FEDERAL REGULATION OF DRUG ADVERTISING
1906-1948

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PREFACE

One of the major social questions facing America concerns the role of consumer advertising, its necessity, its pertinency, its honesty, and its responsibilities. Some popular advertising cynically manipulates the consumer and some of the most blatant of such abuses are found in the field of health products, specifically in the proprietary drug area. The advertising for these products often encourages the consuming public to diagnose and treat themselves for numerous physical ailments, real or imagined. Such preoccupation with health has created a vast public clinic—the media of the country—in which matters of health and personal care are treated.

While the regulation of advertising and promotion of ethical drugs—those advertised directly to physicians—is now tightly controlled by constant and severe federal regulation, similar surveillance of practices in advertising and promotion of proprietaries has historically been inadequate. This study is concerned with the question of why the regulation of proprietary drugs did not develop coincidentally with that of ethical preparations. An analysis of the historical development of controls over all types of drug promotion will document the administrative duplication, personal rivalry, shortsightedness, and erratic implementation which has impeded totally effective federal control of false and deceptive advertising. Of a remarkable nature is the extent to which administrative practice
and judicial interpretation, rather than Congressional legislation, determined the pattern of the development of federal regulation of drug advertising.

The source materials for this thesis were the records of litigation in the federal courts, Congressional records, debates and reports, biographies of notable figures involved, contemporary newspaper and magazine accounts and commentaries, and the reform tracts which exposed some abuses and were, in fact, to some degree instrumental in the progress of regulation.
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CHAPTER I
THE REFORM PERIOD
1889-1906

During the nineteenth century the federal and state governments did very little to regulate the quality, purity, methods of preparation, or content of food and drugs, much less to control spurious advertising. In 1848 the federal government enacted legislation against the import of adulterated drugs. An attempt to secure comprehensive national protection against the adulteration and misbranding of food and drugs in 1879 was unsuccessful. Limited legislation against food and drug adulteration was enacted in 1888 for the District of Columbia alone and, in 1889, Senator Algernon S. Paddock of Nebraska introduced a bill which would have granted investigatory and control powers to the Department of Agriculture in the areas of food and drug production, advertisement, and sale.¹ But Senator Paddock's measure, receiving little support in the Congress and virtually none throughout the country, failed.²

For the next decade, Congress considered no significant legislation in the area of regulation of food and drug practices, and abuses became increasingly flagrant. Headache powders used narcotic substances as the base; some pain killers were potentially dangerous depressants; cough remedies intended for use by children and babies frequently contained opium and morphine. Moreover, advertising and labeling did not disclose content, qualitatively or quantitatively.3

Control of drug promotion in this period was literally non-existent, though the advertising was ubiquitous and almost uniformly deceitful. Print advertising for B and M Remedy, for example, "guaranteed" the alleviation of the following ailments:

Asthma, ataxia, bronchitis, blood poisoning, bowel trouble, coughs, colds, catarrh, cancer, dyspepsia, dandruff, eczema, fevers, gallstones, goiter, gout, hay-fever, influenza, gripe, leucorrhea, lumbago, laryngitis, neuritis, neuralgia, pneumonia, pleurisy, skin diseases, tuberculosis, tumors.4

Drug advertising, in fact, played a major role in the proprietary medicine and publishing industries. The W. T. Hanson Company was reported to have spent $500,000 annually on advertising for Pink Pills for Pale People. Similar expenditures were reported for Paine's Celery Compound and Buchu Compound.5 The Director of the Bureau of Chemistry in the Department of Agriculture was later quoted as saying that "the


4Arthur Kallet and F. J. Schlink, 100,000,000 Guinea Pigs (New York: Grosset and Dunlap, 1933), pp. 137-40.

amount of blood money coming in from patent medicine advertisements in this country at the beginning of the century I estimate to have been about a hundred million dollars annually.  "6

Some appeals for legislation appeared during the 1890's, but most of these were concerned primarily with food inspection.  "7 A national food and drug law was considered the ideal solution, but a uniformity of state laws was recognized to be a more realistic goal.  "8 False advertising was infrequently mentioned, and the philosophy of caveat emptor was, for the most part, unchallenged. Government interference in trade practices, such as advertising, was uncommon, and, as a New York state court remarked in 1891, "all persons must be presumed to have in common (the liberty) of suffering themselves to be humbugged."  "9

There were a number of leading participants in the reform movement, but Dr. Harvey Washington Wiley, Edward Bok, Samuel Hopkins Adams, and Upton Sinclair were probably the most influential. The increase in the size and intensity of the reform movement after 1901 can be

6Mintz, The Therapeutic Nightmare, p. 43.

7"Home Responsibility," Outlook, June 2, 1894, p. 996.

8"Pure Food Reform," Outlook, June 16, 1900, pp. 400-6.

traced in part to the writings and lectures of these men.

The first and most dedicated (in terms of years and effort spent for legislative reform) was Dr. Harvey Washington Wiley. Wiley, a medical doctor with a Ph.D. in chemistry, had not only campaigned for effective food and drug laws since 1885, but had worked actively as well to identify deficiencies and to improve techniques for protecting and preserving edibles. Through the position of Chief of the Bureau of Chemistry, Department of Agriculture, Wiley had the opportunity to oversee all commercial practices in food, drugs, cosmetics, and pesticides. However, without the power to enforce, he was left virtually impotent in practice. At this point, the Interstate Commerce Commission held the sole power of regulation of business activities in the United States, as derived from the Sherman Anti-Trust Act of June 2, 1890, but the Act was limited only to the prohibition of combinations or conspiracies in restraint of trade.10

Nevertheless, Dr. Wiley and his supporters continued to direct their efforts at reform, specifically at the misbranding, mislabeling, and fallacious advertising prevalent in the food and drug industries. For example, one of Wiley's colleagues, Professor E. F. Ladd, Food Commissioner of North Dakota, reported nationally that "potted chicken" and "potted turkey" sold commercially contained in fact no chicken or turkey; that the quantity of maple syrup labeled "Vermont" sold in

10 Sherman Anti-Trust Act, 26 Stat. 209.
the United States each year exceeded the total maple syrup production of Vermont several times over; that 70 per cent of the chocolate on the market was ersatz.11

The work of three other reform-minded writers also assisted in broadcasting the dangers of impure food and drugs. Mr. Edward W. Bok, editor of the Ladies’ Home Journal, had refused to accept advertising for patent medicines in 1892.12 In May of 1903, he wrote an expose of a number of popular proprietary medicines, notably Lydia Pinkham Vegetable Compound and Hostetler’s Stomach Bitters.13 This article, and six which followed,14 caused several popular remedies to be withdrawn from the market.15


Following the series in the *Ladies' Home Journal*, a second popular publication, *Collier's Weekly*, commissioned another reformer, Samuel Hopkins Adams, to continue the exposure of patent medicines. Adams concentrated on the alcohol content in many popular remedies and on the power of the manufacturers' advertising expenditures to affect newspaper content.\(^{16}\)

Another major force in the eventual success of the campaign for food and drug legislation was the appearance in 1906 of Upton Sinclair's *The Jungle*. This expose of the practices in government food inspections and the conditions in the slaughterhouses of Chicago brought to the surface the need for national legislation.\(^{17}\)


In a message to Congress on December 5, 1905, President Theodore Roosevelt recommended enactment of a law to regulate interstate commerce in misbranded and adulterated foods, drinks, and drugs. He suggested that such a law would protect legitimate manufacture and commerce and would tend to secure the health and welfare of the consuming public. Traffic in foodstuffs which have been debased or adulterated so as to injure health or to deceive purchasers should be forbidden, he asserted. On December 6, Weldon B. Heyburn introduced the Federal Pure Food and Drug bill.

The Pure Food and Drug bill did not receive the newspaper attention it might have if introduced at another time. In addition to the headline news of revolution in Russia, contemporary newspapers focused most attention on other elements of the President's message. The question of tariff revision and the maximum railroad rate proposal were the objects of major controversy. The New York Times of December 5, 1905, expressed the common feeling in business circles of the day that government's role does not include interference in business life. "The President cannot get it out of his mind," the Times asserted, "that the big corporations must be controlled at Washington--by the 'sovereign.'"¹

But other newspapers and periodicals did express approval of Roosevelt's message. In addition to the continuing support for a food and drug bill by the Ladies' Home Journal and Collier's Weekly, periodicals such as World's Work complained about nearly twenty years of Senate obstruction of a pure food law. Outlook repeated the warnings of cocaine and morphine contents.

However, many newspapers remained silent because of advertising revenue from patent drug manufacturers. Charities and the Commons printed prominently a letter from the manager of one of the largest proprietary companies in the country charging, in part, that, "Illiberal physicians, jealously desirous of a complete monopoly, are taking advantage of the present mania for muck-raking and psuedo reform to serve their own selfish purposes."

Perhaps the lead editorial in the New York Daily Tribune on December 6 best summed up the sentiments expressed by most newspapers and periodicals:

Some of his suggestions involve, if not novel conceptions of the functions of the federal government, far reaching efforts to adapt its instrumentalities to the new conditions

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under which, with the evolution of our business life, they must work.

The President wisely lays stress on the fact that at the present day much work which was formerly done by state authorities can no longer efficiently be performed by them.6

During the six-month period between the introduction of the legislation and late May of 1906 the Pure Food bill itself was overshadowed by the controversy over the general question of government control of business practices, especially with regard to the railroad rate bill and the meat inspection bill. The newspapers of the day carried virtually daily coverage of these bills during the period.

