Section on Education and Legislation

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THE RELATION OF DRUG STANDARIZATION TO PHARMACEUTICAL EDUCATION AND LEGISLATION.

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My attention was first called to the unsatisfactory condition of the materia medica supply business in 1880. Having at that time introduced rectal gelatin suppository capsules and desiccated blood, and contributed papers describing them to medical and pharmaceutical journals, I was brought in contact with the so-called new remedy business. When these products were placed on the market by a large manufacturing house and my literature distributed to the profession, I was warned by my prominent medical friends of the dangers of "commercialism." I found that if their opinions were correct such a thing as a profession of pharmacy supported by materia medica commerce would be impossible. As a graduate of the Philadelphia College of Pharmacy I was not willing to accept their opinion, and therefore took up the question of the relation of pharmacy to medicine in self-defense.

During the thirty years that have since elapsed I have made the subject one of continual study and investigation. As chairman of committees of the American Pharmaceutical Association, pharmaceutical author, editor, and teacher, physician and social worker, and expert for large pharmaceutical manufacturing houses, I have enjoyed unusual privileges and experiences of a most practical nature. The facts that I shall present in this paper are therefore not based on idealist theories but consists of the expression of thoughts and opinions gained by continuous personal contact with the difficulties which we are all striving to overcome.

In spite of what has been done in the past, we still find today a wide-spread protest against the existing methods of carrying on and increasing the drug business. Remedial legislation is being sought by associations, societies and individuals who have the interests of humanity at heart and who are determined that the public health shall not be exploited for the benefit of individual greed, or in condoning individual inefficiency or ignorance.

A noted political economist and professor in one of our eastern universities, who is chairman of an important committee in charge of a bill now before Congress having as its object the regulation of matters affecting the public health, in

answer to my question why he considered the drug business a menace to the health of the nation, advanced the following argument:

"Social workers throughout the country are engaged in an organized campaign to stamp out tuberculosis. One of the obstacles in the way of the campaign is the drug business. Druggists and manufacturers are engaged in pushing cough medicines and consumption cures. People suffering with incipient phthisis purchase these remedies because they are advertised and recommended for coughs which are, in many instances, symptoms of tuberculosis. While they are engaged in combatting a symptom with medicines which from the very nature of the disease cannot reach the cause, valuable time is lost, and the patients, capable of cure if properly treated in the beginning, become incurable because of this delay. Our campaign is one of education and legislation to remove the causes of consumption and to institute methods of proper sanitation and treatment—treatment in which drugs have little or no part. It is admitted by physicians expert in treating tuberculosis that drugs are for the most part worse than useless in combatting this disease. In this campaign we are opposed by manufacturers and dealers in drugs who care more for money than for human life. I assured this gentleman that thousands of people in the drug business are thoroughly in harmony with social workers in their campaign against tuberculosis and equally opposed to indiscriminate drugging. Yet we are all familiar with cases of incipient phthisis treated by druggists with cough remedies and there is enough of this malpractice going on to justify the criticism.

A Washington official engaged in promoting national legislation for regulating the sale of narcotic and habit-forming drugs, expressed in a recent conversation similar views regarding the attitude of the drug business toward legislation against drug abuses. He stated that certain powerful drug interests employ lawyers of ability as lobbyists who spend their time at Washington and at the state capitals skillfully opposing such legislation.

These lobbyists claim to represent the entire drug trade of the country; and, as the national and state pharmaceutical associations do not repudiate the claim, it is not surprising that those who are promoting bills for the protection of the public health are under the impression that the drug business as such is opposed to all legislation in any way affecting its commercial interests.

Those of us who attended the annual meeting of the Pennsylvania Pharmaceutical Association this year will remember the bitter opposition against the proposed pharmacy bill. Chairman Wallace, the champion of the bill, deserves the thanks of all lovers of true pharmacy for his successful efforts in its behalf. The debate lasted most of the day and far into the night and the friends of the bill won by a vote of 40 to 30.

