

In Table III, it will be observed there is an average increase of 2.439 Gm. over the theoretical weight of 3.250 Gm. when glucose is added as the excipient. The average standard deviation for this series of tests is 0.032 Gm. Fifty-one of the batches of pills filled fall within the average standard deviation of 0.032 Gm.; forty-eight batches fall within twice the average standard deviation, or 0.064 Gm.; while the one remaining batch falls within three times the average standard deviation, or 0.096 Gm.

The data obtained in this series of tests show that the use of different excipients in massing the same ingredients has a marked effect upon the weight of the completed pills. The increase in the average weight and in the average standard deviation on adding different excipients is in the following order: (1) soap and water, (2) honey and (3) glucose.

(To be continued.)

NOTES ON EARLY DRUG LEGISLATION.*

BY F. W. NITARDY.

Recent discussions of drug control by the Federal Government have been chiefly restricted to the problems of the present century. Readers might conclude from these discussions that the passage of the present federal law in 1906 was the first considerable achievement in favor of the consumer, and that in the absence of public interest this was instigated and largely supported by a Government bureau, the Department of Chemistry. Even a casual investigation of the periodical literature of the past century will change such view. The Food and Drugs Act of 1906 was not the first legislation of its kind nor was its passage accomplished by an individual or a group of individuals as a result of a few years of agitation. This legislation was the outgrowth of over half a century of effort in which laymen, physicians, pharmacists and drug manufacturers alike participated. The following isolated instances, while not in any sense representing a complete résumé of the subject, illustrate the extent and ramifications of the campaign to obtain pure drugs for the consumer and professions of medicine and pharmacy.

As early as 1848 Congress passed an "Act to prevent the importation of adulterated and spurious drugs and medicines." In its original form it had been introduced into Congress early in the year and was supported by memorials from various organizations including the American Medical Association, Surgeons in the Army and Navy, the physicians and apothecaries of the District of Columbia and by circulars published by the College of Pharmacy of New York in which attention had been publicly drawn to the large quantities of sophisticated chemical and pharmaceutical preparations imported. The gross adulteration of drugs such as opium, blue pill mass and quinine sulphate had been described by Dr. M. J. Baily, examiner of drugs at the New York Customhouse, who further reported in hearing before the House Committee that more than one-half of many of the most important chemical and medical preparations together with large quantities of crude drugs, arrived in this country so much adulterated or otherwise deteriorated as to

* Section on Historical Pharmacy, A. P. H. A., Washington meeting, 1934.

render them not only worthless as medicine, but often dangerous. This Act, as approved on June 26, 1848, required examination of products used wholly or in part as medicine, at the port or entry, for quality, purity and fitness for medical purposes. Such products found adulterated or deteriorated so as to render them inferior in strength and purity to the standard established by the United States, Edinburgh, London, French and German pharmacopoeias and dispensaries, and thereby improper, unsafe or dangerous to be used for medicinal purposes were refused passage. The owner had option of requesting reëxamination of strictly analytical character at his own expense, and if the examiners' rejection was sustained, the privilege of reëxporting the material within 6 months after payment of costs and depositing surety bond. In lieu of such reëxportation within the specified period the material was to be destroyed by the Collector. Special examiners were appointed for this work; salaries of \$1600.00 for the Port of New York and of \$1000.00 for other ports were specified.¹ Early in 1849 the Act was amended to improve the salaries of special examiners of drugs, medicines, etc.

The American Medical Association had appointed a committee to study this question, the members having been instructed "to note all the facts that come to their knowledge, with regard to adulterations and sophistications of drugs, medicines, chemicals, etc." The report made in 1850 discussed both foreign and domestic adulteration. In the port of New York, certainly, the quality of imported material had markedly improved since the passage of the federal law. On the other hand the law caused certain inconveniences to the manufacturers, largely due to uncertainty with regard to standards. In connection with domestic adulteration the Committee mentioned the frequent adulteration of powdered drugs, mercurial preparations, etc. It recommended that the state legislatures be requested to pass laws authorizing the appointment of inspectors, and making it a penal offence to deal in adulterated drugs and medicines. No such action was taken by the Association but the Committee was continued.² At the annual meeting of the American Medical Association in 1853, the president's report, referring to good results obtained from the federal law, recommended that individual states be encouraged to study the situation.