Popular support for regulation of food and drug products had in the meantime become what the New York Daily Tribune termed "the apparently strong tide" for passage. Thus, as a June vote approached, public support for legislation became more strident. The Tribune conjectured that the "fabricators of fraudulent food products and the makers of patent medicines" would probably have again succeeded in killing a strong bill "had not [the legislators] begun to hear from their constituents in no uncertain terms."7

In Congress, in the end, there was very little disagreement or even discussion of the pure food and drug legislation.8 Joseph W. Bailey of Texas and Porter J. McCumber of North Dakota engaged in mild

   U.S. Congress, House, 59th Cong., 1st sess., June 29, 1906, Congressional Record, XL, 9735, 9740. This record contains only approximately 8 1/2 pages devoted to the bill, including two full readings.
discussion of the possible violation of the proposed measure on the
document of "states rights," but Mr. Bailey was satisfied that the
threat was not serious. A question concerning the powers of the
Secretary of Agriculture to determine standards was settled. A con­
ference committee considered the variant House and Senate provisions
and because "the House bill differed in only a very few respects from
the provisions of the Senate bill," the bill emerged from the conference
committee with favorable agreement.

On June 25, 1906, the bill passed Congress and on June 30, 1906
Theodore Roosevelt signed the Pure Food and Drug Act into law.
Even previous opponents or critics of the bill now applauded its
passage. Although the actual bill-signing occasion was vastly over­
shadowed in the press by the sensational murder of Stanford White by
Harry K. Thaw the previous evening (the ceremony was noted in one
paragraph on page 4 in the New York Times), it was unanimously lauded
by the major publications and by the President himself.

The lead editorial in the previously ardently critical New York
Times on June 30, 1906, stated that never had so much been done, first,
to extend the federal power of regulation and control over the business

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9U.S. Congress, Senate, 59th Cong., 1st sess., June 28, 1906, Congressional Record, XL, 9495, 9496.
10Ibid.
11Ibid. at 9496.
of the country and, second, to cure and prevent abuses of corporate
privilege. The editorial praised the Congress' "unaccustomed" attempt
to meet the people's demands for protection of restraints against trade,
monopoly abuses, unfair discriminations, and the preparation and
sale of adulterated and unwholesome food products. Finally, the
editorial declared, "The Pure Food and Drug bill brings up with a round
turn a multitude of the country's meanest swindlers—the detestable
wretches who sell all manner of alimentary and medicinal preparations
under lying labels."¹³

It is of ironic passing interest that the same issue of the
Times carried advertisements for Warner's Safe Cure for Kidney Disease,
Carter's Little Liver Pills ("Absolutely Cure Biliousness, Sick Headache,
Torpid Liver, Furred Tongue, Indigestion, Constipation, Dizziness,
Sallow Skin") and in the following issue the testimony of Bishop L. H.
Holsey that "Ministers of all Denominations Join in Recommending
PE-RU-NA to the People" for protecting the throat and bronchial tubes
to catarrhal infections.

Most coverage of the signing of the Federal Pure Food and Drug
Act declared its passage as a victory for President Roosevelt, and
fittingly so in view of his initiative and active support. But the
Congress and the public recognized the work of Dr. Harvey Wiley and the
law became known as the Wiley Act.

The Wiley Act ranged over a wide spectrum of problems in food and drug manufacture, distribution, and sale. Particularly important at the time were sections on adulteration and inspection. But for the purposes of this paper the important legislation was contained in Section V, Subchapter III:

That the introduction into any State, Territory, or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of the Act (is hereby prohibited).14

The law granted the power of implementation and regulation to the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor.15 It further provided that,

The examination of foodstuffs and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act. . . .16

So although Wiley's Bureau of Chemistry was entrusted with the determination of adulteration and misbranding under the Act, the law did not grant the Bureau any enforcement power over deceitful promotion. Furthermore, so-called patent or proprietary medicines had been specifically excluded. In his study, The Health of a Nation, Oscar E. Anderson Jr. reports that on June 22, 1906, the Proprietary Association and other trade interests had managed to extract patent

14Pure Food and Drug Act, 34 Stat. 768 (1906).
15Ibid. at 768-9.
16Ibid. at 769.
medicines from the scope of the law by persuading the Congress to narrow the definition of "drugs" to include only products recognized as medicines in the United States Pharmacopeia and the National Formulary. Proprietary drugs were not so listed because, under the traditions of property rights, the manufacturer held a patent to the preparation which did not require him to disclose his manufacturing processes and mixture preparation procedures. They were thus unlisted in the Pharmacopeia and Formulary.

So Section II(g) of the law as enacted provided that only those drugs listed in the Pharmacopeia or Formulary were to be considered "drugs." Furthermore, in cases of adulteration, proprietaries were again excluded by Section 7, Article 1,

If, when a drug is sold under a name recognized in the United States Pharmacopeia or National Formulary, it differs from the standard of strength, or purity, as determined by the test laid down in the United States Pharmacopeia or National Formulary official at the time of investigation [it shall be deemed adulterated]. (Emphasis added.)

And Section 7, Article 2, while encompassing most patent medicines, would not declare them adulterated if the ingredients (though not necessarily proportions) and strength were declared,

If its strength or purity fall below the professed standard or quality under which it is sold [it shall be deemed adulterated]. (Emphasis added.)

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18Pure Food and Drug Act, 34 Stat. 768.
19Ibid. at 769.
20Ibid. at 770.
Thus, to a great extent, the law was meaningless. The term "misbranded" was to cause years of confusion and litigation. The federal authorities were thus left virtually powerless to regulate effectively consumer drugs, even those in interstate commerce. "During the entire era," Morton Mintz states in The Therapeutic Nightmare, "the chief problem concerned non-prescription products. These had been the greatest menace." Dr. Wiley evidently felt this too when he alerted an ally, Representative James R. Mann of Illinois, saying that "the bill might as well not contain anything in regard to patent medicines."21

Few products advertised to the general public in 1906 were listed in the United States Pharmacopeia or the National Formulary. Very few medicines prescribed by physicians were even manufactured as finished products; most prescriptions were compounded by the pharmacists. Not until 1938 did further legislation begin effectively to control proprietary drug advertising.

Even after the passage of the Wiley Act, the realization of its limitations caused some public distress. While a leading magazine could say in May of 1908 that some patent medicines were being excluded from reputable periodicals,23 many other popular magazines decried the ineffectiveness of the Wiley Act. World's Work commented that despite the Food and Drug Act, "there is at present no standard

21Mintz, The Therapeutic Nightmare, p. 50.
23"Victory for Decency," Outlook, May 23, 1908, p. 135.
authority." Further, "this lets the public know that the article will not do any harm [which did not later prove true], but puts no limit on the exaggerated claims for it." The Independent complained that even medicines advertised direct to physicians in medical journals (often published by a manufacturer) were "worthless or fraudulent."

But the Pure Food and Drug Act of 1906 was not totally insignificant. First, it was a piece of social legislation reflecting the conscience of the American people in the field of public health. Second, although regulation of interstate commerce in itself was not the primary intent, the Act did represent another major initiative by Congress to regulate such trade. Third, the law placed a definite responsibility on the federal government to investigate food and drugs. Fourth, it was a major victory for Teddy Roosevelt and a segment of the progressive groups. It did, however, prove totally ineffective in inhibiting false advertising. As Theodore Roosevelt later wrote, "the Pure Food Law represented a great step in the right direction . . . no respectable magazine publishes [false advertising], but the great majority of the newspapers print it without limitation

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and probably gain as much money from it as from the financial advertisements."27

For the next five years, Dr. Wiley's program of reform was hampered primarily by two circumstances. Of paramount importance was the imprecision of the language in the Pure Food and Drug law. The exact meaning of the Wiley Act regarding drugs was not clear to either government or business groups. Concurrently, within the Department of Agriculture itself Wiley encountered opposition led by the Department's Solicitor, George P. McCrab. Two-thirds of the prosecutions recommended by Wiley were blocked by the Board of Food and Drug Inspection of which McCrab was an influential member.28 Solicitor McCrab also assumed control of the enforcement activities of the Bureau of Chemistry by writing into the Department of Agriculture's appropriation request for 1910 the extension of his powers to encompass all legal activities of the Department. He then prepared an order, approved by the Secretary, specifically assuming the authority for the Bureau's enforcement activities. So, while neither had power over false advertising, the solicitor in the Department of Agriculture, rather than the scientists of the Bureau of Chemistry, decided which products contained ingredients not permitted by law.29


29Ibid., pp. 115-6.
In late 1909, the vagueness of the Food and Drug Act with regard to "misbranding" and the proliferation of deceitful advertising prompted the Department of Agriculture to undertake an indictment for false advertising. The federal government alleged untrue advertising against the producers of a preparation known as Dr. Johnson's Mild Combination Treatment for Cancer.

The Federal District Court of Missouri declared that interpretation of the Food and Drug Act must be "restrained to its expressed, reasonable intendment [or else the courts] may extend its operation far beyond the legislative intent," and refused to uphold the Federal Trade Commission's cease and desist order. The government eventually took the case to the Supreme Court.

The argument for the United States revolved primarily around the intent of Congress and the public in demanding a pure food and drug law, as reflected by "public agitation" and legislative history. The Solicitor General pointed out that "the practice of patent-medicine concerns to make extravagant cure-all claims was one of the principal evils denounced in the public agitation contemporaneous with the progress of the bill." The government's arguments concerning the intention of Congress rested rather uneasily on what Congress did not do because they felt it unnecessary to be specific.

