimony which will be taken today. I know that there is concern about certain provisions in S. 1681, and I urge the witnesses to make specific recommendations to the subcommittee regarding those areas which they feel need to be strengthened, those which present practical problems to the industry, and those which they feel need clarification or greater direction given to the Secretary.

At this point I would like to enter in the record a statement from Senator Kennedy.

OPENING STATEMENT OF SENATOR EDWARD M. KENNEDY

Senator KENNEDY. I am pleased to open today's hearing on S. 1681—the Cosmetic Safety Amendments of 1975.

Cosmetics have received little attention in legislation and in regulation. It is difficult to believe that present law does not require that manufacturers register their establishments and products, report injuries which result from use of their products, and test their products prior to placing them on the market.

There are those who would have us believe that this legislation is simply unnecessary and that cosmetics are so safe that Congress need not waste its time to act in protecting consumers. I want to state at the outset of these hearings that I am convinced of the great need to safeguard the American public from exposure to formaldehyde in nail polish, hexachlorophene in talcum powder, chloroform in toothpaste, boric acid in mouthwash and excessive hormones in skin creams. Cases of injury have been reported which include blindness caused by hair dye.

My esteemed colleague on the subcommittee, Senator Eagleton, deserves praise for his leadership in the cosmetic regulation field. Last year he sponsored S. 864, which touched on many of the long-neglected areas of cosmetic regulation. This year he has continued his lead by introducing the bill we are considering today.

The answer to cosmetic safety is not to ban cosmetics but neither is it to discount these products as insignificant and unworthy of legislative and regulatory efforts. Just as drugs, foods, and devices are widely used, so are cosmetics—from makeup and perfume to shaving cream, toothpaste, and shampoo. It is my hope that these hearings will begin to remedy the past neglect of cosmetics regulation.

[Text of S. 1681 follows:]

94TH CONGRESS
1ST SESSION

S. 1681

IN THE SENATE OF THE UNITED STATES

MAY 7 (legislative day, APRIL 21), 1975

Mr. EAGLETON introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to cosmetic safety.

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 "Cosmetic Safety Amend-
4 ments of 1975".

5 TITLE I—COSMETIC SAFETY

6 SEC. 101. Title VI of the Federal Food, Drug, and Cos-
7 metic Act is amended to add a new section as follows:

8 "COSMETIC SAFETY

9 "Cosmetics Deemed Adulterated

10 SEC. 604. (a) A cosmetic shall be deemed to be adulter-
11 ated for the purposes of section 601 (a) if—

1 “(1) its safety has not been adequately substanti-
2 ated prior to the commercial distribution of the cosmetic;

3 “(2) requirements applicable to that cosmetic by
4 or under subsections (c), (d), or (e) of this section
5 have not been met; or

6 “(3) it is a banned cosmetic.

7 “Cosmetic Safety Substantiation

8 “(b) (1) The safety of a cosmetic shall not be consid-
9 ered adequately substantiated unless—

10 “(A) on the basis of all data and information relat-
11 ing to the safety of the cosmetic which is published or
12 known to, or which should reasonably be known to, the
13 manufacturer or distributor, it can reasonably be con-
14 cluded that the cosmetic is safe under the conditions of
15 use prescribed in the labeling of the cosmetic or under
16 such conditions of use as are customary and usual;

17 “(B) such data and information are contained in,
18 or referred to, in records maintained by that manufac-
19 turer or distributor who is designated under section 605
20 (b) (1) (D) as responsible for maintenance of such rec-
21 ords respecting that cosmetic; and

22 “(C) such data and information are submitted to
23 the Secretary—

24 “(i) upon a written request by the Secretary,
25 or

1 “(ii) where required by regulation under sub-
2 section (d) of this section.

3 “(2) The data or information referred to in paragraph
4 (1)—

5 “(A) shall include information on such specific test-
6 ing, in animals or humans, of the potential of the in-
7 gredients of the cosmetic or the finished cosmetic prod-
8 uct, for—

9 “(i) toxicity,

10 “(ii) sensitization, and

11 “(iii) irritation,

12 as is appropriate or necessary; and

13 as is appropriate or necessary; and

14 “(B) may include scientific literature, or unpub-
15 lished data and information in the possession of the man-
16 ufacturer or distributor, relevant to the safety of the
17 ingredients of the cosmetic or the finished cosmetic
18 product.

19 “Requirements for Specific Testing and Screening Levels

20 “(c) (1) The Secretary may by regulation—

21 “(A) determine when specific testing is appropriate
22 or necessary for any cosmetic in order to constitute
23 adequate substantiation of safety;

24 “(B) establish the procedure to be used in such
25 specific testing; and

1 “(C) require that such specific testing be conducted
2 by a qualified person independent of any cosmetic manu-
3 facturer or distributor, with costs of such testing paid
4 such person by the manufacturer or distributor.

5 “(2) The Secretary shall by regulation establish screen-
6 ing levels or other criteria for toxicity, sensitization, and
7 irritation of cosmetics. The manufacturer or distributor of
8 any cosmetic which meets any such level or criteria estab-
9 lished in such regulation shall notify the Secretary of this
10 fact within thirty days after it is found to meet such level or
11 criterion. If the cosmetic is not in commercial distribution at
12 the time the regulation becomes effective, it shall not be of-
13 fered for commercial distribution for a period of ninety days
14 following notification of the Secretary, except as authorized
15 by the Secretary.

16 “(3) Specific testing requirements and screening levels
17 or other criteria established under this section shall be rele-
18 vant to the conditions of use prescribed in the labeling of the
19 cosmetic or to such conditions of use as are customary or
20 usual.

21 “(4) Manufacturers and distributors may perform such
22 specific testing individually or jointly.

23 “(5) The Secretary may in accordance with section
24 606 (e) appoint advisory committees to provide advice con-

cerning the development of specific testing requirements and screening levels and other criteria under this subsection.

“Regulations Requiring Submission of Cosmetic Safety Substantiation Data

“(d) (1) The Secretary shall by regulation—

“(A) designate those cosmetic ingredients or classes of cosmetics which he finds present a significant risk of injury;

“(B) require the submission to him within a reasonable period after such regulation becomes effective, but not to exceed sixty days, of the data and information required to be maintained under subsection (b) concerning cosmetics in commercial distribution containing any ingredient or included in any class designated by such regulation;

“(C) require, as to any product which is not in commercial distribution at the time such regulation becomes effective and which contains any ingredient or is included in any class designated by such regulation, the submission to him of that data and information required to be maintained under subsection (b) within a reasonable period, but not to exceed sixty days, after such data or information becomes known to the manufacturer or distributor of such product; and

1 “(D) require that any product containing any
2 such ingredient or included in such a class, which is not
3 in commercial distribution at the time such regulation
4 becomes effective not be offered for commercial distribu-
5 tion for ninety days after such submission, except as
6 authorized by the Secretary.

7 “(2) The Secretary may by regulation require any
8 manufacturer or distributor of a cosmetic which is proposed
9 to be offered for commercial distribution—

10 “(A) which is not within a type of cosmetic which
11 was previously in commercial distribution, or

12 “(B) which is within such a type of cosmetic but,
13 in accordance with regulations of the Secretary, is signif-
14 icantly different from other cosmetics within that type,
15 to submit to him the data and information required to be
16 maintained under subsection (b) concerning such cosmetic
17 prior to such proposed distribution and to withhold the
18 cosmetic from commercial distribution for ninety days after
19 such submission except as authorized by the Secretary.

20 “Cosmetic Safety Regulations

21 “(e) (1) Whenever the Secretary finds on the basis of
22 all available information, including data and information
23 obtained under this section, that such action is necessary to
24 assure the safety of cosmetics, he may by regulation—

1 “(A) require additional specific testing pursuant to
2 subsection (e);

3 “(B) prohibit the cosmetic from bearing or con-
4 taining any poisonous or deleterious substance or pre-
5 scribe limits of tolerance upon such substance; or

6 “(C) require appropriate labeling pursuant to sec-
7 tion 602; or

8 “(D) declare a cosmetic to be a banned cosmetic.

9 “(2) The Secretary may declare a proposed regulation
10 under paragraph (1) to be effective upon its publication in
11 the Federal Register and until the effective date of any final
12 action taken respecting such regulation if he determines,
13 on the basis of all available information, that making such
14 proposed regulation so effective is necessary to reduce or
15 eliminate a substantial risk of illness or injury associated with
16 the use of the cosmetic which is the subject of the regula-
17 tion. If the Secretary makes a proposed regulation so effec-
18 tive, he shall, as expeditiously as possible, give interested
19 persons prompt notice of his action under this subsection,
20 provide reasonable opportunity for an informal hearing,
21 and either affirm, modify, or revoke such proposed regu-
22 lation.

23 “(3) In addition to such findings as the Secretary may
24 make pursuant to subparagraph (1) of this subsection, a

1 cosmetic or cosmetic ingredient shall be deemed unsafe with-
2 in the meaning of this subsection—

3 “(A) for any use which will or may result in in-
4 gestion of all or part of such cosmetic or cosmetic ingre-
5 dient if the cosmetic or cosmetic ingredient is found by
6 the Secretary to induce cancer when ingested by man or
7 animal, or if it is found by the Secretary, after tests
8 which are appropriate for the evaluation of chemicals
9 liable to be ingested by man, to induce cancer in man
10 or animal, and

11 “(B) for any use which will not result in ingestion
12 of any part of such cosmetic or cosmetic ingredient if,
13 after tests which are appropriate for the evaluation of
14 the safety of such cosmetic or cosmetic ingredient, it is
15 found by the Secretary to induce cancer in man or ani-
16 mal.

17 “Definitions

18 “(f) As used in this section the term—

19 “(1) ‘toxicity’ refers to the short-term or long-term
20 capacity of a cosmetic to produce personal injury or ill-
21 ness to human beings through ingestion, inhalation, or
22 absorption through any body surface;

23 “(2) ‘sensitization’ refers to the capacity of a cos-
24 metic to cause on normal living tissue through an allergic
25 or photodynamic process a hypersensitivity which is

1 manifested on reapplication of the same substance; and
 2 " (3) 'irritation' refers to the capacity of a cosmetic,
 3 on immediate, prolonged, or repeated contact with nor-
 4 mal living tissue, to induce a local inflammatory reac-
 5 tion.".

6 GOOD MANUFACTURING PRACTICES

7 SEC. 102. Section 601 of the Federal Food, Drug, and
 8 Cosmetic Act is amended by adding at the end thereof the
 9 following new subsection:

10 " (f) (1) If the methods used in, or facilities and con-
 11 trols used for its processing do not conform to, or are not
 12 operated or administered in conformity with, current good
 13 manufacturing practices, as determined by regulations
 14 promulgated by the Secretary.

15 " (2) Such regulations shall, where appropriate, include
 16 requirements for the testing of the cosmetic, on a sample
 17 basis or otherwise, if necessary to assure that cosmetic is
 18 not adulterated."

19 CONFORMING AMENDMENTS

20 Definition

21 SEC. 103. (a) Section 201 of the Federal Food, Drug,
 22 and Cosmetic Act is amended by adding the following new
 23 subsection at the end thereof:

24 " (y) For purposes of section 301 (q), 604, and 605,
 25 the term 'commercial distribution' means any distribution

1 outside the establishment manufacturing the product for sale,
2 for promoting future sales (including distribution of free
3 samples of the product), or for measuring consumer
4 acceptance through market testing.”.

5 Deletion of Soap Exemption

6 (b) Section 201 (i) of such Act is amended by strik-
7 ing “articles; except that such term shall not include soap.”
8 and inserting in lieu thereof “articles.”.

9 Prohibited Acts

10 (c) (1) Subsection (e) of section 301 of such Act is
11 amended by striking the word “or” before “512” and add-
12 ing a comma and “604” after “(m)”.

13 (2) Section 301 of such Act is further amended by
14 adding new subsections as follows:

15 “(q) The commercial distribution of any cosmetic which
16 is deemed adulterated under section 604 (a) .

17 “(r) The failure to notify the Secretary of any cosmetic
18 which meets any screening level or criterion required under
19 section 604 (c) .”.

20 Guarantees

21 (d) Section 303 (c) (1) of such Act is amended by
22 striking the period at the end thereof and inserting at the end
23 thereof the following: “, or (6) for having violated section
24 301 (a) or (c) because the cosmetic is deemed adulterated
25 under section 604 (a) , if such person establishes a guarantee

1 in a form and under such conditions as are established by the
2 Secretary by regulations.”.

3 Adulterated and Misbranded Cosmetics

4 (e) (1) Section 601 (a) of such Act is amended to
5 read as follows:

6 “(a) If it bears or contains any poisonous or deleterious
7 substance which may render it injurious to users, or if it is
8 or may be injurious to users, under the conditions of use
9 prescribed in the labeling thereof, or under such conditions of
10 use as are customary or usual, or if it is deemed adulterated by
11 section 604 (a) .

12 (2) Section 601 (e) of such Act is amended to read as
13 follows:

14 “(e) If it is, or it bears or contains, a color additive
15 which is unsafe within the meaning of section 706 (a) . This
16 paragraph shall not apply to any hair dye other than any eye-
17 lash dye or eyebrow dye.”.

18 (f) Section 602 (e) of such Act (21 U.S.C. 362 (e)) is
19 amended by striking “(as defined in the last sentence of
20 section 601 (a)) ” from the second sentence and inserting
21 “(other than any eyelash dye or eyebrow dye)” in lieu
22 thereof.

23

EFFECTIVE DATE

24 SEC. 104. (a) The provision of this title shall take
25 effect upon enactment, except as provided in subsections
26 (b) and (c) .

(b) With respect to cosmetics in commercial distribution on the day immediately preceding enactment of this Act, the provisions of subsections (a) and (d) of new section 604 of the Federal Food, Drug, and Cosmetic Act shall take effect on the first day of the twelfth month following the month in which this Act is enacted, provided that the Secretary may for good cause extend such effective date an additional six months. The definition of "commercial distribution" in new subsection (y) of section 201 of the Federal Food, Drug, and Cosmetic Act shall apply to this section.

(c) The legend required to be placed on the label of a coal-tar hair dye by the proviso of section 601 (a), prior to the enactment of this Act, shall continue to be required until the Secretary promulgates regulations under section 602 prescribing different requirements.

TITLE II—REGISTRATION AND COMPLIANCE

SEC. 201. Chapter VI of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

"REGISTRATION OF COSMETIC PROCESSORS"

"Establishment Registration Required"

"(a) (1) On or before December 31 of each year, every person who owns or operates an establishment engaged in processing a cosmetic shall register with the Sec-

1 retary his name, principal place of business, and the loca-
2 tion of each such establishment, in such manner and form as
3 the Secretary shall prescribe by regulation.

4 “(2) Every person required to register under this sub-
5 section shall, within ten days after commencing operation of
6 any additional establishment, register with the Secretary.

7 “Registration of Cosmetic Lists

8 “(b) (1) Every person required to register under this
9 section shall, for each such establishment, include as part of
10 such registration the following information regarding any
11 cosmetic which is in commercial distribution—

12 “(A) a list of each cosmetic processed in each such
13 establishment by brand name or names;

14 “(B) the product class (as prescribed by the
15 Secretary by regulation) of each such cosmetic;

16 “(C) a list of each ingredient used in each such
17 cosmetic in descending order of predominance by weight,
18 showing the percentage range of each such ingredient,
19 which range shall not deviate by more than 5 per centum
20 from the actual percentage;

21 “(D) the name and principal place of business of
22 that manufacturer or distributor who is to be respon-
23 sible, with respect to each such cosmetic, for the mainte-
24 nance of records relating to safety substantiation required

1 to be kept by section 604 (b) and the location of such
2 records; and

3 “(E) summary information on such cosmetic rele-
4 vant to hazards from accidental ingestion or misuse of
5 such cosmetic (which information shall be based upon
6 such investigations as are necessary to identify such
7 hazards) and, where appropriate, as to antidotes or
8 treatment.

9 “(2) The Secretary may also require the submission by
10 any person required to be registered under this section (as
11 part of annual registration or otherwise) of the following
12 information concerning any cosmetic in commercial distribu-
13 tion if he finds that such submission is necessary or appro-
14 priate to carry out the purposes of this Act—

15 “(A) a quantitative list of the ingredients of any
16 cosmetic,

17 “(B) a list of all cosmetics that include a particular
18 ingredient or fall within a particular cosmetic class or for
19 any particular use;

20 “(C) representative samples of the labeling or all
21 labeling of any cosmetic or class of cosmetics;

22 “(D) information which indicates that there is, with
23 respect to any cosmetic processed by such person which
24 has left an establishment under his control, an unreason-
25 able risk of adulteration; and

1 “(E) information as to any recall of any cosmetic
2 processed by such person which may be adulterated, if it
3 left an establishment under his control.

4 “Changes in Registration Information

5 “(c) The annual registration under subsections (a)
6 and (b) of this section shall include all changes in informa-
7 tion previously submitted. Information previously submitted
8 under such subsections shall not be required to be resubmit-
9 ted in any subsequent annual registration. The Secretary
10 may by regulation specify circumstances under which any
11 changes in the information previously submitted shall be
12 submitted at a date other than that prescribed for the annual
13 registration.

14 “Notification of New Cosmetics

15 “(d) (1) Every person required to register pursuant
16 to this section upon first engaging in processing a cosmetic
17 not previously included in a list submitted by him under
18 subsection (b) (1) shall—

19 “(A) notify the Secretary prior to the proposed
20 commercial distribution of such cosmetic;

21 “(B) submit such information concerning such
22 cosmetic prescribed in subsection (b), as the Secretary
23 shall by regulation require; and

24 “(C) comply with any applicable requirements of
25 section 604.

1 "Notification of Discontinuance and Resumption of

2 Processing

3 "(e) (1) The Secretary shall by regulation require that
4 any person required to register under this section notify him
5 (as part of annual registration or otherwise) of any cosmetic
6 which he has discontinued processing for commercial distri-
7 bution, providing the date of such discontinuance and a brief
8 summary of the reasons therefor.

9 "(2) If such person resumes processing of a cosmetic
10 which is identical, similar, or related to—

11 "(A) a cosmetic which had been the subject of a
12 prior notification under this subsection of discontinuance
13 of processing, or

14 "(B) a cosmetic which had been declared a
15 banned cosmetic under section 604 (e), such person
16 shall, upon such resumption of processing, notify the
17 Secretary of such resumption, the date thereof, and a
18 brief explanation of the reasons for such resumption.

19 "Filing of Adverse Reactions

20 "(f) The Secretary shall by regulation require every
21 person required to register under this section to file with him
22 every report of any adverse reaction received by such
23 person which may have resulted, or is alleged to have re-
24 sulted, from the use of a cosmetic processed by him, within
25 ninety days after receipt of such report. Each such person

1 shall preserve, for at least five years from date of receipt
 2 all such reports, all information regarding such adverse
 3 reaction.

4 "Inspection, Reporting, and Recordkeeping

5 "(g) (1) Every establishment required to register
 6 under this section shall be subject to the inspection and re-
 7 porting requirements of section 704.

8 "(2) Every person required to register under this sec-
 9 tion shall maintain records of all information submitted to
 10 the Secretary under this section. Such information, and other
 11 records relating to such information, may be inspected or
 12 required to be submitted under section 704.

13 "Availability of Information

14 "(h) The Secretary shall make available for inspection,
 15 to any person so requesting, any registration filed pursuant
 16 to this section except to the extent that such information is
 17 a trade secret or other matter referred to in section 1905 of
 18 title 18, United States Code.

19 "Definitions

20 "(i) (1) As used in this section the term—

21 "(1) 'process,' 'processed,' or 'processing' with
 22 respect to cosmetics means the manufacturing, process-
 23 ing, preparing, packaging, labeling, or holding of a cos-
 24 metic in any State, except that such term shall not in-
 25 clude retailers;

1 “(2) ‘name’ shall include in the case of a partner-
2 ship the name of each partner, and in the case of a cor-
3 poration the name appearing on the corporation’s char-
4 ter or certificate of incorporation and the name of each
5 principal corporate officer and director and the State of
6 incorporation;

7 “(3) ‘owns or operates’ means any person who
8 owns, operates, leases, charters, or controls any estab-
9 lishment used in processing a cosmetic;

10 “(4) ‘establishment’ means the premises, building,
11 structures, and facilities used in processing cosmetics;
12 and

13 “(5) ‘adverse reaction’ means any allergic reaction
14 or other bodily injury associated with or contempo-
15 raneous with the use of a cosmetic.”.

16 INSPECTION AND REPORTING

17 SEC. 202. Section 704 (a) of such Act is amended by
18 adding at the end thereof the following new sentence: “In
19 the case of establishments manufacturing, processing, pre-
20 paring, packaging, labeling, or holding a cosmetic in any
21 State, (1) inspection shall extend to all things therein (in-
22 cluding records, files, papers, processes, controls, and facili-
23 ties, but excluding those financial, sales, pricing, personnel,
24 and research data not bearing upon whether the product
25 may be adulterated or misbranded), bearing on whether a

1 cosmetic may be adulterated or misbranded or on whether
2 there has been a violation of section 301; and (2) the owner
3 or operator of any information which may be inspected under
4 this section shall, upon written request by the Secretary,
5 submit such information to him. The district courts of the
6 United States shall have jurisdiction to enforce requests
7 under the preceding sentence and to require access to such
8 information upon application of the Secretary or the Attorney
9 General, in an action brought in any district wherein the
10 person or establishment involved is found or transacts
11 business.

12 ADMINISTRATIVE RESTRAINT AND SEIZURE

13 SEC. 203. (a) Section 304 of such Act is amended by
14 adding at the end the following new subsection:

15 "Administrative Restraint

16 "(g) (1) If during an inspection conducted under sec-
17 tion 704 of an establishment or a vehicle, a cosmetic which
18 the officer or employee making the inspection has reason to
19 believe is adulterated or misbranded is found in such estab-
20 lishment or vehicle, such officer or employee may order the
21 cosmetic detained (in accordance with regulations prescribed
22 by the Secretary) for a reasonable period which may not
23 exceed twenty days unless the Secretary determines that a
24 period of detention greater than twenty days is required to
25 institute an action under subsection (a) to seize the cosmetic,

1 in which case he may authorize a detention period of not to
2 exceed thirty days. A detention order under this paragraph
3 may require the labeling or marking of a cosmetic during
4 the period of its detention for the purpose of identifying the
5 cosmetic as detained. Any person who would be entitled to
6 claim a cosmetic if it were seized under subsection (a) may
7 appeal to the Secretary a detention of such cosmetic under
8 this paragraph. Within five days of the date an appeal of a
9 detention is filed with the Secretary, the Secretary shall after
10 affording opportunity for an informal hearing by order con-
11 firm the detention or revoke it.

12 “(2) (A) Except as authorized by subparagraph (B),
13 a cosmetic subject to a detention order issued under para-
14 graph (1) shall not be moved by any person from the place
15 at which it is ordered detained until—

16 “(i) released by the Secretary, or

17 “(ii) the expiration of the detention period appli-
18 cable to such order,
19 whichever occurs first.

20 “(B) A cosmetic subject to a detention order under
21 paragraph (1) may be moved—

22 “(i) in accordance with regulations prescribed by
23 the Secretary, and

24 “(ii) if not in final form for shipment, at the dis-
25 cretion of the manufacturer of the cosmetic for the pur-

1 pose of completing the work required to put it in such
2 form.”.

3 Seizure of Any Adulterated or Misbranded Cosmetic

4 (b) Section 304 of such Act is further amended (1) by
5 striking out “and” before “(C)” and, (2) by striking out the
6 period at the end and inserting in lieu thereof a comma and
7 the following: “and (D) any adulterated or misbranded
8 cosmetic.”.

9 CONFORMING AMENDMENTS

10 Prohibited Acts

11 SEC. 204. (a) Section 301 of such Act is further
12 amended by adding the following new paragraphs:

13 “(s) The failure to register under section 605, or to
14 submit or maintain any information as required by or under
15 section 605, or to submit any information as required under
16 section 704.

17 “(t) The movement of a cosmetic in violation of an
18 order under section 304 (g) or the removal or alteration of
19 any mark or label required by the order to identify the cos-
20 metic as detained.”.

21 Misbranded Cosmetics

22 (b) Section 602 of such Act is further amended by add-
23 ing at the end thereof the following new paragraph:

24 “(i) If it was processed in an establishment which was
25 not registered as required under section 605, or if informa-

1 tion concerning it is not submitted or maintained as required
2 under section 605, or if information concerning it is not sub-
3 mitted as required under section 704.”.

4 Imports

5 (c) Section 801 (a) of such Act (21 U.S.C. 381 (a))
6 is amended by inserting “(1)” immediately after “(a)”
7 and adding at the end thereof:

8 “(2) The Secretary shall refuse entry of any cosmetic
9 offered for importation into the United States which has
10 been processed in any establishment other than an establish-
11 ment registered or exempt from registration pursuant to sec-
12 tion 605.”.

13

EFFECTIVE DATES

14 SEC. 205. Cosmetic processors shall first register pur-
15 suant to section 605 of the Federal Food, Drug, and Cos-
16 metic Act on the first day of the third month after regula-
17 tions are promulgated under section 605 of the Federal Food,
18 Drug, and Cosmetic Act and registration forms made avail-
19 able by the Secretary of Health, Education, and Welfare.
20 All other provisions of this title shall take effect upon enact-
21 ment.

22

TITLE III—COSMETIC LABELING

23 SEC. 301. (a) Section 602 of such Act is further
24 amended by adding at the end thereof the following new
25 subsections:

1 "Cosmetic Ingredient Labeling

2 "(g) (1) Unless labeling affixed to or within the pack-
3 age bears—

4 "(A) the common or usual name of the cosmetic,
5 if any, and

6 "(B) in case it is fabricated from two or more in-
7 gredients, the common or usual name of each such in-
8 gredient in the order of decreasing predominance by
9 weight.

10 The first sentence of this subsection shall not apply in a case
11 where an ingredient is a color which is declared in a manner
12 that accurately states the nature of the ingredients without
13 regard to order of predominance, and a fragrance and flavor
14 may be designated as fragrance and flavor without naming
15 each ingredient, except that the Secretary may by regulation
16 require any fragrance or flavor ingredient to be named on
17 such labels upon a finding that such disclosure is necessary to
18 protect the public health or to provide information useful to
19 consumers.

20 "(2) Subject to such conditions as the Secretary may by
21 regulation provide—

22 "(A) this subsection shall not apply to cosmetics
23 sold in bulk or to incidental additives that are present in
24 a cosmetic in insignificant levels and which do not have
25 any technical or functional effect in such cosmetic, and

1 “(B) closely related ingredients may be declared
2 by a general term or without regard to order of pre-
3 dominance in a manner that accurately states the nature
4 of the ingredients.

5 “Warning and Other Labeling

6 “(h) Unless its label or labeling bears adequate warn-
7 ings against use where it may be hazardous to health, or
8 such warnings or information as the Secretary may by reg-
9 ulation require with respect to use which the Secretary has
10 determined to be necessary for the protection of the public
11 health or appropriate as a guide to use.”.

12 EFFECTIVE DATE

13 SEC. 302. The amendments made by this title shall be
14 effective on the first day of the thirteenth calendar month
15 following the month in which this Act is enacted.

16 TITLE IV—GENERAL PROVISIONS CONCERNING
17 COSMETICS

18 SEC. 401. Chapter VI of the Federal Food, Drug, and
19 Cosmetic Act, as amended by this Act, is further amended
20 by inserting at the end thereof the following:

21 “GENERAL PROVISIONS CONCERNING COSMETICS

22 “Poison Control Information

23 “SEC. 606. (a) The Secretary shall establish a system
24 for making publicly available, through poison control centers
25 and other appropriate means, the summary information col-

1 lected under section 605 (b) (1) (E) relevant to hazards
2 from accidental ingestion or misuse of cosmetics and anti-
3 dotes or treatment. Such system shall assure that such infor-
4 mation is available at any time to persons (including phy-
5 sicians, hospitals, clinics, and poison control centers) who
6 request such information to aid in treatment of individuals
7 who may be injured as a result of the ingestion of, contact
8 with, or exposure to, any cosmetic. The system shall also
9 include a continuing program by the Secretary to inform
10 physicians, hospitals, clinics, and poison control centers, and
11 other persons to whom such information may be useful, of the
12 availability of such information and the methods by which
13 it may be obtained at any time.

14 "Small Business Assistance

15 " (b) The Secretary shall cooperate with the Small
16 Business Administration with respect to applications (under
17 section 7 (b) (5) of the Small Business Act, as amended
18 (15 U.S.C. 631)) for loans to assist affected small business
19 entities to comply with requirements under sections 604 and
20 601 (f). The Small Business Administration shall direct
21 that applications from such small business entities, regarding
22 proposed additions to or alterations in plants, facilities, or
23 methods of operation which are designed to enable such en-
24 tities to comply with such requirements, shall be reviewed
25 by the Secretary. The Secretary shall evaluate each such

1 application and shall report to the Administrator (or to the
2 bank or lending institution) within sixty days to determine
3 if such additions or alterations are appropriate and necessary
4 to assist the applicant to comply with such requirements and
5 whether he recommends that the loan be granted.

6 "Effect on State Law

7 "(c) (1) It is declared to be the express intent of Con-
8 gress to supersede any and all laws of the States or political
9 subdivisions thereof, insofar as they may now or hereafter
10 provide for information on the label or in labeling of a cos-
11 metic which is in addition to or different from information
12 required on the label or in labeling by or under section 602
13 of this Act, except as provided in this section.

14 "(2) Upon application of a State or political subdivision
15 thereof, the Secretary may by regulation, after notice and
16 opportunity for oral presentation of views, exempt from the
17 provisions of paragraph (1) (under such conditions as he
18 may impose) a proposed safety requirement described in
19 such application, where the proposed requirement—

20 "(A) imposes a higher level of performance than
21 the Federal standard,

22 "(B) is required by compelling local conditions,
23 and

24 "(C) does not unduly burden interstate commerce.

1 "Procedures and Judicial Review

2 "(d) (1) Proceedings to issue, amend, or repeal a
3 regulation under this chapter shall be conducted in accord-
4 ance with the procedures prescribed by section 553 of title
5 5 of the United States Code.

6 "(2) In the case of any regulation or order under this
7 chapter any interested person (including a consumer or con-
8 sumer organization), who may be adversely affected by such
9 regulation or order may, at any time within sixty days after
10 the regulation or order is issued by the Secretary, file a peti-
11 tion with the United States Court of Appeals for the District
12 of Columbia, or for the circuit wherein such person resides
13 or has the principal place of business, for judicial review of
14 such regulation or order. A copy of the petition shall be
15 transmitted by the clerk of the court to the Secretary or other
16 officer designated by him for that purpose. The Secretary
17 shall file in the court the record of the proceedings on which
18 the Secretary based his regulation or order as provided in
19 section 2112 of title 28 of the United States Code. For pur-
20 poses of this subsection, the term 'record' means all notices
21 and other matter published in the Federal Register with
22 respect to the regulation or order reviewed, all information
23 submitted to the Secretary with respect to such regulation
24 or order, proceedings of any advisory committee with respect
25 to such regulation or order, any hearing held with respect

1 to such regulation or order, and any other information identi-
2 fied by the Secretary, in the administrative proceeding held
3 with respect to such regulation or order, as being relevant to
4 such regulation or order.

5 “(3) If the petitioner applies to the court for leave to
6 adduce additional evidence, and shows to the satisfaction of
7 the court that such additional evidence is material and that
8 there was no opportunity to adduce such evidence in the
9 proceeding before the Secretary, the court may order such
10 additional evidence (and evidence in rebuttal thereof) to
11 be taken before the Secretary in a hearing or in such other
12 manner, and upon such terms and conditions, as to the court
13 may deem proper. The Secretary may modify his findings,
14 or make new findings, by reason of the additional evidence
15 so taken, and he shall file such modified or new findings,
16 and his recommendation, if any, for the modification or set-
17 ting aside of his original regulation or order, with the return
18 of such additional evidence.

19 “(4) Upon the filing of the petition under subsection
20 (b) of this section, the court shall have jurisdiction to re-
21 view the regulation or order of the Secretary in accordance
22 with subparagraphs (A), (B), (C), and (D) of para-
23 graph (2) of section 706 of title 5 of the United States Code.
24 If the court orders additional evidence to be taken under
25 subsection (c) of this section, the court shall also review

1 the Secretary's regulation or order to determine if, on the
2 basis of the entire record before the court pursuant to sub-
3 sections (b) and (c) of this section, it is supported by sub-
4 stantial evidence. If the court finds the regulation or order
5 is not so supported, the court may set it aside.

6 “(5) With respect to any regulation or order reviewed
7 under this section, other than a regulation made effective
8 upon publication in the Federal Register pursuant to sec-
9 tion 604(e) (2), the court may grant appropriate relief
10 pending conclusion of the review proceedings, as provided
11 in section 705 of such title 5.

12 “(6) The judgment of the court affirming or setting
13 aside, in whole or in part, any such regulation or order of the
14 Secretary shall be final, subject to review by the Supreme
15 Court of the United States upon certiorari or certification,
16 as provided in section 1254 of title 28 of the United States
17 Code.

18 “Advisory Committees

19 “(e) The Secretary may appoint advisory committees
20 to assist in the administration of this chapter. Any such com-
21 mittee shall consist of members who are individuals appro-
22 priately qualified by training and experience and shall in-
23 clude, as nonvoting members, a representative of consumer
24 interests and a representative of industry interests. The Sec-
25 retary shall prescribe by regulation the procedures to be fol-

1 lowed by such committees and shall assure that each com-
2 mittee provides, to the maximum extent practicable, an
3 opportunity for any interested person to submit data and
4 views on all matters considered by the committee. All meet-
5 ings of the committee shall be open in accordance with the
6 requirements of the Federal Advisory Committee Act.”.

7 SEC. 402. The provisions of this title shall take effect
8 on the date of enactment of this Act, except that new section
9 606 (c) shall be effective on the first day of the seventh
10 calendar month following the initial registration pursuant to
11 new section 605 of the Federal Food, Drug, and Cosmetic
12 Act.

Senator EAGLETON. I am pleased to call Leonor K. Sullivan of my native city of St. Louis.

She is my Congresswoman, and a very great one, indeed.

Mrs. Sullivan, we welcome you, and we are pleased to have you with us this morning.

STATEMENT OF LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Thank you Mr. Chairman.

Mr. Chairman, I am delighted to be able to come before you again this morning.

Sixteen months ago, when this committee held its first hearings in 36 years on the need for improvements in the cosmetics provisions of the Food, Drug, and Cosmetic Act of 1938, I was delighted to have the opportunity to open the testimony by tracing the long history of congressional inaction on a matter of urgent personal, intimate importance to every man, woman, and child in this country—all of them users of some products officially designated as cosmetics.

These products can be freely marketed by anyone who wants to go into the business, without any effective Government supervision over the ingredients used. They do not have to be proven safe before being placed on sale.

True, [the Food and Drug Administration can remove from the market any cosmetic product it discovers is dangerous to the user if it can prove that it is dangerous. But what the FDA does not know about these products can hurt you and me and everyone else because FDA learns about unsafe products only after they have caused harm to some or many consumers.

Most cosmetics are safe for most users. But millions of Americans are allergic to some or many of the multitude of fragrance or coloring chemicals and other ingredients used in toothpastes, mouthwashes, shaving soaps, aftershave lotions, suntan preparations, shampoos, talc, and deodorants as well as lipsticks, skin creams, eyeliners, eyebrow pencils, mascara, eye shadow, depilatories, mositurizers, bath oil or bubble bath products, nail polishes, hair sprays, hair coloring, mudpacks, face powders—the list goes on and on, and everyone in this room uses some or many of these products daily. And not one of us is in a position to know for sure what is in the cosmetic products we buy unless the manufacturer or distributor voluntarily chooses to share that information with us. Few cosmetics sellers are willing to give us that information.

And that is the way it has been ever since the enactment 37 years ago of the Food, Drug, and Cosmetic Act of 1938 first brought cosmetics under even the weak and ineffectual regulation now in effect.

How many more years are the consumers of this country going to stand for such a monumental threat to their well-being?

Must we wait until someone markets a product of such heinous harmfulness that enough people are seriously enough injured—blinded, or scalped, or burned, or blistered, or denailed, or subjected to blood or kidney or liver or other internal injuries—as to force the Congress to legislate effective cosmetic controls?

Sixteen months ago, this subcommittee held very useful and informative hearings on the dangers from inadequately regulated cosmetics. But nothing further happened. No legislation was passed; none was even worked on at the subcommittee level. There were no markup sessions.

In the House, it has been 13 years since there were even hearings on the issue.

I think it is time to get moving. I congratulate you, Senator Eagleton, for championing this issue on the Senate side, and bringing your great ability and enthusiasm for the public welfare to bear on safe cosmetics legislation.

You are going to need help, Senator—far more help than you or I have received on this issue so far. Unless we get some very substantial help from consumers and their organizations, and from the medical profession—particularly the dermatologists who know whereof we speak—the incredibly effective cosmetics lobby is going to succeed in mothballing this issue for another 16 months, or 13 years, or 37 years.

If we cannot pass effective cosmetics safety and labeling legislation in this Congress, with such a preponderance of Members professing to be committed to consumer causes, then we will probably have to wait for the kind of public disaster that will become the thalidomide of cosmetics safety—the kind of episode which, in 1962, precipitated long overdue reforms in drug safety legislation.

Why do we have to kill or maim our way to consumer legislation reform?

The Food and Drug Administration, which should be leading the way for legislative reforms, has been playing a low-profile role on this issue for the past 7 years. They have proposed to handle the problem by voluntary action on the part of the cosmetics industry and regulations based to a large extent on legislative authority which does not exist.

Essential provisions of effective legislation. These are the things we must do:

One: Require pretesting for safety of all ingredients used in cosmetics. The testing should be done by the industry and checked by the FDA.

Two: Require full listing on the label of every ingredient contained in the product which an allergic consumer or careful shopper needs to know about in buying these products and using them without discomfort or injury—including the specific coloring and fragrance chemicals used. This may require a “hang-tag” on a lipstick, but that is no hardship. The claim of “trade secrets” is nonsense. There are few secrets in this trade except where the consumer is concerned.

Three: Open the complaint files of the cosmetics manufacturers and distributors to the Food and Drug Administration so that the agency can become alerted to the products which are causing widespread injuries.

Four: Eliminate the ridiculous exemption since 1938 for soap. Soap was excluded in the original act because the soap manufacturers were the biggest advertisers in the country—remember the “soap operas” of radio?—and the soap industry threatened to throw its full resources into defeating the entire bill if soap were included. They got away with that in 1938. Do they still have that kind of power over the Congress of the United States 37 years later?

Five: Make coal tar hair dyes subject to the same controls as any other cosmetic product, instead of being given further renewal of their 37-year-old license to injure the user without restraint. All they have to do now is place a warning on the container that the product may be dangerous. Very few, if any, patrons of beauty shops ever see the warning on the bulk containers of hair dyes.

Six: Prohibit the use of any ingredient in cosmetics which is carcinogenic to man or animal if ingested or applied.

Seven: Provide for full warnings to the consumer of flammability or other dangers from the use or misuse of a cosmetic product, including instructions on what to do in case of accidental ingestion by a child.

Eight: Regulate the use of dangerous pressurized containers.

Nine: Stop the mounting carnage among consumers who are not now protected either by the Food and Drug Administration or the Consumer Product Safety Commission from unsafe cosmetics.

Ten: Preferably, include safe cosmetics legislation in an omnibus bill, such as H.R. 1235, to attack all of the other major loopholes in the 1938 act, including those applying to medical devices, food labeling, certification of antibiotics or other unstable drugs, the distribution of sample drugs, the use of carcinogenic ingredients in animal feeds, the "grandfather's clause" for food additives in use prior to 1958, mutagenic and teratogenic agents not covered by the "Delaney-Sullivan Clause" of the 1958 Food Additives Act, and so on and so on. They are all spelled out in my omnibus bill, H.R. 1235.

In my testimony before this subcommittee on February 20, 1974, I described the step-by-step history, and all of the frustrations of 21 years of trying to close the loopholes in the 1938 statute, many of which were deliberately written into the law 37 years ago, and others which developed as a result of court decisions and new technology.

Unfortunately, I cannot even refer you to the printed testimony because your 1974 printed hearings turned my statement into a shambles.

It begins on page 29, continues on page 28, then resumes on page 34 to the middle of page 38, and part of it is attributed to Senator Kennedy, and most of it to you, Senator Eagleton. What appears to be most of my statement is a major portion of your opening remarks.

I have looked over my remarks from last year as I gave them, and they are just as valid now as they were then. Rather than reread those remarks to you, I would appreciate it if you would just let me incorporate them as part of my statement this morning, with the hope that this time they might appear in the record correctly.

Senator EAGLETON. Without objection, they will be so printed, and we hope they come in a continuous flow.

[The statement referred to follows:]

STATEMENT OF HON. LEONOR K. SULLIVAN A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF MISSOURI BEFORE SUBCOMMITTEE ON HEALTH ON COSMETICS
SAFETY AND LABELING OF COSMETICS PRODUCTS, FEBRUARY 20, 1974

The first thing I want to do this afternoon is to thank Chairman Kennedy and Senator Eagleton for making it possible for me to participate in what I regard as a historic occasion. I believe this is the first time in a dozen years that a legislative committee on either side of the Capitol which has jurisdiction over the Food, Drug, and Cosmetic Act of 1938 has scheduled hearings on legislation to amend the cosmetics sections of that Act. On behalf of 210 million Americans who use

cosmetics—and who are the guinea pigs for testing the safety of cosmetic products—I sincerely hope that these hearings will lead to effective action by the Congress to close glaring loopholes which were deliberately written into the Food, Drug, and Cosmetic Act 36 long years ago, and which have remained virtually untouched in that Act ever since.

Even the best of laws need updating after 36 years. But the law providing for Federal regulation of cosmetics was defective—and known to be defective—when it was enacted in 1938. Yet in the intervening years, the only change in the law has been in connection with the coloring matter used in cosmetics. That was in 1960. That was 14 years ago. The only reason changes were made in the Act in 1960 was that the cosmetic industry itself came rushing in that year with a fervent plea for immediate passage of legislation which would rescue the industry from what it regarded as a disaster. And Congress was quick to oblige the cosmetic industry by passing the law the industry demanded, the Color Additives Act of 1960.

A brief recital of that history might be instructive to this subcommittee. The 1938 Act provided that no coal tar colors could be used in foods, drugs, or cosmetics unless they were "harmless". The Food and Drug Administration thereupon set up an elaborate system for testing and certifying coal tar color additives on a batch-by-batch basis, and developed numerous colors suitable for use in different types of products, depending upon whether they were ingested by the consumer or whether they were used in ways which would not lead to their ingestion. But as testing techniques became more sophisticated, the Food and Drug Administration discovered that some of its colors officially certified as harmless were not, in fact, completely harmless because, if ingested by test animals in sufficiently large quantities—usually very large quantities—injuries resulted to the liver or other organs. Therefore, some of the popular colors used in lipsticks and other cosmetics had to be withdrawn from certification and use. As soon as this happened, the cosmetic industry came rushing into Congress to ask for a revised color safety law which would eliminate the "harmless" test and permit the use of any coloring matter which was found to be generally safe for the purposes for which it was intended to be used. That was in 1960. But nothing was done at that time, and nothing has been done since that time, to require proof of safety before marketing of any ingredients in a cosmetic product other than the coloring matter.

MOST COSMETICS SAFE FOR MOST USERS

I want to acknowledge the fact that most ingredients used in most cosmetic products are safe for most consumers. Some of these ingredients are as old as civilization itself. But in a highly competitive, advertising-oriented industry where being first on the market with something new is a great sales promotion gimmick, new products can be marketed without adequate testing and if they turn out to be dangerous to the consumer, it is up to the Food and Drug Administration to ferret them out, conduct the testing and establish legal proof that a product is unsafe in order to move against it.

This is wrong. This was also the law as it related to new drugs up until 1938, but the 1938 Act ended that situation by requiring the manufacturer to establish the safety of a drug product before it could be placed on the market. It was also the law as regards food additives until 1958. Between 1938 and 1958, a food manufacturer could market a product containing unsafe food chemicals and it was up to the FDA to prove it was dangerous in order to remove the product from sale. The 1958 Act changed that insofar as food additives are concerned, requiring proof of safety before the product could be sold. But the pretesting of cosmetic ingredients for safety has never been required other than for color during the 36 years in which cosmetics have been subject to any form of Federal regulation.

This is an indefensible situation, jeopardizing the health and safety of 210 million American men, women and children who use products legally defined as cosmetics almost every day in some form or other, from mouthwashes and toothpaste to shaving cream and hair dyes, baby powder or shampoos.

CURRENT EXEMPTION FOR SOAP

I said that most cosmetic ingredients are safe for most consumers, and that is true. But increasing numbers of Americans are discovering that they are allergic to many things in our environment—food additives, color additives, plants, fruits, airborne chemicals from industrial pollution, and a variety of

drugs from aspirin to antibiotics. Once an individual knows what chemicals he or she is allergic to the consumer can look at the labels of foods or over-the-counter drugs and avoid those which pose a threat to one's personal safety or well-being. But the labels of cosmetic products tell the consumer nothing whatsoever about the ingredients to enable the individual to protect himself or herself from a cosmetic which can cause a painful and even dangerous reaction. This, too, is an intolerable gap in consumer protection.

The most ridiculous loophole in the Food, Drug, and Cosmetic Act of 1938 as it relates to cosmetics is the exemption for soap. Under the 1938 law, soap is not a cosmetic. What is it? It is certainly not a food; in rare instances where therapeutic values are claimed for it, it might be regarded as a drug. But under the Food, Drug, and Cosmetic Act, soap is a nothing—it doesn't exist. This loophole, also must be closed after 36 years.

THE COAL TAR HAIR DYE EXEMPTION

Let me cite another: hair dyes—particularly the permanent coal tar dyes—are not subject to any regulation whatsoever as to their safety as long as the manufacturer places a warning on the label of possible danger and advises the user to make a patch test before applying the product. Permanent dyes are usually applied in beauty parlors, rather than at home. The patron of a beauty parlor does not usually see the container in which the product comes from the manufacturer. So every once in awhile an occasional woman loses much or all of her hair, or suffers indescribable agonies from a burned or blistered scalp because the beauty parlor failed to make a patch test before applying the dye. You seldom hear of these cases because they seldom if ever get to court—the manufacturers are quick to settle any claim resulting from the horrible injuries resulting from the use of unsafe hair dyes. How can anyone defend that loophole in the law?

Just as there are ingredients listed on the label of most cosmetics products to warn the allergic consumer of the presence of ingredients that he or she might know to be injurious, the Food, Drug, and Cosmetic Act does not require warnings on the label—other than for a coal tar hair dye preparation—of the danger inherent in the use of a particular product. Hair sprays contain flammable ingredients and also ingredients that can cause lung disease, but any warning that you find on the label is there because the manufacturer voluntarily put it there or else because state law might require it. Many cosmetic products are poisonous if swallowed by children, but there is nothing in the Food, Drug, and Cosmetic Act to require a warning to that effect or to guide the parent on what to do if the child does ingest nail polish remover or other dangerous products. The Hazardous Substances Labeling Act of 1960 required warnings on all household products except that cosmetics, being covered by the Food, Drug, and Cosmetic Act and presumably regulated by that Act, are therefore exempted from the application of the Hazardous Substances Labeling Act. This is in effect a double exemption for cosmetics and is another intolerable loophole.

