SS COMMUNICATIONS TO
RAL TRADE COMMISSION

IN REPLYING PLEASE QUOTE

FEDERAL TRADE COMMISSION
WASHINGTON

OFFICE OF THE MEDICAL DIRECTOR

October 16, 1943.

Dr. Robert A. Kehoe
University of Cincinnati
College of Medicine
Cincinnati, Ohio

Dear Doctor Kehoe:

The Federal Trade Commission is undertaking to determine whether or not there is a strong or dangerous probability that lead and sulfur hair dye may contribute in injury to health. These preparations usually contain from 1 to 3% of lead acetate and about the same quantity of suspended sulfur in a suitable perfumed liquid menstrum. The method of application is generally to use a wet toothbrush and apply the preparation evenly to the hair and permit it to dry. After a lapse of six to 12 hours the hair is shampooed. As the hair grows it becomes necessary, at relatively short intervals, to apply the dye close to the scalp.

In our review of the literature pertinent to lead poisoning we have observed the excellent work which you have reported. We would like very much to have the benefit of your views with respect to the possibility of danger arising from the use of lead and sulfur hair dyes. There would probably be little absorption of lead from an intact scalp. However, if the hands are soiled with the preparation they may convey it to the mouth. If there is a scalp abrasion or an inflammatory process of the scalp, is their danger of absorption under these conditions? Do you feel that the directions for use of a lead and sulfur hair dye should inform the individual that if the hands are soiled they should be washed; that if the scalp is broken or inflamed the product should not be used; and that even in a healthy scalp application to it should be avoided as much as possible?

The legal adviser of the Federal Trade Commission indicates that it is not necessary to prove that cases of injury have taken place, but that if it can be shown that there is a strong or dangerous probability that danger to health may result, steps may be taken under section 15 of the Federal Trade Commission Act to insure that the users of these lead-containing hair dyes are given sufficient information about their use to avoid the danger. A copy of the Act is enclosed for your convenience. We are also enclosing a copy of a memorandum to the Commission. Would you care to comment on the testimony of Dr. M. I. Smith quoted in this memorandum?

Your views will be greatly appreciated and will assist the Commission in arriving at a proper decision in connection with this problem.

Very sincerely yours,

J. J. Durrett

J. J. DURRETT, M.D., Director,
Medical Advisory Division.

Enclosures
FTC Act
Memorandum 12/19/42

FEDERAL TRADE COMMISSION ACT

[PUBLIC No. 203—63d CONGRESS, AS AMENDED BY PUBLIC—No. 447—75th CONGRESS]

[H. R. 15613 and S. 1077]

An Act To create a Federal Trade Commission, to define its powers and duties, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That a commission is hereby created and established, to be known as the Federal Trade Commission (hereinafter referred to as the commission), which shall be composed of five commissioners, who shall be appointed by the President, by and with the advice and consent of the Senate. Not more than three of the commissioners shall be members of the same political party. The first commissioners appointed shall continue in office for terms of three, four, five, six, and seven years, respectively, from the date of the taking effect of this Act, the term of each to be designated by the President, but their successors shall be appointed for terms of seven years, except that any person chosen to fill a vacancy shall be appointed only for the unexpired term of the commissioner whom he shall succeed: *Provided, however*, That upon the expiration of his term of office a Commissioner shall continue to serve until his successor shall have been appointed and shall have qualified. The commission shall choose a chairman from its own membership. No commissioner shall engage in any other business, vocation, or employment. Any commissioner may be removed by the President for inefficiency, neglect of duty, or malfeasance in office. A vacancy in the commission shall not impair the right of the remaining commissioners to exercise all the powers of the commission.

The commission shall have an official seal, which shall be judicially noticed.

SEC. 2. That each commissioner shall receive a salary of $10,000 a year, payable in the same manner as the salaries of the judges of the courts of the United States. The commission shall appoint a secretary, who shall receive a salary of $5,000 a year, payable in like manner, and it shall have authority to employ and fix the compensation of such attorneys, special experts, examiners, clerks, and other employees as it may from time to time find necessary for the proper performance of its duties and as may be from time to time appropriated for by Congress.