The defense presented three primary arguments as summarized by the court. First, on the question of the meaning of the term


31 Ibid.
"misbranded," it was argued that the word is confined to representations concerning the identity of the drug, its constituents, or chemical ingredients; it does not refer to claims for curative properties. Second, with respect to the question of medical opinion, the Johnson Company contended that a claim for beneficial results is not a statement of existing fact, but a forecast and is therefore an expression of opinion. Finally the defendant argued that the construction sought by the government (that the "misleading" statute extends to claims concerning the curative powers of medicines or drugs) would render the statute void as beyond the power of the Congress to enact.

The Court's six-three decision for the defendant was rendered in the opinion read on May 29, 1911 by Associate Justice Oliver Wendell Holmes. He noted that the case revolved on the meaning of the word "misbranded" and fundamentally supported the defense. It is a postulate, he said, that in a certain sense the statement on the Johnson label was false, or at least misleading. The necessary decision, he continued, should be whether such misleading statements are aimed at and hit by the words of the Act. The phrase "misleading" should not be construed, he felt, to be aimed not at all possible false statements, but only at those which determine the identity of the article, possibly

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32 Ibid. at 489, 491.
33 Ibid. at 494.
34 Ibid.
35 Ibid.
including strength, quality, and purity. Finally, to the heart of the question, Justice Holmes said,

But such a statement as to contents, undescribed and unknown, is shown to be false only in its commendatory and prophetic aspect, and as such is not within the Act.

Justice Holmes also supported Johnson, though not as strongly, on the question of medical opinion and the determination of medical effects. The determination whether an article should be declared misbranded, he wrote, was left to the Bureau of Chemistry of the Department of Agriculture, which would be most natural if the question concerns ingredients and kind, but hardly so as to medical effects.

Finally, Holmes' support of the defendant's position on the question of constitutionality was guarded, but, more important, opened the door for further exploration of the question. Congress, he pointed out, was much more likely to regulate commerce in food and drugs with reference to plain matter of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort its constitutional powers to establish criteria in regions where opinions are far apart.

Thus the Supreme Court ruled that advertising statements relate only to the identity of the product and not to its curative powers.

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36 Ibid. at 496.
37 Ibid.
38 Ibid. at 497.
39 Ibid. at 498.
However, the dissenting justices—Hughes, Harlan, and Day—did perceive an injury to the law and their opinions would eventually advance more liberal construction. Justice Hughes' dissenting opinion would, in fact, be cited in the following year as the basis for an amendment to the Wiley Act. He asserted that the court was ascribing "an altogether undue weight to the wording of the clause and [overlooking] the context." He wrote further that "granted the wide domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative powers are downright falsehoods and . . . not expressions of judgment. This field I believe this statute covers . . . ."

In 1912 Representative Swagar Sherley of Kentucky submitted an amendment to include false advertising in the prohibitions under the Wiley Act and used the dissenting opinion of Charles Evans Hughes in the Johnson case as the rationale for the amendment.

This effort to include untrue claims of efficacy under the meaning of "misbranded" was signed into law on August 23, 1912 and became known as the Sherley Amendment. However, during the hearings on the bill, Mr. Charles M. Woodruff of Parke, Davis and Company suggested

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40 Ibid.
41 Ibid.
42 Ibid. at 502.
43 Ibid. at 504.
that the words "false and fraudulent" be used in the law with regard to repugnant advertising. The suggestion was accepted, and Section 8 of the Pure Food and Drug Act of 1906 was thus amended to define "misbranded" as

If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

[emphasis added]

But the words "and fraudulent" enfeebled the amendment by placing upon the government the exceedingly difficult task of proving fraudulent intent. Primarily for this reason the law was, in practice, virtually ineffective; and the six years of effort, 1906-1912, passed with only theoretical control of ethical products and absolutely no regulation of proprietary drug advertising, save for cases of clearly criminal fraud.

\[^{45}{\text{Anderson, The Health of a Nation, p. 236.}}\]

\[^{46}{\text{U.S. Congress, House, 66th Cong., 2d sess., Aug. 19, 1912, Congressional Record, XLVIII, 11322, 11323.}}\]
CHAPTER III
THE FEDERAL TRADE COMMISSION
AND THE YEARS OF VACUUM

The formation of the Federal Trade Commission in 1914 was in no way derivative from the activities surrounding the Pure Food and Drug Act and the Sherley Amendment. "The genesis of the Federal Trade Commission stems directly from the economic history of the latter half of the nineteenth and the first decade of the twentieth centuries."¹ The control of a specific business abuse—monopoly—was the reason for the formation of the Federal Trade Commission. The growth of monopoly since the end of the Civil War had first been effectively challenged by the Sherman Anti-Trust Act of 1890, and it was from this measure that the formation of the Federal Trade Commission subsequently derived.

It was, in fact, more than seven years after the organization of the Federal Trade Commission that a Supreme Court decision in the Winstead Hosiery case² recognized the Commission to have limited jurisdiction over advertising.³ But drug advertising did eventually fall within the jurisdiction of the Federal Trade Commission,

²United States v. Winstead Hosiery, 272 F. 957 (1922).
though at varying times and in varying degrees.

The Sherman Act of July 2, 1890 had never been as effective as envisioned by its drafters. The Act revolved around Section 3 which prohibited "every contract, combination in form of trust or any conspiracy in restraint of trade." But serious difficulty had arisen in the categorization of just what constituted commerce and restraints of trade. In 1895, the Supreme Court had held that the American Sugar Refining Company—although it controlled 90 per cent of the sugar refining capacity of the country—was not restraining or monopolizing interstate commerce. Moreover, even if "commerce" could be adequately defined, which acts to be considered dangerous under the law could be disputable because virtually all contracts or agreements affect trade and commerce. Thus, in 1911, the Supreme Court decided in the Standard Oil and American Tobacco cases that "the Anti-Trust Act must be construed in the light of reason" and, as so construed, "it prohibits all contracts and combination which amount to an unreasonable or undue restraint of trade in interstate commerce." The Court further affirmed the "reasonable construction" dictum in

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noting that all contracts directly or indirectly affect and possibly restrain commerce.\(^9\) So, although the Court had upheld the government, it had also placed the very heavy burden of proving "unreasonableness" upon the federal government and had rendered the Sherman Act useless against many forms of abuse.\(^10\)

Primarily because of what had proven to be such inadequacy in the Sherman Act, Congress passed the Federal Trade Commission Act in September, 1914.\(^11\) Section 5 of the Act carried its import,

That unfair methods of competition in commerce are hereby declared unlawful. The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, and common carriers subject to the Acts to regulate commerce, from using unfair methods of competition in commerce.\(^12\)

A later House amendment (Section 5b) added a significant clause: "and if it shall appear to the commission that a proceeding by it in respect thereof would be of interest to the public."\(^13\) This clause would later form the basis of liberal interpretation of the Act to include false advertising. While the legislative history and debate reveal definitely that Congress intended only to supplement and strengthen the Sherman Act and had no intention of regulating advertising as it affected consumers, the Federal Trade Commission would later attempt,

\(^12\)Ibid. at 719.
\(^13\)Ibid.
with some success, to assume this authority on the basis of the "public interest" phrase which had been inserted originally only "to prevent the Commission from becoming a clearing house to settle the every day quarrels of competitors."\(^\text{14}\) Thus the Federal Trade Commission was to be a "non-partisan, independent tribunal"\(^\text{15}\) with the duty "to aid in enforcement of the Sherman Anti-Trust law"\(^\text{16}\) and especially, in the words of Senator William S. Kenyon of Iowa, one which could "take hold of matters that are not in themselves sufficient to amount to a monopoly or to amount to restraint of trade."\(^\text{17}\)

That the sole purpose of Congress was to control monopoly through maintenance of competition was repeatedly stressed in debate, but false advertising was not a consideration. Debate between Senator Cummins and Senator Borah indicated that unfair competition consisted solely of "that violence of competition conducted through unfair practices and methods and which must ultimately result in the extinction of the rival and the establishment of a monopoly."\(^\text{18}\) Senator Cummins later stated that to sustain competition "is the only justification

\(^{14}\)U.S. Congress, House, 63d Cong., 2d sess., Sept. 10, 1914, Congressional Record, LI, 14930, 14936.

\(^{15}\)U.S. Congress, Senate, 63d Cong., 2d sess., June 27, 1914, Congressional Record, LI, 11235.

\(^{16}\)U.S. Congress, Senate, 63d Cong., 2d sess., June 13, 1914, Congressional Record, LI, 10376.

\(^{17}\)U.S. Congress, Senate, 63d Cong., 2d sess., August 3, 1914, Congressional Record, LI, 13156.

\(^{18}\)U.S. Congress, Senate, 63d Cong., 2d sess., June 25, 1914, Congressional Record, LI, 11103.
for the establishment of a trade commission."¹⁹

Senator Joseph T. Robinson made the only reference to the question of advertising—though not to false advertising—in his statement that unfair competition "may now be said to embrace every unjust, dishonest, and inequitable practice by which one seeks to unfairly destroy or injure the business of a competitor."²⁰ He was referring, however, to unfair competition as enjoined in United States versus American Thread Company.²¹ This injunction prohibited attacking the credit or business reputation or quality of product dealt in by a competitor by means of any report known to be false and which further prohibited "warning, harassing, threatening . . . by . . . advertisements, any other person."²² This obviously was not a reference to spurious and deceitful claims for one's own product.

