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**Intended Use Doctrine: Cautionary Labeling Is Both Permitted and Required by the Statute and Prohibition of Sales in Toy Stores or Store Departments Dealing Predominantly in Toys or Children's Articles Is a Reasonable Method to Assure against Use by Children Not Likely to Heed Warnings for Safe Use.**

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is to draw an artificial distinction barring just claims similar to those already allowed in "foreign object" cases.

Gary B. Weiser

TRADE REGULATION—CHILD PROTECTION AND TOY SAFETY ACT OF 1969—ADMINISTRATIVE REGULATIONS—JUDICIAL REVIEW—BANNED HAZARDOUS SUBSTANCES—LABELING REQUIREMENTS—INTENDED USE DOCTRINE: CAUTIONARY LABELING IS BOTH PERMITTED AND REQUIRED BY THE STATUTE AND PROHIBITION OF SALES IN TOY STORES OR STORE DEPARTMENTS DEALING PREDOMINANTLY IN TOYS OR CHILDREN'S ARTICLES IS A REASONABLE METHOD TO ASSURE AGAINST USE BY CHILDREN NOT LIKELY TO HEED WARNINGS FOR SAFE USE. *R. B. Jarts, Inc. v. Richardson*, 438 F.2d 846 (2d Cir. 1971).

Petitioner manufactured plastic finned lawn darts and had placed the following warning on the container of the lawn darts and on instructions accompanying them after being notified by the Food and Drug Administration of some injuries that had occurred when the product had been used by children: "CAUTION: SHOULD BE USED ONLY UNDER SUPERVISION OF ADULTS." Petitioner had also labeled the outside of the box: "AN OUTDOOR GAME FOR ADULTS." The Deputy Commissioner of Food and Drugs filed a regulation<sup>1</sup> determining the lawn darts to be a toy or other article intended for use by children that presented a mechanical hazard and thereby classified it as a banned hazardous substance under the Federal Hazardous Substances Act.<sup>2</sup> Petitioner asserted that such a classification would have the immediate effect of prohibiting the sale of the product and further that the classification was unwarranted since the game was not intended for use by children and had been labeled to that effect. The regulation provided that the lawn darts would be exempted from classification as a banned hazardous substance if the following conditions were met: (1) They are not sold in toy stores or in store departments dealing predominantly in children's goods. (2) The cartons and accompanying literature bear the following statement in a specified size, color, etc.: "WARNING: Not a toy for use by children. May cause serious or fatal injury. Read instructions carefully. Keep out of reach of children." (3) The game should include in the instructions and rules clear and adequate directions and warnings for safe use.<sup>3</sup> Held—*Petition for review denied*. Cautionary labeling is both permitted and

<sup>1</sup> 35 Fed. Reg. 19266 (1970).

<sup>2</sup> 15 U.S.C.A. § 1261 (f)(1)(D) (Supp. Mar. 1970).

<sup>3</sup> 35 Fed. Reg. 19266, 19267 (1970).

required by the Child Protection and Toy Safety Act of 1969 and prohibition of sales in toy stores or store departments dealing predominantly in toys or children's articles is a reasonable method to assure against use by children not likely to heed warnings for safe use.

The Federal Hazardous Substance Labeling Act, passed in 1960, was intended to regulate certain classes of hazardous substances and to provide for labeling requirements and misbranding prohibitions for failure to carry certain specified warnings.<sup>4</sup> While that act did include some labeling requirements that supplemented the Federal Food, Drug and Cosmetic Act,<sup>5</sup> in the aggregate, it was not sufficient to cover the numerous hazardous chemicals and substances found in households that currently were not subject to any regulatory laws.<sup>6</sup> In 1966, the Child Protection Act<sup>7</sup> was passed to amend the 1960 Act and to further provide for banning of toys and other children's articles containing hazardous substances as well as other hazardous articles.<sup>8</sup> Next in the federal regulatory control was the establishment of the National Commission on Product Safety.<sup>9</sup> The purpose of the commission was to protect the consumer against unreasonable risks of harm to the body from products purchased on the open market for use by the consumer and his family. It reviewed the scope, adequacy, and uniformity of voluntary self-regulation of manufacturers; and surveyed the existing federal, state, and local laws relating to consumer protection against unreasonable hazards. Finally, the commission made recommendations for action by the President, Congress, and industry.<sup>10</sup> In the course of the commission's studies, it found that while the 1966 Act<sup>11</sup> had increased the protection afforded children against hazardous substances, new dangers had become apparent that were not covered. Some of the toys in the possession of the commission were found to be dangerous because they contained sharp projections that could cause puncture wounds, cuts, and abrasions; some had heated surfaces that could burn a child from temperatures in excess of 800°; and some were found

<sup>4</sup> 15 U.S.C.A. §§ 1261-73 (1963).