With the exception of the secretary, a clerk to each commissioner, the attorneys, and such special experts and examiners as the commission may from time to time find necessary for the conduct of its work, all employees of the commission shall be a part of the classified civil service, and shall enter the service under such rules and regulations as may be prescribed by the commission and by the Civil Service Commission.

All of the expenses of the commission, including all necessary expenses for transportation incurred by the commissioners or by their employees under their orders, in making any investigation, or upon official business in any other places than in the city of Washington, shall be allowed and paid on the presentation of itemized vouchers therefor approved by the commission.

Until otherwise provided by law, the commission may rent suitable offices for its use.

The Auditor for the State and Other Departments shall receive and examine all accounts of expenditures of the commission.

SEC. 3. That upon the organization of the commission and election of its chairman, the Bureau of Corporations and the offices of Commissioner and Deputy Commissioner of Corporations shall cease to exist; and all pending investigations and proceedings of the Bureau of Corporations shall be continued by the commission.

All clerks and employees of the said bureau shall be transferred to and become clerks and employees of the commission at their present grades and salaries. All records, papers, and property of the said bureau shall become records, papers, and property of the commission, and all unexpended funds and appropriations for the use and maintenance of the said bureau, including any allotment already made to it by the Secretary of Commerce from the contingent appropriation for the Department of Commerce for the fiscal year nineteen hundred and fifteen, or from the departmental printing fund for the fiscal year nineteen hundred and fifteen, shall become funds and appropriations available to be expended by the commission in the exercise of the powers, authority, and duties conferred on it by this Act.

The principal office of the commission shall be in the city of Washington, but it may meet and exercise all its powers at any other place. The commission may, by one or more of its members, or by such examiners as it may designate, prosecute any inquiry necessary to its duties in any part of the United States.

SEC. 4. The words defined in this section shall have the following meaning when found in this Act, to wit:

"Commerce" means commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.

"Corporation" shall be deemed to include any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest, and any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members.

"Documentary evidence" includes all documents, papers, correspondence, books of account, and financial and corporate records.

"Acts to regulate commerce" means the Act entitled "An Act to regulate commerce," approved February 14, 1887, and all Acts amendatory thereof and supplementary thereto and the Communications Act of 1934 and all Acts amendatory thereof and supplementary thereto.

"Antitrust Acts" means the Act entitled "An Act to protect trade and commerce against unlawful restraints and monopolies," approved July 2, 1890; also sections 73 to 77, inclusive, of an Act entitled "An Act to reduce taxation, to provide revenue for the Government, and for other purposes," approved August 27, 1894; also the Act entitled "An Act to amend sections 73 and 76 of the Act of August 27, 1894, entitled 'An Act to reduce taxation, to provide revenue for the Government, and for other purposes,'" approved February 12, 1913; and also the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914.

SEC. 5. (a) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are hereby declared unlawful.

The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, common carriers subject to the Acts to regulate commerce, and persons, partnerships, or corporations subject to the Packers and Stockyards Act, 1921, except as provided in section 406 (b) of said Act, from using unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce.

(b) Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this Act, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the transcript of the record in the proceeding has been filed in a circuit court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require: *Provided, however*, That the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate circuit court of appeals of the United States, in the manner provided in subsection (c) of this section.

(c) Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the circuit court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days [1] from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith served upon the Commission, and thereupon the Commission forthwith shall certify and file in the court a transcript of the entire record in the proceeding, including all the evidence taken and the report and order of the Commission. Upon such filing of the petition and transcript the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have power to make and enter upon the pleadings, evidence, and proceedings set forth in such transcript a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed, and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgment to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 240 of the Judicial Code.