Further references were made to "competition on the part of one against the other"²³ and to "stifling of competition,"²⁴ and to

¹⁹Ibid. at 11104.

²⁰U.S. Congress, Senate, 63d Cong., 2d sess., June 27, 1914, Congressional Record, LI, 11228.

²¹Ibid. at 11230.

²²U.S. Congress, Senate, 63d Cong., 2d sess., June 27, 1914, Congressional Record, LI, 11230.

²³U.S. Congress, Senate, 63d Cong., 2d sess., June 25, 1914, Congressional Record, LI, 11112.

²⁴U.S. Congress, Senate, 63d Cong., 2d sess., July 16, 1914, Congressional Record, LI, 12210.
"stopping monopoly at the threshold." Finally, Senator LeBaron B. Colt of Rhode Island foresaw and speculated on future judicial interpretations of "unfair competition" and advised that "if Congress desires to enlarge the meaning of unfair competition as known to the law, it should do so in express terms, so that the business community may know what is legal and what is illegal."26

But the Congress declined to define precisely what "unfair competition" should embrace and the bill was signed by the President on September 26, 1914. There is no convincing evidence that the Federal Trade Commission Act was ever intended to protect the consumer, except indirectly through the maintenance of competition. This interpretation was to come later, through administrative practice and case law.

In addition to the internal limitations of the Federal Trade Commission Act, in October of 1914 the Congress reaffirmed its desire not to interfere substantially in business practices by passing the Clayton Anti-Trust Act.27 Fundamentally, this legislation interdicted some commercial practices, but only if their effect was to "substantially lessen competition or tend to create a monopoly. . . ."28


26 U.S. Congress, Senate, 63d Cong., 2d sess., Aug. 3, 1914, Congressional Record, LI, 13154.

27 Clayton Anti-Trust Act, 38 Stat. 730 (1914).

28 Ibid. at 731.
It should be noted here that during the legislative and judicial turmoil of the period 1911-1914—on the question of control over business—there had not been the widespread interest and partisanship outside of the opposing interest groups that might have been expected. But during September and October of 1914, the passage within a month of two apparently far-reaching laws to regulate commerce brought forth a number of journalistic reactions—although the popular interest which carried so much weight for the Pure Food and Drug bill was absent.

On September 1, the New York Times entitled its lead editorial "Hothouse Commerce,"

The idea that capital works hardest when clubbed is still uppermost among the legislators. If capital refuses to invest under conditions which it has rejected for many years, why, then, is it necessary to make the terms of investment still less attractive?²⁹

The Washington Post argued against the Federal Trade Commission Act and the Clayton Bill on September 22, describing them as striking "deliberately at the heart of business" and "filled with pitfalls."³⁰

Again, on September 26, the Washington Post devoted its editorial space to "Unnecessary Legislation,"

If there has been any public demand for the enactment of these measures the evidence of it is not apparent. There has been a strong and determined protest against the Clayton bill from harassed business men, but it is doubtful whether there have been any letters or telegrams advocating the bill.³¹

On October 10, under the headline "Two-Faced Legislation," the New York Times condemned the Federal Trade Commission bill as follows:

The clue through all this confusion seems to be that it is wrong to do by agreement, or by "conspiracy in restraint of trade." Yet all experience shows that law is the worst regulator of trade, apart from trade conduct. It imposes trade standards which are not those of trade. . . . It establishes a statutory morality and substitutes it for the custom of good merchants and the findings of a jury of a business man's peers. It is this element which makes it disturbing to trade and enterprise. The law starts without prestige and has a difficult way to make to the esteem of men upon whom the country's prosperity depends.32

As stated, there was apprehension, misapprehension, confusion, and ignorance about the legislation. It might be speculated that a combination of the textual weaknesses of the bills, the outbreak of World War I, and the feeling in some quarters that the Federal Trade Commission Act was simply an administrative adjustment created the atmosphere of general flux and uncertainty responsible for confusion.

Thus, although there was confusion about what the Federal Trade Commission Act and the Clayton Act did exactly mean, it was apparently generally accepted that neither covered any activities which were not directly injurious to competition and that false advertising per se was not so covered. Therefore the Federal Trade Commission Act and the Clayton Act joined the Wiley Act and Sherley Amendment in ineffectiveness as measures of consumer protection against deceitful and spurious advertising.

The Federal Trade Commission assumed its functions in 1915, then, with the mandate to protect competition. But the Commission interpreted its powers somewhat more broadly than had Congress and began to move against false advertising. The first test case was Sears Roebuck and Company versus Federal Trade Commission, and the decision was read on April 29, 1919. The Federal Trade Commission averred that the Sears Roebuck Company had practiced unfair methods of competition for two years by false and misleading advertisements and acts, designed to injure and discredit their competitors and to deceive the general public. The Commission asked the court to command the petitioners to cease and desist from unfair methods of competition in commerce and also to "review" the powers of Section 5 of the Federal Trade Commission Act.

The decision of the court hinged primarily upon the constitutional question of the quasi-judicial status of the Federal Trade Commission, and, hence the validity of its orders. In this case, the court recognized the powers of the Federal Trade Commission but did not recognize a direct injury to competition because the Federal Trade Commission had not proven that competition had in fact been injured. However, a dissenting opinion directed attention to the alleged false or unfair

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34 Ibid.


36 Ibid., p. 37.
advertising. It noted that the Federal Trade Commission Act authorized the Commission to proceed when it had reason to believe that unfair methods of competition are or have been used and "if it shall appear to the Commission that a proceeding by it in respect thereof would be of interest to the public."37 Although the advertisement in question was too "stale" to deserve revival as a point in evidence, the dissenting opinion in the Sears Roebuck case was the first judicial notice of the public interest in respect of the Federal Trade Commission Act, without regard to the question of competition.

Ironically, as noted above, the phrase concerning the interest of the public was not inserted with any thought of false advertising or even other fraudulent practices. It was added solely because, in the words of Representative J. H. Covington of Maryland, the provision "prevents the Commission from becoming a clearing house to settle the everyday quarrels of competitors, free from detriment to the public, which should be adjusted through the ordinary processes of the courts."38 But, in spite of the obvious intentions of Congress, the question of the domain of the public interest had at least been recognized in a federal court as worthy of argument. The Federal Trade Commission took from this a cue for future litigation.

However, from the Federal Trade Commission's viewpoint, this was still only a minor glimmer of light for its position. Generally,


the courts were not anxious to support a quasi-judicial federal agency against private enterprise. The attitude of the courts is amply demonstrated in the decision in Federal Trade Commission versus Gratz, also in 1919. In this remarkable opinion, the court declared that the words "unfair methods of competition," as used in the Act, "... are clearly inapplicable to practices never heretofore regarded as opposed to good morals because characterized by deception, bad faith, fraud, or oppression, or as against public policy because of their dangerous tendency unduly to hinder competition or create monopoly." Further evidence of the conservative stance of the courts appeared in 1920 in Federal Trade Commission versus Beech-Nut Company. In a question of maintenance of resale prices, the Supreme Court found that "such a method of preventing competition ... between purchasers constituted merely the exercise of a man's right to do what he will with his own," and was not in violation of the Federal Trade Commission Act.

The inevitable question of the constitutionality of the Federal Trade Commission Act was settled, also in 1920, in the case of the National Harness Manufacturer's Association versus Federal Trade Commission. The Manufacturer's Association contended that it was

contrary to Articles 1, 2, and 3 of the Constitution to confer legislative, executive, and judicial powers and functions on an administrative body such as the Federal Trade Commission. The Court found, however, that Congress did have the power to authorize an administrative body to determine questions of fact as to what methods of competition any trader used, and to decide provisionally whether such methods were unfair in terms of law and fact. The Court held the Commission's authority to be a valid executive and administrative one and, since by the terms of the Act creating it no order of the Federal Trade Commission could be enforced without obtaining an order from the Circuit Court of Appeals, no judicial powers had in fact been delegated to the Commission.  

In September of 1921, the original intent of Congress, i.e. the protection of competition, was reaffirmed in Kinney-Rome versus Federal Trade Commission when the court expressed the opinion that there must be some fraud in trade that demonstrably injures a competitor or lessens competition before it can be said that there has been an unfair method of competition.  

What appeared to be a far-reaching breakthrough for regulation of false advertising came in 1922 in Federal Trade Commission versus Winstead Hosiery. In this case, concerning the mislabeling of clothing products as "Australian Wool" and "Natural Wool," the Supreme

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Court reversed a lower court in holding for the Federal Trade Commission. The Court held that "the labels in question are literally false. . . ." All the labels were, as the Commission determined," calculated to deceive and do in fact deceive, a substantial portion of the purchasing public—the facts show that it is in the interest of the public that a proceeding to stop the practice be brought." The Court did point out that such deceitful advertising also injures competitors because trade was diverted from the producer of truthfully marked goods.

So the Court had officially adopted the minority view of the domain of "public interest" expounded in the Sears Roebuck case of 1919, i.e. that there is in fact a public interest in existence which is concerned with the welfare of the general populace apart from questions of competition. The idea that "the public had an interest in stopping the practice as wrongful" became a point of case law.