FEW INJURIES REPORTED TO FDA

Only a tiny fraction of the injuries which are suffered by consumers each year in the use of cosmetics is ever reported to the Food and Drug Administration. The National Commission on Product Safety established that fact four years ago when it surveyed claims made to insurance companies for injuries resulting from cosmetic products. The Commission reported that there are about 60,000 cosmetic injuries a year. The Food and Drug Administration, on the other hand, receives no more than 300 or 400 complaints each year. Furthermore, the inspectors of the Food and Drug Administration do not have access to the complaint files of the manufacturers even though these complaints to the manufacturers could immediately alert the FDA to the existence of a problem product which should be investigated immediately for safety.

Now how have we managed to allow this situation to go on for 36 years under a law which presumably protects the consumer in the use of cosmetics? There are two explanations: the first is that the public doesn't realize how poorly it is protected by Federal law in the use of cosmetics; and, secondly, the Food and Drug Administration—with a variety of other problems it has encountered in recent years—regards the cosmetic safety issue as one of relatively low priority, and has been reluctant for the past five years to ask for the kind of legislation it needs.

The Food and Drug Administration did not always feel that way. Back in the 1950's when I introduced the first cosmetic safety bill along with Congressman James J. Delaney of New York—at the same time that we also introduced the

legislation which became the Food Additives Act of 1958—the FDA strongly supported the kind of legislation which I have been introducing repeatedly in every Congress beginning in 1954. It took us four years to get the Food Additives Act passed, but nothing was done legislatively then or later about the safety of cosmetics. In 1960, as I said, the industry itself came in to ask for the Color Additives Act, and Congress quickly passed it but refused to include in that law anything dealing with ingredients of cosmetics other than the coloring matter. For an extended period after 1960, the Food and Drug Administration attempted to stretch the application of the Color Additives Act to include pretesting for safety of all ingredients in a colored cosmetic product. But the industry went to court to overturn that regulation and succeeded in doing so.

ACTION TO CLOSE LOOPHOLES LONG OVERDUE

In 1961 I introduced for the first time the bill H.R. 1235 to rewrite the entire Food, Drug, and Cosmetic Act of 1938 to close *all* of the loopholes in that Act, dealing not only with cosmetics but with the efficacy of drugs and of medical devices, the certification of all antibiotics and of other erratic lifesaving drugs, the use of coloring matter in dairy products, and so on. As Secretary of Health, Education, and Welfare at the time, Senator Ribicoff endorsed practically everything in H.R. 1235 as introduced in 1961; in 1962, the first Consumer Message ever sent to Congress by a President, President John F. Kennedy also called for re-writing the 1938 Food, Drug, and Cosmetic Act along the lines of H.R. 1235. The House Committee on Interstate and Foreign Commerce held a week of hearings on this legislation in 1962—mostly for educational purposes—in contemplation of legislation in the following Congress. However, when the thalidomide tragedy broke upon the world that summer of 1962, the Committee reopened its hearings, but only on the subject of drug safety and the Kefauver-Harris Act of 1962 was the result. I am proud to say that most of the provisions of the Kefauver-Harris Act came out of the original version of H.R. 1235 as introduced in January of 1961. But cosmetics safety legislation was again put off, as it had been in 1958, until “later”.

In the dozen years since 1962, the House Committee has never held any legislative hearings on H.R. 1235 as an omnibus bill, or on the cosmetic sections of that bill. These, beginning today, are the first hearings, I believe, in the Senate Committee on Labor and Public Welfare on the subject of cosmetic safety in the past dozen years, and perhaps as far back as 1938, although I have not researched that point.

ATTEMPTS TO STRETCH APPLICATION OF OTHER LAWS

I said that the Food and Drug Administration had strongly supported corrective legislation on cosmetics and on other aspects of the loophole-ridden Food, Drug, and Cosmetic Act in the 50's. It also did so in the 1960's. But from the time President Nixon took office in 1969, until last week, I do not believe that the Food and Drug Administration or the Department of Health, Education, and Welfare ever asked for any legislation whatsoever dealing with cosmetic safety. Instead it appealed to the industry for voluntary cooperation in disclosing to the FDA, if not to the public, the ingredients of its formulae. Although hundreds of cosmetics firms have complied with the request, the information on ingredients used is not available to the public and may never become public knowledge.

Also, just as the agency tried after 1960 to stretch the application of the Color Additives Act to cover ingredients not contemplated in the 1960 Color Additives Act, the agency now is seeking to require the ingredient labeling of cosmetic products under the Fair Packaging and Labeling Act of 1966. I think the legislative history of the Fair Packaging and Labeling Act, particularly as it was debated on the House Floor in 1966, would provide any section of the cosmetic industry—if it chooses to fight the FDA's proposed regulation—powerful ammunition to use in the courts to prove that the Fair Packaging and Labeling Act was not designated to accomplish what the Food and Drug Administration is trying to do under it insofar as cosmetic labeling is concerned. A much more forthright approach would be to amend the Food, Drug, and Cosmetic Act to require the listing on the label of all ingredients, as my bill proposes and as Senator Eagleton's bill proposes, permitting exemptions from this requirement only when the Secretary finds that no practical purpose is served. But I certainly oppose any proposal which would exempt color or—as the FDA itself has proposed to do—the listing of specific fragrance ingredients.

I am not a chemist or an allergist and am not qualified to discuss the reactions from specific cosmetic chemicals but I do know, from the many, many women and some allergists I have heard from on this issue that coloring matter and fragrances are often the culprits in cosmetic allergies. A woman in my district has discovered that she has an allergic reaction in the form of raging headaches from all coal derivatives, from aspirin to coloring matter. Her shopping experience is, in itself, a headache in trying to find products free of the kinds of coloring matter she must avoid.

COSMETICS SAFETY IS PART OF A LARGER PROBLEM

I am deeply grateful for the work done by Senator Eagleton in pressing the cosmetics safety issue in this Committee of the Senate. His cosmetic labeling amendment to the Consumer Product Safety bill several years ago would have been a strong step forward; unfortunately, his amendment was not germane to that bill in the House. If you can get a good cosmetics bill through the Senate, I will certainly do my best to help get it through the House. Speaking personally, I would prefer to see this issue handled, as it is in H.R. 1235, as part of an omnibus bill to rewrite—and close all of the many major loopholes in—the 36-year-old Food, Drug, and Cosmetic Act. There are so many outdated provisions of the 1938 Act which pose serious threats to consumer safety that cosmetics safety, important as it is, is only one part of a much bigger problem. I introduced H.R. 1235 as an omnibus bill and have reintroduced and expanded it in every Congress since the 87th Congress because I was deeply concerned over the snail-like pace in which Congress was acting to remedy the faults in the basic Act—one aspect at a time in 1958, 1960, 1962, 1965, and so on.

Many of the major deficiencies in the 1938 Act have been known to us for 36 years. All of them have been known to us for at least 13 years. Much as I want cosmetics safety legislation passed—and I will do all I can to help pass it, either as a separate measure or as part of an omnibus bill to rewrite the 1938 Act—I would hate to see Congress take the attitude that by passing cosmetics legislation alone, it was solving enough of the consumer's immediate concerns to permit postponing further changes in the Food, Drug, and Cosmetic Act for another dozen years or so. In conclusion, I would like permission to append to my statement the title of H.R. 1235 which lists all of the areas covered by his bill. I think anyone reading just the title of that bill cannot help but be struck by the magnitude of the inadequacies of our most basic consumer safety law.

[The title follows:]

(H.R. 1235, a bill To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to amend certain labeling provisions of the food, drug, and cosmetic chapters to assure adequate information for consumers, including cautionary labeling of articles where needed to prevent accidental injury: expand the coverage the "Delaney Clause" to apply to mutagenic and teratogenic agents; eliminate "Grandfather's Clause" for pre-1958 chemical additives used in food; require nutritional labeling of foods; require labeling of all ingredients in foods, listed in order of predominance; prohibit worthless ingredients in special dietary foods; authorize the establishment of standards for medical devices; require medical devices to be shown safe and efficacious before they are marketed commercially; require all antibiotics to be certified; provide for certification of certain other drugs; require records and reports bearing on drug safety; limit the distribution of sample drugs; require cosmetics to be shown safe before they are marketed commercially; clarify and strengthen existing inspection authority; make additional provisions of the Act applicable to carriers; provide for administrative subpoenas; provide for strengthening and facilitating mutual cooperation and assistance, including training of personnel, in the administration of that Act and of related State and local laws; prohibit the use of carcinogenic color additives in animal feeds; safeguard the health of children by banning sweetened or flavored aspirin from commerce; authorize a system of coding for prescription drugs; establish a United States Drug Compendium; *** insure the wholesomeness of fish and fishery products; * * *

Mrs. SULLIVAN. Thank you.

That is my testimony this morning.

Senator EAGLETON. Thank you very much, Mrs. Sullivan.

You have long been a leader in the Congress in terms of consumer legislation and have detailed for us the long history, predating these hearings, both in 1974 and today.

I just have two questions for you, if I may.

One deals with your first point, and one deals with your second point.

In point No. 1, you say that all the testing should be done by the industry and checked by the FDA.

By checked by the FDA, do you mean premarket clearance, or do you mean the FDA should have ready access to safety data?

Mrs. SULLIVAN. It should be premarket clearance. There is a specified period of time given under my bill—and I think yours has a different time, as I recall—during which FDA must come back with an answer, yes, or no. If they don't, the product can go on sale. There are so many days to clear it. They must come back with a yes or no answer within a certain time.

Senator EAGLETON. Ours does not go quite as far as your bill, H.R. 1235. You would have an actual premarket clearance situation before it could go on the market.

Ours tilts the other way. The data would have to be available when the FDA wanted it and requested it. So we will have to ponder the differences between the two bills.

Now, in your point number 2, ingredient labeling, in the draft of our bill we say the ingredients should be listed on the item in descending order of predominance.

A suggestion has been made to us by a cosmetic manufacturer that that is not the best way to do it, that it would be preferable to list the ingredients alphabetically.

Do you have any strong feeling whether it should be in descending order of predominance vis-a-vis alphabetically?

Mrs. SULLIVAN. I can give you one example of why I would like to see it in order of predominance.

For instance, a cosmetic that sells itself on the claim that it contains lanolin.

Lanolin is the one thing the skin will absorb. If that ingredient is just put down under the "L's" instead of up at the top, or in the middle, you will not know how much water has been mixed in compared with that lanolin. And some lanolin can be in there, but if it is in the order of the dominance of the product, then you know that if it is a predominantly lanolin product that ingredient is going to be listed up there at the top of the ingredient list.

Senator EAGLETON. Very good.

Thank you very much, Mrs. Sullivan, once again for the significant contribution you have made in this area.

I have two hopes for this year.

Hope No. 1 is that your statement is printed in the proper form that it should be, and No. 2, that this is the year that we pass meaningful cosmetic legislation.

Mrs. SULLIVAN. I hope we can do so.

No woman wants to do without cosmetics, but they all want to be sure that a cosmetic product they buy and pay for is not going to injure them. I do not want to see a calamity such as occurred before the cosmetic title of the act was passed in the first place, back in 1938, after a number of women suffered blindness from eye lash dyes, and

many were hurt by mascara. I hope we can pass effective legislation without that kind of tragedy.

Thank you very much.

Senator EAGLETON. Thank you, Mrs. Sullivan.

We will now call as witnesses a group of gentlemen who represent the American Academy of Dermatology.

If they will begin to come forward, please.

Dr. Walter G. Larsen presently holds the office of assistant secretary-treasurer of the American Academy of Dermatology, and secretary-treasurer of the North American Contact Dermatitis Group, and president of the Oregon Dermatologic Society. He is an associate clinical professor of dermatology of the University of Oregon Medical School.

Dr. Larsen, we welcome you.

I will ask you to introduce your associates, who you may want to be seated with you, and we will await your testimony with great interest.

STATEMENT OF WALTER G. LARSEN, M.D., SECRETARY-TREASURER, NORTH AMERICAN CONTACT DERMATITIS GROUP; ACCOMPANIED BY WILLIAM P. JORDAN, JR., M.D., ASSOCIATE PROFESSOR OF DERMATOLOGY, MEDICAL COLLEGE OF VIRGINIA, RICHMOND, VA., AND WILLIAM F. SCHORR, M.D., ASSOCIATE CLINICAL PROFESSOR OF DERMATOLOGY, UNIVERSITY OF WISCONSIN AND UNIVERSITY OF MINNESOTA, A PANEL

Dr. LARSEN. Thank you, Senator Eagleton.

I will open with a short comment and my colleagues will then comment.

We would like to thank the committee for inviting us to participate in this hearing. We have been asked by the American Academy of Dermatology to testify at this hearing. However, our testimony is our own opinion since we did not have time to have our statement approved by the Academy.

The three of us who are here are members of the committee called North American Contact Dermatitis Group, which is a task force of the American Academy of Dermatology for contact dermatitis. This is a group of 12 dermatologists in America and one in Canada, which is concerned primarily with allergy patch testing to cosmetics, over-the-counter topical preparations and other environmental allergens that cause contact dermatitis.

This group published a paper on cooperative study of the prevalence of contact dermatitis in America 3 years ago; 2 years ago, we developed a standardized screening patch test kit for use by any dermatologist who is interested in patch testing.

We have recently designed a special preservative patch test series, and also a perfume-screening patch test series.

Now that we have the ability to identify specific components that cause reactions, it becomes important that we have full fragrance disclosure.

Since we believe that perfume allergy represents a significant proportion of adverse reactions, it is essential that the fragrance ingredients or alternately a perfume code be listed on the label or in a pack-

age insert. If a code is utilized for the perfume, then full disclosure of the fragrance must be available to those that need to know.

Without fragrance disclosure, we believe cosmetic labeling will be only minimally beneficial to the consumer and the physician, who is actually the one that tests the patient and determines the specific allergy.

To put this in perspective, I will conclude by stating that most cosmetics today seem to be relatively safe.

However, as dermatologists, we see only those patients that have adverse reaction to cosmetics. Therefore, our statement that perfumes cause a significant proportion of reactions in cosmetics must be taken in context to the overall injury rate to cosmetics, which is unknown actually, but is probably small.

[The prepared statement of Dr. Larsen follows:]

STATEMENT OF WALTER G. LARSEN, M.D. BEFORE THE COMMITTEE ON
LABOR AND PUBLIC WELFARE
JUNE 12, 1975

We would like to thank the Committee for inviting us to participate in this hearing. Doctor William Jordan and Doctor William Schorr and I have been asked by the American Academy of Dermatology to testify at this hearing. However, our testimony is our opinion, since we did not have time to have our statement approved by the American Academy of Dermatology.

The three of us are members of the committee called the North American Contact Dermatitis Group, which is a task force of the AAD for Contact Dermatitis. This is a group of twelve dermatologists in America and one in Canada which is concerned primarily with allergy testing to cosmetics, over the counter topical preparations, and other environmental allergies that cause Contact Dermatitis. Three years ago, this group published a paper on the cooperative study of the prevalence of Contact Dermatitis in America. Two years ago, we developed a standardized screening patch-test kit for use by any dermatologist who is interested in patch-testing. We have recently designed a special preservative patch-test series and also a perfumed screening patch-test series. Now that we have the ability to identify specific components that cause reactions to perfumes, it becomes important that we have full fragrance disclosure. Since we believe that perfume allergy represents a significant proportion of adverse cosmetic reactions, it is essential that the fragrance ingredients or alternately a perfume code be listed on the label or in the package insert. If a code is utilized, then

full disclosure of the fragrance must be available to those that need to know.

To put this in perspective, I will conclude by stating that most cosmetics today seem to be relatively safe. However, as dermatologists, we see only those patients that have adverse reactions to cosmetics.

We would like to propose the following Amendments and Additions to Senate Bill 1681.

I. Cosmetic Labeling

- A. We believe that there should be fragrance disclosure on the label. If there are more than three fragrances in a perfume, we believe an alpha numeric code should be used for the perfume. We believe that the major cause of cosmetic dermatitis is allergy to the perfume component, and therefore if there is no coding, cosmetic labeling will be less effective.
- B. We advocate a physician only phone number on the label to enable the physician to talk directly to the medical director or toxicologist. If this is not feasible, we think a constantly updated phone number list should be circulated to those physicians who investigate cosmetic problems, or alternately, the CTFA or FDA could act as a clearing house for such information.

II. Adverse Reaction Complaints

We believe that there should be two categories of complaints

- A. General Consumer Complaints
- B. Physician-Documented Complaints (i.e. patch test corroboration, etc.)

III. Alphabetic Listing of Ingredients

We see no overriding need for declaration of ingredients according to descending weight. An alphabetic listing is probably more convenient.

IV. Cooperation of Cosmetic Manufacturers with M.D.

The physician should be supplied with information and with patch test materials when necessary by the manufacturer in order to determine the exact cause of the adverse reaction.

Dr. LARSEN. At this point, I would like to introduce Dr. William Jordan from the Medical College of Virginia who will continue with his comments.

Senator EAGLETON. Dr. Larsen, before Dr. Jordan begins to give his testimony, the specific point you made, I take it, is with respect to fragrance disclosure. You think by whatever method that we would define, fragrance disclosure should be made with some degree of specificity; that it is not good enough, in your opinion, just to say "fragrance" on the thing?

Dr. LARSEN. Absolutely, yes.

Senator EAGLETON. Now, Dr. Jordan, would you please identify yourself?

Tell us a bit about who you are and why you are here.

Dr. JORDAN. I am William P. Jordan, Jr., M.D., associate professor of dermatology, Medical College of Virginia; member of the American Academy of Dermatology, on the study section of the National Institute of Occupational Safety and Health; I am a consultant to some cosmetics manufacturers, and am a member of the North American Contact Dermatitis Group.

Senator EAGLETON. You are a consultant to some cosmetic manufacturers?

Dr. JORDAN. That is right.

Senator EAGLETON. Would it be violative of any confidentiality if you would specify for whom you consult?

Dr. JORDAN. It might. I have not asked them.

Senator EAGLETON. OK. Then do not.

But this is a fair question.

Are they sizable manufacturers of cosmetics?

Dr. JORDAN. The biggest.

Senator EAGLETON. The biggest, OK.

[Laughter]

Senator EAGLETON. Go ahead, sir.

Dr. JORDAN. I am also engaged in testing products on volunteer prisoners and street population panels, so I have a rather large experience in testing cosmetics to see what they will do.

The reason that I am pleased to appear is because there are several schools, or schools of thought, about what should be done on cosmetic labeling.

There is one to which the Commissioner of the FDA subscribes, and I believe it is fair to say that this bill also subscribes to the same viewpoint, that fragrance and flavors should be listed as such.

There are the consumer advocates and some in dermatology who insist that the entire fragrance be disclosed. And I come up in the middle ground position. I would like to argue why both points are, in my opinion, unscientific.

The Commissioner of the FDA states that it is impractical to have full disclosure on cosmetic formulations. He says it would be "impractical," which it is, and could distract from the listing of any other ingredients.

Unfortunately, in the real world of cosmetic allergy, which constantly occupies my attention, the distracting thing about the proposed labeling is that it will list the usually innocuous compounds and avoid the major allergens in cosmetics; namely, the fragrances.

This error is further compounded by the mistaken notion that the adverse cutaneous reactions to fragrances when they occur are dose-related. It is almost axiomatic that the ingredients' percent relationship to the whole product is worthless when evaluating any compound as a potential allergen.

There are literally hundreds of compounds that are capable of eliciting a positive patch test at concentrations less than 0.1 percent. Some sensitizers elicit responses at percentages in the range of 6×10^{-3} .

I have rarely seen an allergy from a deodorant or antiperspirant that was not due to the fragrance.

It is also known that some large cosmetic houses sell their regular line cosmetics as hypoallergenic when they remove the fragrance. They know what we know. When trouble is forthcoming, it is likely to be in the fragrance portion.

The next category of known allergic reactions in cosmetics resides in the color ingredients. This is another exempt category according to the proposed regulations.

What we are left with, for the consumer, is the preservative section. These are true allergens from time to time and are worthy of labeling.

Most of the label, as it now stands, will be devoted to ingredients that comprise single case reports in the medical literature. Under the present proposal, no one is protected except in the area of preservatives, and the industry is being forced into a flurry of meaningless activity.

It appears to me that the FDA has been stampeded into cosmetic labeling by outside pressure, and there is strong evidence that there was no input from that small portion of dermatologists that are primarily engaged in evaluating the allergic consumer.

I wrote to the Commissioner and told him that if he was persuaded that a significant portion of cosmetic allergic reactions is due to fragrances, he would have to adopt a titanic ingredient list because he has already rejected the use of official names for other blends. He has rejected the use of blends, yet he accepts fragrances and flavors.

Yet we are trying to tell him that he is just missing one of the significant sections of all allergic reactions in cosmetics, the fragrances.

I respectfully asked him to halt all efforts in this area of cosmetic labeling and convene a meeting with people who really work in the area.

The consumers and the FDA must be told that there are three major areas of allergy in cosmetics. In two of these categories, the consumer cannot be protected by labeling the ingredients unless the label is grotesquely complicated and the consumer has received an inordinate amount of patch test evaluation to determine which one of 30 to 60 components is responsible for the problem.

There are only 10 to 18 patch test laboratories continually engaged in this detective work. Consumer groups should understand that if an allergy resides in the preservative and nonfragranced or colored portion of a cosmetic, he can benefit from the labeling effort. These groups should understand that ingredient labeling will work up to a point but will never help the major portion of the cosmetic allergic population unless they have been exhaustively studied in one of the contact dermatitis laboratories:

One: Ingredient labeling where practical. This would include all ingredients with the exception of colors and fragrances.

Two: List the ingredients by alphabetical order because listing according to concentration is meaningless in regards to allergy.

Three: Colors and fragrances should be numerically coded and the code should be able to reflect alternative formulations yielding essentially the same product. A code is a must for dialog between the physician and the manufacturer. A code is important because a manufacturer could use on occasion two different perfumes in the same product. The physician needs to use specific nomenclature when talking to the manufacturer about his product.

The physician must be able to call and say I am interested in fragrance OX-1995, and the manufacturer knows exactly what he is talking about. You can believe the manufacturer has it coded and has variations of this fragrance coded.

Four: The physician must be supplied with samples on request that are suitable for patch testing. One key thing that I think is important that is a telephone number for physician use only, should be printed on the package so that ingredients can be requested for testing. Nobody can use that telephone number but a physician. This is a physician-use-only telephone number to the manufacturer.

Senator EAGLETON. What is that, Doctor?

Is it just seven numbers like any other telephone number?

Dr. JORDAN. That is right.

This puts you through to a person in the company that knows the formulation. Many allergic reactions are difficult to solve, even with ingredients printed on the label, 95 percent of the time I still have to get in touch with the manufacturer. You cannot get all of the information you need to solve one of these problems by reading off the label when everything is on the label.

We need access to key people in the company that know exactly what the composition is.

Avon has this type of thing. You can call and you get a key man right away. He tells you the entire formulation and sends you the products, and all this takes is about 30 seconds; they tell you about some of the problems you are going to have patch testing these compounds.

Senator EAGLETON. How does the company at the end of the line know the individual calling is a doctor and the information the company is giving the doctor will be treated with confidentiality?

Dr. JORDAN. I will answer that in the next sentence. This is a better alternative than putting it all on the label. The companies cannot lose this way.

I would be perfectly willing to register with the CTFA or FDA, and give the company my code number. If that code number matches my name in a catalog, then they will know I'm legal and give me the information I need.

[Even if you know what component in a perfume you are allergic to, other ingredients are often chemically related and the absence of that known ingredient from alternative perfumes doesn't protect you from an allergic reaction. If you know you are allergic to cinnamic aldehyde, and it is on the label, you can go right out and buy three other perfumes that will break you out, yet there is no cinnamic aldehyde listed but there are many compounds capable of cross-reacting with it.]

You can be allergic to formaldehyde and go out and spray your feet with a foot deodorant, use an underarm deodorant, wash your hair, and break out from all three. You ask your wife to bring in all the labels, and you do not see formaldehyde on the label. It contains quaternium-15, bronopol, and germall-115—that does not tell you they are formaldehyde releasers.

Those compounds break down and give off formaldehyde.

They cannot have a paragraph on the label saying: "Guess what, we liberate to formaldehyde."

Full labeling is semifarcical when it comes down to being informative. It must be informative to the specialist who needs to know. That is the dermatologist.

The way to solve these problems is by physicians using the telephone number manned by informed company employees.

We do insist on a code for the simple reason we just do not say that I want the perfume in product "X" because I want to be able to name the perfume they claim is on there. Otherwise, it is misbranded if the perfume is not in there.

If a patient knows that he is allergic to a component in the perfume, he would have to have 6 months of patch testing with every blood relative of that chemical to be able to figure out what are all the other ingredients he cannot use. He would have to have some sort of computer punchcard in his pocket to figure out the cross-reacting possibility if he is allergic to cinnamic aldehyde, for instance, so it is not going to do him any good if they have all the ingredients because he knows his reaction is cinnamic aldehyde, but he does not know he cross-reacts to benzylbenzoate.

Who are we really helping?

We need a code number and we probably need a physician-use-only telephone number.

The manufacturer can have two phones. He can have a consumer phone. And he can tell the consumer to get off if he is on the physician hotline.

Every company ought to have one of these. We would not solve the problem in 9 cases out of 10 without a direct dialog with the manufacturer.

I spend my entire day on the telephone, very little by mail, because you cannot get the answers that you need and you will never get them all on the label anyway, particularly in the areas of colors, which are notorious for crossreacting with each other. You can cross-react with 10 blood relatives and 10 other equal blood relatives will not crossreact.

You really cannot tell a patient that he is safe, even with the labeling. Sometimes it is still hit or miss.

I say the consumer and FDA should accept the concept that the most troublesome components are the ones that defy complete labeling. Therefore, absolute disclosure as a benefit to the consumer is unworkable. The consumer is best served by making it easier for those with a true need to know to be able to obtain test samples with a minimum of effort and information that is fast and accurate.

This concludes my statement.

[Information supplied for the record follows:]



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MCV Station • Richmond, Virginia 23298

April 4, 1975

A.M. Schmidt, M.D.
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, Maryland 20852

Re: Cosmetic Labeling (701.3), with particular reference to
fragrance and flavors.

Dear Commissioner Schmidt:

I am a member of the North American Contact Dermatitis Group, and I would like to comment on that section of 701.3 dealing with the listing of fragrance and flavors as such. The Federal Register of 3 March 1975 states that you have already received objections from some of the responders because they feel this tactic will deny consumers access to important information. Your reaction to this is that any other labeling would be "impractical (which it is) and could distract from the listing of any other ingredients". Unfortunately, in the world of real cosmetic allergy, which constantly occupies my attention, the distracting thing about the proposed labeling is that it will list the usually innocuous compounds and avoid the major allergens in cosmetics, namely the fragrances. This error is further compounded by the mistaken notion that the adverse cutaneous reactions to fragrances when they occur, are dose related. It is almost axiomatic that the ingredient's percent relationship to the whole product is worthless when evaluating any compound as a potential allergen. There are literally hundreds of compounds that are capable of eliciting a positive patch test at concentrations less than 0.1%. Some sensitizers elicit responses at percentages in the range of 6×10^{-3} . I have yet to see an allergy from a deodorant or antiperspirant that was not due to the fragrance. It is also known that some large cosmetic houses sell their regular line cosmetics as hypoallergenic when they remove the fragrance. They know what we know; when trouble is forthcoming it is likely to be in the fragrance portion.

A.M. Schmidt, M.D.

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April 4, 1975

The next category of known allergic reactions in cosmetics resides in the color ingredients. This is another exempt category according to the proposed regulations. What we are left with (for the consumer) is the preservative section. These are true allergens from time to time and are worthy of labeling. Most of the label as it now stands will be devoted to ingredients that comprise single case reports in the medical literature. Under the present proposal, no one is protected except in the area of preservatives and the industry is being forced into a flurry of meaningless activity. It appears to me that the FDA has been stampeded into cosmetic labeling by outside pressure and there is strong evidence that there was no input from that small portion of dermatologists that are primarily engaged in evaluating the allergic consumer. If you are persuaded that a significant portion of cosmetic allergic reactions is due to fragrances, you will have to adopt a titanic ingredient list because you have already rejected the use of official names for "blends" of ingredients.

I respectfully request that the Commissioner halt all efforts in this area of cosmetic labeling and call for a hearing inviting consumers, industry, and dermatologists who really work in cosmetic allergy. The consumers and the FDA must be told that there are three major areas of allergy in cosmetics. In two of these categories, the consumer cannot be protected by labeling the ingredients unless the label is grotesquely complicated and the consumer has received an inordinate amount of patch test evaluation to determine which one of 30 to 60 components is responsible for the problem. There are only ten to eighteen patch test laboratories continually engaged in this detective work. Consumer groups should understand that if an allergy resides in the preservative and non-fragranced or colored portion of a cosmetic he can benefit from the labeling effort. These groups should understand that ingredient labeling will work up to a point but will never help the major portion of the cosmetic allergic population unless they have been exhaustively studied in one of the contact dermatitis laboratories.

I feel that there are certain alternatives that can be worked:

1. Ingredient labeling where practical. This would include all ingredients with the exception of colors and fragrances.
2. List the ingredients by alphabetical order because listing according to concentration is meaningless in regards to allergy.

A.M. Schmidt, M.D.

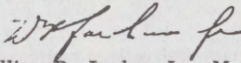
Page 3

April 4, 1975

3. Colors and fragrances should be numerically coded and the code should be able to reflect alternative formulations yielding essentially the same product. A code is a must for dialogue between the physician and the manufacturer. A code is important because a manufacturer could use on occasion two different perfumes in the same product. The physician needs to use specific nomenclature when talking to the manufacturer about his product.
4. The physician must be supplied with samples on request that are suitable for patch testing. The telephone number (for physician use only) should be printed on the label so that ingredients can be requested for testing. Allergies to fragrances and dyes (the coded areas) are often multiple (cross-reacting), and the consumer will eventually need dermatologic help in selecting an alternative product. It makes more sense to enable the physician to have a direct approach to the company to ascertain the presence or absence of an ingredient in these coded areas. All requests for formula information must be answered promptly. Interested physicians could easily be registered with an identifying number to satisfy the cosmetic company. These details would not be difficult to work out.

The consumer and FDA should accept the concept that the most troublesome components are the ones that defy complete labeling. Therefore, absolute disclosure as a benefit to the consumer is unworkable. The consumer is best served by making it easier for those with a true need to know to be able to obtain test samples with a minimum of effort and information that is fast and accurate.

Sincerely,



William P. Jordan, Jr., M.D.
Associate Professor of Dermatology
Medical College of Virginia

WPJjr:lw

CC: Dr. Walter Larsen
Dr. Heinz Eiermann
Mr. James Merritt
Hearing Clerk, FDA

Senator EAGLETON. I understand that Dr. Schorr is with us. I think my colleague from Wisconsin would like to introduce Dr. Schorr.

Senator NELSON. Mr. Chairman, I am happy to introduce to the committee Dr. William Schorr of the Marshfield Clinic in Marshfield, Wis. That is the largest clinic in the State of Wisconsin, one of the largest ones in the country with 140 doctors.

Dr. Schorr is an associate clinical professor of dermatology at the University of Wisconsin. He is associate clinical professor, University of Minnesota. He is a director of the dermatologic residency training program at the Marshfield Clinic. He is a director on the board of directors of the American Academy of Dermatology.

He is on the Food and Drug Administration's over-the-counter drug antimicrobial panel.

Dr. Schorr advises me that he submitted a statement that he had to put together rather hurriedly to meet the timetable of the committee, and he would like to have the opportunity to submit a statement for the record and withdraw the one he has, because he wants to submit some material in greater detail.

How long will the record be open?

Senator EAGLETON. At least 2 weeks, and longer if the doctor needs more time.

Senator NELSON. I am sorry that I cannot stay to hear the testimony. We have a conference on over in the Capitol.

Senator EAGLETON. I thank the Senator from Wisconsin.

I am pleased to yield to the Senator from New York.

Senator JAVITS. I thank my colleagues.

I hope the two witnesses will not consider it invidious, because I am very interested in their testimony, and as you well understand, this is a major matter in my State, New York; but I hope that you will yourselves write the committee a letter showing your objectivity. In other words, that you do not work for interested parties, et cetera.

I understand that is so. But I believe it will be very helpful to us as we use your testimony as a solid base for proceeding if the record shows it.

I am not even questioning it, but I think it would be helpful to show your objectivity as professionals.

So if you would be kind enough, Mr. Chairman, with the Chair's permission to do that, I think it would be helpful.

Senator EAGLETON. Yes.

If each of the doctors would submit that to us in due course, we will appreciate it.

[The information referred to follows:]

MARSHFIELD CLINIC
MARSHFIELD, WIS. 54449

DEPARTMENT OF DERMATOLOGY
Richard J. Rowe, M.D.
William F. Schorr, M.D.

June 20, 1975

The Honorable Thomas Eagleton
United States Senate
Pentagon
Washington, D.C. 20515

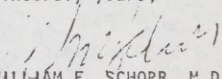
Dear Senator Eagleton:

Thank you for the opportunity to appear before your Committee on Senate Bill S-1681. I have sent the corrected transcript back to Mr. Otley. I would much prefer that this transcript of my verbal testimony before your Committee be used in the Congressional Record in place of the statement I was asked to prepare prior to coming to Washington. I would prefer that my original statement be discarded.

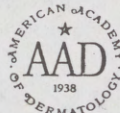
Senator Javits asked that we send a letter to you clarifying any possible conflict of interest. I have no financial involvement with the Cosmetic Industry. I am a member of the FDA OTC-Antimicrobial Panel II. Enclosed, also, are some publications which cover my research and reasons for the testimony before your Committee.

Kindest regards.

Sincerely yours,


WILLIAM F. SCHORR, M.D.

WFS:sa



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Walter G. Larsen, M.D.
EXECUTIVE SECRETARY
Mrs. Betty Suor

June 24, 1975

Senator Thomas F. Eagleton
United States Senate
Committee on Labor and Public Welfare
Washington D.C. 20510

Dear Senator Eagleton:

Thank you for the invitation to present testimony before the Committee on Labor and Public Welfare on 12, June, 1975, relative to Senate Bill 1681.

In response to Senator Javitt's question about objectivity, I would like to state that I have no connection or tie with any cosmetic or pharmaceutical company, nor do I receive a retainer from any such company.

I have enclosed a statement for the written record. I would like to commend you for your interest in Consumer Protection. Ultimately, the consumer in adverse reaction to cosmetics comes to us with their complaints, and we must determine the precise cause of their adverse reaction. Your bill will certainly help us in our investigation of these problems.

Sincerely,

Walter G. Larsen, M.D.
Assistant Secretary-Treasurer

WGL/ckm



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July 14, 1975

Senator Thomas F. Eagleton
 United States Senate
 Committee on Labor and Public Welfare
 Washington, D.C. 20510

Dear Senator Eagleton:

It was a pleasure to come to Washington to testify before your committee regarding your bill on cosmetic safety. I believe it was Senator Javits who requested that a statement be made that our testimony was our own and that we were speaking from our positions in academic medicine.

Although I am a consultant to industry, my statement was entirely my own, reflecting the views that I have acquired as a dermatologist working with the cosmetically injured patient.

Very truly yours,

William P. Jordan, Jr., M.D.
 Associate Professor of Dermatology

WPJjr:lw

Senator JAVITS. I assume the answer to the question is that you are both completely objective.

Dr. SCHORR. I have no involvement with industry. I am a consultant to FDA on occasion.

Dr. JORDAN. I do have involvement with industry and also Government at the same time.

Senator JAVITS. You will give us the details.

Dr. JORDAN. Yes.

Senator JAVITS. Fine. Mr. Chairman, I am going to have to leave, but one of the witnesses this morning is from New York, Leonard Lauder.

They are very well known and a very fine firm. The important thing to me, Mr. Chairman, the reason I came this morning is, from a preliminary review of their testimony, it indicates a kind of self-analysis and willingness to really enter into what we are trying to do in spirit, which I find highly commendable, whether they were from New York or not.

And it is rather refreshing coming from an industrial profitmaking firm, and I came to call attention to it. I am well acquainted with the firm and with the Lauder family, and it is quite characteristic.

Thank you.

Senator EAGLETON. I subscribe to that. The Lauders have been very helpful to us in giving us the benefit of their considerable experience in the manufacture and distribution of cosmetics.

I think they have contributed to our work in a very constructive way. I share the sentiments that Senator Javits has just expressed.

All right, Dr. Schorr, you may proceed.

Dr. SCHORR. Thank you, Senator Eagleton.

When I received the call last Thursday and Friday concerning the request to be here, time did not allow much thought for this. I did not realize until this last 10 minutes that my own approach in my own testimony would probably be quite different from my highly respected colleague and very good friend, Dr. Bill Jordan.

The reason for my appearance before this committee is very singular. It is directed at that phase of the proposed bill which has to do with the declaration of ingredients of the perfume, fragrance, and coloring materials in cosmetics.

North American Contact Dermatitis Research Group, which Dr. Larsen referred to, and the International Committee, and dermatologists in general have realized for many years that the testing systems that are available today to detect skin allergies, known as the allergic form of contact dermatitis, are quite inadequate.

We have realized for a long period of time that the standard patch test, where something the patient is allergic to is applied to a little aluminum tape with backing on the back of the patient, and this standard test system is fraught with errors, and we cannot take a chemical out of industry, a perfume, an essential oil, a solvent product, put it on the back of the consumer patient, and say you have a reaction, you are allergic to that product.

The reason is that if we take these chemicals and put them on normal people who are not allergic to that chemical, and we can have irritant burn reactions. This is the problem with the false-positive patch test. Conversely, we have a more significant problem with the false-negative test.

Respected and eminent European colleagues in dermatology, years ago, prior to 1966, have shown that patch tests, allergy tests to the cosmetic creams and lotions, will routinely give false-negative test reactions for the doctor studying the patient, if the test is applied to the cosmetic cream or lotion that is used by the consumer.

This is merely a limitation of our testing system. This happens if a patient is allergic to many chemicals and the parabens are a good example.

The parabens are chemicals in cosmetic creams and lotions, dermatologic creams and lotions, to prevent microbial growth, growth of bacteria and fungi.

These dermatologists, prior to 1966, found that we have to raise the concentration for testing purposes from above the usual concentration of less than 1 percent to 5 percent to make the diagnosis. And when a diagnosis is made, the creams and lotions are applied to wide areas of the body, extended, and significant dermatologic disease results.

When a patient sees and consults a physician, the disease is further extended, because the same paraben preservatives are found in creams and lotions that the physician prescribes.

In 1966, I reported the first cases of paraben allergy in this country and confirmed what our European colleagues had shown us. We can demonstrate this with many patterns of chemicals.

What do we know about the thousands of chemicals used to make perfume and fragrance?

How little do we really know about the true incidence of cosmetic allergy?

A very similar story can be stated for neomycin. Neomycin is the most popularly prescribed and used over-the-counter antibiotic. We have known for many years if we have a patient who is significantly allergic to neomycin, if we put the allergy test on to that neomycin cream and ointment, we will routinely get a false-negative result because, to define allergy, the concentration of neomycin has to be elevated from the usual usage level of 3 percent to 20 percent.

There are many other chemicals in our environment that we can make a similar story for.

Now, if we do not know the correct testing concentration. If we know that testing of the cosmetic leads to false-positive and false-negative tests, if we know we have to study each and every individual chemical on the normal control volunteers who do not have allergic disease and work out that proper testing concentration, how can we possibly diagnose cosmetic allergy if we do not know the name of the perfume chemicals in the cosmetic?

Some years ago, I published a study out of the Marshfield Clinic in Wisconsin on 70 cosmetic allergic patients from my practice. It took no great effort to find 70 cosmetic allergic patients in my own personal practice.

These were patients who had cosmetic allergy defined and documented beyond any possible doubt. If anyone had asked me what I thought, which group of cosmetics would have caused the greatest number of reactions prior to my doing the study, I would have said hair dyes.

But the study had shown that 31 out of the 70 cosmetic allergic reactions were caused by cosmetic creams and lotions, perfumed cosmetic creams and lotions.

And we have reason to believe that the majority of them are caused by the perfume and fragrance components.

Only 2 out of the 70 patients—and I interviewed these patients personally—only two out of 70 patients had ever written a letter to FDA or to industry. Therefore, 68 out of the 70 were never reported to any agency or to any company.

Now, when a lady becomes allergic to a perfume and she puts a dab of perfume under her ear, anyone can make the diagnosis across the room. The problem is miniscule and not important. This is not what I am addressing myself to.

But when the lady becomes allergic to perfume in a cosmetic cream or lotion, which she applied to wide areas of her body, has it on her hands, and the hands travel from one area of the body to the other, this lady is more apt to wind up with significant inflammatory disease over large areas of the body, and she can go from physician to physician and no one is going to suspect perfume allergy. This is a cream that has been applied to wide areas.

In the evening, her bed clothing rubs, and this is no telltale little dermatitis but significant generalized disease. Any estimates we have of cosmetic allergy today cannot have any degree of accuracy, because the physician does not have the tools with which to make the diagnosis.

Dr. Jordan, a very good respected friend and colleague, talked about ingredient samples, and here is where we differ—I had a great deal of frustration in the last 13 years working with coded ingredient samples. We have a referral practice. The patients come a distance. We have a reaction to a code. Unless we put that code on another 50 normal controlled volunteers, we do not know that we are not producing nonspecific irritant on the patients skin test site rather than defining true allergy.

We show that they are allergic to code A. What does code A mean from one manufacturer?

It could have 5, 10, 50 chemicals in it. How many trips are we going to have this lady make? How many miles for repeated testing? How much physician time are we going to consume trying to decipher and break down that code?

In support of this, a very eminent dermatologist and good friend of all of us sitting here, Dr. Hjorth from Copenhagen, Denmark, in a medical publication known as "Contact Dermatitis Newsletter," of January 1967, reported having studied 865 consecutive patients with contact dermatitis, meaning inflamed skin caused by chemicals from our environment coming into contact with the skin; 32 of these patients reacted to perfumes on patch testing—the doctor was given only coded samples—18 of the 32 showed positive test responses to a detergent perfume mixture; 6 to toilet soap perfume A; and 26 to a coded sample identified only to the doctor as toilet soap perfume B.

The doctor points out that to go back to the lady and tell her she is reacting to code A by X manufacturer hardly helps the patient.

Dr. Hjorth found that when the patients were allergic to one particular perfume, where the doctor had full declaration of the ingredients of the chemicals in the perfume, he had shown that 66 percent of all allergic disease in that group was caused by two chemicals, coumarin

and benzylsalicylate. The simple exclusion of those two chemicals could lead to 66 percent cure.

We do not know as dermatologists about the other thousands of chemicals in cosmetics. We do know, however, as Dr. Jordan has pointed out, that one chemical in the cosmetic can be found in many areas of our environment.

We have reason to believe that chemicals, as cinnamic aldehyde, cinnamic acid, are relatively frequent allergents. But they may not only be found in brand X of a particular cosmetic. It may be found in 70 percent of all the cosmetics the patient uses.

Is she going to go from store to store, sampling cosmetic after cosmetic, and finding out what she is allergic to by applying it and producing the disease?

How much better it might be if we had a package insert defining the chemicals in the package—it cannot go on the label—but a package insert so physicians can begin to get a better understanding of how to test these chemicals, how to make a diagnosis and alert the patient known to be allergic to cinnamic aldehyde, so they can pick the cosmetic which does not have cinnamic aldehyde in it.

In summary, if dermatologists cannot set up correct adequate testing systems for the various chemicals in our environment, he cannot make an adequate diagnosis.

Perfumes and fragrances, we believe, are a relatively common cause of allergic skin disease. We are unable to prove this. We are unable to make a proper diagnosis. We are not able to teach the patient how to avoid the specific perfume chemical to which the patient may be allergic.

It is our hope and our plea that whatever legislation comes out of this, that we will have a declaration of ingredients, above all for perfumes, fragrances and colors.

I thank you for allowing us to be here.

[Articles supplied for the record follows:]

Cosmetics and Perfumery

Volume 89 • Number 7

July • 1974

Cosmetic allergy —a problem and possible solutions

By WILLIAM F. SCHORR, M.D., Dermatologist,
Marshfield Clinic, Marshfield, Wis.

Herein is a study of 70 patients at the Marshfield Clinic who have documented cosmetic allergy proven not only by the appropriate clinical picture but also by either a positive usage test or a positive 48-hour closed patch test.

The following main points will be discussed and elaborated upon:

- 1) Cosmetics today in this country are usually safe and quite free of potent sensitizers.
- 2) Any person can become allergic to almost any chemical.
- 3) There are more than 4,000 different chemicals used in the manufacture of cosmetics. These in turn are applied to the skin of millions of consumers. Relatively weak or moderate sensitizers, therefore, when multiplied by thousands of chemicals used by millions of consumers can cause a significant number of allergic reactions.
- 4) Dermatologists are not adequately equipped to diagnose cosmetic allergy.
- 5) Patch tests^{1,2} to cosmetics as used by the patient may give false negative or false positive reactions. Proper testing demands the application of a 48-hour occlusive patch test with the maximum concentration of each chemical that will not produce a false positive irritant response when studied on appropriate control subjects.
- 6) Chemical allergens in cosmetics are used elsewhere in the consumer's environment. Formaldehyde, the parabens, EDTA and the lanolin fractions all give testimony to this fact. Unless this chemical is identified, chronic contact dermatitis or widespread recurrent eczema can result. With the more generalized skin response cosmetic allergy is not suspected, a proper diagnosis is not made and a cure is not obtained unless the precise allergen and all its environmental sources are identified.

7) Current estimates of the number of people allergic to cosmetics are very faulty. Only two of the 70 patients with documented cosmetic allergy in my practice have ever written complaints to cosmetic manufacturers and none have been reported to the Federal Food and Drug Administration or to any other agency.

8) Current methods of predictive testing may not adequately define weaker allergens. Only clinical studies on a large series of cosmetic allergic patients can accomplish this goal.

9) The North American Contact Dermatitis Research Group is composed of 13 dermatologists in 10 medical centers devoted to the study of allergic diseases of the skin. Perhaps this group or a similar group could work in cooperation with the cosmetic industry to define proper clinical testing techniques for cosmetic allergic patients, and then through the study of a large group of known cosmetic allergic patients, identify those chemicals which account for the largest number of allergic reactions. If only half of the 70 cosmetic allergic patients herein reported from my practice could be patch tested to the 50 most frequently used cosmetic chemicals, each in its own proper testing concentration, we could have more precise data on the relative frequency with which these chemicals actually cause skin disease. A month later another 50 chemicals could be screened. If we could multiply my series by those of another 10 to 15 dermatologists interested in skin allergy, the volume of more precise clinical data could be highly significant. It would serve as a check on the accuracy of currently popular pre-market predictive testing procedures now relied upon. This group of dermatologists could then determine all areas of exposure to these chemicals in our environment. This information could be made available to representatives of the cosmetic industry.

10) The dermatologist, if he is well informed, can help the patient in his office understand that

This article is based on a paper the author presented at the Semi-Annual Meeting of the Society of Cosmetic Chemists on May 3-4, 1973 at Cincinnati, O.

she can become allergic to any chemical, be it one in cosmetics, drugs, clothing or any other area. He can teach this patient that the cosmetics she uses are safe for the general population and that her allergic reaction is not caused by a faulty product. In this way the knowledgeable and informed dermatologist can discourage and most often prevent unjust litigation against the manufacturer.

Contact dermatitis

Contact dermatitis³ is best defined as an inflammatory disease of the skin with redness, itching and scaling produced by some chemical or chemicals from the patient's environment coming into contact with the skin. There are two forms of contact dermatitis. One we will refer to as irritant contact dermatitis and the second as allergic contact dermatitis. Irritant contact dermatitis is a disease that can be produced by any chemical strong enough to cause inflammation on normal skin without requiring an allergic reaction to mediate it. The housewife with her hands in cleansing agents, soapsuds, germicides and the various chemicals she uses in her housework can very frequently acquire irritant contact dermatitis of her hands. In like manner, in industry the worker exposed to acids, alkalis, solvents, cutting oils, greases and other primarily irritating chemicals can also develop an irritant contact dermatitis. This has nothing to do with allergy, and allergy testing plays no part in the evaluation of this clinical picture.