[1] Section 5 (a) of the amending Act of 1938 provides:

SEC. 5. (a) In case of an order by the Federal Trade Commission to cease and desist, served on or before the date of the enactment of this Act, the sixty-day period referred to in section 5 (c) of the Federal Trade Commission Act, as amended by this Act, shall begin on the date of the enactment of this Act.

(d) The jurisdiction of the circuit court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

(e) Such proceedings in the circuit court of appeals shall be given precedence over other cases pending therein, and shall be in every way expedited. No order of the Commission or judgment of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

(f) Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by registering and mailing a copy thereof addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process registered and mailed as aforesaid shall be proof of the service of the same.

(g) An order of the Commission to cease and desist shall become final—

(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b); or

(2) Upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed, or the petition for review dismissed by the circuit court of appeals, and no petition for certiorari has been duly filed; or

(3) Upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review dismissed by the circuit court of appeals; or

(4) Upon the expiration of thirty days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the order of the Commission be affirmed or the petition for review dismissed.

(h) If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the Commission rendered in accordance with the mandate of the Supreme Court shall become

final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(i) If the order of the Commission is modified or set aside by the circuit court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the circuit court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(j) If the Supreme Court orders a rehearing; or if the case is remanded by the circuit court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

(k) As used in this section the term "mandate," in case a mandate has been recalled prior to the expiration of thirty days from the date of issuance thereof, means the final mandate.

(l) Any person, partnership, or corporation who violates an order of the Commission to cease and desist after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $5,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the United States.

Sec. 6. That the commission shall also have power—

(a) To gather and compile information concerning, and to investigate from time to time the organization, business, conduct, practices, and management of any corporation engaged in commerce, excepting banks and common carriers subject to the Act to regulate commerce, and its relation to other corporations and to individuals, associations, and partnerships.

(b) To require, by general or special orders, corporations engaged in commerce, excepting banks, and common carriers subject to the

Act to regulate commerce, or any class of them, or any of them, respectively, to file with the commission in such form as the commission may prescribe annual or special, or both annual and special, reports or answers in writing to specific questions, furnishing to the commission such information as it may require as to the organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals of the respective corporations filing such reports or answers in writing. Such reports and answers shall be made under oath, or otherwise, as the commission may prescribe, and shall be filed with the commission within such reasonable period as the commission may prescribe, unless additional time be granted in any case by the commission.

(c) Whenever a final decree has been entered against any defendant corporation in any suit brought by the United States to prevent and restrain any violation of the antitrust Acts, to make investigation, upon its own initiative, of the manner in which the decree has been or is being carried out, and upon the application of the Attorney General it shall be its duty to make such investigation. It shall transmit to the Attorney General a report embodying its findings and recommendations as a result of any such investigation, and the report shall be made public in the discretion of the commission.

(d) Upon the direction of the President or either House of Congress to investigate and report the facts relating to any alleged violations of the antitrust Acts by any corporation.

(e) Upon the application of the Attorney General to investigate and make recommendations for the readjustment of the business of any corporation alleged to be violating the antitrust Acts in order that the corporation may thereafter maintain its organization, management, and conduct of business in accordance with law.

(f) To make public from time to time such portions of the information obtained by it hereunder, except trade secrets and names of customers, as it shall deem expedient in the public interest; and to make annual and special reports to the Congress and to submit therewith recommendations for additional legislation; and to provide for the publication of its reports and decisions in such form and manner as may be best adapted for public information and use.

(g) From time to time to classify corporations and to make rules and regulations for the purpose of carrying out the provisions of this Act.

(h) To investigate, from time to time, trade conditions in and with foreign countries where associations, combinations, or practices of manufacturers, merchants, or traders, or other conditions, may affect the foreign trade of the United States, and to report to Congress thereon, with such recommendations as it deems advisable.

Sec. 7. That in any suit in equity brought by or under the direction of the Attorney General as provided in the antitrust Acts, the court may, upon the conclusion of the testimony therein, if it shall be then of opinion that the complainant is entitled to relief, refer said suit to the commission, as a master in chancery, to ascertain and report an appropriate form of decree therein. The commission shall proceed upon such notice to the parties and under such rules of procedure as the court may prescribe, and upon the coming in of such report such exceptions may be filed and such proceedings had in relation thereto as upon the report of a master in other equity causes, but the court may adopt or reject such report, in whole or in part, and enter such decree as the nature of the case may in its judgment require.

