Section on Pharmacopoeias and Formularies

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SOME OBJECTIONS TO MATERIA MEDICA STANDARDIZATION WITH REFERENCE TO THE U. S. PHARMACOPŒIA.*

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The text of my sermon will be found in the Journal of the American Medical Association for Nov. 30, 1909, p. 1645: "A thoroughly up-to-date Pharmacopœia —one which will truly reflect the best medical practice of the present time—will contribute more to sane drug therapeutics than any other one thing."

To prepare a new materia medica product for introduction into the United States Pharmacopœia, it is necessary first, to give it a name conformable with scientific nomenclature, (the first step in standardization). This is objected to by certain commercial interests who desire property-rights in the name of each new product, for the purpose of creating a lasting monopoly in its manufacture and sale.

The next step consists in the free discussion of each new drug in medical and pharmaceutical journals, societies, schools and colleges. Certain objectors are entirely in accord with such discussion, provided the discussion is favorable to the therapeutic claims they make for their controlled products. But free and impartial discussion, when it results in diminishing sales, is not viewed with equanimity by commercial introducers, after they have spent, possibly, a hundred thousand dollars in advertising.

The next step is the fixing of tests for identity and purity, and the enforcing of the standards thus evolved by pure food and drug laws. Honest manufacturing houses favor this kind of legislation. It is only the dishonest manufacturers who object.

The standardization of galenical products, to fit them for a place in the Pharmacopœia, includes determination of botanic source, physical and chemical structure, pharmaco-dynamic and therapy-dynamic properties, and therapeutic uses. Manufacturers depending upon concealing one or more of these factors, to obtain and retain monopoly of sales, object to such standardization.

Again, manufacturers depending upon a fictitious demand, created by misleading advertising, object to standardization.

Another objection to standardization, is, that standardization means *leveling* of all materia medica products to common standards, thus taking away from commercial introducers, the advantage to be derived from advertising their products as better than those of their competitors.

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What the medical profession must know in order to treat the sick properly, are the side-effects, limitations and comparative value of new products, in their relation to each other, and to older and better known products, employed as therapeutic agents in similar conditions. It is just this kind of levelization, that the medical and pharmaceutical professions must insist upon, if we are ever to restore public confidence in drugs as remedial agents.

Suppose that the manufacturers of potassium iodide, were able to do so, and should, organize a campaign against the newer syphilitic remedies, because their success meant injury to the sale of potassium iodide. Suppose the manufacturers of quinine should endeavor to prevent the destruction of mosquitoes because malaria is propagated by mosquitoes and the sale of quinine is dependent upon the existence of malaria. Such action on the part of the manufacturers, would be bitterly resented by the public. Yet this kind of opposition to the therapeutic standardization of new materia medica products, is actually going on at the present time.

Demand created by false advertising of unwarranted claims, represents unfair competition. Business taken away from competitors, in this way, is stolen. The remedy for unfair competition, is to be found in drug-standardization. It is not surprising that those guilty of unfair competition object.

Let me quote the exaggerated claims made for a certain alleged new remedy by way of illustration. I have coined the name "Antigonensis" to describe the advertised product.

"Antigonensis is a powerful and harmless systemic antiseptic in the most varied medical and surgical infections. It checks beginning sepses and often effects brilliant recoveries in desperate ones. Recent investigations show that, with its direct bactericide energy, it exerts a marked electrolytic and leucocytogenetic action, and thus greatly aids the natural protective forces of the body.

"Used topically, by mouth, rectally, intravenously or by inunction, Antigonensis forestalls the development of sepsis from accidental or operative wounds, or childbirth, arrests beginning medical and surgical infections, and often achieves brilliant recoveries in apparently hopeless cases."

It is evident that pharmaceutic and therapeutic standardization, would soon *"levelize"* this product and rob the manufacturer of the advantage to be obtained by claiming it to be better than competing products.

The true ideal of pharmacologic practice includes coöperation between the medical and pharmaceutical professions, and the manufacturing houses supplying them with materia medica products, to prevent such kind of advertising. This coöperation can never be secured, until all concerned are willing to consider the public health, as of greater importance, than the *making of money*. It is admitted that the *making of money*, is absolutely necessary, for the existence of the doctor, druggist and manufacturer. The doctor must live on his fees, the pharmacist on his sales of medicines, and the manufacturer on the profit obtained by selling his wares. But dishonest commercialism should be abolished. The principle expressed by the motto "caveat emptor" (let the purchaser beware) is a very dangerous principle, applied to medicine or pharmacy.

