THE UNITED STATES PHARMACOPOEIA IN ITS RELATION TO THE PRACTICE OF MEDICINE AND THE PUBLIC HEALTH

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The United States Pharmacopoeia is the local standard for the purity and strength of drugs and medicines in both interstate and intrastate commerce, and as such is intimately related to the practice of medicine and the public health.

A pharmacopoeia, properly so-called, differs from other books descriptive of drugs in that it possesses an official character. Originally pharmacopoeias derived their official character from the fact that they were compiled and issued under the authority of certain colleges or universities, as the early European pharmacopoeias, or were compiled and issued under the authority of some medical or pharmaco-medical society, as in the United States.

At present every important pharmacopoeia of the world is either issued directly by some government bureau or a committee, or if issued by some non-governmental body, is adopted

later by the law-making authority as a legal standard for the strength and quality of drugs and medicinal preparations. The United States Pharmacopoeia belongs to the latter class, being revised and issued under the authority of the United States Pharmacopoeial Convention, and later adopted as a legal standard for drugs and medicines by the federal and state legislative bodies.

The first United States Pharmacopoeia was prepared and issued under the authority of a convention of American physicians held in 1820.

The early editions were comparatively simple books and were usually ready for distribution within a year or so after the meeting of the convention. With the increasing size and elaboration of the volume the length of time necessary for revision has constantly increased, and the present, or ninth revision, now in press, has been in process of preparation since 1910.

The United States Pharmacopoeial Convention is incorporated under the laws of the District of Columbia. It assembles at Washington, D. C., every ten years, in the year of the decennium ending in zero, and is made up of delegates representing national and state medical societies, national and state pharmaceutical societies, recognized colleges of pharmacy and medicine, the medical departments of the U. S. Army and Navy, the U. S. Bureau of Chemistry, U. S. Public Health Service, American Chemical Society and various other scientific and professional organizations of a similar nature.

An inspection of the makeup of the convention will show that it provides for the representation of a wider range of medical, pharmaceutical and general scientific interests than could possibly be the case if the work were to be revised and issued under the auspices of any governmental department or bureau.

In the case of most foreign pharmacopoeias, the pharmacopoeia becomes part of the law of the land by virtue of its having been prepared and promulgated by some governmental agency. The United States Pharmacopoeia becomes part of the law of the land only by virtue of its adoption as such by the bodies constitutionally entrusted with the duty of law-making.

As to the relative merits of the foreign and United States pharmacopoeias, a critical inspection will usually award the palm of superior excellence to the latter. Although more democratic in its origin than the European volumes, one competent European critic has declared ours to be the "aristocrat among pharmacopoeias."

Scope and Contents of the Pharmacopoeia.—One of the surprising things to the layman is the relatively small size of the Pharmacopoeia when compared to such works on materia medica as he may have seen in libraries and elsewhere. Our present Pharmacopoeia does not run quite to 700 pages, and enumerates less than one thousand—958—drugs and medicinal preparations, while the larger volumes known as dispensatories, commonly seen in the drug stores, may aggregate as many as 2,000 pages and describe several times as many thousand drugs and preparations.

The reasons for this limitation in size of the United States Pharmacopoeia are several:

One reason is that, being the legal standard for the enforcement of the food and drug laws, the Pharmacopoeia must confine itself to such matters as are susceptible of legal proof, namely, to such matters as chemical composition, chemical and physical properties, etc. Since the therapeutic or curative properties of drugs are, and probably always will continue to be, more or less matters of opinion not susceptible of exact proof, the Pharmacopoeia can not properly deal with them, and consequently one may search that volume in vain for an expression of therapeutic opinion or for evidence as to what a drug or medicine is to be used for, except in the case of a few antidotes where some indication of the use of the substance is imperative.

A second reason for the limited size of our official drug book is that, being a legal standard, it must be a conservative volume, and admit only such drugs as have stood the test of long experience. Of the hosts of new drugs and medicinal preparations introduced each year, probably not one in a hundred stands the test of experience and remains a permanent part of the materia medica. Until a drug has successfully withstood this test, it is not fit for pharmacopoeial recognition.

A third and potent reason for the limited scope of the Pharmacopoeia is found in the fact that no article of proprietary origin, that is, no article of secret composition, or one the manufacture of which is controlled by virtue of a patent or trademark, is given recognition. That is to say, no article can be admitted into the Pharmacopoeia unless the right to manufacture it is open to all, and this regardless of its remedial value. If an infallible remedy for tuberculosis were to be discovered tomorrow it could not be admitted to the official list as long as its composition were kept secret, or as long as free competition in its manufacture was prevented by virtue of a patent or by other means.

LACK OF CONFORMITY OF MEDICAL PRACTICE TO THE U. S. P.

At the time of the publication of the first United States Pharmacopoeia, in 1820, that volume probably contained the titles of a majority of the substances then used by the medical profession. The revision in force today probably does not recognize more than 10 per cent of the substances in common medical use. Thus we have the strange situation that the volume popularly supposed to be the standard of medical practice is, as a matter of fact, practically unrecognized by the medical profession. A majority of physicians in practice today probably do not own a copy of the Pharmacopoeia, and probably never saw one.

