CONFERENCE OF PHARMACEUTICAL LAW ENFORCEMENT OFFICIALS

ABSTRACT OF PROCEEDINGS.

The First Session of the Eleventh Annual meeting of the Conference of Pharmaceutical Law Enforcement Officials was convened at 9:00 A.M. with 56 present.

CHAIRMAN'S ADDRESS.—Chairman Swain had no prepared paper, but delivered a very able address on the work of the Conference, which was pleasing to all.

REPORT OF THE SECRETARY AND TREASURER.—Secretary Ford read the following report:

"Under the direction of your chairman, the secretary, during the past year, has mailed to the membership and others interested in the Conference, a copy of the proceedings and other conference information, as follows:

1. Copy of an Opinion rendered by the Attorney General of Maryland on advertising the sale of 'Remedies,' 'Laxatives,' 'Digestives' and 'Tonics.'
2. Copy of the Report of Committee on the Modernization of Pharmacy Laws.
3. Reprints of the Food, Drug and Cosmetic Act and its relation to pharmaceutical legislation.
4. Reprints of Dr. Swain's prelude to sounder pharmaceutical legislation.
5. Copy of court's decision in the Rosenbaum case in New Jersey.
6. A copy of Attorney General's Opinion in the State of Wisconsin on Pharmacy and Drug signs.

The chairman of your Finance Committee has reported to me the following:

RECEIPTS.

October 17, 1938	Idaho	$ 10.00	
October 17, 1938	Montana	3.00	
April 10, 1939	Oregon	5.00	
April 10, 1939	North Dakota	10.00	
April 10, 1939	Virginia	10.00	
April 10, 1939	Wisconsin	10.00	
April 10, 1939	Florida	10.00	
April 24, 1939	West Virginia	5.00	
April 24, 1939	New York	11.00	
April 24, 1939	Kansas	5.00	
April 24, 1939	District of Columbia	10.00	
April 24, 1939	Minnesota	10.00	
July 20, 1939	Arkansas	10.00	
July 20, 1939	New Jersey	5.00	
August 14, 1939	Ohio	10.00	
August 21, 1939	Maryland	10.00	
		$134.00	
Balance cash on hand August 26, 1938		597.66	
Total cash			$731.66

EXPENDITURES.

September 20, 1938, Postage for mailing copy of Attorney General's Opinion, State of Maryland, on Advertising the sale of 'Remedies,' 'Laxatives,' 'Digestives' and 'Tonics'	$ 2.82
October 20, 1938, Railway Express Agency	.77
October 24, 1938, Postage for mailing reprints of reports of Committee on the Modernization of Pharmacy Laws	10.80

November 7, 1938, A. PH. A. for 500 reprints 'Report of the Committee on the Modernization of Pharmacy Laws'	41.14	
November 14, 1938, A. PH. A. for 100 reprints 'The Food, Drug and Cosmetic Act and its reaction to pharmaceutical legislation'	5.73	
November 18, 1938, Railway Express Agency	.50	
November 25, 1938, Druggists Circular, 100 reprints 'A Prelude to Sounder Pharmaceutical Legislation'	7.00	
December 6, 1938, Clintonville Printing Co., Conference Envelopes	4.25	
December 7, 1938, Postage, mailing reprints of Food and Drug act	2.76	
January 6, 1939, R. P. Fischelis, Reprints Rosenbaum Case	1.88	
January 6, 1939, A. PH. A. JOURNAL	75.00	
January 31, 1939, Postage mailing reprints of proceedings	3.18	
February 14, 1939, A. PH. A. reprints of proceedings	14.25	
July 20, 1939, Postage mailing opinion of Attorney General of Wisconsin	3.36	
Total expenditures	173.44	
Balance cash on hand to date		$558.22"

Upon motion of Fred Schaefer seconded by Hugo Schaefer, the report of the Secretary and Treasurer was received and approved.

COMMITTEE ON FINANCE.—Chairman Schaefer submitted a verbal report and stated the receipts and expenditures tallied with those of the Secretary.

COMMITTEE ON NOMINATIONS.—Chairman Swain appointed the following: L. M. Kantner, *Chairman*, Maryland; A. L. I. Winne, Virginia; and E. J. Prochaska, Minnesota.

SYMPOSIUM ON FEDERAL FOOD, DRUG AND COSMETIC ACT.

Chairman Swain explained the Program as arranged and made a verbal report on the Extension of Federal Control over drugs and cosmetics.

Dr. R. P. Fischelis of New Jersey discussed the subject of adulteration as it applies to the new Federal, Food, Drug and Cosmetic Act.

Dr. Hugo Schaefer delivered a very able and interesting address on misbranding, including dangerous drugs. His remarks were discussed quite freely.

NEW DRUG PROVISION.—J. H. Goodness presented the following paper:

"A brief discussion of the new drug provision of the Federal Food, Drug and Cosmetic Act must leave a lot unsaid, but in the next few minutes I hope briefly to mention some of the high lights of the history of this provision, explain, if possible, just what constitutes a New Drug, outline briefly some of the main points of the operation of the provision and, if time permits, venture a few opinions as to possible consequences of this law.