Objections to materia medica standardization, come from manufacturers of commercially-controlled materia medica products of all kinds. For the purpose

of obtaining a clear conception of the objections and objectors, let us classify the objectors into their classes as follows:

1. Secret Medicine Manufacturers.
   a. Retail druggists supplying medicine of their own make, which they recommend for self-medication, trusting patients to make their own diagnosis for the most part, but sometimes venturing to make a diagnosis for them.
   b. So-called "patent" or proprietary medicine manufacturers, who prescribe medicine at wholesale, without diagnosis.

2. Manufacturing Chemists and Pharmacists dealing in commercially-controlled specialties.
   a. Manufacturers of medicinal-mixtures of secret formulas, for doctors to prescribe.
   b. Manufacturers of mixtures concerning which the medicinal ingredients are published, but regarding which the working formulas are suppressed.
   c. Manufacturers of chemical synthetics protected by patent, and registered names.

The objectors to standardization, are as varied as the character of the manufacturers. Behind the objections, are motives equally complex. All object, because they do not want to part with their monopolies. Some object, because, in addition to that reason they wish to create a demand by misleading advertising.

"How can inventors protect capital, invested in the working and development of new inventions, from interference and competition, if inventors publish full knowledge of their inventions, for the benefit of scientific classification and standardization?" This question is frequently asked by the pharmacists and the reputable manufacturers, engaged in the pharmacal and pharmaco-chemical industries.

The answer is to be found in that clause of the Constitution of the United States, that gives to Congress the power "to promote the progress of science and the useful arts, by securing, for limited times, to authors and inventors, the exclusive right to their respective writings and discoveries."

Inventors of new and useful arts, machines, manufactures, and composition of matter, may obtain proper protection by patenting their inventions.

There are good reasons for believing, that the proper application of the patent-law to medical inventions, would promote progress in medical science and in the useful arts of pharmacy and drug-therapy. But to accomplish this object, it would be necessary to establish some kind of a commission, board of control, or bureau of materia medica, working with the Patent Office and the Courts, to limit the patenting of materia medica products to substances new and useful, *in fact*, also to act as experts in infringement-cases, requiring higher knowledge of medical and chemical science and arts, than that possessed by the legal fraternity.

The patenting of new materia medica inventions under such a board of control, would promote materia medica standardization. For the statute exacts, "That, before any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the Commissioner, and shall file, in the Patent Office, a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise and exact terms, as to enable any person skilled in the art or

science to which it appertains, to make, construct, compound and use the same."

It may be answered that the prejudice against patenting materia medica inventions manifested by the medical profession is a serious hindrance. This is true. However, this prejudice might, in all probability, be overcome by the adoption of some plan to prevent dishonest exploitation of new materia medica products by commercial introducers, also to secure free and impartial discussion of commercially-controlled products by the medical and pharmaceutical press.

Much has been done in this direction by the Council on Pharmacy and Chemistry of the American Medical Association, and much by the pure food and drug laws. The Shirley amendment to the national pure food and drug act, aimed against misleading advertising, if properly enforced, will be of great service. Similar bills advocated by "Printers Ink" are being passed by the States, and, as they are backed by the advertising fraternity and their agents, we have a right to expect salutary reform. But we need some kind of strong central board of control, in which the various interests involved may be represented, and have a voice in the administration of affairs.

"But," say some of the objectors, "the seventeen year limit, provided by the patent law, is not long enough to get our money back. It requires an investment of at least one hundred thousand dollars in advertising a new product, before the investment becomes remunerative. And it must also be considered that a certain proportion of ventures prove unprofitable. That is why we devised the scheme of patenting our products, under their chemical names, and registering coined names as trade-marks, to be advertised as the names of the products. By forcing the coined names into the common language, as nouns, and retaining ownership in them, we are enabled to extend our monopolies indefinitely."

