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# Risk and Value Judgments: A Case Study of the Poison Prevention Packaging Act

William E. Hilton\*

## Introduction

How much cost or inconvenience should be put upon one person to reduce the risk of harm or even death to another? Kristin Shrader-Frechette states that the task of risk analysis is to help us discover:<sup>1</sup>

how safe is safe enough;  
how much we ought to pay for safety;  
how equitably we ought to distribute societal risks; and  
how reliable are our scientific measures of risk.

Legislators, regulators and others avoid directly addressing such questions, but they are woven throughout safety regulation. They are often disguised or hidden to keep people from seeing the difficult policy issues. As discussed recently by Julie Roqué, a popular way to disguise policy issues is with a technical cloak.<sup>2</sup> Because it is widely perceived that risk management questions can be determined precisely and conclusively, answers are believed to reflect “scientific truth.”

Yet, the very act of deciding which questions to ask involves any number of value judgments, and ultimate answers reflect those inherent judgments. Moreover, as addressed in a growing body of literature,

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<sup>1</sup> K. SHRADER-FRECHETTE, *RISK ANALYSIS AND SCIENTIFIC METHOD: METHODOLOGICAL AND ETHICAL PROBLEMS WITH EVALUATING SOCIETAL HAZARDS*, 3 (1985).

<sup>2</sup> *Regulating Air Toxics in Rhode Island: Policy v. Technical Decisions*, 2 *RISK: ISSUES IN HEALTH & SAFETY* 123 (1991).

attempts to seek answers to the questions eventually selected are apt to involve a number of methodological assumptions.<sup>3</sup>

One difficulty with many such discussions is that supporting illustrations involve sufficiently sophisticated technical and economic issues that the initiated are soon lost. In an attempt to avoid such problems, this paper considers the subject of child-resistant packaging, a topic with which every reader is presumed to have had first hand experience. It is also one relatively free of difficulties such as attempting to evaluate human risk based on toxicological studies of other species. Moreover, it is a topic under present regulatory scrutiny.

This discussion is in three parts. First, it considers the history and key provisions of the Poison Prevention Packaging Act (PPPA).<sup>4</sup> Second, it discusses implementing regulations, accomplishments under them and proposed regulatory amendments. Finally, it will identify some of the policy questions that should be explicitly addressed in considering those proposals.

## The Poison Prevention Packaging Act

### *Basic Provisions*

The PPPA was proposed by Senator Frank Moss of Utah in 1969 and was enacted in 1970.<sup>5</sup> It requires toxic substances intended for

<sup>3</sup> See L. CLARK, *ACCEPTABLE RISK? MAKING DECISIONS IN A TOXIC ENVIRONMENT* (1989); S. KRIMSKY & A. PLOUGH, *ENVIRONMENTAL HAZARDS: COMMUNICATING RISKS AS A SOCIAL PROCESS* (1988); SCIENCE POLICY, ETHICS, AND ECONOMIC METHODOLOGY: SOME PROBLEMS OF TECHNOLOGY ASSESSMENT AND ENVIRONMENTAL-IMPACT ANALYSIS (1985); C. WHIPPLE & V. COVELLO, *RISK ANALYSIS IN THE PRIVATE SECTOR* (1985); R. WALLER & V. COVELLO, *LOW-PROBABILITY/HIGH-CONSEQUENCE RISK ANALYSIS: ISSUES, METHODS AND CASE STUDIES* (1984); COVELLO, FLAMM, RODRICKS & TARDIFF, *THE ANALYSIS OF ACTUAL VERSUS PERCEIVED RISKS* (1983); KAHNEMAN, SLOVIC & TVERSKY, *JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIAS* (1982); C. HOHENEMSER & J. KASPERSON, *RISK IN THE TECHNOLOGICAL SOCIETY* (1982); J. CONRAD, *SOCIETY, TECHNOLOGY, AND RISK ASSESSMENT* (1980); and FISCHOFF, SLOVIC & LICHTENSTEIN, *FACTS AND FEARS IN SOCIAL RISK ASSESSMENT* (1970).