Allergic contact dermatitis, however, can happen to only a certain percentage of people and it reflects that person's ability to produce antibodies which mediate a true allergic response. This is the patient who with the slightest contact to the smallest concentration of a particular chemical can develop widespread disease. It has nothing to do with cumulative irritant exposure. Dermatologists in their field for years have studied the sensitizing index of various chemicals. We realize that certain chemicals produce allergic disease in a relatively high percentage of the population exposed and others produce disease in a very small percentage of population exposed. From this we define our chemicals as weak, moderate or potent sensitizers or allergens.

This type of study and documentation has been going on for many years with industrial chemicals, household chemicals and those in other areas of our environment. Adequate clinical studies of this type have not been accomplished in the area of cosmetic allergy. The 48-hour patch test has been standardized by the International Contact Dermatitis Research Group⁴ and accepted by the North American Contact Dermatitis Research Group of which the writer is a member. The accepted standard technique is to apply a small amount of the suspected allergen on a closed aluminum test tape for 48 hours to the skin of the upper back. If only one reading is obtained, this must be done at 72 hours or 24 hours after the patch test has been removed. False negative and false positive patch test responses are seen if the testing system does not utilize the correct patch test concentration for each suspected aller-

gen.

If an excessive concentration of the chemical studied is applied in the 48-hour patch test, false positive irritant responses will result. If the chemical is applied in too weak a concentration, false negative patch test responses result. Examples of the latter phenomenon would include neomycin allergy⁵⁻⁸ and paraben allergy⁹⁻¹¹ among many others. Dermatologists have documented a very large number of patients allergic to neomycin and yet to make the diagnosis they must perform their patch test with a 20% concentration of neomycin in petrolatum. If we go very far below 20%, we have a false negative test response and yet this same patient will have allergic contact dermatitis produced on his skin through the usage of an antibiotic cream or ointment containing 1% or less of the neomycin. This reflects merely a limitation in our standardized testing procedure.

For many years it was felt within the cosmetic industry, by dermatologists, and within the pharmaceutical industry that paraben allergy did not exist. Studies in Europe⁹ and in this country^{10,11} demonstrated that patients allergic to parabens will routinely show false negative responses on the 48-hour patch test when the cosmetic or dermatologic cream or lotion is used as a testing material. It is only after increasing the concentration of the parabens to 3% or 5% do we document and diagnose this disease. On large numbers of control volunteers who do not have paraben allergy or neomycin allergy these concentrations do not produce false positive irritant responses.

Damaged or inflamed eczematous skin caused by the varicose or stasis ulcers in women or by an irritant contact dermatitis on the hands of the housewife is more vulnerable to develop allergic reactions to applied chemicals. The housewife who uses her cosmetic cream or lotion on her hands which are already involved in an irritant contact dermatitis has a much greater chance of developing allergic reactions to the cosmetic chemicals or to any other chemical that she is exposed to. If the patient presents herself to the dermatologist at the very onset of her dermatologic disease, the pattern of involvement on her skin will very frequently lead to an accurate early clinical diagnosis.

In the practice of dermatology, however, this is an uncommon event. Most patients who develop contact dermatitis are not initially seen by a dermatologist, but by the family physician, and very frequently these patients are treated with a variety of medications prior to consulting the dermatologist. Time usually elapses, the patient applies medications on her own which she purchases without a prescription and this damaged or inflamed skin very frequently develops either a secondary over-treatment dermatitis on a primary irritant basis, or the clinical picture spreads and is extended by allergic reactions to medications used before she is seen by the dermatologist. As a result the dermatologist sees a relatively significant number of patients who have chronic contact dermatitis over widespread areas of the body wherein the initial event has not been seen and an accurate diagnosis has not been made.

If the dermatologist sees a woman initially with dermatitis about the eyelids or the lips or other areas of cosmetic application, the diagnosis is easily made and the problem remedied. If, however, this person consults the dermatologist weeks or months later and the dermatitis is widespread, cosmetic allergy is not suspected and a diagnosis is not made. With greater than 4,000 different chemicals used in the manufacture of cosmetics by millions of consumers, relatively weak sensitizers account for a large number of patients with allergic contact dermatitis due to cosmetics.

Marshfield Clinic Study on Cosmetic Allergy

In this presentation we demonstrate 70 patients with proven cosmetic allergy diagnosed and treated in the Department of Dermatology at the Marshfield Clinic. Only two out of the 70 have ever written a complaint to a cosmetic manufacturer and none has been reported to the Federal Food and Drug Administration. Table I gives a breakdown of the types of cosmetics that caused allergic reactions in our 70 patients. These had cosmetic allergy proven both by a compatible relevant clinical picture as well as either a positive 48-hour patch test or a posi-

Table I. Seventy cosmetic allergic patients Dx. and Rx. at Marshfield Clinic (female, 57; male, 13).

Creams and lotions	31
Perfumes and colognes	9
Hair dyes and color rinses	6
Deodorants	6
Eye make-ups	5
Facial make-ups	5
Multiple cosmetics	4
Aftershave	3
Shampoos	2
Nail preparations	1
Skin fresheners	1

tive usage test. From Table I we note that 31 of the 70 cosmetic allergic reactions were caused by creams and lotions. Nevertheless we realize that creams and lotions are, by themselves, weak sensitizers. With the millions of women who use the creams and lotions on hands and with the tendency to apply these creams and lotions to hands involved with housewives' eczema or to legs involved with varicose or stasis dermatitis or other inflammatory responses, this incidence can be better understood.

We have seen another 21 patients from the Clinic in whom we strongly suspected cosmetic allergy by their history, but we were unable to prove the diagnosis because of negative 48-hour patch tests or negative usage tests. From the above we cannot help but realize that many of these could represent false negative tests. Again in this list it became evident that creams and lotions caused over half of the problems.

We sometimes see a very red, swollen and inflamed face on a patient. If the diagnosis is made at this stage, it is not difficult to define this as an allergic reaction to cosmetics after an adequate history is taken. However, if this type of patient goes on to more widespread dermatologic involvement, the diagnosis can easily be missed. The allergen causing one problem was shown to be a mercurial in a popular cosmetic bleaching cream.

The value of the usage test and the ability of patients to become allergic to perfume chemicals was shown by a woman with a positive allergic response

to a usage test in her antecubital fossa. After the patient's primary dermatologic disease was remedied we asked her to simply squirt or apply one application of her cologne to the more sensitive skin at the bend of her elbow and return the following day to see the reproduction of the disease. If this woman is allergic to one of the 4,000 or more chemicals used to manufacture cosmetics and if that chemical is used in multiple cosmetics by multiple manufacturers, then this woman can expect to have recurrent contact dermatitis not only from the cologne she is now using but from a wide variety of cosmetics in future years. If the allergen happens to be a chemical which finds usage elsewhere in our environment outside of the cosmetic industry, further disease can be expected. However, if we can with adequate testing techniques define the exact chemical causing this reaction and if this woman can write to the cosmetic manufacturers explaining that she is allergic to a specific chemical and can purchase cosmetics free of it, permanent cure should be expected. This usage test is valuable only when false negative responses do not occur.

During the past year we have seen five patients allergic to one particular underarm deodorant. We received coded ingredient samples from the manufacturer of this particular deodorant and all five reacted to the perfume fraction. A positive usage test on a physician's wife to this particular underarm deodorant was demonstrated. She has tried multiple cosmetics by other manufacturers during the subsequent two years and has had at least four recurrent bouts of contact dermatitis caused by other cosmetics made by entirely different manufacturers because we have not been able to identify the precise chemical within the perfume fraction causing her disease.

A woman with a contact dermatitis to creams and lotions who had a problem for many years was presented in a scientific exhibit at the American Academy of Dermatology on cosmetic allergy in 1968. It was not until we realized that the parabens had to be tested in a concentration of 3% or more that the proper diagnosis was made and the disease terminated after many years of inconvenience. Dermatologic creams containing parabens prescribed by physicians only produced further disease.

We have studied a young woman with a contact dermatitis of her face in which we suspected cosmetic allergy. Patch tests demonstrated a positive allergic response to oil of clove and identified oil of clove as an ingredient in three of the cosmetic items she had been using. Fortunately, the cosmetic items produced a true positive 48-hour allergic response in our testing system. So informed, this woman is better equipped to prevent recurrence of her disease if she knows that oil of clove is her allergen.

Allergic reactions to eye make-up and lip gloss produce readily recognizable clinical pictures. A woman from outside the state of Wisconsin was seen at the Marshfield Clinic with a long history of recurrent contact dermatitis of her eyelids. She had tried hypoallergenic cosmetics and switched from cosmetic to cosmetic to no avail. Testing in our office demonstrated a strong positive allergic re-

sponse to isoeugenol as well as to wool wax alcohol. Upon inquiry to the various cosmetic manufacturers we learned that three out of five of the cosmetics she had been using in this area contained isoeugenol and we suspect that lanolin fractions were also present in these cosmetics. Again, if this woman is able to turn to the manufacturer asking for help in identifying her allergens, could the manufacturers guide her to cosmetics free of isoeugenol and wool wax alcohol? How much value would coded ingredient samples have in the study of this patient? If the coded ingredient samples demonstrated an allergic response to the perfume fraction containing isoeugenol, this would not be sufficient information.

We have studied another woman with dermatitis not only about the eyelids but also about the lips. She has a strong desire to continue the use of cosmetics and in the past switching among cosmetics has not adequately solved her problem. Testing has shown that again she is allergic to wool wax alcohols and whether or not other allergies are involved, we will only know with greater knowledge of the composition of the cosmetics she uses. It would appear that her positive test response to wool wax alcohol is relevant with the known usage of lanolin fractions in the manufacture of gloss-type cosmetics.

Cosmetic allergy can at times present clinical pictures which can very easily mislead the practicing dermatologist. We have seen a woman with contact dermatitis on the inside of a forearm and arm. One would hardly suspect cosmetic allergy in this patient unless one realized that she is unable to sleep in any other position except with her head resting on this portion of her arm. Further questioning of the patient reveals that the dermatitis on her forearm flares each time she has her hair dyed or tinted. Patch testing revealed a strong positive 48-hour test response to para-phenylenediamine.

Dr. Mitchell¹² of British Columbia presented a patient in *Contact Dermatitis Newsletter* in 1972 who gave the picture of nummular dermatitis or coinlike, discrete patches of eczema on the upper arm and periaxillary skin of the man. This would certainly not be a clinical picture reminiscent of cosmetic allergy. Patch testing, however, showed positive responses to the para-amino dyes and a 2+ positive allergic response on a test to his wife's hair with a negative response to the patient's hair. Then through a beautiful piece of detective work Dr. Mitchell found that the patient's wife dyed her own hair with a black dye. She also had the habit of reading books in bed with her head nestled in her husband's armpit. How many dermatologists would have reported this as a cosmetic reaction or would have been suspicious of a cosmetic reaction?

Ingredient information

In the *Contact Dermatitis Newsletter* of January, 1967, Dr. Hjorth¹³ reported having studied 865 consecutive patients with contact dermatitis. Thirty-two of these patients reacted to perfumes on patch testing. They were coded ingredient samples. Eighteen of the 32 showed positive test responses to a detergent perfume mixture, 6 to toilet soap perfume A, and 26 to a coded sample identified only to the

doctor as toilet soap perfume B. It was of no benefit to the patients to know that they were allergic to a coded ingredient sample, be it A or B. However, upon analyzing the testing results on 9 patients who showed positive test responses to one particular perfume wherein the perfume manufacturers gave the physician a precise breakdown of chemicals in their perfume, they found that two of them had positive reactions to coumarin and four had reactions to benzylsalicylate. They noted that the simple exclusion of coumarin and benzylsalicylate could have reduced the incidence of disease by 66%. Even if we are not impressed with the obvious benefit of reducing the incidence of dermatologic disease by 66%, the doctor's ability to explain to each patient that if she avoided perfumes containing coumarin or benzylsalicylate she could be free of disease is certainly worthy of merit. The benefit of proper testing becomes self-evident.

Through the courtesy of the Cosmetic Research Section of the Federal Food and Drug Administration I have a list of 180 cosmetic chemicals and the frequency in which they were found in 138 cosmetic samples analyzed. These 138 cosmetics were those which had been identified in investigational and complaint samples of cosmetic and perfume products to the FDA. Beta-phenylethyl alcohol was found in 63 such samples, diethyl phthalate in 60, linalool in 57, terpineol in 45, and the rest in a smaller number. The practicing dermatologist has no information or knowledge in regard to these chemicals. He is not equipped to apply 48-hour patch tests in the proper testing concentration, and has virtually no information as to how frequently each of these chemicals is used by cosmetic manufacturers. He has no knowledge as to whether or not these chemicals are found in other areas of the patient's environment. We have noted throughout this presentation that we are dealing with relatively weak sensitizers and must realize that predictive techniques utilized by the cosmetic manufacturer may fail to identify relatively weak allergens.

Nowhere in dermatology, with the exception in recent years of the preservative chemicals,^{1,2} the salicylanilides,¹⁴⁻¹⁶ and perhaps the lanolin fractions, can we find adequate studies which have worked out the proper testing concentration to the better than 4,000 chemicals used to manufacture cosmetics. There is no readily available reference where the practicing dermatologist can learn which concentration of the cosmetic chemical will not produce false positive irritant responses on normal control volunteers and yet which will be adequate to produce a true allergic reaction in the patient with cosmetic allergy. Dermatologists in general do not read the cosmetic trade journals and the cosmetic literature and, therefore, are not adequately informed in cosmetic chemistry. In like manner, most dermatologists are not aware of the fact that chemicals in cosmetics can be found elsewhere in our environment. Several years ago I had written inquiries to 20 manufacturers of women's shampoos and learned that half of these shampoos used formaldehyde as a preservative.¹⁷ During the past year at our Clinic we have quantitatively analyzed 112

samples of women's fabrics or women's clothes and found that all of them contained some free formaldehyde. There were samples that contained greater than 3,000 parts per million of free formaldehyde. We also realized that formaldehyde is found in women's shoes, and in tissues that have wet strength and in many other areas of our environment. A similar story can be told for the parabens, for EDTA¹⁸⁻²⁰ and other cosmetic chemicals. In past years we have demonstrated in the literature that the paraben allergic patient can go on for many years with chronic contact dermatitis, cause undetermined, and without a cure until the paraben allergy is adequately defined and documented. We do not have similar information on the majority of the chemicals used to manufacture cosmetics. If the dermatologist is not adequately equipped to diagnose cosmetic allergy, if the allergen can be found in multiple areas of our environment, especially when one notes that any particular cosmetic chemical can be found in many different cosmetics as well as in non-cosmetic exposure, and if we have record of 70 cosmetic allergic patients who have not been reported to any agency, then we have no knowledge of the true incidence of cosmetic reactions.

Proposal

I would like to propose a cooperative study between the cosmetic industry and the North American Contact Dermatitis Research Group or some similar body of clinical dermatologists interested in allergy. If through such cooperation this group with the help of the cosmetic chemists could determine the proper testing concentration of the majority of these chemicals and then apply these tests to a large series of patients with proven, documented cosmetic allergy in a clinical setting, we would expect to gain greater knowledge and understanding of the true incidence of cosmetic allergy and identify those chemicals which more frequently produce allergic cosmetic reactions. With cooperation in such studies perhaps the incidence of allergic disease can be reduced and, more importantly, the consumer or the patient with full knowledge of the precise allergen can return to the manufacturer and obtain guidance as to which cosmetic she may purchase free of the

specific allergen. This information could be shared with the cosmetic industry and as a result the consumer, the industry and the practicing dermatologist can all derive mutual benefit.

The dermatologist with the patient in his office, if he is well informed, can explain to each patient with cosmetic allergy that she can become allergic to any chemical be it in cosmetics, drugs or other areas of her environment. He can teach her that the cosmetics she is using are safe for the general population and that her allergic reaction is not caused by a faulty product. In this way the knowledgeable dermatologist can discourage and most often prevent litigation. We ask for a closer working relationship between the cosmetic industry and interested dermatologic investigators.

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Cosmetic Allergy: Diagnosis, Incidence, and Management

William F. Schorr, MD, Marshfield, Wisconsin

THE RECORDS OF ALL PATIENTS suspected of having cosmetic allergy seen during the last few years were reviewed and the adequacy of documentation was studied. From this study 70 patients were proved to have cosmetic allergy based on the following criteria: 1. Appropriate clinical characteristics with history and documentation of dermatitis produced at the cutaneous site of application, with healing upon withdrawal of that cosmetic; and 2. A positive open test or usage test to the suspected cosmetic applied to the skin of the antecubital fossa and/or a positive 48-hour closed patch test.

The Usage Test—In the open test (usage test) the patient was asked to simply apply the cosmetic to the antecubital fossa b.i.d. as she would normally use it. The patient returned to the office in a few days for photographic recording of the disease reproduction. No cover or occlusion was used.

The Patch Test—The 48-hour closed patch test conformed to accepted international standards.¹ Only concentrations of a cosmetic ingredient which would not produce false positive irritant responses on normal control volunteers were applied under the 48-hour patch test. The upper

back was the testing site. Tests were removed at 48 hours and if only one reading was possible, this was done at 72 hours. Test interpretation was that of a 3+ international system. No testing was performed when the patient presented with active dermatitis.

Inasmuch as there are estimates of greater than 5,000 different chemicals used in the manufacture of cosmetics, and ingredient information was ordinarily not available to the dermatologist, specific ingredient testing was very limited.

Results

Table I tabulates the 70 cosmetic allergic patients together with the number of patients reacting to each type or class of cosmetics. Cosmetic creams and lotions accounted for 31 out of the 70, (almost half) of all cosmetic allergic reactions. Perhaps this great preponderance of cosmetic

Table I—Cosmetic Allergic Patients
Diagnosis and Therapy at the
Marshfield Clinic
(57 Women, 13 Men)

Creams and Lotions	31
Perfumes and Colognes	9
Hair Dye and Color Rinses	6
Deodorants	6
Eye Makeups	5
Facial Makeups	5
Multiple Cosmetics	4
After Shave Lotions	3
Shampoos	2
Nail Preparations	1
Skin Fresheners	1

From the Department of Dermatology, Marshfield Clinic, and the Marshfield Clinic Foundation for Medical Research and Education.

Reprint requests to the Department of Dermatology, Marshfield Clinic, 630 South Central Ave, Marshfield, Wisconsin 54449.

Table II—Number of Cosmetic Allergic Patients with Past History of Other Dermatologic Disease

Previous history of contact dermatitis unrelated to cosmetics	12
Stasis Dermatitis	10
Atopic Dermatitis	9
Hand Dermatitis (Housewives' Eczema)	6
Psoriasis	1
Perianal Pruritus	1
Other Unrelated skin disease	2

41 out of 70 cosmetic allergic patients had a history of other dermatologic disease.

40% of cosmetic allergic patients had a history of either previous contact dermatitis or stasis dermatitis.

cream and lotion allergy can best be understood from a review of Table II. This table shows that 40% of the cosmetic allergic patients had a history of either previous contact dermatitis unrelated to cosmetics or a history of stasis dermatitis. The average woman with housewives' eczema of her hands, stasis dermatitis, or the average worker with irritant or allergic contact dermatitis by history most often resorts to cosmetic creams and lotions for relief of their discomfort prior to consulting a dermatologist. Damaged or inflamed eczematous skin, whether caused by stasis dermatitis or contact dermatitis, is more vulnerable to or has a greater percentage chance of developing allergic reactions to applied chemicals. If this stasis dermatitis or hand dermatitis is exposed several times a day to cosmetic creams or lotions with their very large number of possible ingredients, even weaker allergens can account for a significant incidence of clinical disease. If the allergen is a paraben, a lanolin fraction, a mercurial, a para-amino compound, formaldehyde, EDTA or other similar chemical which finds wide usage not only throughout the cosmetic industry but also in other areas of the patient's environ-

ment, intractable recurrent contact dermatitis can and does result when the precise allergen is not identified.

Table III lists the specific allergens found in the series of 70 cosmetic allergic patients. Some patients had multiple allergens. Therefore, fewer than 65 out of the 70 cosmetic allergic patients had the etiologic chemical identified.

Table III could not be an accurate reflection of the relative propensity of the various cosmetic chemicals to produce allergy. The number of possible allergens available for testing was extremely limited and this Table merely reflects the findings from the chemicals known and available.

The interest in the parabens and universal screening for parabens, lanolin fractions, paraphenylenediamine and dichlorophene represent an obvious bias.

Case Reports

CASE 1—A woman presented with a recent history of using a popular ammoniated mercury-containing skin cream on a Saturday evening, followed by a severe allergic reaction on Sunday morning. Patch tests revealed a strong 3+ reaction both to the Esoterica bleach cream

Table III—Specific Allergens Identified in Cosmetic Allergic Patients

Parabens	8
Sorbic Acid	4
Formalin	3
Mercurials	5
Dichlorophene	6
Hexachlorophene	1
Ethylene Diamine—EDTA	2
Lanolin	5
BRIJ 30 and 72	2
Eugenol	1
Isoeugenol	2
Oil of Bergamot	1
Oil of Clove	1
Cinnamic Aldehyde	3
Lavender Oil	2
Balsam of Peru	3
Oil of Eucalyptus	1

This list does not include positive test reactions to coded perfume samples where ingredients were not identified.



Fig 1. Allergic reaction to a cosmetic cream. Note red, swollen, inflamed face (case 1).

Fig 2. Severe burning due to cosmetics (case 2).



as well as to the ammoniated mercury.

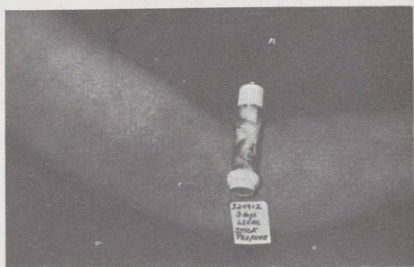
To illustrate an allergic reaction to a cosmetic cream, note her very red, swollen and inflamed face (Fig 1). If the diagnosis is made at this stage, it is not difficult to define this as a contact dermatitis to cosmetics after an adequate history is taken. However, if this patient goes on to more widespread dermatologic involvement, the diagnosis can easily be missed.

CASE 2—A 17-year-old girl first presented in our hospital emergency room with a history of applying the cosmetic two days previously (Fig 2). She stated that during that day she had to wash the cosmetics from her face because of severe burning. All cosmetics were removed from her environment and she was treated with compresses followed by the topical application of a fluorinated corticosteroid cream. One week later, after her skin had healed, she returned for appropriate testing. Patch tests were positive to the cosmetics shown.

The patient was seen again about eight months later with a crusted dermatitis of her cheeks at the site where she had again applied liquid make-up produced by the same manufacturer. Withdrawal of this cosmetic again led to complete skin clearing. Patch tests to the limited number of known cosmetic chemicals used in our 1971 screening tray were negative and the precise allergen was never identified. She had a past history of nickel allergy documented in the office in 1970.

CASE 3—A 23-year-old dietitian was first seen with dermatitis of her arms, shoulders and upper breasts. The possibility of contact allergy to elastic was considered, as there was dermatitis under the elastic of her panties. She stated, however, that she broke out in a rash every time she applied a lilac stick perfume. All elastic and cosmetic items were removed from her environment. After her dermatitis healed, she was instructed in the performance of an open test of her lilac stick perfume applied twice a day to one antecubital fossa and her Carnation Cream Sachet applied in the same manner to her other antecubital fossa. Within 24 hours she presented with a significant dermatitis (Fig 3) only at the site of application of her lilac perfume. This dermatitic response spread beyond the site of open application. Further dermatologic evaluation demonstrated reactions to neomycin and nickel sulfate as concomitant allergens. The precise allergen in

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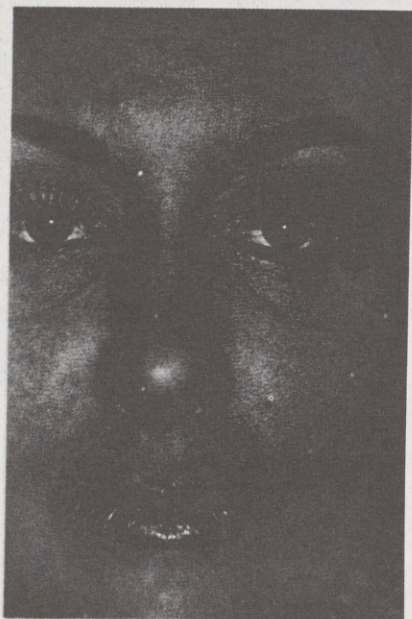


Fig 6. Dermatitis on eyelids and lips from "gloss in a pot" type cosmetics (case 7).

wearing the currently popular "gloss in a pot" type eye and lip cosmetics (Fig 6). As we noted,² these gloss type eye and lip cosmetics are both produced by mixing lanolin fractions in a container and heating to about 85°C. then adding the desired perfumes, pigments and a pearling agent such as titanium coated mica. The mixture is cooled and poured into pots and sold for cosmetic use. These cosmetics have gained popularity because they impart a moist, glossy appearance on the ladies' lips and eyes. Three such patients have been seen with strong positive patch test responses to wool wax alcohols, lanolin fractions found in these cosmetics.

Commentary

During the past year five patients have been observed with allergy to an underarm deodorant. Coded ingredient samples were obtained from the manufacturer of this particular underarm deodorant. All five reacted to the perfume fraction. One of

these five, a doctor's wife with severe dermatitis of the axillae, had tried multiple cosmetics by a number of manufacturers during the subsequent two years and had at least four recurrent bouts of contact dermatitis caused by perfumed cosmetics due to the inability to identify the precise chemical allergen within the perfume fraction.

Cosmetic allergy can at times present clinical pictures which very easily mislead the practicing dermatologist. We have seen a woman with contact dermatitis on the inside of a forearm and arm. Cosmetic allergy would hardly have been suspected in this patient unless it was realized that she was unable to sleep in any other position except with her head resting on this portion of her arm. Further questioning of the patient revealed that the dermatitis on her forearm flared each time she had her hair dyed or tinted. Patch testing revealed a strong positive 48-hour response to paraphenylenediamine.

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Ingredient Information

In Contact Dermatitis Newsletter, January 1967, Hjorth⁴ studied 865 consecutive patients with contact dermatitis. Thirty-

two of these patients reacted to perfumes on patch testing. They were coded ingredient samples. Eighteen of the 32 patients showed positive test responses to a detergent perfume mixture, six to toilet soap perfume A and 26 to a coded sample identified only to the doctor as toilet soap perfume B. It was of no benefit to the patients to know that they were allergic to a coded ingredient sample, be it A or B. However, upon analysing the results on nine patients who showed positive test responses to one particular perfume wherein the perfume manufacturers gave the physician a precise breakdown of chemicals in their perfume, they found that two of them had positive reactions to coumarin and four had reactions to benzylsalicylate. They noted that the simple exclusion of coumarin and benzylsalicylate could have reduced the incidence of disease by 66%. Even if we are not impressed with the obvious benefit of reducing the incidence of dermatologic disease by 66%, the doctor's ability to explain to each patient that if they avoided perfumes containing coumarin or benzylsalicylate, they could be free of disease, is certainly worthy of merit. The benefit of proper testing becomes self-evident. Through the courtesy of the Cosmetic Research Section of the Federal Food and Drug Administration, a list of 180 cosmetic chemicals was compiled, with the frequency in which they were found in the 138 cosmetic samples analysed. These 138 cosmetics were those which had been identified in investigational and complaint samples of cosmetic and perfume products to the Federal Food and Drug Administration. Beta-phenyl ethyl alcohol was found in 63 such samples, diethyl phthalate in 60, linalool in 57, terpineol in 45 and the rest in smaller number. The practicing dermatologist and the practicing allergist has no information or knowledge regarding these chemicals. He is not equipped with the ability to apply 48-hour patch tests to the proper testing concentration and he has virtually no information as to

how frequently each of these chemicals is used by cosmetic manufacturers. He has no knowledge as to whether or not these chemicals are found in other areas of the patient's environment. Since these are relatively weak sensitizers, it must be realized that predictive techniques utilized by the cosmetic manufacturer may fail to identify relatively weak or moderate allergens.

Nowhere in dermatology, with the recent exception of the preservative chemicals,⁵⁻⁸ the salicylanilides,⁹⁻¹¹ and perhaps the lanolin fractions, are there adequate studies for the proper testing concentration to the better than 5,000 chemicals used to manufacture cosmetics. There is no readily available reference wherein the practicing dermatologist or allergist can learn that concentration of the cosmetic chemical which will not produce false positive irritant responses on normal control volunteers and yet which will be adequate to produce a true allergic reaction in patients with cosmetic allergy. Dermatologists in general do not read the cosmetic trade journals and the cosmetic literature and, therefore, are not adequately informed in cosmetic chemistry. In like manner, most dermatologists are not aware of the fact that chemicals in cosmetics can be found elsewhere in our environment. Several years ago I had written inquiries to 20 manufacturers of women's shampoos and learned that half of these shampoos used formaldehyde as a preservative.¹² In this study, two student beauticians in training spent the entire working day shampooing hair. Initially they developed an irritant dermatitis. However, this chronically inflamed skin ultimately became sensitized to formaldehyde in their shampoos and their dermatitis spread and became more recalcitrant. One of the women then treated her hands with a pink hand and body lotion which also contained formaldehyde as a preservative. During the past year a quantitative analysis of 112 samples of women's fabrics or women's clothes showed that all of them contained

some free formaldehyde. There were samples that contained greater than 3,000 parts per million of free formaldehyde. Formaldehyde is found in women's shoes and tissues that have wet strength and in many other areas of our environment. A similar story can be told for parabens,⁷⁻⁸ EDTA,¹³⁻¹⁵ and other cosmetic chemicals. In past years we have demonstrated in the literature that the paraben allergic patient can go on for many years with chronic contact dermatitis, cause undetermined, and without a cure until the paraben allergy is adequately defined and documented. There is no similar information on the majority of chemicals used to manufacture cosmetics. The dermatologist is not adequately equipped to diagnose cosmetic allergy; the allergen can be found in multiple areas of our environment, especially when any particular cosmetic chemical can be found in many different cosmetics as well as in non-cosmetics. Since these 70 cosmetic allergic patients were not reported to any agency, there is no knowledge of the true incidence of cosmetic reactions.

Mitchell and Collins¹⁶ correctly conclude that: "It is unlikely that much progress will be made without close biochemical-dermatological collaboration and possibly resolution of the problem of dermatitis from aroma chemicals will have to await the development of a computerized *in vitro* system for delayed hypersensitivity."

SUMMARY

This is a study of 70 patients with a proven diagnosis of cosmetic allergy based upon appropriate history and findings. The diagnosis was established by resolution of the dermatitis after withdrawal of that cosmetic and by either a positive open test to the suspected cosmetic applied to the skin of the antecubital fossa or a positive 48-hour closed patch test to the appropriate testing dilution of the cosmetic ingredient. Thirty-one out of the 70 cosmetic allergic patients had their allergy produced by cosmetic creams and lotions. The clinical appearance of the various forms of

cosmetic allergy is illustrated. There are greater than 5,000 different chemicals which can be used in the manufacture of cosmetics and many of these chemicals can be found not only in multiple cosmetic items produced by a variety of manufacturers, but also in other areas of human environment. This study shows the manner in which an allergic reaction to one particular cosmetic chemical can produce long-standing, recurrent and disabling eczema if the diagnosis is not properly made and all environmental sources of that allergen are not defined to the patient and eliminated from the patient's environment. Recommendations as to appropriate diagnostic techniques are presented.

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Senator EAGLETON. I will ask a couple of questions, Dr. Schorr, and then I am going to give Dr. Jordan a little rebuttal time. I love it when doctors disagree. It peps things up here.

Doctor, does it make any difference to you in the listing of ingredients whether it be listed in descending order of predominance or listed alphabetically?

Dr. SCHORR. The concentration, the amount in the product has absolutely no meaning to me as a physician—zero.

If you are allergic to it, you can be allergic with the slightest amount.

Senator EAGLETON. Would all three doctors agree with that?

Dr. LARSEN. Yes; we agree with the alphabetical listing.

Senator EAGLETON. Insofar as listing fragrance and color, you would want the specific code numbers listed for both fragrance and colors?

Dr. SCHORR. I do not want code. I want the names of the chemicals on the insert. I would like the chemicals, or at least have those chemicals readily available to the physician.

Senator EAGLETON. Now, Dr. Jordan, we will yield to you at this time and let you rebut in part or in whole.

Dr. JORDAN. It is not rebuttal.

Let the record show that I did not mean for the manufacturer to send coded samples. Just the name on the label should be coded.

The manufacturer obviously does not send a coded sample—he has to tell us what it is. In terms of dialog, when you call the manufacturer, when you discuss his fragrance, you discuss it because it has a given name, because that fragrance may be withdrawn sometimes. The production schedule changes at the middle of the year because of a supplier falling flat on his face and they reformulate.

It still has the same smell. This new formulation gets the same code number with a prefix or suffix added. That is the code I am talking about, not coded samples for patch testing.

The other thing is, the reason I am talking about a telephone number is because the patient may be allergic to cinnamic aldehyde, and she also may have six other allergies related to cinnamic aldehyde. The reason for the hot line number, if I want to say to Avon or Lauder, if I want to say I have a patient with cinnamic aldehyde allergy and she wants to use your perfume, and I can call one of these companies and ask if she can use their product. She does not have to test it. The phone number is an integral part of this; the dermatology cosmetic hot line to the key man.

The patient may know she is allergic to cinnamic aldehyde. She can buy six or seven perfumes, this ingredient listed; she can still react to all of them. It is still going to be trial and error.

I happen to know what most cross reactions are, or a majority of them, to cinnamic aldehyde.

I could call up Avon and say, I have got a cinnamic aldehyde, read me the components, and my patient desires to switch to your product, if he says benzylbenzoate, and I know that compound is out. He reads another one, styrax, and I know that this one is also out.

I call up and say what about unscented? He says that unscented is just a musk fragrance. I say, that is it. You are in.

Senator EAGLETON. Why not have the best of both worlds?

Why not take proposals of both Dr. Schorr and Dr. Jordan, that is, have an insert in the box where there is not room enough on the label and have ingredients, including the fragrance ingredients, and have the medical hot line, too?

Both of you would be happy.

Dr. JORDAN. Many times I still end up getting on the phone to solve the patient's problem. I cannot solve it from the package, and these are prescription medicines I am talking about, topicals that are prescription, they list every ingredient on the label.

So when I am dealing with a prescription medicine that has caused an allergy, I either have to call and get some component that I do not have; I have to ask the relative percent so I can patch test it properly; so, in other words, to get the evaluation done on the patient still requires some dialogue between one informed manufacturer personnel and myself.

Now, as to the suggestion, I am not going to object, except I think it is forcing the manufacturer into—well, after all, it will turn out that all this full disclosure will be for the benefit of Walt, Bill Schorr, and myself and 12 others in America.

Dr. SCHORR. I would hope the patient would benefit.

Dr. JORDAN. Well, indirectly. But he has got to come to us because I am the only one that has got all day to patch test him. That is what I do all day. Nobody else has that time.

If they help me, I can help the patient. But I am not sure any one of the Cinnamic allergies or perfume and fragrance allergies can go through People's drugstore and come up with anything meaningful.

That formaldehyde example is a very true one. There is no formaldehyde that will ever be listed on these products. Yet you can go and find several with completely different names that are formaldehyde releasers.

They are not going to put an asterisk up there and say we release formaldehyde.

One company denies his product releases formaldehyde, but it does.

To get all this information on the label will require a very small encyclopedic text, in my opinion.

We need to get to the right people.

Senator EAGLETON. Would it require this encyclopedic text, Dr. Schorr, and can you diagnose your patient's ills from labels or must you make a phone call?

Dr. SCHORR. First of all, I cannot make the phone calls—the number of patients I see a day make it impossible for me to be on the phone that much.

I think there is a higher order in my mind that is important. If committees, like this North America Committee and International Committee, can come back to the physicians and work out standard testing systems, and then develop testing systems that with 20 tests and 30 tests we will be able to identify 75 or 80 percent of all cosmetic allergy, which I think is possible, then perhaps the physician who sees the patient throughout the country can use this testing system, identify 75 to 80 percent of the cosmetic allergy, name the chemical to the patient, and the patient goes back to the insert and sees that they are allergic to that chemical.

Now, this type of thing is a ways down the pike. This has been accomplished in other areas of dermatology.

We have screening test trays that, with a half-dozen tests, we will pick up 70 percent of all rubber allergy. We can do this with the metals. We can do this with plastic industry. We can do this with many areas in our environment, where cooperative studies, in groups such as ours, have paved the way by identifying the correct testing concentration, study larger numbers of people, and then coming back to the practicing physician and saying, look, here is a testing system that will pick up 70 percent of the allergy.

Then when more physicians are doing it, and when the exact chemical is named, for example, formaldehyde, the physician himself can point out to the patient that bronopol is another name for a formaldehyde releaser.

At least, that patient has something to go back to after he has been diagnosed, after she has been told, so she can find out whether it is there or not.

Senator EAGLETON. What about the encyclopedic nature of the list?

Dr. SCHORR. I would hope that we do not have to have cosmetics that require an encyclopedia to list them.

Any patient can become allergic to any chemical. While these chemicals would be extremely safe, the chance of becoming allergic to any one chemical is small—if there are 1,000 chemicals in that bottle—well, I do not care how small it is, you are going to run into more problems.

I would hope that the ingredients would not have to list more than 75 or 80 or, at the most, 100. I would hope there would be a lot less than that.

In reality, I would think it is in that neighborhood.

If it takes 1,000 chemicals, I would hate to see it put on our skin.

Senator EAGLETON. We will hear some expert testimony, I presume, from manufacturers as to what the ingredient number is, I mean, where the range is; 1 to 100 or 1 to 100,000, could make a difference in terms of complexity.

Dr. SCHORR. How many do we really need to smell sweet?

Is it necessary to have 1,000?

Senator EAGLETON. We will find out.

Dr. Larsen, where do you come down in this disagreement between Dr. Schorr and Dr. Jordan?

Dr. LARSEN. I think, as a practical matter, you cannot list the 100 or 200 ingredients of a fragrance. I would be for a code with a phone number, at least the accessibility to the toxicologist or medical director of a company.

If there are more than three fragrances in any perfume, I think it is futile to list them.

I would like to touch briefly on two other points.

That is, adverse reaction complaints. We believe there should be two categories of complaints. That is the general consumer complaint, which may be true, hearsay or spurious. And then the physician documented complaints including patch test corroboration.

I think there is a possible disparity between the two.

Senator EAGLETON. But do I understand what you are suggesting is that in the complaints that are kept by the manufacturer, they be kept in two separate files, as it were—

Dr. LARSEN. Exactly.

Senator EAGLETON. One, where the consumer writes in and says this is a crummy product, it made me sick. And the other one where the physician made contact by phone or in writing?

Dr. LARSEN. Yes.

And if the physician has patch tested the patient and can show this evidence.

Senator EAGLETON. Are you a consultant, Dr. Larsen, to any cosmetic firms?

Dr. LARSEN. I consult no cosmetic firm, and I have no commercial ties whatsoever.

Senator EAGLETON. In your private practice of dermatology, have you had occasion to call on any of the cosmetic manufacturers?

Dr. LARSEN. Yes, many times.

I have called on Avon, Estee Lauder, Merle Norman, and they are very cooperative. I talk directly to the toxicologist, and they package up the ingredients and send it air mail, special delivery. They are very cooperative.

Other companies, and these are large companies, will not acknowledge my letter.

Senator EAGLETON. The record is mixed?

Some have been very cooperative and some have not?

Dr. LARSEN. That is correct.

I think this should be a requirement, at least a moral commitment, that the cosmetic manufacturers should supply the physician with patch test materials in order to determine the specific cause of the allergy.

Senator EAGLETON. All right.

I have one final batch of questions.

I think I will start with Dr. Jordan, and if either of you disagree with anything Dr. Jordan says, we will have it for the record.

Dr. JORDAN, are there certain chemicals in perfumes that consistently cause contact dermatitis?

Dr. JORDAN. We think so. But that is an ongoing study, it is almost complete, but it is officially not published. And I think Dr. Schorr will agree, we have homed in, in one area that seems to me—it might cover as much as 50 percent of reactions. That is data that needs looking into. And studies are not over.

We have all been looking at it privately—

Senator EAGLETON. Are you making one of these studies?

Who is making these studies and when do you think they will be complete?

Dr. JORDAN. We have done it by ourselves and pooled our data. In other words, we try to solve every fragrance problem possible. And we have had a compound in the patch test kit known as Balsam of Peru, which is related to some of the troublemakers.

We have broken down some of the components of Balsam of Peru, and you heard one of the words dropped here several times, cinnamic aldehyde.

It is not only that, but it is a lot of its close relatives. This is an area we are looking into.

Senator EAGLETON. Dr. Schorr and Dr. Larsen, do you concur?
Dr. LARSEN. Yes.

We think there are primarily five fragrance chemicals that cause possibly the majority of reactions.

Dr. SCHORR. There is an awful lot we do not know about, however. We do not have adequate testing systems. I am sure there is going to be a small group that can define the majority of the problems, and I am not sure we are in a position to——

Senator EAGLETON. We are not ready to know what that group is, but maybe a year or in a year or 2, we might.

Dr. SCHORR. It depends on how much information we have.

Senator EAGLETON. Assume we reach that point, in a year or 2 or 3 from now, do you think it would be possible for the Commissioner or the Secretary of HEW to establish some kind of list of known allergens and fragrances, and require that only those known allergens be listed on the label?

Dr. SCHORR. No, because it is changing technology, and known allergens of today may be different allergens of tomorrow.

We have to keep up with the changing systems of industry, the changing chemicals used by industry.

Dr. LARSEN. I concur.

Dr. JORDAN. Agreed.

Senator EAGLETON. Well, thank you very much.

Our next group is from Estee Lauder. Leonard A. Lauder, president, Estee Lauder, Inc., accompanied by Joseph Gubernick, vice president, research and development.

STATEMENT BY LEONARD A. LAUDER, PRESIDENT, ESTÉE LAUDER, INC.; ACCOMPANIED BY JOSEPH GUBERNICK, VICE PRESIDENT, RESEARCH AND DEVELOPMENT

Mr. LAUDER. Good morning, Senator.

My name is Leonard Lauder. I am president of Estee Lauder, Inc., of New York.

I thank you very much for the invitation to participate in these hearings. I am very pleased to be here and I hope that my testimony will be of some assistance to the subcommittee in its work on the Cosmetic Safety amendments.

With your permission, I will submit for the record a much more detailed statement of the position of Estee Lauder, Inc., with respect to S. 1681, the Cosmetic Safety Amendments of 1975, introduced by Senator Eagleton. That prepared statement goes into considerably more technical detail than the brief remarks I will make today, and I ask that it be received for the record.

Senator EAGLETON. The full and more complete statement will be made a part of the record and inserted at the conclusion of your testimony.

Mr. LAUDER. Before commenting on the provisions of S. 1681, I would like to tell you something about our company and the nature of the fashion cosmetic industry.

At Estee Lauder, Inc., we are concerned solely with the manufacturing and distributing of cosmetics. It is our only business.

The company was founded by my parents, Estee and Joseph Lauder, who now serve, respectively, as chairman and executive chairman of the board, and who continue actively to "mind the store."

Today the company remains wholly family-owned, making Estee Lauder, Inc., the largest privately owned cosmetics company.

Because my family's name goes on our products, I have a personal concern in making certain that every cosmetic we sell is pure, safe, and useful to the customer.

Senator Eagleton. How does your company rank in terms of sales of cosmetics?

Mr. LAUDER. We think in the United States we are probably the fourth largest.

Senator EAGLETON. What is No. 1?

Mr. LAUDER. Avon.

Senator EAGLETON. Avon?

Mr. LAUDER. Followed probably by Revlon and Max Factor. That is within what we consider to be the fashion cosmetic business. I am not including the large toiletries manufacturers in this estimate.

The Lauder companies produce three "lines" of products—Estee Lauder, Aramis, and Clinique—which include approximately 1,000 different items, such as lipsticks, eye shadows, foundation, moisturizers, men's products, and the like.

As I said, we are in the fashion cosmetics business, in that sense, our colors, our fragrances, and our products themselves must be highly responsive to emerging styles and fashion trends.

For example, as the seasons change, certain colors become popular. We are constantly studying new fashions to be able, hopefully, to "scoop" our competitors on cosmetic colors that will best highlight next year's clothes.

We also never stop looking for products which will do an even better job of improving the user's appearance.

Partly because one season can literally make or break a company, advance product and color information is jealously guarded in our highly competitive business.

Before proceeding to a discussion of the specifics of the bill, let me take a minute to say that I welcome your concern, Senator, and that of the other subcommittee members in trying to insure that the cosmetics on the market are the safest and the best that we can provide. I know that has always been a major objective of Estee Lauder Inc.

When Senator Eagleton first introduced his bill, the Cosmetic Safety Act of 1973, we, naturally, began to study it, both through our trade association, the Cosmetic, Toiletry, and Fragrance Association, and in-house, to see what effect it would have on our operations and what input we might be able to provide to the subcommittee.

I was very flattered to receive the invitation to appear at these hearings. I am testifying today as the president of Estee Lauder Inc., speaking from my personal experience in the cosmetics industry.

Although I did not support S. 863, I will actively support S. 1681, if the revisions, which I believe are necessary to perfect it, are made. We need a comprehensive, definitive law on cosmetics—one that would end the never-ending series of regulations and counterregulations which leave us reeling and not able to properly run our business.

My general comments on the bill include three main points:

One: Although I agree that the FDA may need additional authority in some areas of the law to protect the public health and safety, I think that, as the bill is presently written, the FDA is given an excessive amount of discretion, especially in the area of safety substantiation.

We can live with some extension of authority, generally, on safety substantiation, provided the Secretary is required to determine, prior to taking action against a product, for example that on the basis of all available information, the action is necessary to reduce or eliminate a substantial risk of illness or injury to the public. Providing firm guidelines within which the FDA is to exercise its authority provides a much needed degree of certainty for both manufacturers and consumers.

Two: If the bill is to provide for submission to the FDA of any of our confidential files, such as formulas, ingredient lists by percentage range, or product experience files, this information must be given specifically defined trade secret status in order to protect the secrets upon which our company was built from disclosure to our competitors.

Three: I have no objection to ingredient labeling. It can be useful, especially for the consumer who wants to avoid a known allergen.

However, listing ingredients alphabetically will adequately protect this consumer. The only beneficiaries of listing ingredients in descending order of predominance by weight are our competitors.

Let me put an end to the myth that any graduate chemistry student can duplicate a cosmetic in his home laboratory. We estimate that there are less than 12 establishments in the country that currently have the staff or equipment necessary to break down formulations—and, unfortunately, we are not one of them.

However, giving competitors a "road map" with ingredient labeling in descending order of predominance by weight will enable nearly anyone to duplicate our products.)

The statement I am submitting for the record contains detailed section-by-section comments on S. 1681. I would just like to highlight a few of these suggestions now.

As I have said, I believe that S. 1681 places the primary responsibility for safety substantiation squarely where it belongs, on the shoulders of the manufacturer.

However, I want to emphasize that safety substantiation is not to be confused with preclearance of cosmetic products. We do not think that manufacturers should be required to submit testing or other data on new products or any other product either 90 days or some time period prior to marketing.

A system of preclearance is not necessary with products such as cosmetics, even though it obviously serves a purpose in the case of new drugs.

The Eagleton bill, by placing an affirmative duty on the manufacturer to adequately substantiate the safety of his products and also by giving FDA the means to discover product hazards by examining experience files submitted by the manufacturer, will properly protect the consumer, which I want as much as you do because my name is on the product.

