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The Lulling Effect: The Impact of Child-Resistant Packaging on Aspirin and Analgesic Ingestions

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By W. KIP VISCUSI*

In 1972 the Food and Drug Administration imposed a protective bottlecap requirement on aspirin and other selected drugs. This regulation epitomizes the technological approach to social regulation. The strategy for reducing children's poisoning risks was to design caps that would make opening containers of hazardous substances more difficult. This engineering approach will be effective provided that children's exposure to hazardous products does not increase. If, however, parents leave protective caps off bottles because they are difficult to open, or increase children's access to these bottles because they are supposedly "child proof," the regulation may not have a beneficial effect.

Indeed, in this case there was no significant impact of the regulation on aspirin poisoning rates, but there has been an alarming, upward shift in the trend of analgesic ingestion rates since 1972. The source of this pattern appears to be attributable to a general reduction in parental caution with respect to such medicines, which has had an adverse spillover effect on unregulated products. The economic mechanisms involved can be best understood by considering the nature of individuals' response to regulatory protection.

I. The Lulling Effect: A Conceptual Analysis

One can distinguish three different mechanisms by which protective packaging requirements can lead to actions on the part of parents and their children that are at least potentially counterproductive. First, regulations will lead to a reduction in safety-related efforts for the affected product. Second, the regulation may produce misperceptions that lead consumers to reduce their safety precautions because they overestimate the product's safety. Finally, if there are indivisibilities in one's actions (for example, choosing whether to keep medicines in a bathroom cabinet or in the kitchen), regulating one product may affect the safety of other products. These effects are quite general and are not restricted to the case of protective bottlecaps.

The existing theoretical literature on individual responses to regulatory protection began with the analysis by Sam Peltzman (1975), who showed that seatbelts would lead to increased driving intensity (for example, less caution or higher speeds). The economic mechanism generating this effect is similar to that which produces adverse incentives or moral hazard problems in the insurance context. As one reduces either the probability of a loss or the size of the loss, individual incentives to take precautionary actions will be reduced. Regulations function much like insurance in this regard, with the only difference being that one need not pay an insurance premium. (There may, however, be an effect of the regulation on the product price.)

In my 1979 article, I derived a similar result for the case of worker safety for quite general classes of risk-averse preferences, where the safety measures also affected the wage rate. Except in the case of very stringently enforced government regulations, firms would not make technological changes in the workplace that were counterproductive. Compliance with policies such as seatbelt and bottlecap requirements is less discretionary, however, so one cannot rule out counter-

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productive regulatory effects in these instances.

To investigate these effects more formally, consider a simple model that captures the essential features of these analyses. Let s be the stringency of the government policy and e be the precautionary effort, where each of these reduces the probability $p(e,s)$ of an accident at a diminishing rate. Alternatively, one can make the mechanism of influence the size of the accident loss L, as in Peltzman, but for purposes of this model I will make L a constant. The individual's effort e generates a disutility $V(e)$, where $V', V'' > 0$. Finally, let the person have an income level I.

The payoff in the case of an accident is $I - V(e) - L$, and the payoff if there is not an accident is $I - V(e)$. The individual's expected utility (assuming risk neutrality) is $I - V(e) - p(e,s)L$. In setting the optimal level of e, one equates the marginal reduction in the loss $p_e L$ to the marginal value of the effort $-V_e$, leading to the optimal point A in Figure 1.

The effect of the regulation on safety effort will be negative, or

$$\frac{de}{ds} = \frac{-p_{es}}{p_{ee}L + V_{ee}} < 0,$$

provided the $p_{es} > 0$ (or $L_{es} > 0$ in Peltzman's loss model). For safety efforts to decline, the safety regulation must reduce the marginal safety benefits from precautionary efforts, that is, the reduction in the expected loss from higher levels of effort is less negative than before. One will then choose a point to the left of point B on the EL_1 curve in Figure 1. This effect should not be particularly controversial. Few would question the opposite relationship where individuals increase their precautions when moving from EL_1 to EL_0. For example, one will drive more carefully on icy streets and reduce cigarette smoking if exposed to synergistic asbestos risks.

