Iron Quinine and Strych. Phos. Elixir
Lotio Alba
Magnesium Super Oxyl.
Manganese Butyrate 20% Sol.
Melatone
Milk Powder Dry
Mixture of Rhubarb and Soda
Novaspirin
Orthoform
Ovarian preparations
Oxytocin
Phenol Tetraiodo Phthalein
Phenyl Azo Diamine
Potassium Guaiacol Sulphonate
Quinine Di-Hydrobromide
Salipyrin
Salophen
Salysal
Sodium Amytal
Sodium Fluoride
Sodium Salicylate (True)
Tannalbin
Theobromine Sodium Acetate
Theophylline Sodium Acetate
Thyroid preparations
Tolysin
Validol
Vasopressin

CONCLUSIONS.

This effort to determine the present-day importance of substances omitted from the Pharmacopœia during the last two decades, has not received the support hoped for but the results are indicative and valuable and should aid the next Subcommittee on Scope in determining omission or deletion in a few of those instances where doubt has been expressed or in any instance in which errors may have been made due to insufficient information.

CHARACTER AND PURPOSE OF THE UNITED STATES PHARMACOPŒIA.*

BY J. H. BEAL.[1]

For more than a century—to be exact, for a hundred and ten years—an enterprise has been carried on in the United States which, measured by its importance to the life and health of the nation should be of great public interest, but which remains practically unknown, even by name, to all but a comparatively small fraction of the population.

This enterprise, known as the United States Pharmacopœia, and the society responsible for its periodical revision and publication, the United States Pharmacopœial Convention, pass their one hundred and tenth anniversary this year, and both are of greater vigor and importance to-day than at any previous time in their history.

Prior to the first U. S. P. there was, in America, no authoritative list of approved medicinal agents, and no generally accepted system of drug nomenclature. Widely different drugs and preparations were often designated by very similar names, while sometimes the same drug was known by several different names, and consequently, there was no assurance that an article supplied on prescription would be the same as that intended by the prescriber, or something of very different composition and potency. To correct this dangerous confusion and to introduce certainty into the compounding and dispensing of medicines the United States Pharmacopœia was instituted.

* An address before the National Association of Retail Druggists, Atlantic City, Sept. 16, 1930.

[1] Chairman U. S. P. Board of Trustees, Camp Walton, Florida.

This epoch-making forward step in American medicine and pharmacy we owe to the initiative of Dr. Lyman Spalding, of New York City, who was chiefly instrumental in calling together the convention of physicians under whose authority the first volume was compiled and published, and who through this service has conferred greater and more lasting benefits upon his fellow Americans than many of the military and political heroes whose exploits are celebrated in every school history.

Our official volume of drug standards, founded one hundred and ten years ago, has the distinction of having had the longest continuous existence of any national pharmacopœia in the world, save one,[1] and its official sponsor, the United States Pharmacopœial Convention, likewise has the distinction of being one of the oldest of existing professional organizations.

PHARMACOPŒIA MUST POSSESS OFFICIAL CHARACTER.

The primary purpose of a pharmacopœia is to supply an authoritative list of drugs and preparations of established therapeutic value, accurately standardized as to composition, purity and strength, and provided with specific titles which shall have the same meaning to all physicians and pharmacists wherever located.

But not every work presenting a list of standardized drugs is entitled to be called a pharmacopœia. It must also possess a certain public or "official" character, either through its compilation under direct governmental authority or, as in the United States, by virtue of its compilation under the combined direction of the medical and pharmaceutical professions and its subsequent recognition by Federal and State legislative action.

INTRODUCTION OF PHARMACISTS INTO THE WORK OF PHARMACOPŒIAL REVISION.

Revision of the Pharmacopœia was at first exclusively in the hands of the medical profession, but it early became evident that drug standards could best be established by those trained in the handling of drugs, and the assistance of pharmacists was solicited. Valuable improvements proposed by the New York, Boston and Philadelphia Colleges of Pharmacy were incorporated in the 1840 Revision (published in 1842), but it was not until 1850 that delegates from Colleges of Pharmacy were formally admitted to the Pharmacopœial Convention.