This plan, for defeating the object of the patent-laws, was set aside by the decision of the Supreme Court of the United States, in the Singer Sewing Machine case in 1895. According to this decision, the name of a patented article cannot be commercially-controlled after the patent expires.

"Then why 'patent' materia medica products at all?" say the objectors. "Why not 'trade-mark' them, and keep the process of their manufacture secret? A trade-mark never expires and the manufacturer, by controlling the name of the product, possesses a perpetual patent."

The weakness of this argument is apparent, when one considers that any person who discovers, by legitimate means, how to make the same product, has the right to do so, and advertise the fact. He also has the right to employ its currently-used name, either as the title of the product or as a synonym. For example, what is to hinder any manufacturer of hexamethylamine from using on his label, as synonyms, all of the fourteen so-called trade names or trade marks of that drug?

"We are perfectly willing to aid the government in fixing standards for our products and placing them in the Pharmacopœia, if we can still maintain monopoly," say the objectors. "What we desire is, to secure the advertising advantage of having our products listed in pharmacopœias, dispensatories, medical dictionaries, text books and other medical and pharmaceutical literature. We also desire discussion in professional journals and societies. We want the medical

colleges to teach the students how to use our products. But we want to hold on to them."

That is the same as saying, that these objectors want the medical and pharmaceutical professions, colleges, societies and press, to do their detail-work without pay. "No," say the objectors, "we are willing to pay for the work, if we can get it done in this way. What we object to, is giving up our monopoly."

To this, medical scientists reply that to do the work for pay, would be the same as going into partnership with the manufacturers in a commercial business, and the turning of the educational machinery of the profession into a great advertising bureau for the commercial exploiting of alleged "new remedies." Those engaged in materia medica commerce, are no longer in a judicial position in relation to materia medica, and what they say about it must be received *cum grano salis*.

If this objection is true, then the professional ideals taught by the colleges of pharmacy are false, and there can be no profession of pharmacy.

But is it true? I do not believe it. It becomes evident that pharmacy is a profession, when it is considered that the proper introduction of new materia medica products requires the coöperative work of physicians, pharmacists, chemists, botanists, bacteriologists and other professional men, learned in the knowledge of their respective branches and expert in *technic*. Coöperation on the part of the professional societies and press, is also required. The result of this coöperative work belongs to the workers, not to individuals. It must be contributed to the common fund, for the benefit of all concerned. This means, that the introduction of new materia medica products, should be changed from a commercial or monopolistic plan, to a professional or coöperative plan.

Now we are in position to consider the question of patenting new materia medica products, in connection with a professional system. It seems to me, that the question is one for the professions of pharmacy and medicine to decide. If they are willing to consent to it, as adapted to the promotion of progress in medical science, and in the arts of pharmacy and drug therapy, then let it be done.

But it is evident that it is unfair to ask any one person or manufacturing house, to do business on a professional basis, while competitors are doing the same business on a commercial basis.

Until manufacturers are willing to place their business upon a professional basis, they have no right to expect professional coöperation. I believe that the profession is willing to endorse and coöperate with manufacturers, under the protections of the patent laws, just as they are willing to coöperate with the publishing houses, under the protection of the copyright laws, provided that medical science and the arts can be promoted thereby.

The object of the copyright and patent laws, is to promote progress in science and the useful arts, by securing, to authors and inventors, the right to prevent others from copying their respective writings and discoveries for limited times. The object of the trade-mark law is to protect all concerned, from the counterfeiting of labels and brand-marks. But all plans for obtaining and fostering perpetual monopolies, are a hindrance to science, and stand in the way of prog-

ress in civilization. Monopolies of this character, ought to be opposed by all patriotic citizens, and especially by physicians and pharmacists.

It is evident from the foregoing that a thoroughly up-to-date pharmacopœia will contribute more to sane drug therapeutics than any other one thing. The U. S. Pharmacopœia is preëminently the standard for medicinal drugs, chemicals and pharmaceutical preparations in the United States. It is the basis upon which rests all materia medica literature, including the dispensatories and text books. The information contained in the Pharmacopœia, is taught in the medical and pharmaceutical schools and colleges, and circulated throughout the country, in the literature of pharmacy, chemistry, and therapeutics.