The history is important for the reason that it sheds some light on the causes leading up to the creation of the provision, and in a way explains the meaning and the goal of the provision itself.

If the history were to have a title it might be called the 'Story of the Three Roosevelts.' It will be remembered that 'Teddy Roosevelt' signed the first Federal Food and Drug Bill. This Act contained no provisions concerning new drugs. It was thus possible for a manufacturer, when he believed the time ripe, to introduce into the market for human consumption, any medication that his laboratories created. So it isn't surprising that when Sulfanilamide was created its manufacturers offered it for human use. No special attention might have been attracted to the drug had not it been used upon a second Roosevelt, Franklin Delano Roosevelt, Jr. and credit given to the drug for saving his life.

With such prestige-laden free advertising for the drug unprecedented demand was created and especially for a palatable liquid form of it. So again, it is not surprising that one manu-

facturer, after experimenting only with solubles and the drug offered it to the public as an 'Elixir Sulfanilamide.' This preparation as you all know had not been pharmacologically tested and when used as directed contributed toward or was responsible for about seventy-three deaths.

This chain of events furnished an excellent opportunity for Dr. Copeland, who had been struggling in the Senate three or more years to have a new Food, Drug and Cosmetic Act enacted to make this master stroke. He introduced a resolution in the Senate asking that the Secretary of Agriculture make a report on the (what is now called) 'Sulfanilamide Incident.' In record time a report was submitted disclosing facts which you all know. Among them was the formula which had been used in the creation of the 'elixir.' After eliminating the inocuous ingredients, the formula revealed that the 'elixir' contained Sulfanilamide and Diethylene Glycol as a vehicle and solvent. Sulfanilamide had during experiments for about two years proved useful even though slightly dangerous. Diathylene Glycol had been declared by some to be harmless even when taken internally yet because of the combination the deaths had occurred.

These facts are important for they are reflected in the regulations which have been issued to accompany the definition of a New Drug. Incidentally, it was after this incident that the New Drug provision appeared for the first time in the long-pending food and drug bill. It should be noted that the Report above mentioned, perhaps more than any other fact contributed to the passage of the Federal, Food Drug and Cosmetic Act.

Franklin Delano Roosevelt, the third Roosevelt in this story, signed the bill on June 25, 1938 and it became law in most of its sections, one year ater, June 25, 1939.

What Is a New Drug?—Born during the hysteria of the Sulfanilamide incidents, the New Drug provision had but one goal—that of safety in use for all future issued drugs. Safety in use is therefore the basic consideration in all matter pertaining to the New Drug provisions. To assure the public that this safety is present and maintained in the drug after its issuance, the law in Section 505 provides that no new drug may be introduced into interstate commerce (interstate commerce has a broader meaning than formerly) until a permit is issued by the Secretary of Agriculture to the manufacturer. To acquire this permit, a manufacturer of a new drug has to submit to the Secretary certain information to be discussed shortly. The immediate question is, 'What is a New Drug, for which an application must be filed?'

In Section 201, the definitions section of the Act—paragraph (p) provides three stipulations as to what is or is not a New Drug. The two positive definitions of a New Drug are based upon the safety aspect already mentioned.

The first one states, in the usual involved language of law, that a New Drug is one which the experts (plural) do not recognize as safe if used as recommended by the manufacturer. The second definition is that a preparation or substance is a New Drug if it has not been used beyond experimentation. The fact that it has proven safe during investigations does not take it out of the New Drug class.

The third stipulation concerning New Drugs pertains to those already on the market but whose safety may be questioned. This stipulation is really an exemption to the safety goal of the provisions. In other words, if any presently marketed drug introduced before the act, is in fact unsafe. It is not for the New Drug provisions to rectify the condition. That is left to other sections of the Act.

Since these definitions are determined by the desired goal rather than established test which any observer might apply to the drug before knowing its record of safety, the Secretary has issued regulations clarifying the first definition. These regulations help to establish what is a new drug by tests other than safety. If the leading facts of the Sulfanilamide Incident are recalled, they may well act as an outline for some of these regulations; for the regulations provide that a drug may be a New Drug by reason of the fact: (1) that the substance is being used medicinally for the first time. This applies to any substance irrespective of its function in the formula; thus, the active ingredients, the vehicles, excipients, the coatings, the menstruums are all included; (2) that a combination of two or more well-known or 'old' substances are being used as a drug for the first time; (3) that a change has been made in an old established formula, which new formula is being used as a drug for the first time. This particular regulation is restricted to changes in proportion of the formula ingredients; (4) that an old drug is being recommended for some affliction for which it was not formerly recommended. In other words, an old drug may be a New Drug. Through this provision it is possible for a long-time manufactured drug to become

a New Drug when the manufacturer makes new remedial claims for the preparation. The change in this case is a mere label change; (5) that a new dosage or application is recommended. This also means that a drug may become a New Drug by reason of a label change; namely, the recommending of a new and different dose, method of application, or duration of treatment.

Summarizing these five regulations—if they can be summarized—it might be said that unless the drug is one whose formula has been long used and proven safe beyond question any product being marketed for the first time after June 25, 1938 is a New Drug.