Up to this time the work of revision had been more or less a library process, consisting mainly in the consideration of written propositions for the admission of new or the deletion of old drugs or formulas. Of scientific investigation in the modern sense, or of planned research under the direct supervision of the Revision Committee there was practically none.

In the Seventies and Eighties of the last century, a new factor was introduced into the equation, which had the effect of materially influencing the attitude of the medical profession toward the Pharmacopœia.

It was this period which saw the beginning of the wonderful development in manufacturing pharmacy which has culminated in the great pharmaceutical laboratories of the present day. From the first these organizations were indefatigable in the introduction and exploitation of new remedies, in the improvement of pharmaceutical processes and formulas, and in the devising of elegant and

[1] The first French Codex was issued in 1818.

palatable substitutes for the frequently less attractive official preparations, all of which were brought to the attention of the medical profession by clever and insistent propaganda.

With such a wealth of new medicinal agents, and of improved forms of the older ones constantly thrust upon their attention, it was quite natural that physicians should less acutely feel the need of the Pharmacopœia as an aid to prescribing, and that their interest in the periodical revision of that volume should correspondingly decrease. It is not surprising, therefore, that for a time the question of either discontinuing the Pharmacopœia, or of turning its revision and publication entirely over to private enterprise was seriously discussed.

Fortunately as medical interest in revision work declined, pharmaceutical interest increased. From the date of its organization in 1851 the AMERICAN PHARMACEUTICAL ASSOCIATION was a strong supporter of the U. S. P., and its annual programs abounded in papers relating to pharmacopœial processes and products. Fortunately, also, at this critical period there was among the members of the A. PH. A. that master mind of pharmacy, Dr. Charles Rice, the scholarly chemist-apothecary of Bellevue Hospital, who was intensely interested in everything pertaining to the Pharmacopœia, and in whom was combined immense learning with complete devotion to science, while his linguistic ability was such that he could read the literature of pharmacy in any European language.

With Dr. Rice's chairmanship of the Revision Committee in 1880 began the period of revision based upon critical investigation and planned research, involving the experimental comparison of formulas, the development of reliable tests of identity and purity, the devising of practical methods of assay, the adoption of the purity rubric and of more concise and accurate definitions and descriptions for official drugs and products.

To Charles Rice, therefore, belongs the credit of initiating the modern method of pharmacopœial revision which, as expanded by his capable successors, and with the aid of the greater financial resources at their disposal, has given us a volume of drug standards that has been termed "the aristocrat among pharmacopœias," and which commands the profound respect of pharmacopœia-makers throughout the world.

DEMOCRATIC CHARACTER OF UNITED STATES PHARMACOPŒIA.

Ours is the most democratic of all pharmacopœias in the derivation of its authority. While other national pharmacopœias are revised by commissions appointed by their respective governments and are, therefore, in the nature of government bulletins, the U. S. P. Committee of Revision receives its authority directly from the professions of medicine and pharmacy as represented in the *United States Pharmacopœial Convention*, a body incorporated under the laws of the United States, and meeting at Washington every tenth year. This Convention is composed of delegates from all recognized teaching institutions of medicine and pharmacy, from all incorporated state medical and pharmaceutical societies, and from ten or more national associations representing medicine, pharmacy, dentistry and chemistry, or whose members are connected with the enforcement of Federal and State Food and Drug Laws, together with certain delegates directly representing various departments of the United States Government.[1]

[1] Foot-note—see page 1218.

While there may be additional societies and institutions which might appropriately be admitted to membership it would be difficult to conceive of an assembly more thoroughly representative of the professions of medicine and pharmacy, and of their related arts and sciences, than the U. S. P. Convention: and there is probably no other society meeting in the United States which brings together at one time and place so large a number of acknowledged experts in the arts and sciences represented.

