20. Journal and Year Book. The resolutions adopted by the ASSOCIATION and urging that the Committee on Publications and the Committee on YEAR BOOK consider certain suggested changes in the JOURNAL and the YEAR BOOK were read and after discussion were referred to the respective committees on motion of Hunsberger seconded by Adams and carried.

The meeting then adjourned.

E. F. KELLY, *Secretary.*

UNITED STATES PHARMACOPŒIA AND NATIONAL FORMULARY AS STANDARD UNDER THE PURE FOOD AND DRUGS ACT.*

BY DR. J. J. DURRETT.[1]

Mr. President, Ladies and Gentlemen:

The Food and Drug Administration handles the enforcement of the Food and Drugs Act, together with other regulatory acts. The Administration is very much pleased to have this opportunity of talking with you about matters that are of great mutual importance under the Food and Drugs Act.

The Food and Drugs Act was placed upon the statute books 25 years ago. This law was enacted for one purpose, and this purpose is very simple and easy to understand. It is just this: Those who manufacture and merchandise foods and drugs shall not deceive those who consume foods and drugs. From the standpoint of general principles, this is the entire aim of the act.

Those who have had the responsibility of enforcement of the Food and Drugs Act have received a great deal of criticism because of their activities. I am told that in the early days of enforcement of the act, there were differences of opinion as to methods of enforcement, and these undoubtedly arose for the simple reason that enforcing officials did not have behind them at that time court decisions on which to base their enforcement policy. At the present time, however, more than 18,000 court decisions have been written dealing with the Food and Drugs Act, and we have at hand court opinions relative to most of the important details with which the law deals. We do not follow what we think are the requirements of the law, but what the courts have said the law is.

In the press at various times there have appeared sweeping criticisms of our enforcement activities. I think that it will be interesting and helpful to note what the Supreme Court of the United States has said in its most recent decision (1923) under the Act, and then consider some of the outstanding criticisms that have been made.

"The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act." (From opinion of the Supreme Court of the United States, in United States *vs.* 95 Barrels, *et al.*, No. 559, October Term, 1923.)

This decision simply says that if there is any untruthful or misleading statement made about the ingredients contained in a food or drug by the manufacturers or distributors of this food or drug, the enforcement officials are to interpret this as a violation of the Act. It clearly says also that statements are to be construed in the interest of the public. With such a clear-cut decision, enforcement officials feel that they have a mandate from the Supreme Court to proceed to protect the public in respect to those matters dealt with under the Food and Drugs Act, and until the Supreme Court modifies this mandate, enforcement will follow along the lines very much as they are proceeding to-day.

Recently, in the District Court of Connecticut, we tried a case which involved the seizure of a certain preparation, "Lee's Save-the-Baby." This article was composed principally of lard, turpentine, camphor and small proportions of other volatile flavoring oils. The preparation in its labeling said that this article was "Lee's Save-the-Baby," and the diseases referred to in the label-

---

* Address before First General Session, A. PH. A., July 29th.

[1] U. S. Food and Drug Administration.

ing included, among others, croup, influenza and pneumonia. Any interpretation of such labeling would lead to the conclusion that the article would save the baby from croup, influenza or pneumonia. The Government's contention was that this article would not do this and that the manufacturer knew that it was incapable of saving babies from these diseases. We therefore charged that the statement was, under the Sherley Amendment to the Food and Drugs Act, false and fraudulent. The District Court decided that this branding was not false and fraudulent. This decision has not changed the Administration's opinion relative to this labeling. We still believe that the manufacturer knows that this article will not save babies from pneumonia or other diseases mentioned, and that therefore the Food and Drugs Act is violated when the article is shipped in interstate commerce.

Now, since this decision was rendered in Connecticut another case involving the same section of the Act has been decided in Louisiana in favor of the Government. This suit involved the labeling of four preparations instead of one. Very little has been said about this suit in the press, for the simple reason that the decision was not at variance from the established policy of the Food and Drug Administration.

We have been repeatedly asked if we intend to change our policy to conform to the District Court's decision in Connecticut. Our reply is that we have no notion of making any change in our enforcement policy because of a District Court's decision. These two courts have equal weight and are final for their respective jurisdictions, but they have no force outside of their jurisdictions. It is the purpose of the Administration to appeal the adverse decision to the Circuit Court and eventually to the Supreme Court. Any decision rendered by the Supreme Court in connection with the questions involved will be followed by the Administration.