It must be admitted that there are many persons in the drug business who are opposed to all laws which restrict the sale of drugs except such as are devised to give them a monopoly. They think existing restrictions very unfair and view with alarm bills now before Congress containing further restrictions. These bills seem to them very radical, but when one considers the decision of the Supreme Court of the United States in the case of Worden vs. California Fig Syrup Co. (No. 35, October term, 1902), it will be found that in the opinion of the highest legal

tribunal in the land restrictions should be imposed far more stringent than any prepared in the bills referred to. I particularly attended to the following paragraph in the decision:

"Most, if not all, the States of the Union have enactments forbidding and making penal the practice of medicine by persons who have not gone through a course of appropriate study and obtained a license from a board of examiners; and there is similar legislation in respect to pharmacists. And it would seem to be inconsistent to defeat such salutory laws, if medical preparations, often and usually containing powerful and poisonous drugs, are permitted to be widely advertised and sold to all who are willing to purchase. Laws might properly be passed limiting and controlling such traffic by restraining retail dealers from selling such medicinal preparations, except when prescribed by regular medical practitioners."

What would be the effect of such additional legislation as suggested in this opinion? It would place the practice of medicine and pharmacy under the joint control of the medical and pharmaceutical professions, where it properly belongs; it would put an end to lying medical advertising without a special bill for the purpose; it would limit the evils of self-medication and place the question of domestic medicine on a professional basis; it would put an end to the "Great American Fraud" and raise pharmacy to its proper place as a branch of medical practice.

The object for which the pharmaceutical profession is supposed to exist is to cooperate with the medical profession in standardizing the materia medica and in rendering it fit for the use of physicians in treating the sick, but it is not the function of the pharmacist to prescribe or recommend medicine.

This fact is recognized in the chapter of the medical code of ethics dealing with the duties of the profession to the public: Section 4. "By legitimate patronage, physicians should recognize and promote the profession of pharmacy; but any pharmacist, unless he is qualified as a physician, who assumes to prescribe for the sick, should be denied such countenance and support. Moreover, whenever a druggist or pharmacist dispenses deteriorated or adulterated drugs, or substitutes one remedy for another designated in a prescription, he thereby forfeits all claims to the favorable consideration of the public and physicians."

If pharmacy is thus to become practically part of the medical profession, it is important for the pharmacist to consider and practice the professional ideals of medicine.

Medicine is one of the liberal professions. In defining what is meant by a liberal profession, the British Medical Journal for April 6, 1912, says: "Why have divinity, law and physics been for so many centuries grouped together as 'liberal professions' in contradistinction to other associations? Doubtless in the first place, because for admission to them it is necessary to have been initiated to some extent in the study of what are called the liberal arts; one cannot, as it were, become evolved into a clergyman, a lawyer or a medical practitioner by the simple process of apprenticeship. But there is a further common stamp which marks off members of the professions from commercial pursuits of whatever kind; they are each bound by self-imposed laws, generally accepted, although they may be unwritten, by which their practice is regulated. That is what constitutes the bond of union, which Bishop Boyd Carpenter * * * called the freemasonry of the three great professions. They all place professional honor above

the struggle to acquire wealth, which is the aim of commerce, and they place on their members in their professional dealings restrictions which have no place in trade. The needs of mankind are considered fair subjects of exploitation by commerce; a 'corner' in some commodity, even if it be a necessary of life, is considered a clever stroke of business."

According to the code of medical ethics, a profession has for its prime object the service it can render humanity; reward or financial gain should be a subordinate consideration. In choosing the medical profession, an individual assumes an obligation to conduct himself in accord with its ideals.

There can be little doubt that both the pharmaceutical and medical professions could elevate themselves in the opinion of the general public by a strict adherence to ethical dealings, and that to their financial and social advantage. With the lack of suitable legislation and the failure to enforce laws already in existence, the pharmaceutical profession has developed an alarming tendency to degenerate into the commercial business of nostrum vending and quack doctoring in which the expert pharmacist is far excelled by the better storekeeper and skillful impostor.

A study of conditions as they are discloses anything but an ideal, or even sensible state of affairs.

First, we have public self-diagnosis and treatment, which includes purchases of standard drugs from the druggist for this purpose without a physician's prescription.

Second, we have self-diagnosis by means of instructions contained in patent medicine advertisements and self-treatment by the patent medicine which recommends itself to the judgment of the individual who has made his own diagnosis.

