Both the United States and France have developed safeguards against the distribution of unregulated medical remedies. The process by which these safeguards have been put into effect has been very different in the two countries, and reflects a difference in attitude toward the state’s role in social regulation. The effect of these regulations on the licensing of new drugs has also led to a different approach to drug development and testing in the United States and France.

The regulation of patent medicines, or secret proprietary remedies, was begun in France in 1728 when two decrees were issued. One delegated "powers of surveillance over proprietary medications" (1), to the Lieutenant General of Police of Paris; another created a commission to look into the problem of secret remedies. Throughout the 18th century, physicians and scientists analyzed the wide variety of secret remedies that were used by private physicians and in military hospitals, and some attempts were made to determine their efficacy through clinical trials. In 1778, King Louis XVI granted the newly founded Royal Society of Medicine the sole power to approve secret remedies for public use. Although many of these nostrums were found to be worthless, some — such as the antisyphilant rob Boyveau-Laffecteur — were accepted by the medical profession (2).

The manufacture and sale of secret remedies, however, continued to flourish. After the Revolution, reports on the problem were presented to various legislative bodies by such leading physicians and scientists as Guillotin, Braillon, and Fourcroy (3). Finally, the law of Germinal, enacted in 1803, regulated the practice of pharmacy and authorized only pharmacists to fill prescriptions written by licensed physicians. Pharmacists were permitted to stock only those medications approved by the schools of medicine; all other remedies were considered secret and illegal. The advertising, distribution, and sale of secret remedies were punishable by fines and imprisonment (4). Unfortunately, the government was unable to formulate a practical definition of what constituted a secret remedy. Also, many patent medicines were extolled for their nonmedicinal properties, so that the penalties laid down by the law could be circumvented.

Several attempts were made to enforce the prohibition against unauthorized secret remedies. In 1810, Napoleon proclaimed that all secret remedies would have to be authorized by the Minister of the Interior, who would be advised by a commission. The commission "would study the composition of the remedy, determine its safety and efficacy, and, if it was judged valuable, recommend purchase of the formula from the inventor at a fair price" (5). In 1820, the burden of testing and approving secret remedies was shifted to the Commission on Secret and New Remedies of the Academy of Medicine. Both commissions were inefficient; by 1843, they had approved fewer than 20 secret remedies for sale to the public.

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THE REGULATION OF PATENT MEDICINES IN THE UNITED STATES AND FRANCE
The problem of proprietary medicines was closely related to that of the adulteration of drugs. Many drugs were adulterated in the early 1800s but no inspection system existed to ascertain the quality of drugs imported into France. The law of Germinal provided for the annual inspection of pharmacies for the purpose of confiscating substandard drugs, but the problem persisted into the middle of the century, when in 1851, the legislature made the sale of adulterated food and drugs punishable by fines and imprisonment (6). This legislation remained in force until the early 20th century.

The French approach to the regulation of drugs in the 1800s was contradictory and ineffectual. Although a number of laws on the books prohibited the sale of secret remedies and adulterated drugs, these laws were enforced sporadically and thus did little to halt the dispersion of patent medicines.

The situation in France during this period was thus not very different from that in the United States, where virtually no regulation of drugs was done before the Civil War. The use of patent medicines was widespread in the United States in the early 19th century for several reasons. First, because of the lack of physicians in the frontier areas, the self-help approach to health care was a necessity. Second, medicine was still in the early stages of scientific research, and doctors relied on many remedies that had been favored in the past. For example, people feared the malignant influence of the « evening damp », and bleeding was still recommended in many cases (7). Finally, no restrictions were placed on advertising by the sellers of nostrums, whereas physicians themselves seldom advertised. Early Americans were thus undefended against the inflated claims of quacks and faddists.

A problem facing pharmacists and physicians who wished to standardize the manufacture of drugs in America in the early 1800s was that most pharmacopoeias available referred exclusively to European drugs and had little to do with « the consensus of the American medical practice » (8). One of the earliest pharmacopoeias published to remedy this situation was issued by the Massachusetts Medical Society in 1808. It was not until 1820, however, that a serious attempt was made to compile a list of medicines that would serve the needs of the medical profession in the United States as a whole. The resulting work, the United States Pharmacopoeia (USP), has been revised every decade since.

The institution of the USP was an important step toward self-regulation by the medical profession. Another step was the creation of the American Medical Association (AMA) in 1847, which from its earliest years, protested the sale of quack remedies to an ignorant public. The prestigious Journal of the American Medical Association, however, continued to carry advertisements for nostrums until the early 1900s, on the grounds that such advertising was essential to the financial well-being of the magazine (9). A third step was taken in 1852 when the American Pharmaceutical Association was founded, in part to establish standards that could be followed throughout the pharmaceutical profession (10).