In a later important case considered below (L. B. Silver Company versus Federal Trade Commission, 289 F.985) it was determined that the Winstead Hosiery decision actually involved "mere palming off" and was like any other misdescription or misbranding. Thus it was not a fiat necessarily to apply the "public interest" concept to advertising.

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Silver Company v. Federal Trade Commission, 289 F.985,
But the precedent had been made and was to be used in numerous later cases. If nothing else, it would become valuable as an articulation of the concept of public interest.

The Royal Baking Powder case, also in 1922, was clearly a situation of mere "palming off" a product as another and the Winstead Hosiery decision was applied. But perhaps the significance in the decision against the Royal Baking Powder Company was the apparent change in attitude toward unfettered private business displayed by the court. The decision included this stern warning:

The purpose of the Congress in creating the FTC was aimed at just such dishonest practices, and business concerns that resort to dishonest devices of this nature must understand that they cannot add to their revenue or maintain their business standing by methods of competition which the law brands as "unfair" and therefore unlawful.50

The Federal Trade Commission, now apparently encouraged by the minority recognition of "public interest" in the Sears Roebuck case and by the Winstead Hosiery and Royal Baking Powder decisions, attempted to apply these precedents to the L. B. Silver Company, a producer of deceitful advertising of hogs for sale. But the Circuit Court of Appeals struck down the Commission's argument primarily because the general public was not affected. Judge Denison accused the Federal Trade Commission of wasting the federal courts' time and wrote scathingly that the

... commission has adopted the theory that the "unfair methods of competition" denounced by Section 5 [of the Federal Trade Commission Act] include all false [and] unethical advertising and promotion ... by which ... the public ... may be, in a substantial way, misled. The vista of business censorship seen through such an opening is limitless.51

The opinion further stated that the jurisdiction of the Commission was limited to situations indicating at least a substantial appearance of restraint of trade or monopoly.52 The Federal Trade Commission, possibly realizing the basic weakness of the case as a test involving "public interest" did not appeal to the Supreme Court and, following this decision in February, 1923, did not press a significant false advertising case until 1929.

At that time Justice Louis Brandeis in Federal Trade Commission versus Klesner noted that action by the Federal Trade Commission under the "public interest" clause could not be satisfied merely by proof that there had been misapprehension and confusion among purchasers or even that they had been deceived—unless fraud was clearly involved.53 But he left a possible opening for future Federal Trade Commission action "in the public interest" by suggesting that there may be cases in which the real loss to each individual due to confusion might be too small to warrant a private suit, with or without the involvement of fraud, although the aggregate of the loss might be so serious and

52Ibid. at 993.

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widespread as to make the matter one of public interest.\textsuperscript{54}

The frequently vague and contradictory judicial opinions on Section 5 of the Federal Trade Commission Act had hampered, if not actually thwarted, the administrative interpretation of the Act. A final, definitive judgment of the legal validity of the concept of "public interest" without regard to competitive injury became necessary. To force this decision, the Federal Trade Commission filed suit asking that the Raladam Company, manufacturer of the obesity remedy \textit{Marmola}, be ordered to cease advertising the preparation with statements allegedly false and misleading.\textsuperscript{55}

The Commission's order reduced to two prohibitions. First, it proscribed the representation that \textit{Marmola} was a scientific remedy for obesity. Second, the Commission forbade advertising the drug as a remedy for obesity unless the promotional material and literature bear the statement that the medicine is not safe unless taken under the supervision of a competent physician. On the other hand, the Raladam Company alleged that the Commission's findings were not supported by evidence and that it lacked jurisdiction.\textsuperscript{56}

The Court first dismissed the question of fraud on the part of Raladam because the safety of the drug could be a matter of professional opinion. It also dismissed the respondent's contention that the Federal

\textsuperscript{54}\textit{Ibid.} at 28.

\textsuperscript{55}\textit{Federal Trade Commission v. Raladam Company, 283 U.S. 643 (1930).}

\textsuperscript{56}\textit{Ibid.}
Trade Commission injunction was a violation of the First Amendment to the Constitution.\(^\text{57}\)

Associate Justice George Sutherland read the decision in favor of Raladam. However, he accepted several of the Commission's arguments. He concurred that probably the advertising methods were indeed unfair and noted that "if the necessity of protecting the public against dangerously misleading advertisements of a remedy sold in interstate commerce were all that necessary to give the Commission jurisdiction, the [cease and desist] order could not be successfully assailed.\(^\text{58}\) He also agreed that "elimination [of the advertising in question] would tend to the public good\(^\text{59}\) and that prevention of such methods would be in the interest of the public.\(^\text{60}\) But the court found that the third requisite, that the unfair methods of advertising are methods of competition in commerce, was not proven.\(^\text{61}\) Justice Sutherland said that the action forbidden by the statute was "unfair competition," and that nothing can be unfair where there is no significant competition.\(^\text{62}\) He continued:

It is apparent . . . that the Commission does not take this limited view of its jurisdiction, but that it believes itself authorized to issue its "cease and desist" orders in any

\(^{57}\text{Ibid. at 646.}\)

\(^{58}\text{Ibid.}\)

\(^{59}\text{Ibid.}\)

\(^{60}\text{Ibid.}\)

\(^{61}\text{Ibid.}\)
case where it concludes that sales methods may mislead a substantial part of the purchasing public, in a way and to an extent that, in the judgment of the Commission, is injurious to the purchaser. The general law of unfair competition uses the misleading of the ultimate retail purchaser as evidence of the primary vital fact, injury to the lawful dealer; the Commission uses this ultimate, presumed injury to the final user as itself the vital fact.63

And this had in fact been the philosophy of the Federal Trade Commission in its movement against false and spurious advertising—the protection of the consumer as a worthy goal of "public interest" in itself. But the Raladam decision ended the Federal Trade Commission's efforts to enjoin the dissemination of false advertising under the existing laws. The Commission did not undertake major litigation against abuses in this field until it had helped to secure more powerful legislation in 1938. The regulation of non-label drug advertising at this point was virtually nonexistent, but advertising abuses were not.

"There is no federal legal limit to the false and misleading statements which may appear in newspapers, magazines, almanacs, dodgers, and billboards," reported the New Republic in 1927. "As patent medicines are bought primarily by virtue of non-package advertising, the [label] protection is thus more nominal than real."64 The authors pointed to dozens of the worst abuses. La-Mar Reducing Soap was termed "unadulterated hokum" by Dr. Arthur J. Cramp, Director of the Bureau of Investigation of the American Medical Association. Jess Willard's victory over Jack Johnson was attributed to Nuxated Iron;
three years later Jack Dempsey credited Nuxated Iron for his win over Willard. Mailing lists of persons afflicted with specific diseases were offered for sale. Many of the non-label false advertising abuses had been untouched by the legislation which might have been valuable in controlling it.

During the period that the Federal Trade Commission had attempted to establish its authority over proprietary advertising, the Bureau of Chemistry in the Department of Agriculture had not been active in control of drug "labeling." Its inactivity resulted primarily from having been saddled with the burden of proving fraud by the Sherley Amendment and having been forced to cede some authority to Solicitor McCrab. Furthermore, the Bureau had been without the guidance of Dr. Harvey Wiley. In 1911, Dr. Wiley had hired a colleague, Dr. Henry H. Rusby, for consultancy at a fee of $1,600. Solicitor McCrab and Frederick L. Dunlap, both of whom served with Wiley on the Board of Food and Drug Inspection, instigated an investigation and Wiley was charged with the misuse of government funds. He was exonerated by a Congressional Commission but resigned in March of 1912. Mr. Roscoe Doolittle, a long-time subordinate, succeeded Wiley as head of the Bureau. But, perhaps lacking Dr. Wiley's aggressiveness,

65 Ibid.
66 Anderson, The Health of a Nation, pp. 244-5.
the Bureau did little to control mislabeling and misbranding. The Federal Trade Commission, on the other hand, had limited experience in ethical medicines and limited funds, in addition to its jurisdictional difficulties in the courts. There is no evidence that it made any effort to assume authority by default over the promotion or packaging of ethicals.

In 1927, the Bureau of Chemistry was reorganized and renamed the Food, Drug, and Insecticide Administration. The agency remained in the Department of Agriculture with regulation of ethical drugs to be a major function. In terms of statutory authority, however, the new Food, Drug and Insecticide Administration was in no better regulatory position than Wiley's Bureau of Chemistry had been in 1912. Control over advertising of ethical preparations still operated under the "false and fraudulent" clause of the Sherley Amendment. It was not until 1938 that new legislation provided more comprehensive authority.
CHAPTER IV

THE PERIOD OF DIVISION:

THE WHEELER-LEA AND COPELAND ACTS

1933-1948

The Great Depression brought a growing awareness of all social responsibilities and, as a by-product, a resurrection of interest in the control of consumer advertising. Several members of Congress, notably Senators Burton K. Wheeler and Royal S. Copeland and Representative C. F. Lea, advanced plans for new legislation in the regulation of food and drug products. But solutions to more pressing social problems were in planning and development stages and took precedence over major efforts at the control of advertising.