Safety substantiation means that we are primarily responsible for making sure that the products are safe for their intended use on the basis of the information available to us at the time of marketing. We must be able to rely on the judgment of our medical and technical experts on this.

If any testing standards are set by the FDA, they should be based on strictly objective criteria obtained by the Secretary after mandatory consultation with a wide range of scientific opinion, preferably through the device of the advisory committee.

In delegating broad authority to the FDA to classify products according to potential risk of harm, or to establish testing standards, et cetera, we think that explicit standards should be provided in the statute to guide the exercise of this discretion.

If formulas or product experience files are to be submitted to FDA, trade secret status must be provided for this information. Otherwise, such valuable information might be made available to competitors, and a manufacturer would lose the benefits of his research and development efforts and product innovations to his competitors.

Administrative detention should be able to be imposed only by order of the Commissioner, or a specified level FDA official—we are tremendously concerned that an FDA field inspector can, on his own, detain a product. We approve of the provision in S. 1681 for expedited appeal of such detention to the Secretary. However, we also think that before a detention is actually imposed on products, a 72-hour cooling-off period should be observed to enable the pros and cons of the detention to be discussed.

A consumer who wishes to avoid products with certain ingredients, because of a known allergy or other condition, would be provided a quick way to determine the presence of that ingredient if ingredient labeling were done in alphabetical order.

Listing ingredients in descending order of predominance by weight does not help the "sensitive" consumer who will be required to avoid a product no matter what amount of that offending substance is present.

Furthermore, predominance by weight listing does not facilitate value comparisons, as the consumer is not able to ascertain at what price the manufacturer was required to obtain certain raw materials.

An example of identical formula products with different costs to manufacturers is provided in the statement submitted for the record.

Finally, I think that the provisions in S. 1681, exempting color from predominance by weight listing and providing for ingredient labeling within the package, namely the use of a package insert, are quite beneficial.

This provision, which provides that Federal labeling requirements supersede those of State and local entities will help avoid potentially confusing situations of differing labeling requirements and will greatly ease labeling compliance burdens for the manufacturer.

Every fire chief in America has his pet labeling requirement, so we welcome the Federal preemption provision.

As to factory inspection, we do not think it is necessary for the FDA to obtain factory inspection as broad as that it currently holds in the case of prescription drugs, for cosmetic manufacturing establishments, particularly since such broad authority is not applicable to food or over-the-counter drug manufacturers.

In conclusion, let me again thank you, Senator Eagleton, and your colleagues for the opportunity to share my views with you.

I think that if the industry and the members of this subcommittee work together, we can arrive at practical methods of insuring the safety of every cosmetic marketed, at a reasonable cost.

I will be happy to take any questions, with the understanding, of course, that if they get too technical, I will defer to Lauder's resident scientist, Joe Gubernick.

Senator EAGLETON. Thank you very much, Mr. Lauder. We appreciate the constructive nature of your testimony.

The purpose of the hearings of the committee is to receive expert testimony and comments on the bills that are introduced, and you have made a significant contribution in dealing with S.1681, its good points and its bad points.

Could you go back, Mr. Lauder, to page 4, where you made your first point?

I wonder if you could expand on this?

You say: "Although I agree that the FDA may need additional authority in some areas of the law to protect the public health and safety, I think that, as the bill is presently written, the FDA is given an excessive amount of discretion, especially in the area of safety substantiation."

It is a very important section of the bill, the heart of the bill, and I would like any additional comments you could make to spell out the point that you are trying to make.

Mr. LAUDER. The key thing is the difference between preclearance and safety substantiation.

In your opening statement, you said, on the bottom of page 3, "However, the FDA is given that authority to require submission of safety data if it feels that so doing would better protect public health and safety."

What this does is leave to the discretion of one person or one Government body the sole decision that if they think a product may be something that they would like to regulate, that they can simply and immediately require preclearance. That, we feel, would lead to what would be a growing series of regulations on preclearance that would finally wind up in a few years with the cosmetic industry having the same preclearance requirements as an NDA.

I can see NDA for new antibiotics, but I can hardly see it for a new cosmetic in "romantic red."

Senator EAGLETON. There is a significant difference in S. 1681 vis-a-vis the bill we introduced in 1973.

The 1973 bill had a section on premarket submission of safety data, and the manufacturer ran a great risk of marketing a product prior to the 90-day premarket submission.

We have departed from that, and we want safety substantiation. I take it you are telling us that, yes, a cosmetic manufacturer should have to provide safety substantiation data to the FDA, but you want it tied down more specifically to avoid capricious excessive demands made on the manufacturer, just some bureaucrat calling up every day, saying send me down some more data.

Mr. LAUDER. We would like to prescribe the area in which the Commissioner of FDA can require that data.

We agree that if there is definite risk to the health and safety of the consumer that this data should and must be submitted. But, as long as it is carefully prescribed, and that there is a panel that the Secretary can lean on, an expert panel that would say, yes, it shows there is a definite risk, but only on that basis. I would hate to read about myself in the Federal Register every morning.

Senator EAGLETON. Would you agree that the Secretary or Commissioner should have the authority to require premarket submission of safety data if it has been determined that a particular ingredient or class of products presents a significant risk of harm?

Mr. LAUDER. That is a difficult question, because I start on the initial assumption that any ingredient that shows that there is possible harm would therefore never be put into one of our products, or any products approved by CTFA members.

I think, again, that opens up a loophole. I would much prefer to see a situation whereby, if an ingredient is considered to be unsafe, the burden falls on the manufacturer and his safety-substantiation procedure with criminal penalties if it is not safe.

So I think you have built into that safety substantiation a provision, with enough protection, so that it does not have to be pre-cleared. I am terribly afraid that the more loopholes we open up, the more bureaucracy there will be with more preclearance.

Senator EAGLETON. Now, you have been present all morning, during the time when Dr. Schorr, Dr. Larsen, and Dr. Jordan were testifying regarding a coding system for the labeling of fragrances. Could you comment as a manufacturer with regard to any practical problems that might pose for you in the listing on a coding basis the fragrances?

Mr. LAUDER. I would like to turn to Joe Gubernick on that.

We have had some discussions.

Mr. GUBERNICK. I think our discussion has been that we feel that it is possible for us, as a manufacturer, to have a code number for each of our fragrances, and so indicate that on each of our products.

If we use the same fragrance in the makeup as we do in a night cream, and the consumer has already found out she is allergic to that fragrance in the makeup, she cannot use it in the night cream. And it is something we could live with. And it is something we do not find excessive or objectionable.

Of course, it would be a separate code for each company. It would be very, very arbitrary; if the medical profession really felt that would help, we would live with it.

Senator EAGLETON. I will ask you or Mr. Lauder, during the testimony of the three doctors, it was brought out that in the fragrance there could be component parts to which individuals were allergic.

And the thrust of their testimony, I guess two of the doctors, was that the breakdown of the component parts of the fragrance should be on the insert sheet of paper so as to warn the consumer.

From a practical point of view, how difficult or onerous would that objection be?

Mr. LAUDER. I think I can answer that, first, by saying that for some of our products, it would be like writing the Lord's Prayer on the head of a pin.

I do not entirely agree—I believe Dr. Schorr made a statement that all you really need is 100 of the components.

Second, our stock and trade is really the secrecy of our formulas and, most specifically, of our fragrances. I think all of us are familiar, for example, with the well-know secrecy of the Coca-Cola formula. There are apparently two little men who lock themselves into a room in Atlanta, and God knows what they put into that thing, but that is a well-accepted trade secret.

I cannot say that Mr. and Mrs. Lauder do the same thing and mix 300 things together. But those formulas are very, very jealously guarded.

No one person has all elements of the formula. And to simply sit down and list the 200 or 300 ingredients of that individual fragrance would be delivering to my competitors our entire know-how that we developed over the nearly 30 years that we have been in business.

What we could do is work very, very closely with the dermatologists. I believe Dr. Larsen—it was mentioned that he has been in contact with us—and we send off to them complete patch-testing kits. We send them the individual components. We do not make any secret about what they are.

If they are something that the consumer is allergic to, we tell them what it is. We do have a hot line.

Joe Gubernick is in direct contact with a number of dermatologists throughout the country in this respect.

Senator EAGLETON. When Dr. Larsen or any other physician calls your company on the hot line, does Dr. Larsen—I did not quite get it straight in my own mind—does Dr. Larsen ask your chemist or toxicologist is such and such in the product, or is the question asked broadly to just give me the list of everything in the product?

Does he start listing 300 things?

Mr. LAUDER. I will defer to Joe.

Mr. GUBERNICK. Generally speaking, I would say 90 percent of the contact we have with dermatologists comes directly through the mail. They send us a letter to the effect that a patient is reacting to one or more of our cosmetics, and they think that they might be allergic to certain ingredients. Could we supply them with the information?

At that point, if it is very specific as to the product, we will immediately send off patch-test material and formulations if they so request it.

Senator EAGLETON. Even for the 100 or 200 or more component parts of the fragrance?

Mr. GUBERNICK. Well, to date, I do not think that I have had more than one individual ask me for a fragrance, a specific allergy to a known fragrance.

What we do at that point is go and break down this fragrance into sections, and we supply the sections, and as soon as the doctor says this section is what the patient is reacting to, we then tell him the components in that section.

Senator EAGLETON. Dr. Larsen, Dr. Schorr, or Dr. Jordan, for my edification, could you spell out just how you make your inquiries insofar as allergies?

Can you comment on the testimony of the man from Lauder?

Dr. JORDAN. I think I essentially agree. I am surprised of the frequency at which he says he has been asked for fragrance.

We cannot test 100 components or 300 components. Many times, we will call and say break it down into four fractions, and we will look at, say, fractions 1 through 4.

If fraction 3 is hot, that is we get a responder, then we go into fraction 3 and we leave the others out.

If the product is simple—it just depends on what you are asking for—if the product is simple, then I might want the whole thing.

Half the time, I own what he says is in there, and the other half of the ingredients I do not have, and I say I have got these and send me yours.

Sometimes we have to have the manufacturer's ingredient and not the ones we have.

There are a lot of suppliers, lots of different grades of purity, and one man's steric acid is not another man's steric acid. Therefore, if I get all negatives and I own all the ingredients, but I come back and say I want your ingredients, not the ones I have—well, we do it anyway to expedite the patch testing, so we get a quick answer.

The longer you let the patient sit around, the more you lose the patient.

I did not get anywhere in contact dermatitis by writing letters. I picked up the telephone. You know, the stuff is in the mail in 24 hours and the patient is back in 4 days. But I would essentially agree. We all try to expedite it. It depends on the product.

But usually if it is fragrance, you say I want the vehicle, preservatives, antioxidants, so-called additive thing that is supposed to make this thing unique and the fragrance.

And you go through there. If it is fragrance, you throw out the rest. If it is basic perfume, you say can you get it in five easy bottles, knowing there will be overlap. Maybe I can get two bottles to perform and two do not. Therefore, I do not have to worry about 150 ingredients in the other two bottles.

I have broken perfumes fairly nicely, and it takes a fairly cooperative patient to do it—I even pay my patient to come back for the data.

Senator EAGLETON. The AMA will throw you out.

[Laughter.]

Senator EAGLETON. You do make specific inquiry on occasion about the component parts of a fragrance?

Dr. JORDAN. Yes.

Senator EAGLETON. Now, Mr. Lauder points out that the fragrance is the vital key to his business; that the formula of the fragrance is what makes or breaks his company; and he made an analogy with Coca-Cola.

Have the companies been forthcoming to you in giving you the component parts of the fragrance to your medical satisfaction in terms of the performance of your physician duties?

Dr. JORDAN. It would be pure testimonial, by and large I have very good success.

The key to success is knowing who to call in the company. That is why I so made a pitch for a hotline.

If I knew this gentleman, I would call him.

Many companies I call and I get the wrong person. I get somebody in sales and nobody in sales admits anything.

If you happen to know the Ph. D. who has worked, not only for that company, but six other companies, who is a hardcore scientist, you get down on the crap table and say this is what I want. I want it in this. And he says I will give it to you.

It depends on who you get. That is why I thought with coded phone number, the company is not going to give you somebody on the other end in sales. They are going to give you a man like the gentleman at the other end of the table.

That is why I mentioned Avon.

They give you somebody who has the answers in his pocket.

If you write a letter, you are likely to have it in file 13, and then you write another letter and send it to CTFA and, at the same time, send one to a lawyer, then you will hear from them.

By that time, the patient has moved to Albuquerque.

So the real hot stuff goes on on the telephone in my opinion with the proper people. They exist in all the companies. If the phone call comes through the wrong way, in the larger places—now, some companies are very tuned to dermatologists because they use them to test the products before they come out on the market. So they have an idea, when a dermatologist is calling, what he is calling about.

So that makes a difference, who is calling and what he wants.

But, as I say, I have a secret formula book, too. It is telephone numbers, and the man on the other end that will tell me what I want to know.

But the average dermatologist does not have this, the insiders in the different companies to call.

That is why I was hoping that with a phone number, that would automatically mean that the industry has said he is going to cooperate, and at the other end of that is going to be a man or lady who has the data.

Senator EAGLETON Mr. Lauder, is there anything you would like to add before we move on to other witnesses?

Mr. LAUDER. No.

I thank you, Senator, for your courtesy in hearing my testimony.

I think the questions have been most reasonable and most direct. Thank you.

[The prepared statement of Mr. Lauder follows:]

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Comments by Leonard A. Lauder, President of Estee Lauder Inc., before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare on June 12, 1975 on S.1681, the Cosmetic Safety Amendments of 1975.

These comments are submitted by Estee Lauder Inc. with respect to S.1681, the Cosmetic Safety Amendments of 1975, introduced by Sen. Thomas F. Eagleton of Missouri. This statement is submitted for the record and goes into considerably more technical detail than the brief remarks in the statement to the Subcommittee.

This document follows the organization of S.1681; section references in the left margin are those to the sections or subsections to be added by S.1681 to the Federal Food, Drug, and Cosmetic Act ("the Act"). Page number references in the left margin are provided for convenient reference within the printed bill. Section references in the text are to the bill.

Title I - Cosmetic Safety

Section

Section 101

604 (a) We agree that the safety of cosmetic products should be adequately substantiated by the manufacturer prior to commercial distribution. Cosmetics for which safety is not substantiated will be deemed to be adulterated; the Act currently provides criminal penalties for introduction of such products into interstate commerce.

604 (b) (1) Conclusions as to the adequacy of safety substantiation of a cosmetic should be made, as provided in S.1681, based on (pp. 2-3)

the customary or usual conditions of use or those prescribed in the labeling; this is certainly the most realistic approach to this question. The requirement for maintenance of safety substantiation records is entirely reasonable. However, we feel the Secretary should only be able to request submission of these records after he has made a determination that submission is necessary to reduce or eliminate a substantial risk of illness or injury.

604(b) (2)

(p.3)

To be considered adequate, safety substantiation data is required to include information obtained by specific testing to determine the potential of either the ingredients or the finished product for toxicity, sensitization, and irritation, as is appropriate or necessary. The subsection also provides that substantiation data may include published or unpublished scientific literature, data, or information in the possession of the manufacturer or distributor, relevant to safety. Clearly, the manufacturer must be responsible for safety substantiation. Furthermore, the initial decision as to the type of substantiation data needed for each product must be made by the manufacturer, on the advice of his medical and scientific consultants. For example, the manufacturer of a product, such as a commonly used combination of ingredients like a glycerin and rosewater hand lotion should not be required to test provided there is adequate scientific literature or successful long-term company experience to assure the safety of the product. The manufacturer should be able to rely on human experience with the product, including the complaint history from product marketing or qualified scientific judgements, without

mandated fixed testing patterns. The consumer will not benefit from the expenditures necessary to provide clinical testing of products about whose safety no questions have ever been raised.

604(c)(1)
(pp. 3-4)

Under this subsection, the Secretary is given the authority to: determine the circumstances under which specific testing will be appropriate or necessary, establish appropriate testing procedures, and require that testing be performed by persons independent of the manufacturer, at his expense. We submit that the scope of this authority delegated to the Secretary is unnecessarily broad; such governmental actions would be appropriate only in limited cases upon a finding pursuant to a rulemaking that, on the basis of all available information, the action is necessary to reduce or eliminate a substantial risk of illness or injury.

First of all, we suggest that the bill include the following definition:

"'testing' as used herein shall relate to absolute standards of safety as determined by procedures established by the Secretary after consultation with an appropriate advisory committee as provided in [insert appropriate section reference]."

The purpose of this definition is twofold: to provide that any testing standards required by the Secretary shall relate to an absolute rather than a competitive standard of acceptability, and to require the Secretary to obtain a range of scientific and technical opinions before issuing orders in this complex area. The Secretary should be permitted to determine the appropriateness or necessity of testing, or dictate test procedures only after consultation with an advisory committee and after

making a specific finding that, on the basis of all available information, the action is necessary to reduce or eliminate a substantial risk of illness or injury to the public. Such a regulation must not be promulgated as the exclusive means of substantiating a product's safety.

In addition, we question the basis for the provision allowing the Secretary solely at his discretion to direct that new testing be performed by an independent entity, with costs paid by the manufacturer. No specific reasons or circumstances are required under S.1681 to be established by the Secretary prior to directing such studies. In effect, the Secretary is permitted to deprive a company of the expertise of its own scientists. Most reputable cosmetic companies spend a great deal of money to obtain the services of the most competent medical, scientific, and technical personnel available. This subsection clearly implies that reputable individuals will automatically be biased in conducting tests or weighing evidence in favor of their employer. This is, at the least, an erroneous assumption which is not an appropriate basis for a statutory provision. Furthermore, there is no guarantee that these unspecified "outside" organizations would be able to conduct tests with any greater degree of fairness and accuracy merely by reason of their "independence". If the Secretary is to be given authority to require testing by independent laboratories, this authority should be specifically limited to those cases in which the attributes of a test are shown to be so inadequate as to cast the entire study into a significant

degree of doubt. We think that a company must be able to place primary reliance on the advice of its own scientific or technical personnel. If it were to be subject to orders to fund outside studies at any time, a company might be forced by fiscal pressures to reduce its own in-house technical staff, which would not, in the long run, benefit the consumer.

604(c)(2)

(p. 4)

This subsection requires the Secretary to establish certain screening levels for toxicity, sensitization, and irritation. Manufacturers whose cosmetics test beyond the "acceptable" reaction rate must, under S.1681, notify the Secretary of this fact. The concept of a "screening level" is contradictory to a program of safety substantiation, given the fact that the manufacturer is solely responsible for marketing a safe product; a manufacturer should not be marketing an irritating, sensitizing, or toxic product. The Secretary will, under S.1681, have access to complaint files, through which the identity of products causing such unpleasant reactions ought to be readily ascertainable. Furthermore, under S.1681, the Secretary will have ample authority to protect the public against those products posing actual health hazards. (Note: comments on the requirement for presubmission of data for new products is included in the discussion of section 604(d)(1).)

604(c)(3)

(p. 4)

Any testing requirements or other similar criteria imposed under new section 604 must be relevant to a product's

customary and usual conditions of use or those prescribed in the labeling. This is a most reasonable provision.

604(c) (5)
(pp. 4-5)

As we have stated earlier, the Secretary should be required to appoint and consult an advisory committee in developing any specific test requirements or classifying a product involving a risk of injury. This could be an extremely beneficial step, insuring input from experts in diversified medical and scientific fields, as well as participation by consumers and industry. To prevent undue delay, the advisory committee should be directed to file its report within a specified period of time after submission of a proposal by the Secretary.

604(d) (1)
(p. 5-6)

This subsection outlines the Secretary's authority to designate classes of cosmetics which present a "significant risk of injury"; within 60 days a manufacturer is required to submit his safety substantiation data for such products and must delay introduction of new products for 90 days after the submission of such data. The Secretary should have authority to investigate products which may involve such a risk but only on a finding, after a hearing based on all available information, that so designating a product is necessary to reduce or eliminate a substantial risk of illness or injury to the public.

However, we think that the Secretary does not need and should not be given any authority to require submission of data on new products prior to marketing. We re-emphasize that the manufacturer already bears complete responsibility for substantiation of the safety of a new product, with a possible

criminal penalty for failure to do so. Because the Secretary will be given access to complaint files, he will quickly be able to determine whether or not a new product seems to be causing a significant number of adverse reactions. Introduction of a new cosmetic is not nearly in league with introduction of a new drug product - the 90 day presubmission comes perilously close to establishing a type of cosmetic "NDA", which seems entirely unnecessary.

604 (d) (2)

(p. 6)

This subsection deals with new cosmetics "not within a type of cosmetic which was previously in commercial distribution", or which are "significantly different from other cosmetics within that type". Such authority is not necessary - because of access to complaint data and ample power to deal with cosmetics involving a "significant risk", the Secretary will be fully able to deal with uniquely new products which may be suspected of causing harm. As presently written, the definition of new products for purposes of this provision are so vague as to be applicable to nearly any newly-introduced cosmetic, which makes this section appear to institute a broad preclearance system - such a system would be most unwise and unacceptable.

604 (e) (1)

(pp. 6-7)

Contained in this subsection is a list of actions which the Secretary may take to assure the safety of cosmetics including: ordering additional specific testing, prohibiting or setting tolerance levels for the use of poisonous or deleterious substances, requiring appropriate labeling, or banning a cosmetic. In the limited instance in which there may be an imminent danger to public health from a product,

then the Secretary should be able to use these extreme measures. However, such vast discretionary power should be appropriately conditioned; the definition of "testing" outlined in the discussion of section 604(c)(1) should apply. Furthermore, the Secretary should be required to make a finding of necessity to act to prevent imminent hazard to public health and safety, prior to taking any of the steps enumerated.

With reference to the "banning" of a cosmetic, as the bill is presently drafted it is unclear from this subsection what the required mechanics for withdrawal of a "banned cosmetic" from the market might be.

604(e)(2)

(p. 7)

The Secretary is given authority to "expedite" the effective date of a regulation when taking action as provided in section 604(e)(1), above, upon a finding that such action is necessary to reduce or eliminate a substantial risk of illness or injury associated with use of the cosmetic, on the basis of all available information. This is, overall, a good provision - the authority of the Secretary is clearly delineated and limited to situations in which timely action would be appropriate and necessary.

604(e)(3)

(pp. 7-8)

Under this subsection, the Secretary must declare a cosmetic unsafe for some or all uses if tests show that it will induce cancer in man or animal. In no event should the Secretary have this authority in cases in which tests have no relation to the usual and customary use of the cosmetic.

Section 102

601(f) Products not produced according to current good manufacturing practices are deemed adulterated. Here, we think the Secretary should be required to consult with the advisory committee (discussed above) before promulgating final regulations on this subject. Any manufacturing practices should be written along the lines of the Cosmetic, Toiletry, and Fragrance Association's Quality Assurance Guidelines.

(p. 9)

Title II - Registration and ComplianceSection 201 - Registration of Cosmetic Processors

605(b) Registration means providing lists of each cosmetic processed, the product class, each ingredient in descending order or predominance by weight showing percentage range within the product, and a summary of product information on hazards of accidental misuse or ingestion. The Secretary is given additional authority to require more detailed product information, such as the product formula, lists of products with a particular ingredient, samples of labeling, and data on product recall. The data relating to product formulas, etc., is of such a highly valuable nature to a cosmetics company that it is absolutely essential that full and explicit trade secret protection be outlined within the statute. We suggest inclusion of a section stating:

(pp. 13-15)

"All data that relate to formulas, ingredient lists, product recall data, product experience files, and similar information which is used in one's business and which affords him an opportunity to obtain an advantage over competitors who may not know or

use it shall be retained by the Secretary as confidential trade secret information."

Without such protection, competitors could quickly duplicate one's product line, and, in effect, benefit from another company's research and development expenditure.

605(d) For new products, the data (listed above) must be
(p. 15) submitted to the Secretary. Again, we emphasize that any required presubmission of data for new product introduction is entirely unnecessary.

605(e) Under this subsection, if a product is discontinued,
(p. 16) the Secretary must be notified and given a list of reasons why the product will no longer be processed. This requirement is unrelated to the Secretary's function of protecting public health and safety, except in the case of products which are discontinued because they were found to involve some risk of injury to public health. Companies regularly discontinue products for reasons unrelated to safety, including profitability; this kind of information should not be obtainable by the Secretary.

605(f) Adverse reaction reports received by the manufacturer
(pp. 16-17) or distributor must be filed with the FDA within 90 days of receipt. We agree that this information should be made available to the Secretary but only if it is given explicit trade secret status, as outlined in the discussion of section 605(b). In addition, the Secretary should only be able to require submission of screened complaints, i.e., those verified as resulting from allergic reaction or other bodily injury

associated with use of the cosmetic, not based on financial or personal preference complaints. Only such verified product experience reports are actually related to the Secretary's function in protecting public health and safety.

605(g) All registrants are subject to the factory inspection
(p. 17) requirements of an amended section 704 of the Act, which is discussed below.

605(h) This subsection gives trade secret protection as
(p. 17) referred to in 18 U.S.C. section 1905. We think the matter of trade secrets is so critical to certain sections of the bill, posing a special problem within the highly competitive cosmetics industry, that specific protection for ingredient, formula, product experience, financial, pricing, etc. information should be written into the statute, as outlined above.

Section 202 - Inspection and Reporting

704(a) The factory inspection section of the Act is amended to
(pp. 18-19) expand the scope of permissible inspection relating to cosmetic manufacturing establishments; an exemption is provided for financial, sales, pricing, personnel, and research data. This is the same information which is available with respect to inspections of prescription drug manufacturers. It seems unnecessary to enable inspectors of cosmetic establishments to reach the same information which they can obtain when inspecting a prescription drug establishment which is not applicable to food or over-the-counter drug houses. Obviously, the need in the case of prescription drugs is much greater,

given the greatly increased risks to health inherent in prescription drugs. We think a better approach is to allow access to data involving potential adulteration or misbranding of cosmetics only.

Section 203 - Administrative Restraint and Seizure

304 (g)

(pp. 19-21)

This subsection permits an FDA inspector to detain a cosmetic which he has reason to believe is adulterated or misbranded, for up to 20 days, and, if additional time is needed to institute a seizure action, up to 30 days. The appeal from this detainer action is taken directly to the Secretary, who must provide an informal hearing within 5 days after the appeal is filed and confirm or revoke the detention within that time. Although the provision for rapid appeal of a detention to the Secretary is commendable, this subsection, on the whole, gives too much discretionary authority to FDA field inspectors. As the bill is drafted, an inspector could conceivably hold up shipment of an entire warehouse of merchandise based solely on his own opinion; this seems completely inappropriate and unnecessary. Products should be able to be detained only if the Commissioner or other specifically designated FDA official made a finding of probable or reasonable cause to believe that the articles are adulterated or misbranded. The individual inspector should also be required to submit in detail his findings, in writing, to officials at the cosmetic establishment, if he plans to recommend to the designated FDA official that a detention be imposed. Furthermore, any application of a system of detention to cosmetics should be contemporaneous with extension of this system to food and over-the-counter drug manufacturers.

Title III - Cosmetic LabelingSection 401 - Cosmetic Labeling

602(g)

(pp. 22-24)

Labeling is required to be affixed to or within the cosmetic package, including listing of ingredients in order of decreasing predominance by weight. However, colors are not required to be listed in order of predominance. Fragrance and flavor are exempt from disclosure, unless the Secretary finds listing otherwise necessary. Exceptions are provided for cosmetics sold in bulk, incidental additives with no technical or functional effect, or closely related ingredients.

We think that permitting package inserts and exempting colors from order of predominance listing is the most realistic approach, especially because so many cosmetic products are quite small and have many different color ingredients. But we cannot agree that there is any need for labeling other cosmetic ingredients in order of predominance by weight. Listing ingredients in alphabetical order is equally helpful to consumers with an allergy to a particular substance; such a consumer generally should avoid products containing any amount of such a substance. Furthermore, listing in order of predominance by weight does not facilitate value comparisons because basic ingredients with the same chemical name often vary in cost according to quality, purity, etc. A simple example will demonstrate this. Below are two realistic formulations for a hair conditioner. Both have the same descending order of predominance which would appear on a

label, but one costs a manufacturer \$0.40/lb. while the other costs \$1.28/lb., yet to the consumer reading the label these are identical.

CTFA Dictionary Descending Order for Product #1 and #2	Approximate Cost/lb. of Raw Material	Concentration		Cost per 100 lbs. #1	Cost per 100 lbs. #2
		#1	#2		
Water	0	62.89	66.45	0	0
SDA Alcohol 40	0.15	20	20	3.00	3.00
PVP/VA Copolymer	1.00	10	10	10.00	10.00
Collagen	#1 - 2.00				
	#2 -40.00	6	2	12.00	80.00
Fragrance	10.00	1	1	10.00	10.00
Panthenol	10.00	0.1	0.5	1.00	5.00
Biotin	400.00	0.01	0.05	4.00	20.00
				-----	-----
				\$40.00	\$128.00

Predominance by weight listing does provide one's competitor with a road map enabling him to quickly duplicate a product. Admittedly there are presently less than twelve laboratories, appropriately equipped, which with a great investment of time and effort, could come close to a competitor's formula solely through laboratory analysis (and, as large as Estee Lauder is, we are not one of these). Anyone else would have to do expensive and time consuming outside testing. Why then should all this development and testing be handed over to a competitor who may not find it necessary to have more than a single chemist on his staff now that "road map formula" to the most successful cosmetic products in the world are now available free.

Ingredient labeling in descending order of predominance by weight would be of little additional benefit to the consumer and would be extremely difficult and expensive for the manufacturer, from several angles, as well as being unfair to companies who employ scientific personnel for the express purpose of marketing the best products. We strongly urge that you consider elimination of this labeling requirement, and substitution of a requirement for listing of ingredients in alphabetical order.

602(h) Labeling of hazard warnings or directions for use may
(p. 24) be required through rulemaking by the Secretary if he finds it necessary to prevent a health hazard. Provided that the present wording of "label or labeling" is retained, and the provisions of the section are made effective retroactively, this subsection is generally acceptable, as it would ensure that warnings would be permissible on the outer container of, for example, a small decorative aerosol fragrance bottle on which little surface area would be available for labeling.

Title IV - General Provisions Concerning Cosmetics

Section 401

606(c) The federal cosmetics labeling requirements super-
(p. 26) sede any and all state and local labeling laws unless the Secretary specifically approves a state or local petition to impose different standards that: impose a higher level of performance, are required by compelling local conditions, and do not unduly burden interstate commerce. This is a

vital provision and should be included in any cosmetics
legislation, and made retroactive to Jan. 1, 1975.

Senator EAGLETON. Thank you very much.

The committee will stand in recess for 10 minutes. I have another chore I must perform.

I will be back in 10 minutes.

[Short recess.]

Senator EAGLETON. The committee will once again be in order; and at this time we will hear from representatives of the Cosmetic, Toiletry, and Fragrance Association, Inc. This panel will be headed by Mr. J. Richard Edmondson, chairman of the board at CTFA. He is also the vice president of Bristol-Myers, and he testified at our hearings last year.

We welcome you once again, Mr. Edmondson. I believe you will be accompanied by Mr. Eugene Lambert, general counsel, CTFA; Dr. John Menkart, vice president, technology, Clairol, Inc., and, last, Dr. Murray Berdick, director, applied research, Chesebrough-Ponds, Inc.

You may proceed, Mr. Edmondson.

STATEMENT OF J. RICHARD EDMONDSON, CHAIRMAN OF THE BOARD, COSMETIC, TOILETRY & FRAGRANCE ASSOCIATION, INC., VICE PRESIDENT BRISTOL-MYERS; ACCOMPANIED BY EUGENE I. LAMBERT, ESQ., GENERAL COUNSEL, CTFA; JOHN MENKART, PH. D., VICE PRESIDENT, TECHNOLOGY, CLAIROL, INC., AND MURRAY BERDICK, PH. D., DIRECTOR, REGULATORY AFFAIRS, CHESEBROUGH-PONDS, INC.

Mr. EDMONDSON. Thank you.

First, Senator, may I thank you on behalf of our association for this second opportunity to testify before you here. In introducing my remarks I will be reading from the statement we did file with you except that I will attempt to summarize.

Senator EAGLETON. Go ahead.

Mr. EDMONDSON. I should make it clear that the CTFA supports the concept firmly believing that it is the obligation of every manufacturer and distributor to market only cosmetics which have been substantiated for safety. Moreover, it is the obligation of each manufacturer to assure itself of the safety of its products before they are marketed.

We note, too, that the FDA has reaffirmed this obligation, which I will refer to.

However, we feel that it is the purpose of this statement also to indicate that any new legislation is unwise and unnecessary.

In the light of the overall safety record of cosmetics, current industry programs and scientific initiatives and current FDA authority, there is simply no need or advantage for enacting legislation, and particularly not for legislation which we see and the other witnesses have indicated they see that provides for a broad scheme of premarket clearance.

Senator EAGLETON. May I ask right there, do you compare this bill, S. 1681, with the one of 2 years ago? And do you not note a rather substantial modification from the previous bill insofar as what you call premarket clearance is concerned?

Mr. EDMONDSON. There are substantial modifications, certainly, in language, Senator. We feel that the discretionary areas given to the Secretary are so broad that the discretion granted is, in effect, discretion exercise and that he could, or his successors could, convert it into total premarketing clearance just as in last year's bill.

As we have told you before, the CTFA is a national trade association representing 186 manufacturers of cosmetic products as well as 200 manufacturers and distributors of cosmetics, processed ingredients and supplies.

I would also like to point out that within our membership, 60 percent of our members are small in the sense that they have annual sales of less than \$1 million.

Our statement submitted in February 1974, concluded with the caution presented by the panel on chemicals and health, the President's Science Advisory Committee, dated as of September 1973, and I quote:

In the area of chemicals and health, our country requires above all a sense of perspective. Without that we will work on the wrong thing, waste irreplaceable effort, and neglect the truly vital. Next, we need balanced judgment and actions. Without them we will do the right things wrongly or poorly or not at all.

We believe that a sense of perspective remains imperative today because the need for additional cosmetic legislation has not increased in the past 15 months. Our excellent safety record continues to belie this need. Moreover, the need for additional regulation seen by some of those testifying a year ago has lessened in the light of the issuance on March 3, of final regulations by the FDA in the area of warning statements for cosmetic products whose safety has not been adequately substantiated, ingredient labeling for all cosmetic products, warning statements for aerosolized cosmetics, and warning statements for feminine deodorant sprays.

It should be noted, too, that those regulations have now become finalized as of May 30, 1975.

In our February 1974, submission, we offered some preliminary estimates of the probable national total of injuries and you have referred to some of those today that might be associated with the use and accidental misuse of the cosmetics and toiletries. Since that time, two potential new sources of pertinent information have become available.

The first is: The product experience reports, under the industry voluntary program, which now covers over 2.4 billion units of cosmetics, or approximately 40 percent of the cosmetics marketed in that period of time; second: second full-year figures from the Consumer Product Safety Commission.

The first of these items provides FDA with information from a wide variety of companies on a broad range of products whose ingredients are, because of ingredient disclosure, known to FDA, representing a statistical data base of real value and significance.

We consider the first year of product year experience program to represent a highly significant representation of the key feature of the program, to protect the public. We have been assured when administrative and computer problems are resolved by other companies, even greater participation will be seen.

Drawing on FDA available figures, we note first that there has been a 24-percent increase in the number of companies participating from the second period to the first. Product experience reports cover,

as I mentioned, a total of 2.4 billion units of product, including virtually every category of cosmetics and toiletries and the overall average rate of alleged injury is 1.8 per million units of products distributed

Senator EAGLETON. Are all the companies represented at the witness table part of the voluntary compliance program?

Mr. EDMONDSON. Yes, sir.

Senator EAGLETON. Do you have any objection to making mandatory that which you are doing voluntarily?

Mr. EDMONDSON. No.

As we testified last year, that is the association position. We feel that there are some limitations.

Senator EAGLETON. And thus you are filing ingredients with the FDA at the present time?

Mr. EDMONDSON. That is correct.

Senator EAGLETON. You are filing ingredients?

Mr. EDMONDSON. Yes.

Senator EAGLETON. How are these ingredients filed at the present time?

Mr. EDMONDSON. They are listed in range of ingredients. The range is different as set forth in S. 1681. I do not remember the percentage ranges, but it gets narrower as you go down into the smaller.

Senator EAGLETON. Would it be just as easy for you or preferable to you to list the ingredients alphabetically?

Mr. EDMONDSON. In the ingredient disclosure to the FDA?

I would see no problem in listing them alphabetically.

Senator EAGLETON. On the label or in the insert in the little packet?

Mr. EDMONDSON. I have heard there are arguments both ways.

I think the CTFA would have no objection to either alphabetical or descending predominance.

Senator EAGLETON. Are all the companies at the table registered with the FDA in terms of name, address, where the laboratory is, and the like?

Mr. EDMONDSON. Yes, sir. We have all registered with the full information.

Senator EAGLETON. And would the CTFA have any objection to making mandatory that registration which you are doing voluntarily?

Mr. EDMONDSON. No, sir.

Senator EAGLETON. Now, with respect to safety substantiation, do each of the companies represented at the table maintain research files in their own laboratories or home offices that might be classified as safety substantiation of their products?

Mr. EDMONDSON. Yes, sir.

Dr. BERDICK. Yes.

Senator EAGLETON. If requested by the FDA for specific information on any particular product, would each of the companies at the table be forthcoming with that information?

Mr. EDMONDSON. Let me speak to my company and then Dr. Berdick can speak and Dr. Menkart for Clairol.

Our uniform practice is that when the FDA invariably comes up in the terms of a specific problem or a specific alleged injury, we provide them with the data necessary to resolve that problem.

Senator EAGLETON. Would that same answer, more or less, pertain to all three companies?

Dr. BERDICK. I would like to supplement that simply by saying that it is our practice to comply with the Food and Drug Administration, but subject to the provision that it be evaluated by people competent and qualified to evaluate it.

FDA inspectors frequently are the ones that make the request and are not necessarily qualified to evaluate toxicological and safety data.

We do, however, always supply the information on request.

Senator EAGLETON. All right.

Now, based on that testimony, if this legislative language was specific and limited in its scope, we required that such safety substantiation data be maintained in your files, and if—and I repeat the “if”—the language be specific in its operative wording, would the CTFA have any objection to the concept of requiring companies to keep data in their files and such information would be made available to the FDA on request?

Mr. EDMONDSON. No, sir.

Again, given the appropriate language and the protection, we are on record as saying the FDA should have access to our safety substantiation data when problems arise.

Senator EAGLETON. I also asked Mr. Lauder this question. I present it to this panel:

Do you believe that the secretary or the commissioner should ever have the authority, even if tightly tied down, to require premarket submission of safety data?

Mr. EDMONDSON. Let me put it in the context of the way you asked the question of Mr. Lauder, which is, if there was an ingredient which the secretary has found presents a risk, significant risk, or hazard, should he have the right to preclear?

I do not think the question even arises in that situation. He has the authority to find such problems. If he does, and if he says, I consider such a product adulterated, no manufacturer could or would market it.

Senator EAGLETON. Do each of the companies, the three companies represented at the witness table, now, as a matter of corporate policy, keep files and records on consumer complaints?

Mr. EDMONDSON. Yes, sir.

Senator EAGLETON. Do they keep not only consumer complaints from the person who has been using the cosmetic, but also consumer complaints from, say, dermatologists or other physicians?

Mr. EDMONDSON. Of course. Yes; we do.

Any correspondence or memorandum or telephone call, from whoever, would be kept in the files.

Senator EAGLETON. Do doctors, dermatologists, or other physicians contact each of your companies from time to time requesting information about a particular product?

Mr. EDMONDSON. Yes, sir.

Senator EAGLETON. And is it your corporate policy, on request from a licensed physician, to make appropriate scientific and test data available to the physician so that he could properly treat his patient?

Mr. EDMONDSON. I know the answer is yes; but my colleagues may want to comment in more detail.

Dr. BERDICK. Yes.

We not only cooperate with dermatologists when they make inquiry, but frequently, if we are concerned about a consumer complaint, we request that the consumer go to a board certified dermatologist at our expense so that an investigation may be made to learn if the product is related to the complaint and, if so, what the cause or the agent is, if it can be identified.

Dr. MENKART. We follow a similar practice.

I might also comment in relation to some of the comments by the dermatologists, that we supply groups of ingredients of a product in the form of coded samples, which enable a dermatologist to do a blind, unbiased test. When one of those samples is shown to be allergic, we then disclose the ingredients of the elements to the doctor.

Senator EAGLETON. Now, since each of your three companies maintains this data—and I am talking about consumer complaints and letters from dermatologists and the like—would you, your companies, or the CTFA have any objection to making mandatory what you are now doing voluntarily as a corporate practice; to wit, maintaining files on consumer problems and making those files available to the FDA?

Mr. EDMONDSON. Well, it is our practice, where a problem is presented that it could adequately be defined in statutory language.

I should also remind you, Senator, that we are filing our product experience data with the FDA, as is suggested, of course, or mandated, by your bill. Where we object to some of these provisions in your bill, again, we do not object to making that system mandatory.

Senator EAGLETON. Well, the point that I am making, I guess, by these questions—at least, the point I am trying to make—is as follows:

There are about four principal sections of our bill, or four principal precepts. There are four concepts in the bill that are vital. We think that they are vital and important.

One is the registration of all cosmetic companies. That you do. That you have no objection to doing.

Ingredient labeling. You are doing that now to some degree. Whether we require it by law, you are doing it, or will be doing it soon.

Safety substantiation in terms of scientific data in your files. That is in our bill. That you are doing now.

Finally, consumer complaints. That you are doing now and that is in our bill.

So in terms of philosophy, let us call it that, our bill and your present corporate philosophies are not really far apart.

Mr. EDMONDSON. On a strict philosophical basis, I think that is correct, sir.

Senator EAGLETON. Now, you would argue very strongly with us about the specific phraseology of some of these sections. That is your prerogative, and you should.

Mr. EDMONDSON. And some of the philosophy of those sections.

Senator EAGLETON. Well, I have detailed at least what I think are the four sections of the bill; and we are in accord with those philosophies.

Mr. EDMONDSON. If you look at our statement, we are in accord in our specific comments on registration and the other areas you raise are mentioned.

Senator EAGLETON. OK.

Well, go on. I interrupted you.

Mr. EDMONDSON. But I do think there is a philosophical vein in your bill which we oppose, which we see as the preclearance section.

Senator EAGLETON. We think we have gotten away from preclearance, but maybe we have not.

Mr. EDMONDSON. I think it is difficult to do.

Just again referring to the product experience or to reporting, in the Neiss figures we find a correlation in the rate of injury, Neiss figures over 2 years, which show a reported rate, having taken out of their totals containing our accident and accidental ingestion and so limited to the use or accidental misuse, two reports per million units distributed; and that correlates with the 1.8 per million units reported in the product-experience reporting, filed with the FDA.

As we pointed out to you a year ago, FDA has demonstrated adequate authority to act quickly and effectively to protect the consumer and, as previously mentioned in this statement, FDA has recently issued the three final regulations which I outlined for you.

As of May 30, 1975, 830 manufacturing establishments have been registered; 635 firms have submitted over 17,000 formulas, and 147 firms—and that number grows daily—have submitted product-experience reports.

The voluntary program was developed in response to a need. As we indicated, again, last February and just a moment ago, we would have no objection to making that mandatory with the safeguards that we have pointed out in more detail in our statement.

In saying that we feel there is no need for additional cosmetic regulation, we do cite that safety record and existing FDA authority. We also would like to cite CTFA initiative in establishing scientific programs to complement and reinforce FDA's existing authority.

The CTFA board of directors has approved, and officials of the association have had preliminary discussions, with Commissioner Schmidt of the FDA with plans of a broad-scale safety-review program of cosmetic ingredients. We plan to meet with the FDA again on this subject in the very near future.

The program involves expansion of the existing for a development of a safety file on safe cosmetic ingredients, development of cosmetic descriptions, followed by a review by an expert independent panel of the data available for each ingredient.

The solid foundations for this program have already been established in the present industry scientific program, which does include chemical standards and technical guidelines.

Having outlined the reasons why we believe that new legislation is unnecessary, I would like to turn to some specific comments on S. 1681. In doing so, we believe it is important to reiterate briefly two points that were made, both by Food and Drug Administration and by ourselves, at the hearings held in 1974.

First, there should be no remaining doubt that any substantial legislative requirement for premarketing approval for cosmetics would be totally wasteful.

Premarketing approval requirements would impose an economic burden on individual companies, particularly on small companies. It would be intolerable and it would be totally wasteful for this

country's scientific resources. The cost of administering such a program by the FDA would add significantly to the agency's budget. FDA vigorously resisted that statutory imposition.

Second, as a practical matter, there is no distinction between the legislative system that affirmatively mandates premarketing approval and one that on its face does not. This fact is clearly borne out by the practical experience under the new drug provisions of the act between 1938 and 1962, and it was affirmed by Commissioner Schmidt in testimony here last year before this committee when he said mandatory submission of data would be the same as preclearance "because you can imagine what a terribly uncomfortable time I would have in this chair were we to do nothing with the data submitted to us. We did not say yes or no. We just did nothing." Thus, any time there is a mandatory requirement for premarketing notification, a fixed period must elapse before a product can be marketed following that notification. It is illusory.

FDA could not afford just to receive the data. For this reason, industry could not afford to move forward.

Against these important concepts, we look at the crucial provisions of S. 1681 that adds a requirement to the safety of the cosmetic which is adequately substantiated prior to commercial distribution. We believe it is the obligation of every manufacturer to insure the safety of his products.

S. 1861, however, does not stop at that point. Rather, it contains five specific provisions, either authorizing or directing the FDA to obtain substantiation information prior to marketing. These five provisions convert from a safety substantiation bill into a premarketing approval bill. Indeed, the authority is so broad that we would authorize and, as a practical matter, require FDA to examine every product.

The first provision authorizes the Secretary to require the submission of safety substantiation information and data. This authority can be exercised to require premarketing submission of data. This authority can also be exercised, if applicable, to every cosmetic, thus converting, placing into jeopardy, current marketing.

The second provision is 604(c), which authorizes the Commissioner to specify what specific tests must be run for each cosmetic and the procedure to be used for each test, it also authorizes FDA to prohibit companies from conducting their own course, no matter how well equipped many companies are.

The third provision, 604(c)(2), is even more specific, in which it directs screening levels or other criteria and requires the products that exceed these to be withheld from the market for a period of 90 days after the submission of the test results to the Secretary. The only limitation is that the screening levels must be relevant to the conditions of use prescribed in the labeling of the cosmetic.

"Relevant" is a loose word and it can encompass and arbitrarily establish screening levels that would, in effect, cause numerous products to fall under, thus, the preclearance category.

The fourth provision essentially establishes premarketing with a minimum 90-day delay for any cosmetic class.

The final section, 604(d)(2), grants blanket authority, without any relation to premarketing submission and, thus, as a practical matter, approvals for any cosmetic he finds that is not within a type previously

marketed. Again, we find no guidance as to what is a type or when a difference is significant.

The Secretary has indeed essentially unfettered discretion to compel premarketing approval based upon this lack of legislative guidance and appropriate delegation.

Senator EAGLETON. Mr. Edmondson, I do not recall from last year's record whether you are an attorney.

Mr. EDMONDSON. I am an attorney; yes, sir.

Senator EAGLETON. I thought you were.

As an attorney you are familiar with the law of torts in which all throughout that body of law there is the doctrine of the reasonable man, the prudent man. In trust, there is the prudent investment; the theory of the trust is the trustee must act with due caution and as a prudent individual in the investment of funds for the benefit of the beneficiary.

With the use of words such as reasonable and prudent, lawyers are familiar with those words and they have become part of the body of the law; have they not?