The United States Pharmacopœial Convention has supreme power over the Pharmacopœia, including the sole right to amend its Constitution and By-Laws, to prescribe the methods of revision, and to elect and direct those who are responsible for what goes into or is kept out of that volume.

At its decennial meetings the Convention prepares and adopts a platform of "General Principles" to be observed in revising the Pharmacopœia, and elects a General Committee of Revision and a Board of Trustees which are to carry these principles into effect.

THE BOARD OF TRUSTEES AND FINANCIAL AFFAIRS OF THE CONVENTION.

The scientific work on the Pharmacopœia is under the direction of the General Committee of Revision, but all the business and financial affairs of the Convention, including the employment of experts, the authorization of expenditures for supplies, material and clerical expenses, for abstracting of literature, contracts for the publication and sale of the Pharmacopœia, etc., etc., are in the hands of the Board of Trustees.

The income of the Convention is derived solely from the sales of the Pharmacopœia and from copyright charges for use of the text in other publications, and is devoted exclusively to the payment of the expenses of revision and publication of the Pharmacopœia.

Only one person connected with revision work, the Chairman of the Executive Committee, receives a salary, but after the revision is completed the Board of

[1] NOTE: The exact membership of the U. S. P. Convention as at present constituted is as follows: All incorporated Medical Colleges and Colleges of Pharmacy, and Schools of Medicine and Pharmacy connected with incorporated colleges and universities; incorporated state medical and pharmaceutical associations; the American Medical Association; AMERICAN PHARMACEUTICAL ASSOCIATION; American Chemical Society; National Association of Boards of Pharmacy; and the National Association of Retail Druggists. Other societies and institutions represented are the Association of Agricultural Chemists; Association of American Dairy, Food and Drug Officials; National Wholesale Druggists' Association; National Dental Association; American Drug Manufacturers' Association; Mellon Institute of Industrial Research; School of Hygiene and Public Health of Johns Hopkins University; and the Federation of State and Medical Boards of the United States. Delegates are also admitted from the medical and pharmaceutical associations and universities of Porto Rico, the Philippine Islands, and from the Republic of Cuba, the U. S. P. having been officially adopted by the latter government.

In addition to the foregoing, delegates are also received from various local societies which were represented in the Convention prior to its incorporation in 1900.

The United States Government is directly represented in the Convention by eighteen delegates representing the Surgeons General of the Army, Navy and Public Health Service, the Department of Agriculture, the Department of Commerce and the United States Division of Customs, and is indirectly represented through the national associations named above, whose membership is composed mainly of those connected with the enforcement of state and national food and drug laws.

Trustees votes modest honoraria to the members of the Revision Committee in proportion to their respective services, but in no case equal to compensation for the work at commercial rates. Members of the Board of Trustees are repaid for their expenses incurred in the discharge of their duties.

PROFESSIONAL AFFILIATIONS OF MEMBERS OF THE GENERAL COMMITTEE OF REVISION.

Of the present members of the General Committee of Revision (fifty-one, including, ex officio, the President of the Convention), the professional connections are as follows:

One is connected in an executive capacity with the National Wholesale Druggists' Association, but is a trained botanist and pharmacognosist.

One is a research chemist connected with an institution devoted exclusively to research in technical lines.

Three are actively engaged in the practice of pharmacy.

Four are connected with the research departments of manufacturing pharmaceutical laboratories.

Seventeen are physicians engaged in the practice of medicine, or are teachers in medical schools, or both, or are engaged in scientific research in medical institutions.

Twenty-five, several of whom also hold the degree of M.D. in addition to other degrees, are teachers in schools or colleges of pharmacy.

Representatives of the schools of pharmacy are the most numerous of any class for the reason that pharmaceutical technique, chemistry, botany and pharmacognosy constitute the principal subjects involved in the work of revision, and are, therefore, very properly entrusted to those who are specialists in these lines.

In proportion to their assigned part in the research work, the representation of medicine is larger than that of pharmacy, since, aside from certain pharmacological and biological studies, the principal function of the physicians upon the Committee is to report upon the drugs and preparations to be admitted to or excluded from the Pharmacopœia.