If there is any question in the manufacturer's mind as to whether or not the preparation he is making for the first time is a New Drug, he should consider it as such, file application and avoid all the unpleasant circumstances which may result from failure to do so in the event it is declared to be such.

The fact cannot be stressed too strongly; the manufacturer has the responsibility of determining whether his product is a New Drug or not.

What is a recognized and safe formula produces some questions. The manufacturer can be fairly secure in treating the existing official U. S. P. and N. F. preparations as not being New Drugs, but the fact that a competitor has been manufacturing a non-official product for a long time is not conclusive evidence that a duplication of that formula is not a New Drug. Thus, if manufacturer A decides to duplicate one of manufacturer B's nonofficial products and fails to file application for it as a New Drug, he runs a risk of having breached the law if the product is not in fact safe. Manufacturer A has been exempted from the New Drugs provision because he manufactured the product before the New Drugs provision became effective, but manufacturer B has no such exemption. He is marketing the product for the first time. Manufacturer A, of course, is subject to the 'Dangerous Drugs' provisions of the Act (502-j).

Going back to the definition of a New Drug, we saw that the New Drug provision does not usually apply to drugs that were being marketed before the effective date of this act. However, such manufacturers may make a New Drug of an old preparation by doing any of the following acts:

(1) By changing the proportions in his formula. There are circumstances under which a change in formula may not make the preparations a New Drug. In each of these cases the safety factor has in no way been diminished, remembering, of course, that the product must be safe; and second, the change is not one which invokes some other provisions of the Act.

Returning once more to the definition of a New Drug we find that a New Drug is one 'not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs—' as safe. After recognizing that 'experts' is in the plural, the question arises, who is an expert?

This matter has not been regulated upon or explained by the Secretary, although it is almost certain that the ordinary practicing physician will not qualify as an expert. An expert is one whose studies of the facts pertaining to a drug are of a laboratory nature; thus if sulfapyridine is being administered, such observations as its absorption, influence upon red blood cells, white blood cells, untoward effects and other studies must be recorded.

New Drugs for investigational use are exempted from the usual New Drug provisions when shipped to experts properly qualified to make the investigation.

Application for a New Drug Permit.—As has already been mentioned, the law requires that a manufactureer obtain a permit before shipping New Drugs. The law and regulations pertaining to this application are relatively clear and demand practically no discussion. The application must be complete, exact and signed. It must give full information of investigations proving it is safe and must give all details of components, composition, processes, circulars, packaging and other information if the secretary desires it for purposes of investigating the present safety and the safety permanence of the product. In addition to this, a unit of the drug and five copies of the label and labeling material must be submitted. Incomplete applications are not effective. Complete applications become automatically effective on the 60th day after filing unless an affirmative notice is given sooner. The Secretary has the power to delay his investigational period up to 180 days after filing. Permits once issued may be revoked if conditions warrant this action by the secretary. In the event of refusal to issue a permit or a suspension of an issued permit, the manufacturer may appeal to certain federal courts. The appeal must

be brought within sixty days of the Secretary's action. Other technical points, of interest only to attorneys, are omitted in this discussion.

There are several miscellaneous points in the law pertaining to New Drugs. Roughly, they are: The issuance of a permit for a new drug is not to be considered by the manufacturer as a 'patent right.' Issuance of a permit is merely a conditional acknowledgment that the drug is safe. The law forbids the manufacturer from advertising that such a permit has been issued or applied for. (301–1.)

Trade secrets as revealed in the application for a New Drug are protected (301-j). Interstate commerce of New Drugs manufacturer without permit is forbidden (301-d) except for investigational purposes (Regulations of the Secretary of Agriculture, promulgated 12/22/38, Federal Register 12/28/38). A written guaranty obtained from the supplier of the drug is a defense in an action against the second vendor for violating the New Drug sections (303-c). The New Drug Sections became effective upon enactment of the law (902-a).

Conclusion.—Since all laws of this scope have economic and sociological repercussions, I wish to conclude with what I believe shall be the future consequences of the New Drugs sections.

In addition to all general points pertaining to the safeguarding of public health, extension of government control into industry, limitation of the economic concepts of private property and free enterprise, which are not to be discussed, I believe the Federal Act will effect retail pharmacy, proprietary drug manufacturers and colleges of pharmacy in several ways, not easily apparent. In the retail field there may be an increase of proprietaries, which increase will probably be due to the following causes: (*a*) manufacturers will increase their lines.

With formula disclosures of competitor products, a knowledge of manufacturing technique, exact duplication will be even simpler than formerly. And since exact duplication may be announced without becoming unfair competition, selection of proprietary drugs by pharmacists will in the future be based solely upon price.

(*b*) Retail pharmacists, harrassed by the ever increasing number of like or nearly like proprietaries—which fact will be more simply determined in the future by label comparisons—may create their own brand products. Since they will not ship interstate, and because most of the states have no new food and drug laws, and some of those which have such laws are not controlling New Drugs, they will have an economic advantage in competition with national brands. Also, the retail pharmacist who manufactures his own proprietaries will lose the self distrust as a manufacturer when he discovers that nationally advertised products have the same or perhaps inferior formulas to that of his product. Salesmanship confidence for his own products will return when he can compare formulas for doubting customers. The absence of secrecy will rob the large manufacturer's products of the hitherto great advantage acquired through extensive advertising.