<sup>4</sup> 15 U.S.C. §§ 1471-1476, Pub. L. 91-601, §§ 2-7, Dec. 30, 1970, 84 Stat. 1670-73. [Hereinafter, statutory references to 15 U.S.C. unless otherwise indicated.]

use in the home to be packaged so as to exclude children under five years of age. One of its most significant provisions defines “special packaging” as:<sup>6</sup>

packaging that is designed or constructed to be *significantly difficult* for children under five years of age to open or obtain a toxic or harmful amount of the substance contained herein within a *reasonable time* and *not difficult for normal adults* to use properly, but *does not mean* packaging which *all such children cannot open or obtain a toxic or harmful amount within a reasonable time.* [Emphasis added.]

Such packaging of household substances is required when it is found that:<sup>7</sup>

- (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that *special packaging is required* to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and
- (2) the special packaging to be required by such standard is *technically feasible, practicable, and appropriate* for such substance. [Emphasis added.]

Attention is also to be given to (1) the reasonableness of the standard; (2) technical data; (3) the manufacturing practices of affected industries; and (4) the nature and use of the household substance.<sup>8</sup>

#### *The Most Controversial Aspect of the Legislation*

The major controversy raised during consideration of the PPPA was not the characteristics of special packaging but whether it was to be the rule or the exception, i.e., whether consumers should have to seek out special packaging or whether they would have to seek out conventional packaging.

The Senate passed a bill calling for noncomplying packages being available in a single size upon request.<sup>9</sup> In contrast, the House Report

<sup>5</sup> For a historical discussion of the PPPA, see SACHAROW, PACKAGING REGULATIONS 78–85 (1979).

<sup>6</sup> § 1471(4).

<sup>7</sup> § 1472(a).

<sup>8</sup> § 1472(b).

cited census figures indicating that approximately 75% of households in the U.S. did not have children between the ages of one and five and called for child-resistant packages to be the exception.<sup>10</sup> The Report stated that “it seems illogical... to require that all sizes of a substance except one be marketed in special packaging when 3 out of 4 households do not have children in such age groups.”<sup>11</sup>

The Senate view prevailed, and the PPPA provides that noncomplying packages may be made available in a single size if the product is also available in special packages and the noncomplying packages bear the the label “This package for households without young children.”<sup>12</sup> Also, noncomplying packages for prescription drugs are available on request.<sup>13</sup>

## **Administration of the Act**

### *The Regulations*

When the PPPA was enacted, its implementation was given to the Secretary of Health, Education and Welfare and, ultimately, to the Food and Drug Administration (FDA). It required the Secretary to establish a technical advisory committee of not more than eighteen members collectively representing the Departments of Commerce and Health, Education and Welfare, manufacturers of both substances and packaging, consumers, scientists and medical practitioners.<sup>14</sup>

Following a study conducted by Dr. Wilton Krogman and the assistance of the advisory committee, the FDA adopted specifications for special packaging and a testing protocol.<sup>15</sup>

<sup>9</sup> 1970 U.S. Code Cong. and Adm. News. 5329–5331.

<sup>10</sup> 1970 U.S. Code Cong. and Adm. News. 5326–5328.

<sup>11</sup> 1970 U.S. Code Cong. and Adm. News. 5328.

<sup>12</sup> § 1473.

<sup>13</sup> § 1473(b).

<sup>14</sup> The provision was repealed by the Budget Reconciliation Act of 1981, 38 Pub. L. 97–35.

<sup>15</sup> *Supra* note 4, at 83.

Special packaging must meet the following specifications:<sup>16</sup>

(1) Child-resistant effectiveness of not less than 85 percent *without a demonstration* and not less than 80 percent *after a demonstration* of the proper means of opening such special packaging. ...

(2) Adult-use effectiveness of not less than 90 percent. [Emphasis added.]

The testing protocol provides:<sup>17</sup>

(1) Use 200 children between the ages of 42 and 51 months [3.5 to 4.25 years] inclusive, evenly distributed by age and sex. ... The even age distribution shall be determined by having 20 children (plus or minus 12 percent) whose nearest age is 42 months [3.5 years], 20 whose nearest age is 43 months [3.583 years], 20 at 44 months [3.666 years], etc., up to and including 20 at 51 months of age [4.25 years]. There should be no more than a 10 percent preponderance of either sex in each age group. The children selected should be healthy and normal and should have no obvious or overt physical or mental handicap.