Sec. 8. That the several departments and bureaus of the Government when directed by the President shall furnish the commission, upon its request, all records, papers, and information in their possession relating to any corporation subject to any of the provisions of this Act, and shall detail from time to time such officials and employees to the commission as he may direct.

Sec. 9. That for the purposes of this Act the commission, or its duly authorized agent or agents, shall at all reasonable times have access to, for the purpose of examination, and the right to copy any documentary evidence of any corporation being investigated or proceeded against; and the commission shall have power to require by subpœna the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation. Any member of the commission may sign subpœnas, and members and examiners of the commission may administer oaths and affirmations, examine witnesses, and receive evidence.

Such attendance of witnesses, and the production of such documentary evidence, may be required from any place in the United States, at any designated place of hearing. And in case of disobedience to a subpœna the commission may invoke the aid of any court of the United States in requiring the attendance and testimony of witnesses and the production of documentary evidence.

Any of the district courts of the United States within the jurisdiction of which such inquiry is carried on may, in case of contumacy or refusal to obey a subpœna issued to any corporation or other person, issue an order requiring such corporation or other person to appear before the commission, or to produce documentary evidence if so ordered, or to give evidence touching the matter in question; and any failure to obey such order of the court may be punished by such court as a contempt thereof.

Upon the application of the Attorney General of the United States, at the request of the commission, the district courts of the United States shall have jurisdiction to issue writs of mandamus commanding any person or corporation to comply with the provisions of this Act or any order of the commission made in pursuance thereof.

The commission may order testimony to be taken by deposition in any proceeding or investigation pending under this Act at any stage of such proceeding or investigation. Such depositions may be taken before any person designated by the commission and having power to administer oaths. Such testimony shall be reduced to writing by the person taking the deposition, or under his direction, and shall then be subscribed by the deponent. Any person may be compelled to appear and depose and to produce documentary evidence in the same manner as witnesses may be compelled to appear and testify and produce documentary evidence before the commission as hereinbefore provided.

Witnesses summoned before the commission shall be paid the same fees and mileage that are paid witnesses in the courts of the United States, and witnesses whose depositions are taken, and the persons taking the same shall severally be entitled to the same fees as are paid for like services in the courts of the United States.

No person shall be excused from attending and testifying or from producing documentary evidence before the commission or in obedience to the subpœna of the commission on the ground or for the reason that the testimony or evidence, documentary or otherwise, required of him may tend to criminate him or subject him to a penalty or forfeiture. But no natural person shall be prosecuted or subjected to any penalty or forfeiture for or on account of any transaction, matter, or thing concerning which he may testify, or produce evidence, documentary or otherwise, before the commission in obedience to a subpœna issued by it: *Provided*, That no natural person so testifying shall be exempt from prosecution and punishment for perjury committed in so testifying.

Sec. 10. That any person who shall neglect or refuse to attend and testify, or to answer any lawful inquiry, or to produce documentary evidence, if in his power to do so, in obedience to the subpœna or lawful requirement of the commission, shall be guilty of an offense and upon conviction thereof by a court of competent jurisdiction shall be punished by a fine of not less than $1,000 nor more than $5,000, or by imprisonment for not more than one year, or by both such fine and imprisonment.

