I think I have said enough to show that existing laws, relating to the practice of pharmacy in its wider scope, are not being enforced as they should be, and that we as pharmacists owe it to ourselves, and to the communities that have entrusted us with certain responsibilities to eliminate many of the existing abuses.

We must, above all, realize that existing pharmacy laws place all who are registered in accordance with their provisions, on an equal footing, so that we, individually and collectively, must share any discredit to our occupation from the illegal practices of registered pharmacists. The people at large, rightfully look to the law for protection and if we, as beneficiaries under a law, allow others to impose on and to take advantage of persons who rightfully look to us for protection, we are in fact responsible, quite regardless of whether we ourselves are the transgressors or allow our competitors to continue their illegal practices unchallenged.

In conclusion I beg to make the one plea that we, individually and collectively, make an honest and an earnest effort to disabuse our own minds and also the minds of our fellow citizens, of the notion that all existing wrongs can be corrected by the enactment of suitable laws. Let us develop the necessary courage to call attention unflinchingly, to existing abuses and let us insist that, whenever possible, the laws now on our statute books be enforced; that such as cannot be enforced be repealed, and that, in all future-agitations for new legislation, the best interests of the people at large only be considered as the governing incentive.

ENFORCEMENT OF DRUG LAWS.

BY FRANK R. ELDRED.

The effect of a law is altogether dependent upon its enforcement and the construction placed upon it. It is a matter of common observation that the objects of the law maker may be partially or entirely defeated by the method of administration. While there has been a very general discussion in regard to drug laws, the discussion of their enforcement has been confined largely to the officials to whom this work is entrusted. The enforcement of these laws, since the enactment of the Food and Drugs Act of 1906, has resulted in great benefit to the public; no class has profited more than honest drug manufacturers and dealers, and the entire drug trade has been placed upon a sounder foundation. As in every new undertaking, mistakes have been made and it has been necessary to learn by experience; the result has been a rapid improvement in the manner of enforcing the laws. The good accomplished has justified the methods which have been employed, but we have now advanced so far and conditions are so satisfactory, that it is time to enquire thoroughly into the possibilities of further improvement, for while it is important that drug laws should be standardized, it is no less important that the methods used in their enforcement should be standardized. In order to obtain a clear view of the situation, which is necessary before such improvements can be effected, it is necessary to approach the subject

from different angles. The present discussion is from the view-point of the manufacturer.

The first principle to be established, is that the laws were originally designed to protect the entire public, and not one class as opposed to another; only, as one necessary means for accomplishing this, did they provide for the punishment of law violators. In order to protect all classes, the drug dealers, wholesale and retail, and the drug manufacturers, must not be discriminated against and in assisting and instructing them in their efforts to serve the general public, officials can accomplish more than in any other way. The penalty should be reserved for intentional or persistent law violators. It is gratifying to note that this principle is being recognized in some of the states, and that the officials are publishing bulletins of information for the drug trade and for the consumer. Although the prime object of the law, was to protect the public, it has sometimes happened the prime object of the drug-official has been to punish the offender. Such officials have not yet learned the important lesson that most manufacturers and dealers are honest and intelligent, and are anxious to coöperate with them in protecting the public from impure or sub-standard drugs.

Another way in which the objects of certain laws have been perverted, is by arbitrary regulations or standards, which have been promulgated by officials charged with the enforcement of the law. These rulings are too often based upon a technical construction of the law, without due consideration of their effect upon the public.

It can thus be seen that, however excellent the laws may be, their power for good is dependent upon those who enforce them. It is, in some respects, unfortunate that laws relating to foods and drugs are, in most cases, administered by the same officials. When the Federal Food and Drugs Act, which is to a certain extent a model for the state laws, was passed, there were many men qualified as analysts of agricultural and food products, and this class of work had already received general recognition on account of the work of the agricultural experiment stations. Pharmaceutical chemists were few, and their work not generally known, therefore, with very few exceptions, the food chemist was called upon to administer the food and drug laws. The average food chemist, with drug work thus thrust upon him, found that, added to his inexperience in this line of work, the analysis of drugs was much more difficult than the analysis of food products. He was unfamiliar with the literature of pharmacy and disappointed, because drug analysis was not and could not well be treated, within the covers of a single volume, as in the case of food analysis. When chemists in charge of food and drug laboratories, endeavored to employ competent drug analysts, they found that this field of chemistry was practically unoccupied, and they were forced to employ as drug chemists, men without pharmaceutical training or experience. This condition resulted, at first, in the examination of certain drugs whose strength could be easily determined and, in order to make as great an impression as possible in the drug work, those which were known to deteriorate rapidly were usually selected. When this class of drugs was exhausted, attention was then turned to those which required more skill upon the part of the analyst. Under the circumstances, this was probably the best procedure that

could be adopted, but it has led to some unfortunate results which will be pointed out later.