The criticism is frequently offered that practicing physicians and pharmacists upon the Revision Committee are too few in number, but for this fact physicians and pharmacists are themselves solely responsible. During the several months preceding the last Convention it was common for the presidents of medical societies to report that it was extremely difficult to find physicians willing to accept appointment as delegates. Similar difficulty is met in attempting to persuade retail pharmacists to attend the meetings of the Convention or to accept working appointments upon the Committee of Revision. Apparently the majority of pharmacists and physicians are content to leave the work of revising the Pharmacopœia largely or entirely in the hands of professors in the colleges of pharmacy and medicine, confining their own contributions to criticisms of the work after it is issued.

FUNCTIONS OF THE COMMITTEE OF REVISION.

The General Committee of Revision is subdivided into fifteen sub-committees to each of which is assigned some special group of drugs or preparations for in-

vestigation, or some other particular line of research. The fifteen chairmen of the sub-committees constitute what is known as the *Executive Committee*, which is immediately in charge of all revision work.

Under authority of the Board of Trustees there is maintained a continuous search of the world's literature for articles upon subjects in any way related to pharmacopœial revision. All such articles, amounting to hundreds annually, are abstracted, translated when necessary, and in printed or mimeographed form are made available to the members of the sub-committees, who thus have before them at all times a review of whatever is being done in any part of the world bearing upon the subjects they have under investigation.

Only those who have been intimately connected with pharmacopœial work can have any adequate idea of the prodigious amount of labor involved in the task of revision. Sometimes an investigation requiring weeks of intensive laboratory research may yield no more than a physical or chemical constant which will be expressed in a single line or less of the final text.

FUNCTIONS OF THE SUB-COMMITTEE ON SCOPE OF THE PHARMACOPŒIA.

One of the most important of the sub-committees is the *Sub-Committee on Scope of the Pharmacopœia*, composed mainly of the physicians on the General Committee of Revision, but also including five pharmacists, the function of which is to decide primarily upon the drugs and preparations to be admitted to the next Pharmacopœia and those to be deleted therefrom.

Since the pharmacopœial list can, at most, include only a few hundreds of the many thousands of mineral, animal, vegetable and chemical agents which may be used medicinally, the principle upon which the admission of a drug is decided is not the *mere possession of medicinal properties*, but what is termed "therapeutic necessity."

To be entitled to rate as a therapeutic necessity the evidence concerning a drug or preparation should show:

(1) That its therapeutic usefulness is attested by sound medical opinion.

(2) That it possesses valuable properties not sufficiently represented by other drugs already included in the Pharmacopœia.

(3) That it is not privately controlled, or a drug of secret composition.

(4) That it is prescribed by physicians with sufficient frequency to render its standardization a matter of practical importance.

Decisions as to admissions and deletions are not made arbitrarily, nor are they based upon purely theoretical considerations. If there is substantial evidence to show that a given drug possesses valuable properties not equally represented by other official drugs, and that there is a material demand for it in the practice of medicine, the vote will be in favor of its admission; if such evidence is wanting the vote will be adverse.

One of the methods of obtaining evidence is by careful analysis of several hundred thousands of prescriptions from the files of pharmacists at various points in the United States. From a careful study of these prescriptions, and of such other data as are obtainable, supplemented by the personal knowledge and experience of its members, the reports of the Sub-Committee on Scope are made out, and these reports are accepted as final unless re-opened for further consideration by a two-thirds vote of the General Committee of Revision.

THERAPEUTIC USEFULNESS PROVED BY CLINICAL OBSERVATION.

Unfortunately all of the methods available to the laboratory technician are of limited application in the proving of therapeutic usefulness, and of the multitude of new drugs introduced with flattering reports from the pharmacological laboratory only a very small number win a permanent place in materia medica.