<sup>5</sup> 21 U.S.C.A. §§ 301-92 (1961).

<sup>6</sup> H.R. Rep. No. 1861, 86th Cong., 2d Sess. 3 (1960).

<sup>7</sup> 80 Stat. 1303 (1966), amending 15 U.S.C.A. §§ 1261-73 (1963). The 1966 act also amended the short title of the 1960 act by deleting the word "Labeling." 80 Stat. 1303, 1305 (1966).

<sup>8</sup> H.R. Rep. No. 2166, 89th Cong., 2d Sess. 1-3 (1966).

<sup>9</sup> 81 Stat. 466 (1967), as amended 83 Stat. (1969). These acts provided for the establishment of the National Commission on Product Safety.

<sup>10</sup> As set out in H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 3, 4 (1969), the Commission's Interim Report (1969) related certain statistics, the most shocking of which was the fact that some 28 per 100,000 population of children under 15 years old die each year from accidents. This exceeds the rate for death in that age group from cancer, contagious diseases, heart disease, and gastroenteritis combined. The report further states that electrical, mechanical, and thermal hazards appear to predominate in the statistics associated with toy related injuries.

<sup>11</sup> 80 Stat. 1303 (1966), amending 15 U.S.C.A. §§ 1261-73 (1963).

dangerous because they could give a child an electrical shock.<sup>12</sup> As a result of these findings, it was apparent to the commission that a serious gap existed in the current laws and that this gap should be closed.<sup>13</sup>

The passage of the Child Protection and Toy Safety Act of 1969 was the final step in this series of laws.<sup>14</sup> This act amended the previously existing law by adding to the definition of the term "hazardous substance" any toy or other article intended for use by children which the Secretary of HEW, by regulation,<sup>15</sup> determines to present a mechanical, electrical, or thermal hazard.<sup>16</sup> A toy or other article intended for use by children presents a mechanical hazard if it is determined to be within the following standard:<sup>17</sup> If the design of the article presents an unreasonable risk of personal injury from propulsion of the item, from points or other protrusions, or because of any other aspect of its design of manufacture, when in normal use or when subjected to reasonably foreseeable abuse, it may be determined to present a mechanical hazard.<sup>18</sup> A *misbranded* hazardous substance under the act includes toys or other articles intended for use by children that are "hazardous substances" or that contain such substances that make them susceptible to access by a child to whom the toys are entrusted, and which fail to bear the required cautionary labeling such as the signal words "CAUTION" or "WARNING."<sup>19</sup> The most severe classification of a toy or other article is that of *banned* hazardous substances. This class includes (1) toys that are "misbranded hazardous substances" which have not been properly labeled, or (2) such items that are determined by the Secretary of HEW to be so unsafe that the objective of protecting the public health and safety could only be served by excluding the items from the interstate market altogether.<sup>20</sup> If the item is merely mis-

<sup>12</sup> See note 10 *supra*. It should also be noted that the Interim Report also listed, under the heading "Mechanical Hazards," a Rocket lawn dart set. The committee referred to this product as having heavily weighted steel pointed missiles that when hurtled, could foreseeably cause severe injury to even careful young children. This set of lawn darts differs from the product manufactured by R.B. Jarts, Inc. only in that the points were sharper.

<sup>13</sup> H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 6 (1969).

<sup>14</sup> 83 Stat. 187 (1969), amending 15 U.S.C.A. §§ 1261-73 (1963).

<sup>15</sup> By regulation published at 21 C.F.R. § 2.120 (1970), the Secretary of HEW delegated the authority to make these determinations of whether or not an article is a hazardous substance (plus determinations of the other classifications) to the Commissioner of Food and Drugs. To conform with the language of the statute, only the Secretary of HEW is referred to throughout this article.

<sup>16</sup> 15 U.S.C.A. § 1261(f)(1)(D) (Supp. 1970).

<sup>17</sup> Specifically, the scope of this article is limited to consideration of a mechanical hazard.

<sup>18</sup> 15 U.S.C.A. § 1261(s) (Supp. 1970).