My second opinion is that manufacturers of new chemicals and new drugs may create a new problem for themselves. Their desire to have evidence of safety in use for their new drug may lead them to importune hospitals, physicians and other doctors to conduct more investigations upon patients than formerly. This practice if overdone may lead to public resentment and criticism. Patients will resist being 'guinea pigs.' As a final opinion of interest to Colleges—it is possible that manufacturers, even the small ones, will find increasing demand for pharmaceutical chemists, pharmacologists and other experts. This will create an increased demand for the graduates of the advanced schools in colleges of pharmacy. This tendency has already been noted in New England and it is hoped that other parts of the country may make like findings."

THE WHEELER-LEA ACT, AS IT APPLIES TO DRUGS, DEVICES AND COSMETICS.—Mr. Samuel Shkolnik, read the following paper:

"Unfair and monopolistic trade practices were actionable, even under early common law, in a suit for damages at the instance of any injured competitor. However, to overcome the rather narrow limitations which the courts had placed on such common law actions, Congress enacted the 'Federal Trade Commission Act' which was approved September 26, 1914. Under that Act, the Federal Trade Commission, now a familiar and highly important governmental agency, was first created and directed to prevent unfair methods of competition and monopolistic practices in interstate commerce. The Commission's function, however, was limited to the curbing of only such unfair commercial acts and practices as proved injurious to any actual or potential competitor. It was powerless to prevent any unfair or deceptive commercial act or

practice, however injurious to the general public, so long as it could not establish that any competitor of the accused was injured thereby.

As late as 1931, the Supreme Court of the United States in the case of the Federal Trade Commission *vs.* Raladam, emphasized the rather restricted scope of activity of the Commission. In that case, the commission sought aid of the courts to enforce its order requiring a manufacturer to cease and desist from advertising a reducing compound, which was deemed dangerous to health, as safe and harmless and was unsuccessful solely on the ground that it could not prove any injury to a real or a potential business competitor of the manufacturer dealing in anti-obesity remedies in interstate commerce—the possible damage and injury to the masses of consumers, notwithstanding. This decision served to crystallize the inadequacy of the 1914 Act in so far as the protection of the consumer was concerned, except merely as an incident to the protection of a business competitor of the accused.

Thanks to the intelligent annual reports of the Commission to Congress and the efforts of Chairman Wheeler of the Senate Interstate Commerce Committee, and Chairman Lea of the House Committee on Interstate and Foreign Commerce, Congress, almost 24 years after the passage of the original act, enacted law the so-called 'Wheeler-Lea Act,' approved March 21, 1938, as a very important amendment to the 'Federal Trade Commission Act.' In a general way the Act prohibits the dissemination of false or misleading advertisements, other than 'labeling' of foods, drugs devices and cosmetics, by U. S. Mails, no matter whether interstate or intrastate, or by any means in interstate commerce, for the purpose of inducing a purchase of such commodities, or by any means which is likely to induce the purchase of such commodities in interstate commerce. In other words, the Act applies not only to the dissemination of false or misleading advertisement through interstate media for the purpose of inducing a purchase of such commodities either locally or interstate, but also to the dissemination of such advertisement through intra-state media for the purpose of inducing a purchase of such commodities in interstate commerce. The interstate feature of either the advertisement or of the induced purchase is sufficient to bring the practice within the Act. The definition of the term 'false advertisement' is broad enough so as to include not only direct or implied misrepresentations, but also omission or failure to reveal material facts in the light of such representations.

It is interesting to note from the standpoint of enforcement, that prior to the enactment of this Amendment, a violation of the Commissions cease and desist order, as distinguished from a court order, resulted in no penalty to the violator unless and until a proper court has reviewed and affirmed such order and ordered compliance therewith, in which case a violation thereof thereafter constituted a contempt of court and punishable as such. Under this Act, however, the Commission's cease and desist order may become final through failure of the respondent to appeal therefrom within 60 days from the time it takes effect, as well as through affirmation by a proper court, and when it does so become final, a person violating same may be subject to a civil penalty up to $5000.00 for each offense, which may be recovered in a suit by the Attorney General. The Act also empowers the Commission, wherever public interest warrants such action, to apply to the Federal Courts and secure a temporary injunction to prevent the dissemination of any false or misleading advertisement of any food, drug, device or cosmetic, pending its regular and formal proceedings, which in the average case may take months. Thus, an unfair or deceptive act or practice may be 'nipped in the bud' and public health and safety protected long before the commission issued its cease and desist order. Of course, if after a full hearing, the Commission finds the complaint unwarranted, the temporary injunction may be dissolved. In such case, the temporary injunction may work a hardship and may prove an injustice to the particular advertiser involved, and the opponents of the Act have severely criticized it on that ground. However, the record of administration and attitude of the Commission would seem to be sufficient assurance against abuse of its powers in that respect. Furthermore, it would also seem that society as a whole is much better off and public health may certainly be better safeguarded by empowering the Commission to put an end to false and misleading advertisement before, rather than after, innocent consumers are imposed upon or even victimized by it, even though, in an isolated case, the exercise of such power may prove to be an injustice to a particular advertiser.

