The Council on Drugs of the American Medical Association began to publish in 1906 detailed information on the chemistry, pharmacology, clinical utility, and safety of some new drugs in a reference guide, until recently titled *New and Non-Official Drugs*. This book has been redesigned, changed in form and text, and first published in 1965 as *New Drugs* (N.D.). The N.D. does not establish standards at all, as U.S.P. and N.F. do, but rather serves as an annual collection of monographs for the guidance of the practitioner. Like the U.S.P. and N.F., this volume does not provide criteria from the chemical-physical-pharmaceutical subtleties of drug product manufacture and control.

Selected groups depend on other sources for guidance regarding drugs for use in their fields, for example the dental profession generally refers to *Approved Dental Remedies* as a source of information. The Medicare Act (P.L. 89–97) accepts the above four compendia as well as the *Homoeopathic Pharmacopoeia* as lists of drugs qualifying, without further action, for reimbursement under the program.

New Drug Application Specifications.—The Federal Food and Drug Administration (FDA) requires that each new drug application (NDA) include detailed data on the process and control procedures under which the product is to be manufactured. Thus, the new drug application covers a broad range of information and standards not included in the U.S.P. and N.F. For obvious competitive reasons, much of this information is not published. But, even if it were, it is important to note that each manufacturer filing an NDA must include his own production specifications. Therefore, approval of one company's product does not carry with it the assumption that a second or third company's version will be approved or will be identical. In point of fact, the techniques of production and complete formulation inevitably differ. This is further recognized by the FDA's requirement that clinical trials and data are required from each company for each product version as assurance that every formulation is safe and effective.

So, even though all new drugs come under FDA control and there are detailed standards applied to the production of these products, these standards are not and cannot be regarded as *general* across-the-board standards, applying to a group of products with the same generic name.

Purchaser Specifications.—Finally, standards are sometimes applied by purchasing groups having the facilities and staff to prepare and enforce specifications in a more detailed way. Large hospitals, government agencies and other such volume purchasers may consult with suppliers and draw up detailed, but practical, specifications as a guide to competitive bidders for supplies of drug products.

C. Regulation—Enforcement and "voluntary compliance"

Regulation of any private enterprise in this country, of necessity, is composed of two elements—direct enforcement and voluntary compliance. It is impractical to expect the government or any outside agency to observe and then rule over every action of a large industry. Neither is it in the public interest to allow products affecting human health to be made and distributed without regulation. Obviously, the best situation consists of a proper balance, a harmony of purpose between official regulations and private initiative. Our brand name system actively serves to promote this goal, which has been called "voluntary compliance."

As it is, the U.S. prescription drug industry is one of the most intensively regulated industries in the country. Numerous laws affecting the industry are administered by the U.S. Food and Drug Administration, the Division of Biologics Standards of the National Institutes of Health and other federal bodies, as well as state and local agencies.

A proposed drug product is monitored by the government from the time an experimental project is designed through its emergence from the laboratory ready for trial and its marketing for treatment of human disease. Monitoring does not stop here. It continues as long as the product is on the market. A new drug cannot be offered for sale without express approval; its production, promotion and marketing methods must also be approved.

These laws stem from the Pure Food and Drug Act of 1906, which was aimed at barring adulterated or misbranded foods and drugs from interstate commerce. The Food, Drug and Cosmetic Act of 1938 added provisions requiring that the FDA pass on the safety of new drugs before their commercial in-