Federal Food and Drug Legislation: 1906-1938

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FEDERAL FOOD AND DRUG LEGISLATION: 1906 - 1938

BY

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF MASTER
OF ARTS IN LOYOLA UNIVERSITY

JUNE

1946
VITA

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After her entrance into the Congregation of the Sisters of Christian Charity in 1918, she attended Mallinokrodt College, Wilmette, Illinois, the normal training school of the Congregation. She received her Bachelor of Arts degree with a major in English from Loyola University, Chicago, Illinois, in 1923.

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PREFACE

From both the social and the legal point of view, food and drug legislation has been one of the most significant phases of Federal legislation since the turn of the century. The struggle for Federal laws in this field goes back to 1850, but only in 1906 was the first general food and drug bill passed. For thirty-two years this law served the interests of consumers and producers; then it was replaced by the Federal Food, Drug, and Cosmetic Act.

The present study purposes to trace the history and the social and constitutional implications of Federal food and drug legislation from 1906 to 1938.
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CHAPTER I

THE FACTORS THAT LED TO THE PURE FOOD AND DRUGS ACT OF 1906

Early in the first decade of the twentieth century the United States was deluged with a type of literature concerned with the exposure of fraud wherever it existed, whether in politics, in industry, or in society. It was President Roosevelt who first applied the name muckrakers to writers of this type of literature. Thomas W. Lawson, one of the earliest of the muckrakers, pictures the President seated at his desk at midnight on April 13, 1906, and ruminating:

The nation is deluged with a slimy, malodorous sea of fraud. This fraud will in time engulf -- body, heart, and soul -- all the people of the nation. It is vile, nauseating, submerging. Ergo -- Muck.

As these doers are stirring up this muck that it may disintegrate and disappear, and as these are clean people -- I'm one of them -- they would not stir with their hands, but with an instrument. I have it again! A rake! Ergo -- Muck-rakers. ¹

Whether or not Lawson's conjecture is correct, the President's speech of the following day at the cornerstone laying of the office building of the House of Representatives has come down to us under the title "The Man with the Muck-Rake." In it he referred to the splendid service muckrakers could render to society, but at the same time he warned them against the danger of lurid and sensational writing:

There should be relentless exposure of and attack upon every evil man, whether politician or business man,

¹ "The Muck-Raker," Everybody's, XV (August, 1906), 205.
every evil practice, whether in politics, in business, or in social life. I hail as a benefactor every writer or speaker, every man who, on the platform, or in a book, magazine, or newspaper, with merciless severity makes such attack, provided always that he in his turn remembers that the attack is of use only if it is absolutely truthful....

Expose the crime, and hunt down the criminal; but remember that even in the case of crime, if it is attacked in sensational, lurid, and untruthful fashion, the attack may do more damage to the public mind than the crime itself. It is because I feel that there should be no rest in the endless war against the forces of evil that I ask that the war be conducted with sanity as well as with resolution.2

What were the conditions that called forth this war against fraud? They were largely economic. During the latter half of the nineteenth century big business had developed to such an extent that success meant only business success. The public stood in awe of the great fortunes that had been built up, but their awe was mingled with some envy and a good deal of resentment. The muckraking campaign was "the inevitable expression of the long-smouldering public resentment."3 The growth of big business had resulted in what William Allen White called "an extra-constitutional government," a business government, in whose interest "laws were enacted, interpreted, and administered."4 The public no longer had adequate protection at common law. It was impossible, if we are to believe writers of the day, to protect people from the depredations of big business, for

4 Ibid., 7.
whenever a bill promoting the general welfare interfered with the big interests, their extra-constitutional government would promptly defeat it.5

Then came the muckrakers. Armed with the results of painstaking research, they set forth their findings, fearless of the opposition of wealth and prestige. Six in particular performed yeoman service in the great task of awakening public opinion and bringing about concerted action against fraud. In a series of articles which were described as "a fearless unmasking of moral criminality masquerading under the robes of respectability and Christianity,"6 Ida M. Tarbell told the story of the Rockefeller oil trust.7 Lincoln J. Steffens exposed corruption in State and municipal politics.8 The labor problem, the industrial status of the Negro, spiritual unrest, and the controlled press -- these were the major topics on which Ray Stannard Baker wrote.9 Charles Edward Russell denounced the beef trust,10 and Upton Sinclair uncovered the crimes of the meat-packing industry. Samuel Hopkins Adams was the leading writer in the campaign


7 "The History of the Standard Oil Co.," McClure's, XX-XXIII (November, 1902, - October, 1904).

8 Cf. American Magazine, LXIII-LXV (November, 1906, - December, 1907); McClure's, XXII-XXV (April, 1904, - July, 1905).


The majority of the muckrakers used the rising popular magazine as the vehicle for their denunciations. In fact, during the era of muckraking their articles formed an important contribution to McClure's, the Arena, Everybody's, Collier's and the American Magazine. A few preferred to write books on economics and politics. Upton Sinclair alone used the novel to great effect.

In a brief survey of muckraking, C. C. Regier summarizes the various stages of the campaign. Beginning in 1902, it became militant the following year, passed through a period of sensationalism during 1904-5, and reached the peak of its effectiveness from 1905-6 by bringing about a moral awakening of the nation. From that time on, it gradually declined, only to be revived again in 1909 and to develop into the Progressive Party in 1912. By 1914 muckraking as a movement was definitely a thing of the past.

Various factors led to the decline of muckraking. By 1908 the essential reforms had been accomplished, and though there would always be abuses that clamored for exposure, the muckrakers could do little because big business was making every effort to control or to crush the magazines engaged in muckraking. Besides, many of the muckrakers had defeated their

11 The work of Sinclair and Adams is discussed fully in chapter II.
12 Cf. Regier, The Era of the Muckrakers, 10-21, for a detailed account of the rise of these and other popular magazines.
own purpose by making their writing too sensational. Their efforts at exposure were now being replaced in large measure by government investigations. Finally -- and this in the last analysis was the real reason for the decline of muckraking -- people were tired of it. They had looked long enough at the seamy side of American social, industrial, and political life, and they refused to devote further attention to it.14

What precisely, one is inclined to ask, is the status of the work of the muckrakers? When their writings are weighed in the balance, does exaggeration far outweigh truth? Some critics would hold that such is the case. They point to its sensationalism, its denunciation of countless individuals, its exposure of fancied wrongs as qualities that deprive it of credibility. The opinion of F. H. Smith is typical of critics of this class:

Under the guise of exposing graft, corruption, or whatever title we may be pleased to give it, some of the mediums of publicity have magnified petty faults and grossly exaggerated conditions merely for the sake of commercialism -- to increase their circulation.

The sensational periodical and newspaper circulates widely among the classes of our people who do not appreciate that much of the stuff they read is exaggerated or utterly untrue. They do not realize that many of the men who occupy high places are the victims of false attacks. They get distorted ideas of those who deserve to stand high in their estimation. Their standard of civilization is lowered by reading such articles and having the substance preached to them by labor agitators.

But we cannot afford to let this literary muck-throwing continue -- nor will we for long. Our people are very busy and they have much to do. Much escapes us in our working hours, because we are all absorbed in our labor. But when a thing is brought before our notice in all its force, we take hold of it with all

14 Ibid., 10-11.
our might and then the reaction comes. The cheap
magazines and yellow press are not reformers -- and
that the masses will learn very soon.15

Other critics point to the scientific procedure and the understatement of
exposure writers as proofs of the truth of their writings. One author
declares:

In our time there has been adopted a scientific
method even in the popular exposure of great public
crimes, and the writer now sits down to his table, not
to soarify with epithets, but to compress into the
briefest possible compass the results of months of
patient investigation. Not opinions, not judgments, not
censure even, but only facts, facts, facts. And this is
effective beyond the effectiveness of any rhetoric, for
it appeals not merely to those who feel, but to those
who think and reason.16

Another writes:

The great thieves and political traitors are in
terror lest the present campaign of publicity shall be
kept up and by means of continued exposure the thieves
... shall receive their just dues. They realize that
every exposure made by leading magazine writers that
has resulted in an investigation has not only substantiated
the charges made and which were at first savagely de-
nounced as lies and slanders, but that the sworn testimony
adduced has so far exceeded the charges made by the maga-
azine writers that the exposures which were formerly
denounced as sensational appear tame in the light of the
sworn testimony.17

Probably no one will ever be able to determine just how much
truth and how much exaggeration went into the work of the muckrakers. It
is certain, however, that their work did produce great results. In the

15 "The Muck-Rake as a Circulation Boomer," Critic, N.S. XLVIII (1908),
American Magazine, LXII (May, 1906), 111; George W. Alger,
"Literature of Exposure," Atlantic Monthly, XCVI (August, 1905),
210-11.

16 Edward J. Wheeler, "Value of the Literature of Exposure," Current
Literature, XL (January, 1906), 41.

17 B. O. Flower, 61.
field of politics such reforms as the popular election of senators, the secret ballot, direct primaries, and woman suffrage can be traced back to muckraking. 18 Regier summarizes the countless social and economic effects as follows:

The government was induced to attempt to relieve economic and social distress. The convict and peonage systems were destroyed in some states; prison reforms were undertaken; child labor laws were passed by most of the states and a National Child Labor Committee was appointed in 1904 to propose uniform child labor laws to all states; a Federal employers' liability act was passed in 1906, and a second one in 1908, which was again amended in 1910; forest reserves were set aside; the Newlands Act of 1908 made reclamation of millions of acres of land possible; the conservation of natural resources was greatly stimulated; eight-hour laws for women were passed in some states; race-track gambling was prohibited; twenty states passed mothers' pension acts between 1906 and 1913; twenty-five states had workmen's compensation laws in 1915; a tariff commission was established in 1909, abolished in 1912, and revived in 1914; an income tax amendment was added to the Constitution; the Standard Oil Company and the Tobacco Companies were dissolved; public service commission laws were passed in New York for the purpose of checking the corporations; Niagara Falls was saved from the greed of corporations; sanitary measures were promoted; interest in labor welfare became general; Alaska was saved from the Guggenheims and other capitalists; better insurance laws and packing-house laws were put on the statute books; and George Creel's articles on Colorado strike conditions resulted in a "benevolent feudalism," which was more favorable toward non-union labor. 19

Such, in brief, is the history of muckraking in general. In the realm of food and drugs the campaign was of prime importance in bringing about Federal legislation. Indeed, it is not improbable that, but for the muckrakers, there would have been no general pure food and drug legislation


19 Ibid., 11.
at all or it would have come at a much later date.

Besides the development of big business and the growing consciousness of the public that there was fraud in other fields, there were several other conditions that led to muckraking in the realm of food and drugs. During the half century following the Civil War the United States had changed from an agricultural to an industrial nation. In consequence, the food and drug problem changed from an individual or distinctly local one to a national one. Processed foods and patent medicines were demanded more and more. At the same time trade journals were teaching the tricks of adulteration, and modern chemistry, which was later to become a most powerful weapon against adulteration, was now being exploited by illicit manufacturers of foods and drugs.20

The work of Upton Sinclair and Samuel Hopkins Adams, the outstanding muckrakers in this field, may be considered an immediate cause of the 1906 act. The Beveridge Bill, passed almost simultaneously with the Pure Food and Drugs Act, was a direct outgrowth of Sinclair's The Jungle; while the 1906 provisions on patent medicines were due in large measure to Adams' articles, which were subsequently published under the title The Great American Fraud.21

What has been said of muckraking, however, does not warrant the conclusion that this campaign was the only or even the most important factor that led to the Pure Food and Drugs Act of 1906. This act was rather


21 Vide infra, 12-16.
the culmination of a struggle begun as early as 1848.

Federal food and drug legislation evolved gradually during the second half of the nineteenth century, and this for two reasons. In the first place, after the Civil War there was a tendency to increase the jurisdiction of the Federal government and to give it control of problems that directly concern the individual citizen. Sometimes such control was effected through a decision of the Supreme Court; sometimes it was brought about by a bold assumption of power by Congress. In either case this extension of Federal authority was, consciously or unconsciously, tolerated by the people.22

In the second place, food and drug problems arose gradually. So long as the United States was an agricultural nation, housewives brewed many of their own home remedies from herbs which they themselves had gathered. Other necessary drugs were prescribed and often supplied by the family doctor, who alone was held responsible for their effect. If a community had its local druggist, he was intent on winning the confidence of his customers by conscientiousness and reliability. Besides, life was comparatively simple, and there was no need for the drugs and nostrums that appeared in the more complex life of a later period. The food problem, as has already been pointed out, was also an individual or local one during this era. But once the United States changed to an industrial nation, food and drug problems became more and more important. The trend of the population toward the city made it necessary to provide food and drugs in large quantities that were not purchased locally but often came from great

distances and hence could not be controlled by individual states. The extra-legal safeguards that had protected the consumer so long as trade was strictly local, now disappeared.23 Protective legislation did not at first keep pace with economic and social changes. Unethical individuals and groups, however, made haste to profit by these changes at the expense of the well-being of the consumer. By the time measures were introduced into Congress to correct abuses, these groups were prepared to politically defend their interests.24

Until 1906 legislation was confined to specific products because it was determined by current needs. During that half century of struggle, "a patchwork of food and drug laws was laid over the country."25 The first act, that of 1848, which forbade the importation of adulterated tea, met with no opposition simply because it did not interfere with big business. That act provided a pattern for the next fifty years. If a proposed measure did not injure the big interests, it was passed with little or no opposition; if it interfered with the interests, various means were employed to insure its defeat. Sometimes there was open conflict. More often, however, indirect methods were employed -- lobbying, filibustering, and other parliamentary tactics.26

23 Wilson, 151-2.
25 Helen Dallas and Maxine Enlow, Read Your Labels, Public Affairs Pamphlet No. 51, 5.
Much was attempted on behalf of the consumer, but little gained. Between January 20, 1879, and June 30, 1906, ... 190 measures were presented in Congress which were designed in some way to protect the consumer of food and drugs. 'Of these, eight became law, six passed the House but not the Senate, three passed the Senate but not the House, twenty-three were reported favorably from the committee to which they had been referred, nine were reported back adversely, and 141 were never heard of after their introduction.'

Butter, meat, lard, oleomargarine, cheese, canned fish, flour, tea, and unmoral drugs were the specific articles on which laws had been passed before 1902. Then came the first successful attempt at a more general law in the labeling act, which forbade the geographic misbranding of foods and drugs.

By this time the muckrakers had begun their work of exposure. The stage was set, and from 1903 to 1906 the country witnessed the final struggle for the first general pure food and drug act.

CHAPTER II
THE FIRST GENERAL FOOD AND DRUG ACT

To attempt to make arbitrary divisions in the history of pure food and drug legislation would be to disregard the law of growth, which is essential in history as in life. Hence the factors to be discussed in the present chapter as immediate causes of the 1906 act must not be considered as having necessarily come after those discussed in chapter I, for some of them had their inception in the 'nineties. They became immediate causes merely because their combined influence forced the consideration of the food and drug bill on a reluctant Congress.

The efforts of interested groups and individuals constitute the first of these immediate causes. Farmers, who resented the fact that some of the makers of oleomargarine were trying to sell it as butter, began the work of agitation. In States where they were particularly powerful, they secured the establishment of departments of agriculture, with chemists and officials whose function it was to investigate adulterated butter and imitations of butter. Their inquiries paved the way for research in other food products and, subsequently, in drugs. Eventually, a number of States established departments of food and drugs, devoted to the investigation of food and drugs sold within the respective States. Such was the beginning of food analysis by government officials on behalf of the consumer. In 1898 the State chemists formed the National Association of State Dairy and Food Departments. Almost immediately it became evident to them that their
work would be hampered unless a Federal law would set up standards for the entire country and regulate food and drug shipment from State to State.¹

One of these State chemists, Dr. Harvey W. Wiley, became the outstanding official champion of pure food and drugs. After a brief career as chemist at the newly founded Purdue University and as State chemist of Indiana, he was, in 1883, appointed chief chemist of the Department of Agriculture at Washington. Later he was made head of the Bureau of Chemistry, and in this capacity he labored against overwhelming odds until his retirement in 1912. Wiley believed, as other crusaders have believed, that if the public could be made aware of the abuses practiced by manufacturers of food and drugs, they would demand a Federal law. With this idea in mind he wrote pamphlets and delivered numerous lectures. In 1902 he attracted the attention of the entire country and of the world by means of a series of experiments on a group of healthy young officials of the Department of Agriculture. "Doctor Wiley's poison squad," as the group came to be called, was kept on a controlled diet of foods containing preservatives. The experiments, which were carried on for a number of years, proved conclusively the harmfulness of commonly used preservatives.²

At the St. Louis Exposition of 1904, State chemists presented the food problem from another angle. They exhibited

... brilliantly hued pieces of wool and silk, colored with dyes that had been extracted from well-known,

artificially colored foods, ... in a booth close by the space allotted to makers of some of the foods in question.3

This display was followed in 1905 by Senator Porter J. McCumber's article "The Alarming Adulteration of Food and Drugs,"4 which was based on facts discovered by the Food Commissioner of North Dakota, E. F. Ladd. He pointed out the wide use of chemical preservatives, particularly in meats, and the misbranding of imitations in both food and drugs.