Third, we have diagnosis by the druggist and treatment by means of standard drugs, his own mixtures, or patent medicines.

Fourth, we have continued public self-medication by means of repeated filling of doctors' prescriptions.

Fifth, we have substitutes or use of deteriorated drugs by the pharmacist in compounding physicians' prescriptions.

The methods for combatting this condition lies in (1) the education of the public; (2) the restoration of the professions of medicine and pharmacy to their proper dignity and place, and (3) the standardization of the entire materia medica.

What is drug standardization?

"Drug standardization consists in fixing a nomenclature for drugs and preparations; it consists of determining methods for insuring uniformity in composition and physiological action and therapeutic effects; it consists in adjusting finished products to fixed standards and keeping them there for a sufficient length of time to permit their proper application as therapeutic agents; it consists in reducing this knowledge to law and embodying it in system and then teaching it in medical and pharmaceutical colleges, universities and journals."

Cooperation between the medical and pharmaceutical profession is necessary to do this work of standardization. Once in ten years the representatives of the two professions assemble in congress at Washington and appoint a committee to

do the work. The assembly is known as the United States Pharmaceutical Convention, and the committee is called the Committee of Revision.

Before the advent of the Pure Food and Drugs Act of June 30, 1906, compliance with the standards of the U. S. Pharmacopoeia was purely voluntary. This legislation made the Pharmacopoeia the "law of the land" so far as interstate commerce is concerned. Most of the states have followed the National Government in this legislation for the establishment of standards, and as a result pharmacy is assuming an importance never before attained in this country.

I do not believe that either of the professions realize what a weapon of offense and defense they possess in drug standardization in the warfare against pretense and error.

Take, for example, the results that might be accomplished by adopting a plan for the proper classification and standardization of every alleged new remedy as soon as introduced.

The first step in standardization consists in fixing a nomenclature for the new materia medica product under consideration. At the present time this is fixed by the commercial introducer, who gives the product a name, registers the name as a trade-mark, and claims it as his personal property, thus creating a system of monopoly.

The medical and pharmaceutical professions are not called upon to endorse any such system of monopoly. It is contrary to ethics and a violation of the best traditions of the profession handed down from the time of Hippocrates.

The remedy is very simple and is already being applied by the medical and pharmaceutical text-books. It consists in giving each new product a generic name and using the so-called trade-name as a synonym. By what law can the introducer of a new product prevent the medical and pharmaceutical professions and manufacturers generally from adopting this plan?

The second step in standardization consists in fixing tests for identity, character, quality and strength. This ought to be the function of the central government at Washington, under the Pure Food and Drugs Act.

The third and final step consists in ascertaining the true therapeutic value of the product. Therapeutic verdicts require the cooperative work of experts in chemistry, pharmacy, pharmaco-dynamics, and therapy-dynamics as well as clinicians. The drug must be prepared in suitable forms—this requires experts in pharmacy. It must be examined by chemists to verify the claims made for chemical composition. Chemists and experts in pharmaco-dynamics are required for its chemical and pharmacodynamic standardization. Chemical, physiological and pathological knowledge is required for the study of its effects on healthy and diseased tissues. If a new plant is undergoing examination, the services of experts in pharmacognosy are also required.

To aid the clinician in carrying on the work of investigation, convenience requires that the knowledge thus evolved shall be properly classified and sent to physicians engaged in hospital and private practice, in the form of Working Bulletins. I suggested the Working Bulletin System in 1881. By this plan it becomes the function of all concerned to report the results of observations and verifications in the medical and pharmaceutical journals. After passing the cen-

sorship of the press, the information thus obtained is collected, classified, and published in subsequent editions of the bulletins.

These bulletins, when collected and bound, would furnish very comprehensive literature concerning the new products submitted to this collective investigation.

Therapeutic standardization of the newer materia medica by means of the Working Bulletin System thus promotes progress in the science of the materia medica and in the useful arts upon which that science is dependent.

It is evident that such a system of drug standardization applied promptly to each new materia medical product introduced to commerce would soon put an end to imposition, nostrum production and monopoly. It is also evident that it is not safe for physicians to freely use new materia medica products introduced by advertising unless they are first submitted to impartial tests by competent observers.