Mr. EDMONDSON. Yes. And I guess that is why we have so many reporters with so many cases arguing telling us what reasonable or prudent means.

Senator EAGLETON. Sure.

You have all kinds of situations where 12 men sitting on a jury try to decide whether the company acted with reasonable care, whether it is a railroad that has had an accident or an insurance company that is insuring the motorist. The question is did the motorist act with reasonable care.

The point I am getting at is: The thrust of the last couple of pages of your testimony is that you want definitions of the word relevant. You want definitions of the word significant. You want definitions of the word type.

What I am getting at is, in practically any statute or doctrine of the law, words of this general category are used and I do not know why these words should be any more mysterious to cosmetic manufacturers than they are to 12 jurors who sit in judgment on some of these cases.

Mr. EDMONDSON. It is not so much that we seek a definition, but I think the words are relevant and appropriate when there are legal phrases which we use that lack—I think any lawyer would agree with this—lack specificity. It is not just a question of definition. It is a question of discretion; and whatever adjectives you use we think in the real world the discretion would result in premarketing clearance.

I am pointing to these words because they happen to be the ones in the statute. It is not just a question of semantics.

Senator EAGLETON. I would daresay—and I will make a guess—that if we get the most up-to-date legal dictionary that there will be definitions of some of these words already in the dictionary—Black's or whatever—that is the dictionary I used to use as a law student. I do not know what the newest one is.

That is, in drafting the statute, yes, the people covered by the statute are entitled to know for specificity what they are obliged to do under the law. But there is just no way that we can define these words, with the kind of precision that you seem to be hinting at. There is no way to quantify it.

Mr. EDMONDSON. Yes; but I think our argument is really two-pronged: (1) That it is impossible to define so as to avoid abusive discretion, to avoid unnecessary economic burden, to avoid unnecessary testing and delay; and, (2) that there is no need for such a program.

In some cases where the need is high you have to use the legal words that are available to you to describe it, however frail they may be, in giving the specificity. We would say here that is just not necessary.

Senator EAGLETON. With regard to the present legal authority of FDA as far as cosmetics are concerned, I am not convinced as one lawyer to another that they have the requisite legal authority to issue some of the regulations.

That is really one of the purposes of this bill; to give them the legal authority that we think they need.

You seem to assume that they already have authority in these areas based on existing law; is that correct?

Mr. EDMONDSON. I do in many of the areas; yes.

I will touch on it briefly.

Good manufacturing practices: I think the industry recognizes the requirement to manufacture its products by such practices as will assure the quality, integrity they purport to possess. However, we have some difficulty with the second paragraph of that section, which seems to require additional testing.

Senator EAGLETON. Where are you reading?

Mr. EDMONDSON. From the memorandum attached to our statement.

We feel that the definition of commercial distribution is too broad in that it would prevent us from testing our products for safety and, incidentally, or primarily for consumer preference away from the plant. We believe that should be tightened up.

You and I and this panel have discussed our feelings on section 201, registration. Here, again, we point out some of the things we feel should be in a mandatory program to protect trade secrets and the possibility of abuse of the data.

Factory Inspection: It appears to us that your bill for cosmetics is even broader than that for prescription drugs. We would agree with Mr. Lauder, who spoke earlier. This is a subject that should be attacked and certainly there is no reason in cosmetics for it to be as broad or nearly as broad as it is for prescription drugs.

On ingredient labeling there has been much discussion this morning. As I indicated, we have now withdrawn any objections that CTFA had to any ingredient labeling. There are one or two minor matters that are still in the petition stage but, basically, we are ready to go forward.

We do not have a strong view, I do not think, or a CTFA position, on alphabetical rather than predominance.

Mr. Lauder has stressed one point of view and he is one of our members. However, we feel that the statutes should be clear about the kind of flexibility that is in the label ingredient regulation now, which overcomes some of the practical possibilities.

Precautionary labeling, section 602(h); we object to the extent that it goes beyond authorizing the Secretary to adopt cautionary regulations where there is a hazard to health.

I would just point out to you a problem: Under Federal statutes, many advisory committees are crippled because of imposition of conflict-of-interest which are a little bit archaic to draw on panels.

Again, what Mr. Lauder said, we do support preemption in Federal labeling. We do have to fight a lot of fire departments on various labeling requirements. That is a real problem.

Senator EAGLETON. You want the Federal law to preempt the field, but you are not sure what Federal law you want to preempt the field?

Mr. EDMONDSON. On ingredient labeling we are quite clear. The ingredient labeling, Eagleton bill, we support.

Senator EAGLETON. Let me ask you this: I think you were present when the three dermatologists testified and specifically with respect to the components or ingredients of fragrance. Their testimony was that one of the ingredients in the fragrance might be the one to which their pateint is allergic.

How should we treat the fragrance problem, in your opinion?

Mr. EDMONDSON. I was confused by what I thought were three different points of view, and I asked my colleagues to think about it and speak to it.

Dr. MENKART. Let me start by addressing the point which I think needs to be clarified and which was raised several times this morning: the large number of components in a fragrance. Many of our products may contain four or five ingredients other than the fragrance, which itself may consist of as many as 300 chemical entities.

The reason for that is not that we frivolously like to put that many in. About half of our fragrances are derived from natural products, and that is just the way they come. We find that when we make synthetic fragrances, the human nose is indeed so sensitive and discriminating that we need to put about that same number in to deliver the effect that we want, whether it is imitation of a natural effect or whether it is a novel one; and very often leaving out one ingredient that represents a minute proportion is indeed perceptible by the human nose.

As long as one wants to have fragrance materials, this situation is one that we have to live with. It is clearly impossible to put those 100 or 200 ingredients, some of them with long chemical names, onto a label, or even on a package insert or a hang tag. This, incidentally, would create an economic impact problem of some magnitude in most products, because you have an additional component.

We feel that, by some of the mechanisms which were touched on this morning, or possibly by some combination of these, such as submission of samples, provision of information by telephone to a dermatologist, one can indeed provide the necessary data to the expert and at the same time work within practical feasibility.

I would hate to see any specific requirements written into the law, because the way in which you do it will depend on the particular class of material, and the particular type of distribution. It will change as products change and as science and technology change.

The general concept that the dermatologist and the public is entitled to find out is what it is in a product that causes allergy. We support, and we feel it can be accomplished.

Senator EAGLETON. So if I hear you correctly, you say that there could be as many as 200 component parts of a fragrance.

I think Mr. Lauder used a similar figure and said it would just be a practical impossibility to print all 200 of them alphabetically. You would have trade secret problems probably, I would think.

But do you support the notion of Dr. Jordan that there be some kind of a hotline number printed?

Dr. MENKART. Yes, indeed.

Many companies, including ours, operate in this way; and this in combination, for example, with submission of groups of ingredients of the product to the dermatologist for patch testing, so he can identify which material was responsible for the allergy. But I think we should stress that this is a very rare situation.

A dermatologist, of course, is in the same kind of situation as a policeman who believes that everybody is a criminal. He sees only the problem cases. But it is a very small proportion of the exposure that people are subjected to in cosmetics that results in dermatology problems.

Senator EAGLETON. Sir, did you want to add anything?

Dr. BERDICK. I am a little disturbed at the suggestion that the hotline be publicized on the label of every single package of product on the market because the inevitable result of this is that such a telephone line would be overwhelmed by phone calls from consumers who wished to make some other type of complaint related to price or dissatisfaction or packaging or advertising.

I certainly agree with the concept of the hotline being available to the physician who needs access to this information. We do have such a number. It is available 24 hours a day, 7 days a week. We try to publicize it in appropriate circles.

The publicizing of such a physician-oriented piece of information to the public, I think, would be an impractical scheme.

Senator EAGLETON. I am not talking about the cosmetic field, but many companies advertise nationally on television their 800 lines, whether it is Hertz Rent-a-Car or what.

Mr. EDMONDSON. The hotline ought to be a line that is available to the doctors. I think if we had it on the label it would be tied up.

Senator EAGLETON. We could write the number in Latin.

Mr. EDMONDSON. I do think that we are sympathetic with their approach. Many companies have various ways of approaching the problem and we stand ready to work with the committee on a solution to the problem.

Senator EAGLETON. Mr. Edmondson, you mentioned your proposed safety review program.

Can you tell me a little more about that?

Would it be what is sometimes called GRAS, Generally Recognized As Safe? Is that what you were talking about?

Mr. EDMONDSON. In the sense that the GRAS list bears a strong resemblance in relation to that kind of review in ingredients.

Again, I could ask my scientific colleagues if you want the program to be described.

Senator EAGLETON. We could take a few minutes on it, if you will, sir.

Dr. MENKART. In broad outline, what we are working on is an institutionalization and industrywide effort in what we feel is our responsibility as individual companies today, which is the substantiation of the safety of the ingredients which we use.

What we propose, and what we have in broad terms discussed with the FDA, is a program wherein we will subject our ingredients to a thorough literature search in the area of toxicology, where we will

develop chemical standards for those ingredients, and then have this information exposed to an expert panel drawn from nonindustrial sources, who would review each one and decide whether it is to be categorized as reasonably expected as safe, or needing further evaluation.

Senator EAGLETON. Do you know what the meaning of reasonably expected as safe means? You must know enough about it to put something on that list. Those words do not throw you for a loss; do they?

Dr. MENKART. I am not a lawyer.

Senator EAGLETON. You have more common sense than a lawyer and you know what that definition means; so you can put those things on that list; right?

Dr. MENKART. I think it is worth adding one important point here.

The FDA has recently published, arising from our ingredient submission formula submission data, the list of the 67 most frequently-appearing ingredients in cosmetics. We have looked at that list and find that indeed a substantial proportion of these, more than half, are already in some official compendium or other. They have been as an element of the products in the OTC review and so forth. There is, in fact, already a vast amount of information, safety information, in hand on a great many.

One of the things that we are hoping to do is to codify this and put it on a consistent and evident basis.

Senator EAGLETON. Very good.

Well, gentlemen, thank you very much. I think your testimony has been helpful.

I much appreciate the degree of specificity, Mr. Edmondson, with which you critiqued our bill. I repeat, that is the purpose of the hearing.

This year's bill, S. 1681, is really substantially different than the bill 2 years ago; and one of the reasons that it is different is because we had a hearing on the old bill; you heard the comments of the FDA, of the CTFA, of consumers, et cetera; and we thought some of them had some merit. Therefore, we modified our bill based on that testimony.

So the hearings are not just for Senators to sit up here and pontificate. The hearings really serve a very useful purpose and you have helped in that role by making suggestions. We will not agree with every suggestion you make, but I dare say we will agree with some; so it has been very helpful to us.

Mr. Lauder has been very helpful and we very much appreciate it.

I really think the philosophy—whatever that word means—I took a course in it once—but in philosophy we are not too terribly apart. We are much closer together than we are at polar extremities. So there is hope.

Mr. EDMONDSON. I think your end goal and ours is the protection of the consumer; and I think there we are very close together.

Senator EAGLETON. Precisely.

Mr. EDMONDSON. We look forward to working with you and your staff as the days progress. Please call us.

[The prepared statement of the Cosmetic, Toiletry and Fragrance Association, Inc., and other information supplied follows:]

STATEMENT

OF

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION, INC.

ON

S. 1681

BEFORE

THE

SUBCOMMITTEE ON HEALTH

SENATE LABOR AND PUBLIC WELFARE COMMITTEE

JUNE 12, 1975

INTRODUCTION

The CTFA supports the concept of safety substantiation, firmly believing that it is the obligation of every manufacturer and distributor to market only cosmetics which have been substantiated for safety. Moreover, it is the obligation of each manufacturer to assure itself of the safety of its products before marketing. The FDA has reaffirmed this obligation in regulations issued March 3, 1975.

However, it is the purpose of this statement to point out that S. 1681, or, indeed, any new legislation, is unwise and unnecessary. In light of the overall safety record of cosmetics, current industry programs and scientific initiatives, and current FDA authority, there is simply no need or advantage for enacting legislation, and certainly not legislation which provides authority for pre-market clearance.

We have also included in our statement, a section-by-section analysis of our position on other key provisions, and in some instances, suggested revisions. Thus, it is the express intent of this statement, first, to affirm our belief in the concept of safety substantiation; second, to object to any form of premarket clearance or submission; and third, to demonstrate the lack of need for any additional legislation; our comments and suggestions here speak to the practical applications of S. 1681.

CTFA PROFILE

The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), is 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. CTFA, initially organized and incorporated in 1894, was known from 1935 until 1971 as The Toilet Goods Association, Inc. 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.

CTFA's members include small and large cosmetic companies with annual sales of individual members ranging from less than \$100,000 to nearly \$1 billion. Most CTFA members are small businesses; approximately 60% of the membership in the CTFA have annual sales of less than one million dollars. Its members include companies which sell through selected franchise outlets, primarily independent drug and department stores; those which sell through the mass merchandise outlets, including chain drug, grocery and variety stores; and those which sell by mail order, by direct selling, through beauty salons, or through franchised independent stores carrying only the product line of the manufacturer granting the franchise.

Our products cover a broad range -- cleansing creams, perfumes, lipsticks, eye makeup, nail lacquers, deodorants, hand creams, toothpastes and shaving cream -- to name a few. Within the total industry volume, there are both many small-volume companies and small-volume products sold by even the largest companies. In many cases, product composition is relatively stable, with the same product being marketed for years without change. In some very important areas the products are oriented towards fashion and like fashion, are subject to relatively rapid change. These changes are often not significant in the sense that the change effects the substantial nature of the product. It may only be a change of shade in a lipstick or nail enamel line, but the ability to make such changes, and bring them to the marketplace rapidly, is critical to a large segment of our industry. Obviously, questions of safety take precedence over marketing demands, but we believe that it is important that you be aware of this facet of the industry as you consider S. 1681.

LEGISLATION IS NOT NECESSARY

The CTFA statement submitted to this subcommittee in February, 1974, concluded with the caution presented by the Report of the Panel on Chemicals and Health of the President's Science Advisory Committee (Attachment I, Page 1) dated September, 1973:

"In the area of chemicals and health our country requires, above all, a sense of perspective. Without that we will work on the wrong things, waste irreplaceable effort, and neglect the truly vital. Next, we need balanced judgments and actions. Without them we will do the right things wrongly, or poorly, or not at all."

A sense of perspective remains imperative today, because the need for additional cosmetic legislation has not increased in the past 15 months. The cosmetic industry's excellent safety record continues to belie the need for additional regulation. Moreover, the need for additional regulation as seen by some of those testifying a year ago has lessened in light of issuance on March 3, 1975 of final regulations by the FDA in the following areas:

- warning statements for cosmetic products whose safety has not been adequately substantiated
- ingredient labeling for all cosmetic products
- warning statements for aerosolized cosmetics
- warning statements for feminine deodorant sprays

It is important to note that these regulations are final. On May 30, 1975, FDA confirmed effective dates for all of the above regulations.

As this industry testified in 1974, the one objective body that has considered the issue of cosmetic safety, the Panel on Chemicals and Health, concluded no need for additional and extensive cosmetic regulation. The Panel reached the following conclusions with respect to cosmetics:

- (1) "From what may be judged from human experience, the incidence of injury is small." (Page 74)
- (2) "In the total pattern of environmental risks, those from cosmetics are both infrequent and slight." (Page 74)
- (3) "While there are no formal pretesting or preclearance requirements for cosmetics, the total effect of individual and informal review (usually private rather than governmental), together with the innocuousness of most materials used, has made the injury rate fairly low by comparison with other widely prevalent sources of hazard." (Page 75)

The Panel thus confirms the industry's excellent safety record. As noted previously, approximately 6 billion units are sold by the industry each year. Consumer use of these units involves tens of billions of applications of cosmetic products each year. Adverse reactions, virtually all temporary and mild, are very few, both in total number and in proportion to use. Despite the growth of the industry, the Panel on Chemicals and Health (Pages 74 and 75) concluded:

"It seems likely, though solid information is lacking, that the actual injury rate from cosmetics has declined, while the complaint rate has increased as a result of greater consumer awareness of the Food and Drug Administration as a regulatory agency, and of the existence of legal and insurance remedies."

Further, the April, 1973 issue of FDA Consumer Magazine concluded:

"Safety measures developed by manufacturers, in cooperation with the FDA, have achieved a high degree of safety in cosmetic and toiletry products." (Page 23)

In our February, 1974 submission we offered some preliminary estimates of the probable national total of injuries that might be associated with use and accidental misuse of cosmetics and toiletries. Since that time, two potential new sources of pertinent information have become available:

- (1) Product Experience Reports under the Voluntary Program on over 2.4 billion units (approximately 40% of total volume) of products distributed in 1974;
- (2) A second full year of figures from the National Electronic Injury Surveillance System of the Consumer Product Safety Commission.

The first of these items provides FDA with information from a wide variety of companies on a broad range of products (whose ingredients are known to FDA) of all types, representing a statistical data base of real value and significance. We consider the first year of the PER program to represent a highly significant initiation of a key feature of FDA's program to protect the public. We have been assured that when administrative and computer problems are resolved by other companies, even greater participation will be seen in the second year.

The full FDA report for calendar 1974 reveals that:

- (1) There has been a 24% increase in the number of companies participating, from the first half to the second half of 1974;
- (2) The product experience reports cover a total of 2.4 billion units of products, including virtually every category of cosmetics and toiletries;
- (3) The overall average rate of alleged injuries is 1.8 per million units of products distributed.

These figures relate more directly to cosmetic safety than figures from other sources which include accidents from containers, or accidental ingestions resulting from the inherent curiosity of children under age 5.

Last year, we took figures from the NEISS reports for fiscal year 1973 and separated out container accidents and accidental ingestions, leaving an estimate of 11,800 injuries associated with (but not necessarily caused by) normal use and accidental misuse of cosmetic and toiletry products.

The same analysis of the fiscal year 1974 NEISS figures gives 15,700. In its analysis of the NEISS data, FDA's Office of Planning and Evaluation ascribed the increased numbers to improved reporting of injuries to NEISS, rather than to an increase in cosmetic-related injuries.

Reducing our estimates to rates, assuming approximately six billion units of products distributed, we get approximately 2 per million units distributed for the two full years of NEISS reports. This rate is consistent with the rate reported by FDA from voluntarily submitted data from industry in the Product Experience Reporting Program.

Several things should be noted about the NEISS data for cosmetics. The overwhelming bulk of the incidents fall in the two lowest classes of severity, representing mild, transient injuries to small areas of the body, and absolutely no incidents have fallen in the two highest classes of severity.

CURRENT FDA AUTHORITY IS ADEQUATE

As we pointed out a year ago, FDA has demonstrated adequate authority to act quickly and effectively to protect the consumer. And, as previously mentioned in this statement, FDA has recently issued three final regulations involving warning statements and a fourth providing for ingredient labeling of all cosmetic products. These new regulations were issued by FDA under existing authority and provide FDA with essential regulatory powers.

As a result, many of the essential elements of S. 1681 have been adopted by FDA regulation in recent months.

FDA has often expressed a need for more information about the industry and industry has attempted to provide FDA with this information under the three-part Voluntary Program. As of May 30, 1975, 830 manufacturing establishments have registered; 635 firms have submitted 17,445 product formulations; and 147 firms have submitted product experience reports. The Voluntary Program was developed in response to this need and, as we indicated in February, 1974, we would have no objection if the present Voluntary Program were made mandatory with provisions for continuing existing safeguards concerning confidential submissions.

In sum, we believe there is no need for additional cosmetic regulation for the following reasons:

- (1) The safety record of the cosmetic industry belies the need for additional legislation;
- (2) Existing FDA authority is adequate as exemplified by the regulations promulgated earlier this year. Moreover, regardless of whether the Voluntary Program were made mandatory, FDA has sufficient information to regulate adequately what is already a very safe industry;
- (3) CTFA initiatives in establishing scientific programs complement and reinforce FDA's existing authority. The CTFA Board of Directors has approved and officials of the Association have had preliminary discussions with Commissioner Schmidt of FDA on plans for a safety review program for cosmetic ingredients. We plan to meet again with the FDA in the near future.

The program involves expansion of existing programs for the development of a central file on safety literature on cosmetic ingredients, and the development of chemical descriptions followed by the establishment of a review by an expert panel of these data for each ingredient. The solid foundations for the program have already been established in the industry's present scientific program which include chemical standards and technical guidelines.

- (4) There is a need to guard against more and more government regulation. We are in an era of high inflation and high unemployment and it is high time we paid tribute to a segment of our free enterprise system which is working in an efficient and safe manner. This, of course, includes the vital role of the small businessman. To do otherwise, would lead to a serious misallocation of resources and lead to increased consumer prices with no resultant benefit.

TITLE I of S. 1681

Having outlined the reasons why we believe that new legislation is unnecessary, we would like to turn to specific comments on S. 1681, introduced by Senator Eagleton. In doing so, we believe it is important to reiterate briefly two points that were made by both the Food and Drug Administration and the CTFA at the hearings held in 1974.

First, there should be no remaining doubt that any substantial legislative requirement for premarketing approval of cosmetics would be a totally wasteful and unnecessary allocation of government and industry resources. As the economic studies that we have submitted demonstrate, premarketing approval requirements would impose an economic burden on individual companies that would be intolerable, and that would be totally wasteful of this country's scientific resources. The cost of administering such programs by the FDA would either add significantly to that agency's budget or would require diversion of existing resources from other, higher priority, health needs without any commensurate return in terms of enhanced public health and safety. No witness at last year's hearings could make a substantial case for premarketing approval of cosmetics, and FDA vigorously resisted the statutory imposition of such a scheme.

Second, there is, as a practical matter, no distinction between a legislative system that affirmatively mandates premarketing approval and one that on its face purports only to require "premarketing notification." This fact is clearly borne out by the practical experience under the new drug provisions of the Act between 1938 and 1962 and was also affirmed by Commissioner Schmidt in testifying before this Committee on S. 863 last year. As the Commissioner emphasized:

"Mandatory submission of these data would be the same thing as preclearance because you can imagine what a terribly uncomfortable time I would have in this chair were we to do nothing with a set of data submitted to us and later that product turned out to have been hazardous and we did not say yes or no -- we just did nothing."

Thus, any time there is a mandatory requirement for premarketing notification, and a fixed period that must elapse before a product can be marketed following that notification, it is both illusory and disingenuous to view the system as other than one of premarketing approval. FDA could not afford to receive the data without acting on it; for this reason, industry could not afford to move forward with marketing with an unknown FDA action pending.

It is against these two important concepts that we must look at the crucial provision in S. 1681, Title I, that adds a requirement that the safety of a cosmetic be adequately substantiated prior to commercial distribution. We should emphasize at the outset that that is not a legal requirement with which we disagree, and it is a requirement that currently exists. We believe that it is the obligation of every manufacturer and distributor to assure itself of the safety of its products before marketing. FDA has, of course, reaffirmed this obligation in regulations issued March 3, 1975.

Had S. 1681 stopped at the point of confirming that legal obligation, we could certainly not quarrel with the concept, although the statutory reiteration would appear to duplicate existing FDA initiatives.

S. 1681 does not, however, stop at that point. Rather, it then contains five specific provisions either authorizing or directing FDA to require the premarketing submission of safety substantiation information. These five provisions convert S. 1681 from a safety substantiation bill into an elegantly-drafted and highly comprehensive premarketing approval bill. Indeed, the authority is so broad that it would authorize (and as a practical matter require) FDA to reexamine every existing product as well as every new product.

The first of these provisions is Section 605(b)(1)(C)(i), which authorizes the Secretary to require the submission of safety substantiation information and data. This authority can be exercised to require the premarketing submission of these data for every new cosmetic, thus in one stroke converting the entire program into a pre-marketing approval system. This authority can also be exercised to be applicable to every existing cosmetic, thus converting it into a system of approval placing into jeopardy every currently-marketed product.

The second provision is Section 604(c). This provision authorizes the Commissioner to specify what specific tests must be run for each cosmetic, and the procedure to be used for each test. It also authorizes FDA to prohibit companies from conducting their own tests, no matter how well equipped many companies are to do these tests. Indeed, it would appear that this provision would authorize FDA to require that the tests be run by the government on a cost-reimbursable basis. The information generated under these requirements is, of course, among the data that could be required to be submitted prior to marketing under Section 604(b)(i)(C)(i).

The third provision, Section 604(c)(2), is even more specific in that it directs the Secretary to establish "screening levels or other criteria" and requires that products that exceed those screening levels be withheld from the market for a period of 90 days after the submission of the test results to the Secretary. The only limitation is that the screening levels "be relevant to the conditions of use prescribed in the labeling of the cosmetic or to such conditions of use as are customary or usual." "Relevant" is a very loose word, and could encompass screening levels into which are built significant safety factors that would in fact cause numerous products to fall into the premarketing submission and thus preclearance category.

The fourth provision, Section 604(d)(1), directs the Secretary, based upon a finding of "significant risk of injury" (with neither "significant" nor "injury" being statutorily defined) essentially to establish premarketing preclearance requirements with a minimum 90-day delay for any cosmetic class or any cosmetic containing an ingredient that meets the definitional test.

Finally, Section 604(d) (2) grants blanket authority without any relationship to health or safety for the Commissioner to require premarketing submissions and thus, as a practical matter, approvals, for any cosmetic if he finds that it is "not within a type" previously marketed, or, if within such a type, "significantly different from other cosmetics within that type." No guidance is provided as to what is a "type" or when a difference is "significant." The Secretary has indeed essentially unfettered discretion to compel premarketing approval based upon this lack of legislative guidance and appropriate delegation.

We believe that the essential fallacy built into these last three provisions in particular is the unstated premise that it is possible to identify certain classes of cosmetics where the mechanism of premarketing approval will provide a greater assurance of consumer protection than the existing requirement of premarketing substantiation of safety. If, indeed, for some class of cosmetics, there is some level of irritation or sensitization that poses a public health concern, FDA could certainly today by regulation recognize that such a level exists, and that marketed cosmetics should not exceed that level. We do not see, however, that a level could be identified above which cosmetic safety can be substantiated, but which cosmetics are made safer by FDA's premarketing review and approval of the safety data.

Our central criticism of S. 1681 is thus not that it proposes to require the premarketing substantiation of the safety of cosmetics. This obligation currently exists. Rather, our objection is that the bill is, in careful disguise, both an invitation and a mandate to FDA to embark upon the premarketing approval of cosmetics, a system that is unwise, unwanted and unnecessary.

Appended to this statement is a memorandum reviewing additional criticisms of various aspects of S. 1681. In our view, however, the criticism that we have just outlined is the crucial one. Whatever our views on other aspects of legislative proposals, we maintain our central opposition to any legislation that creates a system of premarketing approval for cosmetics. Any such legislation would be highly wasteful of industry and governmental resources and would have a wholly undesirable adverse economic impact on the majority of members of this industry that are small businesses. As strongly as we believe that there has been no demonstrated need for any legislation, and that existing FDA and industry initiatives adequately protect the consumer, we are even more strongly opposed specifically to S. 1681 in its overreaching imposition of premarketing approval for cosmetic products.

MEMORANDUM RE EAGLETON BILL, S. 1681

The following memorandum is a critical review of provisions of the Eagleton Bill, S. 1681, other than Section 101, dealing with cosmetic safety. Where that bill amends the Federal Food, Drug, and Cosmetic Act, references will be made in terms of new sections of the FD&C Act.

(1) Section 102 -- Good Manufacturing Practices.

The CTFA, through its quality assurance guideline program, has long supported the view that cosmetics should be manufactured in a manner to assure that they possess the quality and integrity they purport to possess. Section 601(f)(2), on the other hand, gives the FDA new authority to mandate testing by manufacturers. Such specificity is unnecessary, and without Congressional guidance as to how it is to be used, unwise. For example, the lack of safety substantiation constitutes "adulteration," so that FDA could arguably, and in our view improperly, convert any "testing" authority into a new grant of authority in the safety area.

(2) Section 103 -- Definitions.

The definition of "commercial distribution" is unnecessarily broad, and could unreasonably include the company use of test panels located at other than the factory site to determine safety and, concomitantly, consumer acceptance. It should be made clear that "market testing" is conducted through commercial channels and does not include individual placements with known and identified consumers.

(3) Section 201 -- Registration.

The CTFA has testified in 1974 that it would not oppose converting the current three-part voluntary program into a mandatory one, so long as current safeguards and limitations are maintained. The provisions with respect to registration of cosmetic ingredients and experience reporting are unsatisfactory to

the extent that they go beyond the current program.

Section 605(b)(1)(C) is unsatisfactory (probably both to CTFA and FDA) in defining semi-quantitative formula disclosure. Section 605(b)(1)(E) is unacceptable as a submission to FDA; there will be no objection to making this information available to Poison Control Centers or to FDA upon request. The requirements for defect reporting and recall reporting in Sections 605(b)(2)(D) and (E) are burdensome and unreasonable, particularly in the context of a criminal statute. Section 605(d)(1)(A) is unacceptable; the timing as a premarketing submission creates the premarketing clearance problem outlined in the statement.

Section 605(e)(2)(A) places an unreasonable burden on the manufacturer in that he must not only make the submission required under Section 605(d)(1), but also then determine whether the product is "identical, similar or related" to a product previously marketed. Either the issue involves the identical formula or all lipsticks are related to all previously-marketed lipsticks and similarly with other related cosmetics.

Section 605(f) is unacceptable when compared with the current product experience reporting program. Reports should not be required on a "rolling" basis, but should be cumulated for periodic reporting. Moreover, the requirement for adverse reaction reporting for an entire industry regardless of FDA approval or disapproval is unique. The purpose of the program is not to identify individual products as being in violation of law, but to correlate adverse reactions with ingredients as well as products to see if there are any patterns to consumer reactions. Accordingly, the same protection against the dissemination of individual reports as is applicable to mandatory census reports should apply here. The FDA is not operating a program for the purpose of being a resource tool for the plaintiffs' bar.

(4) Section 202 -- Factory Inspection.

Factory inspection poses issues that are common to all articles subject to the Act; there is no reasonable basis for treating all generally available consumer products under different standards. Accordingly, this subject should be taken up by Congress apart from bills dealing with specific substantive areas of regulation. Certainly, the proposed factory inspection provision inadequately protects financial, sales, pricing, personnel, and research data. The subsection with respect to submission of inspectable data upon written request should also be deleted pending a Congressional review of this subject with respect to all articles subject to the Act. The same point is applicable with respect to administrative restraint proposed under Section 304(g). In addition, administrative restraint should not be authorized for FDA employees to exercise in their total discretion without prior review and authorization by superior officers.

(5) Section 301 -- Cosmetic Labeling.

CTFA has withdrawn its objections to ingredient labeling now that adequate means of compliance have been worked out with FDA. Proposed Section 602(g) appears to be directed toward maintaining that labeling pattern, as promulgated by FDA March 3, 1975. While we do not object to confirmatory legislation, the statute should make clear that ingredient information need not be on inner containers if it is visible at the point of sale, and the other elements of the labeling regulation should be recognized by the Congress as falling within the exemption authority in statutory language. CTFA does take exception to any requirement for identifying specific flavor or fragrance ingredients; it is both totally impracticable and unnecessary.

Exception is also taken to proposed Section 602(h) to the extent that it goes beyond authorizing the Secretary to adopt cautionary regulations where a cosmetic "may be hazardous to health." Such vague standards as "protection of the public health" or "as a guide to

use" are inadequate and an invitation to harassment.

(6) Section 401 -- Preemption.

The Association strongly supports proposed Section 606(c) preempting state regulation.

(7) Section 401 -- Advisory Committees.

The provision on advisory committees, while appropriately including representatives of consumer and industry interests, should be modified to resolve the present dilemma facing FDA with regard to the Freedom of Information Act and the FACA. FDA needs the ability to hold FACA-sanctioned closed meetings to review confidential data and formulate policy recommendations without the necessity for non-voting advisory committee members to become special government employees who forever afterwards face very unnecessary, but nonetheless difficult problems, under conflict of interest statutes.

(ATTACHMENT I)

EXCERPTS FROM . . .

Chemicals & Health

Report of the Panel on
Chemicals and Health of the
President's Science Advisory Committee
September 1973

Science and Technology Policy Office • National Science Foundation

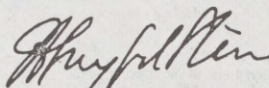
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FOREWORD

A large and growing number of chemical substances are introduced into man's environment each year. To many of these substances man is involuntarily exposed. Some exposures represent identified and recognized hazards to his health and well being, but to a great extent our ability to understand the biological effects of chemical substances such as pesticides, food additives and therapeutic drugs has not kept pace with our technological ability to develop and use new substances.

In May 1970, a panel of the President's Science Advisory Committee was established to review a broad set of issues concerning chemical substances and human health. This panel was a reflection of the initiative and concern of two previous Science Advisers, Drs. Lee A. DuBridge and Edward E. David, Jr. It was their belief that the time had come to take stock of the scope of the intrusion of chemical substances into man's environment, of the known or implied threats to human health which they represented, and of the degree of protection which regulatory processes could be reasonably expected to provide. The report of the panel is the product of almost two years of deliberation and contains much useful information on the size and nature of both the risks and the benefits that are involved in the use of chemicals.

The report was prepared by an outside advisory group. It has been reviewed by the Federal agencies most concerned with these matters. Many of its recommendations deal with administrative, resource, organizational and procedural matters. Implementation of such recommendations involves a weighing of broad policy questions that a technical group cannot adequately undertake. Several of the report's recommendations, however, have already been implemented. Others will quite likely be the source of continuing debate and study. I am releasing the report, therefore, in order that it may contribute to the state of public knowledge and deliberation on this difficult and complex subject.



H. Guyford Stever
Director
and
The Science Adviser.

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May 1970

Terms of Reference for a PSAC Panel on Chemicals and Health

A very large number of chemical substances are purposefully introduced into society which impinge directly on man. Therapeutic drugs are perhaps the most obvious. In addition, however, there are more than 60,000 registered pesticide formulations on the Federal rolls and there is an uncertain but very long list of food additives which are used to improve certain qualities of food substances.

Large segments of the population are subjected to these chemicals for very long periods of time. In spite of this level of exposure, the understanding in any depth of the physiological hazards and toxicity of many of these chemicals is generally not available. The technology of development of these chemicals has not been matched by corresponding biological understanding of them. Of particular concern are potentially deleterious effects on health resulting from long-term exposures to low levels of these chemicals, alone or in combination.

Occasional incidents call this matter to public attention. Recent examples have included cyclamates, pesticide residues, and oral contraceptives. Thus far, each case has been treated individually—usually in a manner reactive to a variety of pressures of the moment and rarely if ever reflective of a sufficient background of objective information. At the same time, the number of chemical substances in use continues to increase as do the corresponding chances of human exposure. It appears desirable that the whole situation be addressed at once with a view towards ascertaining whether the public health and well-being are adequately safeguarded, and if not, what actions should be set in motion.

A PSAC panel is being established to explore this situation. It should consider such questions as:

1. How much assurance of safety should we require?
2. What kinds and levels of research must be performed to reach a desired level of understanding?
3. What resources will be required? What will be required in terms of organizational and financial arrangements, including research facilities?
4. How are the results of research best put to use in the decision-making process? How should the research and research results be related to the regulatory process? What organizational and institutional arrangements are needed for social decision-making and education at the various levels of decision-making within the Federal Government and in the community-at-large?

Note: There are many other substances that result from man's activities that may affect man directly, such as asbestos fibers, air pollutants, etc. To the extent reasonable, the study may consider these, too, although it is recognized that the actions to control these substances may be quite different from those required to control the previously described substances.

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SECTION I—Summary and Recommendations

CHAPTER 1

INTRODUCTION

The charge to this Panel—Chemicals and Health—could have been unmanageably broad—since both we and our environment are complexes of chemical systems. Choices had to be made. Guided by various public concerns, by scientific and technological developments, and by recent regulatory history, our detailed attention has focused on those established or implied threats to health attendant upon medicines, agricultural chemicals, food additives, household and industrial chemicals and, to a lesser degree, other pollutants of air and water.

We have chosen to exclude from any detailed consideration the admittedly critical areas of drug abuse, dietary choice, and undernutrition, although foods and illicit drugs, as we will later emphasize, are important parts of our chemical environment.

We have attempted to consider the size and nature of the risks inevitably involved in the use of chemicals, and the magnitude and character of the benefits they provide, including the role they play in improving public health. This is a subject as complex as life itself, and just as full of uncertainties and conflicts.

Public attention is now focused on what might once have seemed quite minor threats to health, in large part because our younger citizens are the first generations ever to grow up nearly free of major threats from once common infectious diseases—*whooping cough*, *scarlet fever*, *typhoid*, *pneumonia*, *streptococcal infections*. They are also nearly free of the serious nutritional diseases such as *ricketts*, *pellagra*, and *goiter*.

Along with a host of other factors, a wide variety of chemicals—*drugs*, *fertilizers*, *vitamins* and *pesticides*—have helped to achieve these

gains. Yet the very absence of these former scourges has left clear the field for the chronic degenerative diseases, some of which are likely to have external chemical causes. We need now to develop ways to deal with these slower acting and less direct causes of death and chronic sickness.

In the area of chemicals and health our country requires, above all, a sense of perspective. Without that we will work on the wrong things, waste irreplaceable effort, and neglect the truly vital. Next, we need balanced judgments and actions. Without them we will do the right things wrongly, or poorly, or not at all.

In seeking an adequate perspective, we have looked broadly at the threats to health linked to chemicals. Several of the largest involve voluntary exposure—*cigarette smoking*, *alcohol abuse*, *dietary composition*—have been extensively discussed elsewhere. (The involuntary aspects of death from alcohol-related automobile accidents and homicides cannot be neglected.) Our recommendations recognize their importance despite the fact that they have not played a central role in our investigation, and we urge increased effort and new measures of education and control.

The bulk of our report and recommendations, however, deal with lesser threats in our environment, and focus on possibilities for their more effective control and more rapid discovery.

Public expectations and government philosophy have called for increasing protection of the public health and welfare and increasing prevention of exposure to dangerous substances, with emphasis on protection from involuntary exposures but with attention to voluntary exposures as well.

The health-related regulatory agencies of the government dealing with chemicals, now the Food and Drug Administration and the Environmental Protection Agency, have evolved stage by stage. Their present organizational positions reflect an increasing public desire to separate health-protection functions from the encouragement of the production and use of products.

With time, the spectrum of items to be regulated and the character of regulation have changed. While the threats to health and the pattern of disease of a century ago have been altered, there has been an enormous increase in the number of substances to be regulated, and the scope and complexity of regulation have correspondingly increased. The tools of analysis and detection and the advances in scientific understanding have combined not only to heighten our awareness of environmental chemical agents and of varied possibilities of disease causation, but also to raise our expectations that these might be better controlled.

During the last few decades many exposures, involuntary and voluntary, have become more recognized, some as they increased in significance like air pollution and cigarette smoking, others as they remained constant or declined. The next few decades, as our knowledge and understanding increases further, will see the recognition of many new exposures, involuntary and voluntary, of some health significance. We will have to learn much more about how we should meet threats from voluntary exposures. (The history of our national experience with prohibition suggests that governmental regulation will not always be a successful tactic for meeting such threats to human health.) Our attention in this report is mainly to regula-

tion, but both our concern and our nation's need extend far beyond it.

For regulation to function properly, we must know more about the biological mechanisms by which chemicals can or do threaten us, we must have more effective and more efficient ways of testing both individual substances and all the materials that will touch or feed us, we must recognize more diverse and more subtle threats more rapidly. To this end we are badly in need of new knowledge today; tomorrow our needs for it will grow greater and greater.

Both to regulate wisely and gain needed new knowledge, we will need more highly skilled people, trained in appropriate specialties. We have not studied the needs in detail, and do not make detailed recommendations. Among many others, the need for a great increase in appropriately trained clinical pharmacologists and toxicologists and the need for persons of diverse specializations in environmental epidemiology are too great, however, not to be at least noted.

It is time to take stock. Is regulation of chemical agents in our environment performing the health-protection function to a degree that coincides with our expectations? More important, can regulation do so? Are regulatory decisions based on a suitable foundation of scientific knowledge—one that is growing fast enough? Do the decisions reflect an appropriately broad set of considerations in each case? Are all the parties of interest able to contribute appropriately to the body of facts and arguments on which decision is based?

The answers to all these questions are encouraging, yet in each case there is more that we can do, as our recommendations show.

The most important thing we can do now is to make our regulatory decisions better balanced, to ensure that positive effects on health are balanced against negative ones and that non-health effects are duly considered.

The next most important thing is to increase public understanding and

acceptance of these better balanced regulatory decisions. This involves not only bringing to public attention much more of the pros and cons of administrative actions—and much more about what we do or do not know—but also offering the public more effective channels through which to express its interests, concerns and doubts.

We stress the following themes:

Perfect Safety Is Not Attainable.

We must always live with some risks both because nature forever confronts us with hazards, and also because the contributions of chemicals to human welfare are so vital. Our knowledge is never complete; as it increases, it will make us reconsider, and often revise, past decisions.

Improved Safety Is Possible. But to make the greatest possible health advance, we ought to react most to the gravest threats, as judged by their total consequences for all our people, particularly when these threats are either well-established, or both plausibly true and long-delayed in impact. We need also to react appropriately to less-certain threats that can be avoided without appreciable disadvantages. Threats of lower priority should not be neglected but need not be reacted to as strongly.

Our Present Mechanisms Have Generally Worked Well. both in providing useful new chemicals and in safeguarding the public health from involuntary exposures to threatening chemicals, new and old. The Federal Government's basic responsibility, more stringent for involuntary exposures than for voluntary ones, has been effectively implemented through general legislation and detailed administrative actions. The steady growth of knowledge has demanded detailed up-to-date decisions that apply general legislation on a case-by-case basis.

Improvements in These Mechanisms Are Still Needed. We should expand the coverage of regulation in certain areas and should accelerate the functioning of our regulatory

institutions. But above all we must increase our knowledge and learn how to make more balanced judgments.

To Improve Our Human Health Substantially by changing our exposure to chemicals, we must turn to:

a. Reducing our consumption—or otherwise reducing the adverse effects—of such voluntary chemicals as alcohol in beverages and substances from cigarette smoke.

b. Learning more about the biological basis of disease, in particular:

- Learning more about the impact of dietary composition on health and altering our choices of what we eat.

- Identifying and learning to deal with, threats from still unidentified chemicals.

- Continuing to develop new medicines, especially for diseases and conditions not now adequately treatable.

□ □ □

While there are many actions that we recommend, the major points can be summarized under three heads:

a. **Improve the Gathering and Availability of New Knowledge** by increasing support and by strengthening procedures and mechanisms so as to:

(1) Gain further understanding of the biochemical mechanisms by which chemicals—in foods, medicines, and our environment—affect man.

(2) Improve and expand studies, both in the laboratory and in the world at large, of the impact of chemicals to which humans are currently exposed.

(3) Improve our gathering of safety and efficacy information about new chemicals.

(4) Make publicly available, in a routine and appropriately timely way, the data of safety studies for all chemicals submitted for approval, and the data of efficacy studies for all those approved.

b. Improve Public Information and Understanding:

(1) Inform the public about the inevitable incompleteness of the knowledge we have gained up to any given date.

(2) Make public the bases of regulatory actions, including both the extent and character of the scientific knowledge involved.

(3) Make clear to the public the content and importance of the themes stressed above.

c. Improve the Balance of the Decision-making Process:

(1) Use advisory Committees including both expert and public members, in connection with important decisions.

(2) Make public the pros and cons supporting regulatory decisions of public interest, including both affirmative actions and decisions to delay or refuse to act. These "white papers" should recognize the diversity of interests that each one of us has in such decisions, and should make clear what is not known, as well as what is.

(3) In preparation for each of these "white papers," emphasize the gathering of diverse views and considerations, so as to broaden the range of the pros and cons presented.

(4) Introduce institutional modifications to eliminate undue regulatory delay.

(5) Revise legislation and administrative procedures to make regulation more responsive to increasing knowledge and increasing measurement capability.

CHAPTER 4

GENERAL SUMMARY

A. CHEMICAL EXPOSURES

What is the role of chemicals in our attempts to protect and advance human health? Are we concerned only with the new chemicals to which attention had been called in recent years? Hardly.

Man has been exposed to chemicals in the environment since time immemorial. Plant, animal and human life have always depended on natural transformations continuously recycling huge quantities of chemical substances through the biosphere. Photochemical smog based on the organic chemicals added to the atmosphere from pine forests, a myriad of mycotoxins, the botulinus toxin, and the "red tide" occasionally seen off our coasts—all these have been with man since prehistoric time.

Man has long been aware that the continuing risk of illness and death cannot be completely avoided by any known substance or mode of existence. He, nevertheless, has persistently utilized chemicals in his attempts to extend life, to minimize ill health, and to reduce both the risks and the labor associated with getting his daily bread. Man has so persisted even while knowing that no single chemical substance, natural or artificial, can be guaranteed harmless to him.

Some of his chemical interventions have brought overwhelmingly beneficial effects. Were 1901 death rates still prevailing, nearly 50 million of this nation's 200 million citizens would now be dead. A significant portion of these lives were saved by suitable uses of chemicals. At the other extreme some uses of chemical interventions, often incidental and unanticipated, were almost wholly undesirable in their

effect on man and his environment.

With increasing industrialization, new chemicals have been contributed to the environment. Both new and old chemicals have increased in amount to meet the needs of growing populations and to assist in improving living standards. Opportunities for utilizing a myriad of naturally occurring and synthetically manufactured chemical substances have increased with almost similar speed. The rate of production of petrochemicals from oil and natural gas has been quadrupling every ten years. Large quantities of such inorganic chemicals as chlorine, sulfuric acid and Portland cement are now made. (See Chapter 9, "Industrial Chemicals," for further detail.) The total for manufactured consumer organic chemicals now corresponds to 500 pounds per capita in a population of 200 million!

What adverse impacts do uses of chemicals exercise on man's health today? The firmest basis for answering this question is to begin from estimates of death linked to chemical causes. The available data, which are detailed in chapters 5 and 14 below, reveal that most deaths linked to chemical impact occur primarily because of individuals' own actions, as in smoking cigarettes and in the abuse of alcohol and illicit drugs. A substantial segment of deaths may indeed be linked to dietary choices. A second substantial group of causes depend on unknown chemical factors in the environment, which initiate or promote cancer—possibly in combination with viruses, genetic factors, etc. The third, and smallest, substantial group includes deaths that arise from adverse reactions to medication and from recognized environmental exposures—such as common air pollution and exposures of workers on their jobs.

Action to reduce the first, and largest, group of chemically linked deaths would require society to make difficult choices. Changing the behavior of millions of individuals in their choice of diets, in their decisions to smoke cigarettes or consume alcohol could not be simple. Reducing the deaths associated with unknown risks faces no such difficulties: it requires chiefly a vigorous and persistent attempt to increase our scientific knowledge. Only in this way can we hope to locate and then to strike at the causes of such deaths. (Recommendations to improve such knowledge appear above.)

Adverse reactions to medication are not yet well enough studied, and we have recommended appropriate action. Community air pollution and occupational exposures are being actively attacked. There remain a large variety of chemical exposures which produce few deaths, an uncertain amount of ill-health, but much public concern.

Today's concern about chemicals and health is stimulated by more than the revelations that modern toxicology is making about both the chemicals in natural foods and the chemicals made by man. A large part of this concern comes from the rapid expansion of the latter, which can reach man and the environment through a remarkably complex labyrinth.

Fortunately, many industrial chemicals do not reach the general public. Acrylonitrile, for example, is shipped in sealed tank cars to plants for conversion to synthetic fibers. Textile mills may then weave carpets from the fibers. The carpet buyer will not be exposed to acrylonitrile, only to the synthetic fiber, although some occupational exposures must still be guarded against.