Bearing in mind this general discussion of the situation, let us examine in more detail, the procedure now followed in enforcing these laws. The first step to be considered is the collection of samples for examination. An important regulation under the Federal law, requiring three samples to be taken, one of which is available to the seller, has not been adopted by many of the States. The Federal law, also, requires a preliminary hearing for the alleged violator of the law, while some of the State laws do not provide for such a hearing. As the State laws differ among themselves, as well as from the Federal law, and as the methods adopted for the enforcement of the laws, differ even more than the laws themselves, no general statement can apply in all cases, and, in pointing out the abuses which exist, it must be recognized that these abuses are far from universal; in fact, most of the suggested reforms are already in effect in one locality or another. In those states where law does not provide for the collection of more than one sample of each product, the seller has no recourse in case of an error in analysis, indeed the samples taken are frequently too small to allow the chemist in the state laboratory to confirm his own results by a second analysis. It is usual in such cases for the state chemist to maintain his position; neither he, himself, or any one else can establish proof of the error, for there is no official sample left, and the statement of the seller, that any subsequent sample, which he may supply, is from the same stock as that obtained by the inspector, is usually discredited. In fact, the long delay in publishing or prosecuting such cases frequently makes it impossible for him to supply another sample from the same lot of goods.

The selection of products to be investigated, is of importance, and this has too often been decided by the ease of analysis and the probability of finding substandard goods, rather than by the importance of the product to the community. It was known that precipitated sulphur frequently contained calcium sulphate as an impurity, and although this product was of no practical importance, it became a favorite subject for examination. Drugs known to deteriorate rapidly, have also been much more frequently selected than drugs known to be stable. While it is conceded that these drugs should be pure and of full strength, time has often been devoted to them which should have been given to more important drugs. Because of this manner of selecting products for examination, statistics in regard to the percentage of adulterated drugs on the market, which have been compiled in the various states, give an entirely erroneous idea of the extent of drug adulteration. These statistics are also misleading on account of the use of the terms "illegal" and "adulterated," when only a slight variation from the legal standard exists, or even when an error has been made by the official chemist. The figures thus obtained are heralded by newspapers and other agencies, until a false idea of the entire drug trade is created in the public mind.

The collection of the sample, is followed by its examination in the laboratory, and it is here that the standard by which it is judged and the method of analysis, become matters of vital importance. Some of the standards are established by the Pharmacopœia, others are published in the form of regulations for the enforcement of the law, while still others exist only in the mind of the chemist

in charge of the work. If the standard is established by the Pharmacopœia, it has had the sanction of a committee chosen from recognized authorities on the subject, but the regulations are often framed by persons having no practical knowledge of the matter which they attempt to regulate. Manufacturers may have studied for years the preparation of a product which will best serve their trade, and such a regulation may force them to forego all the advantages derived from their study and to supply a product which is not what the trade demands, or to increase the price without a corresponding increase in value. There are instances where it has even been necessary to lower the quality, in order to comply with the regulation. The unwritten standards are usually arbitrary and represent purely personal opinions, some are supplementary to published standards and others are not based upon any such standard. They exist for the case in hand, and while they are not made the basis of legal action, it must be remembered that publicity may do more damage to a seller than a legal penalty.

The Pharmacopœia also establishes many methods of analysis, but where an official method is not available, some other method is arbitrarily selected, usually without a thorough investigation of its accuracy. The inconsistency has been observed of recognizing the need for coöperative work to determine the accuracy of a method, and, at the same time, using results obtained by it as a basis for prosecuting a manufacturer. Moreover, many recognized methods will give accurate results only when the chemist employing them has had long experience in their use and this is particularly true of the methods used in drug assaying. The difficulty of obtaining competent drug chemists has already been noted and it is therefore not uncommon to find erroneous results reported by state laboratories.

