

GOVERNMENTAL MEASURES TAKEN TO
PROTECT CONSUMER PRODUCTS AGAINST TAMPERING

By Attorney Michael H. Wald

In September and October of 1982 the Food and Drug Administration (FDA) responsible for insuring the safety and effectiveness of consumer foods and drugs, was bombarded with reports of drug tampering which was potentially or actually detrimental to the health of the consumer. As a direct result of the mass-media coverage concerning these alleged occurrences, there was a dramatic increase in this type of crime. (I have used the term alleged since some of the adulterations did not actually happen. They were falsely communicated in an attempt to receive a financial settlement from the accused company.) Although the public was promptly informed about the tampered products, specifically the Extra-Strength Tylenol laced with cyanide, most people are not aware of the enormous financial losses incurred by the manufacturers of the affected products. For the protection of the consumers, as well as the manufacturers, the FDA revised its regulations concerning the packaging of many over-the-counter drugs. Congress also acted upon the situation by passing the Federal Anti-Tampering Act.

The revised FDA regulations require the manufacturers of most over-the-counter drugs and some cosmetics, such as mouth wash, to take two steps in protecting their products from adulterations.

First the package must be sealed in a manner that will easily alert the consumer to signs of tampering. Some examples of such tamper-resistant packaging include film wrappers, bubble packs, foil, paper or plastic pouches, foil or paper bottle seals, and breakable caps. These various packaging techniques make signs of adulteration very visible.

The second revision requires that any affected product contain, on its label, information about the tamper-resistant packaging. This is to inform the consumer that should the protective seal be broken or removed, possible tampering may have occurred.

The cost of these packaging requirements varies according to the type used. However, the FDA estimated a one time cost of \$5 - \$10 million in the labeling of all affected products. The cost of packaging equipment can be as low as \$100.00 or as much as \$100,000.00 depending on the type selected. However, these costs are depreciated over the life of the equipment and do not increase the cost of the individual units more than one or two cents. Compared to the costs incurred by the manufacturers of Tylenol, which was estimated at \$100 million, the mandated expenditures appear nominal.

The Federal Anti-Tampering Act outlines the legal penalties for people who actually taint a product, as well as those who falsely communicate that a product has been tampered with. These fines and imprisonment terms vary according to the degree of injury a person or a business suffers due to the ingestion or use of an adulterated product. If only an attempt to tamper with a product is made, but no bodily damage occurs, the fine could be a maximum of \$25,000 and/or imprisonment for not more than ten years. These fines and imprisonment terms increase to not more than \$100,000 and a maximum term of life imprisonment should the tampering cause the death of an individual. Should the act be done to intentionally damage a business by altering the labeling or packaging of a consumer product, the fine may be as much as \$10,000 and/or a maximum of three years imprisonment.

Some people have suggested the penalties still do not seem to be severe enough, and that in order to better protect the public from adulterated products the FDA needs to make additional revisions

which encompass not only over-the-counter drugs, but food products as well. Hopefully a tragedy will not be necessary to turn these ideas into law.

My thanks to Carol Burson, a student in my law class at the University of Texas at Dallas, who assisted in preparation of this column.

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