(2) The children shall be divided into groups of two each. The testing shall be done in a location that is familiar to the children. ... Each child shall be allowed up to 5 minutes to open the special packaging. For those children unable to open the special packaging after the first 5 minutes, a single visual demonstration without verbal explanation, shall be given by the demonstrator. A second 5 minutes shall then be allowed for opening the special packaging. ... If a child fails to use his teeth to open the special packaging during the first 5 minutes, the demonstrator shall instruct him, before the start of the second 5 minute period, that he is permitted to use his teeth if he wishes. ...

(4) One hundred adults, ages 18 to 45 years inclusive, with no overt physical or mental handicaps, and 70 percent of whom are female, shall comprise the test panel for normal adults. ... The adults shall receive only printed instructions ... as will appear on the package ... Five minutes shall be allowed to complete the opening, and if appropriate, the resealing process.

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<sup>16</sup> 16 C.F.R. § 1700.15.

<sup>17</sup> 16 C.F.R. § 1700.20(a).

### *The Reported Effect of the Act*

In 1972, when the Consumer Product Safety Commission (CPSC) was created as an independent regulatory commission, the PPPA was transferred to it.<sup>18</sup>

In January 1990, a CPSC staff report disclosed a statistically significant decrease in fatalities among children under age five from accidental ingestions of prescription drugs coincidental with the institution of the special packaging rules. The report, based on an analysis of prescription drug data from 1964 to 1986, concluded that special packaging for *prescription drugs*<sup>19</sup> may have prevented an estimated 340 fatalities between 1974 (when the regulations went into effect) and 1986.<sup>20</sup>

Yet special packaging is not the sole factor in reducing serious consequences of accidental poisonings. Consider the following examples. Children's aspirin, once the leading cause of accidental poisonings,<sup>21</sup> currently enjoys a much smaller market, in part because of the threat of Reye's syndrome.<sup>22</sup> More young children are in day care facilities (that arguably pose less such risk than the typical home). Also, fewer accidental ingestions may be the result of increased awareness of the problem, e.g., through annual observance of Poison Prevention Week.

In fact, during Poison Prevention Week in March 1990, CPSC Chairman Jacqueline Jones-Smith reminded consumers of the importance of storing hazardous substances out of reach of children. She indicated that, during 1987 alone, more than 30 children under five

<sup>18</sup> P.L. 92-573, 86 Stat 1231.

<sup>19</sup> This is, of course, but one of the many types of product posing a hazard. In 1962 alone, 450 children under the age of five died from accidental poisonings.

<sup>20</sup> 44 Consumer Prod. Safety Guide (CCH), January 11, 1990, at 3.

<sup>21</sup> *Federal Hazardous Substances Act: Hearings on S.2162, Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong., 1st Sess., at 161 (referring to Poison Control Center Data).

<sup>22</sup> See, e.g., *Public Citizen Health Research Group v. FDA*, 740 F.2d 21 (D.C. Cir. 1984).

had died and another 100,000 had received hospital emergency room treatment after accidentally swallowing medicines or household chemicals.<sup>23</sup>

Worse, some of these may be caused by use of the term “poison prevention” rather than “child resistance.” As previously mentioned, the margin for error is not large. Under the best of circumstances, special packaging can be breached by 15–20% of children under the age of five within ten minutes.<sup>24</sup> An adult not knowing this may be less diligent than warranted.

Also, of course, if packaging is too difficult for adults, they may purchase products in conventional containers, repackage them or fail to resecure special packaging. This problem more than any other has led to reconsideration of the regulations originally promulgated by the FDA.

#### *Proposed Revisions to the Regulations*

In January 1983, the CPSC published an advance notice of proposed rule making, stating that “Since the existing requirements were developed before the widespread use of such packaging, there may be ways to improve their effectiveness and efficiency.”<sup>25</sup> It also observed that:<sup>26</sup>

... Information now available, including recent consumer surveys, reveals that many consumers find child-resistant packaging to be either too difficult or too inconvenient to use. When given the choice, therefore, many consumers purchase products in conventional rather than child-resistant packaging. Consumers are also making a substantial number of child-resistant packages ineffective after bringing them home. [Notes omitted.]

However, not until October 1990 were proposed rules published for comment.<sup>27</sup> Comments were originally to be submitted by January 3,

<sup>23</sup> 45 Consumer Prod. Safety Guide (CCH), March 29, 1990, at 2.

<sup>24</sup> *Supra* note 15.

