

not been able to test all batches of imported antibiotics. Has FDA capability reached a level where this is now the case?

It would be of interest to have FDA state specifically how many different drugs have been tested and just how many of them were found to be equivalent.

It is also highly questionable what can be accomplished by class labeling in assuring drug equivalency. To suggest that such labeling is an umbrella, under which all prescribers can safely huddle, ignores reality. This type of labeling can hardly be equated with quality and equality assurances across the board.

I have publicly commented on the actions which have been taken to remove drugs in the "possibly effective" category from Federal programs. This is clearly violative of due process and convicts drugs prior to final decisions on the issue of their place in therapy.

We also question seriously FDA's recent handling of NAS-NRC panel results. The raw figures, and the words used in designating categories, have been extremely confusing not only to the general public, but to the health professions and the press itself. Press accounts have been notoriously inaccurate or misleading, at least in part, because the FDA has failed to put these figures into sufficient perspective. I enclose the notices we have released on this subject in case they have not come to your attention.

I note that your statement dealt at some length with the defects of labeling, without any reference to the role of FDA in its preparation and approval. It would certainly have been appropriate for you to stress that labeling represents honest effort made in good faith by both industry and the FDA at the time of preparation, and that of necessity, it is in a state of flux as new information comes to the fore. Surely industry is just as anxious as FDA to have complete and up-to-date labeling on its products. If labeling is obsolete, the responsibility of updating should be shared by the FDA and industry.

Your testimony raised additional questions with respect to combination products, marketing and other areas. However, the above indicates some of the major reasons for our concern.

Sincerely yours,

C. JOSEPH STETLER,
President.