I first advocated a national bureau at Washington, and an investigation of the materia medica of the world under governmental auspices. This plan was favored by the Smithsonian Institute and the medical departments of the Army, Navy and Marine Hospital Service, also the American Medical Association, but opposed by powerful commercial interests. Then I advocated a national bureau of materia medica. This was endorsed by the Journal of the American Medical Association. Shortly afterward I took part in organizing the National Bureau of Medicines and Foods and the National Pharmacy Company to support it. This plan received extensive professional endorsement.

A plan was suggested to reorganize the bureau under the joint control of the American Medical Association and the American Pharmaceutical Association, and the joint committee reported favorably, but again commercial interests interfered. Then the Council on Pharmacy and Chemistry was organized, and adopted part of the plan.

The Council did not see fit to make use of the Working Bulletin System, but it has been taken up by the scientific departments of manufacturing houses, with the approval of the profession.

While an ardent admirer of the work of the Council, I still believe that the working bulletin system, carried on by the Council, or by a strong board of control, working in cooperation with the Council, or by a government bureau, such, for example, as the Bureau of Hygiene, would prove a valuable addition to the means by which the profession is enabled to obtain therapeutic results.

Summary: Progress in materia medica science is dependent upon materia medica standardization by the cooperative work of the medical and pharmaceutical professions. As the result of that work, we already have the pharmacopoeia and scientific literature relating to materia medica, pharmacy, and drug therapeutics.

Progress in drug standardization is dependent upon the researches and discoveries of persons engaged in the practice of the pharmacologic arts, viz., pharmacognosy, or the art of identifying and selecting drugs; pharmacy, or the art of preparing, preserving, compounding and dispensing; pharmacodynamics, or the art of determining their effects on healthy tissues and of applying the knowledge to the standardization of drugs by physiologic testing; and therapydynamics, or the art of determining the effects of drugs on diseased tissues and applying drugs as medicines in the treatment of the sick.

The only way in which new materia medica products can be standardized and properly introduced to science is by the cooperative investigation and researches of many chemists, pharmacists, pharmacologists and clinicians, working under different conditions of environment, in all parts of the world, comparing and verifying each other's observations, impartially discussing results, classifying and publishing the same in the forms of science, and teaching this knowledge to the medical and pharmaceutical professions so that it may be freely used for humanitarian purposes. This work cannot be successfully accomplished under a system of commercial monopoly by secret processes, product patents, or commercially controlled names.

The knowledge of drugs, to be classed as a science, must be reduced to law, embodied in system, and protected by a stable nomenclature. The name of that science, advocated by the author of this paper since 1881, should be Pharmacology. This name is now so recognized by the National Committee representing the boards and colleges of pharmacy in its pharmaceutical syllabus.

The professions of medicine and pharmacy are mutually dependent, and both are the servants of the public. The public demands that the physician shall take care of the sick, and the pharmacist supply the medicine for that purpose. Unfortunately for the peace and harmony that should be maintained between the two professions, the public also demands the privilege of self-diagnosis and self-treatment, and the pharmaceutical profession is expected by the self-medicating public to supply the medicine for that purpose. Consequently, there has always been more or less friction between the two professions, and always will be, until both are willing to consider this question of domestic practice in a rational manner and come to a dignified compromise.

While the two professions have been fighting between themselves like the dogs of the fable, the nostrum manufacturers have improved the opportunity to run away with the bone.

It is the duty of these professions to free the materia medica from commercial control. It is their duty to unite for the standardization of the entire materia medica. The public has intrusted this work to their hands, yet they have not only neglected their duty in this regard, but have become recalcitrant. The parable of the talents applies to the situation. Beware lest the fate of the servant who hid his talent in the earth overtake us for this neglect and repugnance.

This is by no means an idle threat. Political economists, sociologists, philanthropists, sanitarians and others have become cognizant of the situation and are closing in their ranks for stronger organization. They are behind the bills in Congress, and sooner or later legislation will be effected for the protection of the public. Shall we, as professions, take part in guiding and shaping this legislation, so that it may accomplish its purpose speedily and harmoniously? Or shall we sit back complacently and permit outsiders to do the work that we ought to do, to our lasting shame and disgrace?