Most of us, by contrast, are at least

somewhat exposed to the gaseous propellants used in spray cans and to the chemicals used to make detergents effective. Further, every paint solvent evaporates into the atmosphere and every detergent drains through sewage systems to lakes, rivers, or oceans. Man is exposed directly to such materials both as they are used and as he uses air and water. Still other groups of chemicals, the drugs and food additives, are intended for primary use by man. Agricultural chemicals reach man to the extent that residues persist in his food.

Thus man's manufacture, distribution, use and disposition of both artificial and naturally-occurring substances can lead to new and possibly significant hazards.

B. THE APPROACH TO PUBLIC POLICY

Amid this vast array of exposures both to naturally occurring toxicants and to chemicals that man produces in increasing volume, what is a proper perspective for public policy on health? Each day's policy must, we believe, turn upon as careful and close a judgment as we can draw from the continuing expansion of knowledge—knowledge of what benefits and risks are associated with chemicals today. That judgment cannot rest simply on the basis of an arbitrary preference for the natural or for the synthetic; for the new or for the old; for the creations of man's technological genius or for the accidents of what chemicals become preferred in certain cultures. We must instead judge by the current values and needs of the American people, a judgment to be closely considered, reviewed and reconsidered as knowledge accumulates and conditions change.

New chemicals, not already in use or mass production, are especially easy to review and regulate. Our procedures have taken advantage of this, and it is with new products that our existing regulatory mechanisms

operate most effectively. Chemicals, natural and synthetic, already widely used may also deserve our careful attention, but almost certainly on a selective basis. Here we have not yet adequately developed the procedures we need to guard ourselves from possible threats—and, of course, we have often not acquired the knowledge needed to recognize these threats.

To enforce effective regulation, and to develop principles that can guide regulatory bodies, two kinds of comparisons must constantly be made. One concerns risks and benefits. The more certain a chemical is to save lives the more willing we should be to accept dangers in its use. And the more readily it could be replaced by something harmless—either by nothing at all, or by a very safe product—the more willing we are to deny a new chemical entry into use. The enormous gray area between these extremes is one that regulatory bodies confront constantly. There are no simple principles to guide that choice. But we recognize that the better our scientific knowledge becomes, and the more clearly the public understands this dilemma of choice, the more satisfactory regulatory decisions will be.

Precautionary destruction of foods or beverages because of suspected contamination, or a restriction against the use of some drugs or food additives, does not merely ensure against harm. It also shifts usage to other foods, beverages, drugs, or food additives in ways not always predictable or advantageous. Thus, removal of an implied hazard may entail a hazard of its own, and always restricts freedom of choice.

A second comparison must constantly be made—by scientists, by regulators, and by members of the public—as they assess the soundness of regulation. This is a comparison of two knowledges. One is the knowledge afforded by human experience with chemicals in widespread and prolonged human use. [Such usage typically is so

unsystematic and unfocused that untoward effects may be hidden or masked by the complexity, or ignored.] The other knowledge is that following from careful scientific inquiry, in laboratories and/or controlled experimentation. (Such knowledge is also often partial, sometimes rests on observations on organisms whose reactions may not parallel those in man; and rarely measures long-term consequences, particularly in those occurring only in man.) We expect both citizens and regulators to recognize the worth, and the limitations, of each kind of knowledge. And, as the recommendations above indicate, we would urge substantial commitments to needed research as a way to moderate this dilemma by increasing our knowledge of both kinds.

With the aid of scientific understanding, sound medical practice, and public health and preventive measures, the threat of acute infectious bacterial disease has been virtually eliminated as a cause of death in this country. Several chronic degenerative diseases, including cancer, are now the most prominent causes of death. Some, notably lung cancer, are rising to epidemic proportions.

United States mortality rates in the past two decades reveal a recent attenuation—even a reversal—of the, previous declining trends. Among the causes of this excess mortality or early death one finds cigarette smoking, dietary patterns, and other voluntary social habits implicated as major or even overwhelming contributing influences.

The American public, in part through the legislative process, has paid a great deal of attention to uncertain or implied risks while ignoring certain large and unequivocal risks to health.

C. KNOWLEDGE FOR DECISION

Knowledge is preeminently important for good decisions. While some

environmental chemical agents seem clear causes of ill-health, we must readily admit that detailed and systematic knowledge in this area lags far behind the levels of quantification and reliability accessible to contemporary science. The acquisition of knowledge may be expensive, but the absence of knowledge may be much more expensive. When considering a decision and faced with incomplete and insufficient information, the administrative and legislative processes tend strongly to the side of a conservative prudence in the name of health. There are several notable examples, in which Congress has replaced scientific discretion by statutory mandates to "protect" human health inflexibly. The Delaney Amendment to the Food, Drug, and Cosmetic Act is probably the best known. It is not clear that such absolute restrictions always achieve the desired protection of human health. At times they may even work against it. (The rigidly prescribed standards for automobile exhaust emissions, mandated by the Clean Air Act Amendments of 1970 raise a clear issue to what extent have resources been diverted from other and perhaps clearer contributions to health.)

There is a further cost of ignorance, one associated with wrongful or injudicious decisions. Regulatory decisions in the name of protection of health and environmental integrity often have expensive consequences. They typically obligate large expenditures of money, they are meant to remain in effect over long periods of time, and they typically rearrange large areas of our lives. Given the large impact of these consequences, the decisions producing them deserve the best foundation possible. Errors in regulatory judgments can be extraordinarily expensive, in human and monetary terms.

Finally, there is another cost implication. Public and private expenditures in the name of human health in the United States are large, yet they must always be limited. Expenditures made for, or as a conse-

quence of, regulatory activity are not available to be made toward health in any other ways. We should always be sure that what we purchase in the way of extra health through regulation does in fact have that benefit, since we thereby remove the option of making the same expenditure toward health in some other way.

Knowledge about environmental concentrations of chemicals and firm information on the probabilities of human exposures to them are not generally available. Except for therapeutic drugs, there is a major accounting problem to be solved if one is even to begin to appreciate the routes and quantities distributed. Knowledge about inherent biological effects is much less available than is generally appreciated. The technology to produce and distribute chemicals has outstripped the ability to understand their pathways in the environment and their biological effects.

What kinds of knowledge are needed? A wide spectrum of different kinds of information is necessary. At one extreme is an aggregate of fundamental information about disease processes in general as well as about those that may derive from exposure to environmental agents. We generally are better informed about the details of acute toxicity and acute disease processes than we are for chronic ones. There are many chronic degenerative diseases for which we know little about causes or mechanisms.

There is, in addition, a clear need for more research on an intermediate level, applying sound scientific insight and the current tools of scientific investigation toward the understanding of how chemical agents act on biological systems and toward the utilization of this knowledge. In the past, our evaluation of such actions has often been confined to "testing" using relatively unsophisticated techniques of classical toxicology. Clearly the improvement of testing depends on utilization of the newest concepts and methods

developed in pharmacologic and biochemical research. Much of our knowledge of the health effects of chemical exposures in man must come from population group studies made by epidemiologists oriented toward the major chronic diseases and the major environmental exposures. If we look to epidemiology for the amount of new knowledge and guidance we require, we must encourage this orientation and the inclusion of a wider variety of scientists in this field. We must, moreover, face the need for assured support over several years for those studies that cannot be done any faster. We must give epidemiologists better access to relevant data, for example through the institution of a National Death Index. Such questions as "has a specific person exposed long ago to some possible cause of ill health in fact died? What state holds his death certificate?" might be more quickly answered with the aid of the index.

D. ACQUIRING KNOWLEDGE AND ACTING ON IT

Having declared the importance of knowledge what do we as a society do to acquire it?

For new regulated chemical products, such as food additives, pesticides and therapeutic drugs, the government generally relies on the manufacturer and developer of the product to underwrite or perform all necessary research. The results of this work are used by the government in its regulatory decision-making.

There remain, even here, some areas where there is no clear responsibility for research and information. Prominent among these is the problem of old decisions versus new scientific insight or information. For products once approved or certified, there exists little or no incentive for either the manufacturer or the government regulator to consider

and seek out new (and sometimes discomforting) scientific information.

Knowledge about utility or benefit is typically as deficient as information about risk or hazard. Judgments about risks versus benefits or about penalties to be paid for restrictions on use appear particularly difficult to exercise in the face of this ignorance.

Although it is clear that in selected cases such new or additional information on safety or utility would be of great value, it has to be gathered selectively. Otherwise we would drown in a sea of unmanageable, and largely, valueless data. The mechanisms to select what is needed, especially in advance of data acquisition efforts, are not obvious.

E. HOW REGULATION IS—AND SHOULD BE—DONE

The regulatory outcome cannot be treated symptomatically. Any serious consideration of the patterns and products of regulation in behalf of health must include a serious examination of how regulation is done.

Risk-benefit and cost-benefit analyses have become commonplace concepts. In the litany of many administrators and public officials such concepts are included as desirable elements in regulatory decision-making. In fact they are desirable; yet the practicality of rigorous risk-benefit and cost-benefit analyses in any detailed sense may be quite circumscribed. What is both desirable and attainable is the concept of balanced decisions. Balancing should be done in a way to account for all of the important considerations and implications of each decision. Balancing should include the several important points of view espoused by both those with general as well as special interests. Regulatory decisions are always difficult decisions. It is clear that, no matter what the outcome, they can never satisfy all parties. Explicit

examination and candid explanation are essential if the decisions are to be understood and be credible.

We have relied too long on isolated or apparently isolated administrative decision-makers. Balanced decision implies a broad audience of constituents and a broadly based group of participants. The rewards and penalties for regulatory decision-making have traditionally resided strongly in the direction of narrowly-based considerations of protection alone. True balancing has generally not been encouraged and, at times, has been actively discouraged. It is not to the benefit of the American people to sustain this pattern.

The administrative agency responsible for regulatory decisions should be fully and appropriately equipped with the resources for arriving at balanced judgments. It must be careful, and able, to separate the scientific issues requiring only skilled professional judgments from those broader value determinations in which a more diverse assemblage of backgrounds and perspectives should be involved. The pattern of bolstering the administrator's own judgment by a competent, high-level advisory panel appears to have great merit. This pattern, traditional in many Western European countries, deserves consideration.

Health related regulatory judgments will necessarily reflect a changing scientific base. This fact dictates flexibility and discretion in the decision process rather than rigidity and legislatively-mandated actions.

Habitual reliance on appeal mechanisms for ultimate regulatory decisions is unwise. Avenues of appeal should clearly be available. Yet, the continuous expectation that an administrator's decision will be supplanted by later administrative and judicial appeals renders the primary process perfunctory, and undermines its credibility. Most or all of the elements of appeal processes are clearly desirable and

generally are in the direction of broadening the base of the decision. Thus, it would be logical to incorporate such institutions as the external advisory board, the public hearing, broad information gathering, and public information into the original decision process and to lead to relatively less reliance on the appeal processes by making the decision less vulnerable to subsequent reversal upon appeal.

Balanced, well supported decisions deserve and need clear and explicit presentation to the public in order to improve their understanding, acceptance, and the prospects for balanced decisions in the future. A number of mechanisms, public, private, and professional, need to be improved, expanded, or added to achieve this goal.

F. WHERE DO WE STAND?

The panel is confident that we can cope capably with our natural and man-altered chemical environment if we reorder our priorities soundly with the help of more and better data, improve regulatory mechanisms, strive for more balanced decisions, and achieve a higher level of public understanding and support.

Looking ahead, we give primary emphasis to gaining new knowledge, all the way from principles of chemical action to details of impacts of particular chemicals. As reliable knowledge of chemical impacts is expanded, regulatory agencies become able to monitor for safety more promptly and exactly. They thereby achieve a better balance between losses because improved chemicals are unavailable and losses that arise because specific chemicals are unwisely used. Finally, as basic knowledge expands and as new insights are uncovered by Federal and other non-profit research enterprises and by individual firms through their research activities, ways to produce safer and more efficacious chemicals will be dis-

covered. Given the vast market that has in the past snapped up new life-saving medicines, and other chemicals of high social value, private firms have major incentives to continue developing ever more socially useful products.

Our recommendations for advancing scientific knowledge of chemical impacts are central because

they would lead those who use, regulate or produce chemicals to act more prudently. Our recommendations for stimulating creation of new and more desirable chemicals rely primarily on the private market given the incentives that are already and effectively operative. But we would add Federal research for intermediate biological and chemical

investigation, plus Federal support for certain rare health needs of high social value. We rely on the combination of direct Federal regulation (to rule unsafe products off the market) and of private incentives (to create new products) that together will replace existing products by ones of greater, or more certain, safety.

vanced" societies support this statement. Next to food for the body, and food for the soul, comes food for the ego.

The ancient history of cosmetics, like that of foods and drugs, offers many instances of the use of hazardous materials, usually through ignorance, sometimes through indifference. As our knowledge of toxicity of the materials we use has increased, those that present known hazards have been dropped (as happened with thallium compounds in depilatories) or restricted in use so that the remaining hazards are minimal (as with lead salts or aniline dyes used in hair coloring).

Cosmetics usage covers a wide range of types and frequencies of exposure. Some may be ingested, as lipstick. Others involve exposure solely on or through the skin. Still others, such as hair spray, may be partially or unintentionally inhaled, and a number are applied to sensitive areas like the eyes or genital regions. Some cosmetics are used daily by a large fraction of the population. Others, such as moustache wax, are used rarely, or by only a few. Some are on the hazy borderline between cosmetics and drugs, such as mouth washes; others are clearly drugs; e.g., dandruff treatments and antiperspirants.

The total market for cosmetics is about \$6 billion annually. One published source²⁸ reports estimates that cosmetics and toiletries can be divided into 30 major product categories which in 1971 consumed 2 billion pounds of chemical raw materials valued at \$520 million. Clearly, this industry spends a high proportion of its sales on packaging and promotion. A breakdown of the categories is in Exhibit 8-9 and of the raw materials in Exhibit 8-10.

From what may be judged from human experience, the incidence of injury is small. There have been no reported recent deaths. In 1971, FDA had 314 complaints reporting injuries from cosmetics. Obviously, these are a small fraction of the total.

The total injuries from the use or

misuse of cosmetics are unknown; one rough and doubtful estimate from the report of the National Commission on Product Safety, is about 60,000 cases per year²⁷. Important as these are to the individuals involved, even this estimate is only 0.4 percent of the reported accidents or injuries from a partial list of consumer products, not including foods, drugs, automobiles, firearms, or cigarettes. These figures receive a degree of confirmation elsewhere in the Commission's report. Beauty aids were responsible for 48 injury cases, or 0.5 percent out of 9,376 cases reported in a physicians' survey. In the total pattern of environmental risks, those from cosmetics are both infrequent and slight.

The majority of injuries, whether judged by complaints which FDA has received and investigated²⁸ or by the insurance claim data used by the Commission on Product Safety^{29, 30}, involve allergic responses—skin eruptions, itching, asthma, etc. Unfortunately, allergenicity is one of the adverse effects for which animal tests have quite limited predictive value. Animal tests may be helpful in ruling out potent sensitizers or irritants in preparation for decision as to the safety of proceeding with human studies. The latter are essential—even though cumbersome, expensive, and uncertain—for prediction of very weak or infrequent effects. It is customary to carry out not only experimental human prophetic patch testing, but also some form of practical usage tests. A combination of such testing, chance anecdotal observations recorded in the literature, and the reported results of accidental or occupational exposures, have provided some basis for judgments.

As a result of such information and judgments, a number of sensitizers and other potentially hazardous ingredients have either been dropped from use or accompanied by suitable instructions and precautionary labeling. It seems likely, though solid information is lacking, that the actual injury rate from cosmetics has

COSMETICS

Other than food and religious practices, there are few areas of human activity in which large, private expenditures of time, money, and effort are more culturally controlled, and supported or modified by subjective preference than in the use of cosmetics. Examples drawn from ancient civilizations and from contemporary, primitive, and "ad-

declined, while the complaint rate has increased as a result of greater consumer awareness of the Food and Drug Administration as a regulatory agency, and of the existence of legal and insurance remedies.

While there are no formal pretesting or preclearance requirements for cosmetics, the total effect of individual and informal review (usually private rather than governmental), together with the innocuousness of most materials used, has made the injury rate fairly low by comparison with other widely prevalent sources

of hazard. As March and Fisher comment,²¹ "Dermatitis due to the use of cosmetics is uncommon. The low incidence is especially noteworthy when one considers the innumerable cosmetics that are used daily by both men and women." Trade associations, such as the Cosmetic, Toiletry and Fragrance Association (CTFA), provide an advisory service on materials and standards. The CTFA has recently petitioned²² the FDA to issue a regulation for the voluntary reporting of cosmetic product experience. This arrangement, if it works well,

will provide a far more adequate basis for assessing product safety and the possible need for further measures. The manufacturers have also agreed to make available information on the identity of the ingredients to assist users with specific allergies in avoiding those to which they are sensitive. Additionally, the fragrance industry has currently under way a comprehensive review of fragrance ingredients which seems likely to eliminate from use any remaining agents, not now recognized, which may be significantly sensitizing.

EXHIBIT 8-9 ESTIMATED U.S. PRODUCTION OF MAJOR COSMETICS AND TOILETRIES (1968 AND 1971)

	Million lb		Avg. Increase
	1968	1971	Percent per year
Toilet soaps	550	600	2.8
Women's hair sprays	350	420	6.3
Mouthwashes	200	250	4.8
Dentifrices	150	175	5.2
Shampoos	125	160	8.6
Face creams	100	130	9.2
Deodorants	60	95	16.4
Shaving creams	43	50	5.0
Hand lotions and creams	40	45	4.0
Shaving lotions and colognes	36	58	10.0
Baby powder	40	45	4.0
Hair colorings	35	40	4.5
Men's hair dressings	29	30	1.5
Men's hair sprays	--	30	--
Denture products	20	25	7.6
Talcum powder	15	17	4.2
Cream rinses	13	17	9.5
Face powder	13	14	2.5
Women's fragrances	8	11	11.2
Women's hair dressings	7	10	12.7
Suntan preparations	7	10	12.7
Bath oils and salts	6	9	14.6
Nail and cuticle removers	8	9	4.0
Makeup bases	6	7	5.2
Feminine hygiene sprays	--	7	--
Permanent wave kits	6	5	(9.4)
Lipstick	4	5	7.5
Nail polish	4	5	7.5
Eye products	1	2	26.0
Depilatories and other	3	4	10.0
Total	1,879	2,285	6.7

EXHIBIT 8-10 ROUGHLY ESTIMATED U.S. SALES OF PRINCIPAL COSMETIC RAW MATERIALS IN 1971

Millions of Dollars	
Perfume oils	\$170
Fluorocarbon propellants	90
Tallow	40
Coconut oil	30
Alcohol, denatured	25
Surfactants	25
Flavors	15
Glycerine	15
Mineral oil	10
Fatty acids	10
Fatty esters	8
Sorbitol	8
Antiperspirants	7
Bacteriostats	7
Calcium phosphates	7
Dyes	7
Hair polymers—proteins	7
Lanolin and derivatives	5
Caustic soda	4
Pigments	4
Thickeners and gums	4
Sunscreen agents	2
Talc	2
Thioglycolic acid and salts	2
Miscellaneous inorganic chemicals	4
Miscellaneous organic chemicals	7
All other materials	5
Total	\$520

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(ATTACHMENT II)

REPORT TO THE
LEGISLATIVE PLANNING GROUP OF CTFA

76302

February 15, 1974

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SUMMARY AND CONCLUSIONS

A study was conducted to evaluate the scientific research and economic impact of cosmetic safety testing designed to meet the requirements of the Eagleton Bill (S. 863). The testing would by a conservative estimate take thirty years to complete for the more than 25,500 cosmetic products and ingredients now commercially available. Work required by the Bill would include the preparation and micropathological examination of 30,000 to 60,000 histology slides for each product. In arriving at the thirty year estimate, it is assumed that all of the estimated 1,340 qualified experimental and veterinary pathologists now practicing in the U.S. would work on this project half of their time. The estimate makes no provision for testing an estimated 4,000 new formulations each year. Further, this Bill would result in a staggering use of laboratory animals; estimated to be a minimum of 60 million mice, 38 million rats, 6 million rabbits, and 1/2 million dogs. The proposed cosmetic testing would thus almost certainly have a serious adverse impact on other major research activities, such as the cancer and heart programs, new drug and food additive testing, etc., which compete for the same relatively limited number of qualified scientific personnel and facilities.

Cosmetic testing as described in the detailed report would cost in the range of \$160,000/product tested by one route of administration to almost \$400,000/product tested by three routes. For all products now in distribution the cost has been estimated to be at least \$6.5 billion. This contrasts to annual manufacturers' sales to \$4.3 billion. While the cost is not the limiting factor, it would undoubtedly affect consumer prices and restrict the ability of new firms to compete in the field.

A realistic indication of how rapidly such a program might be initiated and expanded can be obtained by examining the growth of the National Cancer Institute Carcinogenesis Program, which over a ten year period has increased from evaluating about thirty to approximately five

hundred compounds per year.

It is obvious that priorities are needed to insure the most appropriate utilization of the nation's research facilities and scientific personnel to permit continuing progress in areas of health care as well as insuring the safety of products intended for human use.

INTRODUCTION

The scope of the study for the Legislative Planning Group of the CTFA was to assess:

- A. The possible impact upon investigations related to problems of public health by the diversion of facilities and trained personnel to the testing of cosmetic and toiletries products required by pending legislation (especially the Eagleton bill).
- B. The ability of available laboratories to carry out and complete the vastly increased number of tests within the time specified in the proposed legislation.
- C. The economic impact of the legislation, if enacted, on the cosmetic and toiletries industry.

Preliminary investigations were initiated in all of the above areas. However, due to time limitations to conduct this study, we concentrated our efforts on one of the primary areas for which information was most readily obtainable. This was the number of qualified experimental and veterinary pathologists available in the United States to evaluate histology slides which would be produced in the course of a biological testing program as indicated in the proposed Eagleton legislation.

The U.S. Department of Commerce reports that industry sales at the manufacturers' level amounted to \$4.24 billion in 1972. Measured at the retail level, industry sales for 1972 are reported as \$5.3 billion. Table I presents the retail sales of cosmetic and toiletries products for the years 1965 to 1972.

An examination of the rate of change of the retail sales reported for the industry over the past few years indicates the rate of growth for the cosmetic segment of the industry to be about 10 percent per annum, and that for toiletries, approximately 7 percent per annum. It should be noted that material shortages now experienced in many other industries will probably adversely affect the rate of growth of the cosmetic and toiletries industry, at least over the next year.

In addition to the above information, we have presented in Table II retail sales reported in terms of various product categories.

TABLE I - RETAIL SALES OF COSMETICS & TOILETRIES
1965-1972

	Retail Sales (\$000,000)		
	<u>Cosmetics</u>	<u>Toiletries</u>	<u>Total</u>
1965	1,062	2,162	3,224
1966	1,169	2,389	3,558
1967	1,243	2,551	3,794
1968	1,359	2,725	4,084
1969	1,457	2,931	4,388
1970	1,573	3,145	4,718
1971	1,695	3,394	5,089
1972	1,815	3,509	5,314

Source: Drug Trade News 1965-1970, Product Management (October, 1973),
and Arthur D. Little, Inc. Estimates

TABLE II - RETAIL SALES THROUGH ALL OUTLETS OF MAJOR CATEGORIES
OF COSMETICS & TOILETRIES 1965, 1970, 1972

Category	1965		1970		1972	
	\$MM	% of Total	\$MM	% of Total	\$MM	% of Total
Hair Preparations	771	24	1,083	23	1,262	24
Makeup Preparations	540	17	803	17	859	16
Oral Hygiene Products	465	14	661	14	763	14
Men's Toiletries	374	12	521	11	566	11
External Personal Deodorants	176	5	430	9	466	9
Fragrances	236	7	380	8	448	8
Toilet Soaps	299	9	333	7	366	7
Face Creams	154	5	217	5	239	4
Hand Preparations	132	4	174	4	198	4
Misc. incl. Suntan Preparations	77	2	116	2	147	3
Total	3,224	100	4,718	100	5,314	100

Sources: Drug Trade News, Product Management, and Arthur D. Little, Inc. Estimates

IV-

ESTIMATE OF THE NUMBER OF COSMETIC
PRODUCTS AND INGREDIENTS

In order to proceed with an estimate of the number of cosmetic products and ingredients produced by the cosmetic and toiletries industry which may be subject to safety testing under the proposed Eagleton bill, we had to establish definitions for the terms "product" and "ingredient." We chose to use literal definitions of these terms since the bill gives no clear guidance on the matter, although it does define "cosmetic" and "commercial distribution." The definitions are as follows:

(1) The term cosmetic is "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleaning, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component [ingredient] of any such articles."¹

(2) The term product is "anything produced by human or mechanical effort or by a natural substance."²

(3) The term ingredient is "something added or required to form a mixture or a compound."²

(4) "The term 'commercial distribution' means any distribution outside the establishment manufacturing the product, whether for sale, to promote future sales (including free samples of the product), or to measure consumer acceptance through market testing."³

To ascertain the number of cosmetic and toiletries products available for sale in retail outlets, the CTFA sent questionnaires to approximately 750 companies which manufactured these articles, asking that they indicate the number of products they have on the market, and the number of new products introduced into the market during the previous year. About 26 percent, or 197, of the companies queried, responded to

this questionnaire. A tabulation of the results reveals that these companies have 24,943 products on the market and that they introduced 3,987 new products during 1972.

To determine the number of ingredients, we counted the materials listed by chemical name in the CTFA Cosmetic Ingredient Dictionary⁴ and obtained a total of 1,521. When we attempted to obtain an estimate of the number of fragrances and commercially available components used for formulating fragrances, we contacted several fragrance industry representatives. They were, however, unable to supply actual numbers and, instead, suggested a method they believed to be reasonable for estimating the number of fragrances sold: by taking somewhere between 5 percent to 15 percent less than the number of individual cosmetic and toiletries product entities, we can obtain an estimate of the number of fragrances. If we assume that 85 percent of the number of products reported by the 197 companies responding to the CTFA questionnaire had different fragrances, the estimated number of fragrances amounts to 21,000, a figure that must be added to the total of 1,521 given above.

When one adds all of the product figures mentioned in the previous paragraphs, one realizes that the testing requirements would apply to more than 47,000 materials. We were, however, exceedingly conservative and eliminated all figures that cannot be immediately substantiated. The only figures we employed in reaching a total were the number of products reported by the 197 companies responding to the CTFA questionnaire and the number of ingredients listed by chemical name in the CTFA Ingredient Dictionary, both of which sources gave us a rounded-down figure of 25,500. It should be noted that in choosing to incorporate the chemical names of the ingredients rather than the trade names, we opted for the figure of 1,521 instead of 4,968. It should be recognized that many of the chemical compounds are made by more than one manufacturer and, although they bear the same generic name, they may, in fact, differ in physical and chemical properties.

In deciding upon which figures to use in reaching our total of 25,500, we did not add the estimated 4,000 new products which the 197 responding companies anticipate introducing next year and in each succeeding year. While some products drop out of the market and others appear, the important fact to emphasize is that each of the new products would have to be tested under the proposed legislation.

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V- DESCRIPTION AND BRIEF DISCUSSION OF TESTS FOR PRODUCT
SAFETY REQUIRED BY THE EAGLETON BILL

The following description of tests required as a minimum by the Eagleton Bill should be considered only as guidelines and not as firm requirements of a particular agency, administration or department. In fact, opinions of many scientists are known to differ somewhat, not only as to the number and type of animals to be employed, by what route, and how long they should be dosed and subsequently observed, but even which is the most appropriate test method. It is generally agreed, however, that testing protocols should be flexible enough to accommodate products with different pharmacological characteristics. Therefore, the test methods briefly described here represent our understanding of those which in the opinion of qualified experts appear to produce the most reliable data under the present state of the art. The number of animals, duration of the tests, costs etc. are often presented as a range to reflect the various methods currently employed in a variety of laboratories. See Table IV.

A. Preclinical

1. Acute oral toxicity^{1,4} - Six groups of 10-20 male and 10-20 female rats or mice are given a single oral dose of the test material at graduated dose levels (generally spaced at 0.1 log dose intervals). This is most often administered by intubation. The animals are observed for gross signs of systemic toxicity, pharmacological effects and mortality frequently on the day of dosing, and at least once daily during the observation period of 2-4 weeks. Autopsies are performed on animals that succumb and on preferably all or at least selected survivors. It is recommended that two species of animals be used to reveal possible species differences in toxicity. The LD₅₀ value and slope of the dose response curve are calculated by one of the approved methods such as the Cornfield-Mantel modification of Karber's⁶ method.

TABLE III
SUMMARY OF SAFETY TESTS CONSIDERED TO BE REQUIRED BY EAGLETON BILL

INFORMATION REQUIRED by EAGLETON BILL	TEST	REPRES- TATIVE SPECIES	SUGGESTED NUMBER OF ANIMALS OR TEST SUBJECTS	APPROXIMATE DURATION	COMMENTS	ESTIMATED COST/POPULATION
EXPOSURE Degree of ingestion Degree of absorption Degree of percutaneous absorption	acute inhalation acute dermal percutaneous absorption	rat	6	72 hr.	Labelled material. This will produce only a very rough estimate of the quantity of the prod- uct which might be absorbed by man.	\$300-600
		rat	6	72 hr.	Radio-labelled material on intact and abraded skin.	\$300-500
ANIMAL STUDIES Short-term	Acute - oral - inhalation - dermal (intact and abraded skin)	mouse rat rabbit	6 groups 10-20 M & 10-20 F (120-240) 6 groups 10-20 M & 10-20 F (120-240) 6 groups 10-20 M & 10-20 F (120-240) 4 groups - 4-6 (16)	2-4 weeks 2-4 weeks 2-4 weeks 2 weeks	Micro-pathology evaluations recommended at all dosage levels. In inhalation studies a limited number of studies may be more appropriate for some test materials. In some cases subcutaneous tests might be desirable.	\$1000-2000 1000-2000 1000-2000 \$500-1000
	Subacute - oral - inhalation - dermal	rat dog rabbit	6 groups 10-20 M & 10-20 F (120-240) 4 groups 2-4 M & 2-4 F (16-32) 6 groups 5-10 M & 5-10 F (30-120) 3-4 groups 6-8 (24-32)	1-3 months 1-3 months 1-3 months 21-30 days	In inhalation studies a limited number of studies may be more appropriate for some test materials. FDA Advisory Committee (1971) recommended including reproduction study, can combine chronic toxicity and carcinogenicity test- ing. Recommend exposure from conception to weaning.	\$10,000-30,000 7,000-15,000 5,000-10,000 \$85,000-150,000
Long-term	Chronic - oral - inhalation - dermal	mouse rat rabbit	4 groups 50 M & 50 F (400) 4 groups 50 M & 50 F (400) 4 groups 50 M & 50 F (400) 3-4 groups	2 years 2 years 2 years 2 years	In inhalation studies a limited number of monkeys may be more appropriate for some test materials. Reproduction study not considered adequate.	85,000-150,000 50,000-85,000 \$85,000-150,000 42,500-75,000
	Carcinogenesis	Randomly bred mouse. rat	10-20 M & 10-20 F (80-160) 4 groups 50 M & 50 F (400) If part of chronic, an addi- tional 25 M & 25 F/group	2 years 2-2 1/2 years 2-2 1/2 years		
	Mutagenesis	- dominant - recessive + host mediated - in vivo cytogenetics	mouse 4 groups 10 M & 30 F/week (750) 4 groups 3-10 (12-80) 20 groups 3-5 (60-100) 4 groups 13-25 M & 25-50 F (132-300)	3 months 1-2 months 48 hours-1 wk 6-9 weeks	Salmonella as the test organism	\$5,000-10,000 1,000-5,000 1,000-2,500 \$15,000-35,000
	Teratogenesis	rat hamster rabbit	4 groups 5-10 M & 10-15 F (60-100) 6-12 (6-12) 6-12 (6-12)	6-9 weeks 72 hr - 2 wks. 1-3 wks.		\$300-600 300-600 300-600 1000-2000 \$200-500 300-500
Irritant	Skin Eye Other mucous membranes	rabbit or dog	6-12 (6-12)	48-72 hr.		
Sensitizing	skin Photensensitizing	guinea pig rabbit	6-12 (6-12) 9-12 (9-12)	6 weeks 2-3 weeks	Not possible to determine a "no-effect" level according to Dr. Lee Fraum (FDA) at a WHO session (1973). View held by most experts.	
SAFETY FACTOR						
HUMAN EXPERIENCE Contact Sensitivity Photosensitivity	patch or use test.	humans	100 M & 100 F (200)	~ 6 weeks		\$10,000-25,000

2. Acute inhalation toxicity⁴ - Six groups of 10-20 male and 10-20 female rats are placed in inhalation chambers and exposed under controlled conditions for one hour to graduated atmospheric concentrations of the test material in gaseous or aerosol form. The rats are observed during the exposure period and daily for 2-4 weeks for gross signs of systemic toxicity. Autopsies are performed on animals which die and on all or selected survivors. Both static and dynamic exposures have been used.

A limited number of rabbits or monkeys may be more appropriate for some test materials.

3. Acute dermal toxicity^{1,4} - Four groups of 4-6 rabbits are prepared by clipping the hair from the trunk. Half of the animals are further prepared by making epidermal abrasions every two or three centimeters longitudinally and sufficiently deep to penetrate the stratum corneum but not deep enough to produce bleeding. A rubber or plastic sleeve is placed on each animal and the test material is introduced under the sleeve at graduated dose levels. After 24 hours the sleeves are removed, the volume of unabsorbed material is measured, the skin reactions are noted and the animal is cleaned and placed in metabolism cages for a two-week observation period. The animals are checked for gross signs of toxicity and blood and urine are examined for abnormalities. Autopsies are performed on animals that die and on all or selected survivors.

4. Subacute oral toxicity¹ - It is recommended that at least two species of animals be employed in this test to indicate if there are species differences in toxicity. Six groups of 10-20 male and 10-20 female rats and four groups of 2-4 male and 2-4 female dogs are given daily oral doses of the material at graduated dose levels for 1-3 months. The animals are observed for general condition, food and water consumption and gross signs of toxicity. At regular intervals blood chemistry, hematology and urinalysis tests are carried out. All animals are autopsied at death or at sacrifice at the completion of the study and examined for organ weights and gross and microscopic pathology.

5. Subacute inhalation toxicity¹ - Six groups of 5-10 male and 5-10 female rats are exposed daily for 1-7 hours to graduated atmospheric concentrations of the test material vapor or mist, or for two continuous spray exposures (preferably several hours apart) to an aerosol preparation for graduated periods of time (e.g. 30 seconds). Observations are made on symptomatology, food and water intake, body weight and of the blood for morphological changes. At the conclusion of the study all animals are sacrificed and autopsied. Histopathological examination is carried out on all major organs. Additional data on the lung and chest effects may be obtained by comparing radiographs taken prior to and immediately following a series of exposures.

Other species including rabbits, dogs and monkeys are also utilized in lieu of the rat. Both dynamic and static exposures have been employed.

6. Subacute dermal toxicity^{1,4} - Four groups of 6-8 rabbits are dosed daily for 90 days by application to clipped intact and/or abraded skin at graduated dose levels. In some cases it may be adequate to use three groups of six rabbits dosed daily for 21 days on clipped intact and abraded skin. In both cases the animals are observed throughout the study for symptomatology, food and water consumption and body weight. Blood and urine are examined periodically. All animals are autopsied at the conclusion of the experiment. Histopathological evaluations are generally restricted to the area of application and major organs.

7. Chronic oral toxicity^{1,3} - At least four groups of about 50 male and 50 female rats or mice are administered daily oral doses of the test material. This is most often introduced into the diet. If carcinogenicity testing is to be combined in the same study, the number of animals in each group should be at least 50 males and 50 females. Several animals of each sex at each dose level may be sacrificed at intervals, e.g. 6, 12 and 18 months, for examination. Throughout the study the animals are observed for gross signs of toxicity, food and

water consumption, body weight and the appearance of tumors. At regular intervals blood and urine samples are examined. At the conclusion of the study all animals are sacrificed and autopsied. The principal organs are weighed and preserved for histopathological examination. The FDA Advisory Committee² in 1971 recommended that chronic toxicity testing should involve exposure from conception until death, and that chronic studies should include reproduction tests.

8. Chronic inhalation toxicity - may be desirable for products whose use involves exposure primarily by inhalation. The procedure is the same as in the 90-day subacute study, except that exposure should continue for 2 years. The number of animals to be examined is similar to the chronic oral study.

If monkeys are the appropriate species 4-8 ♂ and 4-8 ♀/dosage level are utilized.

9. Chronic dermal toxicity - may be necessary for preparations which are usually applied to the skin daily for long periods of time. The procedure is similar to the subacute dermal toxicity test but with greater numbers of animals.

10. Carcinogenesis^{3,5} - As noted above "lifetime" carcinogenesis studies in rodents may be combined with chronic toxicity testing to eliminate some duplication of effort. At the present time the only recommended methods for carcinogenesis testing are "lifetime" studies. More rapid screening methods utilizing other species, microbiological techniques, etc. are being investigated for reliability. One of the more promising of these involves injecting the test material into a pregnant hamster and removing the exposed embryos 48 to 72 hours later. The embryonic cells are grown in tissue culture. Cancerous transformation is detected by standard microscopic study of colony morphology. Neoplastic transformation is confirmed by injecting the transformed cells into healthy

x-irradiated weanling hamsters to see if they produce tumors. Changes in colony morphology can often be seen within two weeks. In the trials to date three to 16 weeks were required for tumors to develop in the healthy animals, although the animals were observed for one year. If this method is confirmed as being reliable it would result in considerable savings of both cost and time in carcinogenesis testing.

11. Mutagenicity² - There is no one recommended method for detecting mutagenic effects due to a chemical. Methods with a high degree of presumptive human relevance include in vivo cytogenetics, the host-mediated assay, and the dominant lethal assay.

In the dominant lethal assay three groups of 10 males (mice or rats) are treated by an appropriate route and are mated during sequential weekly periods with groups of untreated virgin females (3 per male) for a total of 8 weeks. The females are sacrificed in mid-pregnancy (Day 12 or 13 for mice) and scored for total implants comprising early and late fetal deaths and living fetuses.

In the host mediated assay an indicator organism (Salmonella) is injected into the peritoneal cavity of a mammal. About four groups of 3-10 host animals (mice or rats) are then treated with the test compound by an appropriate route other than intraperitoneal. Several hours later the hosts are killed and the indicator organism is recovered and scored for mutants.

In the in vivo cytogenetics assay the test compound is administered to four groups of 4 animals (mice or rats) by an appropriate route. Bone marrow and/or lymphocyte samples are taken at intervals by biopsy or at sacrifice of the animals and the chromosomes are examined.

12. Teratogenesis² - It is recommended that studies of

teratogenesis be carried out in at least two species. The mouse, rat, hamster and rabbit are suitable species. Four groups of at least 25 female rats or 15 female rabbits are treated with the test material by an appropriate route for at least 14 days prior to mating and during pregnancy. The day sperm are detected in a vaginal smear is considered Day 0. All dams are observed daily for changes in appearance or behavior. Autopsies are performed on all animals that die. Surviving animals are sacrificed at Day 20 or 21 for mice and rats, respectively and Day 30 for rabbits and the fetuses and reproductive organs are examined. The number of dead and resorbed and living fetuses are recorded. The fetuses are examined for external, visceral and skeletal malformations.

13. Skin irritation^{1,4} - Primary irritation of the skin is measured by a patch-test technique on the abraded and intact skin of a minimum of six albino rabbits per preparation tested. Equal numbers of exposures are made on abraded and intact skin. The abrasions should cut through the stratum corneum, but not into the derma. These animals often are observed for 2 weeks to monitor lesions and their return to normal condition. The test substance is introduced under a one-inch patch and the animals is immobilized and wrapped in rubberized cloth or plastic for 24 hours. The skin is examined at the end of the 24-hour period and again at 72 hours.

14. Eye irritation^{1,4} - The test material is instilled into one eye of 6-12 albino rabbits. The other eye serves as the control. In one-third of the animals the treated eye is left unwashed. In the remaining animals the eye is washed two seconds or four seconds following treatment. The eye is examined at 24, 48 and 72 hours and at 4 and 7 days after treatment or as long as injury persists.

15. Irritation of other mucous membranes¹ - For some preparations it may be necessary to determine irritation to vaginal or penile mucosa. For the former the dog is the species of choice - although the rabbit is the preferred species for other tests on mucous membranes.

The preparation is applied as directed and in excessive amounts to 6-12 animals. Reactions are read at 1, 2, 24, 48 and 72 hours after application.

16. Skin sensitization^{1,4} - The hair on the back and flanks of 6-12 male guinea pigs is removed by close clipping. The material being tested is injected intracutaneously every other day or three times weekly until a total of ten injections have been given. The injections are made at random over the back and upper flanks. Two weeks after the tenth injection a retest injection is made just below the region of the previous injections. After 24 hours readings are made of the diameter, height and color of reaction are compared with the reactions after the initial injections.

17. Photosensitization¹ - Nine-twelve albino rabbits are exposed to UV irradiation to determine the amount which constitutes a suberythematous dose. Six of the rabbits are then treated with the test substance. All of the rabbits are exposed once daily until a total of 10 exposures (2 weeks) has been made. The degree of photosensitization is determined by comparison of the local effects in the treated and untreated subjects. More recently guinea pigs have replaced rabbits as the subject of choice.

B. Clinical

1. Skin sensitization¹ - Human tests should employ at least 200 individuals (100 male and 100 female) covering a range of ages appropriate for the product. The test material is applied by patch to an area on the arms or back. The patch is removed after 24 hours and a reading of the reaction is made. The area of erythema and edema is measured. The subjects are given a day's rest and then given a second patch application. This procedure is repeated until a series of ten consecutive exposures has been completed. The subjects are then given 10 to 14 day's rest after which a challenge dose is applied once. A comparison is made of reactions observed during the ten sensitizing

doses with the reaction following the challenge dose.

Other procedures have also been reported in the scientific literature.

In some cases a "use" test where the product is distributed to a large test panel for use according to directions is conducted. However, the method lacks supervision and is generally considered less satisfactory.

2. Photosensitization - Photosensitizing potential of a material is tested by determining the reaction to UV irradiation following treatment with the material. A large population of appropriate subjects is necessary for adequate testing and the test should only be made if animal testing has failed to provide evidence of photosensitization.

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DISCUSSION OF PERSONNEL REQUIREMENTS
FOR PRODUCT SAFETY TESTING

In safety testing of foods, drugs and cosmetics the scientific and professional staff most likely to be involved are toxicologists, pharmacologists and pathologists. To estimate the present number of scientists with these specialties, the 1972-1973 membership lists of the Society of Toxicology, The American Society of Pharmacology and Experimental Therapeutics, The American Society for Experimental Pathology and The American College of Veterinary Pathologists were examined. There is some overlap in memberships of these societies so an attempt was made to ensure that individuals with dual or multiple memberships would not be counted more than once. From these membership rosters it was determined that the numbers of active U.S. members employed in academia, industry or government are 344 toxicologists, 1595 pharmacologists, 1078 experimental pathologists and 262 veterinary pathologists. Among these, 10 toxicologists, 155 pharmacologists and 247 pathologists are associated with hospital and medical centers and may be engaged full time in clinical activities. These figures may also give some indication of the relative numbers of personnel available to do clinical studies as compared to preclinical studies.

It is reasonable to assume that among these specialists needed for safety testing the most limiting would be the number of pathologists, since pathologists would be required to interpret the microscope slides produced in the course of testing. No other scientist could properly perform this task. The lack of an adequate number of qualified pathologists was underlined only last month by the designation of the training of experimental pathologists as a critical area among the National Cancer Plan Project Areas. It was estimated above that there are 1078 experimental pathologists and 262 veterinary pathologists active in the United States. It was assumed that members of the American College of Pathologists would be either engaged full time in patient-oriented work and

hospital-related research, or, if interested in outside research, would be listed among the members of the American Society for Experimental Pathology. Therefore, it was assumed that there are now about 1340 qualified experimental and veterinary pathologists available in this country who could participate in safety testing. It was further assumed that those pathologists who might be interested in participating in the safety evaluation of cosmetics would be able to spend not more than half of their time on this work because of current commitments in other areas. We recognized that the amount of time required by the pathologist to evaluate each slide could vary tremendously depending on the nature of the lesions involved. However, if one assumes that the average number of slides that might be evaluated per day by a pathologist is 200, each containing one or more sections of a given organ, the number of slides resulting from cosmetic safety evaluations which each pathologist might be able to process would be 100 per day or 500 per week. Using these figures the total work load capabilities of the pathologists presently available would be 670,000 slides per week.

The Eagleton bill requires that each product and each ingredient of cosmetics, fragrances and toiletries be tested for safety. As noted in a previous section of this report, the total number of currently existing products and ingredients has not yet been determined. However, the number of products and ingredients is now definitely known to exceed 25,500. The tests required for each cosmetic product would, of course, vary with the nature of the product and its proposed use. Since the number of each type of cosmetic (face powder, lipstick, perfume, after-shave lotion, deodorant, etc.) contributing to the total number of products is not known at this time, for the purpose of estimating the work load involved, we have assumed that one third of the products would require testing by only one route of administration e.g. oral; one third would require testing by two routes e.g. oral and dermal; and one third would require testing by three routes e.g. oral, dermal and inhalation. Concerning the ingredients, it may be adequate to test by one route of administration only.

Using these estimates, 9500 products and ingredients would be tested by one route, 8000 by two routes and 8000 by three routes.

For the relatively complete testing by each route of administration as outlined in Table III a minimum number of animals (mice, rats, rabbits, dogs etc.), used in acute, subacute, chronic, carcinogenesis and irritation of mucous membrane studies on which micropathology would be required would be 1576 for test materials administered by the oral route only, 1712 for materials tested by oral and dermal routes and 3102 for materials tested orally, dermally and by inhalation. The number of slides for each animal varies depending on the species and on the test performed but might conservatively average about 20 slides per animal. Therefore, there would be 31,520 slides produced for each product tested by one route, 34,240 for each product tested by two routes and 62,040 for each product tested by three routes. These figures do not include the slides produced in testing for mutagenicity since these slides often are evaluated by microbiologists and cytogeneticists and might not necessitate a pathologist.

Using the number of products and ingredients estimated above, the total number of slides produced would be 299,440,000 for materials tested by one route, 273,920,000 for materials tested by two routes and 496,320,000 for the materials tested by three routes. The number slides produced in testing all of the cosmetic products and ingredients currently on the market, therefore, might be 1,069,680,000, all of which must be interpreted by a qualified pathologist. Since the estimated additional work load which the available pathologists might be able to assume is 670,000 slides per week, it would take approximately 1597 weeks or about 30 years to evaluate the slides generated in this program.

The severe research impact of the requirements of the Eagleton bill can be readily illustrated if one assumes, as we have, the utilization of all of the estimated 1,340 qualified experimental and veterinary pathologists on a half-time basis. With this restriction one might evaluate about 2,000 products in the required two and one-half year period. (John A. Wenninger in the Food Drug and Cosmetic Law Journal, April 1972, pg, 213,

reports . . . "one of the larger cosmetic manufacturers . . . produces over 2,000 separate cosmetic products, exclusive of shade variations, and introduces about 50 new products each year.") It appears obvious that the effect of testing the 2,000 products, which is less than 10% of those currently on the market, would have a strong and adverse impact on such major research programs as the testing of new drugs, food additives, agricultural and industrial chemicals and chemotherapeutic agents which must compete for the same facilities and personnel.