The system of free enterprise that characterized the drug industry before the Civil War was hampered only slightly by the institution of compulsory controls. Four southern states and several local jurisdictions, including New Orleans and New York, enacted legislation to regulate the practice of pharmacy (11). These local attempts at regulation were ineffectual, however, in the face of widespread adulteration of drugs. It was not until 1848 that a national drug-import law, designed to halt the importation of adulterated drugs, was enacted. The Secretary of the Treasury was directed to examine the purity and strength of all drugs at their point of entry into the United States. Approximately 90,000 pounds of drugs were turned away within the first 10 months after the passage of the law (12). Unfortunately, the standards used to determine drug quality were unclear and few inspectors were qualified to perform the required examinations.
Drug regulations after the Civil War also focused on the problem of drug adulteration rather than on patent medicines. Before the end of the 19th century, virtually anyone could bottle and sell a mixture of drugs and chemicals and make claims in good faith or bad about its effectiveness in the treatment of a wide range of ills. Because physicians usually dispensed their own medicines, pharmacists were forced to compete for business by both diagnosing and treating disease (13). Manufacturers of nostrums could protect their monopoly over a popular mixture either by patenting the medicine (in which case the ingredients would be listed at the Patent Office), or by selling a secret mixture under a trademark. The use of a trademark protected the manufacturer and allowed him to keep the formula and the method of preparation a secret (14).

By the early 20th century, many physicians and medical writers were rebelling against the secrecy of nostrum manufacturers: « Among the objections given were that intelligent use was impossible when the ingredients were kept secret and that secrecy induced the possible conclusion that the maker of the product was monopolizing the product for selfish reasons and that the actual cost of the product was entirely out of proportion to its sales price » (15). Many physicians suspected that manufacturers used some ingredients secretly that would not be accepted if their presence were identified, a belief that played no small part in the passage of the Pure Food and Drugs Act of 1906.

In the years immediately following the passage of the 1906 Act, most actions taken under the new regulations involved the control of food additives; less than a fourth of them involved drugs. Of these, however, most were aimed at patent medicines. When state chemists found a « shocking disparity » between the claims made on the labels of patent medicines and the therapeutic powers of their ingredients, the provisions of the Act were brought to bear on manufacturers who misbranded their products (16). Makers of headache cures containing acetanilid were prosecuted, as were the makers of tonics that claimed to cure narcotic addiction, cancer, and other dread diseases. The punishments in these cases, however, were often light, and most manufacturers were content to pay their fines and go back into business after making slight changes in their products. As late as 1922, the maker of a « cure » for tuberculosis was permitted under the law to continue selling his product after a finding that he had not intended to defraud the public (17).

The limited ability of assayers to determine the amount and the quality of the ingredients used in patent medicines had always made enforcement of patent medicine laws difficult. Progress had been made in this field by the mid-1920s, however, and by 1930, the Food and Drug Administration had established tolerance levels for the manufacture of most major drugs. Even so, regulation was not successful because the major concern of legislators in this period seemed to be that of how best to protect the public against quacks (18). The problem of unregulated patent medicines was not solved in the United States until the passage of the 1938 Food, Drug and Cosmetic Act, which required that dangerous or habit-forming drugs be administered only by prescription. Pharmacists became criminally liable for selling drugs over the counter that should have been sold by prescription only. All medicines that were sold over the counter were required to have a label that listed their ingredients and provided clear instructions as to the proper dosage. Thus the dangers inherent in the indiscriminate use of patent medicines in the United States were effectively allayed.

Similar steps were taken in France during the early 20th century to suppress the distribution of patent remedies and halt the adulteration of drugs. A national laboratory was established in 1918 for the analysis of medicinal products. Another national laboratory was established in 1922 for the use of the Codex Commission,
which, like the USP, assays drugs for their purity and efficacy. Finally, in 1926, the problem of secret remedies was resolved when a law was passed that required the full disclosure of the quantity of active ingredients, and the name and place of the manufacturer, on the label (19). Thus, the information on the package of a medicine now can be used to determine whether it conforms to the regulations established by the Codex.

REFERENCES

2. Ibid., p. 5.
6. Ibid., p. 9.
9. Ibid., p. 155.
14. Ibid.
15. Ibid., p. 414.
17. Ibid., p. 150.

SLIDES