Another important provision of the Act makes it a misdemeaner to disseminate any false or misleading advertisement of any food, drug, device or cosmetic in case it is done with an intent to defraud or mislead, or where the use of the commodity advertised may be injurious to

health if used in the usual and customary way or as prescribed in the advertisments. In either of such cases, the Commission may certify the facts to the Attorney General for criminal prosecution which carries a penalty up to six months imprisonment or a fine up to $5000.00 or both, for a first offense, and double such penalties for each subsequent conviction.

A recent Chicago case under this Act will serve to emphasize the justification for and effectiveness of the 'Wheeler-Lea Act.' A local Chicago retailer advertised in a large newspaper of interstate circulation a certain preparation as a safe and harmless reducing remedy. It should be pointed out, in all fairness to the retailer that the advertisement was placed in reliance upon the manufacturer's representation of the safety of the product. Upon complaint to and investigation by the Chicago office of the Federal Trade Commission, it was found that the preparation contained 'Di-nitrophenol' a dangerous drug producing cataracts. The Commission promptly applied for and obtained a temporary injunction from the U. S. District Court of Chicago prohibiting the continuation of such advertisement pending the issuance of a formal complaint by the Commission and the completion of the proceedings thereunder. Thus, without proving injury to any real or potential business competitor of the advertiser, and without waiting for months, yea, years—for the issuance of its cease and desist order and the affirmance thereof by a proper court, all of which it would have had to do under the Act of 1914, the Commission, under the 1938 Act, was able to protect the public and prevent possible physical injury to the innocent and unsuspecting masses of consumers in a very short time and in a most effective way.

In conclusion, it should be pointed out that the 'Wheeler-Lea Act,' administered by the Federal Trade Commission, covers such media of advertisement as the U. S. Mails, the radio, periodicals, newspapers and the like, but it does not cover 'labeling,' which includes pamphlets, wrappers and inserts accompanying the immediate package or container of any food, drug, device or cosmetic, and which is covered by the new 'Federal Food, Drug and Cosmetic Act,' administered by the Food and Drug Administration of the Department of Agriculture. Although much criticism has already been voiced against such division of control, from the standpoint of efficiency, desirability, motive, effect, etc., it is entirely too early to either justify it or prove its fallacy. Only such old reliable factors as time, experience, trial and error and results will ultimately tell the story.

In the meantime, it may be said with certainty that both the 'Wheeler-Lea Act' and the new 'Federal Food, Drug and Cosmetic Act' and the agencies administering same, are filling a long felt public need. The writer has heard and read about charges of 'departmental jealousies,' and the 'race to the bag,' but all of these, even if true, could hardly be said to be detrimental to the great masses of consumers or the general public. After all, the public at large is more interested in the curbing of unfair, false, fraudulent and deceptive advertisement of foods, drugs, devices and cosmetics which is likely to result in injuries to health than it is in the particular governmental agency accomplishing it."

SYMPOSIUM ON STATE FOOD, DRUG AND COSMETIC ACTS.

The states having adopted Acts similar to the Federal Act were discussed as follows: New Jersey, by R. P. Fischelis; Virginia, by A. L. I. Winne and New York by Hugo Schaefer. States having introduced similar bills, but not passed were: Montana, by L. R. Richards, West Virginia by Roy B. Cook; Wisconsin by S. H. Dretzka and Maryland by R. L. Swain.

The Session adjourned at 12:00 P.M.

The Second Session of the Conference was called to order by Chairman Swain at 2:40 P.M.

Chairman Swain asked Mr. Dretzka of Wisconsin to lead the discussion on law enforcement in the several states.

PUBLICITY AND EDUCATION IN LAW ENFORCEMENT WORK. MINNESOTA STATE BOARD OF PHARMACY.—Mr. Prochaska read the following paper:

"It has been a privilege and a pleasure for members of the Minnesota Board of Pharmacy to attend the meetings of the National Association Boards of Pharmacy for many years. We

have gained much in the way of knowledge and ideas from the pioneers in the enforcement field which we have endeavored to pass on to the rank and file of druggists of Minnesota.

Effective law enforcement is largely a matter of education. When we are able to convince the proprietors of pharmacies who observe the law, the registered pharmacist employees, the leaders in the various fields of Pharmacy, that this program is for their economic interest, that it contributes to the development of the whole profession and if they demand that the pharmacy laws be enforced, and will coöperate with the enforcement officials, our leaders can then do a more effective and efficient job. A unified objective on the part of all groups is really imperative.

Pharmacy Journals are a great aid in selling these ideas to our own profession and are an important factor in giving publicity to enforcement programs. We in Minnesota have been most fortunate in having this type of support from the *North Western Druggist.*

Another possibility in the development of pharmacy law enforcement is the coöperation of the State Medical Board. We have found the Minnesota Medical Board very willing to coöperate in this respect.