<sup>25</sup> 48 F.R. 2389.

<sup>26</sup> *Id.*

<sup>27</sup> 55 F.R. 40856.



1991, but the time was subsequently extended to July 1.<sup>28</sup>

Six proposed amendments would address: (a) sequential testing of smaller groups of children, (b) reducing ten children's test age groups to three, (c) preventing variability in child and adult testing through site and tester requirements, (d) refining the determination of whether adults properly resecure special packages after opening them, (e) standardizing test instructions, and (f) using a older adult test panel and shortened test times.<sup>29</sup> Effective dates for compliance with any adopted changes are also proposed.<sup>30</sup>

The last is the most complex and potentially far reaching. As proposed, it would change the last part of the regulation quoted above, at note 17, to read:<sup>31</sup>

(4) (i) Younger adult panel. One hundred adults, age 18 to 45 years inclusive, with no overt physical or mental handicaps, and 70 percent of whom are female, shall comprise the test panel for younger adults.

(ii) Older adult panel. One hundred adults, age 60 to 75 years inclusive, with no overt physical or mental handicaps, and 70 percent of whom are female, shall comprise the test panel for older adults. Only persons who can open conventional (not child-resistant) snap and continuous-threaded type plastic closures in a 1-minute screening test shall be selected for the older adult panel. The screening tests for this purpose shall use snap and continuous-threaded (CT) plastic closures having a diameter of 28 mm  $\pm$  18%, the CT closures having been resecured 72 hours before testing at 10 torque-inch-pounds, and round plastic containers, in sizes of 2 ounce  $\pm$  1/2 ounce for the CT type closure and 8 drams  $\pm$  4 drams for the snap type closure.

(iii) Test procedures. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to

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<sup>28</sup> 56 F.R. 9181.

<sup>29</sup> 55 F.R. 40857-40863

<sup>30</sup> 55 F.R. 40863.

<sup>31</sup> 55 F.R. 40865.

open and properly secure the special packaging as will appear on the package as it is delivered to the consumer. Prior to the timed test, the adults shall be given a 30-second period to attempt to become familiar with how the package works, during which time they may read the instructions and attempt to open the package. The regulations establishing child-resistant standards for particular substances shall specify which of the following times shall be allowed to complete the opening and, if appropriate, the resealing process.

(A) For the younger adult panel (§ 1700.20(a)(4)(i)), 30 seconds.

(B) For the younger adult panel (§ 1700.20(a)(4)(i)), 5 minutes.

(C) For the older adult panel (§ 1700.20(a)(4)(ii)), 1 minute.

(D) For the older adult panel (§ 1700.20(a)(4)(ii)), 5 minutes.

However the discussion considers several alternatives combining the idea of substituting or supplementing the present adult panel<sup>32</sup> with that for shorter test times.<sup>33</sup>

### Policy Issues and Value Judgments

From the beginning, special packaging has attracted criticism. Even with the able and youthful adult test panel specified in the present regulations, as many as one in ten subjects may be excluded for over five minutes. In retrospect, it should not be surprising that some fraction of those adults take measures to avoid such inconvenience. This was recognized as early as 1980,<sup>34</sup> and a 1989 CPSC study of children treated for ingestion of *medications* revealed that 44% of consumed *prescription* drugs (40% overall) were not dispensed in child-resistant packaging. Also, it was found that products originally dispensed in

<sup>32</sup> Note that the gender allocation remains the same; see 55 F.R. 40862.

<sup>33</sup> 55 F.R. 40861.

<sup>34</sup> The quotation *supra* at note 24 cites an August 1980 report entitled, *A Pilot Study of Effectiveness and Functionality of Child-Resistant Containers and Related User Attitudes* as authority.

child-resistant containers were obtained by children getting into, e.g., improperly secured original containers or conventional containers to which the contents had been transferred.<sup>35</sup>

Assuming that options are available, adults should not be unnecessarily forced to choose between packaging that is difficult for them and packaging that is not difficult for children. The use of conventional packaging substitutes one kind of inconvenience for another, an inconvenience that may be acute — particularly where potentially harmful substances are medicines beside a sick bed or where children are only rarely present. If containers are *both* child resistant *and* easier for adults to use, obviously more adults will use them and everyone will benefit.