But in 1937 a national tragedy ensured the speedy passage of corrective legislation. The Massengill Company of Tennessee marketed a brand of sulfa-family drug, trademarked "Elixir of Sulphanilamide."\(^1\) The preparation had been compounded with a toxic solvent, though simple animal testing would have exposed the poisonous solvent, and at least 108 Americans died within a few weeks. Under existing law there was no basis for the Food, Drug and Insecticide Administration even to seize the product. However, the federal government was finally able to seize the drug—but only on the basis that the word "Elixir" in the trade

\(^1\)Ernest Q. King, "New Drugs" in Welch and Martí-Ibanez, The Impact of the F.D.A. on Our Society, pp. 30-1.
name implied the presence of alcohol while there was in fact, none; hence the medicine was misbranded.\textsuperscript{2} Had the product been trademarked a "Solution," the regulatory authorities would have been powerless.\textsuperscript{3}

Public realization of the impotence of the government in controlling the activities of pharmaceutical manufacturers brought demands for immediate legislation. Although the contamination of an ethical product, sulphanilamide, was for the most part responsible for the agitation for reform, a movement for regulation of proprietary medicine and its advertising also arose from the incident.

As late as May, 1933, reputable magazines advertised such products as Lashiure, an eye make-up which caused at least one case of permanent blindness;\textsuperscript{4} thallium acetate, sold as Koremlu, was advertised as a depilatory (today it is considered too dangerous even for public sale as rat poison);\textsuperscript{5} the control of pneumonia and tuberculosis was the platform of the Listerine campaign.\textsuperscript{6}

While there was considerable pressure within the government and from the citizenry for the creation of truly effective controls, there was divisive and ineffectuating conflict over which agency of the

\begin{itemize}
\item \textsuperscript{4}Ruth deForest Lamb, \textit{The American Chamber of Horrors} (New York: Farrar and Rinehart, 1936), pp. 15-23.
\item \textsuperscript{5}Kallet and Schlink, \textit{100,000,000 Guinea Pigs}, p. 80.
\item \textsuperscript{6}Lamb, \textit{The American Chamber of Horrors}, p. 309.
\end{itemize}
government would exercise control. Some legislators argued for an autonomous Food and Drug Administration, independent of inter-department conflicts and theoretically less prone to influence; other legislators favored a stronger Federal Trade Commission; still others sought control by the Department of Agriculture, the Department of Commerce and Labor, or the Department of the Treasury.

After some agitation, the forces in favor of a new federal agency appeared to be dominant and increased support developed for passage of Senator Royal Copeland's Federal Food, Drug, and Cosmetic bill, with broad power given to a Food and Drug Administration. Simultaneously, however, a plan to strengthen the Federal Trade Commission was being developed by the Federal Trade Commission's supporters, led by Senator Burton K. Wheeler.

In March of 1938, the supporters of the bill strengthening the Federal Trade Commission managed not only to secure passage of the bill (the Wheeler-Lea Act) but also succeeded in inserting a provision granting control of advertising of "food, drugs, cosmetics, and devices" to the Trade Commission. "Labeling" was specifically excluded.

Three months later, in June, 1938, the Food, Drug and Cosmetic Act passed. The Food and Drug Administration acquired control only of drug "labeling," which had been excluded from the Wheeler-Lea Act. Although definitions of "advertising" and "labeling" were not clear, the Food and Drug Administration did assume jurisdiction not only of the printed matter on the label of the container but also control over explanations, instructions, and other material "accompanying" the
product. Both proprietary and ethical materials in this category fell under FDA control.

The federal government had split its forces. The Federal Trade Commission, assuming responsibility for the regulation of "advertising" for ethical products, simultaneously relinquished to the Food and Drug Administration the control of "labeling." Thus, the Food and Drug Administration controlled labeling (ethical and proprietary), and the Federal Trade Commission was to regulate advertising. Later court decisions (discussed below) left this jurisdictional compromise in shambles by declaring certain promotional material to be both labeling and advertising, thus ensuring that the task of effective regulation was virtually impossible in administrative practice.

The point has been made here that both the Pure Food and Drug Act of 1906, as amended, and the Federal Trade Commission Act of 1914 had not possessed the precision and authority necessary to implement the regulatory function that many felt to be required. The words of the laws did serve to indicate strong moral reprobation toward unfair and devious practices, but the activities to which the statutes were applicable were difficult to identify. Furthermore, between 1906 and the early 1930's, advertising had grown staggeringly; the radio was a major medium of communication; the circulation of popular periodicals, especially women's magazines, had multiplied a number of times. The increasingly sophisticated techniques of advertising were applied virtually without control.

7Toulmin, A Treatise on the Law of Food, Drugs, and Cosmetics, p. 818.
The development of rules and precedents had been left to the process of interpretation and decision of controversies by administrative and judicial tribunals, and their erratic judgments had not satisfactorily defined the law. The Food and Drug Administration, on the one hand, did virtually nothing to regulate drug promotion; on the other, the Federal Trade Commission's authority in advertising had been mauld by the Raladam decision. Furthermore, the courts, assuming whatever quasi-judicial role Congress intended them to possess, were required, as a result, to decide business and economic questions as well. 8

Senator Burton K. Wheeler of Montana had become involved in the problems of trade practice regulation and the Federal Trade Commission in 1930 and on January 14, 1935, submitted an amendment to the Federal Trade Commission Act. The bill, Senate 944, stipulated that (1) "unfair methods of competition" be broadened to include unfair or deceptive acts or practices in interstate commerce, and (2) that the FTC be granted power over unfair methods, acts, and practices in interstate commerce, whether or not the offender was engaged in commerce (thus allowing a financially disinterested consumer to suffer recognizable injury) or the acts were even done in the course of commerce. 9 But it was felt by some, notably by Senator Warren Austin of Vermont, that the Act


would reach intrastate commerce, and the bill died on the calendar.\textsuperscript{10}

The Wheeler bill, however, received considerable support. The \textit{American Mercury} noted the need for coverage of cosmetics as provided in the bill.\textsuperscript{11} Even President Roosevelt mentioned in a message to Congress on March 22, 1935 that a measure was needed which would "extend the controls formerly applicable only to labels to advertising also."\textsuperscript{12}

Senator Wheeler again introduced his amendment to the FTC Act in 1936 in response to a request for the amendment by the Federal Trade Commission. The Commission felt that it needed clear jurisdiction over a practice which "may be unfair or deceptive to the public but not necessarily unfair to a competitor."\textsuperscript{13} The bill passed the Senate but died in the House Committee on Interstate and Foreign Commerce after debate exposed some fears of extension of the Commission's power to legislative and judicial areas.\textsuperscript{14} Three companion bills were introduced in the House in the 74th and 75th Congresses, but all died in committee.

\textsuperscript{10}Ibid.


\textsuperscript{12}U.S. Congress, Senate, 74th Cong., 1st sess., March 22, 1945, \textit{Congressional Record}, LXXIX, 4262.

\textsuperscript{13}Dunn, \textit{The Wheeler-Lea Act}, p. 197.

Senator Copeland's bill was reintroduced on January 22, 1937 and, with minor alteration, it passed the Senate on March 29, 1937. The bill met opposition in the House, however, where there was feeling that it would be an ineffectuating division of responsibility and would "cripple the efficiency and power of the Food and Drug Administration." Although the House Committee reported favorably, the Minority Report (Representatives Virgil Chapman, Edward Kenny, and Carl Mapes) asserted that the competence and authority of the FDA was greater in some areas and as a "police measure" the Food and Drug Act was vastly superior to the Trade Commission Act.

By now the contest between the supporters of the FDA and those of the FTC was apparent in public statements. Representative Mapes said,

> Whether the Federal Trade Commission shall have jurisdiction over the advertising of food, drugs, cosmetics, and devices, or whether the Pure Food and Drug Administration in the Department of Agriculture shall be given such jurisdiction. This is the real issue involved in the bill under consideration . . . some of us believe it would be unfortunate to put this power in the hands of [the FTC] instead of [the PFDA] in the Department of Agriculture.

Representative Coffee of Washington spoke of his objections to the Wheeler-Lea bill based on the preference of the patent medicine manufacturers for it and presented a letter to fellow

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manufacturers from W. K. Burgess, president of the Knox Company, which manufactured a patent medicine called Cystex. Burgess predicted that advertising would decrease 60 to 90 per cent if the Food and Drug Administration received power over advertising. He insisted that they would demand advertising be in the same terms as information supplied on the label while the FTC, understanding that advertising was necessary for profit, would not interfere with "those kinds of advertisements that will sell merchandise."  

Business in general supported the patent medicine manufacturers, though on more philosophical grounds. Business Week reported that "this bill [the Wheeler bill] is frankly an advance on a new front in the struggle to bring business more firmly under government 'guidance.'" Another journal called for a letter-writing campaign in support of the Copeland bill. It was stated that the Wheeler bill was anti-NRA, would seriously affect employment in the affected industries, put thousands out of work, and close plants and stores.

The supporters of FTC control of advertising also presented a strong case. It rested upon the fact that the Commission had some experience in litigation against false advertising and had the machinery

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18 Ibid. at 419.

19 Ibid. at 420.


and trained personnel to investigate in all industries and all commodities. They further argued that public protection should be harmonized and unified under one organization with consistent and standard methods of enforcement and penalization. They claimed that vesting the FTC with control over all advertising would result in efficiency, uniformity, and economy.\(^2\)

The House passed the bill in January, 1938 and it was returned to the Senate for ratification of amendments. Here Senators Wheeler and Copeland, the latter a champion of a strong Food and Drug Administration, met in a final contest. Copeland demanded assurance that the Wheeler bill had nothing to do with the functions of the Food and Drug Administration. Wheeler insisted that the two agencies would be separate and act concurrently, although he admitted the possibility that there might be jurisdictional conflict "to some slight extent." Copeland was not assured, but Congress passed the Wheeler bill on March 14, 1938.\(^2\)

Sections 5 and 12 contained the amendments to the Federal Trade Commission Act which directly affected drug advertising. Section 5 was altered to include deception in competition.\(^2\) Section 12 struck directly at false advertising by any means likely to induce the purchase of food, drugs, devices, or cosmetics. Such advertising was


\(^{23}\) U.S. Congress, Senate, 75th Cong., 3d sess., Jan. 13, 1938, Congressional Record, LXXXIII, 446, 447.