For some time members of the New York College of Pharmacy had been studying the problem of adulterated drug imports. Since the passage of the law of 1848 difficulties were considered to be due chiefly to lack of standards for the guidance of Drug Examiners and to some extent to the appointment of unqualified examiners. In 1851 the Board of Trustees of that institution appointed a committee to investigate the subject. The Committee considered that other Colleges of Pharmacy should take part and invited the Colleges of Boston, Philadelphia, Baltimore and Cincinnati to send delegates to a Convention to be held in New York on April 24, 1851, for the purpose of recommending a tariff of standards for the use of Drug Inspectors—which it proposed to bring before the National Medical Association, to meet on the 6th of May, at Charleston, S. C., that its influence might be brought to bear with Congress. Delegates from these institutions did

¹ *Trans. Am. Med. Assoc.*, 1 (1848), 336.

² *Ibid.*, 3 (1850), 291-308.

³ *Ibid.*, 6 (1853), 77.

not arrive but several of them sent communications expressing approval of the project. The duration of the Convention—four days—was such that little was accomplished but the delegates of the New York College adopted the report of their Board of Trustees and sent it to the meeting of the National Medical Association.¹ The recommendation of the Convention with regard to standards was submitted to the National Medical Association with the Report of the Committee on Adulterated Drugs, which unfortunately, was for other reasons refused publication by the Association.² The proposed establishment of standards was fully approved but it was the opinion of the Medical Association that the subject was properly the province of the pharmaceutical profession.

A subsequent convention of delegates from the colleges at Philadelphia, Boston and New York was held in October 1851.³ This convention recommended the adoption of standards for but a few drugs: Opium, scammony, elaterium, iodine, gum resins, cinchona bark and rhubarb. More important was its action in calling a further convention to be held in Philadelphia a year later to consider the formation of a National Association to meet every year. This was the beginning of the AMERICAN PHARMACEUTICAL ASSOCIATION.

In 1857 the Treasury Department published the regulations, explanations and standards which had been adopted up to that time.

The AMERICAN PHARMACEUTICAL ASSOCIATION, in its *Proceedings* of this period, repeatedly mentioned adulteration of imported drugs and apparently decided that its continuance was due to unqualified examiners, for in 1858 it presented a petition to Congress describing evasion of the law of 1848 by re-shipment from port of rejection to other ports where less vigilance was employed in examination. It requested amendments to the law which would change the mode of appointment of examiners, increase in salaries of examiners and the furnishing of chemicals so that examiners might apply chemical tests when necessary to determine quality of drugs.⁴

By 1861 the incorporated medical and pharmaceutical bodies of the collection district of New York had proposed, through a joint committee, to take some decided action to secure the proper execution by the Federal Administration of this law to prevent the importation of adulterated and spurious drugs and medicines. The Committee appointed by the Medical Society of the State of New York consisted of Drs. Frank H. Hamilton, John H. Griscom and Edward R. Squibb. The joint committee comprised also committees appointed from the Kings County Medical Society, the New York County Medical Society, the New York Academy of Medicine and the New York College of Pharmacy. This joint committee sent memorials to President Lincoln and to the Secretary of the Treasury, Salmon P. Chase, protesting the necessity of appointing as examiners under the law of 1848 candidates who were graduates of medical or pharmaceutical colleges and whose competency had been established by the medical boards of examination of the Army and Navy. Copies of similar memorials were sent to the Secretary of the

¹ *Am. J. Pharm.*, 23 (1851), 288.

² *Trans. Am. Med. Assoc.*, 6 (1853), 77.

³ *Am. J. Pharm.*, 24 (1852), 22.

⁴ *Proc. A. Ph. A.*, 7 (1858), 234.

