Senator NELSON. Well, I think quite clearly they market 95 percent, but since they also purchase from generic manufacturers, the latter are also producing some percent of that 95 percent. Up until about a year ago, there was not any bulk meprobamate produced in the United States. All was imported into the country. Domestic manufacturers merely put it into tablet form and then put it into bottles. Carter-Wallace, the marketer of Miltown, produced the drug neither in bulks or finished form, but merely put its own label on it. I ask that a speech on this subject be inserted in the record at the appropriate place. So it would be interesting to have the statistics. I suspect the reason they are trying to upset the Crown law in California is it might be a good opportunity to find out how much is produced by the manufacturers that their association is attacking all of the time, and that could be embarrassing.

Dr. APPLE. We have the same problem, frequently, with pharmacists in terms of convincing our own membership as to who is the actual manufacturer—a pharmacist may inquire as to a certain product, and we inform him that that product is actually being made by so-and-so for the well-known company that is distributing the product, and the first reaction of the pharmacist is total disbelief. But when we can cite some of the evidence to them, the pharmacist then says, "well, why should I not buy it directly from Mylan, or Strong-Cobb-Arner, or this firm, or that firm, instead of buying it under a brand name from the other manufacturer? And this is one of the issues that is involved in the so-called Crown Act.

Now, the Food and Drug Administration is requesting additional statutory authority from Congress now to improve its capacity and ability to function, and we have specifically suggested already to Dr. Edwards that the legislation the administration is currently seeking ought to be amended to include the requirement of the identity of the actual fabricator of the dosage form.

Senator NELSON. Thank you very much.

Gentlemen, we appreciate your very valuable testimony this morning.

Dr. APPLE. Thank you, Senator.

Senator NELSON. Our next witness is Dr. Daniel Banes, Director, Drug Standards Division, United States Pharmacopeia. Dr. Banes?

## STATEMENT OF DR. DANIEL BANES, DIRECTOR, DRUG STANDARDS DIVISION, UNITED STATES PHARMACOPEIA, ACCOMPANIED BY DR. JOSEPH G. VALENTINO, EXECUTIVE ASSOCIATE, UNITED STATES PHARMACOPEIA

Dr. BANES. Thank you, Mr. Chairman.

I am Daniel Banes, Director of the Drug Standards Division of the United States Pharmacopeia, and I am accompanied today by an associate of the headquarters staff of the United States Pharmacopeia, Dr. Joseph G. Valentino on my right.

My professional history and qualifications are detailed on the