What is more problematic is whether the reduction in precautions will be so great that there will be a reduction in safety to a point to the left of point C on EL_1. The conditions

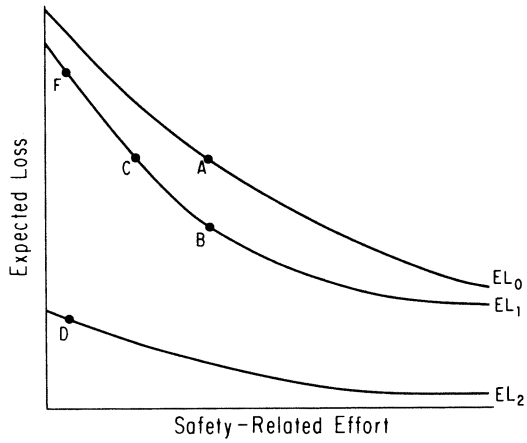

FIGURE 1. PRECAUTIONARY BEHAVIOR AND EXPECTED LOSSES

for this to occur have never been investigated and are quite stringent. It is not sufficient that the marginal expected loss reduction at point C be no greater than at A. The requirement is stronger since the marginal disutility of effort V_e will be lower at lower effort levels. To equate the marginal expected loss reduction $p_e L$ to the marginal effort cost $-V_e$, the loss curve EL_1 must be flatter at point C than EL_0 was at point A. Since there is the additional restriction that EL_1 lie below EL_0, it will be difficult to meet these requirements.

The chance that the impact of protective regulations may be counterproductive may be enhanced if individuals either do not perceive accurately the accident probabilities, or do not fully bear the accident costs. If parents assume "child-resistant" caps are child proof, they may overestimate the safety associated with these products. Similarly, since there is some evidence that individuals tend to set very small probabilities equal to zero, the safety-enhancing properties of caps may reduce the risk so much that parents ignore the poisoning risk. In each case, safety precautions will decline, perhaps to so great an extent that overall safety is reduced. For example, parents may select point D off of their perceived loss curve EL_2 in a situation where the true loss curve is EL_1 and the actual outcome is point F.

A similar effect could occur if parents do not fully value the welfare of their children, or if drivers do not fully internalize the accident costs to pedestrians and other parties. Unlike the case of biased probabilistic beliefs, this modification in the problem need not entail a shift in the relative values of the accident loss in the regulated and unregulated situations. Thus, the EL_0 and EL_1 curves may both simply shift proportionally. In contrast, misperceptions such as those discussed above necessarily lead to a comparatively greater downward shift in the perceived expected loss, increasing the chance of a counterproductive effect.

One's precautionary actions may affect the safety of unregulated products as well as those that are regulated. In the case of child-resistant bottlecaps, parents may make overall decisions regarding the storage of medicines. Should they keep all of the medicines in the bathroom cabinet, on a kitchen shelf, or in a safety-latched drawer? More generally, should they worry about access to medicines or undertake only a mild level of precautions, since the most hazardous products are presumably protected by child-resistant containers?

The analytics of this effort decision parallel that given above, where the only difference is that the EL_0 and EL_1 curves are a weighted average of the component risks, where some products are protected and others are not. A joint risk curve EL_1 will tend to shift downward less in response to a regulation than a comparable curve for a particular regulated product, since the presence of the unregulated product will dampen the response.

There is a clearcut empirical test of whether indivisible actions such as this play a role. If there are such spillover effects, the reduction in safety-enhancing efforts induced by the regulation should increase the risk posed by the unregulated product. In addition, the safety improvement of the regulated product will be reduced at least in part by the reduction in individual precautions. The net effect on safety could be adverse for the regulated product or for both products combined, but one must satisfy fairly stringent conditions for the net effect to be adverse unless misperceptions of the risk play a major role.

