

9100 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

CONCLUSION

Effective corrective actions to remove violative products from the market may--in addition to protecting the consumer from harmful or potentially harmful products--serve to encourage a higher degree of compliance by industry with those requirements of law designed to insure consumer protection.

However, we believe that neither seizures nor voluntary recalls provide FDA with a means of effectively removing products from the market. Seizure actions, beside being slow, are limited in scope, and recalls--being voluntary--are not enforceable by FDA.

We believe that a new regulatory measure, recall authority, is needed. This measure would combine the scope of voluntary recalls with the enforcement authority of seizures while adding an element of speed. It would also eliminate the need for initiating time-consuming and burdensome court actions for each location involving violative products. At the same time, it would provide the statutory authority needed by FDA to eliminate the delays that can plague recalls.

The House of Representatives is now considering legislative proposals, such as the proposed Pure Food Act of 1972 which, if enacted, would provide FDA with recall authority for food commodities. We believe, however, that this authority should extend to all products under FDA's responsibility.

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary of HEW propose legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with the authority to require firms to recall violative products for all products under FDA's responsibility.

HEW advised us that it was giving serious consideration to the inclusion of our proposal in its legislative program for the Ninety-third Congress. (See app. I.)