

With respect to the former possibility, we note that then—Brig. Gen. George J. Hayes of the Medical Corps, U.S. Army, Principal Deputy Assistant Secretary of Defense, had testified before your subcommittee, Mr. Chairman, on February 3, 1971, and in his prepared statement—again, I will not read the entire quote that is reproduced here. But I would specifically call your attention at the top of page 8 to where he says,

We cannot procure competitively without generic specification. Our standards are basically those of the USP and the NF, supplemented with such additional standards as are necessary to ensure suitability not only at the time of procurement, but also following possible long-term storage throughout the world in Arctic, temperate or torrid zones.

So, as General Hayes states, the DPSC standards are basically those of the official compendia simply supplemented with additional standards peculiar to the special needs of the military. Consequently, although additional specifications may be adopted by the DPSC, this does not mean that the official compendia standards are inadequate as applied to drug products as intended for use by the general public.

For example, the critical consideration of minimizing unnecessary weight might necessitate specifying the use of a lightweight plastic container for drug products to be carried on board spacecraft. On the other hand, the use of somewhat heavier containers, such as those made of glass, would be perfectly appropriate for use in packaging drug products intended for normal channels of distribution.

However, the speeches and articles by DPSC officials previously mentioned have suggested that deficiencies in products and manufacturers are not simply related to the special needs of the military, but that they are far more serious and represent a public health hazard.

Senator NELSON. Have these suggested deficiencies ever been delineated by the DOD?

Dr. FELDMANN. I am sorry, Mr. Chairman?

Senator NELSON. Have they ever described what the deficiencies were?

Now, the statement by General Hayes does not suggest any deficiencies whatsoever.

All he is saying is that they use the compendial standards. That is all we have ever heard specifically, and that is that in the handling of products overseas there may be circumstances which would be quite different from handling products within the boundaries of the United States. They may have to be hauled into a jungle and be there a month or two or three in a humid climate, which does not exist here. They may be taken into the Arctic under circumstances which do not exist here, and that, therefore—understand them to be saying—we require in some circumstances certain specifications for packaging, handling, that would not be necessary in this country.

But I have not seen any description of any deficiencies in the drug products themselves from a medical or therapeutic standpoint. Have you?