Much of the responsibility for the failure of the medical profession to recognize and use the pharmacopoeial preparations rests upon the manufacturers of patented or otherwise protected proprietary remedies. Hosts of these proprietaries have been introduced, and as their popularity has increased with physicians, the popularity of U. S. P. remedies has declined.

The extent to which proprietary and semi-proprietary medicines are used by the medical profession cannot, of course, be determined with any degree of exactness, but it is certain that the quantity is very much greater than of the remedies recognized by the Pharmacopoeia and National Formulary. It is perhaps not strange that this should be so.

Physicians are like other people in that they are most likely to concern themselves with the things most frequently brought

to their attention. No one is interested in the exploitation of non-proprietary drugs, or those which can be freely manufactured and sold by every one, and such drugs must derive their reputation for therapeutic value from the formal description of them in text books on materia medica and from the experience of those who have used them.

Proprietary remedies, on the other hand, are liberally exploited by advertising in the medical journals, by samples sent to physicians, by exhibits made at medical conventions, and by other adroit commercial methods. The physician is bombarded with literature describing the preparations and the classes of affections in which they have been found helpful, and these descriptions are not in the formal and unemotional phraseology of the text books, but in the enthusiastic language of a partisan. The physician is persuaded to try, finds a preparation effectual, and continues to use it thereafter, although it may be no better than some corresponding official preparation, or it may even be an official preparation differing only in some immaterial particular, such as color or flavor.

Owing to this extensive use of patented and other proprietary preparations by the medical profession the Pharmacopoeia might almost be said to be merely a theoretical standard for the physician, since the majority of drugs he makes use of are not found in it, and his information as to the composition and value of those he does use is derived mainly from the literature supplied by the manufacturers of such preparations. Sometimes a manufacturer gives one formula on the label, and at the same time uses a different formula—as proved by the fact that an exact following of the published formula will not reproduce the preparation—so that the composition is in fact secret, though pretending to be non-secret.

As might be expected, this large use of proprietary preparations in preference to official medicines has been productive of much controversy in medical and pharmaceutical circles. Those who support the use of U. S. P. preparations justly say, "What is the use of having an official list of medicines, if it is not observed in prescribing?" To this the physician who uses proprietaries replies, "What difference does it make to me or to my patient whether remedies I use are official or proprietary, if they produce the desired results? Proprietary remedies are

put up in attractive form, are usually of pleasant flavor, and, being always made by the same firm, are uniform in strength and appearance. The manufacturer's name on the label is a guaranty of genuineness and uniformity; when I write a prescription for a proprietary I know exactly what will be dispensed. Prescriptions compounded from U. S. P. drugs by different pharmacists frequently vary in color, flavor and strength; when I order a mixture of U. S. P. drugs I do not know how the mixture will look and taste when finished."

THE READJUSTMENT OF THE U. S. P. TO MEDICAL PRACTICE

The question then is, shall we drive physicians back to the limits set by the Pharmacopoeia, or shall we extend the limits of the latter so as to suit the prevailing practice among physicians?

The readjustment of conditions so as to bring the contents of the Pharmacopoeia and the practice of medicine into something like substantial agreement is a complex and delicate problem. To arbitrarily command the physician to restrict his prescriptions to a particular list of drugs would be of itself a kind of medical sectarianism, and of a peculiarly offensive kind, since it would have to be a sectarianism supported by legal penalties.

To attempt to limit medical practice in this manner would unduly infringe upon the right of the physician to select such medicinal agents as he thought most useful, and would tend to prevent progress in the discovery and application of new medicinal agents.

We would not undertake to compel artisans to use the same kind of tools for the purpose of doing the same kind of work, but would leave it to each workman to select the tools he preferred; why, therefore, should the physician be prevented from using the tools with which he is best acquainted and with which he gets the best results?

On the other hand, it would manifestly be impossible to extend the U. S. P. so as to include the thousands of proprietary and semi-proprietary articles in common use.

Probably a compromise between these two extremes would be the better course, viz., a continuous propaganda to induce physicians to limit the range of medicaments employed by them, and also a liberalizing of the pharmacopoeial list so as to include a wider range of remedial preparations. The Pharmacopoeia already contains a list of formulas which are confessedly imitations of, or substitutes for, certain proprietary compositions of established reputation, and there is no reason why the list of official formulas should not be extended to cover all of the usual daily wants of the physician.

The drainage engineer who should undertake to regulate water-flow without regard to the natural drainage channels established by topography would certainly meet with disaster. Those who would regulate the flow of social and professional affairs must likewise take into account known tendencies and dispositions.

If proprietary remedies did not present certain advantages for the use of physicians the latter would not use them. If the official list of remedies does not afford the physician a sufficiently wide range of choice, or if they are lacking in elegance or uniformity as commonly dispensed, we cannot blame him for resorting to proprietary preparations which are especially devised with a view of meeting his desires and satisfying his convenience.