

Senator NELSON. How many are manufacturers?

Mr. BARROWS. We have not broken it down. I could get that information for you, Mr. Chairman.

Senator NELSON. Do you know the dollar volume of the manufacturing done by your manufacturers?

Mr. BARROWS. I have no idea what the actual dollar volume is. I know it is considerable, and I know that many of our member firms do in fact manufacture many dosage forms for the larger firms.

Senator NELSON. Do you happen to know what percentage of the product manufactured by your members are marketed directly by them either into the wholesale or retail market, or by bid to hospitals, municipalities, State agencies, Federal agencies?

Do you know how much goes to other manufacturers?

Mr. BARROWS. I will make this information available to the committee, Senator.

Senator NELSON. If you would.

Now, you represent 80 some manufacturers and distributors.

Mr. BARROWS. That is correct.

Senator NELSON. Do any of them produce drugs under their own brand name?

Mr. BARROWS. Yes. They do.

Senator NELSON. And some of them produce drugs for other companies, is that correct?

Mr. BARROWS. That is right.

Mr. ADAMS. Mr. Barrows, on page 5 of your testimony, the third full paragraph, you state that:

The USP XVIII does not set a chloride limit nor does it require a residue of ignition test; both of which have no significance as modern techniques that all impurities are eliminated.

Mr. BARROWS. That is correct.

Mr. ADAMS. Would you tell me what the net effect of that particular requirement is on small manufacturers?

Mr. BARROWS. The net effect of that on small drug manufacturers is that it increases the overhead with regard to excessive testing which proves nothing; because if you are going to test for chlorides, for impurities which you know are not there, you might as well test for sulfates and phosphates, and where do you stop.

And it seems just a redundant thing to include into a procedure which just ups cost and reduces competition.

Mr. ADAMS. Thank you.

On page 7 you compare rotational requirements of certain specifications at the top of that page?

Mr. BARROWS. This is specific rotation requirement and specific rotation of -115° or -121° —the exactness of it is not that necessary, as the British Pharmacopeia gives you a wider range of -113° to -123° as versus -115° and -121° that the DPSC requires. The USP apparently does not require any because they probably feel it has no significance; that the existing compendial monograph requirements are sufficient to warrant not using the specific rotation test.