The U. S. Pharmacopœia is "the law of the land," not only for Inter-state commerce, but also for state commerce, in most of the States. Whatever goes into it, is placed there, after mature consideration by a convention of representative physicians, pharmacists and chemists, who, collectively, decide its policy and appoint the committee for its decennial revision. The influence of the Pharmacopœia upon the pharmaceutic, pharmaco-chemic, and therapeutic arts is therefore incalculable.

To prepare new materia medica products for admission to the Pharmacopœia, their standardization is necessary. Materia Medica products cannot be properly standardized, except by the coöperative work of the medical, pharmacal, and chemical professions, whose functions are to determine, for each product, its nomenclature, source or genesis, physical and chemical properties, pharmacodynamic and therapy-dynamic actions, therapeutic applications, and proper methods of preparation. This function is being constantly exercised by the Committee having charge of the revision of the Pharmacopœia.

To obtain a thoroughly up-to-date Pharmacopœia, the commercially-controlled materia medica must be considered. The rule adopted concerning the admission of controlled-materia medica products, to the Pharmacopœia follows,—the Committee was authorized to admit,

"Any synthetized product of definite composition which is in common use by the medical profession, the identity, purity, or strength of which can be determined. No compound or mixture shall be introduced, if the compositions or mode of manufacture thereof be kept secret, or if it be controlled by unlimited proprietary patent rights."

Some of the synthetic products still controlled by patents were admitted, because the patents were about to expire. So-called "trade names" were not admitted. Abbreviations for long chemical names were coined and adopted.

In the light of the above facts, it is evident that the rule adopted by the committee, which was doubtless the best that could be devised under circumstances then existing, is not adequate to secure proper standardization. Something should be done to clear up the question of nomenclature, so that a new product may be admitted under its currently-used name, the same to be adopted either as the official title or as a synonym. Also the question of ethics, in regard to patenting new materia medica products, either as to product, or process, or both, should be decided, and proper action taken in the premises.

The proper application of the patent law to materia medica inventions, the same to be administered under the advertisement of a board of control, repre-

sentative in character, working with the Patent Office and the Courts, would probably result in securing the object of the patent law in this connection, i. e., the promotion of progress in medical science, and in the useful arts of pharmacy, chemistry and drug therapeutics.

The *personnel* of such a board of control is well exemplified by the U. S. P. Revision Committee. It is truly representative in character, and is already engaged in the work of standardization. If to this Committee, Congress would give advisory authority to act in expert capacity, in conjunction with the Patent Office and the Courts, and would provide sufficient appropriation to meet the necessary expense, all objections to drug standardization, on the part of inventors and manufacturers, would disappear, also the ethical problem would be solved, and an embarrassing situation relieved.

THE PHARMACOPŒIA, THE DRUGGIST AND THE PHYSICIAN.*

R. H. NEEDHAM.

That the Pharmacopœia is the "Book of Books" among chemical and pharmaceutical publications must be conceded, when we look about and, after reviewing the great mass of literature, we find that we are compelled to turn to it, as a rule and guide in selecting and standardizing drugs and chemicals. It is not perfect, and probably never will be, but this does not detract nor lessen its value, when considering it as a book of standards, because there is no other work equal to it, let alone being its superior.

Druggists who are familiar with the Pharmacopœia are aware of its value, though we regret to say that but few of them make any use of it, except as a reference to simples. When it comes to formulas and preparations, almost every one of the rank and file, consult a Dispensatory, instead of the Pharmacopœia. As a Dispensatory consists of notes taken from one or more pharmacopœias, the matter is second-hand in a way, and coming from so many sources, it gives the reader, if he is not very careful, quite confused ideas as to some preparations. Druggists will not agree upon the procedure for making a preparation for this reason, each claiming their preparations U. S. P. Should you ask them to make the preparation, using the U. S. P. text, you would be apt to receive a mild protest, as they would probably inform you that they preferred to use the Dispensatory rather than the Pharmacopœia as the latter gives all quantities in the metric system and they have difficulty in converting weights and measures. I consider it a shame and disgrace for the druggist to make such an excuse, when metric weights and measures can be so readily obtained and at such reasonable prices. Yet this bugbear is in the way, and nothing short of a national law making the metric system the official one will place the pharmacopœia where it ought to be among the druggists.

From my view-point and experience in teaching, I wish the other systems of

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