Any person who shall willfully make, or cause to be made, any false entry or statement of fact in any report required to be made

under this Act, or who shall willfully make, or cause to be made, any false entry in any account, record, or memorandum kept by any corporation subject to this Act, or who shall willfully neglect or fail to make, or cause to be made, full, true, and correct entries in such accounts, records, or memoranda of all facts and transactions appertaining to the business of such corporation, or who shall willfully remove out of the jurisdiction of the United States, or willfully mutilate, alter, or by any other means falsify any documentary evidence of such corporation, or who shall willfully refuse to submit to the commission or to any of its authorized agents, for the purpose of inspection and taking copies, any documentary evidence of such corporation in his possession or within his control, shall be deemed guilty of an offense against the United States, and shall be subject, upon conviction in any court of the United States of competent jurisdiction, to a fine of not less than $1,000 nor more than $5,000 or to imprisonment for a term of not more than three years, or to both such fine and imprisonment.

If any corporation required by this Act to file any annual or special report shall fail so to do within the time fixed by the commission for filing the same, and such failure shall continue for thirty days after notice of such default, the corporation shall forfeit to the United States the sum of $100 for each and every day of the continuance of such failure, which forfeiture shall be payable into the Treasury of the United States, and shall be recoverable in a civil suit in the name of the United States brought in the district where the corporation has its principal office or in any district in which it shall do business. It shall be the duty of the various district attorneys, under the direction of the Attorney General of the United States, to prosecute for the recovery of forfeitures. The costs and expenses of such prosecution shall be paid out of the appropriation for the expenses of the courts of the United States.

Any officer or employee of the commission who shall make public any information obtained by the commission without its authority, unless directed by a court, shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine not exceeding $5,000, or by imprisonment not exceeding one year, or by fine and imprisonment, in the discretion of the court.

Sec. 11. Nothing contained in this Act shall be construed to prevent or interfere with the enforcement of the provisions of the antitrust Acts or the Acts to regulate commerce, nor shall anything contained in the Act be construed to alter, modify, or repeal the said antitrust Acts or the Acts to regulate commerce or any part or parts thereof.

SEC. 12. (a) It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

(1) By United States mails, or in commerce by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.

(b) The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in commerce within the meaning of section 5.

SEC. 13. (a) Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is engaged in, or is about to engage in, the dissemination or the causing of the dissemination of any advertisement in violation of section 12, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission under section 5, and until such complaint is dismissed by the Commission or set aside by the court on review, or the order of the Commission to cease and desist made thereon has become final within the meaning of section 5, would be to the interest of the public,

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States or in the United States court of any Territory, to enjoin the dissemination or the causing of the dissemination of such advertisement. Upon proper showing a temporary injunction or restraining order shall be granted without bond. Any such suit shall be brought in the district in which such person, partnership, or corporation resides or transacts business.

(b) Whenever it appears to the satisfaction of the court in the case of a newspaper, magazine, periodical, or other publication, published at regular intervals—

(1) that restraining the dissemination of a false advertisement in any particular issue of such publication would delay the delivery of such issue after the regular time therefor, and

(2) that such delay would be due to the method by which the manufacture and distribution of such publication is customarily conducted by the publisher in accordance with sound business

practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such false advertisement or any other advertisement,

the court shall exclude such issue from the operation of the restraining order or injunction.

SEC. 14.[2] (a) Any person, partnership, or corporation who violates any provision of section 12 (a) shall, if the use of the commodity advertised may be injurious to health because of results from such use under the conditions prescribed in the advertisement thereof, or under such conditions as are customary or usual, or if such violation is with intent to defraud or mislead, be guilty of a misdemeanor, and upon conviction shall be punished by a fine of not more than $5,000 or by imprisonment for not more than six months, or by both such fine and imprisonment; except that if the conviction is for a violation committed after a first conviction of such person, partnership, or corporation, for any violation of such section, punishment shall be by a fine of not more than $10,000 or by imprisonment for not more than one year, or by both such fine and imprisonment: *Provided*, That for the purposes of this section meats and meat food products duly inspected, marked, and labeled in accordance with rules and regulations issued under the Meat Inspection Act approved March 4, 1907, as amended, shall be conclusively presumed not injurious to health at the time the same leave official "establishments."