II. The Effect of Child-Resistant Bottlecaps

A widely touted product safety regulation success story is child-resistant bottlecaps. The first caps required under this regulation were for aspirin and selected drugs in 1972. Before the advent of protective packaging, manufacturers concentrated their efforts on measures such as decreasing the number of tablets per bottle, warning labels, and educational campaigns. Here I will summarize some of the results from my forthcoming study regarding the effectiveness of safety caps, which provides very strong evidence regarding the role of individual actions that differ in character from the seatbelt case (see Glenn Blomquist, forthcoming, for a review).

In 1971 aspirin was responsible for a fatal poisoning rate of 2.6 per million children under age 5, and by 1980 this rate had dropped to 0.6. The overall aspirin poisoning rate exhibited a similar drop, from 5.0 to 1.7 per 1,000. While these declines were dramatic, after taking into account the trend in aspirin poisonings and the decline in aspirin sales in the 1970's, there is no statistically significant impact of the regulation. This result was obtained using both a regulation dummy variable, which assumed a value of 1 in the 1972–80 period, and a variable that reflected the fraction of aspirin sold with safety cap bottles.

This fraction of capped bottles remained at just over half of all aspirin sold since firms were permitted to market one size of aspirin container without a child-resistant cap. Typically, firms chose the best selling size (the 100-tablet bottle).

Despite the constant sales share of safety capped aspirin, there has been a sharp increase in the proportion of aspirin-related poisonings associated with protective packaging. Whereas 40 percent of all aspirin poisonings in 1972 were from safety cap bottles, this figure rose to 73 percent by 1978. This pattern is noteworthy for two reasons. First, safety cap bottles are by no means risk free, as they account for a majority of the poison-

ings and a disproportionate amount compared to their sales. Almost half of all aspirin poisonings are from bottles that had been left open. Second, there appears to be an alarming increase in the rate of safety cap poisonings. While each of these effects may be attributable in part to consumers matching their aspirin bottle-type choice (with or without a cap) to whether or not they have young children, another factor may be that there is an increased degree of irresponsibility regarding medicines.

Such irresponsibility is consistent with evidence of an apparent spillover effect on previously unregulated analgesics, which include acetaminophen preparations such as Tylenol. Analgesic poisoning rates for children under age 5 escalated from 1.1 per 1,000 in 1971 to 1.5 per 1,000 in 1980. Even after taking into account increases in analgesic sales, 47 percent of this increase is attributable to an unexplained upward shift in the analgesic poisoning rate beginning in 1972. The coupling of the absence of any shift in the trend of aspirin poisoning rates with an upsurge in analgesic poisoning rates is consistent with the hypothesis that there is a significant indivisibility in safety precautions. Moreover, absence of a significant effect of safety caps on aspirin poisonings and the 47 percent unexplained shift in analgesic poisonings suggests that the impact of the regulation on balance was counterproductive, leading to 3,500 additional poisonings of children under age 5 annually from analgesics.

It is possible but unlikely that such a strong impact could emerge from fully rational consumer decisions. Moreover, this effect is not only large but reasonably widespread, as I have identified a similar pattern for prescription drugs, and for cleaning and polishing agents. A more likely explanation for these dramatic effects is that consumers have been lulled into a less-safety-conscious mode of behavior by the existence of safety caps. The presumed effectiveness of the technological solution may have induced increased parental irresponsibility.

A variety of regulatory efforts have sought to reduce individual risks through mandated technological changes. These measures will be effective if individual actions remain unchanged. In practice, these regulations will produce a lulling effect on consumer behavior because the perceived need for precautions will decline, potentially producing adverse spillover effects on the safety of other products. The strength of these impacts should highlight the importance of taking individual behavior into account when designing regulations intended to promote safety.

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