Women too played an important part in bringing about the 1906 act. In 1904 the General Federation of Women's Clubs organized a Pure Food Committee, which aroused interest in the subject by means of letters, exhibits, lectures, and circulars.5

While all these groups were fighting the dishonesty of large corporations, some of these very corporations were contributing their share to the campaign. As early as 1903 representatives of manufacturing interests held joint meetings with State officials, members of the Interstate Pure Food Commission, and representatives of the Department of Agriculture at St. Paul, Minnesota. Their discussions revealed the fact that much of the adulteration in fruits and vegetables was due to problems with which the big interests were unable to cope. This meeting and the following one, which was held in St. Louis, proved that many business men were ready to co-operate with the Federal Government, for they realized that a Federal

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3 Helen Dallas and Maxine Enlow, Read Your Labels, Public Affairs Pamphlet No. 51, 5.
4 Independent, LVIII (January 5, 1905), 28-33.
5 Regier, 9.
law would be to their own advantage. 6

Two groups, however, remained adamant in their attitude toward any kind of legislation: the makers of patent medicines and the meat-packers. Both became the targets of some of the most successful muckraking of the age; against them in particular the 1906 legislation was directed.

The majority of the makers of patent medicines 7 were men who had


7 Most of the drugs popularly known as patent medicines are, in the legal sense of the term, not patent medicines but nostrums. In a paper read before the Chicago Medical Society on March 26, 1919, Dr. Arthur Cramp explained the two classes of nostrums and the difference between them and real patent medicines. He said: "Broadly speaking, the nostrum belongs in one of two general classes; one class comprises those unscientific mixtures that are advertised primarily to the medical profession, and first reach the public by way of the prescription; the other class includes those mixtures that are sold direct to the public. Nostrums in the first class are sometimes spoken of as 'proprieties'; those in the second class are colloquially known as 'patent medicines.' There is no clearly defined line of demarkation [sic] between these two classes. Many of the 'patent medicines' of today were the 'proprieties' of yesterday. Shrewd manufacturers -- or, more correctly, exploiters, for many of these products are not manufactured by those that sell them -- discovered years ago that one of the least expensive methods of introducing a nostrum to the public was by way of the medical profession.... after the patient had learned with disgust that his physician had merely prescribed a 'patent medicine' that could more cheaply have been purchased direct -- then the one-time 'proprietary' threw off its 'ethical' mask and became frankly a 'patent medicine.' ... Correctly speaking, there are practically no true patent medicines on the market; first, because few if any of the products of this type could be patented, and second, because patenty or openness is the last thing the average 'patent medicine' seller wants. ... A product to be patentable must ... represent something new and useful; and this requirement of the patent law rules out the 'patent medicine.' A patent when granted gives the owner a legal monopoly on his product for seventeen years, after which time the product becomes public property. The 'patent medicine' seller finds it easier and far more profitable to put together a simple mixture of drugs that represents nothing either new or useful, to which he gives a fancy name, and obtains a trade-mark on that
little formal education. Far from being professional men, they were keen-
sighted business men\textsuperscript{8} who were profiting by the need of people in urban cen-
ters for prepared drugs and who were taking advantage of the large influx
of foreigners to fill their own pockets. Shrewd advertising was the secret
of their success. Organized under the name of "The Proprietary Association
of America," they controlled many of the newspapers and periodicals. By
inserting in their contracts a clause to the effect that the contract would
be void if adverse State legislation were passed, they insured to themselves
the support or at least the neutrality of most publishers, who were unwilling
to endanger their income from this source.\textsuperscript{9}

The great crime of patent-medicine makers was not so much a finan-
cial as a social one, for they were undermining the health of the nation
while professing to advance it. Soothing syrups were loaded with morphine;
cough medicines, with opium or some other narcotic. Highly advertised
"cures" of cancer or consumption actually caused the disease to make more
rapid progress. Writing for \textit{Popular Science} in 1906, Dr. Horatio Wood of
the University of Pennsylvania deplored the silence of the press in the

\begin{quote}
name. The trade-mark gives him a perpetual monopoly to the name
and places no restrictions on the composition of the product;
nor, in the granting, is he required to give any information re-
garding its composition." ("The Nostrum and the Public Health,"
printed in 'Patent Medicines' -- \textit{The Nostrum and the Public
Health}, a pamphlet published by the \textit{American Medical Association},
26.) In the present study the term \underline{patent medicine} will be used
in its popular, not in its legal, sense because it is used thus
in most of the literature dealing with the subject.
\end{quote}

\textsuperscript{8} Arthur Kallet and F. J. Schlink, \underline{100,000,000 Guinea Pigs}, The Vanguard
Press, New York, 1933, 158.

\textsuperscript{9} Cf. Regier, 7.
face of such crime. "The mouthpiece of the nation," he wrote, "is stopped with gold; let the people speak directly and bid legislators save the ignorant and innocent from the voracity of the conscienceless degenerates who are robbing them of health and money at the same time."  

Not all periodicals, however, had been muzzled by the proprietary interests. Edward Bok and Mark Sullivan were exposing these interests in the Ladies' Home Journal, and Samuel Hopkins Adams was writing a series of articles for Collier's that was to work havoc in the patent-medicine business. Adams' work was far more outstanding than that of Bok and Sullivan. In the introduction to his first article, which appeared on October 7, 1905, he explained his purpose:

This is the introductory article to a series which will contain a full explanation and exposure of patent-medicine methods, and the harm done to the public by this industry, founded mainly on fraud and poison. Results of the publicity given to these methods can already be seen in the steps recently taken by the National Government, some State Governments, and a few of the more reputable newspapers. The object of the series is to make the situation so familiar and thoroughly understood that there will be a speedy end to the worst aspect of the evil.

"The Nostrum Evil," as his first series was called, analyzed such panaceas as Peruna and Liquozone, warned against the poisonous drugs in many popular headache cures and pain-killers, mercilessly lashed the makers of cures for incurables, and exposed the tricks of advertising that brought wealth to the patent-medicine makers. One sentence from the final

12 Ibid., 3-68.
paragraph of his concluding article strikes the keynote not only of this series but also of the two later ones, which were published immediately after the passage of the 1906 act and in 1912: "Our national quality of commercial shrewdness fails us when we go into the open market to purchase relief from suffering."\(^{13}\)

Adams' exposure of the patent-medicine fraud may be considered the second of the immediate causes of the 1906 act. The third was Upton Sinclair's *The Jungle*, which denounced the crimes of packers and was being written while Adams was publishing his articles.\(^{14}\) This novel, unique as a vehicle of muckraking and unique also in its effect on legislation, deserves more than a cursory treatment here.

From the point of view of effectiveness, *The Jungle* ranks even higher than Harriet Beecher Stowe's *Uncle Tom's Cabin* and Helen Hunt Jackson's *Ramona*; for although the former helped to bring about the emancipation of slaves and the latter caused the amelioration of the treatment of the Indians, yet no definite piece of legislation can be traced to either book. *The Jungle*, however, was the cause of the Neill-Reynolds investigation and of the Beveridge Amendment, the immediate precursor of the 1906 act.\(^{15}\)

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13 Ibid., 68.


15 Mark Sullivan, however, holds that it was merely "the final, spectacular, fictionistic climax to a long agitation that had been carried on in solid and convincing ways by patient investigators, food chemists in the employ of the State and Federal Governments, journalists of the exact-minded 'Muckraker' type, leaders of women's clubs, and other reformers and altruists." (II, 483.)
The Jungle tells the story of Jurgis, a Lithuanian peasant, who in Packingtown -- as Sinclair called Chicago -- becomes the victim of practically every industrial and political evil of the day. The book is fundamentally socialist, but through its exposure of the packing industry it became hygienic, for it was the part dealing with food which impressed its readers most.

Five publishers rejected Sinclair's manuscript. Finally, Doubleday, Page & Co. accepted it. Its effect was instantaneous. The public seized upon it avidly, and it became a best seller for a year. The packers, in particular Mr. Armour, freely denounced the book through their controlled press and declared that its charges were 95% false. Sinclair's reply was an article entitled "The Condemned Meat Industry," in which he presented some of the facts at the basis of his book. When this article was disregarded, he made a public statement which concluded:

One hundredth part of what I have charged ought, if it is true, to be enough to send the guilty man to the gallows.

One hundredth part of what I have charged ought, if it is false, to be enough to send me to prison.

If the things which I have charged are false, why has Mr. Armour not sued me for libel?

All I ask of Mr. Armour is a chance to prove my charges in court. Is he afraid to give me a chance?17

Evidently Armour was afraid to give him a chance. He merely responded with more advertisements. But the time had come when the Federal

16 Everybody's, XIV (May, 1906), 608-16.
17 Quoted in B. O. Flower, "The Campaign Against the Wholesale Poisoners of a Nation's Food," Arena, XXXVI (July, 1906), 68.
government was to take a hand in the matter and Sinclair's claims were to be vindicated by an official investigation.

The Jungle fell into the hands of President Roosevelt, who, disgusted though he was by what he considered Sinclair's exaggeration, resented the condemnation of the United States government that was implied on every page of the book; for if even a single accusation of Sinclair's was true, government inspectors in the packing houses were failing miserably in their duty. Accordingly, he called the attention of Secretary Wilson of the Department of Agriculture to the book. Wilson sent three officials to Chicago to investigate.

Meanwhile, however, Doubleday, Page & Co., the publishers of Sinclair's book, were preparing to print three articles on the packing business in their magazine, The World's Work: the first was the report of a lawyer whom they had sent to Chicago to find out whether conditions were actually what Sinclair said they were; the second was a paper by a former city bacteriologist of Chicago; the third was the statement of a physician who cared for stockyard workers. The firm sent proofs of the articles to the President. "Instantly Roosevelt became 'all act.' Allegations made in fiction by a writer for whose mind Roosevelt had qualified respect were one thing; allegations made by a serious and responsible magazine were quite different."18 Fearing that the officials sent by Wilson might gloss over matters, he sent two special commissioners, Charles Neill and James B. Reynolds,19 to investigate conditions in Chicago.

18 Sullivan, II, 536.
19 Neill was a professor of political economy at the Catholic University of America and United States Labor Commissioner; Reynolds was a settlement worker on the East Side of New York.
One detail in particular of the preliminary report of these commissioners caused the President deep concern: the government inspection label, which read "Inspected and passed by the United States Government," actually referred only to the carcasses of animals that had not been condemned on the killing floors; virtually, however, since it was placed on prepared products, it sanctioned all the processes between the killing of the animal and the shipping of the product. 20 His first impulse was to forbid the use of government labels, but realizing the damage such an act might do to trade with foreign countries, he determined to secure the enactment of a law for government inspection of all phases of meat-packing. At his suggestion, therefore, Senator Beveridge of Indiana attached a rider to the Agricultural Appropriation Bill. Its principal provisions were: that animals be examined both before and after slaughtering; that packing and canning establishments be kept in a sanitary condition; that food products be inspected, that canned meats bear the date of inspection on the label, and that there be no falsification of labels on canned goods; that a fee be charged for government inspection service, which should take place at night as well as during the day; and that animals for export be examined. 21

This "Beveridge Amendment" unanimously passed the Senate on May 25, 1906, three days after it had been introduced. More than a month was to intervene before it passed the House. For the frenzied packers made every

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20 Sullivan, II, 537.

effort to defeat or at least to devitalize the bill. Their own protests were abetted by the opposition of House leaders. The President's response to both groups was an ultimatum on June 4. He had received the Neill-Reynolds report two days before. Now he sent the first part of the report to the House with a message that began:

I transmit herewith the report of Mr. James Bronson Reynolds and Commissioner Charles P. Neill, the special committee whom I appointed to investigate into the conditions in the stock yards of Chicago and report thereon to me. This report is of a preliminary nature. I submit it to you now because it shows the urgent need of immediate action by Congress in the direction of providing a drastic and thoroughgoing inspection by the Federal government of all stock yards and packing houses and of their products, so far as the latter enter into interstate or foreign commerce. The conditions shown by even this short inspection to exist in the Chicago stock yards are revolting. It is imperatively necessary in the interest of health and of decency that they should be radically changed. Under the existing law, it is wholly impossible to secure satisfactory results.22

The press immediately published the first part of the Neill-Reynolds report. Public sentiment was aroused, and the packers were forced to adopt a new method of defense. Verbally, they still objected to the Beveridge Amendment and branded the Neill-Reynolds report as false and sensational; actually they began a campaign to clean up the packing houses. This latter tactic was due not so much to their fear of the Beveridge Bill, which they still hoped to emasculate through the instrumentality of House leaders, as to the losses they were suffering in foreign markets. Now they began to advocate a bill that would arm their products with the Federal stamp of approval and thus recover their lost trade, but they hoped to gain their end with little or no expense to themselves. Their champion,

Congressman Wadsworth, accordingly drew up a substitute amendment, which provided that the government pay the cost of meat inspection and that no date be placed on the label. Eventually, Wadsworth's bill passed the House and came before the Senate. Almost the only senator in favor of the House measure was Warren of Wyoming, the defender of the cattle raising interests. Conferees from both houses were appointed, but the House conferees refused to compromise on the question of paying for meat inspection. The matter of labeling was not touched upon. Finally the senators, fearing to jeopardize the entire bill, gave way, and the bill was passed, though not without some resentment. In the House too the motion was carried, and on June 30, 1906, Roosevelt signed the Agricultural Appropriation Bill. The meat inspection rider went into effect the following day, July 1, 1906.23

Even if many of the senators felt that they had suffered a signal defeat at the hands of packers because the meat inspection rider placed the burden of payment on the public by means of a government appropriation, yet the very day on which the President signed the Appropriation Bill witnessed a memorable victory on behalf of food and drugs. For on this day the President also signed the first general food and drug act passed by the Federal government.

As has been pointed out in chapter I, agitation for a law of this kind had been carried on for some time, but it had met with three types of opposition. The first type came largely from Southern Democrats, who objected that Federal legislation would be a violation of State rights. The second was a rather negative type of opposition, coming from those who were

23 For a detailed account of the struggle of. Congressional Record, XL (1906), passim, especially 8763, 9076-8, 9470-2, 9650; Sullivan, II, 540-50; Regier, 13-15.
indifferent because they were ignorant of the seriousness of the problem. Both these groups withdrew their objections as the issue became clearer, but the men from whom the third type of opposition proceeded fought on to the end. Indeed, the delay in the passage of the first general food and drug act was due mainly to the resistance of these men, who were personally interested in the perpetration of frauds upon which their financial success depended. \(^{24}\) Whiskey blenders, wine merchants, manufacturers of jellies and of imitation olive oil, and, above all, makers of patent medicines constituted this group of opponents.

Before 1905, food and drug bills had been consistently shelved if they were called up at all. If one house passed a bill, the other was sure to kill it. Besides, excuses for refusing even to consider such bills were numerous: more urgent bills, the prevention of hasty legislation, and the advisability of letting the States handle their own problems were the most common ones. \(^{25}\) Eventually, this repeated shelving became matter for public raillery. As Life put it:

"Who is that shabby-looking, patched-up individual trying to get on the floor of the House?" asks the Legislative Enactment of the Appropriation Schedule.

"That?" answers the Appropriation Schedule. "O, that's old Pure Food Bill. When he first came here he looked pretty good, but now he has been knocked around and changed so much that his former friends don't know him at all. In a minute you'll see him thrown out bodily again." \(^{26}\)

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\(^{24}\) Regier, 4-5.