<sup>19</sup> 15 U.S.C.A. § 1261(p) (Supp. 1970). By regulation in 21 C.F.R. § 191.106 (1970) when the Commissioner of Food and Drugs determines that for a particular hazardous substance the requirements of § 1261(p) of the act are not adequate for protection of the public health and safety because of some special hazard, he shall, by appropriate order in the Federal Register, specify such reasonable variations as he deems necessary. If the regulation is not complied with, the substance is deemed "misbranded."

<sup>20</sup> 15 U.S.C.A. § 1261(q) (Supp. 1970). See also H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 10, 11 (1969).

branded, it shall be exempted from being classified as a "banned hazardous substance" if the label gives adequate warnings and directions for safe use and care, and if it is intended for use by children that are sufficiently mature that they may be reasonably expected to read and heed the warnings or directions.<sup>21</sup>

The 1969 Act provides for two alternative methods the Secretary of HEW may use in determining which, if any, of the classifications a given item may come within. The act also provides for a judicial review of any such determination.<sup>22</sup> First, the determination may be made by regulations issued in accordance with the rule-making process described in the Federal Administrative Procedure Act.<sup>23</sup> This is an informal process providing for notice of the proposed rule-making in the Federal Register, unless the parties have actual notice of it, followed by a hearing. The hearing gives the interested parties an opportunity for participation in the rule-making leading to the final incorporation of the rule in the Federal Register.<sup>24</sup> The second alternative method is in accordance with the formal procedure set forth in the Food, Drug and Cosmetic Act providing for a formal regulation and hearing process and judicial review.<sup>25</sup> Under the first alternative in accordance with the Federal Administrative Procedure Act, if the adversely affected party seeks a judicial review of the determination, it must petition a United States court of appeals within 60 days after publication of the regulation in the Federal Register.<sup>26</sup> On review, the court may set aside the determination if it finds that it is either: (1) arbitrary, capricious, or otherwise not in accordance with law; or (2) is in excess of statutory immunity, or short of statutory right; or (3) is contrary to constitutional right, power and privilege or immunity; or (4) was made without observing the lawful procedure.<sup>27</sup> The court may order additional evidence and it may set aside the determination on the grounds that it was not supported by substantial evidence.<sup>28</sup> If the reviewing

<sup>21</sup> 15 U.S.C.A. § 1261(q)(1) (Supp. 1970).

<sup>22</sup> 15 U.S.C.A. § 1262 (Supp. 1970).

<sup>23</sup> 5 U.S.C.A. § 553 (1967).

<sup>24</sup> *Id.*

<sup>25</sup> 21 U.S.C.A. § 371(e)(f) (1961). This alternative is mentioned merely to show that it exists. The procedure under the Federal Administrative Procedure Act was used in the present case.

<sup>26</sup> 15 U.S.C.A. § 1262(e)(3)(A) (Supp. 1970).

<sup>27</sup> 5 U.S.C.A. § 706 (1967). *See, e.g.*, *Brown v. United States*, 396 F.2d 989, 991 (Ct. Cl. 1968):

The customary rationale of the limited scope of judicial review of agency determinations is that deference should be accorded the judgment of an administrative decision-maker, either because the legislature granted it a measure of discretion on facts or policy, or because of the agency's expertise in handling the subject matter. Most often, this leads to confining court intervention to instances in which the administrative decision was arbitrary and capricious, inconsistent with applicable statutes or regulations, or unsupported by substantial evidence.

<sup>28</sup> *Id.* *See generally*, Jaffe, *Judicial Review: "Substantial Evidence on the Whole Record,"* 64 HARV. L. REV. 1233, 1238 (1951). The author points out that "consideration and weight

court finds it necessary it may order other types of relief including postponing the effective date of the agency action or preserving the status of the parties pending conclusion of the review proceedings.<sup>29</sup>

The most severe immediate action that the Secretary of HEW may take is the determination that distribution of a particular children's article presents such an "imminent hazard" to the public health and safety that it should be classed as a banned hazardous substance immediately by publication of notice in the Federal Register without regard to the normal proceedings.<sup>30</sup> This "stop order"<sup>31</sup> may be given at any time the article is determined to be an "immediate hazard" either before or after the procedure for hearings have begun. If the hearing procedure has not begun, it must be initiated as quickly as possible—if the hearings have already begun when the "stop order" is issued, they must be completed.<sup>32</sup> The effect of this action is that the manufacturer would have to immediately comply with the order or be in violation of the act because he would be distributing a "banned hazardous substance." All of the review procedures will remain available to the manufacturer after such an order has been issued.<sup>33</sup>