(b) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates, shall be liable under this section by reason of the dissemination by him of any false advertisement, unless he has refused, on the request of the Commission, to furnish the Commission the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the United States, who caused him to disseminate such advertisement. No advertising agency shall be liable under this section by reason of the causing by it of the dissemination of any false advertisement, unless it has refused, on the request of the Commission, to furnish the Commission the name and post-office address of the manufacturer, packer, distributor, or seller, residing in the United States, who caused it to cause the dissemination of such advertisement.

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[2] Section 5 (b) of the amending Act of 1938 provides:

SEC. 5. (b) Section 14 of the Federal Trade Commission Act, added to such Act by section 4 of this Act, shall take effect on the expiration of sixty days after the date of the enactment of this Act.

Sec. 15. For the purposes of sections 12, 13, and 14—

(a) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

(b) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(c) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(d) The term "device" (except when used in subsection (a) of this section) means instruments, apparatus, and contrivances, including their parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(e) The term "cosmetic" means (1) articles to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof intended for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap.

Sec. 16. Whenever the Federal Trade Commission has reason to believe that any person, partnership, or corporation is liable to a

penalty under section 14 or under subsection (l) of section 5, it shall certify the facts to the Attorney General, whose duty it shall be to cause appropriate proceedings to be brought for the enforcement of the provisions of such section or subsection.

Sec. 17. If any provision of this Act, or the application thereof to any person, partnership, corporation, or circumstance, is held invalid, the remainder of the Act and the application of such provision to any other person, partnership, corporation, or circumstance, shall not be affected thereby.

Sec. 18. This Act may be cited as the "Federal Trade Commission Act."

Approved September 26, 1914.

Amended and approved March 21, 1938.

U. S. GOVERNMENT PRINTING OFFICE: 1938

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MEMORANDUM FOR THE COMMISSION:

Re: Lead and Sulfur Hair Dyes

This Division has been requested to express its views with respect to the danger to health of hayr dyes containing lead and sulfur. Before this request was made we asked the library to locate and make available to us a copy of a recently-compiled bibliography of the scientific literature pertaining to lead toxicity covering the period from 1745 to the middle of 1942, which embraced some 5,000 references. This bibliography was not available in Washington but access to it was given Mr. Irish who forwarded to us about 20 references to reports (in various languages) of lead poisoning due to cosmetics.

Lead poisoning was recognized and described by Hippocrates, Pliny and Dioscorides. Acute lead poisoning is rarely met with, as only a fraction of the lead consumed is absorbed into the bloodstream.

Chronic lead poisoning causes colic, constipation, anemia, loss of energy, incoordination of muscles, muscular atrophy, arteriosclerosis, kidney and liver damage and injury to the central nervous system, which may be manifest by paralysis, convulsions, delirium, coma, and death. The condition may completely disable, and last for years, with remissions and exacerbations depending on variations in the total intake of lead. Severe cases are typical and easy to recognize, but it is important to realize that milder cases of lead intoxication are difficult to recognize and may escape diagnosis entirely. Withdrawal of lead usually results in complete recovery but recovery may not occur in advanced cases, particularly where the symptoms arise as a result of extensive injury to the central nervous system.

It is necessary in this country to protect about 800,000 industrial workers from lead injury, but lead poisoning is decreasing at the same time that the use of lead in industry is increasing. This favorable change is entirely due to measures taken to protect persons from contact with lead. The following data shows the decline in reported cases of lead poisoning in England: In 1900 there were 1,058 cases of lead poisoning reported; in 1910, 505 cases; in 1920, 289 cases; in 1930, 265 cases; in 1934, 198 cases.

The principal industrial sources of lead sufficient to produce lead poisoning are paint manufacturing, painting, pottery-glazing, and mining, smelting, working, and salvaging lead. A large variety of non-industrial accidental household contacts with lead result in more reported cases of lead toxicity today than are attributed to industrial causes.