\(^{25}\) Ibid., 4.

Two months before this taunt appeared, however, President Roosevelt had taken a decisive step. In his fifth annual message to Congress, December 5, 1905, he strongly urged the need of food and drug legislation:

I recommend that a law be enacted to regulate inter-State commerce in misbranded and adulterated foods, drinks, and drugs. Such law would protect legitimate manufacture and commerce, and would tend to secure the health and welfare of the consuming public. Traffic in food-stuffs which have been debased or adulterated so as to injure health or to deceive purchasers should be forbidden.27

That same month Senator Heyburn of Idaho reintroduced bill S. 88, which had been defeated in both the fifty-seventh and the fifty-eighth Congress. It was directed against the manufacture, sale, and transportation of adulterated, misbranded, poisonous, or deleterious foods.

When the bill came up for consideration on January 10, 1906, a struggle lasting over a month began. Senator McCumber of North Dakota was Heyburn's chief supporter. Senator Aldrich of Rhode Island, a Republican, led the opposition. On February 21, when a vote was taken, 22 senators refused to vote, 4 objected on constitutional grounds, and 63 voted in favor of it. The bill was sent to the House and placed in charge of Representative Hepburn of Iowa.

During the four months that elapsed before the bill was taken up the House Committee on Interstate and Foreign Commerce drew up a new bill, which was substantially identical with the Senate bill but added a provision on narcotics and another for the fixing of food standards. After a three-days' debate, the House passed its bill 241-17. A committee consisting of Senators Heyburn, McCumber, and Latimer, and Representatives Hepburn, Mann,

27 Richardson, XIV, 7012.
and Rice drew up a report embodying all the important features of the Senate bill and the narcotic provision, but canceling the provision on food standards. On June 29 both houses agreed to this report, and the following day the President signed the bill.\textsuperscript{28}

The Food and Drugs Act of June 30, 1906, consisted of thirteen sections, which may be summarized as follows:

1. Prohibitions of the manufacture of adulterated of misbranded foods or drugs, and the penalty for violations.

2. Prohibition of traffic in adulterated or misbranded foods or drugs, and the penalty for violations.

3. Enactment of regulations for the enforcement of the act by the Secretaries of the Treasury, Agriculture, and Commerce and Labor.

4. Examination of specimens of foods and drugs by the Bureau of Chemistry of the Department of Agriculture.

5. Duty of district attorneys to initiate proceedings in the proper courts when violations are reported.

6. Definition of the terms drug and food.

7. Meaning of the term adulterated.

8. Meaning of the term misbranded.

9. Immunity of retail dealers from prosecution for violations.

10. Proceedings in the case of violations; seizure and disposal of adulterated or misbranded foods, drugs, or liquors.

\textsuperscript{28} For the legislative history of the 1906 bill, cf. Congressional Record, XL (1906), passim, especially 894-5, 2652-65, 8910-15, 8767-9, 9656, 9660; Legier, 10-12. In connection with the final struggle for passage of the pure food bill, an article appearing on p. 7 of the Chicago Record Herald, March 2, 1906, is of interest. In it W. Post of the Postum Cereal Company explains the need of legislation and presents the public with the text of a pure food bill, a copy of which he would have the readers of the paper send to their congressman with their signature.
11. Duty of the Secretary of the Treasury to submit samples of imported foods and drugs to the Secretary of Agriculture for inspection.

12. Meaning of the terms Territory and person.

13. Date on which the act goes into effect -- January 1, 1907.

From the moment the Food and Drugs Act went into effect, difficulties began to arise in its enforcement. Some of these were inherent in the law itself; others arose from violations of the law; still others proceeded from internal dissension in the administration boards.

Despite the fact that the authors of the bill had made every effort to define terms clearly, it soon became evident that the terminology of the act was one of the strongest loopholes for violators. The terms adulterated, misbranded, false or misleading, and distinctive name caused the most difficulty. Two important cases -- one in the realm of drugs, the other in that of food -- hinged on the terminology of the act, and the decision of the Supreme Court in both instances well-nigh paralyzed the law.

O. A. Johnson of the Johnson Remedy Co. of Kansas City was prosecuted by the Federal government on the charge of misbranding because his so-called "cancer cure" was absolutely worthless. On May 29, 1911, the Supreme Court decided that section 8 of the Food and Drugs Act, on which the charge was based, referred to the ingredients and not to the curative qualities of a drug. When the government prosecuted the Lexington Mills Co. of

29 Statutes, XXXIV, 768-72; Service and Regulatory Announcements, Food and Drugs No. 1, U. S. Department of Agriculture (November, 1930), 16-20.

30 As a matter of fact Johnson was forbidden to use the mails for his product. But he did not retire from business. Instead, he required victims of cancer to come to him in person. Cf. George Creel, "Law and the Drug Sharks," Harper's Weekly, XL (February, 6, 1915), 135.
Mississippi on the charge of adding certain nitrates or poisonous ingredients in order to bleach flour and thus hide its inferiority, the Supreme Court ruled that flour may be bleached without violation of the law provided the material added in the bleaching process is not sufficient to harm infants, the aged, and the infirm. 31

The provisions for labeling likewise caused difficulties in enforcing the law. In the case of drugs, there were only eleven dangerous ingredients that had to be mentioned on the label; yet many other ingredients used in drugs for the home treatment of diseases are dangerously potent. Some do not produce the harmful effect immediately, and for that very reason they are the more dangerous. In the case of foods, any article sold under a "distinctive name," provided the label bore the place of manufacture, was exempt from the jurisdiction of the law. 32

31 "Limiting the Pure Food Law," *Literary Digest*, XLVIII (March 7, 1914), 479-80.

22 Closely associated with the question of labeling was the fraudulent use some manufacturers were making of what was apparently a Federal guarantee. In April, 1907, Secretary of Agriculture Wilson explained precisely the meaning of the label "Guaranteed under the Food and Drugs Act," and warned manufacturers against a continuance of its misuse. He declared: "The serial number and the statement that a food or drug is 'guaranteed under the food and drugs act, June 30, 1906,' does not mean that the United States government guarantees the purity of the article or guarantees that it is what the label says it is. On the contrary, ... the statement means that the manufacturer of the article guarantees it to be pure, free from adulteration, and that he warrants every fact stated on the label to be true. It is the guarantee of the manufacturer, not the guarantee of the government. The department allows manufacturers to file a general guaranty, covering all their food or drug products. It then assigns a number and permits the manufacturer to print the number and a statement that the article is guaranteed on the label of each package. ... the serial number is assigned to fix responsibility where it belongs -- upon the manufacturer. ..." Quoted in "Food Law Used to deceive," *Chicago Daily Tribune*, Film No. 326, April 17, 1907, p. 3, column 6.
Finally, lack of control over advertising crippled the enforcement of the 1906 law. The manufacturer was allowed to make no false or misleading statements on the label of a product. But in any other form of advertising he might make any kind of claim; however false it might be, it could never make him liable to prosecution.

Further difficulties in the enforcement of the 1906 law arose from violations. First of all, there was the problem of formulating policies: the appropriation of funds, the division of labor, co-operation between local State, and Federal officials. Second, the law did not make clear precisely what constituted an offense. Since makers of drugs could set up their own standards if they did not adopt those set up by the United States Pharmacopoeia or the National Formulary, each case had to be interpreted individually. Again, the law placed the burden of proof on the government rather than on the manufacturer: the former had to prove that a particular product was harmful; the latter was not obliged to prove its harmlessness. 33

The method of procedure when a violation did occur was likewise a source of great difficulty in the enforcement of the Act. Much time and expense were entailed in the collection and chemical analysis of samples. Judicial proceedings, once they were instituted, were also slow and expensive. Cases involving drugs were particularly disheartening, for on account of an almost universal belief in "miracle" pills, it was hard to convince the ordinary lay jury even with scientific data. Even if a lower court decided in favor of the government, the defendant could appeal to higher courts, and by means of political control some of the larger

corporations could make a case drag on for several years, only to end in defeat and added expense for the government. 34

Perhaps the greatest difficulty in the enforcement of the Food and Drugs Act, however, arose from administrative dissension. Congress had made the Bureau of Chemistry, of which Dr. Harvey Wiley was the Chief, responsible for examining specimens of food and drugs and for determining which were adulterated. Yet only a few months after the Act became effective, on April 25, 1907, Secretary Wilson of the Department of Agriculture created the Board of Food and Drug Inspection, whose purpose was to investigate questions of enforcement and to submit its findings to the Secretary of Agriculture for decision.

This board consisted of Dr. Wiley, Chief of the Bureau, Dr. F. L. Dunlap, Associate Chief (who was selected by the President, appointed by the Secretary of Agriculture, and took no orders from the Bureau Chief), and G. P. McCabe, Solicitor for the Department of Agriculture. At least two members of this Board were required to approve all Food Inspection Decisions before they were sent to the Secretary for his signature. Under such procedure Dr. Wiley found himself a permanent minority with his authority effectually nullified. 35

Early in 1908, the President issued an order creating the Referee Board of Consulting Scientific Experts, commonly known as the Remsen Board. This order was the outgrowth of a conference at which food


35 Wilson, 74.
manufacturers presented objections to Wiley's ruling that saccharin was injurious to health and hence its use as a sweetening agent should be prohibited. There seems to have been a certain amount of prejudice in the President's action, for he himself was taking saccharin at his physician's orders. Dr. Ira Remsen, the discoverer of saccharin, was appointed chairman of the Board. He selected the other three members. As a result of the creation of this board, the action of the Bureau of Chemistry was further controlled. The Board permitted the use of sodium benzoate as a food preservative, of sulfur dioxide and sulfites as bleaching agents and preservatives, and of limited quantities of saccharin as a sweetening agent. Some of its decisions were given the force of law by the signature of the Secretaries of Agriculture, Commerce, and the Treasury. These were, for the most part, direct contradictions of studies previously completed by the Bureau of Chemistry. Investigations by the Bureau were ordered suspended after the creation of the Remsen Board, and several of its monographs were refused publication. Eventually, discouraged by a losing struggle against internal opposition, Dr. Wiley resigned his post in 1912. Yet he continued his fight on behalf of the consumer until his death in 1930. Meanwhile the legality of the Remsen Board was challenged, but the question was never decided in court. 36

It must not be supposed, however, that the Food and Drugs Act of 1906 was a complete failure. It had a number of good results, both directly and indirectly. Labeling became decidedly more honest than it had been. Harmful preservatives were less frequently used. Sanitary conditions in food plants were improved. In a number of States similar laws were enacted

to control intrastate traffic. An attempt was made at securing a certain amount of standardization in methods of production. Scientific research was stimulated. Finally, public interest in the vital problem of food and drugs was aroused, and the people were educated to attack the problem intelligently. 37

The effect of the 1906 act may perhaps best be evaluated by examining the reply sent by officials of a number of States to the question: What has been the effect of the Food and Drugs Act in your State? 38 From Kentucky came the answer:

The National Pure Food Law has had the effect of causing a widespread cleaning up among the manufacturing concerns throughout the country.

The Commissioner of Ohio replied:

In some respects the Act has been of much assistance in our State in the enforcement of food and drug laws. The principal reason why it has been of benefit is because of the fear most people have of Uncle Sam.

The State Chemist of Washington declared:

The quality of goods received from other states is undoubtedly better than it was prior to the passage of the Federal Law.

The Secretary of the Board of Health of Massachusetts had not noticed any particular effect. His reply was:

Little, if any. If any, it has not been observed by those in authority.


38 All of the quotations that follow are taken from Alice Lakey, "The Pure Food Law -- What Has It Accomplished?" Outlook, LXXXVIII (February 1, 1908), 263-4.
The answer from the Connecticut Agricultural Experiment Station mentions both good and bad effects:

It has somewhat frightened the wicked, done much to strengthen the moral purpose of the makers of food products. ... It has stimulated the ingenuity of those whose business it is to "beat the law."

The ingenuity of this group was one of the principal reasons for the need of further legislation.
CHAPTER III

FURTHER LEGISLATION: 1907-1935

Thirty-two years were to pass before a new act would supplant the Federal Food and Drugs Act of 1906. Meanwhile the early act was amended time and again in an attempt to overcome difficulties of enforcement and to meet new needs as they arose. Several new acts on individual products were also passed.

As was suggested in chapter II, lack of control over advertising was one of the greatest hindrances to the effective administration of the Act. Makers of patent medicines in particular availed themselves of this weakness of the law. So, for example, quacks who sought customers among foreigners made use of newspapers in foreign languages. Not satisfied with the ethical and legitimate procedure of merely stating their address and their office hours, they made use of an elaborate formula extolling their own skill and goodness. Both quacks and patent-medicine makers used various appeals to insure a large clientele. The advertisement with racial appeal would be addressed to "my sick Rumanian brothers" or would contain the comforting statement that "we speak Polish." Again, an advertisement might appeal to both the fear and the hope of an individual by assuring him that neglect might prove serious, but that "What I have done for others I can do for you." Makers of patent medicines flaunted their honesty by suggesting that their patrons pay after they had been cured.¹ Frequently they

used a saint's or a priest's name to lure people into buying the medicine. A classic example of this kind of salesmanship is "Father John's," which is said to have been merely recommended by a Father John J. Lowell, but was given his name. Finally, patent-medicine makers attracted patrons by means of testimonials, many of which, when analyzed, proved to be false.

While quacks and makers of patent medicines succeeded in evading the law by clever or false advertising and, especially after the Johnson case, by making extravagant therapeutic claims on the labels, manufacturers of food evaded the law by the "distinctive name" loophole, and packers avoided the charge of misbranding on the plea that wrapped meats were not to be construed as food in package form.

Such and similar abuses, as well as new problems, became the targets at which further legislation was directed. The present chapter offers a brief summary of the laws passed between 1906 and 1935, whether they were amendments to the 1906 act or laws relating to individual foods and drugs. So far as possible the chronological order has been preserved, but amendments to a specific act have been discussed with the original act.

The Meat Inspection Act of March 4, 1907, repeated the


provisions for the inspection of cattle, packing establishments, and meat products contained in Beveridge's rider to the Agricultural Appropriation Bill of the preceding year.

The purpose of the Insecticide Act of April 26, 1910, is to prevent the sale of insecticides and fungicides that fall below the strength claimed for them and hence cannot accomplish their function, or that are injurious. Ever since its passage, this act has been of particular interest to fruit growers, farmers, and poultry raisers. After defining the terms insecticide, Paris green, lead arsenate, fungicide, territory, and person, the Act goes on to explain prohibited acts and penalties, and the administration of the various provisions.

The Sherley Amendment, passed on August 23, 1912, was the first amendment to the Food and Drugs Act and was designed to overcome the loophole that had lost the Johnson case to the United States government. For the Supreme Court had held that section 8 of the 1906 act, which defined the term misbranded, did not apply to therapeutic claims on the labels of medicines. The Sherley Amendment became the third sub-point under section 8, "In case of drugs," and provided that a drug should be deemed misbranded

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.

Charles M. Woodruff of Parke, Davis and Co. had suggested the

5 Statutes, XXXVI, 31; Code, title 7, sections 121-34.
6 Statutes, XXXVII, 416.
insertion of the words "and fraudulent" at the end of the amendment, and these words constituted its appalling weakness. The amendment came to be known as the "fraud joker." Although it was comparatively easy to prove that claims were false, it was well-nigh impossible to prove them fraudulent, that is, published with intent to deceive. No matter how scientifically correct the contentions of the government might be, the attitude of the judge and the reaction of the lay jury were of paramount importance in every court decision. When the government lost a case, it was usually not for lack of scientific or technical accuracy, but for legalistic reasons, on account of the generally accepted significance of a label by the ordinary layman. Even when an article had been condemned, the manufacturer might pay the fine, change the name of his product, and go on making and selling his medicine.

The "false and fraudulent" phrase was the explicit loophole of the Sherley Amendment. Two other loopholes were implicit in it. First, it exercised no control over therapeutic devices and appliances, such as fake sun lamps, nose straighteners, and whistles for developing weak lungs. Second, it not only failed to control advertising, but, by limiting its jurisdiction to labels and material contained in the package, actually stimulated false advertising in newspapers, magazines, and motion pictures, on billboards, and over the radio.