Experiments upon the lower animals are frequently of great value in explaining the action of drugs upon the human organism, and at times are strongly suggestive of their medicinal use, but the only decisive evidence of the therapeutic utility of a medicinal agent is that derived from careful observations of its effects when administered to the human patient. After the pharmacologist has told us whether a drug should be classed as an analgesic, hypnotic, cardiac depressant or stimulant, etc., it still remains for the clinician to determine to what extent its properties can be made useful in the treatment of disease. The supreme test of therapeutic usefulness must always be the results of clinical experience, and the final verdict will always be delivered by the clinician.

With certain drugs clinical observations have been so numerous and the conclusions have been so nearly unanimous that their respective therapeutic value may be said to be established with a high degree of certainty, but with respect to numerous others, opinions may be so widely divergent that drugs considered by some physicians to be of great importance are by other physicians of equal eminence considered to be of little or no value.

It may fairly be said, therefore, that the usefulness or lack of usefulness of a given drug in the treatment of specific departures from health is largely a matter of opinion based upon clinical observations, the value of which will depend upon the competency of the observers, upon the care with which the observations are made, and upon the number of cases in which its effects have been observed.

A PRIORI CONCLUSIONS FREQUENTLY MISLEADING.

Efforts to deduce the therapeutic values of drugs from *a priori* considerations have rarely been successful, and on more than one occasion have proved misleading.

For example, when it was discovered that many plant drugs contained various chemical entities, such as alkaloids, glucosides, volatile oils, etc., nearly all of which were active physiological agents, the theory was advanced that drugs in which such principles could not be discovered by chemical methods must necessarily be inert and valueless.

Many of the present generation can remember when eminent therapeutists taught that the only value of Cod Liver Oil was that of a fatty food which might better be replaced by other fats less liable to disturb the digestive processes. Notwithstanding this condemnation on theoretical grounds, various practical-minded practitioners clung to this old-fashioned remedy for the very excellent reason that they obtained results from its use which could not be obtained from any of its suggested substitutes. To-day with the aid of the newer biological methods, we have learned that the valuable properties of Cod Liver Oil are not merely imaginary, and it is now definitely recognized as having an important place in modern materia medica.

If during the prevalence of the earlier theory of active principles certain of the vitamin-containing substances had been proposed for the treatment of rickets,

scurvy, etc., they would undoubtedly have been condemned as valueless by some authorities and might also have been denounced as fraudulent.

These and numerous other examples which might be cited suggest the thought that when a drug has been long in medical use with apparently favorable clinical results, we should hesitate to condemn it as valueless simply because it does not contain an active constituent discoverable by present known methods, or because we cannot reconcile its reputed usefulness with existing theories of drug action.

THE LIMITED LIST OF REMEDIES EMPLOYED BY INDIVIDUAL PHYSICIANS.

No physician will ever have occasion to use all of the drugs listed in the Pharmacopœia, or even any considerable proportion of them. As a matter of fact, the average physician regularly employs only a comparatively small list of remedies from which he rarely departs.

If, however, a large number of physicians were to name the drugs they deemed useful, the lists would exhibit a wide range of therapeutic agents. Outside of a few staple drugs found in nearly all of the individual lists, there would be great variation in the preferences of different physicians.

Such differences in drug requirements are because of differences in the classes of patients which physicians see, and variations in the conditions under which they practice. The eye and ear specialist will naturally use remedies not needed by the nose and throat specialist, and neither of these will need some of the remedies very important to the stomach specialist; while the general practitioner will naturally require a different assortment of drugs than the physician who confines his practice to a small group of related diseases. Physicians in crowded industrial districts will meet with classes of patients requiring the use of remedies rarely or never employed by those who practice in thinly populated rural sections; and physicians located on the dry mountain plateaus will have different drug needs than those who practice in the moist interior valleys or coastal plains, etc.

It will, of course, be conceded that the physicians of each class are best qualified to decide upon the remedies most necessary for themselves, but this is also equivalent to saying that no single class of physicians is qualified to pass final judgment upon the therapeutic requirements of other classes.