Treasury by several of the New York hospitals, by two prominent New York pharmacists, three druggists and importers, and two importers. The Colleges of Pharmacy of Boston, Philadelphia, Baltimore and Chicago took similar action. In spite of such representations the next Examiner for the Port of New York, although in early life a druggist, was said to have had slight suitability for the work and to have been appointed for "strong political reasons."¹

At the annual meeting of the American Medical Association in 1860 a committee consisting of Drs. Joseph Carson, Henry J. Bowditch and E. R. Squibb, was appointed to report on the "Practical Working of the U. S. Law to Prevent the Importation of Adulterated and Spurious Drugs and Medicines." No report was made but the committee was reappointed in 1863. In 1864, it was found impossible on account of lack of accordance to prepare a report, and the committee was discharged. At the time of the discharge, Dr. Edward R. Squibb presented in the form of a paper such data as had been collected by him. His conclusions make it evident that the law was not administered in a manner satisfactory to the ethical manufacturer. He stated, "This law to prevent the importations of adulterated and spurious drugs and medicines has not prevented, and does not now prevent, such importations." He considered the principal reasons why it did not to a much greater extent fulfil its important objects to be the failure of the Secretary of the Treasury to appoint "suitably qualified persons" and because the incumbents of the more important of these offices failed to perform diligently and faithfully the duties of the office, as prescribed by the act. He further claimed that the standards used by these examiners were uniformly below those specified by the U. S. Pharmacopœia.

"For some time after the passage of the law, numerous instances of rejection of most of the common drugs were heard of, and these continued some time after the operation of the law had made it known at the sources from whence these foreign drugs come. Inferior foreign drugs, however, were never absent from the market at any time, and the effect of the law seemed rather that of increasing the proportion and the demand for good drugs, than of excluding bad ones. . . . A little later in the history of its application, however, glaring instances of maladministration appeared to become more numerous, and political party influences took possession of the offices under the law, so that by the year 1860, when the Association's first committee was appointed, abundant evidence could be adduced to show that the law was rarely administered at all, and that its value to the medical profession consisted mainly in its existence upon the statute book."²

In 1868 the AMERICAN PHARMACEUTICAL ASSOCIATION appointed a committee to draft a law regulating the entire practice of pharmacy. This committee, reporting in 1869, proposed a law intended also to prevent adulteration of drugs and medicines. Section 16 of this law would have made it illegal to mix knowingly any inert or foreign substance with drugs or medicinal preparations with the effect of weakening or destroying medicinal power, or to sell the same otherwise than in the unbroken original package put up by the manufacturer or to sell such unbroken package knowing the article contained therein to be so adulterated. Discussion of the proposed law as reported in the PROCEEDINGS did not cover this section but was restricted largely to that portion covering the qualification of pharmacists. The ASSOCIATION could not agree upon the Committee report and did not approve

¹ *Trans. Med. Soc. State of New York* (1862), 423.

² *Trans. Am. Med. Assoc.*, 15 (1865), 141-150.

it. It did, however, send copies of the proposed law to the legislatures of the various states suggesting the desirability of enacting legislation on the subject.¹

The singular lack of agreement over the necessity for stringent Government control of drugs has been evident for a great many years. In 1879 a committee appointed by the Philadelphia Drug Exchange to consider the need for such legislation reported that adulteration was of limited extent. The Board of Directors adopted this report which expressed opposition to legislation owing to the difficulty of wise and just administration, the possibility of financial losses resulting from price changes occurring during the examination of drugs and the difficulties of fixing of responsibility for adulteration.²

Legislation to prevent the adulteration of drugs and medicines was considered in 1878-1879 by a committee composed of representatives from the New York Academy of Sciences, the New York Academy of Medicine, the New York County Medical Society, the Therapeutical Society, the New York College of Pharmacy, the New York Medico-Legal Society, the Public Health Association and the American Chemical Society.³