In mailing out our applications and drug store permits different bulletins have been enclosed so as to make the pharmacists more conscious of the responsibility of a pharmacist in the proper supervision of the pharmacy or drug store at all times, having it fully equipped so as to adequately take care of all public health needs. These bulletins are also distributed by our inspectors when calling at the different stores. Along with other information contained therein, is an invitation for coöperation and constructive criticism. One of the bulletins sent out by the Board of Pharmacy is as follows:

BULLETIN NO. 5.

(Quote) 'Recognizing that the health of their citizenry is protected by having drugs distributed under the jurisdiction of registered pharmacists who have been trained in the detection of dangerous and deleterious adulterants, Legislatures in all states have enacted laws to that effect. This special professional privilege imposes a grave responsibility upon the members of our profession. In order that we may better assume this responsibility and also exercise this privilege most efficiently in the interests of the public health, the standards for the practice of pharmacy have been raised by the enactment of prerequisite laws, by minimum equipment regulations, by requiring the latest revisions of the U. S. Pharmacopœia and the National Formulary in every pharmacy, etc. Pharmacy is the most highly developed medical specialty and to enter its practice to-day, a minimum of four years of professional training is essential. Futile attempts on the part of the few pharmacists to practice with inadequate utensils made the minimum equipment regulations imperative. It is just as inconceivable that a pharmacist can practice pharmacy without a U. S. Pharmacopœia and National Formulary as it is for a physician to practice medicine without adequate reference books on Medicine, Pathology, Obstetrics, Minor Surgery, etc. The U. S. Pharmacopœia and National Formulary make available to every pharmacist the latest therapeutic agents used in medical practice and also give tests for identity, purity and assays. With this information at hand, the pharmacist is in a position to check the purity of all drugs and chemicals that he dispenses to the public.

The following is an excerpt from the Minnesota Pharmacy Laws:

Section 16—(*a*) It shall be unlawful for any person to compound, dispense, vend or sell at retail, drugs, medicines, chemicals and/or poisons in any place other than a pharmacy except as hereinafter provided.

(*b*) No proprietor of a pharmacy shall permit the compounding or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals or poisons in his pharmacy except under the personal supervision of a pharmacist or of an assistant pharmacist in the temporary absence of the pharmacist.

The intent of this Section of the Pharmacy Law is very clear. It is a legal acknowledgment that the public will be better protected and will receive a better health service when drugs are dispensed by or under the supervision of a trained registered pharmacist. If all pharmacists would respect and meticulously observe the laws governing the practice of pharmacy, the members of other health sciences and the general public would also come to respect them very soon. Con-

versely; the flagrant violation and open disregard of pharmacy laws by some pharmaceutical practitioners themselves is anything but conducive to the creation of respect by others for pharmacists and the laws that govern their practice.

It is certainly to the interest of the profession of Pharmacy that a high grade of pharmaceutical service be available to the public in all drug stores at all times. Untrained persons cannot and must not be substituted, even temporarily, for the trained pharmaceutical personnel because if this is done, the quality of service is markedly inferior, the pharmacy law has been broken and our Code of Ethics has been violated. Now, as never before, are Minnesota pharmacists demanding the strict enforcement of Section 16 of the Pharmacy law because: (1) they appreciate that it is in the interest of public health to do so; (2) they know it will eliminate, to a large degree, the competition which they now have from unethical and illegally operated stores in which "cheap help" is being substituted for registered pharmacists with resulting lowering of operating costs; (3) they believe that the young persons who are now entering retail pharmacy as clerks and who are duly qualified by educational training, experience and state examination, should not be subjected to competition that originated in and is maintained because of the violation of this Section of our Pharmacy Law.

The demands of our practitioners cannot and should not be disregarded and, therefore, we are requesting that every proprietor check his own store and then use his good offices to assist the State Board of Pharmacy in discharging its duties to the people of our State'.

We are noticing an improved observance of the law, receiving more criticism of those who are evading the law and less bitterness on the part of those who are taken into court as they recognize it is for the welfare of the whole profession.

Some of the objectives of Boards of Pharmacy I believe should be:

1. To aid in raising the professional and economic standards of Pharmacy in order that the members of the profession can contribute an improved health service;
2. To endeavor to enforce the pharmacy law so that drugs are dispensed either under the jurisdiction or by registered pharmacists;
3. To aid in education of both the members of our own profession and the public relative to the responsibilities of the members of the profession to the public and to the profession itself;
4. To regulate the practice of pharmacy, the sale of drugs, medicines, chemicals and poisons;
5. To regulate the quality of drugs, using the U. S. P. and N. F. as the standard;
6. To examine and register applicants.

There is very little of original accomplishment in our work as we feel it is mostly the result of the knowledge and the ideas we have received from these conferences."

Professor Canis of New York reported on violations of manufacturers in cases of Citrate of Magnesia.

Dr. R. P. Fischelis of New Jersey discussed the subject of control over distribution of drugs and medicines. The definition for same will apply to Vitamins, White Pine Compound, etc., and the boards should so class them.