The final amendment made by the 1969 Act to the previous acts<sup>34</sup> was the provision for repurchasing of items determined to be "banned hazardous substances."<sup>35</sup> This section provides that the manufacturer, distributor, or dealer must repurchase any article sold by them that has been classified as a "banned hazardous substance" whether or not classed as such at the time of the original sale. However, this repurchasing is necessary only as provided for by regulations issued in the Federal Register.<sup>36</sup>

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must be given the whole record, but the reviewing court is not to treat the matter as before it de novo." He further states that:

[U]nderlying the vexed word "substantial" is the notion or sense of fairness. . . . The word "substantial" coming as it does from a spectrum of words such as "scintilla," "preponderance" and "weight," connotes the mechanics of judging. The concept of fairness relates to the attitude of judging. I would say, then, that the judge may—indeed must—reverse if as he conscientiously sees it the finding is not fairly supported by the record; or to phrase it more sharply, the judge must reverse if he cannot conscientiously escape the conclusion that the finding is unfair.

<sup>29</sup> 5 U.S.C.A. § 705 (1967).

<sup>30</sup> 15 U.S.C.A. § 1262(e)(2) (Supp. Mar. 1970).

<sup>31</sup> H.R. Rep. No. 91-581, 91st Cong., 1st Sess. 7 (1969).

<sup>32</sup> 15 U.S.C.A. § 1262(e)(2) (Supp. Mar. 1970).

<sup>33</sup> *Id.* See also H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 11, 25 (1969).

<sup>34</sup> Provisions of the Federal Hazardous Substances Act, as amended in 1966, that remained in force were the general provisions classifying hazardous substances generally without regard to children's toys or articles; the section providing for prohibited acts such as introduction into interstate commerce of a misbranded or banned hazardous substance, 15 U.S.C.A. § 1253 (Supp. 1970); the section providing for penalties for violation of the act, 15 U.S.C.A. § 1264 (Supp. 1970); and other sections not considered here providing for seizures, imports, etc. H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 21-34 (1969).

<sup>35</sup> 15 U.S.C.A. § 1274 (Supp. Mar. 1970).

<sup>36</sup> In the amendments provided by the issuance of the regulation in 35 Fed. Reg. 19266, 19267 (1970), which amended 21 C.F.R. § 191, the last paragraph of § 191.65a provides for the effective date of the regulation as follows: "Effective date. This order shall be effective

In the instant case, petitioner was first officially notified of respondent's concern about Jarts<sup>37</sup> in a letter stating that respondent had become aware of a number of injuries arising from the use of the product by children. Pursuant to this notification petitioner revised the labels and warnings accompanying Jarts to read: "CAUTION: SHOULD BE USED ONLY UNDER SUPERVISION OF ADULTS," and "AN OUTDOOR GAME FOR ADULTS." Subsequently petitioner was advised of a proposed regulation that would classify the product as a "banned hazardous substance"—this proposal was published in the Federal Register.<sup>38</sup> The petitioner submitted comments on the proposed regulation alleging that Jarts was a game intended for use by adults and therefore it could not be the subject of a regulation classifying it as a "banned hazardous substance" on the grounds it is a "toy or other article intended for use by children" that presents a mechanical hazard.<sup>39</sup> The regulation classifying Jarts as a "banned hazardous substance" and providing for exemption from the classification if petitioner revises the labeling and distribution methods of the product is the subject of the instant judicial review.<sup>40</sup> The petitioner again contended that the nature of the product along with the existing label refutes the conclusion that Jarts are "toys or other articles intended for use by children" as required for the classification as a "banned hazardous substance" in this instance.<sup>41</sup> This contention would seem to be supported in *United States v. 681 Cases, More or Less, Containing "Kitchen Klenzer"*,<sup>42</sup> which construed a section of the Federal Insecticide Act.<sup>43</sup> The issue in that case was if the statute which purported to place labeling requirements on all substances "intended

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on its date of FEDERAL REGISTER publication. It would be contrary to the public interest to delay the effective date because the toys are hazardous and should be removed from the market to prevent possible injury." It is important to note that nothing was provided for the repurchase of the goods as required by 15 U.S.C.A. § 1274 (Supp. Mar. 1970), except the last sentence of the above quoted paragraph. Since § 1274(a) specifically provides that "(a) In the case of any article . . . which is a banned hazardous substance . . . such article or substance shall, *in accordance with regulations of the Secretary*, be repurchased. . . .", in the instant case it would seem that the game is not yet required to be repurchased (emphasis added).