In 1879, Dr. Edward R. Squibb proposed an "Act to Prevent the Adulteration of Food and Medicine"⁴ which is interesting because of its severity and because it included also cosmetics. He proposed that for the purpose of this law, the term "Food" should include every article used for food or drink or in food and drink, of man and animals; and that the term "Medicine" should embrace every article, other than food and drink, used for the preservation of health, or for the relief or cure of disease in man or animals, including antiseptics and disinfectants and cosmetics. As standards he specified the U. S. Pharmacopœia for articles embraced by that authority, and for other articles the national pharmacopœias of other countries or other commonly accepted standard authority. He defines adulteration as (1) the adding of one or more substances to another or others whereby the strength, purity, quality or true value of the resulting substance or mixture is reduced or lowered from its original or true value, (2) the substitution of one substance for another, (3) the abstraction of any part of any substance with the effect that the separation shall reduce that value of the substance, (4) the application of a name commonly known or understood to indicate any substance, to any part or parts thereof, or to any other substance, (5) the presence in any substance of any impurity, or any foreign matter that is either natural or accidental to it, if in unusual proportion, (6) the admixture of different qualities of the same substance with the effect of tending to deception and fraud, (7) any debasement or dilution of any substance whereby it is reduced in intrinsic value, and is yet liable to be given, bought, sold or used as though it were not debased or diluted, (8) any coloring, coating, polishing or powdering, or any other alteration in the physical condition or sensible properties of any substance, with or without addition to, or subtraction from it, whereby damage is concealed, or it is made to appear better and greater than it really is, either in quality, weight or measure; or whereby im-

¹ YEARBOOK, A. PH. A., 17 (1869), 51-56.

² *Natl. Board of Health Bull.*, 2 (1880-1881), 522.

³ Squibb, *Trans. Med. Soc. State of New York* (1879), 209.

⁴ *Trans. Med. Soc. State of New York*; "Economic Monograph No. XIV," G. P. Putnam's Sons (1879).

purities or defective quality are partially or wholly masked or hidden, (9) the giving or selling or offering for sale, or the possession of any adulterated article by any person whose business it is to make or to deal in articles of food or medicine. It is declared that "the sole and entire object and intention of this law [is] to protect the public against deception and fraud in the cost and quality of food and medicine through adulteration."¹

In 1881, legislatures of New Jersey and New York passed practically identical laws controlling Food and Drug adulteration. They required that "drugs must conform to the U. S. P. standards or if not sold under or by a name recognized in the U. S. P. must not differ materially from standards laid down in other pharmacopœias or standard works of *Materia Medica*." They also specified that prosecution under the law be based on analysis requested by an agent or board of health appointed under the act. State legislation was passed in Michigan during the same year and in 1882 by Massachusetts, Minnesota, Tennessee, Texas and Louisiana. Several of these laws prescribed no standards for determining adulteration.² Undoubtedly many of the other states passed similar laws prior to the Federal law of 1906.

The above legislation was sponsored by the National Board of Trade and National Board of Health. A bill prepared by a committee of experts under direction of the former organization was also introduced before the Senate of the 47th Congress by Mr. Miller of New York on Dec. 20, 1881. In its definition of adulterated drugs this bill resembled the present Food and Drugs Act but was much broader since it covered also drugs sold under or by names not recognized in the United States Pharmacopœia.³ This bill was criticized by Dr. Edward R. Squibb because it made no legal provision for obtaining or identifying samples nor for examining them, but delegated this to the National Board of Health.⁴ This bill restricted the term "drug" to include medicines for internal or external use. It did not therefore attempt to control the composition of cosmetics.

In 1883 Dr. Harvey W. Wiley became Chief of the Division of Chemistry in the Department of Agriculture and soon thereafter began his efforts to force the passage of federal legislation on adulteration of food and drugs. The subsequent history of the movement and the passage of the Food and Drugs Act of 1906 is described in Dr. Wiley's Autobiography published in 1930. It is evident, however, from the material discussed above that the passage of such legislation was to a considerable extent due to the continued attempts of various individuals and scientific and professional organizations to obtain similar regulation.

¹ *Trans. Med. Soc. State of New York* (1879), 214-221.

² *YEARBOOK, A. PH. A.*, 29 (1881), 369; 30 (1882), 391-395.

³ *Natl. Board of Health Bull.*, 2 (1880-1881), 664.

⁴ *Ephemeris*, 1 (1881), 21.

PHARMACY WEEK WINDOW DISPLAY COMMITTEE.

The following committee members will serve as judges of the 1934 Window Display Contest: *Chairman*, Dean John F. McCloskey, Loyola University, New Orleans College of Pharmacy; E. A. Kimzey and J. Culver, wholesale druggists; P. Grossiman and A. Worner, retail pharmacists, all of New Orleans.