Senator JAVITS. That seems to me to lead to the key thing which our chairman has directed our discussion. It seems as if you have the authority to work out names for these drugs, so the public can buy generic drugs and be confident in purchasing drugs. Is this a field where you have inadequate staff and inadequate organization to do what needs to be done?

Dr. GODDARD. I believe we have an adequate staff in this area, Senator. We have been working with the USAN, U.S. Adopted Name Council. Last fall we did propose for adoption 27 names that they had recommended. We now have membership on the council, something that we did not have before so we have a voice in the actual selection of the generic name that is to be used.

Senator NELSON. What is the composition of the committee that selects the names?

Dr. GODDARD. A representative of the USP, a representative of the industry, a representative from the American Medical Association, a representative from the National Formulary, and an FDA representative.

Senator JAVITS. But the 1962 amendments, you say, authorized FDA to establish simple useful names for drugs. Now, people who have been in business, and I have very extensively as a lawyer, realize that when you have the muscle, it is a lot easier to get cooperation than when you have not. Has the FDA asserted this authority to fix the brand names itself in a wholesale way—that is, fix the names itself, if the industry did not? Twenty-seven certainly sounds like a real drop in the bucket.

Dr. GODDARD. We have not on the generic names. Now, every firm that brings a drug into the marketplace has to suggest a generic name at that same time. This has been done since 1962, but FDA as an agency has not exercised that authority and did not until last fall.

Senator JAVITS. Will you be good enough to give us also a memorandum as to what it will take to exercise that authority effectively so we get some action in this field which as one Senator, I feel is more important than anything else in this business. That is how competitive forces operate. If a fellow calls for a drug with a very simple name, it takes all the Romans out of the name business.

Thank you, Senator Nelson.

(The information referred to, subsequently received, follows:)

STATEMENT ON A PLAN OF ACTION BY FDA FOR IMPLEMENTING THE PROVISIONS OF THE 1962 AMENDMENTS WITH RESPECT TO ADOPTION OF OFFICIAL NAMES OF DRUGS

The United States Pharmacopeia (USP) and the American Pharmaceutical Association (APhA) through its publication of the National Formulary (NF) have been selecting nonproprietary names as the official names for drugs included in these compendia since well into the last century.

The Council on Pharmacy and Chemistry—later the Council on Drugs—of the American Medical Association (AMA) undertook in 1910 the selection of nonproprietary names for new drugs in collaboration with the respective sponsoring pharmaceutical firms. This served a useful function in that the inclusion of newly developed drugs in official compendia was often delayed for several years or they were never accepted as official drugs. On eventual acceptance of new drugs by these compendia, however, the nonproprietary names selected by the Council on Drugs of the AMA were usually adopted as official names. This mutual interest between these organizations led to the formation of an AMA–USP Nomenclature Committee in June 1961 and then to the United States Adopted Names (USAN) Council in January of 1964 for the purpose of selecting nonproprietary names.