Lead may readily enter the body through the respiratory tract or the alimentary tract. Some organic compounds of lead (tetraethyl lead) may enter the body in significant amounts through the unbroken skin, but absorption through the unbroken skin of the inorganic compounds of lead is very slight. Lead is very slowly excreted and piles up in the body acting as a cumulative poison. A daily intake of as little as 1/65 of a grain will frequently produce lead toxicity. It is therefore necessary to deal with the problem of lead toxicity on the basis of the total amount of lead which reaches the individual from all sources, rather than from the amount of lead which reaches the individual from any single source.

In 1870, fifteen of sixteen hair tonics then available in New York City contained lead, and the other preparation contained silver nitrate. In 1884, one of five face powders, three of eight liquid face-enamels, and all of three cosmetic lotions contained lead. This condition fortunately does not exist today. Lead and sulfur hair-dyes in use at this time usually, but not always, contain from one to three percent of l ad acetate and about the same percentage of sulfur in a perfumed menstruum of glycerine and water to which is sometimes added coloring and a local scalp irritant and rubifacient such as cantharides.

We are concerned here with the extent to which these lead-containing hair dyes are responsible for lead poisoning. Of approximately 5,000 references to lead toxicity in the scientific literature since 1745, the source of the lead was determined by the compilers of the bibliography in about 3,000 instances, of which eighteen involve cosmetics (face powders, liquid face-enamels, theatrical grease-paint, and rouge) and three references indicated that lead-containing hair dyes had caused poisoning. The cases attributed to cosmetics were fatal or severe and the opinion of those reporting was that many cases escaped recognition, especially mild cases.

In the literature we have found no statement which indicates that lead applied indiscriminately to the hair and scalp is safe. We have discussed this problem with the U. S. Public Health Service and the Food and Drug Administration, and they are in agreement with this view. They also agree that if the person who uses a lead and sulfur hair dye uses proper precautions in its application the lead contained therein will not be a source of danger to health.

The Food and Drug Administration has instituted no cases in court charging danger to health against this class of preparation. They are advising manufacturers of lead and sulfur hair dyes that they should in their directions for use clearly indicate that the preparation should be applied sparingly to the hair, avoiding contact with the scalp, as much as possible, and if the hands are soiled in applying the preparation to the hair they should be washed immediately thereafter to avoid transfer of any lead from them to the mouth. They emphasize that the preparation should not be applied to the scalp where there exists inflammation or breaks in the continuity of the skin since it is known that therapeutic use of lead preparations on broken skin surfaces has resulted in lead toxicity to an extent sufficient to discourage such treatment. The authority for such recommendation to which they direct the attention of the manufacturer is contained in Section 201(n) of the Food, Drug, and Cosmetic Act, as follows:

> [Sec. 201. For the purpose of this Act-]
> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

This section of the Act is strikingly like Section XV of the Federal Trade Commission Act.

KE 0013879

Before Dr. Miller left Washington he indicated to me that the problem presented by lead and sulfur hair dyes had not been finally and satisfactorily disposed of. He indicated that in his opinion these preparations were not safe unless the recommended method of use took into account certain precautions. He also indicated that he had been unable to find instances of lead poisoning which had been caused by the use of hair dyes.

We have now reviewed all of the opinions by the Medical Advisory Division since 1938, which deal with lead and sulfur hair dyes. They have not been entirely consistent. These opinions in the aggregate clearly reflect a reluctance to agree that nothing should be attempted by the Commission to accomplish the observance of reasonable care in the use of these preparations, but they also recognize that proof of danger may only be accomplished, if at all, by expert opinion testimony. Also, this Division in all of its opinions has definitely resisted and refused to give an opinion that these articles are entirely safe except where the directions for use call for reasonable care in their application to the hair. In all instances where the manufacturer has stated or implied that the preparation is safe, the opinion has expressed the view that such a claim is false. This is the generally-held opinion and both the Food and Drug Administration and the U. S. Public Health Service subscribe to it.

The Sanitary Code of the Department of Health of the City of New York requires the following to appear in the labeling of lead and sulfur hair dyes: "CAUTION: This product contains metallic salt. It is for external use only and must be used with care." This statement appears in the labeling of some preparations which have come to our attention. The Division has been handicapped by not having before it in all instances complete labeling for these preparations so that it might be exactly determined what the manufacturer's recommended conditions of use are. The customary or usual conditions of use are almost universally not set forth in the advertising.