On March 3, 1913, Congress passed the Gould Amendment, commonly known as the Net Weight Amendment. The 1906 act had provided that an article of food should be deemed misbranded

If in package form and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.10

This provision had made the statement of weight or measure optional. The Net Weight Amendment made it a positive requirement,11 but dishonest manufacturers still found a loophole. They made use of slack-filled packages and deceptive containers -- bottles with thick bottoms or deep panels or exceptionally long necks, boxes with superfluous cardboard packing, containers with hollow bottoms.12 A further loophole was the provision that "reasonable variations shall be permitted," for who was to determine the meaning of the word reasonable?

On July 24, 1919, the Kenyon Amendment, also called the Wrapped Meat Amendment, amplified the Net Weight Amendment by applying its provisions to wrapped meat. Packers had declared that the word package did not apply to meats. The new amendment provided that the word package as used in this section "shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale."13

One of the most important pieces of drug legislation between 1906

10 Section 8, "In the case of food," subpoint 3.
11 Statutes, XXXVII, 732.
12 Wilson, 80.
13 Statutes, XLI, 271; Code, title 21, section 321 b.
and 1938 was the Harrison Narcotic Act of December 17, 1914, together with its amendment of February 24, 1919. In a drastic attempt to control the narcotic trade, this act forced all dealers in these drugs to obtain a license at the cost of an annual tax of one dollar. Before this license can be secured detailed regulations must be carried out. The penalties for failure to secure a license are severe. The amendment of 1919 increased the tax to twenty-four dollars.

The passage of the Narcotic Act had evil as well as good effects, for it increased illegitimate trade, particularly smuggling over the Mexican border, and made the legitimate users of these drugs pay exorbitant prices. But judging from a report of the Public Health Service, the evil effects were not so great as some people had anticipated:

It has been predicted that the result of the enforcement of this law would be a besieging of hospitals by drug addicts, and a crime wave of national scope accompanied by a trail of suicide and death. While the effect of the enforcement of the federal anti-narcotic law has been clearly evidenced by hospital reports, the results have been by no means so far reaching or so startling as had been expected.

The Naval Stores Act, passed on March 3, 1923, apparently has little connection with food and drugs, but since it is administered by the Food and Drug Administration, it deserves mention here. The Act defines naval stores as spirits of turpentine and rosin, establishes official

14 Statutes, XXXVIII, 785; XL, 1130-3; Code, title 26, sections 2550-61, 2563-4, 3220-8.
15 Cf. "World-Wide Control of Narcotics," Literary Digest, LIV (February 17, 1917), 400.
standards for them, lists prohibitions, regulates traffic, and decrees penalties for violations. 17

Several acts dealing with milk and butter were passed in the 'twenties and early 'thirties. The Filled Milk Act of March 4, 1923, prohibits the manufacture and shipment in interstate or foreign commerce of filled milk, which is defined as "any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, ..." 18 No definite agency was charged with the enforcement of this act until an amendment of August 21, 1935, empowered the Secretary of Agriculture to "make and enforce such regulations as may in his judgment be necessary to carry out the purposes of this Act." 19 "Enforcement is solely by means of criminal prosecution since the Filled Milk Act contains no provision for seizure or injunction." 20

The Import Milk Act of February 15, 1927, provides that all importers or shippers of fluid milk or cream into the continental United States must procure a permit issued on a twelve-months' basis. It requires

17 Statutes, XLII, 1435; Code, title 7, sections 91-9.
18 Statutes, XLII, 1486; Code, title 21, sections 61-3.
19 Statutes, XLII, 1487; Code, title 21, section 64.
that all milk entering the United States should meet definite standards of quality, and that these standards be maintained through inspection of animals and testing of samples. 21

The Butter Act of March 4, 1923, defines butter as "the food product ... made exclusively from milk or cream or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, ..." 22 This act was one step in the long struggle between farmers and the makers of oleomargarine and similar products.

The Federal Caustic Poison Act, approved on March 4, 1927, was designed to safeguard "the distribution and sale of certain dangerous caustic or corrosive acids, alkalies, and other substances in interstate and foreign commerce." 23 It classifies twelve materials as "dangerous caustic or corrosive substances," and declares misbranded any container whose label does not bear the following information: the common name of the substance, the name and place of business of the manufacturer or dealer, the word POISON printed in special type parallel to the main body of the reading matter, and, on packages intended for household use, directions for treatment in case of accidental injury. In connection with the regulations for

21 Cf. ibid., 22. Formerly several countries shipped milk and cream into the United States. Today all milk and cream within the scope of the Import Milk Act is produced in Canada, and the Canadian Department of Agriculture lends valuable assistance in the enforcement of the Act.

22 Statutes, XLII, 1500.

23 Ibid., XLIV, 1406; Code, title 15, sections 401-11.
the enforcement of the Act, the Department of Agriculture has published a list of internal and external antidotes approved by medical authorities for treatment in case of accidental injury.\(^{24}\)

The McNary-Mapes Amendment of July 8, 1930, popularly known as the Canners' Bill, is unique in the history of food legislation in that it sprang from the canners themselves. Hence it represents a moral victory and shows that fair dealing predominates. The amendment, which constituted the fifth subpoint under section 8 of the original Food and Drugs Act, provided for the promulgation of standards of quality for canned goods by the Department of Agriculture. Unless canned goods falling below such standards bore a conspicuous statement to that effect, they were to be deemed misbranded.\(^{25}\)

On June 22, 1934, section 10 A was added to the Food and Drugs Act. This amendment authorized packers of sea food to request the government to inspect their products in the various stages of packing and labeling.\(^{26}\) The amendment was amended on August 27, 1935.\(^{27}\) The contents of the 1935 version were substantially the same as those of the previous version, but in addition the Secretary of Agriculture was authorized to promulgate regulations for the carrying out of this section. Packers of shrimp are the only packers who have thus far availed themselves of this service; hence this section of the Act is often called the Shrimp Amendment.

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25 Statutes, XLVI, 1019-20.

26 Ibid., XLVIII, 1204.

27 Ibid., XLIX, 871; Code, title 21, section 372a.
The sea-food-inspection service represents a distinct innovation in Federal food-law enforcement in that the food manufacturer pays part of the cost of inspection and is free to accept it or reject it, as he wishes. The service corrects potential violations at their source. Compliance with the regulations promulgated under the amendment insures the integrity of the products and thus renders the provisions for seizure, criminal prosecution, or injunction unnecessary. Not only is this advantageous to the packer but the consumer is more effectively guaranteed a sanitary, safe, and wholesome product. 28

At the same time that food and drug legislation itself was being amended and amplified, various changes were being made in its administration.

In 1914 the Food Standards Committee was appointed to further the work of enforcement by formulating standards to be adopted by both Federal and State agencies. It consists of nine members appointed by the Secretary of Agriculture: 3 from the Food and Drug Administration, 3 from the Association of American Dairy, Food, and Drug Officials, and 3 from the Association of Official Agricultural Chemists. After the standards prepared by the Committee have been approved by the various States, they are issued as a regulatory announcement.

The Office of Co-operation, likewise established in 1914, furthers enforcement of food and drug legislation by the mutual co-operation of Federal and State officials. Federal officials turn over to State officials cases of violation that call for State action, and vice versa.

The Federal Trade Commission Act of September 26, 1914, 29 indirectly affected food and drug administration by establishing the Federal

28 The Food and Drug Administration, 15-16.

29 Statutes, XXXVIII, 717; Code, title 15, sections 41-51.
Trade Commission and giving it control of interstate advertising. This was the first step toward overcoming one of the outstanding weaknesses of the 1906 act, its lack of control over food and drug advertising.

On July 1, 1927, the Bureau of Chemistry was superseded in its administrative capacity by the Food, Drug, and Insecticide Administration. The purpose of the new organization was to place under one unified control the enforcement of six laws: the Federal Food and Drugs Act, the Tea Act, the Insecticide Act, the Naval Stores Act, the Milk Act, and the Caustic Poison Act.

In the report of the Food, Drug, and Insecticide Administration for 1928, Walter G. Campbell pointed out that for twenty years most members of the industries had not violated the law deliberately, and hence the Administration had adopted an advisory attitude that would enable manufacturers to comply with the law. His remarks may be regarded as an official estimate of the accomplishments of food and drug legislation:

No better illustration of the working out of this policy can be given than to cite the activities under the food and drug act, discussed in earlier reports, involving canned blueberries, ... and citrus fruits -- choosing at random commodities characteristic of the different parts of the country.

30 The Board of Food and Drug Inspection, commonly known as the Remsen Board, was merely advisory and was abolished in 1915.

31 On July 1, 1930, the name of the organization was changed to Food and Drug Administration, but there was no change in functions.

Some years ago it was discovered that the Maine blueberries were so heavily infested with worms that it became necessary to prevent the distribution of many lots of the canned fruit by instituting seizure action. As blueberry canning is one of the vital industries of Maine, giving a livelihood to a large part of the population of at least one county, the possibility of having the output of many of the canneries seized was a serious prospect. Accordingly, experts were sent into the field to study the problem at first hand. As a result, a method was devised whereby the wormy and otherwise unfit fruit could readily be removed from the berries delivered to the canneries, leaving only those that were fit for canning. The simple and effective piece of machinery developed for this purpose has been almost universally adopted by the Maine packers. Cooperative efforts by the Federal and State officials since that time insured a high-quality pack of blueberries in Maine.

Disastrous freezes have worked havoc in the citrus orchards of Florida and California. Although the effect of a severe frost is not immediately apparent in the uncut fruit, the edibility of frosted fruit is seriously affected by a more or less complete drying of the tissues by the time it reaches the consumer. Farsighted packers were quick to recognize the danger of the loss of their markets if public confidence in the quality of the citrus fruit were shaken. ... The industry thereupon appealed to the administration to maintain, in cooperation with State authorities, that supervision which would preclude the necessity for making frequent seizures on the markets, with subsequent damage to the reputation of the industry as a whole. State assistance, which checks at its source the shipment of frosted fruit, is of great value in law enforcement. As a result of this cooperative effort, very little unfit fruit was shipped during 1928.

This constructive work, which has been of great value in carrying out the terms of the food and drugs act, has met with the enthusiastic approval of the industries.  

But if the industries co-operated with the government, the public, once their confidence had been restored, no longer continued to show the interest that had brought about the Food and Drugs Act of 1906. In his report of 1926, C. A. Browne lamented this lack of public vigilance when

he declared:

The enactment and enforcement of the Federal Food and Drugs Act and State Food legislation has restored the confidence of the public in the purity and wholesomeness and truthful labeling of the food supply of the nation. So marked has been this change that many consumers are sometimes too complacent in regard to the food supply. Some consumers, relying upon the efficiency of the enforcement of food laws, do not take the trouble to read labels on the packages of food they buy, nor do they inspect the contents with any degree of care. They expect food officials to do what only the buyers themselves can do. It was never intended that food legislation should relieve consumers of the duty of carefully inspecting the food they buy. Vigilance on the part of consumers, as well as on the part of officials, is necessary for the full protection of the public. 34

Even though public opinion was languishing, much had been accomplished in the realm of food and drug legislation. On the eve of the F. D. Roosevelt administration, however, it was evident that a new era in food and drug legislation was at hand. The problem of cosmetics had assumed vast proportions, and only a new law embracing food, drugs, and cosmetics could adequately deal with the current situation.

CHAPTER IV

THE FOOD, DRUG, AND COSMETIC ACT OF 1938

As in the early years of the twentieth century, so in the 'thirties an attempt was made to rouse the public from their lethargy by several writers of exposure literature, which had the characteristics of muckraking though it did not bear the name. Prominent among the books that appeared were three: Your Money's Worth, by Stuart Chase and F. J. Schlink, 100,000,000 Guinea Pigs, by Arthur Kallet and F. J. Schlink, and American Chamber of Horrors, by Ruth de Forest Lamb.

The first of these three books, Your Money's Worth, is not limited to food and drugs. Its subtitle indicates its content: "A Study in the Waste of the Consumer's Dollar." So far as food and drugs are concerned, therefore, the book aims to show how the consumer is deceived about their value, particularly by means of clever, though misleading, advertising, the psychological principle of which is: "Repetition is Reputation." Current magazine articles and government publications form the basis of the book, which, during a period of nine years, was reprinted nineteen times.


2 Ibid., 14.
100,000,000 Guinea Pigs,³ as its subtitle indicates, points out how dangerous many common foods, drugs, and cosmetics are. After presenting numerous cases of fraud in each of the three fields under discussion, the authors lament the failure of the government to protect the consumer. They explain what should be done about the food and drug law itself, suggest issues of a new law, and urge the individual consumer to do his part in bringing about better legislation and enforcement by keeping informed about notices of judgment, by being careful in the purchase of foods, drugs, and cosmetics, and above all, by protesting again and again against "the indifference, ignorance, and avarice responsible for the uncontrolled adulteration and misrepresentation of foods, drugs, and cosmetics."⁴ That the book produced its desired effect seems evident from the fact that thirty-seven printings of it were made between January 12, 1933, the date of its publication, and October 16, 1941.⁵

American Chamber of Horrors⁶ is by far the most convincing of the

³ Arthur Kallet and F. J. Schlink, 100,000,000 Guinea Pigs, The Vanguard Press, New York, 1933.

⁴ Ibid., 302-3.

⁵ The material in the Guinea Pig books, of which the book here discussed is the first, is corroborated by notices of judgment under the Food and Drugs Act as well as by Arthur Cramp's brochure on patent medicines and a brochure on cosmetics, both of which were issued by the American Medical Association. The entire series was rather scathingly condemned by G. L. Eskew in Guinea Pigs and Bugbears (Research Press, Chicago, 1938). The style and general make-up of this volume savor of the kind of attack that was made upon Upton Sinclair and other muckrakers prior to the 1906 act.

three books simply because its author had access to official records and because the appendices are filled with incontrovertible data. Written shortly after President Roosevelt's official appeal to Congress for a new food and drug act, the book purposes to answer questions like the following:

Why do we need a new law? What's the matter with the old Food and Drugs Act? Is it still being enforced? What has the Department of Agriculture to do with it? Where does Senator Copeland come in? Who actually drafted the Copeland Bill? What was in it? Who opposed it? Who fought for it? Who emasculated it -- or wasn't it emasculated? What happened to it?

The book takes its name from the so-called "Chamber of Horrors" at Washington, one of the rooms occupied by the Food and Drug Administration, in which were exhibited samples of injurious and fraudulent products that inspectors had picked up in the course of their work. The first chapter demonstrates the legal impotence of the Federal Public Health Service, the Post Office, the Federal Trade Commission, and the Food and Drug Administration to cope with current problems in food and drugs as well as in cosmetics. Succeeding chapters frankly present the fraud and death-dealing that are being systematically carried on by men who value their own money more than other people's lives. Finally, chapter eleven deals with the struggle for a new law, carrying its account up to the summer of 1935. The titles of the chapters and the illustrations might draw the verdict of "sensational" on the book, but a careful reading will lead to the conclusion that it is a sober account of one of the major problems of the day.

Despite the wide circulation that these books attained, the 1938

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7 Ibid., Preface, vii.
8 Ibid., ix.
bill never became the object of widespread public opinion. The industries and some women's organizations kept in touch with the bill, but the public in general knew little of what was happening in Congress. Newspapers rarely gave prominent mention to the new law. Only three consistently supported the measure: the St. Louis Post-Dispatch, the Christian Science Monitor, and the Emporia Gazette. Magazines, too, maintained a silent or unfriendly attitude. This policy on the part of the press was undoubtedly due to the fact that the new bill threatened advertising, an important source of revenue for both newspapers and magazines.