NUMBER OF MEMBERS OF THE SOCIETY OF TOXICOLOGY

<u>Member's Designation of Principal Activity</u>	<u>No.</u>
Academic (A)	179
Government (G)	103
Industry (I)	202
Consultant (C)	31
Retired (R)	13
Other (O)	13
Not indicated *	74
AG or AGC	10
AC or ACR	13
CR or CO	2
AIC, IC, ICO, ICR, AGIC, AI, IO, GIO	18
	<u>658</u>
Total number of members	658
Foreign members	75
Retired or semi-retired	17
No. of active U. S. members	<u>566</u>
No. of members who are also members of one or more of the Societies of Pharmacology and Experimental Therapeutics and Experi- mental Pathology or the American College of Veterinary Pathologists.	<u>232</u>
No. of Toxicologists not included in other societies	<u>334</u>

* (Apparently a similar distribution of activities as those indicating).

AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS

Total Number of Members	1856
Honorary Members	3
Retired Members	115
Foreign Members	95
Members also members of Society for Exptl. Pathology	<u>6</u>
Number of Active U. S. Members	1637
Members in Private Practice	<u>42</u>
Members in Academia, industry or government	1595

Of these active members 155 are associated with hospitals and medical centers or drug abuse centers. Many of these may be involved full time in clinical practice.

AMERICAN SOCIETY FOR EXPERIMENTAL PATHOLOGY

Total Number of Members	1250
Honorary Members	17
Retired Members	60
Foreign Members	<u>64</u>
Number of Active U. S. Members	1109
Members in Private Practice	<u>31</u>
Members in Academia, industry or government	1078

Of these active members 247 are associated with hospital and medical centers. Many of these may be involved full time in clinical practice.

AMERICAN COLLEGE OF VETERINARY PATHOLOGISTS

Total Number of Members	315
Foreign Members	28
Number who are members of the Society for Experimental Pathology	<u>25</u>
Members not included in other societies	262

VI-B

PRELIMINARY ESTIMATES OF FACILITIES AVAILABLE
FOR CONDUCTING PRODUCT SAFETY TESTING

The Animal Welfare Act of 1966 (Public Law 89-544) as amended by the Animal Welfare Act of 1970 (Public Law 91-579) (7 U.S.C. 2131 *et seq.*) requires the registration of all laboratory facilities including those in academia, hospitals, industry, research institutes, etc., that utilize animals for research purposes including product safety testing.

A current listing of the registered research facilities in the United States appeared in the Federal Register, Vol. 37, No. 147, July 29, 1972. This listing, along with a more recent listing of additions to the published list obtained from the U.S.D.A., shows a total of 775 registered research facilities in the United States including Puerto Rico.

A review of the listing was made to establish the types of facilities in order to further determine the potential number of laboratories that could be considered available to conduct the tests described in Sec. V of this report and contained in the proposed legislation (Eagleton Bill).

The table below summarizes the results of a review of the registered research facilities listing.

<u>Type of Facility</u>	<u>Total Number</u>
Universities and Hospitals	510
Industrial (Captive)	125
Independent	104
Government (Federal, State, County)	14
Other (Zoos, Museums, Associations, etc.)	<u>22</u>
Total	775

A review of the 1972 American Council of Independent Laboratories, Directory of Toxicology Laboratories indicates a total of 23 independent toxicology laboratories. A cross check of this directory with the U.S.D.A. registered research facilities listing further indicates that only 7 of the 23 are registered research facilities.

It is highly unlikely that even all of the 104 independent registered research facilities out of the total of 775 listed would be available to perform the preclinical (animal) studies required in the proposed legislation.

It is readily apparent from the information presented above that additional bioscientific personnel and facilities will be required to evaluate the more than 25,500 cosmetic products and ingredients as required by the proposed Eagleton bill. A realistic indication of how rapidly such a program might be initiated and expanded can be obtained by examining the growth of the NCI Carcinogenesis Program. Under this program the work is carried out by outside contractors in addition to the NCI Frederick Cancer Research Center¹ which was instituted about 2 1/2 years ago. This large-scale bioassay program is designed to determine the carcinogenicity and chronic toxicity in rats and mice of chemicals including insecticides, herbicides, commercial products and industrial compounds selected by the NCI. The test protocol states that fifty males and fifty females of each species are given each compound at the maximum tolerated dose (MTD) and 1/2 MTD. Twenty control animals of each sex are used for each compound. After necropsy 32 tissues from each animal will be examined histologically. In summary, the NCI protocol utilizing only 2 dose levels is specifically designed to detect carcinogens. It is less rigorous than is necessary to not only evaluate carcinogenicity but also determine a non-toxic level as would be required for a cosmetic product.

We understand that in 1961-62 the initial Field Studies, as they were designated at that time, were conducted by about 4 contractors and were concerned with the effects of about 30 compounds. We also understand that about 500 compounds will be under study during 1974. Approximately 30 of these compounds will be investigated at the NCI Frederick Cancer Research Center, the remainder by contractors. Using this example two factors appear clear: 1) If one attempts to gather appropriate personnel and facilities, building an entirely new organization such as the Frederick Center to conduct toxicity studies, more

¹ Carcinogenesis Program - Second Annual Collaborative Conference, November 25-29, 1973 El Tropicano Motel, San Antonio, Texas.

than 2 years would be required for its assembly and the anticipated initial capacity might be about 30 compounds/year; 2) Growth within the NCI Carcinogenesis Program, in terms of the number of compounds/year which have been studied from 1962-1973, has been in the order of 30 expanding to about 500 or an increase of about 50 compounds/year. Comparing these figures with the more than 25,500 cosmetic products and ingredients to be evaluated shows the staggering nature of the task outlined in the Eagleton bill.

Senator EAGLETON. Thank you, gentlemen, very much.

We will now hear from Mr. Allen Lightman, the president of the Independent Cosmetics Manufacturers and Distributors, Inc.

Mr. Lightman is executive vice president-director of sales for Irma Shorell, Inc.; and we are anxious to hear from Mr. Lightman, because he will present us with the concerns of the small and medium-sized cosmetic firms which, just as the large ones, will be covered by this bill.

STATEMENT OF H. ALLEN LIGHTMAN, PRESIDENT, INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., AND EXECUTIVE VICE PRESIDENT—DIRECTOR OF SALES, IRMA SHORELL, INC.; ACCOMPANIED BY WALTER E. BYERLEY, ESQ., REPRESENTING I.C.M.A.D. INC.; IRMA SHORELL, PRESIDENT, IRMA SHORELL, INC.; AND MARILYN MIGLIN AND LEE MIGLIN, MARILYN MODEL MAKEUP

Mr. LIGHTMAN. Yes, Senator.

First, may I thank you for the opportunity you have given our organization to testify. I am speaking not as an individual, but on behalf of 121 members that we have.

May I ask, one, that our counsel, Mr. Byerley, join me at the table to expedite matters, and the other is for moral and morale support, may I have the two ladies that we have in our organization? Because women have been sort of completely missing from this table today.

Senator EAGLETON. Please.

Mr. LIGHTMAN. This is Miss Shorell, president of her company and Miss Miglin, who is president of her own company.

Senator EAGLETON. Please give your names for the record.

Ms. SHORELL. It is Irma Shorell.

Senator EAGLETON. You are President of Irma Shorell, Inc.?

Ms. SHORELL. Yes.

Senator EAGLETON. And, ma'am, could you give us your name and name of your company?

Ms. MIGLIN. My name is Marilyn Miglin. The name of my firm is Marilyn Miglin Model Makeup. I own seven salons in the Chicagoland area.

Senator EAGLETON. Just for the record, unless you do not want to divulge it, Ms. Shorell, what are the gross sales of your company?

If you do not want to give it, you do not have to.

Ms. SHORELL. I am very pleased to.

I think there are \$3 million retail. It would be about \$1½ million wholesale.

Senator EAGLETON. And, ma'am?

Ms. MIGLIN. I am a little fellow and I am under \$1 million.

Senator EAGLETON. Under \$1 million. All right.

For the record, Mr. Lauder, could you give us the gross sales of your company in 1974? Is that a trade secret?

Mr. LAUDER. Well, it is a trade secret. I am sorry.

Senator EAGLETON. That is all right.

What I am trying to do for the record—because I think it is important to have a complete record—is to show that we are considering not only the problems of Chesebrough and Avon and what have you,

but I want to establish in the record that we are now hearing from people that do not have the sales of some of those others, but are just as much affected by the scope of the law as the big companies.

Mr. LIGHTMAN. Senator, also, if I may preface my remarks by saying, since we have learned that medical doctors differ, as we have this morning, and I understand that on occasion people in the political arena differ in opinion. We also differ in opinions in the cosmetic industry and we do not feel that the CTFA represents the small manufacturer's viewpoint.

Although we have the smallest in volume figures—because they state, I understand, they control 90 percent or more of the business—we are the forgotten minority, but we are the largest group in the field and we are the ones that are going to be most affected; because we have to contend with the daily problems.

In the case of Ms. Miglin, she deals with the consumer herself directly.

In the case of Ms. Shorell, she does also.

I think it would be helpful when I finish my remarks if there are any questions I cannot answer that they be allowed to answer for me.

The purpose of our organization, is that it is a national trade organization, composed of independent firms in the cosmetic, skin care, allied, and supporting industries. It is a new baby. It was organized on April 29, 1974, to present the viewpoints and serve as a vehicle of expression for the small- and medium-sized firms which had been hitherto ignored and unrepresented. The activities of the organization consist of informing its members on all phases of these industries, including new merchandising techniques, new products, new packaging and sales promotion material. It supplies speakers on all phases of industry as well as serves as a vehicle to inform all branches of government—city, State, and Federal—concerning the problems of the independents in the various fields, as regards standards and practices and to make available experts to counsel these bodies on the intricacies of the field—thereby, we feel, benefiting the consumer.

It is hoped to thus promote better and safer products in these industries and to insure participation by both women and men in the various activities designed to improve the standing of the cosmetic industry in the business community. To make every effort to benefit the consumer with safer, purer, and more innovative cosmetics, fragrance, and skin-care products.

The present membership consists of 111 firms who are involved in the processing, manufacturing, or distributing of almost every type of cosmetic product.

Now, we actively support the purpose of progressive legislation such as Senator Eagleton's bill, S. 1681, to amend the Federal Food, Drug, and Cosmetic Act, with respect to cosmetic safety; but we would be failing to exercise our responsibility both as small- and medium-sized cosmetic business people and consumers if we did not point out that certain safeguards should be instituted so that it may carry out its avowed purpose without being inflationary, misleading, or deceptive.

We, the small- and medium-sized businesses of the cosmetic field, even more than the regulatory agency—the Food and Drug Administration—desire that the cosmetic products offered for sale in the free, competitive marketplace are adequately—and I have underscored “adequately”—tested for safety before they find their way to the shelves of the department, drug, makeup, specialty, variety, and other commercial establishments as well as through the mails.

It is the principal reason for our organization's existence.

We, the I.C.M.A.D. (Independent Cosmetic Manufacturers and Distributors), desire that all our and other cosmetic products are meaningfully prepared for the good of the user and because no responsible manufacturer and/or distributor wishes to sell a bad product which would reflect upon their future business, not to mention the repercussions from a product liability standpoint.

We, therefore, suggest and ask that the safety substantiation standards should be based upon usual conditions of use or according to the instructions contained in the labeling and packaging. It is, however, vital that the safety substantiation provisions as well as other provisions of the Eagleton Cosmetic Safety Amendment of 1975, S. 1681, should not become in reality the establishment of a premarket clearance entity which, according to our understanding and the assurances we have heard, it is not meant to be.

For if the bill, S. 1681, should not be clearly enumerated and is used to set up a premarket clearance agency by overzealous bureaucrats it would be the death knell for many of the smaller companies of the cosmetic industry and create a monopolistic group of giant companies to the detriment of the consumer. It would curtail and possibly eliminate freedom of choice for the consumer. It has already happened in too many other industries.

I would now, with the Senator's permission, like to go into detail on each of the vital topics of the Eagleton amendment, S. 1681, and their effect upon the consumer and the small businessperson:

1. COSMETIC SAFETY SUBSTANTIATION

This portion of the Eagleton cosmetic safety amendment we must take exception to because it is really not cosmetic safety substantiation but premarket licensing in disguise. It places in the hands of one man the life and death decisions of what can and cannot be sold in the marketplace without regard to the stifling of initiative and the catastrophic effect upon manufacturer and employee—both of whom are consumers.

Senator EAGLETON. May I ask you what if we were to more tightly confine these areas or this area along the lines of substantial risk of injury? Would that in any way satisfy it?

Mr. LIGHTMAN. Yes, sir.

I have gone into this as I go along.

I am not a lawyer, unfortunately, so I do not understand legal terminology. I am a person that works day in and day out to support his family, as many of the other people do in the business field. I have taken the commonsense approach.

Senator EAGLETON. Let the record show lawyers also support their families.

Mr. LIGHTMAN. Putting in a word you have used a few moments ago, we have taken the commonsense approach to what we think and are suggesting to the committee.

Today with the unemployment situation amongst minority groups constantly rising, can we really have a law that has potentiality of destroying—yet can be made to benefit with certain modifications and obtain the desired effect—an even safer record for cosmetic products which presently has one of the safest of all our industries?

We concur that it is necessary that the Food and Drug Administration, while it should be given adequate recommendation-making authority, should only be able to promulgate regulations, order new tests for a product, be given the authority to ban a product, compel the screening of a product prior to the marketing of the product only when it finds and is able to establish on the record "the action is absolutely necessary to reduce or eliminate a substantial risk of illness or injury to the public."

A great many cosmetics made by or for small cosmetic firms have had a long history of safe use. In many instances, formulations have been handed down as treasured family recipes from one generation to another. I think Mr. Lauder has hit that point definitely. To subject such products to lengthy, elaborate, and expensive needless tests would not just change the nature of the cosmetic industry; it would virtually wipe it out.

A few large, well-financed companies—usually controlled by a conglomerate—would flourish and the loser would certainly be the consumer, since invariably higher prices would be encountered.

Few new innovative products would come into being; few new businesses started that would employ women and minority groups. The initiative to create would be reduced to a trickle.

There are presently available many products that would give the public safe products without the cost of excessive testing. Esoteric and unnecessary testing requiring the expenditure of tens of thousands of dollars will not yield the public a safer product but a costlier one . . . something that is not needed during this inflationary period.

There are simplified procedures that we recommend be adopted and included in this bill that will assure as safe a cosmetic product as possible.

We recommend therefore that standards be established by the Food and Drug Administration of the predistribution testing of cosmetics presently employed by most reputable companies—large and small:

One: Assaying of all ingredients used by the supplier or manufacturer of the chemicals.

Two: Microbiological test of finished product by manufacturer and/or distributor.

Three: Primary skin irritation study.

Four: The Draize eye irritation test for primary irritants and sensitizers [where they are applicable].

Five: Guinea pig sensitization study [where applicable];

Six: Acute inhalation toxicity study [where applicable].

[Short recess.]

Senator EAGLETON. The subcommittee will please come to order. We will take up with Mr. Lightman where we left off.

Mr. LIGHTMAN. Senator, continuing on, we submit that our proposal will resolve these problems and, if adopted, will assure a fairly high degree of safety and avoid the waste of thousands of dollars and valuable resources.

I would like to close this section with a statement by one of the leading authorities in the field:

We recognize that safety testing will have a significant economic impact on the cosmetic industry, but we cannot escape the fact that unless the testing is sufficiently adequate to assure a fairly high degree of safety, it serves no useful purpose either to the consumer or to the industry.

We also recognize that multiple testing of the same or similar products by various firms is a duplicative and nonprofitable undertaking as well as a waste of scarce scientific resources.

That statement, Mr. Chairman, was dated August 2, 1974. [Made by Dr. Alexander Schmidt.]

2. INGREDIENT LABELING

With respect to ingredient labeling, we must first stress that the possibility of "value comparison" as it relates to cosmetics today is a myth insofar as the consumer is concerned.

We are convinced that the "average consumer" and, for that matter, the "above-average consumer" cannot make any reasonable judgment whatever as to comparative value by simply reading a list of cosmetic ingredients on a label. The consumer has no base of knowledge upon which to judge value as between products because the names of the chemicals used are largely unfamiliar and, unlike food ingredients, cannot usually be understood as representing "value."

We have objection to ingredient labeling per se; but if it must be done, it should be done alphabetically.

Senator EAGLETON. The Food and Drug Administration has promulgated a rule that it should be done.

Mr. LIGHTMAN. We are in opposition to it and we hope, Senator, through your efforts we can correct that.

Senator EAGLETON. There is going to be an ingredient labeling bill either by law or by regulation. How do you prefer it, the descending order of dominance or alphabetically?

Mr. LIGHTMAN. We have an alternative suggestion.

Senator EAGLETON. Let us have it.

Mr. LIGHTMAN. We would like a four-part system because there is no standardized grading system of ingredients such as has been set up in foods so as to prevent deception.

The cost of an ingredient used in a cosmetic can run 28 cents per lb. to possibly \$10 or more per pound yet have the same name. We think that if a proper grading system is set up that the entire question of ingredient labeling can be resolved.

We recommend therefore that a list be set up and what I have done in my testimony and I think I can avoid it is put down the same formulation in two ways to show that it is an absolute myth, and I would challenge anyone in this room to tell me which one is more costly.

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

INGREDIENT LABELING AS A BASIS FOR VALUE COMPARISON

HAND LOTION "A" CONTAINS

Distilled water
Polyethylene glycol 1500
Diethylene glycol monethyl ether
Quince seed mucilage
Propylene glycol
Stearic acid
Perfume
Triethanolamine
Potassium hydroxide

HAND LOTION "B" CONTAINS

Distilled water
Alcohol
Waxes (e.g. spermaceti)
Vegetable oil
Colloidal magnesium aluminum silicate gel
Sodium carboxymethyl cellulose
Borax
Perfume oil
Methyl parahydroxybenzoate

Based on the ingredients in each hand lotion above, can you tell which is a better hand lotion—and therefore worth more?

Please check answer:

Yes:

No:

I don't know:

Senator EAGLETON. Let us get away from the cost. You heard the testimony of the doctors. They said it would be helpful to them in administering to the medical needs of their patients.

Do you dispute that?

Mr. LIGHTMAN. Not if done correctly.

Senator EAGLETON. Maybe we ought to leave it in the hands of the doctors and let them tell us how to do it. We want it for health and safety purposes.

Mr. LIGHTMAN. We would suggest—and in speaking with the doctors—we do suggest a far more practical way of helping alleviate this problem of listing of all contained ingredients is that three or possibly four categories be set up.

One: We should have a G.R.A.S.—generally regarded as safe.

Two: KA—known allergens, the use of which above a certain percentage must be listed on the package.

Three: BAN—those ingredients that are banned for use in all cosmetics.

A fourth category might be established for new or untested ingredients—all this subject to FDA standardization in consultation with both large and small industry and consumer representatives.

Senator EAGLETON. The doctor said the percentage does not make any difference.

Mr. LIGHTMAN. Then list them anyway if they use them, regardless of percentage.

Senator EAGLETON. They would not be on the label because they would not be in there.

Mr. LIGHTMAN. Let us put it this way. We feel they should be on there anyway. [Known allergens.]

We think if the grading system is set up it would be far more effective. We feel that in this manner the consumer can best be served who has so-called allergic problems; and that this would at the same time assure her of finer products that would be available in the free, competitive marketplace.

It would also help keep prices down because it is far more effective and far easier for a small company to add a package insert than to possibly have to destroy bottles they have ordered that they may be using for 4 or 5 years for which they have to pay higher prices than the larger manufacturers.

I have jumped the gun quite a bit but I would like to go back to my statement at page 10.

We therefore feel that in this manner the consumer can best be served who has so-called allergic problems and at the same time assure her of finer products that will certainly be available in a free, competitive marketplace. It will also help to keep the prices down in the inflationary spiral we are all living in; for if the system set forth is followed, it will mean a material increase in price for nothing.

If, however, after consideration, the committee and Senator Eagleton decide not to accept our practical suggestion, we respectfully request that any listing of ingredients be done alphabetically so as to enable the consumer at a glance to find something she may be looking for—and at the same time not violate the trade secrets of the various companies by revealing their formulations to the world. These are the most precious assets of many of our members and must be protected. I feel certain the committee will agree.

To illustrate my point, I have listed a formulation both ways for the committee's consideration. Suppose you were allergic to cetyl alcohol. Which ingredient list makes it easier for you to locate?

List 1: B.H.A., beeswax, candelilla wax, castor oil, ceresin, cetyl alcohol, iron oxides, lanolin alcohol, lanolin oil, mineral oil, octyl dodecanol, oleyl alcohol, perfume, petrolatum, propyl paraben, syn. cocoa butter.

List 2: candelilla wax, oleyl alcohol, castor oil, lanolin alcohol, lanolin oil, syn. cocoa butter, mineral oil, octyl dodecanol, cetyl alcohol, petrolatum, ceresin, beeswax, perfume, propyl paraben, B.H.A., iron oxides.

We commend Senator Eagleton for his foresight in allowing the manufacturers to place the necessary information—when finally determined—on a folder which can be contained in a package, for this will save millions of dollars for the consumer over the years who would have ultimately had to pay for all of the new packaging, new boxes, bottles, et cetera, that would have been required, not to mention the difficulties that would have had to be resolved every time a single ingredient might have to be changed because of shortages, unavailability, or product improvement.

3. TRADE SECRETS

There must be protection for the small manufacturer whose greatest assets are their formulas. Thus, the provisions of the final bill should provide that all formulas filed with the FDA or any other governmental agency would be afforded and guaranteed trade-secret protection.

The Freedom of Information Act defines a trade secret as:

Any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.

This is an absolute must for the smaller companies, for the demise of the smaller companies will mean the unemployment of thousands of our older citizens, women, and members of minority groups who are beginning to acquire skills so they do not have to live on welfare.

No large company will give these people the opportunity that the small one does because of the accent on the "youth culture" and automation. We have in our own company a preponderance of women, many over 50, black and veterans who certainly would be hard put to relocate.

I feel, at this point, it is important that I bring to light certain facts about the overall cosmetic field. It was started on a small scale by women who were vitally interested in improving the appearance, the outlook, and the desires of their sex. No place can I find mention of this in any past legislation.

These women started successful businesses—worked diligently—and for the large part, many are no longer here. Their names, however, are still household words and control of our industry under these names now is in the hands of the giant conglomerates since no new company of any consequence has been able to be successfully introduced into the market in the past 5 years.

These are: Elizabeth Arden, owned by Eli Lilly & Co., Helena Rubinstein, owned by Colgate-Palmolive; Lanvin-Arpege, owned by Squibb; Charles of the Ritz, owned by Squibb; Coty, owned by Pfizer; Breck, owned by American Cyanamid; Germaine Monteil, owned by British American Tobacco; Scandia, owned by British American Tobacco; and Yardley, owned by British American Tobacco.

Senator EAGLETON. Were all of these companies started by women?

Mr. LIGHTMAN. No, not every one; Elizabeth Arden, Helena Rubinstein; I do not think people would know the name Chesebrough; but they would know Germaine Monteil as these are words well known.

It would seem that small companies following the old tradition should not be forced out of business but should be encouraged and every assistance given to them to survive. I should like the record to be kept open so that our organization may submit additional data and their viewpoints on detention, good manufacturing practices, precautionary labeling, and the recommendations concerning small business in the amendment.

In closing, on behalf of many of the small, independent cosmetic manufacturers and distributors, may I thank this committee for asking us to testify on proposed legislation which affects our very existence. It is a first for us—and we greatly appreciate it.

Senator EAGLETON. Thank you, Mr. Lightman. I think you have made a valuable contribution. We do intend to keep the record open.

Will 2 weeks be enough?

Mr. LIGHTMAN. Yes.

Senator EAGLETON. We can keep it open for 3 weeks if you like.

Mr. LIGHTMAN. If we might do that. Our members are all over the United States.

Senator EAGLETON. Let us make it 3 weeks and we will be glad to receive any other statements or data that you wish to submit from your association or members. It is important that we hear from the small businessman and the small businesswoman.

The giant companies with laboratories and all the people they can hire might be affected one way, whereas, the small businessperson with a few employees does not have all the luxury of a huge laboratory and what have you. So we have to take into account the pragmatics of modern-day commercial life.

You have made a good contribution. Mr. Lightman, we do appreciate your appearance and it was good to have the rest of you folks with us.

Mr. MIGLIN. Senator, my name is Lee Miglin. We have a small business and the laboratories we use are long-established laboratories. All of the ingredients they use in our formulations are ingredients that are on the CTFA list, or the approved list, by the Food and Drug Administration.

I think every responsible small company like ours takes every precaution that they do not put on the market a product that is unsafe or that is going to be injurious. If they did, they would not be able to grow to be the Helena Rubinsteins or the Estee Lauders of the future.

Mr. Chairman, no kind of legislation or no amount of legislation is going to take off the market unsafe products that are put on the market by irresponsible parties. If they are irresponsible, they will not care about the legislation to begin with.

Let me just make one more comment, and that is the dollars, which nobody has brought up, which are very important to a small business.

Our laboratories tell us that if we follow the excessive testing demands that are in your bill presently, that it will cost us anywhere from \$3,000 to \$10,000 per product. If we come out with 40 or 50 products a year, which are products that change now because of fashion and that is primarily our business, fashion makeup, this means it will cost us \$500,000 to comply with your bill. We do not make that much. We do not even make close to that much; so we are out of business.

The people that are now on our payrolls will be unemployed. The costs are added on to the other companies that have to do this thing, and I think it does not benefit the consumer at all.

Senator EAGLETON. Very good, sir.

Once again, we thank all of the witnesses that are at the table.

Mr. LIGHTMAN. May I add one other point, and this is on the subject of the hotline.

Senator, we have discussed this with the doctors. In the case of a small company, they all have what you would call hotlines because they get right through to the boss. If you were to call our company with a problem, whether you be a consumer or a doctor requesting

information, you would be immediately put through to myself or Miss Shorell, or the person involved, and all the information necessary given to you; and we endorse that kind of an idea.

Senator EAGLETON. Thank you again very much.

Our next will be the statement of Evelyn Marshall, presented by Walter E. Byerley.

STATEMENT OF EVELYN MARSHALL, PRESENTED BY WALTER E. BYERLEY, ESQ., REPRESENTING EVELYN MARSHALL COSMETICS LTD.

Mr. BYERLEY. Thank you.

This is actually the statement of Evelyn Marshall, of Evelyn Marshall Cosmetics.

Evelyn Marshall Cosmetics is a member of the ICMD, the group for which Mr. Lightman is speaking, but Evelyn had a desire to present her own views. She agrees with the views of ICMD and endorses them; but she wished to present her own views.

Unfortunately, she could not be here today and she asked me to present the testimony and I thank you for the permission to do so.

Senator EAGLETON. I do not know how long the statement is, but could you highlight it for us?

Mr. BYERLEY. About 5 minutes, Senator.

We generally support the concept of cosmetic safety legislation. and generally endorse S. 1681. Our support is altruistic and selfish: altruistic in that we believe consumers should have cosmetics that are as safe as possible; selfish in that some of the provisions of this bill would overrule certain cosmetic labeling regulations newly promulgated by the FDA regulations, which we feel are ill conceived.

In keeping with our support of the bill, and in conjunction with your suggestion, we wish to offer a few suggestions which we feel would improve the bill, if adopted by this committee.

First, with regard to cosmetic safety substantiation, section 604(b) of the bill.

Subsection 1 of this section provides that the safety of a cosmetic shall not be adequately substantiated unless the manufacturer has adequate information on hand upon which he can reasonably conclude that the cosmetic is safe.

Subsection 2 of section 604(b) provides that the data on hand (a) "shall include information on such specific testing * * * as is appropriate or necessary" and (b) "may include scientific literature" and so forth.

We believe that the intent of these two subsections is to require specific testing only where the scientific literature is inadequate to establish safety. This is a reasonable requirement, and one we endorse.

However, the use of the intractable "shall" in conjunction with testing and the permissive "may" in conjunction with scientific literature can be interpreted to mean that there must be some testing of all products by each manufacturer, and that scientific literature can be, at best, only corroborative evidence.

We believe the best solution to this problem is the establishment of a list of substances generally recognized as safe, or GRAS, analogous to the GRAS list for food ingredients. Such a list could be established

as was the original food GRAS list, by sending qualified experts a list of substances and asking for their comments. It could, like the good GRAS list, be expanded or contracted continually, as the need arose.

Establishment of such a list would certainly be in keeping with other provisions of section 604. Section 604(c) envisions the establishment of a list of cosmetics that require specific testing; section 604(d) envisions establishment of a list of cosmetics or cosmetic ingredients that require preclearance; and section 604(e)(1)(D) envisions a list of banned substances. It seems only logical to complete the circle by establishing the fourth list—GRAS substances.

Our second point deals with the definition of the word "process." Section 605 requires every processor to register annually with FDA and provide certain information concerning the ingredients and formulation of each product, and a summary of all relevant safety information. Under 605(i), process includes manufacturing, processing, preparing, packaging, labeling, or holding of a cosmetic, and excludes only retailers.

Under this language, every person in the chain of distribution of every single cosmetic, except a retail store, would have to file identical information. Aside from the unnecessary time and expense to the industry of obtaining and filing this information, and to FDA in reviewing and maintaining those files, there is a real problem of knowledge. No manufacturer wants to give to a wholesaler, or a beauty shop operator, or to a distributor, the quantitative and qualitative formulae of his products. These formulae are the major asset of any cosmetic firm, and, indeed, are often the only appreciable asset of many small firms.

We suggest, instead of everyone in the chain of distribution—save the retailer—being required to file duplicatory information, that the actual manufacturer of the cosmetic be required to file it in a master file at FDA, similar to the drug master files already established at that agency.

Other persons who are processors as defined could then simply refer to that master file in their own registration. We also suggest that the definition of processor be made akin to that in the drug administration requirements and include only those persons who actually change the product or its packaging, rather than all persons in the chain of distribution.

Such master files, of course, would have to be accorded strict trade secrets confidentiality, as are drug master files under the existing section 314.11(b) of existing FDA regulations.

Our next point concerns title III of the bill, which requires cosmetic labeling to bear the common or usual name of every ingredient in order of decreasing predominance by weight, except for colors, fragrances, and flavors.

Incidentally, diverting for a moment from the prepared text, we agree with the doctor's testimony this morning that if we must have a listing of ingredients, that it is probably much more important to get into colors, fragrances, and as far as the listing, since the primary reason is to allow people who are allergic to the cosmetic to find the substance to which they are allergic, we suggested that only the nonallergants be listed.

I was happy to hear from the doctors this morning that there are tests being done to try to determine the principal malefactors; and if this is done, it would seem to me to be a simple matter, a much simpler matter to require the lifting of the three or four or five, however many there may be, ingredients that may be known allergants on the label or on the package insert rather than have these three or four or five known allergants buried in a list of 30 or 40 or 300 ingredients.

[Short recess.]

Senator EAGLETON. We will go back on the record and we will continue with Mr. Byerlye.

Your testimony was that they are doing these studies and they may, in time, narrow it down to a few ingredients that are causing lots of allergies, but that would not be the whole list.

Mr. Byerlye. The author of this bill, in introducing it, gave two reasons why consumers need to have an ingredient listing: (1) To alert the allergic consumer to the contents so she can avoid any item to which she is allergic; and (2) to facilitate value comparisons.

We wholeheartedly agree with the listing of allergies so that consumers can avoid them. We do not agree that listing by order of predominance assists the consumer in making value comparisons. All that predominance listing tells the consumer is that any particular ingredient is present in an amount less than the ingredient which precedes it and greater than the ingredient which follows it. Two cosmetics labeled exactly alike insofar as descending order of predominance is concerned may in fact differ greatly in their respective amounts of desirable ingredients.

Thus, the only real benefit to the consumer of an ingredient list is disclosure of allergens. We, therefore, suggest that only the allergens be listed.

Such a listing would be beneficial both then to consumers and manufacturers. The consumer would benefit because she would need to examine a list of only four or five ingredients, rather than a list of 30 or more, to see if the substance to which she is allergic is listed. Since fewer ingredients are listed, they could be listed in a more prominent type size, and, indeed, could be highlighted with the word caution or some similar means of directing the consumer's attention to the list.

The manufacturer would benefit, of course, by not being forced to reveal to his competitors the complete qualitative formula of his product, and cogent clues to the quantitative formula.

There is another alternative to predominance listing. This alternative is alphabetical listing of all ingredients. We candidly admit that this is less desirable than the first alternative suggested, but at least it is better than predominance listing.

From the consumer's viewpoint, alphabetical listing would facilitate location of allergens. Instead of reading all ingredients, she need only look to the pertinent letter or letters of the alphabet. Indeed, since this bill allows the ingredient list to be on labeling rather than the label—a privilege for which we thank the author—we will even suggest that the ingredients be listed, one to a line, in a vertical column, to further facilitate location of the sought-for ingredient.

From the manufacturer's viewpoint, alphabetical listing would reveal the qualitative formula, but would give no clues to the quantitative formula.

These, then, are our suggested improvements to the bill. In order to facilitate the committee's work, we have drafted language which we feel will be suitable to accomplish these changes, if the committee so desires. I have appended these suggested changes to the statement submitted to the record, but I will not read them now unless the committee so desires.

Thank you.

Senator EAGLETON. Thank you very much, Mr. Byerley, for your very helpful testimony.

Mr. BYERLEY. Again, we thank you for the opportunity.

[The information referred to follows:]

Suggested Amendments to S. 1681

Submitted by Walter E. Byerley
on Behalf of Evelyn Marshall

First: Amend section 604(b)(2) to read as follows:

(b) * * *

- (2) The data or information referred to in paragraph (1) may be comprised solely of scientific literature, or published or unpublished data or information in the possession of the manufacturer, relevant to the safety of the ingredients of the cosmetic (including inclusion of such ingredients on a list of cosmetic ingredients generally recognized as safe) or the finished cosmetic product; PROVIDED, however, that when the manufacturer deems it appropriate or necessary, or the Secretary shall require, by regulation issued pursuant to subsection (c), that specific testing be conducted on one or more ingredients or on the finished product, then such data and information shall include the results of such testing.

Second: Amend section 604(d)(1) to read as follows:

(d)(1) The Secretary shall by regulation --

- (A) Establish a list of cosmetic ingredients generally recognized as safe, under such terms, and upon such conditions, as may be appropriate.
- (B)(i) - Same as present (A)
- (B)(ii) - Same as present (B)
- (B)(iii) - Same as present (C)
- (B)(iv) - Same as present (D)

Third: Amend section 605(b)(1) to read as follows:

- (b)(1) Every manufacturer required to register
(as in original)

Fourth: Amend section 605(i)(1) to read as follows:

"(i)(1) As used in this section the term - -

(1) 'process,' 'processed,' or 'processing' with respect to cosmetics includes the repackaging or otherwise changing the container, wrapper, or labeling of any cosmetic package in furtherance of the distribution of the cosmetic from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

"(2) 'manufacturer' means the person who actually formulates or compounds the cosmetic."

(3) Same as present (2).

(4) Same as present (3).

(5) Same as present (4).

(6) Same as present (5).

Fifth: Amend section 602(g)(1) to read as follows:

"(g)(1) Unless labeling affixed to or within the package bears --

--- (A) the common or usual name of the cosmetic, if any, and

(B) in case it contains any known allergen, a prominent list containing the common or usual name of each such known allergen."

Senator EAGLETON. Our final witness today will be Anne Clark of Women's Lobby, Inc.

**STATEMENT OF ANNE CLARK, DIRECTOR, HEALTH RESEARCH,
WOMEN'S LOBBY, INC.**

Ms. CLARK. May I invite those members of the lobby to join me at the table?

I come before you this morning as a woman and as a consumer.

Senator EAGLETON. Would you care to identify the two associates with you?

Ms. CLARK. Certainly; Ms. Kay Snowden and Ms. Julie Miller, both of Women's Lobby, are with me. Let me get these things out of the case, as part of my testimony. Then I shall proceed.

I come before you this morning as a woman and as a consumer and as a mother, and I am very much interested in these products which I will be discussing with you a little later on as to how they affect women. I will also touch on the whole media and how it affects women in advertising.

I will be coming back to that in my testimony.

Senator Eagleton, I am Anne Clark, director of health research for Women's Lobby, Inc. It is a pleasure for us to appear before you today.

Women's Lobby supports S. 1681 because we feel women should be given an informed choice about the products available to them as individual consumers and in their dual roles as purchasing agent for their families.

S. 1681 begins to require the labeling and testing of cosmetics for the first time as a Federal mandate. It is a mild measure, a simple first step toward providing safety in many personal-care products. I know you, Senator Eagleton, as its sponsor, and its champion in the House, Congresswoman Sullivan, will forgive me if I call this a modest proposal.

When I use the term "modest," I am not making any literary reference.

Only the amount of opposition mounted by the cosmetic industry could convince us they have this much to hide. Only entrenched industry opposition leads us to believe that testing procedures are cursory, that women's needs are ignored, that labeling is a threat, that consumers must be ignorant for their own good, and that the industry profits from all this.

Most insulting of all, of course, is the assumption that these products would not sell without this covert information * * * that women are not able to discern their own needs.

Since I have allergies, I have brought with me a selection of products that would be dangerous to me and some indication of the lack of information given to consumers.

Here is Love's Natural Essence Shampoo, advertising in bold type that it contains pure honey, milk, and protein. Fortunately, I know I am so allergic to honey that the smallest exposure to it involves cortisone treatment for me. I would never use this product.

However, Clairol's Sunshine Harvest Shampoo, Red Raspberry Fragrance only tells me "For external use only."

If you would be interested in smelling this, you might be persuaded this could be a cross between Red Raspberry, Kool Aid, and Jello. And despite the best efforts of Sesame Street, most 2- or 3-year-old children cannot read "Keep out of the reach of children." Children also have great climbing ability.

Parenthetically, I made a call to the poison control office of Maryland yesterday saying that I had this product in my hand and could they please tell me what the contents were. They suggested a call to the Food and Drug Administration. They did not know. So if a 3-year-old had, in fact, consumed a great amount of this, there is no easy access to what antidote should be used, and his stomach would have to be pumped. This assumes, of course, that a hospital or physician is within easy reach.

I should not drink it, and it smells wonderful. Both of these products should be kept away from children because they resemble food products that are appetizing. We have also picked these products because they represent the industry's "return to nature" movement.

Frankly, their lack of labeling resembles the trek of the city slicker through poison ivy. It is natural, but it's a poor way to learn about the countryside. In this case, the industry is the sage farmer, telling us the rash will heal.

This country is youth oriented. It is undesirable and disgraceful to grow old in the United States. An insidious advertising campaign, urging women to become girls again by using baby shampoo, exemplifies this emphasis upon youth. A look at the labels of some baby shampoos, not including the leading one, incidentally, which is unlabeled, reveals a high percentage of formaldehyde. We have been listening this morning to the allergenic reactions to formaldehyde. The labels also read "Keep out of the reach of children."

I can see the advantage of using formaldehyde for pickling frogs. I have trouble understanding why the industry is marketing a baby product so dangerous that it has to be kept away from babies, lest they or their mothers become specimens for a biology class.

One sign of growing older is gray hair. "Does she or doesn't she? Only her hairdresser knows for sure." If only the woman, herself, knew for sure. This box has a caution label warning that exposure to eyelashes or eyebrows may cause blindness. However, the size of the print cautioning such dangers as blindness is so miniscule as to almost require a magnifying glass to read it.

Lanolin is a basic ingredient in most lipsticks and lip glosses. The lip gloss I have with me carefully labels its contents, but the lipstick made by the same manufacturer, Love, is not labeled for content at all. How is the woman allergic to lanolin going to know Love lipstick can cause her a reaction short of enduring that reaction and its potentially dangerous consequences? That kind of Love is the kind of love we all can do without.

Women can also suffer from adverse side effects from vaginal sprays and douches. Vaginal sprays and douches can cause blisters, burning, and irritation. Massengil, a vaginal douch powder, when packaged in packettes, labels all of its contents, the most significant one being boric acid. Massengil in vaginal spray has no indication of content on the can, short of the fact that it contains no hexachlorophene. To add

insult to possible injury, the powder makes 12 quarts of liquid, or 384 ounces, or 0.00492 cents per ounce. The spray is 0.56 cents per ounce.

My display of "show and tell" should have given you ample evidence that women need an inordinate amount of help—this year from fruits, next year from vegetables. The assortment of flavors is more like a fruit cocktail than the needs of an adult human being. My modest assortment, incidentally, cost \$10.39, including tax.

One of our concerns this year has been the number of repeat bills women's lobby has worked on. Now, we are testifying again, while the National Commission on Product Safety reports that 60,000 Americans, most of them women, reported injuries by cosmetics in 1970. How many women are maimed and hurt while we discuss this bill this morning.

We in the women's movement want women to make a free choice of their lifestyles and their lives. Choice is meaningless without information and that is the essence of this legislation.

We hope this subcommittee acts swiftly to make this law.

Thank you very much.

Senator EAGLETON. Thank you.

Ms. CLARK. I would like at this point, with your permission, to give a demonstration.

I wonder if I could have you and the audience, deliberately inhale for a minute, while I spray this hair spray. Please take a deep breath.

Somewhere along the way you are going to exhale deliberately and, then again inhale deliberately. According to the contents of this can, voluntary inhalation can be harmful or fatal.

Senator EAGLETON. What is the content of the can?

Ms. CLARK. Protein 21 hairspray.

Senator EAGLETON. Well, Ms. Clark, I think you have made some very telling arguments and it is quite wise and proper that you be here and testify because although the word "cosmetic" in a generic sense, includes shaving creams and toothpaste and the like, by far the bulk of the people affected by the products we are dealing with in this bill will be women; and you have every right and obligation to speak up.

You described our bill as being modest. I think that is a fairly good description of it.

Could you tell us the areas in which you think it could perhaps be strengthened?

Ms. CLARK. I am frankly unhappy that the 90-day provision of last year's bill has been dropped. I can see from the testimony this morning why that provision was dropped. I do feel that the consumer is not protected adequately in terms of the cosmetic industry despite the fact that there has been a great deal of talk this morning about consumer concern. At this particular moment I feel that I am the only person who is the consumer at that end of the line.

I would hope, for the record, that other consumer groups could come before you and present their points of view.

Senator EAGLETON. Surely. I am told by Ms. McCord that three other consumer groups will be submitting statements for the record and also we are going to incorporate in this year's record the record of a year ago where we had several individuals who had personal problems with one or more cosmetics.

Ms. CLARK. I would appreciate that.

Senator Eagleton, I also feel that the efforts made on behalf of the industry to keep their trade secrets from the consumer can be a great danger and my example of yesterday calling the poison-control center in the State of Maryland, being put on "hold" for 15 minutes to find out an ingredient which the industry said to keep out of the reach of children and in the end not being able to get that ingredient is one example of why exposure of content, particularly the allergens, has got to be revealed. Title II and title III of your bill, give us strength in this area of concern.

Senator EAGLETON. Do you have any feeling about the question of alphabetical listing of ingredients versus descending order of predominance?

Ms. CLARK. I have mixed feelings.

The women in the consumer movement have been educated in terms of food, to look for the product in proportions on the can.

There is going to have to be a major educational emphasis if cosmetics are treated differently. However, listening to the testimony this morning, indicates that an alphabetical listing can bring the medical profession and the industry to a closer understanding. If this is the case, I would endorse the alphabetical listing, with the understanding that massive educational work has got to be done; because you're going to have people who, when they look at the label of a can of soup which says it is chicken stock, water, et cetera, know that what they are getting is in descending order of predominance; whereas, with cosmetics, you will have to be educated to look through an alphabetical list.

Yes; I can see the advantages, if alphabetical listing will make action on S. 1681 easier.

Senator EAGLETON. What about the suggestion of the hotline?

Ms. CLARK. The hotline suggestion, if it includes only doctors to manufacturers, I take a very dim view of. If it truly involves the consumer and the consumer has access to it then I support the hotline idea. Most of us have been educated to call poison control and then the content of a cosmetic can be given to the consumer directly. In that case, I endorse the idea of a hotline.

Senator EAGLETON. Thank you very much, Ms. Clark

Thank you, ladies and gentlemen, for being with us today. We do appreciate your appearance.

At this point we will include in the record the statements and other pertinent material supplied for the record by persons unable to be present for this hearing.

[The following material was subsequently supplied for the record:]

STATEMENT
FOR
THE RECORD

FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON LABOR AND PUBLIC WELFARE
UNITED STATES SENATE

JUNE 12, 1975

Mr. Chairman:

We are pleased to join today in discussing S. 1681, the proposed "Cosmetic Safety Amendments of 1975," intended to increase the authority of the Food and Drug Administration (FDA) to ensure the safety of cosmetics.

We are pleased that S. 1681 has incorporated many of the changes we discussed during hearings on similar legislation in the last Congress. Then, as now, we agreed that:

- cosmetic products should be safe; and
- consumers should have the information they need to make informed purchases.

Present Authority and Programs

The FDA has recognized a number of deficiencies in the Federal Food, Drug, and Cosmetic Act which impair our ability to design effective programs to regulate cosmetics. In recent years we have employed new programs which attempt to obtain adequate information on:

- the number of products marketed;
- the composition of such products; and
- the adverse reactions to such products.

We established and are continuing three major voluntary programs to assemble this information.

Registration

In our February 1974 testimony, we described as moderately successful our efforts to obtain an inventory of all cosmetic producers. Firms have continued to register with us, and as of May 30, 1975, a total of 830 manufacturing establishments out of an estimated total of 1,200 had registered with us. The products marketed by those registrants comprise approximately 95 percent of the volume of cosmetic products presently on the market. This is a good response for a voluntary program.

Formula Data

While there has been an increase in the submission of formula data from last year's 50 percent of the market's current formulations to about 65 percent, we believe the industry response should be better. Registrations of formulation changes amount to approximately 5 percent of the filings. This suggests that companies may not be updating their filings to reflect formula changes. Having formula information is essential to our regulatory program, since chemical analysis to determine ingredients and composition, without the knowledge of the formula, is expensive, time consuming, and often imprecise.

Adverse Reactions

The voluntary reporting of adverse reactions and injuries is intended to yield important data on safety problems. While we have had only two reporting periods to evaluate this program, participation in this

program to date has been totally inadequate. Only about two percent of manufacturers, packers, and distributors have filed product experience reports. The low participation may stem both from the sensitive nature of the information submitted and the fact that this is a voluntary program. We will continue to seek ways to improve participation in this program, but I must conclude that experience to date indicates that success would depend on FDA having the authority to require participation by cosmetics firms.

In addition to the three major voluntary programs directed towards industry, we are also assembling accurate and specific information on the actual incidence of consumer injuries attributable to cosmetics.

The National Electronic Injury Surveillance System (NEISS) reporting process is a hospital based system which provides information on cosmetic related adverse reactions recorded in hospital emergency rooms. This data source contains primarily acute or extremely severe incidents of cosmetic product related adverse reactions for persons entering emergency rooms of hospitals included in the NEISS system. This system is an ongoing program with reports compiled on a semi-annual basis.

The results of our most recent survey, The Investigation of Consumer Perception of Adverse Reactions to Cosmetic Products, will be available shortly. This study, which was conducted by a private firm under a

contract with FDA, will help us increase our knowledge of adverse reactions experienced by consumers. Prior to this study, our sources of information concerning the types and severity of adverse reactions caused by cosmetic products were limited to consumer complaint letters, the voluntary industry reports, and the NEISS system. With each of these we experienced one or more limitations in reporting the extent of cosmetic product related adverse reactions, such as unverified reports, under reporting of actual incidents and little information on cosmetic use patterns. The consumer perception survey was designed specifically to help fill in the gaps and to develop useful methods for gathering substantive data for future research. A total of 35,000 people from 10,050 households were monitored very closely over a three month span to develop a diary of cosmetic uses. Medical history data were collected, usage of cosmetic producers was recorded, adverse incidents were confirmed by dermatologists and categorized as to severity. Dermatologists also identified those persons who might be considered as "atopic" or prone to experience allergic reactions. We are looking forward to the publication of the report as a source of very useful information and will provide a copy for the record.