<sup>37</sup> The game consists of plastic-finned dart shaped objects with a slightly blunted tip, each weighing approximately one-half pound. These Jarts are weighted in the tip so that when thrown underhanded at a circular target some distance away, they will stick in the ground. The game is similar to horseshoes in its object. The respondent had become aware of numerous injuries caused by Jarts which the court sets out in footnotes to its opinion. Some injuries were caused solely by children playing the game without adult supervision and some occurred even when the game was played under adult supervision, with adults actually participating in the game.

<sup>38</sup> 35 Fed. Reg. 17663 (1970).

<sup>39</sup> 35 Fed. Reg. 19266 (1970). The comments received by the Commissioner of Food and Drugs after the first notification are set out in the preface to this regulation along with the Commissioner's considerations and determination.

<sup>40</sup> *Id.* at 19267.

<sup>41</sup> 15 U.S.C.A. § 1261(q) (Supp. Mar. 1970).

<sup>42</sup> 63 F. Supp. 286 (E.D. Mo. 1945).

<sup>43</sup> Act of April 26, 1910, ch. 191, § 6 Stat. 331 (now 7 U.S.C.A. §§ 135-135k [1964]).

to be used" for repelling fungi would cover a particular scouring agent that contained certain properties of a fungicide and purported to "remove germs." The court held that Congress had used the phrase in reference to objective intent as evidenced by what the product held itself out to be. This refers to how the general public would take the words on the label regardless of how or what the manufacturer's intent may have been.<sup>44</sup> Applying this standard to the instant case, it would seem that the petitioner's current label could only purport to be what it said—"intended for use by adults;" thereby taking it out of the classification of a banned hazardous substance as provided by the regulation.<sup>45</sup>

The court, however, did not apply the above standard in the instant case. In construing the phrase "toy or other article intended for use by children" it concluded that any ambiguity that may have been in the phrase is taken away when the following circumstances are considered. The container had a picture of a family on it with a girl "scarcely over ten" who was either watching her mother play the game or actually holding a Jart; the accompanying literature provided that the game could be played by "old or young . . . expertly by all"; and common-sense logic would indicate that a child who has learned the delight of Jarts while competing with adults may decide to experiment with them when an adult is not around. Also noted are the facts that the manufacturer knew lawn darts could and had been used by children and that the distribution method included selling the product in toy stores. Finally the court refers extensively to the Interim Report of the National Commission on Product Safety which did, in fact, refer to a product almost identical to petitioner's as being a toy or other article "intended for use by children" that presented a mechanical hazard within the meaning of the then proposed act.<sup>46</sup> It would appear that the court could have resolved the issue without resorting to "common-sense logic" or the other available factors. First, a regulation carries a presumption of validity and should be upheld unless it is inconsistent with the statute.<sup>47</sup> Even when there is some doubt as to the validity of the regulation, that doubt is required to be resolved in favor of the regulation.<sup>48</sup> If the regulation is attacked, the burden is on the party attacking it to show its invalidity by way of its being unreasonable, inappropriate, or plainly inconsistent with the statute.<sup>49</sup> In the instant

<sup>44</sup> United States v. 681 Cases, More or Less, Containing "Kitchen Klenzer," 63 F. Supp. 286, 287 (E.D. Mo. 1945).

<sup>45</sup> 35 Fed. Reg. 19266, 19267 (1970).

<sup>46</sup> *Supra* notes 10, 12.

<sup>47</sup> Hoffenberg v. Kaminstein, 396 F.2d 684 (D.C. Cir. 1968), *cert. denied*, 393 U.S. 913, 89 S. Ct. 235, 21 L. Ed.2d 199 (1968). (Action on a copyright.)