Because there was considerable divergence of interest among the industries themselves, there was no concentrated opposition on the floor of either house. The industries realized the need of some new measure; their aim, therefore, was to promote the enactment of a law that would protect their individual interests without laying too heavy a burden of Federal regulation upon them. This they could best accomplish not in the open forum of the Senate or the House, but through the less public action of committees. Hence the five-year struggle for the new food and drug law took place

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11 Cf. Lamb, 292-5 and 297, for samples of letters and circulars sent out by patent-medicine makers to insure an unfriendly attitude to the proposed measure on the part of the press.
chiefly in the House and Senate Office Buildings. 12

The preliminary steps in the drafting of a new bill were taken in the spring of 1933, when Dr. Rexford G. Tugwell, the newly appointed Assistant Secretary of Agriculture, sounded out the Chief of the Food and Drug Administration, Walter G. Campbell, on the deficiencies of the old law. He immediately set about obtaining presidential approval for a revision of the 1906 act. Once this had been secured, he organized a competent group to draft the measure. 13 Three members of the Food and Drug Administration -- Walter G. Campbell, Chief, P. B. Dunbar, Assistant Chief, and C. W. Crawford, Chief of Interstate Supervision, and three officials from the Solicitor's Office of the Department of Agriculture -- P. M. Cronin, J. B. O'Donnell, and J. F. Moore, were most active in the drafting of the bill, although other members of the Food and Drug Administration who were specialists in certain fields were also consulted. Three other experts were added as advisers to the group: Milton Handler of the Columbia Law School, Frederick P. Lee, a former drafting expert of the Senate, and David E. Cavers of Duke University Law School. 14

The group began its work in March, 1933. It had been entrusted with the task of revising the 1906 act within the framework created for that

12 Cavers, 4-5.

13 It is interesting to note that although the new bill from the moment it entered the Senate was dubbed the "Tugwell Bill," Dr. Tugwell had no part in the drafting of it. His office was distinctly that of sponsor.

14 Lamb, 286.
act, that is, to keep the Food and Drug Administration a policing organization, not to make of it a quasi-legislative or a quasi-judicial body.Very soon, however, it became evident that only an entirely new bill could successfully deal with the problems that had arisen since the 1906 act had been passed as well as with weaknesses in that law itself. To obtain suggestions from the affected industries, it was decided to hold conferences of representatives of these trades. Accordingly, representatives of the drug industry were consulted on April 27, 1933, and representatives of the food industry on the following day. These conferences were, on the whole, unsatisfactory, although some valuable suggestions were made. The representatives of the industries were disappointed that no draft of the proposed bill was submitted for their consideration.

On May 31 the work was finished, and the following day Secretary Wallace sent copies of the completed draft to the respective chairmen of Senate and House Committees on Agriculture. Their evident indifference and the eagerness of the Department to have the bill at least on record before the close of the one-hundred-day session, led to its introduction on June 12, 1933, by Senator Royal S. Copeland of New York, a doctor who had shown interest in food and drug legislation. After the customary double reading of the bill by title, it was referred as S. 1944 to the Committee on Commerce, of which Senator Copeland was a member.

15 Cavers, 6.
16 Ibid., 7.
17 To trace the history of the bill in detail would lead too far afield. The present study purposes rather to summarize the main steps in the development of the bill. For a more detailed analysis, cf. Lamb, 286-327; Royal S. Copeland, "Protection for the Public," Scientific American, CLVIII (February, 1938), 88-9; "Fight over
What were the provisions of this bill, which, during the subsequent five years, was modified to such an extent that it could scarcely be recognized? Ruth de Forest Lamb summarizes them as follows:

First of all, it covered cosmetics, banning outright such products as Korumlu and Lash-Lure, and regulating the manufacture, advertising, and sale of all other beauty products in interstate commerce. It eliminated the fraud joker, ... It forbade the advertising of any drug for tuberculosis, diabetes, cancer and other specified diseases in which self-medication is especially dangerous. ... It outlawed entirely patent medicines which might be dangerous to health under the conditions of use prescribed in the labeling -- things like dinitrophenol or cinchophen; and required hypnotics or habit-forming products to carry warning labels. It forbade the representation of drugs as cures when they had only a palliative effect; stipulated that antiseptics give an accurate account of themselves on their labels; provided for the declaration of formulas; and required that drugs liable to deterioration be packaged and labeled in such a way that the consumer could be sure they were properly effective when he bought them. It provided much-needed control over curative devices... It gave the Department of Agriculture special authority to regulate the advertising of foods, drugs, and cosmetics. It demanded fully informative labels on both foods and drugs. It authorized the Secretary to fix not only standards of identity for all food products, but multiple standards of quality as well (with the grades declared on the labels), and also tolerances for poisons in foods and cosmetics. It forbade slack fills and the use of deceptive containers. It eliminated the distinctive-name joker. It provided for factory inspection and voluntary supervision of food production, as well as authorizing the Government under certain circumstances to put the manufacturer under a permit which would insure sanitary conditions and a wholesome product. And it provided more drastic penalties, with injunctions against chronic offenders.


18 Lamb, 288-90.
From the very first the industries did not give S. 1944 a cordial welcome. They dubbed it the Tugwell Bill, though normally it should have been called the Copeland Bill since it was the Senator who introduced the bill and sponsored it in the Senate. The drug industry in particular regarded the bill with hostile eyes. Early in September the United Medicine Manufacturers of America, assembled in convention at Chicago, drew up seventeen plans for opposing the bill:

1. Increase the membership of the association at once to present a united front in combating the measure.

2. Secure cooperation of newspapers in spreading favorable publicity, particularly papers now carrying advertising for members of the association.

3. Enlist all manufacturers and wholesalers, including those allied to the trade, and induce them to place the facts before their customers through salesmen, and in all other possible ways to secure their cooperative aid.

4. Secure the pledge of manufacturers, wholesalers, advertising agencies, and all other interested affiliates to address letters to Senators to gain their promise to vote against the measure.

5. Line up with other organizations, such as Drug Institute, Proprietary Association, National Association of Retail Druggists, and others, to make a mass attack on bill.

6. Appoint a committee to work in conjunction with the organization's lawyers.

7. Every member to forward to headquarters newspaper clippings and all available data as basis for bulletins and favorable publicity.

19 This tagging of the bill as the Tugwell Bill may lead to some confusion in the mind of the reader, for sometimes the bill is referred to as the Tugwell, sometimes as the Copeland, Bill. In this study it will hereafter be called the Copeland Bill or be referred to by its number, which changed from year to year as the original bill was revised. In 1933 it was S. 1944; in 1934, S. 2000 and S. 2800; in 1935 and 1937, S. 5.
8. All members to do missionary work in home districts to arouse the public to the dangers of the legislation proposed.

9. Convey by every means available ... the alarming fact that if the bill is adopted, the public will be deprived of the right of self-diagnosis and self-medication, and would be compelled to secure a physician's prescription for many simple needs.

10. Arrange for conferences between association committee and representatives of all other trade associations interested.

11. Enlist the help of carton, tube, bottle, and box manufacturers.

12. Defeat the use of ridicule by the American Medical Association -- who favored the measure -- by replying with ridicule.

13. Convince the newspapers of the justness of the cause and educate the public to the same effect.

14. Set up a publicity department for the dissemination of information.


16. Maintain direct and constant contact with the situation at Washington.

17. Pledge of 100 per cent cooperation on the part of every member of the association present for continued and unremitting activity in every possible direction to defeat measure.20

When hearings on S. 1944 were held on December 7 and 8, 1933, the principal objections were the rule-making power granted to the Secretary of Agriculture, the alleged attempt to deprive American people of the right of self-medication, and the provision authorizing the Secretary to promulgate

grades of quality for foods.\textsuperscript{21}

By the time the hearings came to a close, it was evident that some revision was necessary if S. 1944 was not to be defeated by rival bills drafted by the industries. Accordingly, a new bill was drawn up, which was introduced by Senator Copeland on January 4, 1934, as S. 2000. Though the opposition was not materially lessened, this new bill drew forth a scathing denunciation on the part of Consumers' Research. Only the representatives of women's organizations refused to adopt a defeatist attitude and continued in their efforts to secure the best possible bill. In his endeavors to compromise with both the industries and the consumer interests, Senator Copeland consented to a number of suggested amendments. Eventually the bill was revised and introduced as S. 2800. One important change had been made to conciliate both the food and the publishing industries: the Secretary of Agriculture was not permitted to establish standards of quality for any food.\textsuperscript{22}

During the hearings before the Committee on Commerce, held on February 27 and March 3, there first appeared what was to become one of the major issues during the next three years. Commissioner Davis of the Federal Trade Commission suggested that cases of false advertising be submitted to the Commission rather than to the courts.\textsuperscript{23}

On January 4, 1935, Senator Copeland introduced a new bill

\textsuperscript{21} Cavers, 9.

\textsuperscript{22} Ibid., 11.

\textsuperscript{23} Ibid., 12.
numbered S. 5. Substantially it differed little from S. 2800 at the end of the previous session of Congress. Early in the year, on March 22, President Roosevelt brought some pressure to bear on Congress by sending a special message in the interest of food and drug legislation. After stressing the need of honesty in every enterprise and deploring the fact that no standards of identity and quality had as yet been set up for food and drugs, he continued:

These principles have long been those on which we have founded public policy. But we have fallen behind in their practical application. No comprehensive attempt at reform in the regulation of commerce in food and drugs has been made since 1906. I need not point out to you how much has happened since that time in the invention of new things and their general adoption, as well as in the increase of advertising appeals. Because of these changes loopholes have appeared in the old law which have made abuses easy.

It is time to make practical improvements. A measure is needed which will extend the controls formerly applicable only to labels to advertising also; which will extend protection to the trade in cosmetics; which will provide for a cooperative method of setting standards and for a system of inspection and enforcement to reassure consumers grown hesitant and doubtful; and which will provide for a necessary flexibility in administration as products and conditions change.

I understand this subject has been studied and discussed for the last two years and that full information is in the possession of the Congress.

No honest enterpriser need fear that because of the passage of such a measure he will be unfairly treated.... Present legislation ought to be directed primarily toward a small minority of evaders and chiselers. At the same time even-handed regulation will not only outlaw the bad practices of the few but will also protect the many from unscrupulous competition. It will, besides, provide a bulwark of consumer confidence throughout the business world.

It is my hope that such legislation may be enacted at this session of the Congress. 24

24 Congressional Record, LXXIX, 4262.
By April 1, 1935, when the bill reached the floor of the Senate, the material for debate had resolved itself into three major issues, which continued to occupy a dominant place in the controversy until the bill was passed. The first of these was the question of limiting the power of the Food and Drug Administration to make multiple seizures of foods or drugs which were either dangerous to health or grossly fraudulent.25 The second was concerned with the control of interstate advertising of food, drugs, and cosmetics, which until then had been exclusively controlled by the Federal Trade Commission, but which, it was believed, should be placed under the jurisdiction of the Food and Drug Administration since Federal Trade Commission control had proved inadequate in recent years.26 The Commission itself was an interested party in the debate on this question, and it was supported by the various associations of patent-medicine makers.27

The third major issue was of particular interest to fresh-fruit and vegetable dealers. It dealt with the court review of regulations established by the Secretary of Agriculture. These regulations, according to a number of provisions in the bill, had the force of law; but the crucial provision was the one empowering the Secretary to make regulations on the tolerances for poisons, such as insecticide sprays, which could not be entirely eliminated in the preparation of foods for market. If the Secretary had this power, judicial proceedings would be much simplified, for the Food and Drug Administration would have to prove only that the tolerance had been

26 Cf. Wilson, 127-8, for the principal objections to the continuance of the Federal Trade Commission's control of advertising.
27 Cavers, 13-14.
exceeded instead of proving besides that a particular amount of poison was really dangerous to health. The International Apple Association was the chief opponent of this provision and, by implication, of the other provisions empowering the Secretary to promulgate regulations having the force of law. 28

Senators Bailey of North Carolina, Clark of Missouri, and Vandenberg of Michigan led the opposition to the Copeland Bill and introduced a series of emasculating amendments. So violent did the debate become that Senator Copeland cried out:

Mr. President, if these amendments, [the Bailey amendments, especially the third, which provided for a single seizure] plus one presented by the Senator from Missouri, which is also a blanket amendment, which proposes the transfer of supervision of advertising to the Federal Trade Commission shall be adopted, I shall have no further interest in the bill. The provisions affected by all these amendments are those which implement and make possible the successful administration of the proposed law. 29

Nevertheless, S. 5 as it had been amended was passed by the Senate on May 28, 1935. 30

During July and August Representative Virgil Chapman of Kentucky conducted public hearings on the bill. The unusual feature of these hearings was the fact that Chapman investigated both the records of the witnesses and those of the products they represented.

In 1936, after the bill had been amended in committee, it reached

28 Ibid., 14-15. For an account of the discussion on all these issues cf. Lamb, 309-16.
29 Congressional Record, LXXIX, 5022; cf. also ibid., 5139.
30 Ibid., 8356.
the House floor and was passed on June 19, 1936.31 In the conference between representatives of both houses which followed, there was a deadlock on the question of control of advertising, over which the House had given the Federal Trade Commission exclusive jurisdiction. Senator Copeland suggested as a compromise that the Food and Drug Administration be given control of advertising affecting drugs. The motion was carried, but the following day the bill was defeated in the House by a vote of 190-70.32

At the opening of the first session of the seventy-fifth Congress, Senator Copeland again introduced his bill under the same number, S. 5. Again the bill was amended in committee. It reached the floor of the Senate on March 8, 1937, and was passed the following day.33 At the request of Senator Copeland the Congressional Record for that day carried a summary of the objections to S. 5 made by women's organizations. They held that the bill as reported on March 8 did not give adequate consumer protection, since it limited the number of seizures, did not provide for effective control of advertising or for sufficient labeling of drugs and cosmetics, exempted coal-tar dyes from cosmetic regulation, did not authorize the establishment of several standards of quality, and provided court review of regulations, which definitely weakened the law.34

The House did not take action on the bill until the third session

31 Ibid., LXXX, 10244.
32 Ibid., 10680.
33 Ibid., LXXXI, 2019.
34 Ibid., 2021.
of the seventy-fifth Congress. Meanwhile, however, the Wheeler-Lea Act, sponsored by Senator Wheeler of Montana and Representative Lea of California, occupied the attention of both houses. It gave control of food and drug advertising to the Federal Trade Commission. With its passage the advertising provisions in S. 5 lost all meaning. 35

A new and very important provision, however, became a part of S. 5 as the result of the Elixir Sulfanilamide tragedy, which had occurred shortly before the opening of this session. In an attempt to make the valuable drug sulfanilamide available in liquid form, the Massengill Company of Tennessee had used diethylene glycol, a deadly ingredient, as a solvent. Seventy-three persons died as a result of taking the drug. The Food and Drug Administration succeeded in seizing almost the entire stock of the drug and so prevented further fatalities. But the only legal basis for this action was that the drug had been misbranded, because only an alcoholic solution may properly be called an elixir. 36

To prevent similar tragedies and to place Federal action on a firmer basis than the tenuous thread of an unfortunately selected name, Senator Copeland and Representative Chapman introduced bills in their respective houses forbidding the introduction into interstate commerce of drugs not considered safe for use under the conditions indicated on the label, unless the particular drug had been declared not unsafe for use by

35 Cf. ibid., LXXXIII, 3287-93. The provisions of this act are discussed below, in connection with the Food, Drug, and Cosmetic Act.

the Secretary of Agriculture. The Chapman bill was eventually incorporated into S. 5 and thus became part of the Food, Drug, and Cosmetic Act.37

One further issue was still pending: the judicial review of food and drug regulations. The apple growers succeeded in having a provision inserted into the bill which would prohibit the Secretary from enforcing regulations, for within ninety days of the issuance of regulations suits could be instituted in any of the more than eighty Federal district courts. One adverse decision would prevent the enforcement of a regulation throughout the country for months, perhaps for years. Secretary Wallace objected strenuously to this judicial-review provision, declaring that it would be better to keep the 1906 act than to pass S. 5 with the provision. In the House, however, "apples outweighed arguments,"38 and the bill containing this provision was passed on June 1, 1938.39

Thereafter events moved rapidly. The Senate revised the judicial-review section and removed its objectionable features. In its final form the bill was passed by the Senate on June 10, 1938;40 three days later it was passed by the House;41 and on June 25, 1938, it was signed by President Roosevelt.