Recent Developments

Last year we provided your Subcommittee with a summary of our cosmetic activities. Before presenting our views on the legislation currently before you, I think it would be useful to mention actions we have taken during the past year.

Ingredient Labeling

In March, 1975, in order to increase consumer information on the labels of cosmetics and certain other products, we moved to require:

- Ingredient information in labeling of cosmetics;
- A warning on food, drug, and cosmetic products in pressurized aerosol containers;
- A special cautionary statement on feminine deodorant sprays and overall body sprays;
- A warning on all cosmetics containing ingredients for which safety has not been substantiated prior to marketing; and
- That "manufacturers of cosmetics labeled 'hypoallergenic' must show through clinical tests that their products cause significantly fewer adverse reactions than competitive products."

Zirconium Antiperspirants and Deodorants

In a review of nonprescription drugs for FDA, a panel of experts questioned the safety of zirconium as an ingredient of aerosolized antiperspirants and deodorants, and denied that aerosolized zirconium could be generally recognized as safe. Our recent proposed regulation therefore declares an aerosol drug containing zirconium to be a "new drug," and an aerosol cosmetic containing zirconium to be adulterated under the Federal Food, Drug, and Cosmetic Act. If this proposal is issued as a final regulation, all present drug and cosmetic aerosol products containing zirconium will be removed from the market until their safety can be established.

TITLE I OF S. 1681Cosmetic Safety

Turning to the bill (S. 1681), we are in basic agreement with the principle that manufacturers of cosmetics are responsible for the safety of their products and have the duty to perform adequate premarket testing to assure safety.

The Department supports the provision of title I of S. 1681 which sets forth procedures for the safety substantiation of cosmetics and adopts the principle of our recent regulations, and of general law, that manufacturers have the duty of substantiating the safety of their products before marketing. This would impose a requirement of premarket testing, to which we have no objection, but not require premarket clearance or even mandatory premarket notification, except in certain limited cases. We are pleased to see the deletion from the previous bill

(S. 863) of the blanket requirement for submission of such data.

We prefer the language of S. 1681, which provides FDA with the authority to require premarket submission of safety test data when we believe such submission is necessary to ensure safe cosmetics.

These provisions in S. 1681 are similar to the Department's bill submitted to the last Congress, which also provided broad, discretionary recordkeeping and reporting authority for food, drugs, and medical devices. As we mentioned in our statement on S. 863, your bill in the previous Congress, we agree that manufacturers of cosmetics are responsible for the safety of their products and have the duty to perform adequate testing to assure safety. This provision has become a familiar principle of private products liability law. The only question is the extent to which Government should get involved in assuring that the manufacturer's duty to substantiate safety is not neglected. Our basic concern is that manufacturers actually perform this substantiation and that we can monitor to their results, to enable any appropriate regulatory action.

We do not object to the specific statutory language authorizing FDA to develop guidelines on toxicological testing to define what types of tests need to be carried out as a minimum requirement for safety substantiation, to set screening levels, or to require approval of cosmetics containing certain ingredients or within certain classes. We do not believe it is necessary to identify the actions that FDA may take to address problems of cosmetic safety.

Section 102 of the bill which explicitly provides that our good manufacturing practice regulations for cosmetics have the force and effect of law is unnecessary. Recent court decisions have affirmed the authority of FDA to issue good manufacturing practice regulations under 701(a) which are substantive and have the full force and effect of law.

TITLE II

Establishment Registration

As we stated before this Subcommittee in the last Congress, we agree that manufacturers should be required to register with FDA and report such information as formulas, adverse reactions and other information needed by FDA. In addition, we think it wise to broaden factory inspection authority to include records. These provisions of S. 1681 are similar to those in the Department's bill submitted to the last Congress.

In addition, title II of S. 1681 includes provisions for administrative detention of adulterated or misbranded cosmetics. This authority would improve FDA's ability to prevent marketing of violative products and is similar to that now exercised by the United States Department of Agriculture and the Food and Drug Administration under the meat, poultry and egg laws.

We would emphasize the importance of obtaining adequate authority to obtain information on regulated products, either through records inspection or through reporting. It is essential that FDA possess sufficient authority to determine the processes through which cosmetics are being

manufactured. Although FDA's primary source of such information is factory inspection, our present authority to inspect cosmetic processors is severely limited. FDA inspectors, under our current law, are limited to a visual examination of the processing in a particular establishment. They are not entitled to inspect records concerning formulas, processes, and complaints, nor can they require access to shipping records and files showing the source of materials and quality controls. This makes it difficult for an FDA inspector to detect potential microbiological contamination, the use of uncertified colors, or the truthfulness of statements in cosmetic labeling.

It is also important that FDA be able to obtain needed information without having to send out an inspector each and every time it is believed that such records may shed light on a potential hazard posed by any particular cosmetic. To answer this need, FDA should have authority to require firms subject to the Act to maintain records and make reports necessary to assure implementation of the Act. Provisions of S. 1681 are similar to those in the Department's bill submitted to the last Congress.

Your earlier bill provided FDA with the authority to subpoena witnesses. FDA has been unique among regulatory agencies in lacking subpoena authority. Our main concern is authority to require the production of reports, records and other documents to assist the

Agency in its investigations and proceedings. Our own bill submitted in the last Congress would grant us this authority, which would be comparable to that exercised by the Federal Trade Commission for 60 years under its laws.

TITLE III

Cosmetic Labeling

We agree that consumers are entitled to have information regarding ingredients in cosmetics, and any other necessary information which will help avert injury. We are pleased to note that S. 1681 provides clear statutory authority to the FDA to promulgate substantive regulations in the areas of ingredient labeling and warnings.

Your bill corrects certain defects in our present cosmetic ingredient labeling authority under the Fair Packaging and Labeling Act (FPLA) which we discussed in our previous statement. However, the bill does not assure us authority to require that ingredient information be available both at the time of purchase and at the time of use. This can be done by requiring such information to appear on the product's label. We would also recommend inclusion of a provision allowing exemptions and alternative methods for ingredient declaration where placement of such information on the label is impractical. Of course, in the absence of an explicit congressional mandate that ingredients be disclosed in labeling or in some other particular way, the

FDA has inherent authority to promulgate reasonable exemptions from requirements of the Act.

In developing our cosmetic ingredient labeling regulations, we found it appropriate to allow certain alternative methods of ingredient declaration. For example, ingredients present at a concentration of less than one percent need not be declared in order of predominance. This eliminates certain problems for manufacturers without depriving consumers of any useful information. Another alternative method in our regulations is off-package labeling at the point of purchase for small unpackaged products now sold in racks. Without this alternative, these products would have to be sold in packages which would entail price increases that would be substantial in some cases. It would be appropriate to give FDA discretion to provide for off-package ingredient labeling in such cases, where availability of ingredient information to consumers can reasonably be assured.

With respect to warnings on labels, we are confident of our authority to require warnings where there is a potential health hazard that may be prevented or alleviated by a warning, but we would not object to the explicit authority provided in S. 1681. We have already required warnings on aerosols and on feminine sprays. In addition, S. 1681 would expressly allow us to require other information in labeling which would be helpful to consumers.

TITLE IVPoison Control Information System

We believe that it is essential that physicians have ready access to information which may save lives in cases of emergency. We will continue to provide such toxicological information as we have in the past. We believe this objective can be met without a statutory requirement if the legislative history of the recordkeeping and reporting provisions of the bill makes it clear that providing such information to poison control centers does not violate any statute protecting confidential information.

Small Business Assistance

S. 1681 contains a new provision which requires the Secretary to cooperate with the Small Business Administration (SBA) with respect to applications for loans to assist affected small business entities to comply with FDA requirements. The Secretary is required to evaluate each application and report to the Administration (or to the bank or lending institution) to determine if proposed additions to or alterations in plants, facilities, or methods of operation which are designed to enable small firms to comply with such requirements are

appropriate and necessary and to make recommendations as to granting the loans. We have no objections to this provision.

Preemption

S. 1681 also provides for preemption of all State laws concerning labeling requirements which are in addition to or different from information required under section 602 of this Act. A State may be granted an exemption from supersession, however, where the State imposes a higher level of performance. The Department has consistently favored uniform Federal and State food and drug laws and regulations. We believe this can be achieved by a variety of mechanisms. This Agency has diligently sought to coordinate its operations with the States to strengthen their individual efforts.

701(a) Regulatory Authority

Section 701(a) of the Federal Food, Drug, and Cosmetic Act provides FDA with general rulemaking authority by authorizing the FDA to issue regulations for the efficient enforcement of the Act. The bill provides that all Agency rulemaking concerning cosmetics would be in accord with the informal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553). Judicial review of cosmetic regulations would be in a United States court of appeals under the substantial evidence standard.

We would not object to legislation that expressly confirms our authority to promulgate substantive rules for cosmetics in statutory language. However, we would want to be assured that there be no implication that FDA lacks the power under section 701(a) to adopt substantive rules concerning cosmetic labeling or safety, or other matters under the Act.

We share the view of experts in administrative law that the informal rulemaking procedures are appropriate for the adoption of such requirements as cosmetic regulations. We also believe that all judicial review of FDA regulations should be in the United States courts of appeals and would not object to tightening the standard of review from the arbitrary and capricious test to the substantial evidence standard.

Advisory Committees

Finally, S. 1681 authorizes the Secretary to appoint advisory committees to assist in the administration of this Act. While we recognize that this provision allows the Secretary discretionary authority, there is no need for specific statutory authorization for new advisory committees concerning cosmetics or other areas subject to FDA jurisdiction. Currently, FDA can and does establish such committees whenever we believe they are necessary to help us carry out our responsibilities.

CONCLUSION

In summary, Mr. Chairman, we agree that consumers ought to be able to purchase safe cosmetics. We also agree that our regulatory authority in this area should be strengthened. Our bill in the last Congress provides the basic regulatory tools we need to provide the protection. We believe that S. 1681 offers a number of desirable improvements in Federal cosmetics law since Senator Eagleton has incorporated our suggestions on his previous bill. Implementation of this legislation would not require any additional resources for FDA in the coming fiscal year other than those already requested in the President's fiscal year 1976 budget. We favor enactment of S. 1681, subject to the comments above.



July 3, 1975

Mr. Allen Fox
Senate Subcommittee on Health
Committee on Labor and Public Welfare
Washington, D.C. 20510

Dear Mr. Fox:

I am writing to inform you of our views on the Eagleton Cosmetics Bill, S. 1681. While there are some useful provisions in the Bill, the core provisions are extremely weak, and probably would not result in increased marketplace safety for cosmetics. The Bill would cost the taxpayer more money to administer than it is worth in terms of increased safety.¹

For the vast majority of cosmetics, all the Eagleton Bill requires is that the files of the manufacturer contain "adequate substantiation of safety." Adequate substantiation merely means that from existing evidence, "it can be reasonably concluded that the cosmetic is safe" under "customary and usual" conditions of use. The manufacturer is not required to generate safety data; rather, on the basis of information that for some reason or another already exists, a reasonable man could conclude that the product was safe. The conclusion would be based on what a reasonable man might conclude on any basis, rather than the sturdy "substantial evidence" from well-controlled studies required of drugs or the "scientific procedures" required of food additives.

In addition, the manufacturer is not required to submit his material to the FDA. It merely stays in his files unless FDA determines, on the basis of other information not in his files and after lengthy APA rulemaking procedures, that there is a significant risk of injury from the product or that the product is not yet on the market and is of a type not already marketed.²

1. The Senate Commerce Committee has drafted a reasonably good cosmetics bill, which, in contrast to the Eagleton Bill, would be likely to result in a safer market place.

2. It is unlikely that the Secretary would know of a product not yet on the market and of a new type, since premarket notification to FDA by manufacturers is not required. Moreover, the provisions requiring submission of information by manufacturers to FDA apply only to products not on the market when the regulation "becomes effective." When FDA proposes a rule that a product is a significant risk or is of a new type, the manufacturer can avoid sending in his information by selling his product before the proposed regulation is commented upon and finalized and effective--at FDA usually a period

Mr. Allen Fox

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The great need in the cosmetics area, as in the area of environmental chemicals generally, is for safety testing. There is little or no safety data on most cosmetic ingredients, and without such tests, we are unlikely to be alerted to any adverse effects other than the most outstandingly bizarre and the most immediate. The fact that a product has been on the market many years, does not mean it does not cause breast cancer or liver damage, since such effects are unlikely to be noticed without controlled studies.¹

Even if scientific tests were required to be run on cosmetics, which this Bill does not do, it would be bad to leave them in the hands of the manufacturers. Our experience with manufacturer analysis of manufacturer-generated data has led us to the firm belief that such analysis should not be trusted without careful review by outside parties such as government scientists. With the drug metronidazole (Flagyl), for example, the manufacturer, Searle, told FDA that cancer studies available to them showed that the drug did not cause cancer. FDA statisticians found that in fact one study demonstrated that Flagyl caused large increases in the total number of tumors in test animals, and that the manufacturer had analyzed the data in such a way as to obscure the results -- by dividing the tumors into narrow types, and analyzing only by type. In a second study, Searle obscured the fact that Flagyl caused a significant increase in female breast tumors by submitting only an analysis of tumors in both sexes together. Miles Laboratories announced to FDA that its product Alka-Seltzer did not cause stomach bleeding in normal people without ulcers. Analysis of their data, by us and subsequently by an FDA scientist revealed that there was substantial stomach bleeding in normal people taking Alka-Seltzer but that those people who bled were dropped from the computations because they were deemed "aberrations." Shell Company has claimed that its laboratory studies of DDVP, the nerve-gas-like ingredient of its No-Pest Strip, show that the chemical does not cause cancer. However, our recent analysis shows that their data was twisted and analyzed in such a way as to silence the real results of their study that DDVP causes cancer in mice. These are but three of many such incidents we have in our files; and there are many many more in FDA and EPA files. The plain fact is that the manufacturer has such high stakes in concluding that the product is safe, that his analysis is not reliable. Medical officers at the FDA, those physicians who analyze and evaluate safety and efficacy data sent in by manufacturers wishing to market new drugs, have stated repeatedly that they cannot rely on manufacturers' summaries and conclusions of drug studies, without reanalyzing for themselves what the data actually says.

of many months and often years.

1. A Doctor does not even ask his patients which cosmetics they use; if he did, it is unlikely that patients would remember very far back what their cosmetic exposures were.

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In short, even if there were studies performed on cosmetics, the idea of letting the manufacturer in the privacy of his plant conclude that safety has been shown, is ridiculous and dangerous.

The Eagleton Bill gives FDA discretion to take stronger steps in some cases. FDA may require a manufacturer to submit safety "substantiation", to send safety information newly received by the manufacturer to FDA, or to take a premarket 90-day pause after sending information to FDA, if FDA finds that the products constitute a "significant risk of injury." This discretionary power will not be very useful, since without testing, FDA will have no knowledge on which to conclude that a significant risk exists. It is the classic Catch-22. Also, it requires that such measures be undertaken only if the Secretary first promulgates a regulation, with the attendant delays and opportunities for compromise.

Another discretionary power is that FDA may for cosmetics of a "type" not already on sale or significantly different from other cosmetics, require the substantiation to be submitted and then wait 90 days before marketing. This provision would have some usefulness if it applied to all new cosmetics. But it only applies to new types and moreover, to new types that the Secretary has, through some mystical knowledge, anticipated and formalized into an effective rule before the "type" was marketed.

The other main discretionary power granted to FDA is to "determine when specific testing is appropriate or necessary for any cosmetic, in order to constitute adequate substantiation of safety. . . ." Again, this determination is by lengthy rule-making procedures, which have in the past involved a lengthy trial-type procedure with cross-examination when the manufacturer objects. Certainly FDA should have the power to specify what types of evidence are necessary to prove safety. But this power should be mandatory so that industry cannot talk its way around FDA.

FDA does not operate well in an atmosphere of complete discretion, where immediate pressures from industry are enormous and consumer pressures slight. The head of the cosmetics program is a former cosmetics industry executive. Understandably, he is not known for his injury-prevention zeal. FDA officials like him operate well only where the law is clear and straightforwardly states what the public expects. Otherwise the atmosphere of camaraderie with industry takes over, and public money is spent for nothing.

There are good parts in the Eagleton Bill such as a Delaney Clause, a provision requiring that when specific tests are required to be a part of the substantiation in the manufacturer's files, they be conducted by independent laboratories, a cosmetic manufacturer registration system, a labeling provision, deletion

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of the soap and the hair dyes exemptions to current law, detention power for nonconforming goods, etc. If the core provisions of the Bill, described above, cannot be radically improved, we would suggest proceeding with the good parts alone.

Several years ago, the Eagleton Bill was a strong consumer protection bill. Gradually it has been worn down by industry. Industry has apparently been able to convince some pertinent parties that cosmetics really aren't dangerous enough to warrant firm law. And in fact there is a common belief that cosmetics are innocuous because the skin provides an impenetrable barrier which could protect the body no matter what the chemical. The prevailing view has been that the worst harm a cosmetic could wreak was skin irritation. This belief is an anachronism. Today we know that there is a very high absorption into the bloodstream of chemicals applied to the skin. Once beyond the skin, cosmetics have as much likelihood of damaging the body as chemicals which are eaten or injected. Moreover, cosmetics also enter the body through the eye or lung. Here are a few examples of past cosmetics hazards to health which have been identified:

- animal studies have shown that zirconium, contained in Super Dry Sure deodorant, presents a risk of lung disease.
- hexachlorophene in talcum powder was responsible for the deaths of dozens of infants, and is associated with neurological damage in animals and in premature infants washed with hexachlorophene soaps.
- an ingredient in Mennen deodorant caused frequent rashes, in some cases over the whole body.
- "Long Nails" plastic nail lengthener contained methyl methacrylate, a chemical known to repress respiration and lower blood pressure.
- Some coal tar hair dyes may cause cancer.

Because of their intimate and continuous exposure, cosmetics should have as much health attention as food additives.

Sincerely,

Anita Johnson
Anita Johnson



CONSUMERS UNION / A NONPROFIT ORGANIZATION / PUBLISHER OF CONSUMER REPORTS
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September 11, 1975

Honorable Thomas Eagleton
United States Senate
Washington, D.C. 20510

Dear Senator Eagleton:

In response to your request of September 3, 1975, I am forwarding the views of Consumers Union of United States, Inc. on S.1681, the Cosmetic Safety Amendments. We regret that scheduling conflicts made it impossible to accept your invitation to testify on this legislation in June but understand that these comments will be included in the hearing record.

Before turning to the specific provisions of S.1681, several general comments should be made.

S.1861 unquestionably makes several substantial contributions to the effort to achieve greater cosmetics safety. These provisions include those restricting the exemption for hair dyes; extending the Delaney Clause concept to cosmetics; eliminating the soap exemption; requiring the registration of cosmetics processors, formulations, and adverse reaction reports; sanctioning informal rulemaking procedures for regulations promulgated under this statute; clarifying FDA's authority to require ingredient and warning labeling; and strengthening FDA's inspection and enforcement authority with respect to cosmetics. While we have offered some comments with respect to some of these provisions, we support enactment of these aspects of S.1681.

With respect to the safety substantiation provisions of the bill, however, we have some reservations. The current version of this legislation has been substantially weakened from the pre-market notification procedure which characterized the predecessor legislation, S.863, which we prefer. It is not at all certain that S.1681 as currently drafted would substantially upgrade the pre-market testing of cosmetic products so as to give consumers greater assurance that these products are safe.

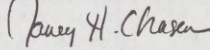
Cosmetics manufacturers insist that cosmetics are generally safe, that few injuries occur as a result of their use, and that these injuries are generally quite minor. Unfortunately, inadequate attention has been paid to the fact that cosmetics are not merely applied to the exterior surfaces of the body. Through cosmetics use, chemicals are absorbed into the system, where at least the possibility of systemic damage arises. Too little has been done to explore the possible relationship between chemicals associated with

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cosmetics use and serious internal damage. This legislation must insure that manufacturers are not merely permitted to rely on an inadequate, existing body of data rather than taking affirmative steps to explore the potentially serious short-term and long-term effects of their products on the human system. (More specific comments relating to Title I are attached.)

More specific comments on the provisions of S.1681 are attached.

Sincerely,



Nancy H. Chasen
Attorney, Washington Office
Consumers Union

Att.

TITLE I -- COSMETIC SAFETY

1. Section 604(b)(1). (Page 2)

This subsection establishes the standard of safety which manufacturers must meet before marketing a cosmetic product. Under this provision, a cosmetic is "adequately substantiated" for safety (and thereby marketable) if a manufacturer can reasonably conclude that the cosmetic is safe on the basis of information which is known or should reasonably be known to him.

If the Committee determines that manufacturers need not forward substantiation data to FDA for an independent determination of its adequacy, this legislation must establish clear and stringent boundaries to guide manufacturers in the exercise of their responsibility for assuring adequate substantiation prior to marketing. If the standard is imprecise or if it lodges excessive discretion in the manufacturer, the substantiation procedure will provide little more than illusory protection to consumers. We believe that the "reasonable conclusion" standard fails both tests.

So deficient is this standard, that it is possible that it may relieve manufacturers of any affirmative burden to establish the safety of their products prior to marketing. This provision appears to allow a manufacturer to proceed with marketing a cosmetic product in the absence of existing information which establishes a hazard associated with the product. That is neither the intent of the sponsor nor of FDA, as hearings on S.1681 and its predecessor S.863, indicate. (See related discussion, #2, infra.)

We strongly urge that a clearly affirmative, judicially recognized standard be incorporated in §604(b)(1). Adoption of a "substantial evidence" standard, for example, would place the burden clearly on the manufacturer to develop a portfolio of data affirmatively supporting the safety of his product.

2. Section 604(b)(2). (Page 3)

This related provision defines the kind of information which should form the basis for the manufacturer's determination under §604(b)(1). It is unclear in the present drafting whether this provision is intended to establish a requirement that a minimum amount of animal/human testing be undertaken (or that adequate testing have been undertaken previously). Such a requirement would disallow "substantiation" based merely on the absence of generally known adverse data, and would establish a minimum level of required animal/human testing. However, to achieve this result, the following changes are necessary:

In subparagraph (A):

- The underscored words in the phrase "such specific testing" (emphasis supplied) should be omitted. These words have no antecedent in the bill and may raise the inference that "specific" refers only to tests specifically designated by the Secretary under §604(c)(1)(A) or 604(e)(1)(A).
- Sensitization and irritation testing should be required on human, as well as animal, subjects prior to marketing. To do otherwise makes the marketplace consumer the unwitting subject of human safety testing.
- There should be an assumption that toxicity, sensitization, and irritation testing are "appropriate" and "necessary" prior to marketing of cosmetics. While this section, at best, leaves considerable discretion in the manufacturer, the bill should contain no implication that in some cases these tests are not appropriate or necessary.

3. Section 604(b)(1)(C). (Page 2)

If the Committee determines that all safety substantiation information need not be routinely submitted to FDA, FDA must be granted clear and ready access to such information, in the Secretary's discretion. This subsection does provide that the Secretary may require such submission simply upon request. ((C)(1)). Thus, the cumbersome subsection (d) rulemaking procedure referred to in (C)(ii) is entirely unnecessary. (See further discussion of subsection (d) in #4, infra)

4. Section 604(d)(1). (Page 5)

First, as discussed in #3 supra, this cumbersome process is (and should be) unnecessary in view of the Secretary's authority merely to request submission of substantiating data in the possession of the manufacturer.

Secondly, it is fatally flawed in concept. Where the Secretary has already made a finding that a cosmetic or cosmetic ingredient presents a "significant risk of injury", the time for assembling data by way of a time-consuming rulemaking procedure has passed. It is time for the Secretary to act by setting tolerance limits, requiring cautionary labeling, or banning the commercial distribution of the product. We urge that §604(d)(1) be deleted. (Conforming amendment would be necessary on page 12, line 3.)

5. Section 604(d)(2). (Page 6)

With respect to the marketing of a new "type" of cosmetic, we support the concept of this provision but believe it is in need of substantial revision. We suggest, first, that the legislation

(or the legislative history) include a clear definition of a cosmetic which is "not within a type of cosmetic which was previously in commercial distribution" or which is within such a type of cosmetic but is "significantly different from other cosmetics within that type." (For example, is a disposable douche either a new "type" of cosmetic, or one that is "significantly different" from other douches by virtue of its innovative packaging?) Secondly, the relationship between this subsection and the general "notification of new cosmetics" provision of 201(d)(1) should be clarified. Presumably, the pre-market notification requirement applies to new "types" of cosmetics, but this would be clearer if §604(d)(2) were integrated as a new subsection of §201(d).

Thirdly, however, a more stringent obligation should apply to new "types" of cosmetics than is generally applicable under §201(d)(1) to any new cosmetic product. Manufacturers should be obligated to submit to FDA substantiating data 90 days prior to marketing. This is an area peculiarly inappropriate for rule-making, however. The Secretary is not likely to have the forewarning necessary to promulgate specific rules relating to an anticipated new "type" of cosmetic. If it is the intent of the Committee that a general rule require submission of data to FDA prior to marketing in these cases, this requirement should be included in the legislation itself.

6. Section 604(e)(1). (Pages 6-7)

Under this section, the Secretary may take certain action when he finds that such action is "necessary to assure the safety of cosmetics." While this standard may be appropriate for such actions as setting tolerance limits or banning a cosmetic product, it is too strict as a threshold determination prior to requiring certain specific testing. The standard for requiring testing in §604(c)(1), that the Secretary determine that such testing is "appropriate or necessary", is preferable. (The relationship between subsections 604(c)(1) and 604(e)(1) is unclear. Presumably one reference to the Secretary's authority to require specific testing is adequate.)

In any redrafting of this provision, the expediting provisions of subsection 604(e)(2) should be preserved with respect to the requirement of additional specific testing.

TITLE II -- REGISTRATION AND COMPLIANCE

7. Section 201(h). (Page 17)

The reference to 18 U.S.C. §1905 in this subsection should be changed to refer to the "trade secret and commercial or financial information" exemption of the Freedom of Information Act, 5 U.S.C. §552(b)(4). The Freedom of Information Act represents the Congress' determination of the kinds of information which should be readily available to the public and that for which withholding may be justified. Section 1905, on the other hand, is

not a statute itself prohibiting disclosure but rather a statute setting the penalty for disclosure of information for which disclosure is "unauthorized" by some other statute.

The intention of the Committee is presumably to protect from public disclosure only information the disclosure of which would result in substantial competitive harm. Under National Parks and Conservation Association v. Morton, 498 F.2d 765 (D.C.Cir. 1974) it is clear that only commercial or financial information which will result in substantial competitive disadvantages may be withheld under Exemption (4) of the Freedom of Information Act. While the case law also indicates that §1905 and Exemption (4) cover the same body of information, the excessively broad language of §1905 may nonetheless lead to the withholding of information the disclosure of which would cause no competitive disadvantages. See, Grumman Aircraft Engineering Corp. v. Renegotiation Board, 426 F.2d 578 (D.C.Cir. 1970), and Charles River Park v. H.U.D., Civ. Action No. 73-1930 (D.C.Cir., March 10, 1975, modified June 17, 1975).

As this is a section restricting public disclosure, it should be consistent with the FOIA, the major law governing disclosure and nondisclosure to the public.

8. Page 17.

While FDA is given substantially improved authority to conduct inspections and require recordkeeping, S.1681 does not provide for subpoena power. FDA has requested such authority with respect to cosmetics as well as foods and drugs and we support their contention that such authority is essential to a regulatory agency.

TITLE III -- COSMETIC LABELING

9. Section 602(g)(1). (Page 23)

It should be clarified in lines 10-13 that color is not exempt from the labeling requirement but merely exempt from the order of predominance requirement. Moreover, it should be stated either in the statute (which is our preference) or in the report that identification is to be by FD&C number so as to facilitate easy comparison by consumers.

We agree with FDA that the legislation should make clear that ingredient information is to be available to consumers both at the time of purchase and at the time of use and that, toward this end, the legislation should require such information to appear on the product's label. The legislation should not authorize the placing of such labeling within the package; where such an alternative is necessary, it should be accomplished through the rulemaking process.

10. Section 602(g)(2). (Pages 23-24)

This subsection provides for certain exemptions, which may be modified by regulation, to the ingredient labeling requirement. These exemptions are for (1) incidental additives that are present in insignificant levels and which do not have any technical or functional effect, and (2) closely related ingredients which may be declared by a general term. Both exemptions run headlong into the policy which we espouse that consumers are entitled to full disclosure of ingredients, unless overriding considerations justify exceptions and where these exceptions present no risk to public health and safety.

Both of these exemptions incorporate conclusory terms to define the scope of the exemption. But who decides, and when, that an additive is "incidental", that is, that it has no technical or functional effect? The "closely related ingredients" exemption has two ^{sub-issues} ~~damaging~~ deficiencies. First, it carves a potentially large loophole in the proposed program of full and specific ingredient labeling. Secondly, the language of the subsection lacks precision, lodging vast discretion with the manufacturer in the absence of rulemaking by the Secretary.

11. Section 606(c). (Page 26)

While we do not oppose inclusion of a pre-emption section, we do oppose the second requirement of this subsection, that the proposal "be required by compelling local conditions." What might constitute compelling local conditions" is not yet known, but we think the requirement is both unnecessary for protection of industry from undue regulation and subject to capricious interpretation. If citizens of a state or other political subdivision wish to provide a greater measure of health or safety regulations for their own protection, they should, subject to the other conditions of this subsection, be able to do so without having to prove that they are somehow more susceptible to the harm sought to be prevented than the rest of the country.

We are including as an attachment a proposed alternative to this section, which you may want to consider.

TECHNICAL AMENDMENTS

1. Page 1, line 10. After the word "cosmetic" insert the words "or cosmetic ingredient."
2. Page 2, lines 24-25. Strike line 24 and insert in lieu thereof the words "(1) where so requested in writing by the Secretary."
3. Page 8, line 1. Strike the words "unsafe within the meaning of this subsection and insert in lieu thereof the word "adulterated--."

4. Page 8, lines 7-8 and 13-14.

5. Page 7, line 8. After "cosmetic" insert "or cosmetic ingredient."

6. Page 11. A conforming amendment to §706(a) of the Act is necessary, as this subsection refers to language in §601(a) of the Act which is stricken by proposed §601(a) of this bill.

Section —. Preemption; Application for Exemption

(a) Declaration of Congressional intent to preempt any laws or regulations of the states or their subdivisions in the area of food labeling.

(b) (1) Upon application of a state or political subdivision thereof, the Secretary is empowered to exempt by regulations from the provisions of subdivision (a) a proposed law or regulation which (1) imposes a higher standard of performance than the federal standard [presumably requiring more information to appear on the label], and (2) does not unduly burden interstate commerce. If the Secretary fails to exempt or refuse to exempt the applicant without thirty (30) days of the receipt of the application, the exemption shall be considered granted. The exemption decision shall be based upon all the materials gathered by the applicant in its legislative or administrative consideration of the proposed regulation and upon information available to the Secretary.

(b) (2) Notice of the receipt of an application and the Secretary's decision shall be published in the *Federal Register*.

(b) (3) The Secretary's decision shall be subject to judicial review to determine whether it was based upon substantial evidence.

[The procedural parts of this subsection assure expedited consideration of the application, in order to minimize interference with the applicant's legislative or administrative processes.]

(c) (1) Upon receipt of the application for exemption, the Secretary shall publish that application in the *Federal Register* as a proposed regulation under the Federal Food, Drug, and Cosmetic Act and allow 60 days for public comment.

[This subsection incorporates our belief that wherever possible, labeling regulations should be uniform nationwide. Political subunits which wish to impose more stringent labeling requirements in their own jurisdictions should also be presumed to be offering those standards as a proposal for federal acceptance. Regardless of the Secretary's exemption decision under the statutorily provided criteria, the proposal should receive full and prompt consideration for federal promulgation.]

(c) (2) Thirty (30) days after the end of the comment period, the Secretary shall announce the decision of the applicant's proposal as a federal regulation.

(c) (3) The decision shall be subject to judicial review, with the Secretary's decision to stand if supported by a preponderance of the evidence in the administrative record.

We believe that this preemption-plus-exemption provision, albeit complicated, would assure that the consumer's desire to obtain adequate and useable food labeling or any other consumer protection goal could be properly balanced with the industry's interest in freedom from multiplicity of regulation.

STATEMENT OF THE
NATIONAL BEAUTY AND BARBER MANUFACTURERS' ASSOCIATION
REGARDING S 1681

Pursuant to a letter from Senator Edward M. Kennedy, Chairman, Senate Health Subcommittee, dated June 2, 1975, the National Beauty and Barber Manufacturers' Association (NBBMA) offers the following comments concerning S 1681 for inclusion in the record on S 1681.

The NBBMA is a not-for-profit corporation organized and operated to promote, foster and advance the progress and development of the beauty and barber industry. NBBMA's particular area of concern is the manufacture of professional beauty supplies and equipment for use in, and cosmetics, toiletries and related items for sale in, beauty salons and barber shops. The sale of these service cosmetics manufactured by the organizations who are members of NBBMA is very small (less than three hundred million dollars) compared to the sale of the consumer-used products (over six billion dollars). The estimated annual beauty salon business volume (consumer dollars) is \$4,000,000,000*. The industry employs over one million persons**. When barber shop business is included, an additional \$1,400,000,000*** volume and 150,000*** employment can be added. Thus only a relatively small dollar volume in sales of these cosmetic items is necessary for rendering services which generate almost five and one-half billion dollars (\$5,500,000,000) for over a million wage earners.

* Modern Beauty Shop Magazine Annual Facts and Figures Report for 1972.

** Compiled from a survey of State Board License data by American Hairdresser/Salon Owner Magazine.

*** Compiled from a survey of State Board License data by Professional Men's Hairstyling Magazine.

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The approximately 100 members of the NBBMA constitute a substantial portion of the manufacturers supplying beauty and barber products and equipment to beauty salons and barber shops in the United States. Indeed, members of NBBMA supply approximately 70 percent of all products and equipment sold. Thus, NBBMA is especially concerned with the provisions of S 1681 as they would relate to manufacturers supplying merchandise and equipment to beauty salons and barber shops.

NBBMA opposes S 1681. This opposition is based upon two grounds. First, the outstanding safety record of the cosmetics industry, and specifically the professionally applied cosmetics industry which we represent, demonstrates the complete lack of necessity for legislative action. Second, most of the programs in S 1681 are already in existence either as mandatory or voluntary programs. In those instances where actions mandated by the bill are not currently in existence, such as the proposed new subsections 604 (c), (d), and (3) of Title 21 of the United States Code, it appears the bill would probably result in undue burdens upon the cosmetics industry without any potential for commensurate gains in product safety.

Regarding the safety of cosmetic products, testimony presented by the industry in February 1974 demonstrated the low level of adverse reactions related to cosmetics products, compared to the literally billions of applications of such products each year. The Government's own NEISS data affirms that the level of general cosmetic injury is at a low level. Further, the April 1975 NEISS report shows that 76.4% of the reported injuries were to children under 14 years of age. Injuries to this age group resulted primarily from misuse and abuse, not proper use.

In addition, in the field of professionally applied beauty and barber products, the area of special concern for NBBMA, there is an additional safety factor of second person application which is further enhanced by the professional cosmetologist's knowledge of hair and skin. Because of this outstanding safety record, it does not appear any cosmetic safety legislation is warranted.

Further, with regard to the provisions of S 1681, such requirements as product experience reporting, formula disclosure and plant registration are already in existence. Also, prominent package warning statements on products that are not adequately safety substantiated have become mandatory by FDA regulations. In view of this existing regulatory scheme, it does not appear Congressional action is necessary.

The one area where S 1681 does implement, or at least gives FDA authority to implement, new programs is in proposed subsections 604 (c), (d) and (e) of Title 21 of the United States Code. The potential impact of these provisions upon the industry is more severe than is warranted by the safety record of the industry. These provisions would likely become a mechanism for pre-market clearance of cosmetic products, and, as noted in the 1974 Hearings on S863, such pre-market clearance would entail burdensome and wasteful obligations upon both industry and the Food and Drug Administration. No direction is given the Food and Drug Administration with regard to a specific policy that should govern their implementation of the very broad discretionary powers granted in these provisions. Therefore, the Food and Drug Administration would be left with a vague mandate and extremely broad authority. Under such circumstances, it is difficult to fully anticipate the direction the Food and Drug Administration might take in implementing these provisions,

but certainly the broad powers open a real possibility of the imposition of most severe and unnecessary burdens on the industry.

With regard to the proposed deletion of the special hair dye provision from 21 U.S.C. 601 (a) there certainly seems to be no basis in the outstanding safety record for these products to justify or necessitate any change in current legislative and regulatory controls. NBBMA believes deletion of the hair dye provision from Section 601 (a) would constitute an action not justified by the facts of hair dye usage.

While NBBMA opposes new cosmetic safety legislation on the basis of the safety record of the industry, if new cosmetic legislation is enacted, we strongly advocate that legislation be confined to a statutory implementation of the existing voluntary and mandatory programs of the Food and Drug Administration. In particular, NBBMA vigorously opposes the granting of "blank check" authority to the Food and Drug Administration under the proposed new Subsections 604 (c), (d) and (e) of Title 21.

Further, NBBMA recognizes and supports the distinction between professional and consumer cosmetic products. The conditions for use of a product are clearly an important element in its safety, and "second person" application by a professional cosmetologist increases the safety of cosmetic products. Should the Food and Drug Administration enact regulations, such regulations should take fully into account the conditions of use for the product. The importance of the professional cosmetologist's knowledge of hair and skin in the second person application of the cosmetic products manufactured by the companies NBBMA represents is underscored by the training and licensing requirements of the cosmetologist's profession. In order to become licensed in most

states, a hairdresser or barber must study a thousand or more hours in vocational training institutions. Further, the beauty salons themselves must be licensed in most states, again demonstrating the important professional focus of the conditions of use of professional cosmetic products.

In summary, cosmetics are now safe. S 1681 will not increase their safety, but will only result in additional governmental interference where the FDA already has exercised its powers in such a way as to demonstrate its capacity to protect the public under current laws. Consequently, NBBMA believes that S 1681 will not result in increased public safety, but will create additional burdens on the cosmetics industry, the government and ultimately the public. For these reasons, S 1681 should not be enacted.

7/31/75

THE SOAP AND DETERGENT ASSOCIATION

475 PARK AVENUE SOUTH AT 32nd STREET

NEW YORK, NEW YORK 10016

TELEPHONE (212) 725 1262

June 13, 1975

The Honorable
Thomas F. Eagleton
United States Senate
Washington, D. C. 20510

Dear Senator Eagleton:

We have quite serious, and we believe well-founded, concerns over the deletion of the soap exemption proposed by your bill, S. 1681. We have had the opportunity to discuss these concerns briefly with your Legislative Assistant, Ms. McCord, and Mr. James Murphy of the Health Subcommittee Staff, and will reiterate them herein.

In broad outline, our concerns are these:

1. Soap has been used for hundreds of years with virtually no problems concerning its safety.
2. Soap is adequately regulated under the Food, Drug and Cosmetic Act at the present time, and any further regulation of soap as a "cosmetic" under the Act would be superfluous.
3. The proposed classification of soap as a "cosmetic" would require a substantial expenditure of money on unnecessary tests, the economic impact of which would fall most heavily on small producers and might well force many of them out of business.
4. This major increase in industry costs, occasioned by the potential requirement of extensive testing, would inevitably be reflected in higher prices to consumers.

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I shall comment in more detail below on each of these points.

1. Soap's long history as a safe product.

Congress recognized the safety history of soap 36 years ago when it wrote the soap exemption into Section 201 of the F-D-C Act, and the circumstances which motivated its action then are even more pertinent today. Improvements in the quality of raw materials as well as processes, and quality control improvements have led to the finest bar soap quality of any time in history.

The excellent safety record of soap is borne out by industry experience. For example, one of our member companies has had less than one mildness complaint for every 10 million soap bars shipped. Moreover, based upon 1972 statistics of the National Clearing House for Poison Control Centers it is estimated that in cases of ingestion (about once for every 10 million soap bars used), symptoms of any kind occurred less than once for every 100 million soap bars used.

In the FDA's Tabulation of Cosmetic Product Experience Reports, issued Nov. 29, 1974, the Bath Soaps and Detergents category shows only 35 experiences out of 202,500,000 units distributed, or 0.17 experiences per million products distributed. This covered a 6-month period and reflects figures for 14 major firms.

Certainly these figures indicate that these products have an excellent safety record and help to position soap as one of the safest products available to consumers today.

2. Soap is regulated adequately at the present time.

- A. The Consumer Product Safety Commission has authority over soap products by virtue of its administration of the Hazardous Substances Act.

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This Act would require cautionary labeling on soap products if they are found to be irritating, to cause sensitization or to exhibit any other specific hazard. Further, in the highly unlikely event that a soap product should be classed as a "substantial hazard," the Consumer Product Safety Act itself gives the CPSC the power to administer swift action.

- B. With respect to labeling and advertising, the Federal Trade Commission already exercises appropriate jurisdiction.
 - C. Although the term "soap" is not defined in the F-D-C Act itself, the FDA has established a very narrow definition of soaps by administrative regulation (21 C.F.R. § 701.20). Those bar products which fall outside of this soap definition are classed as drugs or cosmetics because of their ingredients, and are thus already under the supervision of the FDA. Therefore, a regulatory framework adequate and appropriate to insure their efficacy and safety is already in place.
3. Classification of all soap as a "cosmetic" would require a substantial expenditure of money on needless tests. Further, ingredient labeling requirements would require numerous printing plate changes -- both to comply initially with the new law and to make recurring changes occasioned by minor formula variations.
- A. A conservative estimate is that there are over 4,000 bar soap products sold in the United States -- most of which are brands in extremely limited distribution and which are marketed under the seller's own label. Were a full battery of tests, as contemplated in S. 1681, to be required for each of these products, at an approximate cost of \$150,000 per brand the overall burden in the bar soap field could reach \$600,000,000.

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- B. Even if carcinogenicity, mutagenicity, teratogenicity and similar tests were not required, and a less demanding schedule of research were imposed for these products, the total impact on the industry could approximate \$12,000,000.
- C. Label change costs are difficult to predict, but it has been estimated that it would cost the soap industry \$4,000,000 to convert to ingredient labeling on just one-half of the presently exempted products (assuming that the remaining brands could combine this change with other desired label modifications, and thus be spared any extra expense). Thereafter, on-going label changes to reflect minor ingredient changes could cost as much as \$800,000 per year.

The economic impact of these requirements would fall most heavily upon the small soap producers and might well cause many of them to go out of business. The present proposal would subject manufacturers-distributors of bar soaps, especially small companies, to a burden of potentially tremendous proportions. This is a burden which seems particularly needless in view of 1) the long history of safe usage of such products, and 2) the fact that the basic soap ingredients today are essentially the same ones used in soap at the turn of the century.

- 4. This projected major increase in industry costs would inevitably be reflected in higher prices to consumers. The cost increases would have a major inflationary impact because soaps are used by virtually all consumers in large volume. They are not a discretionary item. These cost increases are clearly unnecessary, seem totally incompatible with the Federal Government's desire to control inflation, and clearly conflict with what we perceive to be a general desire to eliminate unnecessary regulation.

In summary, we strongly believe that S. 1681's proposed deletion of the soap exemption will not serve the public interest, but rather

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will unnecessarily burden both industry and the consumer, as well as the Federal agency that would be charged with the implementation of additional supervision and control of several thousand products.

We therefore respectfully request that the present soap exemption in the F-D-C Act be retained and that Section 103(b) be deleted from S. 1681.

Sincerely,

Theodore E. Brenner

Theodore E. Brenner
President

cc: Members of the Subcommittee on Health,
Senate Committee on Labor and Public Welfare

Marilyn Miglin Model Makeup

June 27, 1975

Senator Thomas Eagleton
Dirksen Building
Room 6235
Washington, D.C.

Re: Eagleton Bill S 1681

Dear Senator Eagleton:

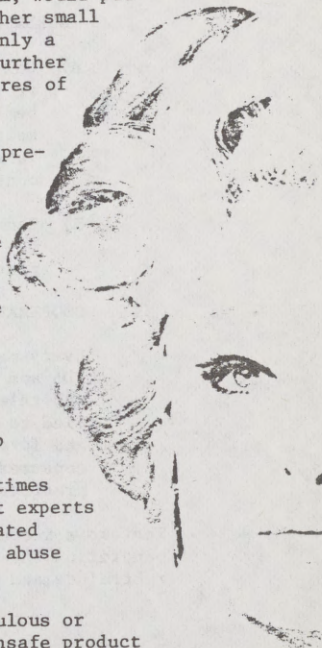
Marilyn Miglin Model Makeup is a small business (under \$1,000,000) selling and distributing cosmetic products made to order for them by reputable private label cosmetic manufacturers. We employ minority groups, and we also donate our services and a great deal of products to many hospitals, psychiatric patients, and other people who cannot afford makeup.

Your Bill S1681, if passed in its present form, would put us out of business, as well as hundreds of other small businesses such as ours. This would be not only a blow to small business generally, but would further increase unemployment and further feed the fires of inflation.

We are not opposed to the general concept of pre-testing cosmetic products, since all of our manufacturers currently test our products before they are even submitted to us for marketing. No ingredients are used that have not already been submitted to FDA.

We do not think your bill is necessary, since cosmetic manufacturers and raw material suppliers already do considerable amount of testing in order to safeguard their name and reputation so they can build their business. As you know, many experts also consider cosmetics among the safest products available to consumers. Water that is used in cosmetic formulations, for example, is more than ten times as pure as water that we normally drink. Most experts also state that the majority of cosmetic related injuries are usually the result of misuse or abuse of the product.

No amount of regulation will stop an unscrupulous or irresponsible manufacturer from putting an unsafe product on the market. Other means must be employed to stop this.



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However, if a cosmetic safety bill is to accomplish meaningful results for the consumer, and still allow small business the opportunities of our free society, it should be based upon common sense laws -- without excesses, costly government red tape, and strangulation of small business. I submit the following constructive suggestions for your sincere consideration:

I. TESTING

Microbiological tests by the manufacturer and raw material suppliers should be a requirement. Only chemicals and ingredients that have been submitted to FDA should be used. FDA should have the right to disapprove any chemical submitted. FDA should also have the right to discontinue the manufacture of any product that they can prove is unsafe or harmful for use by the general public.

II. INGREDIENT LABELING

- A) Only the principal ingredients that are easily or generally identifiable by the consumer should be listed on a label. Technical names and meaningless (to the consumer) ingredients on the label can be misleading and harmful to the consumer.
- B) Each label should have proper instructions for use listed on the label. This would help to prevent misuse or abuse of the product.

III. COOPERATION WITH FDA AND MEDICAL GROUPS

Every manufacturer should be required to list with FDA and Dermatologist and Medical Groups the name and telephone number of an individual who is qualified to assist with information regarding chemicals and formulations in order to correct or treat any consumer problem related directly to cosmetic products.

The above recommendations would be far more effective in benefiting the consumer and manufacturer alike. Excessive restraints and costs placed upon small business only serve

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to eliminate competition and create monopolies -- without meaningful benefits to the consumer.

We would appreciate your sincere consideration of our statements above, and your cooperation and assistance in changing your Bill S1681 so that it does not eliminate small businesses in the cosmetic industry, and so that it has more meaningful and useful benefits to the consumer of today.

Very sincerely,

MARILYN MIGLIN MODEL MAKEUP

Marilyn Miglin
Marilyn Miglin
President

MM:lm

Senator EAGLETON. This will conclude today's hearing on S. 1681. As previously stated, the record will be kept open for 3 weeks to receive other statements.

My thanks again to everyone who has participated.

[Whereupon, at 1:25 p.m., the hearing in the above-entitled matter was adjourned sine die.]