After the analysis has been made and the product is measured by the standard, it frequently happens that legal proceedings are not instituted, but the results are published in one way or another. Even though the manufacturer or dealer may have been entirely in the right, he has in this case no recourse, for any suit which he might bring to force a retraction, would only place him in the light of opposing the enforcement of the drug laws and he is usually handicapped also by having no official sample. The only hope of the seller, is that the official who has occasioned the undesirable notoriety will voluntarily correct his statements, even though this involves considerable embarrassment to himself. Publicity in such cases is deplorable, as also in cases of unintentional or technical violations of the law. It has been suggested, by certain malicious individuals, that agitation and publicity of this kind are necessary to justify the office and show the efficiency of the officer, but if any drug official ever shared this idea, experience quickly dispelled it, as the most successful officials are those who recognize the need for constructive work. It is difficult to see how publicity of this kind can be of service to the public, for it places the seller who may have committed no offense, or only an unintentional or technical one, in the same light as the dishonest or persistent violator of the law and thus affords no opportunity to guard against the latter class.

This discussion of drug law enforcement, is based upon specific cases which have come under the observation of the writer, and in order to illustrate what

has been said, a few of these cases will be presented, omitting, for obvious reasons, names and localities.

Several druggists received notice that the Tincture of Digitalis purchased from them was below standard. The manufacturer was also notified that his product was below standard but not where it had been obtained, this information, however, was given upon request. Further inquiry brought out the fact that the "standard" referred to was an extractive-standard which had been arrived at by making several tinctures by the U. S. P. process and taking the average of the total solids as a standard. It is needless to point out to any one familiar with the great variations in strength of digitalis that this unpublished standard was absurd and moreover, it had no legal standing in the state. The tinctures which were declared to be below standard, had been standardized physiologically and, as nearly as could be determined by such means, they were uniform in strength and represented ten per cent. of the strength of an active digitalis leaf. Upon calling the official's attention to these facts, he evaded the question as to the propriety of a physiological standard, and refused to modify his statement to the druggists. In the opinion of the writer, this and some of the other cases cited, would furnish just grounds for legal action against officials who thus attack the reputation of a manufacturer and whose only justification is that they do not hold the manufacturer legally responsible, since the original package was broken.

A somewhat similar experience, illustrates also the danger of erroneous analytical results. A number of druggists in a certain section of the country were notified that the Tincture of Belladonna, which had been taken from them, was found to be below standard. After an exchange of several letters, the manufacturer of the preparation learned the names and addresses of the druggists from whom the tincture had been obtained and also that the strength of the various samples was from 42% to 82% of the official requirement. Samples obtained from several of the druggists concerned, were found to be of full strength and upon assaying samples from all lots manufactured during the previous six years, the weakest was only seven per cent. below the U. S. P. standard. These results showed conclusively that errors had been made in the state laboratory, but they maintained the correctness of their assays and refused to send any portion of their samples to the manufacturer, or to give credence to the statements of some of the druggists, that samples supplied to the manufacturer were identical with those taken up by the inspector.

An almost identical experience with Tincture of Opium, could be cited, although it is well known that inexperience in assaying opium preparations is a frequent cause of low results. The same situation was met in a wiser way, by an official who has always recognized the value of conservative and constructive work. All the samples of Tincture of Opium collected, were below standard. Suspecting that this was due to an error on the part of the analyst, the director of the laboratory consulted an experienced drug analyst, and it was found that such was the case. The results were therefore not reported and no injustice was done.

Arbitrary methods of analysis are often stumbling blocks. Only recently it was insisted that 8.8% of water be declared upon a label, although by actual manufacturing data it was known that less than 5% was present.

The interpretation of results is a matter which requires the exercise of good judgment. When several pharmaceutical preparations were classed as "illegal" in a board of health report, it was pointed out to the chemist in charge, that the reported results varied from the official standards by less than the inherent error of the methods and that if a second determination had been made in each case (which had not been done) the result might have been as much above the standard as the first was below. The original statement, however, was never modified, for it was argued that, as the determinations which had been made were below the official requirements although ever so little, the clerks who compiled the statistics must class the products as illegal; thus the injustice to the manufacturers whose names had been published was not corrected. Fortunately, the forthcoming Pharmacopœia will provide against such errors of judgment, by establishing maximum and minimum limits, instead of giving exact figures as standards.