Mr. Dretzka reported the progress made in his state and the aid he has received from the Minnesota Board.

Messrs: Wilson of Georgia, Antonow of Illinois; Beard of South Carolina and Winne of Virginia all discussed the more effective way of law enforcement.

KENTUCKY BOARD OF PHARMACY ACTIVITIES IN PHARMACY LAW ENFORCEMENT.—Mr. Hoskins read the following paper:

"You have undoubtedly read of a few of the activities of the Kentucky Board during the past year in the national press. We are pleased with the results we have so far obtained and shall continue our program as outlined with possible adjustments until we have control of at least the proper distribution of poisons, prescription products, dangerous remedies, prophylactics and the usual items classified as drugs and requiring the attention of a pharmacist.

Kentucky is divided into a hundred and twenty counties, extending along the Ohio river for about six hundred miles, bounded by the States of Virginia, West Virginia, Ohio, Indiana, Illinois, Missouri and Tennessee. Now all of these states have various laws that more or less affect certain portions of our state geographically. Approximately 75% of the states population is rural and we have the problem known as the General Merchandise Stores which still serve many of these communities and compel us to draw a line around certain products and remedies, so that these sections shall be able to procure their needs and packaged medicines. We have ten counties that do not have a drug store, fourteen of them have but one store and twenty-six have but two stores, there being 769 stores throughout the State, located chiefly in the population centers. The city of Louisville being the largest of these centers alone has about 300 stores, representing nearly half the total in the State.

Well, you can easily understand what a problem was before us after being informed by the Attorney General's office that we did not have authority to hire an inspector under the existing laws, but that it was possible for us to do our own inspections. This method was very unsatisfactory and required too much of the members' time, etc., but we did get acquainted with conditions confronting the profession, so it was necessary to have our law straightened out, this not being easy, since I have already mentioned we have the general store problem and the sections that do not have stores, and the Patent Medicine lobbies, the Raleigh man *et al.*, to content with when we go to the legislature. You may imagine how easy it is to do anything that would so affect these folks in the eyes of the legislature, of course, I mean the rural population.

Our set-up actually began five years ago and we have gradually built up interest among the pharmacists of the state, and we now have complete coöperation of the industry. President Markendorf assisted by our able inspector T. W. Hoskins, began as educational program and inter-professional relations work in different sections of our State meeting with local groups of physicians and pharmacists and enlisting them in a clean up campaign, and the U. S. P. and N. F. products. To-day half our stores have all-white prescription departments, which they keep clean and spotless and are glad to display to the public, this fact alone probably confines the activities of the so-called ethical shops which are in many instances, monopolizing the prescription business.

Our present methods of inspections simply contradict the old way of bringing them into the courts for prosecution, which simply humiliated the pharmacist and reacted unfavorably toward the Board, ultimately we had the ill will of the law-abiding as well as the offenders. We check their poison records and insist upon registration of all poisons. We insist upon accurate narcotic records, we ask them to confine the sales of dangerous drugs and remedies, we insist upon adequate equipment and reference books. We ask for and get their full coöperation in all our efforts to advance the profession. In cases of first offenders, either narcotic violations or pharmacy law violations, we summon them before the Board at their own expense, we usually penalize them according to the severity of the offense, often suspending their license for certain periods of probation. It being much easier to regulate the practice of pharmacy within our industry, than to seek relief in strange courts. However, when we are unable to get the ordinary results expected we are ready to go to court, since we now have the coöperation of all law-abiding factors and it is easy to get convictions that stand up in the higher courts.

As you know Louisville having about 300 stores of all types to contend with, was hard to handle. Many so-called drug stores were causing a reflection upon the industry, these fellows just wouldn't stay in line; we would call them up time after time, yet they would slip back into the ruts, next inspection would find them short again. After a consultation our President Markendorf decided to hold a general investigation; with full coöperation from the Attorney General's office, we issued warrants or summons for all offenders after a thorough inspection program. We summoned all clerks, pharmacists, relief pharmacists, delivery boys and such personnel and with the aid of an assistant Attorney General, we held a regular grand jury type of hearing, asking them questions under oath related to the conduct of these various establishments as well as the morals and character of all personnel. We did not bring indictments, but we did get plenty of attention from the press, the public and the industry. We are glad to report this had its effect. Pharmacy received its share of favorable publicity, the public was acquainted with just what to expect from a drug store and its responsibility to them, and they were also informed that 90% of the Louisville stores were law-abiding, efficient and performing a real service, and were not the dumps as painted by certain propagandists.

We hold private hearings periodically and go into the investigation of complaints and reports and in many cases summon the parties concerned, in this way we avoid public exposure and likewise get desired results. When we do make an arrest, you may be sure we get convictions, the courts being sympathetic as well as the community. Our President Markendorf is to be commended for his untiring and many times discouraging efforts in this excellent work, he having instituted this program upon his admission to the Board. To-day, though seriously ill he may point with pride to his great accomplishment. Our stores are now real drug stores, serious about the public requirements and able to compete with all brands of competition.