The Federal Food, Drug, and Cosmetic Act, as the new law was called, consists of nine chapters, each dealing at length with some

37 Cavers, 20.
38 Ibid., 21.
39 Congressional Record, LXXXIII, 7903; cf. Fuchs, 43-69.
40 Congressional Record, LXXXIII, 8738.
41 Ibid., 9101.
particular phase of the subject. An outline of the Act follows:

I. Short title of the act

II. Definitions of terms used in the act, the most important of which are: food, drug, device, cosmetic, label, labeling, and new drug

III. Prohibited acts and penalties

A. Prohibited acts, the most outstanding of which are: the introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded; the adulteration or misbranding of any such product in interstate commerce; and the manufacture of any such product

B. Injunction proceedings

C. Penalties

D. Seizure

E. Hearing before report of criminal violation

F. Report of minor violations

G. Proceedings in the name of the United States

IV. Food

A. Definitions and standards

B. Adulterated food

C. Misbranded food

D. Emergency permit control

E. Regulations making exemptions

F. Tolerances for poisons and certification of coal-tar colors for food

V. Drugs and devices

A. Adulterated drugs and devices

B. Misbranded drugs and devices

C. Exemptions in case of drugs and devices

D. Certification of coal-tar colors for drugs

E. New drugs

VI. Cosmetics

A. Adulterated cosmetics

B. Misbranded cosmetics

C. Regulations making exemptions

D. Certification of coal-tar colors for cosmetics

VII. General administrative provisions

A. Regulations and hearings

B. Examinations and investigations

C. Records of interstate shipment
D. Factory inspection
E. Publicity
F. Cost of certification of coal-tar dyes

VIII. Imports and exports

IX. Miscellaneous

A. Separability clause
B. Effective date and repeals

A folder distributed by the Federal Security Agency lists the provisions of the 1938 act on food, drugs, and cosmetics in language that is more intelligible to the ordinary layman than the technical terminology of the law itself. A copy of this folder constitutes Appendix A. Appendix B is a copy of a mimeographed folder also distributed by this agency, which points out the principal differences between the 1938 and the 1906 act, with references to specific sections in the new law.

The Federal Food, Drug, and Cosmetic Act controls the labeling of all foods, drugs, devices, and cosmetics — that is, the label itself, and all "other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." In


43 On June 30, 1940, the functions of the Food and Drug Administration were transferred to the Federal Security Agency, and the functions of the Secretary of Agriculture in regard to the administration of the Act were transferred to the Federal Security Administrator.


45 Section 201 (m).
this it marks a decided advance over the 1906 act, which gave the Secretary of Agriculture jurisdiction over the label only.

The new act, however, does not apply to false and misleading advertisements of foods, drugs, and cosmetics. This phase of the problem, for years one of the greatest loopholes of the old act, is taken care of by the so-called Wheeler-Lea Act, passed in March, 1938. In reality this act consists of amendments to the Federal Trade Commission Act of 1914. From the time of its establishment, the Commission had exercised control over advertising of all industries engaged in interstate commerce. The Wheeler-Lea Act simply augmented its powers and made specific provisions with regard to foods, drugs, and cosmetics.46

The crux of the Wheeler-Lea Act lies in its definition of a false advertisement:

... an advertisement other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.47

By taking into account not only what an advertisement says but also what it fails to reveal, this act marks a great advance. Its defect, however, as

47 Section 55 (a).
Milton Handler points out,\textsuperscript{48} lies in the ambiguity of its language and in its failure to adopt an uncompromising standard of truth. Further defects in the Act are the inadequacy of the penalties it prescribes and the fact that it divides the enforcement of food and drug legislation between two agencies.\textsuperscript{49}

The Federal Food, Drug, and Cosmetic Act and the Wheeler-Lea Act represent the latest attempt of the Federal government to gain adequate control over foods and drugs. Their failure to attain the strength intended by the original promoters of new food and drug legislation must be attributed largely to the pressure brought to bear upon Congress by interested parties. They do, however, constitute a decided step forward in the solution of a major social problem.


\textsuperscript{49} Ibid., 103-10.
CHAPTER V

CONSTITUTIONAL ASPECTS OF FEDERAL FOOD AND DRUG LEGISLATION

Throughout the long struggle for Federal food and drug legislation, the constitutionality of such legislation was frequently questioned. Opposition rested on one of three grounds: that it violated the individual rights of the consumer, that it disregarded the property rights of the producer, or that it trespassed on State rights. Ultimately this question of constitutionality resolves itself into the question of national police power -- its nature, its extent, and the manner in which it is exercised. The present chapter, therefore, purposes to present a brief survey of police power and its relation to food and drug legislation, and to discuss existing legislation in the light of the three issues involved.

There is in every sovereignty an inherent and plenary power to make all such laws as may be necessary and proper to preserve the public security, order, health, morality, and justice. This power is called the "police power."1

By this power "the government abridges the freedom of action or the free use of property of the individual in order that the welfare of the state or nation may not be jeopardized."2 It has its origin in the fundamental purpose of organized society. It is an inherent and essential power of


For the state ... must have the right of self-protection and the right to preserve its own existence in safety and prosperity, else it could neither fulfill the law of its being nor discharge its duties to the individual. And to this end, it is necessarily invested with power to enact such measures as are adapted to secure its own authority and peace, and to preserve its constituent members in safety, health, and morality.3

In its broadest sense, police power may be construed to embrace all legislation and every function of government. In the sense of constitutional law, however, (and this is the sense in which it is used here) its scope is limited to laws that prevent and punish crime, preserve peace and order, and promote or preserve public health, safety, and morals. It may not exceed the legitimate demands of public welfare nor may it trespass on the fundamental rights of the individual.4 It may restrict freedom of action or the free use of an individual's property only when either of these would endanger the public welfare.

Is legislation concerning food and drugs a legitimate exercise of police power? Yes, such legislation comes within its scope, for it ordinarily has one of two purposes: to protect the public health or to prevent fraud. In other words, food and drug legislation in general centers around two evil practices, adulteration and misbranding. On the first of these subjects, Black declares:

It is undoubtedly within the legitimate scope of the police power to prohibit the adulteration of articles intended for human food, and to impose penalties upon those who sell, or offer for sale, tainted,

3 Black, 335.

unwholesome, or adulterated products. Where the adulteration consists in the addition of something dangerous or deleterious to health, the ground of state interference is very clear. When the added ingredient is harmless in itself, the sale of the adulterated compound may still be forbidden, on the ground of the fraud and deception practiced in its sale.5

Misbranding is suggested in the last phrase of this passage, for misbranding in its final analysis is fraud. On this subject Black writes:

The protection of the whole community, or of classes of individuals, against fraud, ... is a legitimate department of the police power. Historically this is shown by the old markets laws, against engrossing and forestalling, and the criminal laws against fraud and conspiracy which have always existed; and theoretically it is justified by the consideration that one of the functions of the state is to protect all citizens in the equal enjoyment of their rights.6

But according to some of the opponents of both the 1906 and the 1938 law, food and drug legislation interferes with the free choice of the consumer and hence violates individual liberty. In an attempt to defeat the 1906 bill by heaping ridicule upon it, Senator Aldrich, one of the leading opponents, declared:

Are we going to take up the question as to what a man shall eat, and what a man shall drink, and put him under a severe penalty if he is eating and drinking something different from what the chemists of the Agricultural Department think desirable?7

Manufacturers of patent medicines used a similar plea when, during the 'thirties, they informed the public that the Copeland Bill would deprive

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5 347.

6 361.

them of the right of self-medication. Both the Senator and the patent-medicine manufacturers were guilty of fallacies in their argument. The Senator was making himself ridiculous, for no food and drug law penalizes the consumer in any way. It rather upholds his right to health and an honest deal by penalizing a manufacturer who attempts to foist adulterated or misbranded foods upon him. Nor does such legislation prescribe what a man should eat or drink; it merely makes it possible for him to know the ingredients and, in some instances, the quality or standard of the food he is buying. The intelligent consumer welcomes the service the government is rendering him by means of food legislation. So far as the right of self-medication is concerned, far from depriving the individual of this right, drug legislation insures safe self-medication by its regulations on labeling. Drug legislation interferes as little with the individual's right of self-medication as warning signals at railroad crossings interfere with his right to walk.

Absolutely speaking, it is indeed true that food and drug legislation does interfere with personal liberty by restraining the free choice of the consumer -- even if this restraint is concerned only with filthy, deleterious, or poisonous products. Every law, however, restricts the freedom of an individual or a group of individuals in order to attain a social or an economic gain. When laws are attacked as unconstitutional on the basis of violating the Fifth Amendment, the restriction on the individual's

rights is balanced against the social gain. Only if the former outweighs the latter, is the Fifth -- or, in the case of State legislation, the Fourteenth -- Amendment violated. In the case of food and drug legislation it is obvious that the restriction decried by Senator Aldrich in 1906 and by patent-medicine manufacturers in 1938 is a negligible one in comparison with the social gain achieved. In reality, opposition to legislation on this score was, in both instances cited, a bit of propaganda, for the business interests of both parties were involved.

But if the charge of violating the free choice of the consumer could be so easily set aside that it never became an important controversial point, the second challenge to the constitutionality of food and drug legislation became the issue of some of the most bitter legislative battles in Congress. Its promoters declared that food and drug legislation interfered with the property rights of the producer. Seizure of adulterated or misbranded goods, inspection of factories, establishment of grades of quality and of poison tolerances -- all these are, strictly speaking, violations of property rights. Worst violation of all, in the minds of patent-medicine and food manufacturers, was the provision demanding the disclosure of secret formulae. They

... desperately argued that disclosure of their formulae would destroy their entire businesses as their competitors and all the world would know their secrets. The counter-argument was that processes were more important than constituents, and that through chemical analysis competitors were probably well acquainted with each others' formulae anyhow, and what they really feared was revealing the ingredients to the consumer. This charge was partly confirmed by the manufacturers' attempt to compromise by suggesting a provision requiring the filing of secret

9 Robert Eugene Cushman, What's Happening to Our Constitution? Public Affairs Pamphlet No. 70, 7-8.
formulæ with the Secretary of Agriculture instead of publication on the label. The fact that most reputable manufacturers were already practicing full formula disclosure counted heavily against the proprietary interests. The truth is that the real value of many secret-formulæ products lies not so much in the formula as in the good-will built up in the name of the product by advertising. 10

The orux of the property-rights argument lies in the interpretation of the term due process of law. For the Fifth Amendment forbids the Federal government, and the Fourteenth forbids individual States, to deprive any citizen of life, liberty, or property "without due process of law." What is the meaning of this term?

It may be defined as the conformity of an act -- legislative, executive, or judicial -- "to the requirements of the constitution and to the settled principles of right and justice." 11 It is equivalent to the expression law of the land, which appears in the Magna Charta, and has always been regarded as one of the great safeguards of liberty. 12 In connection with police power, due process has acquired a specific meaning.

From the last quarter of the nineteenth century on, the guaranty of due process of law has been interpreted as a check upon all governmental action affecting liberty and property. All such action must be capable of justification upon some theory of public interest which is both rational and regardful of individual liberty and property as rights essential to a free state. In view of this requirement the idea of police power asserted itself by way of distinction from other governmental powers as the power which has for its immediate object the furtherance of the public welfare through restraint and compulsion exercised over private rights. 13

10 Wilson, 158.
11 Black, 481.
12 Ibid., 479.
13 Cyclopedia, II, 706.
If this power is exercised "in strict accordance with the rules of the constitution and the laws, the requirement of due process is fully complied with."\textsuperscript{14}

Existing food and drug legislation makes ample provision for the observance of due process of law. Seizure must follow certain rules to the letter.\textsuperscript{15} One entire chapter of the 1938 bill is devoted to \textit{general} administrative provisions, all of which, while they aim at protecting the consumer, are likewise designed to shield the producer.\textsuperscript{16} Not the least important, from the point of view of the producer, are the provisions for court review of regulations for the efficient enforcement of the Act.\textsuperscript{17}

The individual-liberty and property-rights arguments against the constitutionality of food and drug legislation would be equally valid whether State or Federal laws were concerned, although here they have been discussed in relation to Federal laws only. But the third, and perhaps the most serious, constitutional challenge had reference to Federal legislation only. Its proponents declared that the enactment of such laws was a violation of State rights since they constituted a direct exercise of police power, one of the powers reserved to the States.\textsuperscript{18} The advocates of Federal legislation, on the other hand, argued that the problems were national in scope, that they

\textsuperscript{14} Black, 482.
\textsuperscript{15} Section 304.
\textsuperscript{16} Sections 701-6.
\textsuperscript{17} Section 701 (e), (f).
\textsuperscript{18} Cf. \textit{Congressional Record}, XL, 8910; Wilson, 35-6.
could be adequately handled only by the Federal government, and that the Constitution authorized their enactment.\textsuperscript{19} The issue at stake here is the nature and extent of Federal as opposed to State police power.

In the United States, police power is vested in both the individual States and the nation as a whole, that is, in Congress. That the States should have this power is clearly evident. That Congress should possess it may not be immediately evident, but it is nevertheless reasonable. The preservation of safety, health, and morals, is, for the most part, a matter of State police power. But Congress has the right to pass laws for the preservation and protection of the nation as a whole. "The police power," argues Black, "being primarily a right of self-defense, as applied to organized civil society, it must belong of right to every independent government, including that of the United States."\textsuperscript{20} As a matter of fact, however, two fundamental principles underlie Federal police power and make it something unique in the history of law and government: the principle of enumerated powers and the principle of implied powers.

Congress enjoys only those powers delegated to it by the States. All other powers, as the Tenth Amendment declares, "are reserved to the States respectively, or to the people." Hence the doctrine that the powers of Congress are enumerated has always been a constitutional axiom.\textsuperscript{21} Since the Constitution nowhere vests Congress with authority to legislate on behalf of the health, morals, or general welfare of the nation, it follows

\textsuperscript{19} Cf. "Has America the Right of Self-Defense?" \textit{Outlook}, LXXXIII (June 16, 1906), 351-4.

\textsuperscript{20} Black, 340.

\textsuperscript{21} Cushman, "National Police Power," 291.
that in the exercise of police power Congress may use only its enumerated powers; in other words, it must find a constitutional peg for every law in the interest of the public welfare. These constitutional pegs, as enumerated in section 8 of Article I, are three:

The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and provide for the common defense and general welfare of the United States; ... 22

To regulate commerce ... among the several States ...

To establish post offices and post roads; ...

The doctrine of enumerated powers, under which it would have been practically impossible to develop a Federal police power, is supplemented by the doctrine of implied powers, which hinges on the omission of the word expressly in the Tenth Amendment. This amendment was carried over, as it were, from the Articles of Confederation, the second provision of which was:

Each State retains its sovereignty, freedom and independence, and every power, jurisdiction, and right, which is not by this confederation expressly delegated to the United States in Congress assembled.

The Tenth Amendment reads:

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

The question as to whether or not Congress may exercise powers not expressly delegated to it was conclusively settled in 1819, when Chief Justice Marshall of the Supreme Court gave what is considered the classic statement

22 Regarding the phrase "to pay the debts ... general welfare," Cushman remarks: "It has been generally agreed ... that this clause does not confer a general police power upon Congress, but merely of levying taxes, etc., for the purpose of paying the debts and providing for the common defense and general welfare of the country." ("National Police Power," 291, footnote 4.)
of the doctrine of implied powers:

Let the end be legitimate, let it be within the scope of the Constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but are consistent with the letter and spirit of the Constitution, are constitutional.23

Although the doctrine of enumerated powers makes it necessary for Congress to find a constitutional peg on which to hang every exercise of its police power, the doctrine of implied powers has made it possible to hang all kinds of police legislation on these pegs.