The Pharmacopœia being in the nature of a public document and having a general public purpose, must provide for the therapeutic requirements of all classes of physicians: for the various specialists and for general practitioners; for those who enjoy hospital facilities and those who must practice without them, and also for the varying requirements of those who practice under differing climatic and social conditions.

NECESSITY FOR LIMITING THE PHARMACOPŒIAL LIST OF DRUGS.

While at first thought it might seem reasonable that every drug known to be possessed of useful properties should be standardized by the Pharmacopœia, there are nevertheless some very practical reasons for restricting the official list to moderate proportions.

One of these practical reasons is the importance of avoiding needless multiplication of medicinal agents which have practically the same therapeutic properties. For example, there are hundreds of laxative drugs, and perhaps thousands

which are astringents. There are many iron preparations with substantially equivalent medicinal properties, and a very considerable number of mercurial compounds, the properties of which are practically the same. Besides these there are the salts of numerous other metallic bases and a multitude of synthetic organic compounds, many of which have very similar or identical properties. To include and standardize all of these thousands of drugs would increase the Pharmacopœia to encyclopedic proportions by the mere multiplication of therapeutic equivalents without adding to the means of combating disease.

No sharp dividing line can be drawn between drugs which are therapeutic necessities and those which are not. Probably there will always be certain drugs admitted to the Pharmacopœia which some physicians will consider unnecessary, and some omitted which other physicians will think should have been included. The best the Committee can be expected to do is to give careful consideration to the evidence on all sides, and to avoid taking an extreme view on any side.

PRIVATELY CONTROLLED AND NEWLY INTRODUCED REMEDIES NOT ELIGIBLE TO ADMISSION.

In addition to the exclusion of unnecessary therapeutic equivalents, privately controlled drugs and articles of secret composition are likewise excluded, regardless of their possible remedial values or of the extent of their employment by physicians.

Every proprietary drug is a law unto itself, and has the title and standards of composition and strength which its proprietor is pleased to adopt, and which he may change at will. If the Pharmacopœia should prescribe a different title and a different standard of purity and strength than those fixed by the proprietor, it would no longer be the same product, and such liberties might also be construed as an unlawful interference with property rights. On the other hand, should the Pharmacopœia accept the title and standards fixed by the owner, nothing would be accomplished except the gratuitous advertisement of the proprietary article. Obviously, therefore, privately controlled products have no proper place in the Pharmacopœia.

This rule of exclusion does not apply to products marketed under controlled titles but which can also be freely produced and sold under other names. If such products are considered to be therapeutic necessities the Committee may admit them under distinctive titles and may prescribe the standards of strength and purity with which they should comply when dispensed under such titles.

So, likewise, a privately controlled drug may be admitted after it loses its proprietary character. Some of the oldest drugs and preparations included in the U. S. P., as Rochelle Salt, Glauber's Salt, Dover's Powder and various others, were originally introduced as nostrums, or "patent medicines," but their proprietary character having lapsed, they can now be admitted to the official list with entire propriety.

Since the Pharmacopœia is intended to be a repository of agents of established merit, and not as a proving ground for untested drugs, admission is also refused to new or recently introduced remedies. Probably several hundred new remedies are introduced to the medical profession each year, of which perhaps not more than one or two gain permanent acceptance, while the others are speedily forgotten.

Not until a drug has been used for a sufficient length of time and by a sufficient number of physicians to demonstrate its therapeutic utility, and that its use is not merely a passing fad will it be considered as eligible for admission to the official list.

EXCLUSION FROM PHARMACOPŒIA DOES NOT IMPLY ABSENCE OF THERAPEUTIC VALUE.

The omission of a drug from the official list does not necessarily imply that it lacks valuable medicinal qualities. There is no reason, for example, to presume that many of the preparations of iron, mercury, arsenic and other metals, or of the laxative, astringent, hypnotic and analgesic drugs which have been excluded from the official list are any less efficient than some of those which have been admitted.