<sup>48</sup> *Id.*

<sup>49</sup> McMahon v. Ewing, 113 F. Supp. 95 (S.D. N.Y. 1953). (Action under the Social Security Act to review a decision of the Federal Security Administrator.)



case, it would be difficult for the petitioner to show the invalidity in view of the intent of Congress in passing the act—it is directly within the broad purpose of the act as shown by the House Reports to do what is necessary to protect children from unreasonable risks of bodily harm or injury.<sup>50</sup> As to the requirement for a change in the labeling to avoid being classified as a misbranded hazardous substance, it was held in *Wilmington Chemical Corp. v. Celebrezze*,<sup>51</sup> that under the Federal Hazardous Substances Labeling Act of 1960 a substance which had carried a previously changed and approved label could be required to change it a second time. The court stated:

If the purpose of the Statute [Federal Hazardous Substances Labeling Act] is to protect the public, that protection is the paramount consideration, and it is the defendant's [Secretary of HEW] duty to do a complete job of protection and not trust to luck that purchasers . . . will be aware enough to understand the previously approved but inadequately specific label.<sup>52</sup>

It appears that there are several more factors than the mere objective intent as evidenced by what the product held itself out to be when considering the "intended use" of the product. First, in an action against a cosmetics manufacturer on an injury from use of one of its hair products, it was said that: "[T]his doctrine [intended use] is composed of two factors: The marketing scheme of the maker and foreseeability of harm."<sup>53</sup> The doctrine was elaborated on further in *Spruill v. Boyle-Midway, Inc.*,<sup>54</sup> which involved the inadequacy of a warning on a bottle of furniture polish which merely warned that it "may be harmful if swallowed, especially by children." The court pointed out that the doctrine of intended use was but an adaptation of the basic test of reasonable foreseeability and the manufacturer, besides having to foresee the injuries arising from use of the product for the purposes for which it is manufactured and sold, must also anticipate the environ-

<sup>50</sup> H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 3-7 (1969).

<sup>51</sup> 229 F. Supp. 168 (E.D. Ill. 1964). (The particular substance was X-33, an extremely flammable water repellent.) X-33 was mentioned in H.R. Rep. No. 2166, 89th Cong., 2d Sess. 2 (1966), as having caused at least 3 deaths, and injured 30 or more and yet, under the 1960 Federal Hazardous Substances Labeling Act, 15 U.S.C.A. §§ 1261-73 (1963), it could not be banned.

<sup>52</sup> *Id.* at 171. See also *United States v. 7 Cases, Cracker Balls*, 253 F. Supp. 771 (S.D. Tex. 1966). In this case the government successfully contended that children tended to be injured by these firecrackers because they look like jelly beans and the child would bite down on them causing them to explode in the child's mouth since they were the type firecracker that exploded on impact. These "cracker balls" were mentioned in H.R. Rep. No. 2166, 89th Cong., 2d Sess. 2 (1966), as an article that had injured numerous children but they could not be regulated or banned under the 1960 Federal Hazardous Substances Labeling Act, 15 U.S.C.A. §§ 1261-73 (1963).

<sup>53</sup> *Helene Curtis Industries, Inc. v. Pruitt*, 385 F.2d 841, 859 (5th Cir. 1967), *cert. denied*, 391 U.S. 913, 88 S. Ct. 1806, 20 L. Ed.2d 652 (1968).

<sup>54</sup> 308 F.2d 79 (4th Cir. 1962).

ment that is usual for the use of the product.<sup>55</sup> Finally, "intended use" was expanded even further in *Larsen v. General Motors Corporation*,<sup>56</sup> to cover an unintended use where the injury resulting from that use could have been foreseeable or should have been anticipated.<sup>57</sup> Taking into consideration all of the above factors, *i.e.* the market, the environment to be used in, the foreseeability and even the foreseeability of an unintended use, it would appear that the "intended use doctrine" as applied to the phrase "toy or other article intended for use by children" would encompass the Jarts as marketed before the issuance of the regulation. The reasoning or "common-sense logic" that could then be applied becomes apparent: The Jarts were marketed in toy stores and toy departments of other stores—this type of marketing scheme would surely indicate that the manufacturer intended the item to be bought for and used by children—if not, logic would indicate that he was missing the very market he was trying to capture which was purportedly the adult market. The foreseeability test is met by the actual knowledge of injuries to children caused by the use of the article which was, as the court suggests, present in this case. Even if the article did in fact purport on its face to be intended for use by adults, the picture on the box of the small girl playing the game or "gleefully watching" would indicate that an unintended use by children could reasonably be foreseen. Finally, the National Commission on Product Safety's report on a similar article and the statute itself provide a sound basis for the conclusion that Jarts could validly be determined to be a "toy or other article intended for use by children."