In its exercise of police power, Congress is likewise subject to two other limitations. It must abide by the specific prohibitions on its authority contained in the Constitution and in the Bill of Rights; and in its use of a constitutional peg it must maintain a proper balance between the regulation and the peg. In other words, Congress must always be conscious that it is using a specific delegated power, the exercise of which incidentally protects or promotes safety, health, or morals.24 Commenting on the last-named limitation, T. Swann Harding remarks that the food law of 1906 was actually based on a joker, for it would have been impossible to make a law whose primary purpose was to protect public health or money from unscrupulous manufacturers of food and drugs. "That scientifically fundamental social end," he writes, "had to be incidental to the major legal purpose of the act, augustly to prevent the pollution of the stream of interstate commerce."25


24 Ibid., 297-9.

But if Harding deplored the indirectness of legislation hung on constitutional pegs, others viewed this use of the commerce and postal powers to deal with broad social problems as almost dishonest. It was called "covert" or "backstairs" legislation, and it was felt that Congress was depending upon subterfuge to usurp powers clearly denied it by the spirit of the Constitution.26

Granted that there is some indirectness in this method of exercising police power; yet there is neither dishonesty nor usurpation. It is simply a question of modernizing the Constitution, of adjusting constitutional principles to social and industrial changes. The same conditions that created a need for Federal food and drug legislation likewise demanded new applications of the principles laid down in the Constitution. Food and drugs as well as other social problems became commerce problems. The facilities of interstate commerce and the mails were being used to the detriment and injury of the people. Since the Constitution makes Congress the sole guardian of interstate commerce and the postal system, it became the clear duty of Congress to prevent these national systems of transportation and communication from being so used. The modern view of this use of constitutional pegs is that it is not usurpation, but merely the assumption of a responsibility.27

But even after the honesty of thus making use of the constitutional pegs was no longer questioned, members of the Supreme Court were still undecided as to the extent to which the commerce clause might be used in exercising police power. Was the authority of Congress limited to what was


interstate commerce in the strict sense of the word, or could it legislate in matters that affected commerce but were, absolutely speaking, outside its sphere? Toward the end of the nineteenth century, when Congress began in earnest to regulate interstate commerce, the question of the relationship between commerce and manufacture was brought up. Since manufacturing is under State control, and interstate commerce begins after manufacturing has ceased, the Supreme Court decided that the two problems should remain distinct. But this apparent solution was no solution at all, for certain practices of manufacturers clearly affected interstate commerce adversely. In 1905 Chief Justice Holmes ruled that certain transactions in the stockyards, though local in the sense that they occurred within a single State, actually fell under the federal laws because of their intimate relation with interstate commerce. A few years later, in the Shreveport Case, which was concerned with local vs. interstate rates, the Court held that if purely local transactions resulted in discrimination against interstate commerce, Federal power could deal even with these problems. Then in 1935 came the case of Schechter vs. United States, which attacked the constitutionality of the N.R.A.'s. attempt to regulate intrastate activities. The Court decided that there was a difference between indirect and direct effects on interstate commerce and that Federal law had no control over matters that affected interstate commerce only indirectly. The question still remained, however, which situations had a direct, and which had an indirect, effect. From 1937 onward, the Supreme Court has ruled that all important aspects of manufacturing of goods for interstate commerce are within the reach of Federal law, and hence that there is no distinct line between manufacturing and commerce. 28

So much space has been devoted to the commerce clause because food
and drug legislation depends almost exclusively on this constitutional peg,
other than on the postal clause or the power of taxation. The title of
the 1906 act reads:

AN ACT For preventing the manufacture, sale, or
transportation of adulterated or misbranded or poisonous
or deleterious foods, drugs, medicines, and liquors,
and for traffic therein, and for other purposes.

The amendments to the 1906 act naturally fall under the commerce clause also.
Of the laws passed between 1906 and 1938 only the Narcotic Act of 1914 and
its amendment depend on the Federal power of taxation. No food and drug act
rests on the postal clause, although postal authority has been used to aid
in the enforcement of these laws. The 1938 act is most explicit of all
in its mention of interstate commerce. It is

AN ACT To prohibit the movement in interstate
commerce of adulterated and misbranded food, drugs,
devices, and cosmetics, and for other purposes.

A hundred years ago, even fifty years ago, the Supreme Court
would have looked with disfavor upon the 1938 act. It would simply have
followed the old method of approach to constitutional problems, that of
placing the challenged statute alongside a specific article of the Constitu-
tion and deciding whether or not the two agree. But today, thanks to the
modernization of methods of approach, the Supreme Court realizes that the
validity of social and economic legislation cannot be intelligently settled
without regard for the conditions with which it deals. "The modern method
of interpretation permits the courts to adjust the basic principles of our
constitutional system to the shifting demands of our national life." 30

29 Vide supra, 27, footnote 30.
CHAPTER VI
AN APPRAISAL OF FOOD AND DRUG LEGISLATION

The 1938 act was passed primarily in the interest of consumers, but it also exerted a strong influence on the food, drug, and cosmetics industries. Each of these groups played an important role in the enactment of the law. Their reactions after it had been passed constitute a partial appraisal of Federal food and drug legislation in general, for the 1938 act, supplemented by the Wheeler-Lea Act, embodies the major portion of Federal legislation now in force. The attitude of these various groups is well expressed in three articles forming part of a symposium on food and drug legislation that appeared in Law and Contemporary Problems in the first quarterly issue of 1939:

"An Appraisal of the New Drug and Cosmetic Legislation from the Viewpoint of Those Industries," by James F. Hoge;¹

"The Federal Food Legislation of 1938 and the Food Industry," by Robert W. Austin;²

"Consumers Appraise the Food, Drug, and Cosmetic Act," by Louise G. Baldwin and Florence Kirlin.³

Written by well-qualified authors⁴ shortly after the Copeland Bill was

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¹ Law and Contemporary Problems, VI (1939), 111-28.
² Ibid., 129-43.
³ Ibid., 144-50.
⁴ At the time of writing, James F. Hoge was a member of the firm of Rogers, Ramsay, & Hoge, counsel for the Proprietary Association; Robert W. Austin was a member of the Committee on Federal Legislation.
passed, these articles present both the positive and the negative reactions of the respective interests.

The food industries recognized a serious problem in the provision of the new act which empowered the Secretary of Agriculture to set up standards of identity, of quality, and of fill of container for all foods. Standards of identity had been established for some foods before this time, and after the McNary-Mapes Amendment a standard of quality could be set up for canned goods. Henceforth, however, standards of both identity and quality could be set up for all foods, and any food that failed to abide by these standards would have to be labeled "Below U.S. Standard" -- and thus practically doom it to failure -- or run the risk of being deemed misbranded. In itself this provision did not seem so formidable, but in its application to labeling it presented a serious problem. Once a standard of identity and of quality had been promulgated, a manufacturer could arrange to have his product comply with it. But if no standard were prescribed (that is, if his was a fabricated product sold under a distinctive name), he would have to make a statement of the common name of each ingredient on the label of the package. Such a requirement would, in some cases be impracticable or result in unfair competition; in such instances the Secretary was empowered to exempt manufacturers from disclosing the ingredients.

The liability of the manufacturer, however, began only when regulations were promulgated and after public hearings had been held. Even then the manufacturer could, if he regarded the standards of quality as

of the New York State Bar Association; Louise G. Baldwin was first Vice President in charge of legislation, National League of Women Voters; and Florence Kirlin was Congressional Secretary of the same league.
unfair, have recourse to the judicial-review provision of the Act and thus secure adequate protection for himself. But the problem of labels would still remain. For manufacturers and distributors of food ordinarily have a twelve- to eighteen-months' supply of labels on hand. To have to discard such a supply because of the promulgation of standards of identity and quality would be a heavy financial loss, and to provide a new set would require a considerable amount of time.

During the first months after the passage of the Copeland Bill, therefore, food manufacturers were rather apprehensive of the effect that promulgation of standards would have on their business. A second factor of the new law that caused them some concern was the control of labeling and advertising by two separate organizations, the Food and Drug Administration and the Federal Trade Commission respectively. Whereas a food was deemed misbranded if its labeling was "false or misleading in any particular," an advertisement was considered false only if it was "misleading in a material respect." In determining whether labeling or advertising was misleading, both organizations were charged with taking into account not only what the label or advertisement actually stated but also what it failed to reveal. As a consequence of the intimate connection between labeling and advertising, the food industries foresaw the difficulty of their position unless there were some co-ordination between the two administrative bodies. Austin states the problem succinctly:

For instance, a statement in advertising might be held not to be misleading in a material respect by the Federal

5 Austin, 130-8.

6 Cf. section 403 (a) of the Federal Food, Drug, and Cosmetic Act, and section 15 (a) of the Wheeler-Lea Act.
Trade Commission where the same statement on a label or in a circular sold with the merchandise might well be held to be misleading in some way by the Food and Drug Administration and therefore to be deemed a misbranding under the phrase "misleading in any particular." Second, that which the Food and Drug Administration held not to be a vital failure to reveal facts material to the use of a product might, in an advertisement, be held under the Wheeler-Lea Act to be a vital failure to reveal such facts and therefore false advertising and an unfair or deceptive act or practice under the Federal Trade Commission Act, as amended.

That the recognition of these problems indicates a sincere desire for the successful enforcement of the new food and drug act rather than disapproval of it, is evidenced by the concluding sentence of the article under consideration:

It, therefore, behooves all members of the food industry in all branches of the industry to study the provisions of this new law and to cooperate as much as possible with the Department of Agriculture in the evolution of new regulations under the new statute. ⁸

Need of co-operation between industry and government is likewise the keynote of the article that discusses the reaction of drug and cosmetic industries to the new law. ⁹ For the latter industry governmental control, except of its advertisements as a means of unfair competition, was an entirely new experience. The products of the drug industry, it is true, had been under Federal supervision since 1906, and its advertisements had likewise been subject to the Federal Trade Commission. With regard to advertising, the drug and cosmetic industries faced problems similar to those confronted by the food industry. But their principal concern was the

⁷ Austin, 140-1.
⁸ Ibid., 143.
⁹ Hoge, 111-28.

The new food and drug act vastly widened the scope of Federal supervision by extending the definition of a drug to all articles used in the treatment or prevention of disease, by including therapeutic devices and cosmetics, by enlarging the definitions of misbranding and adulteration, and especially by its affirmative provisions. Whereas the 1906 law had been mainly prohibitive in character, the 1938 was distinctly directive, demanding affirmative action on the part of manufacturers and distributors. Silence on labels would no longer bring immunity.10

The terminology of the new law, members of the drug and cosmetic industries believed, would give rise to problems of territorial jurisdiction.11 Again, the exemption provisions regarding adequate directions for use of a drug might remove liability from a manufacturer and fix it on a local dealer.12 All of these problems, they realized, however, would eventually be settled by interpretative regulations issued by the Food and Drug Administration.

Another even more serious difficulty in the minds of manufacturers of drugs was the question of "official" drugs. The official compendiums mentioned in the 1938 act are the United States Pharmacopoeia, the

10 Ibid., 113-4.
11 Ibid., 114.
12 Ibid., 114-5.
Homeopathic Pharmacopoeia, and the National Formulary. As a matter of fact, the drug industries held, these compendiums were privately owned and controlled. Suppose the owners should sell their rights. Would the purchasers ipso facto be authorized to fix drug standards for the United States?  

Finally, makers of drugs foresaw in the provisions regarding new drugs a possible problem in the field of therapeutics. The definition of a new drug they considered especially provocative of thought. The approval of experts is necessary for the recognition of a new drug as safe. But since the opinion of experts is not always synonymous with fact and since safety, as applied to drugs, is a relative term, members of the drug industry wondered whether Federal regulation might not impede the progress of therapeutics.  

The voicing of so many difficulties almost immediately after the passage of the 1938 law might lead the reader to believe that the drug and cosmetic industries condemned the Act. But the conclusion of Hoge's article belies the truth of such an inference:

The existence of these problems does not condemn the new legislation. Its scope, both as to provisions and application to large and diversified industries, naturally involves at the start, and for a considerable period thereafter, problems such as those discussed here and many others not now foreseen or too numerous for inclusion in the allotted space of this article. The balance between its problems and its ultimate benefits is overwhelmingly in favor of the latter. Its purpose is the protection of the public health. It provides the definitions and procedures necessary to accomplish its purpose. In so doing, it will, at the same time, benefit industry. The interests of the consuming public are not adverse to the interests of the producing industry. Producer and consumer

13 Ibid., 117.
14 Ibid., 120-1.
are necessary to each other. What serves the ultimate good of one serves the ultimate good of the other.

Perhaps the effects of the new legislation will be most generally noticeable among proprietary medicines advertised and sold to the public. It will work many changes in the composition, labeling, and advertising of many of them. But it will work ultimate good for them as a class. They will the better serve the public. Only as they serve the public have they a right to existence. 15

The reaction of the food, drug, and cosmetic industries to the 1938 law may be summarized as a sincere desire to co-operate with the Federal government in the enforcement of the Act, combined with a degree of apprehension concerning problems of interpretation. What was the reaction of consumers?

While the Copeland Bill in its various forms was under consideration, women's organizations had worked most assiduously in the interests of the consumer. Their contribution had consisted in quiet but steady lobbying in Congress and -- what was ultimately of greater importance -- educational work among the members of the organizations by means of study groups, public meetings, tours of inspection, and other devices. Their interest in the proposed bill had centered around three objectives: adequate information about products so that the consumer might make an intelligent choice, the prohibition of "products injurious to the health or purse of the consumer," and "sound administrative procedures and enforcement machinery." 16 Their attitude toward the enacted law would be determined,

15 Ibid., 127.
16 Baldwin and Kirlin, 144-5.
therefore, by the degree in which it attained or failed to attain these objectives.

Provisions regarding consumer information were satisfactory as far as they went, but women's organizations regretted that manufacturers of cosmetics were not required to list ingredients, that hair-dyes were not subject to the same regulations as other cosmetics concerning coal-tar products, and that only a single standard of quality was to be set for foods.17

But if consumer information as prescribed by the new law did not quite attain the goal which these organizations had set, the regulations against adulteration and deception fulfilled their hopes.18

Two factors were a source of disappointment to the consumer group. First, the procedural provisions, especially the seizure and the court-review regulations, were, they believed, a necessary, though somewhat deplorable, concession to the industries. Second, they considered the fact that advertising was not placed under the jurisdiction of the Food and Drug Administration but under that of the Federal Trade Commission, a distinct disadvantage to the consumer, since the general practice today is to buy, not after reading the label of a product, but after reading the advertisement.19

Despite these weaknesses in the law, women's organizations looked

17 Ibid., 146-7.
18 Ibid., 147-8.
19 Ibid., 149-50.
upon the 1938 act as a great step forward in consumer protection. Its effectiveness, however, would depend not only on a sound administration but also on continued citizen interest and co-operation. 20

Such was the reaction of interested groups to the new food and drug act within six months of its enactment. Their attitude constitutes a partial appraisal of existing food and drug legislation. But an adequate appraisal can be made only in the light of what the new act has accomplished. The complete official record of these accomplishments is contained in the annual reports of the Food and Drug Administration. For the purposes of the present study the report for 1944 has been chosen as a source of information, both because this report brings the history of food and drug legislation practically up to the present day and because the year 1944 marked a milestone in that history inasmuch as it witnessed the retirement of Walter G. Campbell after thirty-seven years of service, first as chief inspector of the Bureau of Chemistry and then as head of the Food and Drug Administration. 21

Wartime conditions, particularly the loss of trained employees and the deterioration of equipment, had created serious problems for both the industries and the Administration. New problems of transportation and storage had arisen. The volume of food and drugs produced was making it increasingly difficult to protect goods from decomposition and from rodent and insect contamination. "Only eternal vigilance," wrote the Commissioner

20 Ibid., 150.
of Food and Drugs, "and intensified effort on the part of enforcement officials and of leaders in the industries will make possible the avoidance of serious difficulties. The need for pure and wholesome food and for standard-potency drugs becomes progressively more urgent."22

It is evident that only a brief summary of the actual enforcement work of the Food and Drug Administration can be presented here, but even the briefest summary will indicate the tremendous service being rendered to both consumers and producers.

Definitions and standards of identity for enriched flour and for various types of bread, including enriched bread, were promulgated in July and August, 1943, respectively, but at the request of the War Food Administration further action on bread standards was postponed until the emergency control of that organization ceases.23 Definitions and standards of identity for sweetened condensed milk and for cacao products were also published.24

Regulations governing the certification of drugs composed wholly or in part of insulin were amended. As the fiscal year closed, amendments of the regulations for the new-drug section and for exemptions from labeling requirements were under consideration.25

The struggle against food adulterations involving health showed some improvement over conditions of the previous year. Comparatively few

22 Ibid., 5.
23 Ibid., 6.
24 Ibid., 7.
25 Ibid., 7.
seizures were made because of deleterious chemical substances. Fruit and vegetable growers were keeping well within the tolerances fixed by the government. Only one domestic case of the presence of dangerous and non-nutritive substances in food occurred in 1944, and this was found to have been accidental. Despite wartime conditions there was no notable increase in the number of food-poisoning cases reported.