If a drug is unused by physicians, if its medicinal qualities are fully represented in other drugs already recognized, or if it is a newly introduced or a secret or proprietary remedy it cannot be considered a therapeutic necessity in the pharmacopœial sense, no matter how great its medicinal value from the theoretical standpoint.

Therapeutic fashions vary less frequently, perhaps, but not less certainly than feminine fashions in hats and gowns. An official drug may lose its popularity with physicians and be dropped from the Pharmacopœia, then at a later date again come into frequent use and be re-admitted. If one of the present official iron preparations should cease to appear on prescriptions during the next ten years, it will be discarded; and if any of the preparations now omitted shall appear with sufficient frequency in prescriptions during the next decade they will be regarded as therapeutic necessities and admitted to the next official list. Such alterations in the official status of drugs may occur with any revision of the Pharmacopœia.

It should be remembered that the U. S. P. was originally planned exclusively for the guidance of physicians and of those who produce and dispense medicines on physicians' prescriptions or for physicians' use, and that the U. S. P. Convention has never authorized a change in this original plan. Whether in order to meet modern conditions its scope should be expanded to include all drugs which have an extensive medicinal use, whether employed by physicians or not, is an open question, but until the Convention shall authorize such a radical departure from the policy established more than a century ago, the Committee on Scope will have no other option than to consider primarily the needs of practicing physicians.

The complete liberty of the physician to select whatever remedy his judgment suggests as proper for his patient is of the first importance, and is so recognized by the revisers of the Pharmacopœia. Every manual of materia medica and therapeutics, and every professor who teaches these subjects describes and recommends numerous drugs not included in the official list. If the physician desires to use one of these non-official drugs he is at perfect liberty to do so, and in fact it is by such excursions outside of the official list that the usefulness of new remedies is discovered. If he desires to use a patented or proprietary preparation, as he frequently does, he has the literature of the manufacturer for guidance, or if he

prefers less biased advice, he can consult *New and Nonofficial Remedies*, published by the American Medical Association, for information concerning its composition and claims, and also to learn whether it complies with the rule against advertising to the laity, and with the other ethical rules of that association.

RELATION OF THE PHARMACOPŒIA TO THE FOOD AND DRUGS ACT.

The United States Constitution provides that: "All legislative powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."

As construed by the courts this grant of law-making power is exclusive, and cannot be delegated by Congress to another department of government nor to any other agency, either public or private.

This rule, however, does not operate to prevent the law-making body from conferring upon an excutive department authority to make regulations necessary to the enforcement of a law, provided such regulations do not alter the intent or scope of the law as enacted by Congress.

It has also been held that Congress can enact a law in which authority is delegated to some other agency to ascertain or determine a fact or state of things upon which it is intended the operation of the law shall depend.

From the nature of their constitution legislative assemblies are not qualified to conduct scientific investigations nor to make technical measurements of physical phenomena, and if, for the purposes of the law, they could not authorize the acceptance of the physical and chemical constants of nature as determined by other agencies, they would be unable to provide for some of the most important needs of an age in which the application of technical and scientific data are common incidents of every-day life.

Keeping these considerations in view, is it a fair question whether the mention of the U. S. P. in the Food and Drugs Act of June 30, 1906, constitutes a delegation of legislative power to the semi-public corporation known as the United States Pharmacopœial Convention?

The question of constitutionality was considered when the Act was drafted,[1] and a careful reading of its language will disclose the fact that it nowhere declares that the U. S. P. and N. F. shall be accepted as standards of the law, and nowhere declares or implies that manufacturers of drugs must follow their prescribed formulas or processes.

The first mention of the U. S. P. and N. F. occurs in Section 6, which declares "*That the term 'drug' as used in the act, shall include all medicines and preparations recognized in the United States Pharmacopœia and National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.*"

[1] NOTE: An important part in the formulation of the text of the act was taken by the old "National Food and Drug Congress," a voluntary association of food and drug chemists, retail druggists, representatives of colleges of pharmacy, of manufacturing pharmacists and of other interests, which formerly met annually at Washington for the purpose of considering proposed legislation relating to the adulteration and misbranding of foods and drugs. Some years after the passage of the Act of June 30, 1906, this society was re-organized into what is now known as the "Association of American Food, Drug and Dairy Officials."