We are aware also of the great amount of criticism of the Administration because of multiple seizure. For your information I wish to say that since 1924 we have seized 1 preparation 7 times; 1 preparation 8 times; 1 preparation 9 times; 4 preparations 10 times; 2 preparations 11 times; 2 preparations 13 times; 1 preparation 15 times; 1 preparation 16 times; 1 preparation 19 times; and 1 preparation 32 times. This is about 2 preparations per year which have been subjected to 7 or more seizures. When you recall that we have had approximately 18,000 cases under the Food and Drugs Act, this number of articles subjected to 7 or more seizures since 1924 certainly is not very great. These 15 preparations constitute the multiple seizures which were made because of adulteration, misbranding or both adulteration and misbranding. Recently a case was tried in the Federal Court of the District of Columbia where the manufacturer of the goods seized questioned our right to seize his preparation wherever it was found in interstate commerce until a court decision had determined whether or not the article was misbranded or adulterated. In the District Court the decision was in favor of the Government. In the Appellate Court, much to our surprise, the judgment sustained the contention of the manufacturer. Efforts have already been made to appeal this decision to the Supreme Court for review. In substance, the decision of the Appellate Court was that the Department of Agriculture had no right to seize multiple drugs found in interstate commerce until after the manufacturer had had an opportunity to try the issues involved. It clearly implied that if an article was in violation of the terms of the Food and Drugs Act, then the Department of Agriculture had the right to seize the multiple article. This decision is exactly in line with the activities of the Administration in the past, as you can see from the small number of drug articles seized 7 or more times during the last 6 years. However, the court did not have before it the facts relative to the labeling of the article involved in the decision in the Appellate Court in Washington, and the Administration is decidedly of the opinion that the article was misbranded and adulterated, and that any consideration of this branding on its merits would settle this question in favor of the Government's contention, as in fact the claimant actually admitted in the District Court of Baltimore and various other jurisdictions, where he consented to a judgment and destruction of the goods. If this article was not both misbranded and adulterated, and subject to seizure wherever it was found in interstate commerce, no article on the American market to-day can be properly regarded as subject to multiple seizure.

There has been a great deal of criticism of me personally, and also of the Administration, because we have followed the consensus of medical opinion to determine whether or not drugs found in interstate commerce are misbranded under the Food and Drugs Act. However, the truth of the matter is that the Court of Appeals of the District of Columbia some 5 years ago reversed a case which had been appealed, because one of the witnesses was asked to state his expert medical

opinion on the therapeutic claims made for the article, and when he was asked if his opinion conformed to the opinion held by physicians generally, the lower court denied him the right to answer this question. The Appellate Court held that this question was material and competent, and should have been answered. It was one of the points on which it based a reversal of the lower court's judgment and instructed that a new trial be granted. Since this decision was had, it has been the practice of the Administration to determine in advance of causing cases to be placed in court against therapeutically misbranded foods or drugs, whether or not the therapeutic claims made for them in the labeling are at variance with the accepted medical opinion based on the composition of the article. Just so long as Appellate Courts continue to reverse decisions of lower courts because they refuse to allow medical witnesses to state that their opinion is or is not in harmony with the generally accepted medical opinion, the Administration will continue to take into account accepted medical opinion when it judges the accuracy of therapeutic claims made for foods or drugs. We have no notion of making any change in this practice until the courts change.

So much for some of the outstanding things for which we have been criticized. I wish now to consider a rather large and important class of drugs, the active principles of which are known to deteriorate in certain of the galenicals prepared from the crude article. As a rule, the present standards contained in the National Formulary and Pharmacopœia for these preparations require that they be of a certain strength, and allow little or no variation from this required strength which will adequately care for deterioration as time passes. For instance, fluidextract of ergot is required to be of a certain definite set strength which we will regard as 100%. If it is above or below this strength, it is illegal. It is the opinion of the Administration that such drugs should have provision made in the descriptive monograph whereby the manufacturer can prepare, we will say for example fluidextract of ergot, of 130% strength, and that this preparation remain standard until it falls below the equivalent of 100% strength. Most fluidextract of ergot will have a legal marketable life under such an arrangement sufficiently long to insure its consumption before a 30% deterioration takes place. We feel that the extra 30% strength thus allowed for fluidextract of ergot is not detrimental to health. We feel that for all such preparations the revision committees of the National Formulary and the Pharmacopœia may make liberal allowances in the strength of deteriorating preparations, taking primarily into account whether or not these allowances might result in detriment to health. We feel that druggists who handle such preparations should not distribute them after they have been on their shelves for an unreasonably long period of time, without first determining whether or not they still retain the required potency.

It has been the policy of the Administration in the past to devote its major activity to the most flagrant violations of the Food and Drugs Act. Certainly a great number of these have been found in the field of therapeutically misbranded drugs. We are certain now that considerable progress has been made in ridding the interstate market of such preparations, and our efforts will be expanded in other directions. This will also be facilitated by the fact that we have received additional funds for enforcement of the Act. The Administration has, therefore, decided that much greater attention will be paid in the future than has been possible in the past to those drug preparations mentioned in the Pharmacopœia and National Formulary. This will result in making the 11th revision of the Pharmacopœia and the 6th revision of the National Formulary of very much greater importance than their predecessors. The standards there laid down should for this reason, if for no other, be fair, explicit and accurate, so as to avoid unfair action and differences of opinion as to what is actually required for these articles. If errors are made in the various monographs, the committees responsible for the standards should make prompt correction of these. If scientific advancement renders the standards obsolete, or for any other reason they become untenable, modifications should result.

