

9098 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Our review of 142 recalls monitored by three FDA districts during fiscal year 1971 showed that 106 of them were initiated at FDA's request. For the FDA-initiated recalls, an average of 15 days passed before the firm acted on FDA's request to remove a product from the market. Further, 23 percent of the recalls required more than 25 days to initiate action and in these cases we found that an average of 38 percent of the product was sold during the delay.

For 111 of the 142 recalls, we were able to determine (1) the number of days the recall action was delayed by the firm after it learned of the problem and (2) the percent of the product removed. The following table illustrates the relationship between the length of the delay and the percentage of the product removed from the market.

<u>Number of recalls</u>	<u>Percent of recalls</u>	<u>Days delayed</u>	<u>Percent of product removed</u>
70	63	0 to 10	44
15	13	11 to 20	32
12	11	21 to 30	32
<u>14</u>	<u>13</u>	over 30	21
<u>111</u>	<u>100</u>		

As shown, the success of a recall depends on the speed with which it is initiated.

The following two examples show that, once identified, significant amounts of a product suspected or known to be violative are still reaching the public because of delays by firms in taking recall actions.

Example H--FDA notified a drug firm on April 27, 1971, that the production of one of its drugs, digitalis (a heart stimulant), was superpotent and was considered a potential health hazard. Although FDA had tested the drug, the firm requested time to retest and perform its own analysis. After 111 days and an appeal to the firm by the Deputy Associate Commissioner for FDA, the firm agreed on August 16, 1971, to recall the superpotent drug. However, this delay made the recall less effective, because about 84,000 pills,