

The "hyperkinetic," or the "hyperactive," syndrome may disappear spontaneously.

Dr. YAFFE. Not very many of these children in my opinion need drugs for their management.

Senator NELSON. Go ahead, Dr. Prout.

Dr. PROUT. I think when obesity is eliminated as an indication most of the amphetamines will be withdrawn from the market. Certainly all of the combinations of drugs including these amphetamines will be withdrawn, but this prohibition should be extended to the amphetamine-like compound as well.

Finally, I think if we are going to have any new preparation of these drugs, or any other substituted amines for the treatment of obesity that they must pass the test of efficacy and safety that the FDA requires, perhaps more rigidly based on FDA protocol in order to eliminate any trivial products.

I think there is one further extension of this that might actually be voiced here as well. The Federal Government spends an enormous amount of money and effort trying to take over-the-counter products for obesity off the market as well.

There have been two suits, one by the FTC, and one by the U.S. Postal Service, related to propanolamine. This is a very wasteful way to spend the taxpayer's money, when we could in fact eliminate them all at once rather than drug by drug.

As we chase each one of these manufacturers through their trade name, they have only to come back under a new name and a new trade name, to be back in business. That makes it very difficult to fight on a one-on-one basis, and I think the sweeping review of that whole area is well worth this committee's surveillance.

This is where the original FDA Committee, in its earlier recommendations, fulfilled its charge in its single-purposed review of whether or not these drugs were or were not useful in the treatment of obesity. But I now think we should probably also go to other considerations and this is the practice of the pharmaceutical companies of bulk shipping of these drugs directly to clinics.

Senator NELSON. I did not understand that. This is what?

Dr. PROUT. As noted in my prepared statement there is a practice in the pharmaceutical companies of making bulk shipments of these drugs directly to certain clinics.

Now, if these facilities will in the future be unable to stay in business if obesity is withdrawn as an indication for use it will be very hard to justify the sending a bulk shipment of 100,000 doses to any single clinic or individual. The risk here is in losing track of the drugs. Surveillance, even of the drugs in schedule II, would be very, very difficult to follow under these circumstances.

A second important point to be reviewed is the whole basis of the relationship of pharmaceutical houses to the medical profession which needs to be looked into. Indeed, Senator Nelson, you touched on it this morning when you noted that certain investigators who come up with "bad answers" may no longer be supported by drug companies for their "research." Or to state it positively, one finds that the pharmaceutical companies are very likely to support "research," "consultation," "teaching," "goodwill," or whatever other term might be used to describe the favor that they curry from these excess funds that