We are likewise making the Prophylactic Law produce beneficial results in Kentucky. We have understood it was impossible to enforce such a law; however, with a twelve hundred mile border line as mentioned previously and across the river from a state that produces 90% of these products, with all types of peddlers, we have confined the distribution to legal producers, wholesalers and pharmacists to about 75% after one year with two inspectors working full time. We are encouraged with the results.

We have regulations available to interested Board men and we have so far been able to limit distribution entirely to the industry. We have also won our case in the Court of Appeals as to the constitutionality of this law.

REPORT OF DRUG INSPECTION WORK FROM AUGUST 1, 1938 TO AUGUST 1, 1939.

Total Number Counties in State	120
Number Counties inspected	115
Number Counties reinspected	40
Number Counties not inspected	5
Number Counties without pharmacists or drug stores	10
Number Counties having only one drug store	14
Number Counties having only two drug stores	26
Total number of drug stores in 110 counties	769
Number of drug stores owned by pharmacists exclusively	631
Number of drug stores owned by non-pharmacists	133
Number of drug stores owned by pharmacists and non-pharmacists (partner)	14
Total number of inspections (routine form)	1327
Total number of drug inspections (routine form)	1220
Total number of patent, grocery or general merchandise stores	71
Total number of chemical houses and manufacturers	36

There are in this number of inspections, forty counties which have been inspected a second time, and to possibly gain a false impression of the number of inspections reported herein, would be an easy matter since some stores have been inspected several times for some reason or another, usually not having a schedule worked out so as to have a pharmacist on duty when open for business. The State of Kentucky is faced with a seemingly peculiar condition, due to the fact that there are an estimated 60% to 65% one-man drug stores without relief by are gistered pharmacist.

The inspection of drug stores by the State Board of Pharmacy is just now being done for the first time in a regular routine manner. Heretofore, the work was carried on spontaneously and usually the inspector worked mostly on complaints. Seldom, if ever, is there an announcement made of an anticipated inspection tour to the full Board and never made to anyone outside, and to state they are made at infrequent intervals is positively correct.

OBJECTIVES OF INSPECTIONS.—1. Promotional activity toward a true friendship between pharmacists and Board.

2. Inspections done in a dignified business like manner and always friendly.
3. Advising pharmacists, upon request, of the new Federal Food and Drug Law and regulations.
4. Encouraging respect for drug and pharmacy laws.
5. Educational work on laws relating to Pharmacy and pharmacists.
6. Collecting statistical data relative to drugs, drug stores and pharmacists.
7. Promotional work on prescriptions.
8. Promoting hearings before Board on violations rather than Court Action.
9. Promotional activities on Inter-Professional Relations Committee.

10. Promotional activities on new or remodeled prescription laboratories. (350 new or remodeled within five years to date.)

11. Promotional work on cleaning up drug stores without a law.

12. Promotional work on requesting pharmacists to subscribe and read A. PH. A. JOURNAL.

13. Accelerating the respect for the U. S. P. and N. F. preparations.

14. Aid in selection of Supplemental Drug Library.

15. Encouraging and supplementing activity in Physician Professional contact.

16. Asking for better equipment with which to compound prescriptions.

17. Promotional work with Northern Kentucky Independent Druggists Association, Covington, Kentucky, in professional program.

18. Encouraging membership in the AMERICAN PHARMACEUTICAL ASSOCIATION.

ELECTIVE ACTIVITIES.—An attempt has been made to remove from Patent Medicine, Grocery and General Merchandise stores, all poisons, chemicals pharmaceutical products, specialties and proprietary or patent preparations, which contain poisons or dangerous drugs. The program being new, it has been quite a task explaining to the operators of these stores why they must discontinue the sale of all such products since they have been stocking and selling products of this nature for many years. Our greatest difficulty is progressing by the indiscriminate sale of these products by the unscrupulous wholesale drug houses (and it seems there are many of this type) or wholesale grocery stores. Attached to this report is a list of drugs, poisons etc., which have been purchased by and are in the possession of the State Drug Inspector of Kentucky Board of Pharmacy."

Messrs. Busch of Georgia, Kuether of Kansas, Goodness of Massachusetts, O'Hara of Indiana, Richards of Montana, all discussed methods of enforcement procedure.

Mr. Dretzka of Wisconsin displayed a large sign giving the Attorney General's opinion, in which he holds a drug store cannot be open for business unless a registered pharmacist is present.

COMMITTEE ON NOMINATIONS.—Chairman Kantner submitted the following report: *Chairman*, R. P. Fischelis; *Secretary-Treasurer*, M. N. Ford; *Delegate*, F. C. A. Schaefer; and *Chairman Emeritus*, R. L. Swain. Upon motion duly seconded the report was received and approved.

Chairman Swain briefly reviewed the origin of the Conference and his pleasant work with its members and expressed his pleasure to be Chairman Emeritus.

The officers were then installed and the new chairman made reference to the wonderful work done by Dr. Swain since the organization of the Conference and requested his counsel and advice in the future. Chairman Fischelis stated he would continue the Finance Committee with Mr. F. C. A. Schaefer as Chairman.

The Session then adjourned at 5:30 P.M.