It is the opinion of this Division that the directions for use of a given lead and sulfur hair dye which a manufacturer places in the labeling of the preparation reflect the customary and usual conditions of use for that particular product.

It is the further opinion of this Division that if such directions for use neglect to instruct the user of the generally accepted steps required in the safe use of the article, the advertising should do this. We hold the view that this information need not be set apart or segregated and identified either in the labeling or in the advertising as a caution or warning, but that it will serve its purpose best if it is made an integral part of any descriptive matter that outlined the method of use of the article.

In the event a manufacturer refuses to provide such directions for use and the Commission is required to produce proof that injury may result, we will not be able to produce witnesses who have recognized instances of such injury in their practice. The testimony which can be produced and which is rather generally held by informed scientists is represented by the following excerpt from the testimony of Dr. M. I. Smith of the U. S. Public Health Service, who appeared for the Commission in the Arvil Company case (Docket 3472), the only case in this class that we know of where testimony has been a part of the procedure before the Commission. Dr. Smith has not changed his opinion since he gave this testimony in 1939.

A ***Lead acetate is not very often prescribed in the treatment of scalp diseases. It presents a distinct hazard of lead poisoning.

Q What is the percentage of lead acetate in this product?

A There is about one per cent lead acetate and while that much--while lead acetate is usually not very readily absorbed from the skin it may be absorbed in some cases especially if there is any injury or trauma or abrasion or inflammatory conditions or eczematous condition of the scalp to which it is applied. In such instances it is likely to be absorbed in small amounts.

Q Would it be harmful, Doctor?

A It may be. It does not take very much lead, in continuous absorption to cause lead poisoning. According to the best authorities it is believed that daily absorption of a milligramme, one milligramme of lead--that is about 1/65 of a grain, per day--is sufficient to cause chronic lead poisoning.

Q What would be the effect of the use of this product over a period of time because of the presence of lead acetate?

A I think there is a distinct hazard of absorbing lead to a sufficient extent to cause lead poisoning in some cases.

Q What are those cases? What do you mean by "in some cases?"

A Well, the susceptibility--

Q (Interposing) Of the individual.

A --to lead poisoning varies a great deal. There is no way of telling whether a small amount of lead such as one milligramme per day will cause lead poisoning in all cases, or 50 per cent of the cases, or whether it will take two weeks to cause chronic poisoning of lead, or two months, or two years. It varries according to the individual. And then it is a question of absorption, it would depend, of course, upon the extent of absorbability of lead through the skin. If there is an abrasion on the skin there is a great chance of the absorption of lead, there is a greater chance of the lead poisoning, but if the skin is healthy there is probably little chance for lead to be absorbed from the skin.

Q What results, Doctor, in cases where lead is absorbed through the scalp?

A Well, you get chronic lead poisoning which causes lead lime on the gums, anemia, lead colic, a general condition of malaise, a condition of general muscular weakness. These are the characteristic symptoms of chronic lead poisoning. We do not have to have all the symptoms to make a case of chronic lead poisoning. Any one of them is sufficient to make a diagnosis of chronic lead poisoning if there is reasonable evidence of lead absorption and that is generally determined by an analysis of the urine that lead is present.

In the event such testimony is deemed by the Commission to be insufficient to justify the position we recommend for lead and sulfur hair dyes, we express the hope that the decision will not rest on the point that positive proof of actual instances of injury is needed, for if this is in fact required to maintain such a case, (we interpret Mr. Kelley's memorandum of November 5, 1942, to suggest this) much of the possible protective value to the public health of the Federal Trade Commission Act is lost in other more important but generally similar circumstances.

Respectfully submitted:

J. J. DURRETT, M.D., Director,
Medical Advisory Division.

December 19, 1942.

RE 0013383