Many more such instances might be cited, as well as instances showing wise and judicious administration of the drug laws, but it is not desired to multiply examples and only one more will be given to show how premature publication of results affects the conscientious official. Two druggists were notified that their Tincture of Nux Vomica was below standard; the manufacturer being also notified at the same time. Samples were obtained from the druggists, assayed by the manufacturer and found to be of standard strength. This fact was communicated to the drug official with a request for portions of his samples, the request was granted and they were found to be of standard strength, the mistake was acknowledged and rectified by letters to the druggists.

These criticisms and examples have been given only for the purpose of justifying the suggestions which are to be offered. The basis of any plan for the enforcement of the drug laws should be coöperation between drug officials and all branches of the drug trade. In the first place, products should be selected for examination on account of their power for good or evil to the community. Three samples should be taken and sealed in the presence of the inspector and dealer, one should be kept by the dealer, one used for examination and the third filed for use in case of a disagreement. If the law does not provide for duplicate or triplicate samples, then the druggist or manufacturer should insist on keeping a sample which has been sealed by the inspector, and this should be retained until a report is received from the official in charge of the work. Should the druggist or manufacturer fail to take this precaution he should be requested to do so by the inspector. In case the product is reported below standard, this sample can then be examined by the manufacturer or by a commercial chemist and, if their findings do not agree with those of the official chemist, the triplicate sample, which should be in reserve, can be used in settling the controversy. In any event, after the sample has been examined by the official chemist, his findings, if adverse, should be reported first to the manufacturer of the product. If he can show that the product is of standard quality, of course the report should go no further. Should it appear that only a technical or unintentional violation exists, not due to ignorance or carelessness, it is difficult to see how any good can be accomplished by making the matter public. Of course, honest differences of opinion will arise, but if the manufacturer cannot prove that he is in the right, the drug official can then have recourse to publicity or legal proceedings. After

the matter has been discussed with the manufacturer, the dealer should receive notice of the disposition of the case, and, in fairness to both dealer and manufacturer, notices should also be sent when the drugs examined are found to be of standard strength. This course would unite the honest manufacturers and dealers with the drug officials in their campaign against impure and adulterated drugs and would thus result in a more adequate protection of the public against them.

Much constructive work can be done by the drug officials, with expert assistance which they can easily enlist, in working out proper standards and in establishing accurate methods of analysis. It is needless to say, that both standards and methods should be published, and that intelligent criticism should be encouraged. Bulletins of information for the drug trade and the public, can also be made very valuable and a good start has already been made in this direction by some of the states.

If some such plan of action could receive the support of this and other organizations interested in the enforcement of the drug laws, it would be only a short time until all antagonism between officials and dealers would disappear and everybody concerned would be working harmoniously for the enforcement of these laws.

Scientific Division Eli Lilly & Company, Indianapolis.

A PLEA FOR A HIGHER STANDARD FOR ENTRANCE TO THE PROFESSION OF PHARMACY.

C. B. JORDAN, PH. C., M. S.

We are living in an age of progress in which the arts, sciences, and trades are making rapid advancement. Old methods and standards are inadequate to cope with modern problems. The professions allied to pharmacy, medicine and dentistry, have changed their methods and raised their standards and are giving to the public better service than ever before. It behooves us, the pharmacists of the country, to advance with and keep abreast of this progress or we will lose out and the profession will be seriously injured.

If pharmacy is a profession, the standard for entrance to it should be comparable to the present-day standards for entrance to the other professions. But is pharmacy a profession? I am ashamed to say that this question is asked in all seriousness by the pharmacists themselves. A short time ago, a series of articles appeared in Merck's Report in which this question was viewed from all standpoints by the pharmacists of the United States and some men who are prominent in pharmacy to-day declared that it is not a profession but a commercial business. Careful consideration of these articles, showed clearly that pharmacy will be what we pharmacists desire to make it. If we wish, we can make it a commercial proposition, or we can make it a dignified profession.