The PPPA requirements for containers that, on the one hand, exclude “not all” young children “for a reasonable time” and, on the other, are “not difficult” for “normal” adults to use properly pose a great number of factual issues.

The definition of “normal” adult is value laden, but it can be considered in factual terms, i.e., however defined, what fraction of the adult population is excluded? What level of what kinds of difficulty will what fraction of the remaining “normal” adults tolerate under what circumstances? Depending on the answers to those further questions, how many adults (with children at least occasionally in their homes) will fail to take measures adequate to prevent a child from getting into some harmful substance?<sup>36</sup> To what extent is adult tolerance of inconvenience a function of the nature of a particular substance? For example, would adults be more tolerant of difficult drain cleaner packaging than of analgesic packaging?<sup>37</sup> How many adults using

<sup>35</sup> Schacter, *Unintentional Ingestions of Medications by Children Under 5 Years of Age* [January–March 1989] (1990). The study is discussed in a bit more detail at 55 F.R. 40860.

<sup>36</sup> However, it is clear that some attention has been given to such matters; *see supra* note 30.

<sup>37</sup> While 15 U.S.C. § 1472(b)(4) appears to give CPSC the power to discriminate

child-resistant packaging would take additional measures if they knew that up to 20% of children under the age of five can get into it within ten minutes?<sup>38</sup>

On the other side of the ledger, how much difficulty will children tolerate to get into something that can cause them harm? For what products will they expend greater effort? Should the testing protocol evaluate only empty, unmarked containers or ones containing candy and having attractive labels?<sup>39</sup> At what age does the risk diminish; what role does, e.g., intelligence play? How many children, if given a chance, will persist for greater than ten minutes? What are their characteristics? What are the characteristics of those tending to succeed most quickly? What role should that play in setting child effectiveness specifications?

Some of those issues are highly normative, as is, e.g., the question of whether children should be urged to use their teeth.<sup>40</sup> But, perhaps the key normative issue is: How much money should Congress provide to answer these and similar questions without CPSC's having to resort to, at best, incomplete data collected by emergency room personnel?

With more information, it might be easier to choose among options. But lack of information does not excuse failure to consider a broader range of choice. While the CPSC proposes to improve adult accessibility, it fails directly to address inherent tradeoffs between adult and juvenile accessibility to harmful substances. It mentions containers with increased child resistance and adult utility but does not propose increasing child resistance.<sup>41</sup> Nor does it consider, should that be

along these lines, it is not apparent that it has done so.

<sup>38</sup> See 16 C.F.R. § 1700.20(a)(2) quoted *supra* note 17.

<sup>39</sup> Neither the present nor the proposed protocol contemplates any such thing. See 55 F.R. 40866, setting forth proposed standardized child test instructions. Yet, 15 U.S.C. § 1472(d) gives authority to prohibit packages that might be attractive to children.

<sup>40</sup> See proposed instruction 25 at 55 F.R. 40866. See also proposed instruction 27, cautioning subjects not to try to open such packages at home.

<sup>41</sup> 55 F.R. 40863, indicating that at least some packaging is now available with

necessary for certain types of packaging, compromises.

Consider, for example, a container that would exclude “only” 10% of tested adults (however that group might be defined) after *two* minutes while 99% of children under the age of five would be excluded for *ten* minutes and 95% would be excluded for fifteen minutes. Should the package be permitted? Under the present protocol that container would be acceptable, but under the proposed protocol it would not be. Given the current state of knowledge, however the issue is characterized, it is difficult to call it “technical.”

It may well be that the abilities of illiterate older adults are simply too similar to those of bright, strong children to enable distinguishing the two populations. If this is so, the bulk of these proposals represent nothing more than value judgments in a technical cloak.

### Conclusion

Most risk management concerns potential hazards where risk is difficult to assess without training well beyond that of the average citizen, and it is easy for ultimate issues to be obscured by intervening technical questions. This is not the case for child resistant packaging. Typical adults can understand juvenile and adult measurements of packaging difficulty. Moreover, they should be aware that, once the options are laid out, setting respective specifications of difficulty for those populations is not, under the present state of knowledge, a task calling for technical expertise.

Technical questions posed in the proposed amendments to PPPA regulations should not be allowed to dominate the agenda. If they are permitted to do so, this would offer little hope for areas that are far more technically complex.




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97% effectiveness in restricting child access and permitting 60–75 year old adults access within one minute.