\(^{24}\) Toulmin, A Treatise on the Law of Food, Drugs and Cosmetics, p. 1323.
to be considered an unfair or deceptive act within the meaning of the amended Section 5.\textsuperscript{25}

However, in spite of the sweeping powers this gave to the FTC actually to make judgments about the intangibles of advertising, the amended Act neutralized these powers to some extent by limitations on the two methods of enforcement, preliminary injunctions and FTC orders. Orders to cease false advertising became, under the Wheeler-Lea Act, final and enforceable sixty days after service on the advertiser unless he seeks a court review.\textsuperscript{26} During a period of court review, an advertiser is under no legal compulsion to cease the promotion practice (unless the Commission can demonstrate possible injury to health—discussed below), and the judicial process moves slowly. An example of the effects of this provision may be the FTC order against "Carter's Little Liver Pills," which was finally enforced sixteen years after it was served.\textsuperscript{27}

The FTC received also the power and right to obtain a preliminary injunction against false advertising—requiring the advertiser to stop the advertising practice in question pending the judgment of a court review—if the Commission can demonstrate that the continued use of the advertising may be injurious to health.\textsuperscript{28} The Wheeler-Lea

\textsuperscript{25}Ibid., 1235.

\textsuperscript{26}Ibid., pp. 1232-34.


\textsuperscript{28}Simon, The Law of Advertising and Marketing, p. 506.
Act, then, was a strong declaration of outrage and intent but something less than strong, practically and legally sound correction of abuse.

In early 1933, President Franklin Roosevelt commissioned Senator Royal S. Copeland of New York, a medical doctor, to plan and guide through the Congress a new program for control of all aspects of the manufacture, preparation, and sale of food, medicines, and cosmetics. Senator Copeland introduced his bill on June 12, 1933. Because of active support for the legislation by Rexford G. Tugwell, the new Assistant Secretary of Agriculture, it was known as the "Tugwell Bill."

As opposed to earlier imprecise legislation, the Tugwell Bill was very specific in its intentions. A major clause read, in part:

an advertisement of a food, drug, or cosmetic shall be deemed false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression regarding such food, drug or cosmetic.29

Another section provided that a drug would be considered misbranded, if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.30

But a major thrust of the bill appeared in Section 8 (f) which asserted that drugs not recognized in the United States Pharmacopeia or the National Formulary must also meet the standards under which they are

29Mintz, The Therapeutic Nightmare, p. 46.
30Ibid.
Understandably, the entire bill, and obviously this clause aimed at proprietary advertising, met bitter opposition, primarily from the proprietary medicine industry and the advertising industry. Amid industry's clamor about the right of self-medication and the First Amendment, the United (patent) Medicine Manufacturers of America quickly launched a seventeen-point attack on the bill in its own industry as well as among advertising and publishing groups.\(^32\)

The power of the opposition to legislation was strong. The bill encountered in Congress what Secretary of Agriculture James Wilson called a "conspiracy of silence," during which the measure was diluted while being blocked.\(^33\) The Tugwell Bill of 1933 died in Committee in the Senate. A successor to the Tugwell Bill, introduced by Copeland in the Second Session of the same Congress (73d) on January 4, 1934 also died in Committee.\(^34\)

However, in 1933, a book by Arthur Kallet and F. J. Schlink, *100,000,000 Guinea Pigs* (Grosset and Dunlap, New York, 1933), which dealt primarily with abuses in the food industry went through twenty-seven printings and fanned public indignation.\(^35\) Also at this time, the Department of Agriculture prepared a public display of fraudulent,


\(^{32}\) Mintz, *The Therapeutic Nightmare*, p. 45.

\(^{33}\) Ibid.


harmful, and misleading food, drug, and cosmetic products and their advertisements, examples of which were given in Chapter I. But even the public response generated by the book and the display were not sufficient to overcome the medicine, advertising, and publishing industries' opposition to reform.

In February, 1934, Senator Copeland introduced a new bill (Senate 2800) which was substantially identical to the two previous attempts, except, among other changes, that it relieved publishers of responsibility for false advertising. It died on the Senate Calendar. Senator Copeland again introduced the food and drug bill, amid increasing interest in the Congress and in the country, on January 4, 1935. The bill was again substantially the same as Copeland's previous proposals. It passed to the Senate Committee on Commerce and emerged with the committee's approval. The minority opinion of the committee, however, argued that the Federal Trade Commission should control advertising. This constituted a preview of the battle in Congress between the supporters of the FDA and those in favor of FTC control.

There continued strong opposition to the Copeland measure in the Senate and a strong effort, led by Bennett C. Clark of Missouri and Josiah William Bailey of North Carolina, developed to recommit the

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36U.S. Congress, Senate, 73d Cong., 2d sess., Feb. 19, 1934, Congressional Record, LXXVIII, 2728, 2729.

bill to committee, where it had twice previously died. Furthermore, debate revealed serious misgivings about granting Department of Agriculture officials the power of arbitrary action over advertising.

But the Senate felt the pressure of growing public sentiment for regulation, and some members had come to resent the pressures of industrial organizations and concerns. Senator William King of Utah provided an insight to the position of drug manufacturers when he read a telegram from a Utah drug concern, McKesson Ogden Wholesale Company:

We urge your opposition to the so-called "Copeland food and drug bill," particularly portions requiring formula disclosures as destroying in many cases property rights built up over many years; also removal of advertising control from FTC, where effective procedure has been built up through long experience . . .

Senator Copeland assured the members that there was no intent to require formula disclosure, simply a listing, without quantities, of the active ingredients.

The bill was passed by the Senate on May 31, 1935 and sent to the House of Representatives, where strong opposition again arose. The opposition centered around the problem of jurisdiction, as it had in the Senate. Representative Edward Kenny (N.J.) asked, "do we want this

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39 Ibid., pp. 424-38.
40 U.S. Congress, Senate, 74th Cong., 1st sess., April 4, 1935, Congressional Record, LXXIX, 5018.
41 Ibid.
administration [the FDA] to be prosecutor, judge, jury, and executioner?" And B. C. Reece of Tennessee asserted,

If you want to place the advertising under Dr. Tugwell (Assistant Secretary of Agriculture) and give him a whip lash not only over business, but over the press of this country, vote for the motion made, but if you want to give it to the Federal Trade Commission, a quasi-judicial body, vote against it.43

A House-Senate Conference Committee could not reach agreement, specifically on the question of whether the FTC or the FDA would control advertising. The House conferees maintained their insistence on control by the FTC and finally Senator Copeland proposed a compromise amendment giving control of health advertisements to the Food and Drug Administration and control over all other advertising to the FTC.44 But the House rejected the amendment by a vote of 190-70, and the bill died in the House.

On January 6, 1937, during the first session of the 75th Congress, Senator Morris Sheppard of Texas re-introduced the Copeland Bill (as it was now universally known) in Senator Copeland's stead.45 The heart of the bill had always been the provisions against false advertising, but the Wheeler-Lea Act had assumed this control and had been passed and signed three months before. So the authority of the FDA

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42 U.S. Congress, House, 74th Cong., 2d sess., June 20, 1936, Congressional Record, LXXX, 10677.

43 Ibid.

44 Ibid. at 10657.

in this field was to be limited to "labeling" which was defined as "all labels, and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 46

The bill now met only minor opposition, most of it objecting to the delegation of powers to Secretary of Agriculture Henry A. Wallace. 47 But the measure passed the Senate and was sent to the House. The House committee reported favorably, and it passed to a conference committee to resolve minor amendments. The Copeland Act passed on June 15 and became law on June 25, 1938.

So the Food and Drug Administration received far greater powers under the Copeland Act, although control of "advertising" was not among them. The regulation of cosmetics (defined as any substance intended to enhance personal beauty except toilet soap) had previously been subject to the Pure Food and Drug Act of 1906 only if medicinal claims were made for them. 48 But in the area of consumer protection against false and misleading packaging and promotion, the control of "labeling" became a major function, though labeling of "non-official" proprietary drugs (those not listed in the United States Pharmacopeia of National Formulary) did come under supervision. 49

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49 Ibid., pp. 59-60.
The Copeland Act upgraded standards significantly—particularly in areas of safety—but the law fell short in some other respects. The following deficiencies, with respect to marketing, were to prove particularly troublesome:

1. A drug manufacturer was not required to establish efficacy as well as safety.
2. If the FDA could not act upon a manufacturer's request to market a new drug within 180 days, approval had to be automatically extended.
3. There was no provision requiring regular record keeping and reporting of clinical experience.
4. After a drug had been marketed, the burden of proof in removal for unsafety was on the FDA.
5. Prescription drug advertising had come under the control of the FTC.
6. There was no requirement to associate trade names with common generic names for drug products.50

The Copeland Act did go far in protecting the public in some areas, particularly in standards of production techniques and in control and inspection. However, control of advertising, the goal of Dr. Wiley and later of Senator Copeland, had not been realized. The FDA simply could not do anything in this field even when the FTC could not or would not.

