

source. It is inconceivable that a practitioner would clutter his office with all this labeling in loose form.

Compilation of a Drug Labeling Compendium will be a difficult task. The central issue, from FDA's standpoint, is how to abbreviate the package insert without compromising public health protection. If we are to condense such labeling, it will still have to adequately reflect current knowledge about the drug. However, we believe that an objective summary, approved by FDA, would be preferable to a package insert which is never read. Also, we believe it will be possible to group several drugs into one category with a general summary covering all the drugs included in the group.

Another pressing consideration is whether or not the package insert should be completely done away with in view of the Compendium, or merely the requirement of distributing it with each package. As this complete labeling is the basis of a new drug approval, we do not recommend that such labeling be completely eliminated. Additionally, the package insert type information should remain available for those persons, such as clinical researchers, in need of such exhaustive data. In a few instances, it will probably not even be possible to provide for an exemption from distributing the "package insert." For example, we believe it is essential to have complete, unabridged information actually accompanying the package when such information may be needed by the physician at the actual time of administration.

Another factor which prompts our endorsement of a Compendium is that it will list all drugs, thereby increasing the physician's prescribing range. And, of course, pricing information could be included as a supplement to the Compendium thereby fostering more economic prescribing. However, listing in the Compendium could be construed as Governmental approval of a product. As we have stated on numerous occasions, FDA is not presently in a position to guarantee the quality of all drugs on the market, although we are constantly striving toward this goal. Nor could we assure the effectiveness of a drug listed in the Compendium. As you know, the NAS/NRC review of effectiveness of drugs marketed between 1938 and 1962 is not yet completed. However, if this review results in the removal of any drug from the market, it would likewise be removed from the Compendium. Thus, the Compendium would if adopted, have to grow with the FDA as we draw closer to our ultimate goal of complete assurance. In this context we would recommend quarterly supplements be published in order to keep the Compendium current.

With sufficient funds (approximately \$5 million per annum) the FDA could publish a Compendium. FDA could also provide that listing in the Compendium would satisfy the requirements of full disclosure. Although the project could thus be achieved without increased authority, it would not be the most advantageous manner in which to proceed. As the drug industry will be relieved of the cost of "package inserts" by this proposal, it would be appropriate to shift the cost of the Compendium to that industry. This, of course, would necessitate legislation. Additionally, legislation would be desirable to clarify the scope and purpose of the Compendium and to realign some present provisions of the Act in greater conformity with the Compendium concept.

A final comment on this subject—we believe that increasing access to the complete labeling of prescription drugs is in itself enough to justify publication and distribution of a Drug Labeling Compendium. Additionally, the Compendium would list generic products together with their well-known trade name counterparts, thereby facilitating the economic prescribing of generic drugs and increasing the physician's familiarity with presently complex drug nomenclature.

Mr. Chairman, we appreciate this opportunity to clarify our position with respect to marihuana.

As evidenced by the attention given by representatives of Government, the press, and the professions, it is plain that the increasing use of marihuana is a matter of national concern. I am aware, Mr. Chairman, that statements attributed to me, but which I did not make, have caused additional concern. Let me clarify the record in this regard at the very outset.

I did not say that I would not object to my daughter smoking marihuana.

I did not, and I do not, condone the use of marihuana.

I did not, and I do not, advocate the abolition of controls over marihuana.

I did not, and I do not, propose "legalizing" the drug.

With your permission, Mr. Chairman, I would like to call your attention to one point which arose as the result of an erroneous news dispatch from Minne-