The broad policy aspects of the 1969 Act along with the presumptive validity of the regulation determining the classification of the product and the factors used in determining its intended use all point to the soundness of the decision in the instant case. Now, R.B. Jarts, Inc. will be required to comply with the provisions of the regulation in order to exempt its product from the classification as a banned hazardous substance—if it does not, the product will not be allowed to be sold, and if it is, it will be in violation of the act, for which penalties are provided.<sup>58</sup> In examining the effect of the present statute in light of this case and the considerations herein, it may be concluded that the manufacturers of toys or other children's products now must conform to a set of standards and regulations heretofore not observed in this general area. These new standards and regulations give rise to interesting

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<sup>55</sup> *Id.* at 83, 84.

<sup>56</sup> 391 F.2d 495 (8th Cir. 1968).

<sup>57</sup> *Id.* at 501.

<sup>58</sup> 15 U.S.C.A. §§ 1263, 1264 (1963), *as amended* 15 U.S.C.A. §§ 1263, 1274 (Supp. Mar. 1970).

questions yet to be answered concerning possible applications of the type ruling in the instant case in the area of tort law—*i.e.* how could a plaintiff apply the effect of a violation of the regulation made pursuant to the act in an action for injury to or death of a child caused by a toy which, prior to the injury, was determined to be within one of the classifications provided in the act?<sup>59</sup>

In *Courtney v. American Oil Company*,<sup>60</sup> the court acknowledged that the Federal Hazardous Substances Act as it existed in 1966 was designed to protect the general public and not a limited class. At most, the court reasoned, the violation of the act would constitute negligence, but would not, as a matter of law, conclude the issue of proximate cause.<sup>61</sup> In *Rumsey v. Freeway Manor Minimax*<sup>62</sup> a label for roach poison had been registered in accordance with the Federal Insecticide Act.<sup>63</sup> The label also complied with the Texas Hazardous Substances Act.<sup>64</sup> A boy died after eating the poison. The court held that the statute and regulations set by the agencies in accordance with the statute merely set minimum standards and compliance with them is evidence on the issue of negligence.<sup>65</sup> Generally, it is held that violation of a statute or regulation is only evidence of negligence, as the foregoing cases suggest, if the act applies to a general class instead of a specific class which it is designed to protect.<sup>66</sup> But, if the statute or regulation was intended to protect the class of persons to which the plaintiff belongs against the type of risk of harm that actually occurred, its violation is negligence per se.<sup>67</sup> In view of the purpose of the Child Protection and Toy Safety Act, it would seem that a violation of it would be within the latter category. To prove violation of a regulation,

<sup>59</sup> An interesting issue is posed at the outset. What would be the result if the article was in violation of the act by being a banned hazardous substance still on the market, but the determination was made in accordance with the "immediate hazard"—"stop order" method of § 1262(e)(2)? Presumably this would not be a problem since if on completion of the hearing process and review the product remained classed as such in its form at that time, the initial "stop order" would be valid. If the article was not kept under the classification because of action by the Food and Drug Commission or on review, the article would be wholly outside of the statute. (For the effect of a "stop order," see H.R. Rep. No. 91-581, 91st Cong., 1st Sess. 7 [1969]).

<sup>60</sup> 220 So.2d 675 (Fla. Ct. App. 1968). Sale of gas to two children 10½ years old in unlabeled containers, with no warning—in violation of the Federal Hazardous Substances Act.

<sup>61</sup> *Id.* But, it would seem that the purpose of the 1969 Act was to protect a specific segment of the population—a particular class of person to which only a certain part of the class of children would belong.

<sup>62</sup> 423 S.W.2d 387 (Tex. Civ. App.—Houston [1st Dist.] 1968, no writ).

<sup>63</sup> 7 U.S.C.A. § 135 *et seq.* (1964).

<sup>64</sup> TEX. PENAL CODE ANN. art. 726-1 (1961).

<sup>65</sup> *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Civ. App.—Houston [1st Dist.] 1968, no writ). See also Noel, *Products Defective Because of Inadequate Direction or Warnings*, 23 Sw. L.J. 256 (1969).

<sup>66</sup> See, e.g., *Green v. Sanitary Scale Company*, 296 F. Supp. 625 (E.D. Pa. 1969).

<sup>67</sup> See, e.g., *Marshall v. Isthmian Lines, Inc.*, 334 F.2d 131 (5th Cir. 1964). Coast Guard regulations pursuant to a statute providing it was unlawful to transport hazardous articles—the regulation prohibited transportation of cotton with damaged bindings.