The Administration is aware of certain attitudes held by various persons which are improper in connection with the setting of drug standards. The motives which actuated the enactment of the Food and Drugs Act were of a nature the purpose of which was to protect the consumer. The present enforcing officials are actuated by exactly the same motives. The last Supreme Court decision, which I quoted earlier in this talk, shows that that court holds this identical view. Therefore, all of the Governmental agencies having to do with the Food and Drugs Act are in harmony. Those agencies which are under the Act made official—that is, the revision committee of the National Formulary and the Pharmacopœial convention—must of necessity hold the same high motives or else they will run counter to the Governmental forces which

now prevail in the administration of this act. Pharmacy has, in this respect, a very great opportunity and an important obligation to perform. The motives which actuate these committees must be beyond question.

Particularly at the recent Pharmacopœial convention, a great many who participated in that convention became aware of very unfortunate opinions and activities on the part of some of those who set themselves up as leaders. These persons were actuated by thoroughly selfish motives, either for personal or group reasons. It appeared at one time that they actually had control of the convention. As a result, you are no doubt aware of certain movements which are now in full force, which are designed to relieve the Pharmacopœial convention and the National Formulary revision committee of their obligations under the Food and Drugs Act. If these groups cannot avoid the leadership and influence of such individuals, the work of these revision committees will be of low grade and intolerable. Such a result will give force and substance to the contentions of those who are now actively opposing the present arrangement, and will result, no doubt, in a change. The Department of Agriculture has taken a definite stand in regard to this situation. We have said publicly and with determination that so long as the present Act provides for the standards being set by the National Formulary and the Pharmacopœia, we will defend the Act against any who presume to attack it. If the work done is of a grade which is indefensible, then the time will have arrived for changes to be made.

It is clearly the duty of American pharmacy to realize completely its opportunity and its obligations under the Food and Drugs Act, and perform the duties in conformity with the spirit which is behind that Act. It is necessary for American pharmacy to cease to be influenced in any respect by leaders that are selfish, either for themselves or for the group which they represent, in so far as legal drug standards are involved.

"LECTURES ON THE ADULTERATION OF FOODS, ETC."

BY JAMES CUTBUSH.

Dr. James H. Beal has presented to the AMERICAN PHARMACEUTICAL ASSOCIATION a copy of "Lectures on the Adulteration of Foods and Culinary Poisons, the Detection of Poisons in General, and of Adulteration in Sundry Chemical Preparations, Etc. in Medicine and the Arts in a Means of Discovering Them and Rules for Determining the Priority of Substances" delivered in the United States Military Academy by James Cutbush, A. S., U. S. A., member of the American Philosophical Society, Correspondence member of Columbia Institute, etc., and acting Professor of Chemistry and Mineralogy in the U. S. Military Academy, by Ward M. Gazley, Newburgh.

The volume contains also a note by the author donating this volume to Professor Douglas whom he asks to accept the volume as a mark of appreciation and esteem from his friend. Another notation states that the author has not had time to make corrections of errors which have occurred in the book, notwithstanding his care and attention. The volume is a very rare one and to that extent adds to the value of the book.

A smaller volume has been presented with the foregoing on "James Cutbush—an American chemist, 1788–1823," prepared by the late Edgar Fahs Smith, who says in the latter volume that, "recently, attention has been called to a volume by Cutbush entitled 'Lectures on Adulteration of Foods and Culinary Poisons, Etc.' It was published at Newburgh, N. Y., in 1823." The writer (Edgar Fahs Smith) has never seen this volume. "A search for it has been unsuccessful."

James Cutbush was assistant Apothecary-General at the age of twenty-six years. His activities are of record in the many papers contributed to the publications of his day, a number of them pertaining to the manufacture of explosives. We are also interested in the fact that James Cutbush was an apothecary. His advertisement appears in a newspaper of Philadelphia, October 1819, which reads:

"James Cutbush—Chemist and Apothecary—No. 25 South Fourth St., Philadelphia, where complete collections of chemical reagents are kept as usual." We also find that he delivered "Lectures on Theoretical and Practical Pharmacy." An advertisement of 1812 reads, "The subscriber at the solicitation of several medical gentlemen proposed to give a series of lectures on Theory and Practice of Pharmacy accompanied by the necessary chemical elucidations. Tickets may be had at 25 S. Fourth St., price $20.00." Signed, "James Cutbush."