The battle between supporters of the various regulatory organizations had resulted in small victories for almost everyone, yet it left a legacy of separation of power and responsibility for federal regulation as a whole. The control of "advertising" and "labeling" had been separated very precisely in the legislation, though the practical

definitions of these words were sufficiently ambiguous to ensure confusion. The situation obviously demanded judicial interpretation, as had the imprecisions of the FTC Act of 1914. But when the matter of demarcation of responsibilities did finally reach the courts, the decisions resulted in jurisdictional chaos.

The first major case to damage the integrity of the spheres of responsibility laid down for the FTC and the FDA by Congress in 1938 involved one Royal Lee, d.b.a. Vitamin Products Company (United States versus Lee, 131 F.(2d) 464, 466). The defendant, Lee, had a number of circulars printed which presented therapeutic claims for his drug products, asserting that they would, in the court's words "cure and constitute adequate treatments for human ailments." These circulars were sent in interstate commerce, but separately from the products themselves.

The District Court held that this was advertising within the meaning of the FTC Act, providing that "false advertising" means an advertisement other than labeling. Especially important was the fact that the materials did not actually accompany the goods.

The Circuit Court of Appeals ruled in November, 1942, that the Federal Food, Drug and Cosmetic Act of 1938 was "enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction." The court supported its decision with this statement:

52Ibid.
53Ibid. at 466.
The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising.\textsuperscript{54}

The fate of the compromise of 1938 was thus mortally threatened. Although this case was not appealed, the Supreme Court was to seal this judgment six years later.

Meanwhile the federal courts extended wide latitude to the Federal Trade Commission in its role as an arbiter of fairness in advertising. In Aronberg versus Federal Trade Commission (132 F.(2d) 165), also in 1942, the court confirmed the Commission's authority to practice judgment over intangible advertising appeals, recognizing that the ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied.\textsuperscript{55}

Noting that the people, as a whole, are not experts in grammatical construction, the court maintained that "the law is not made for experts but to protect the public—that vast multitude which includes the ignorant, the unthinking and the credulous, who, in making purchases, do not stop to analyze but too often are governed by appearances and general impressions."\textsuperscript{56}

This, of course, is essentially what Dr. Harvey Wiley had insisted in 1906. Then, in 1943, the courts disposed finally of the constitutional question and of the Commission's fact-finding powers in

\textsuperscript{54}Ibid. (Also see United States v. Research Laboratories, 126 F.(2d) 42) (1942).


\textsuperscript{56}Ibid.
one paragraph (American Medicinal Products, Incorporated et al. versus FTC, 136 F. (2d) 426). The defendant, the court pointed out, was not required to reveal trade secrets by advertising because they were not required to advertise at all. The FTC had simply and constitutionally ordered them to cease advertising untruthfully.57

So, although the courts now formally recognized the intentions and authority of Congress in this field, they could not certify the advertising-labeling political compromise contained in the Wheeler-Lea and Copeland Acts. Thus, in 1948, the Supreme Court affirmed the judgment of the Circuit Court of Appeals in the Royal Lee case of 1942 with its 5-4 decision in Kordel versus the United States (93 S.Ct. 52). Again the court was called upon to determine if promotion material, in this case sent not only separately but some eighteen months later than the goods, constituted advertising or labeling in the sense of the Acts of 1938. The court said:

We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense advertising.58

While deciding in both the Royal Lee and Kordel cases in favor of the FTC, the courts had, in effect, refused to sanction a division of authority. The Supreme Court was certainly expressing its displeasure with the advertising-labeling dispute when it again held in favor of


58 Kordel v. United States, 93 S.Ct. 52 (1948).
the FDA, that "labeling" may include non-simultaneous shipments, and
noted that "the Food, Drug and Cosmetic Act is not concerned with the
purification of the stream of commerce in the abstract, and the problem
with which it is concerned is a practical one of consumer protection,
not dialectics."59 Thus the ultimate tribunal for determination of
the legal intent of the Acts of 1938 had, by 1948, held that non-
simultaneous shipments of promotional matter can be advertising under
the Federal Trade Commission Act, as amended, and/or can be labeling
under the Food, Drug and Cosmetic Act.

59 United States v. Fred Urbutet, 93 L. Ed. 61 (1948).
CHAPTER V
SOME RECENT EVENTS

The years following the passage of the Wheeler-Lea and Copeland Acts were somewhat anticlimactic. The period 1948-1959 brought little progress of substance in the movement to control drug advertising. The Federal Trade Commission and the Food and Drug Administration (now an independent agency\(^1\)) did issue directives and orders against specific practices of individual advertisers. However, the serious problems of flagrantly false advertising, of FDA-FTC jurisdictional areas, and of legal delays remained and were inhibitory to aggressive regulation.

To further confuse the regulatory situation, by the middle of the decade 1950-1960 other government organizations were becoming involved. The Post Office Department exercised its jurisdiction over fraudulent advertising sent through the mails; the Treasury Department had some degree of control over products containing alcohol (which many suspension and solution drug preparations do); the Federal Communications Commission was increasingly uncomfortable about some of the proprietary drug advertising being broadcast.

As more agencies entered the field of advertising regulation, the situation grew proportionally more confused. No two agencies had

\(^1\)The Food and Drug Administration had been transferred out of the Department of Agriculture in 1940 and had become one of the agencies and commissions in the Federal Security Agency. (See James S. Turner, The Chemical Feast [New York: Grossman Publishers, 1970].

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the same procedural methods; none had blanket powers over all of even one type of advertising. Each followed different standards of proof and different statutes; investigative work done by one agency could not be used by any other and had to be duplicated; none (even the FCC) possessed capabilities to deal with the realities of large-scale mass communications.

The Kefauver Committee investigated the situation in the drug industry for three years in the early 1960's. This work resulted in an amendment to the Food, Drug and Cosmetic Act which required compliance with the following major points concerning drug advertising.

1. Substantial evidence of therapeutic efficacy as well as safety.
2. That a responsible officer of each firm sign a sworn statement attesting the accuracy of clinical data used in advertising and labeling of prescription drugs.
3. That all promotion include necessary warnings, contraindications, side effects, and untoward reactions, and that all labeling carry all necessary information for prescribing.
4. That jurisdiction over the advertising of prescription products be assumed by the Food and Drug Administration.

Thus the regulation of ethical drug advertising became an effective instrument of public policy. But controls over proprieties still depend, for the most part, on the Wheeler-Lea Act of 1938. The Federal Trade Commission has taken action in some cases involving proprietary preparations, but a number of possible abuses remain unhindered. Cold and flu preparations often claim some degree of "cure" when they are only palliatives. Diet control preparations

sometimes contain dessicated thyroid—which may not be safe for some common conditions. Headache preparations claim effectiveness for discomforts unrelated to the headache. Some laxatives do not warn adequately of the dangers of some stomach and bowel problems. Caffeine, while being scrutinized as a contributing agent in heart disease, is virtually ignored in soft drinks.

In March of 1969 the Federal Trade Commission made public the "Proposed Guides for Advertising Over-the-Counter Drugs." These proposals have not yet been completely implemented, but more aggressive action based on prior legislation and case law has become evident. Nevertheless, the matter of proprietary advertising is not yet in hand. At present there is no requirement to prove efficacy; no really scientific in vivo or in vitro clinical data are required; side effects and reactions are often effectively ignored. It is probable that the Federal Trade Commission does not have the resources, in manpower or funds, to challenge the power of the large consumer products companies if it were necessary.

But with the increasing interest and action in the field of consumer affairs, more aggressive and effective movement toward necessary control may be expected. As has been proven in other fields, all that is required is the commitment in manpower and resources to achieve honest, undeceitful drug advertising that informs rather than misinforms or confuses.

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3 Federal Trade Commission, Proposed Guides for Advertising Over-the-Counter Drugs, Section 7914.10, Number 421-31, July 8, 1969, pp. 12,869-12,873.
The primary difficulty throughout the relatively short history of the regulation of drug advertising in the United States has been one of jurisdictional confusion. There appear to be two identifiable points in time at which the problems of regulation could have been resolved with the correction of jurisdictional misunderstanding.

While Dr. Harvey Wiley's Bureau of Chemistry certainly did not receive sufficient authority in 1906 and derived little assistance from the Sherley Amendment of 1912, the problem of jurisdiction began with the formation of the Federal Trade Commission in 1914. It was at this point that the Congress created a division of authority. It may not have been the intention of Congress to endow the FTC with power over false advertising, but it is not surprising that the warrant to oversee "unfair methods of competition" came to include supervision of advertising. A strict delineation of authority might have avoided the eventual problem of FTC-FDA overlap.

A second point of correction might have been in the Congress of 1938. Although by that time both the Pure Food and Drug Department and the Federal Trade Commission had their individual champions in Congress, it was clearly the point to settle, rather than aggravate, the jurisdictional question. The legislation affecting the FDA and FTC is even less understandable at that point because there was experience that had demonstrated the problems of authority and jurisdiction and there was, in fact, substantial discussion of the subject. The deliberate
continuance of jurisdictional vagueness, as well as the "advertising-labeling" question, resulted in years more of inefficiency in regulation.

Thus, though the problems might have been corrected at any time, we may see the legislative periods of 1914 and 1938 as the points at which the opportunities for an efficient regulatory system were greatest, and were lost.
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