

by Henry E. Simmons, M.D., M.P.H.

It's one of the most significant issues in the prescription drug area today: are "generic" drugs equivalent to "brand" drugs? Each side has its proponents. Some of the traditional views of the brand-generic controversy are no longer accurate. In this article, Henry E. Simmons, M.D., director of FDA's Bureau of Drugs, presents his views on this subject and tells what FDA is doing to assure that all drugs are of the highest quality. This story is based on a speech Dr. Simmons presented before the California Council of Hospital Pharmacists in San Diego September 30, 1972.

Generic equivalency is one subject we've always been very much concerned about at FDA. I am constantly discouraged at the quality of the dialogue in this important area—an area significant not only because of the quality of health care in this Nation, but also because it is a basic economic issue as well. The pronouncements made by members of the various camps are often biased and, occasionally, frankly and intentionally misleading or exaggerated.

The generic-brand issue presents us at FDA with a unique opportunity as well as a major responsibility.

As the world's largest repository of original and frequently unpublished information on drugs, we are in a unique position to be able to examine both sides objectively. Unlike either side in this issue, we achieve no financial gain regardless of which camp carries the day.

With our responsibility for the public welfare, we and the public "lose" if the American patient does not receive drugs of uniformly high quality. We and the public "win" only if both generic and brand manufacturers consistently produce a quality product.

This then is the Government's role in the public interest: to do everything within its power to assure that all drugs—generic and brand, made by big and small

manufacturers—are both safe and effective, honestly labeled, and of the quality necessary to produce the intended effect. We must maintain a surveillance system which will assure that this quality continues once it is attained. Should quality be found wanting, appropriate steps must be taken to correct the situation or stop production. We must also assure that physicians are provided sufficient information on drugs so that the wisest therapeutic decisions can be made on behalf of the American people.

We recognize our responsibility and accept it. We are aware that the job cannot be done if manufacturers do not also recognize and accept their responsibility. Fortunately, in general, drug manufacturers, large and small, generic and brand, have accepted their responsibility and are taking appropriate steps to fulfill it.

Given our responsibility, how do we meet it? What are the programs and resources of the Federal Government, specifically the Food and Drug Administration that are addressed to this area? To understand this, let me examine some facts about the rapidly changing and growing FDA.

FDA today is an agency of more than 6,000 people with a budget of over \$150 million. FDA's drug responsibilities are vested in the Bureau of Drugs, which has about 1,000 people backed by a field force

of about 400 inspectors.

The Bureau of Drugs is a highly technical bureau with approximately 120 physicians, 100 microbiologists, 50 pharmacists and pharmacologists, and 50 chemists, plus statisticians, epidemiologists, and other professional personnel.

No new drug can be marketed in this country until teams of physicians, pharmacists, chemists, and statisticians from the Bureau of Drugs have completed a thorough assessment of it. Any firm wanting to place a new drug on the market not only must first develop data to show that it is safe and effective, but also must demonstrate to FDA's satisfaction that adequate controls have been provided to assure proper identification, quality, purity, and strength of the new drug.

In this context the New Drug Application must include a list of all the components; a statement of the composition of the new drug dosage form; a description of the facilities and personnel involved in the manufacture of the drug, which is verified by factory inspection; acceptance specifications and test methods for the raw materials and new drug substance to assure uniformity from batch to batch; a description of the manufacturing process for the final dosage form, which includes manufacturing process, packaging, and labeling; a description of the analytical controls, specifications, and test procedures for the drug; and stability studies to assure continued quality for the time it will be in a retail outlet before being used by the consumer. All of these data are carefully reviewed, and approval is given only after all the requirements are satisfied.

Whenever other manufacturers want to place chemically equivalent drug products on the market, they must submit for FDA approval adequate data to demonstrate the equivalency of the product. It then goes through the same review. All