The fight against food adulteration involving filth and decomposition had to be carried on with increased vigor during the fiscal year 1944. Records show "that approximately 67 percent of all food seizures involved charges of filth and decomposition." A constant battle was waged against rodents and insects as well as against general filth in the cereal, candy, and baking industries and in dairies. In the egg and the fish industry the fight was against decomposition rather than unsanitary conditions. Seizures in the processed-food industries -- whether dried, frozen, or canned fruits or vegetables were concerned -- were usually made on the charge of decomposition, which resulted from improper techniques, the use of defective cans, or difficulties in handling the fresh products quickly enough.

26 Ibid., 8-9.
27 Ibid., 9.
28 Ibid., 9-11.
29 Ibid., 12.
31 Ibid., 15-16.
32 Ibid., 16-18.
Strict watch was kept so that food violations involving economic cheats might be prohibited or at least nipped in the bud. Various types of debasement were attempted: cheap substitutes and imitations appeared on the market; food standards were violated; deceptive and slack-filled containers were used. Prompt action on the part of Federal inspectors quickly terminated these frauds.33

Actions on drugs were directed against dangerous and adulterated, misbranded, and deceptively packed products.34 Inadequate labeling of dangerous drugs, the marketing of new drugs without an effective new-drug application, contamination in the manufacturing process, and deviation from declared standards were the principal charges preferred against manufacturers of drugs. A retail druggist was prosecuted for selling sulfathiazole tablets in unlabeled packages and without a physician's prescription. This case was given wide publicity because, as the court declared, "the indiscriminate and unrestricted sale of sulfathiazole and other sulfonamide drugs to the public is a pernicious practice that should be suppressed."35 Many cases of misbranding were tried. Laxatives, mineral waters, so-called "cures," and products containing vitamins were the principal articles seized.36 Two hundred forty new-drug applications were received and acted upon.

The most important seizures of cosmetics involved products containing dangerous or harmful ingredients, misbranded hair and scalp products.

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33 Ibid., 16-18.
34 Ibid., 21-2.
35 Quoted in ibid., 27.
36 Ibid., 34-5.
and deceptively packed cosmetics. 37

The foregoing summary of the 1944 report indicates the status of food and drug administration today. Since 1938 much has been accomplished through the co-operation of producers and consumers with the Food and Drug Administration. But the final word in food and drug legislation has not yet been spoken. As in the period between 1906 and 1938, so too in our own day social changes and economic and scientific progress will create new problems in the realm of food and drugs. In the light of the achievements of the past forty years, however, it is safe to predict that the Federal government will ever keep pace with the needs of the day and will solve, as well as any government can, the problems that may still arise.

37 Ibid., 35-6.
APPENDIX A

CONSUMER PROTECTION

BY

THE U. S. FOOD AND DRUG ADMINISTRATION

The Food, Drug, and Cosmetic Act of 1938 affords much more protection than was provided by the act of 1906.

FOODS

Standards

* The act authorizes the Administrator to promote honesty and fair dealing in the interest of consumers by setting a reasonable definition and standard of identity and a reasonable standard of quality and fill of container for food.

Health Guards

A food must not be injurious to health.
Candy must not contain alcohol or any "prizes" or other inedible substance.
* The Administrator may limit the amount of added dangerous substances that cannot be avoided in the manufacture of a food.
Food containers must be free from any substance which may cause the contents to be harmful.
Coal-tar colors contained in food must come from a batch certified as harmless.

Labeling Information

The following facts must appear in the labeling:-
1. The name and address of the manufacturer, packer or shipper.
2. An accurate statement of the quantity of contents.
3. If composed of two or more ingredients, and it is not a standardized food, the common or usual name of each ingredient must be listed.
* 4. The labeling of food for special dietary uses must bear information considered necessary to fully inform purchasers.
5. Artificial flavoring, artificial coloring or chemical preservative in foods must be listed in the labeling.
6. All the information required by the act must be shown in the labeling in a form easily noticed and readily understood.

Sanitation

Food must be prepared, packed, and held under sanitary conditions.
A food must not be filthy, putrid, decomposed, or otherwise unfit. A food must not be the product of a diseased animal.

Prohibited Deceptions

Food labels must not be false or misleading in any particular. Damage or inferiority in a food must not be concealed in any manner. No substance may be added to a food to increase its bulk or weight or make it appear of greater value than it is. A food must not be sold under the name of another food. Imitations and food substandard in quality must be so labeled. A substance which is recognized as being a valuable part of a food must not be omitted. Food containers must not be so made, formed or filled as to be deceiving.

* In these instances the Federal Security Administrator is authorized to hold public hearings to receive evidence upon which the necessary regulations are based.

DRUGS

Health Guards

Before a new drug is placed on the market an application must be filed with the Federal Security Administrator. This application must be accompanied by ample evidence of the safety of the drug. Drugs must not be dangerous to health when used in accordance with the printed directions. Containers for drugs must not be composed of any poisonous substance which may render the contents harmful. Drug products must not contain any filthy or decomposed substance. Drugs must not be prepared, packed, or held under insanitary conditions. A drug liable to deterioration must be suitably packaged and informatively labeled. Drugs that do not meet official standards must be labeled to show exactly wherein they vary from the standards. Official drugs must be packaged and labeled as prescribed by the official pharmacopoeias and formulary. No substance may be added or substituted to reduce the quality or strength of any drug. A drug must not differ in strength, purity, or quality from that claimed in its labeling. Coal-tar colors contained in drugs must come from a batch certified as being harmless.

Labeling Information

The labeling of a drug must bear the following information:
1. The name and address of the manufacturer, packer, or distributor.
2. An accurate statement of the quantity of contents.
3. A statement of the quantity or proportion of certain habit-forming
drugs together with the statement "Warning -- May be habit-forming."

4. (a) The common or usual name of the drug.
   (b) When the drug is composed of two or more ingredients, the common
       name of each active ingredient and the amounts of certain ingredi-
       ents listed in the act.

5. Adequate directions for use.
6. Warnings against unsafe use by children.
7. Warnings against use in disease conditions where cautions are necessary
   to insure against danger.
8. Warnings against use in an amount or for a length of time or by a
   method of administration which may make it dangerous to health.
9. All the information required by the act must be shown in the labeling
   in a form easily noticed and readily understood.

Prohibited Deceptions

Drug labeling must not contain false or misleading statements.
A drug must not be an imitation or offered under the name of another drug.
Containers for drugs must not be so made and filled as to be deceptive.

COSMETICS

Health Guards

A cosmetic must not contain any substance which may make it harmful to
users when used as is customary or under the directions for use indicated
in the labeling.
Dangerous coal-tar hair dyes must be labeled with the caution statement
stipulated in the act.
Cosmetic containers must not be composed of any substance which may render
the contents harmful.
Cosmetics (except hair dyes) may contain only those coal-tar dyes which
come from a batch certified as being harmless.

Sanitation

A cosmetic must not consist of any filthy, putrid or decomposed substance.
Cosmetics must be prepared, packed, and held under sanitary conditions.

Labeling Information

Cosmetic labeling must include the following information:-
1. The name and address of the manufacturer, packer or distributor.
2. An accurate statement of the quantity of contents.
3. All the information required by the act must be shown in the labeling
   in a form easily noticed and readily understood.

Prohibited Deceptions

The labeling of a cosmetic must not be false or misleading in any partic-
ular.
A cosmetic container must not be so made, formed, or filled as to be misleading.

DEVICES

Health Guard

A device must not be dangerous to health when used with the frequency or duration prescribed in the labeling.

Prohibited Deception

The labeling of a device must not be false or misleading in any particular.

Labeling Information

The labeling of a device must contain the following information: -

1. An accurate statement of the quantity of contents.
2. The name and address of the manufacturer, packer or distributor.
3. Adequate directions for use.
4. Warnings against unsafe use by children.
5. Warnings against uses which may be dangerous to health.
6. All the information required by the act must be shown in the labeling in a form easily noticed and readily understood.

In the new Federal Food, Drug, and Cosmetic Act of June 25, 1938, are preserved all the worthy features of the Federal Food and Drugs Act of June 30, 1906, which the new law replaced. In its principal differences from the old law it --

1. Brings all cosmetics except toilet soap under control (sec. 201 (i)); outlaws cosmetics which may be injurious to users, except poisonous coal-tar hair dyes which bear warning labels (sec. 601 (a)); prohibits false or misleading labeling (sec. 602 (a)).

2. Prohibits traffic in food which may be injurious to health (sec. 402 (a) (1)). (The old law prohibited injurious food only when the poisonous substance was added.)

3. Prohibits the addition of poison to food except where such addition is required in the production thereof or cannot be avoided by good manufacturing practice; where added poisons are so required or cannot be so avoided, tolerances are authorized limiting the amount to a point insuring protection of public health (sec. 402 (a)(2), sec. 406 (a)).

4. Authorizes emergency permit control of food that may be injurious because of contamination with microorganisms, if public health cannot otherwise be protected (sec. 404).

5. Forbids traffic in confectionary containing metallic trinkets and other inedible substances (sec. 402 (d)).

6. Specifically required label declaration of artificial coloring, artificial flavoring, and chemical preservatives in food, but exempts butter, cheese, and ice cream from this requirement insofar as artificial coloring is concerned (sec. 403 (k)).

7. Requires labels of food for special dietary uses to inform purchasers fully of its vitamin, mineral, and other dietary properties upon which its value for such uses depends (sec. 403 (j)).
8. Provides for the promulgation of a definition and standard of identity, a standard of quality, and standards of fill of container for each food, but exempts from this provision fresh and dried fruits and vegetables, except avocados, cantaloupes, citrus fruits, and melons (sec. 401, sec. 403 (g), (h)). Butter is also exempt from this provision, but the act preserves the statutory definition and standard of identity for butter which became law in 1923 (sec. 902 (a)). (The old law contained no authority for the establishment of definitions and standards of identity, and the authority to establish standards of quality and fill of container was limited to certain canned foods.)

9. Requires the labels of food for which no definition and standard of identity has been fixed to bear the common or usual name of the food, and if it is made from two or more ingredients, the common or usual name of each, except that spices, colorings, and flavorings, may be declared simply as spices, colorings, and flavorings without specifically naming them. Authorizes regulations prescribing exemptions from this requirement where compliance is impracticable or results in deception or unfair competition (sec. 403 (i)).

10. Does not contain the "distinctive name" joker of the old law under which any mixture or compound of food not injurious to health could escape control.

11. Brings under control drugs used in the diagnosis of disease and drugs intended to affect the structure or any function of the body (sec. 201 (g) (2), (3)).

12. Brings therapeutic devices under control, and subjects them to the same general requirements as are set up for drugs (sec. 201 (h), sec. 501, 502).

13. Prohibits traffic in drugs and devices which are dangerous to health under the conditions of use prescribed in the labeling (sec. 502 (j)).

14. Prohibits traffic in new drugs unless such drugs have been adequately tested to show that they are safe for use under the conditions of use prescribed in their labeling; authorizes exemption from this requirement of drugs intended solely for investigational use by qualified scientific experts (sec. 503).

15. Makes the Homeopathic Pharmacopoeia of the United States the legal standard for homeopathic drugs (sec. 201 (j), sec. 501 (b)).

16. Requires labels of official drugs -- i.e., drugs recognized in the United States Pharmacopoeia, National Formulary, or Homeopathic Pharmacopoeia of the United States -- to reveal any differences of strength, quality, or purity from the official standards (sec. 501 (b)). (The old law required merely that the label bear a true statement of the strength, quality, and purity of the drug, without showing the difference from the official standard.)

17. Requires drugs intended for use by man to bear labels warning
against habit formation if they contain any of a list of narcotic or hypnotic habit-forming substances, or any derivative of any such substance which possesses the same properties (sec. 502 (d)).

18. Requires the labeling of drugs and devices to bear adequate directions for use, but authorizes exemptions from this requirement where it is not necessary for the protection of public health (sec. 502 (f)).

19. Requires the labeling of drugs and devices to bear warnings against probable misuse which may be dangerous to health (sec. 502 (f)).

20. Requires special precautionary labeling for drugs that are liable to deterioration (sec. 502 (h)).

21. Does not contain the fraud joker in the old law under which the Government had to prove that false claims of curative effect on the labels of patent medicines were made with willful intent to deceive.

22. Requires official drugs to be packaged and labeled as prescribed by the Pharmacopoeias and Formulary (sec. 502 (g)).

23. Declares non-official drugs illegal if the standard of strength thereof differs from the standard claimed (sec. 502 (c)). (The old law prohibited only those which fell below the strength claimed.)

24. Requires that antiseptics possess germicidal power (sec. 201 (c)).

25. Requires the labels of non-official drugs to list the names of the active ingredients, and in addition to show the quantity or proportion of certain specified substances. Authorizes regulations prescribing exemptions from this requirement where compliance is impracticable (sec. 502 (e)).

26. Proscribes the use of containers for food, drugs, and cosmetics which may render the contents injurious to health (sec. 402 (a) (6), sec. 501 (a) (3), sec. 601 (d)).

27. Prohibits traffic in food, drugs, and cosmetics which have been prepared or handled under insanitary conditions that may contaminate them with filth or that may render them injurious to health (sec. 402 (a) (4), sec. 501 (a) (2), sec. 601 (c)).

28. Forbids the use of uncertified coal-tar colors in food, drugs, and cosmetics, other than hair dyes (sec. 402 (c), sec. 501 (a) (4), sec. 601 (e)).

29. Proscribes slack filling of containers for food, drugs, and cosmetics, and prohibits the use of deceptive containers (sec. 403 (d), sec. 502 (i) (1), sec. 602 (d)).

30. Authorizes factory inspection of establishments producing food, drugs, devices, and cosmetics for interstate shipment (sec. 704).
31. Provides for the procurement of transportation records and other documents necessary to establish federal jurisdiction (sec. 703).

32. Requires that part of samples collected by the Government for analysis be given to the manufacturer on request, but provides exemption from this requirement to the extent necessary for proper administration of the act (sec. 702 (b)).

33. Authorizes the Government to charge fees for the certification of coal-tar colors in amounts necessary to defray the expenses of the service (sec. 706).

34. Specifically authorizes abatement of administrative proceedings in minor violations through written notice or warning from the enforcing agency when the public interest can thus be adequately served (sec. 306).

35. Provides increased criminal penalties for violation (sec. 303).

36. Authorizes the Federal courts to restrain violations by injunction (sec. 302).

37. Limits seizure for misbranding to a single interstate shipment of the product unless the misbranding has been the subject of a prior court decision in favor of the Government, or unless the misbranded article is dangerous to health, or its labeling is fraudulent or would be in a material respect misleading, to the injury or damage of the purchaser or consumer (sec. 304 (a)). Authorizes consolidation of multiple-seizure cases (seizures of two or more interstate shipments of identical goods from the same shipper) for trial in a single jurisdiction (sec. 304 (b)). Also authorizes such consolidated cases, as well as cases involving seizure of a single interstate shipment for misbranding, to be removed for trial to any district agreed upon by stipulation between the Government and the shipper or owner of the seized goods. In case of failure to reach an agreement, the shipper or owner of the goods may apply to the court in which the seizure was made, and the court is required, unless good cause to the contrary is shown, to specify a district of reasonable proximity to the applicant's principal place of business in which the case will be tried (sec. 304 (a), (b)). (The old law placed no limitation on the number of shipments of illegal goods which might be seized; contained no provision for change of venue for trial; and seizures thereunder were tried in the districts in which the seizures occurred, which ordinarily were the districts to which the goods had been shipped for sale and consumption.)

38. Provides for a judicial review in United States Circuit Courts of Appeals to determine the validity of certain regulations. This form of review is an addition to and not in substitution for any other remedies provided by law (sec. 701 (f)).

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APPROVAL SHEET

The thesis submitted by Sister Louisa (Schmidt), S.C.C. has been read and approved by three members of the Department of History.

The final copies have been examined by the director of the thesis and the signature which appears below verifies the fact that any necessary changes have been incorporated, and that the thesis is now given final approval with reference to content, form, and mechanical accuracy.

The thesis is therefore accepted in partial fulfillment of the requirements for the degree of Master of Arts.

May 21, 1946

Signature of Adviser