From a study of this language it will be observed that the entire substance of the definition is concentrated in the second clause, "*any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either man or other animals,*" which clause taken alone is sufficiently comprehensive to cover all drugs of every kind. The only effect of the first clause, therefore, is to emphasize the fact that, as far as the law is concerned, U. S. P. and N. F. drugs are on the same footing as all others, and are not entitled to special consideration because of their inclusion in these two volumes.

Since the first clause neither extends nor restricts the scope of the definition as intended by Congress it can hardly be contended that mention of the United States Pharmacopœia and National Formulary constitutes a delegation of legislative power to the makers of these two volumes.

The second reference to the U. S. P. occurs in Section 7, in which it is declared that an article shall be deemed to be adulterated: "*If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation.*"

It will be noted that this language does not declare that drugs shall possess the qualities prescribed by the U. S. P., but requires only that *when sold under pharmacopœial titles they shall be of pharmacopœial quality.*

To insure certainty in the important functions of compounding and dispensing, the titles of the U. S. P. are derived from the Latin, or are latinized in form, and have specific implications developed through more than a century of pharmacopœia-making, in order that a prescription shall mean exactly the same thing to a pharmacist in Portland, Oregon, as to a pharmacist in Portland, Maine.

The correct use of drug titles is one in which the issues of life and death are closely involved, and disaster is almost certain to result from the dispensing of a drug of different composition and strength than that intended by the prescriber. It was for the express purpose of preventing jeopardy to human life through the loose and inaccurate application of titles in the dispensing of medicines that the U. S. P. was founded and its specialized nomenclature developed, and this constitutes one of the principal reasons for the continuance of that volume.

Before there was a Food and Drugs Act it was always understood that the use of a U. S. P. title upon a drug implied that it was of U. S. P. strength and quality, and it was always understood also that the intentional dispensing of an article of different strength and quality was a fraudulent act. The only effect of the law, therefore, is to add its sanction to this long standing rule of common honesty.

To further make it plain that the only intent of this section is to prevent the *misuse* of the official titles the statute adds the proviso: "*that no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality or purity be plainly stated upon the bottle, box or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmaocpœia or National Formulary.*" This is stating about as clearly as it can be expressed in English that it is not the purpose of the law to compel manufacturers and dealers

to accept the standards of the U. S. P. and N. F., but to prevent them from using the specialized titles of these volumes as the cloak for fraud.

Under this language the manufacturer and dealer is at liberty to either accept or reject both the standards and the titles of the U. S. P. and N. F., or he is at liberty to use the titles upon articles of different quality, provided he does not use them deceitfully.

This obligation of producer and dealer does not vary from revision to revision, but always remains the same, namely, not to use an official title unless supplying official quality, or unless the difference be plainly stated on the label.

It is specifically stated in the Pharmacopœia that its prescribed standards of purity and strength "are intended to apply solely to substances which are used for medicinal purposes and when professedly bought, and sold or dispensed as such." This declaration automatically excludes the vast bulk of drugs and chemicals employed in the arts and industries, thus leaving to pharmacopœial supervision probably less than one per cent in bulk of such substances as found in commerce, and then "only when professedly bought, sold or dispensed" for medicinal purposes, in which case the requirement that they shall be true to the implications of their labels is an elementary and indispensable necessity of public safety.

In view of the guarded manner in which the U. S. P. is referred to in the Food and Drugs Act, and the evident intent both of the law and of the Pharmacopœia not to restrict the liberty of manufacturers and dealers beyond the requirement that they use truthful labels, it would seem to be a strained construction to hold that there has been an unconstitutional delegation of law-making power to the United States Pharmacopœial Convention.

Left, J. T. Humphrey, retiring Chairman of British Pharmaceutical Conference; right, A. R. Melhuish, President of British Pharmaceutical Society and of the Conference.