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Food and Drug Law: The Infant Formula Act of 1980

Randal D. Shields

FOOD AND DRUG LAW: THE INFANT FORMULA ACT OF 1980

INTRODUCTION

OUR CHILDREN have been characterized as this country's most valuable natural resource.[1] Without their normal mental and physical development, they would simply not be capable of living a happy and fulfilled life. This development depends, in large part, on their consumption of nutritional foods during their first year of life. Because of omissions made in the reformulation of two soy-based infant formulas in 1978, many children developed blood and growth disorders; there is a strong possibility that the children who ingested these formulas may suffer in the future.

The Infant Formula Act of 1980[2] (hereinafter the Act) was a culmination of the efforts of mothers, physicians, reporters, administrators, businessmen and congressmen to provide regulations and guidelines to prevent similar tragic episodes in the future. This comment will focus on the Act, as well as the events leading up to its promulgation. The examination will begin with the remarkable discovery in infants of the rare affliction known as metabolic alkalosis and the subsequent research which has established a direct correlation between the defective formulas and the infants' conditions. Despite an expedient voluntary recall of the formulas, controversy raged in the media and in the Congress concerning the effectiveness of that recall, criminal sanctions for alleged liable parties, and the enforcement policy of the Food and Drug Administration (hereinafter FDA). Resolution of these issues, however, will not foretell the future development of the affected children. Only time and long-range studies will provide reliable answers to the questions of worried parents.

I. DISCOVERING THE DEFICIENCIES

Satisfactory infant formulas have only been on the market since the late nineteenth century; the modern era did not begin until 1915 when researchers adapted the fat content of cows' milk to simulate human milk.[3] Many of today's formulas are modifications of this basic formula which was named S.M.A., for Synthetic Milk Adapted.[4] Infant formulas are available as pow-

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[1] Infant Formula Act of 1980, 16 WEEKLY COMP. PRES. DOC. 1936-37 (Sept. 26, 1980).

[2] Pub. L. No. 96-359, 94 Stat. 1190 (codified sections at 21 U.S.C. §§ 301, 321, 331, 350a, 374 (Supp. IV 1980) and 21 U.S.C.A. §§ 830, 841-43, 873 (West 1981)).

[3] Anderson, *A Background Paper on Infant Formulas,* LIFE SCIENCES RESEARCH OFFICE (Feb. 1980) (prepared for the Bureau of Foods, Food and Drug Administration), *reprinted in Nutritional Quality of Infant Formula: Hearings on H.R.* 6590, 6608, 5836, 5839 *Before the Subcomm. on Health and the Environment of the House Comm. Interstate and Foreign Commerce,* 96th Cong., 2d Sess. 77, 79-80 (1980) [hereinafter cited as *Nutritional Quality Hearings*].

[4] *Id.* at 80.

ders, liquid concentrates, and ready-to-feed products. Presently, the ready-to-feed products are the most popular.[5] By 1972, about seventy percent of infants two months of age were receiving commercially prepared formulas.[6] This trend has reversed within the last eight years, however, with forty-five to eighty percent of mothers breast-feeding their infants after returning home from the hospital.[7] This practice follows the prevailing opinion in favor of breast-feeding infants whenever possible.[8]

Because of specific disorders or intolerance to human milk, or other milk-based products, many infants must rely on synthetic formulations. The most widely used are those derived from soybean components.[9] Neo-Mull-Soy and Cho-Free, manufactured by the Syntex Corporation, were two such formulas.[10] Before 1979, the ability of these formulas to supply adequate amounts of nutrients had never been questioned.[11]

In June of 1979, Dr. Shane Roy, a pediatric nephrologist at the University of Tennessee, examined two infants with symptoms that indicated failure to thrive: poor appetite, failure to gain weight, diarrhea and blood in the urine.[12] These symptoms originally indicated a Bartter-like syndrome,[13] however, the diagnosis of metabolic alkalosis was finally made.[14] Both infants were receiving Neo-Mull-Soy. Prior to these cases which were diagnosed in the same week, Dr. Roy had seen only seven cases of Bartter's

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[5] *Id.* at 83.

[6] *Id.* at 88.

[7] *Id.*

[8] *Id.* (citing as authority the American Academy of Pediatrics, the American Medical Association, and the Infant Formula Council).

[9] *Id.* at 89.

[10] Syntex Corporation is a Panamanian corporation with offices located in Palo Alto, California. The Company has facilities located throughout the world and produces a variety of products such as pharmaceuticals, chemicals and nutritional goods. Infant nutritional products were obtained when Syntex purchased the infant formula line from the Borden Company in 1971 and turned the production of these products over to Syntex Laboratories, Inc. in Palo, Alto. Vaundell and Scott, *FDA Establishment Inspection Report,* Palo Alto, Cal. (August 28, September 5, 17, 1979), *reprinted in Infant Formula Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce,* 96th Cong., 1st Sess. 46-47 (1979) [hereinafter cited as *Gore Hearings*]. *See id.* at 95 (testimony of Paul E. Freiman, President of Syntex Laboratories, Inc.).

[11] *Gore Hearings, supra* note 10, at 95 (testimony of Paul E. Freiman). The product was originally manufactured in 1940 and marketed under the name Mull-Soy. Telephone interview with Jack Dillon, Assistant Director of Engineering, Borden, Inc. (March 26, 1982).

[12] *Gore Hearings, supra* note 10, at 5-6 (testimony of Shane Roy). *See* Report, *Infant Metabolic Alkalosis and Soy-Based Formula,* MORBIDITY WEEKLY REP. 358 (Aug. 3, 1979); Roy & Arant, *Alkalosis From Chloride-Deficient Neo-Mull-Soy,* 301 NEW ENG. J. MED. 615 (1979); Roy & Cordero, *Withdrawal of Two Soy-Based Infant Formulae,* THE LANCET 462 (Sept. 1979).

[13] *See infra* text accompanying notes 62-63.

[14] Metabolic alkalosis is a chemical imbalance in the blood characterized by low levels of chloride (Cl) (hypochloremic metabolic alkalosis), potassium (K) (hypokalemic metabolic alkalosis), or combinations thereof. *See infra* text accompanying notes 61-68.

Syndrome in fourteen years of practice.[15] At first he did not feel that the formula was at fault.

Approximately one month later, on July 24, 1979, Dr. Roy was notified of another infant who was diagnosed as having metabolic alkalosis. When Dr. Roy asked the resident what formula the child was receiving, the resident told him it was Neo-Mull-Soy.[16] The same day, Dr. Roy reported the cases to Dr. John Ingram, Director of the Medical Services Department of Syntex Laboratories. They had no prior cases on record.[17] The following day, Syntex called Dr. Roy to report that they had been notified of two additional cases in Boston. Syntex requested that Dr. Roy obtain case lot numbers of the formula used by his patients.[18]

Dr. Roy called Syntex the next day (July 26, 1979) to report the lot numbers and was informed that there were two more calls from Staten Island, New York about infants who had received the formula and had been affected. At this point, Dr. Roy called the county health department, the hospital dietary department and the county pediatric society.[19] The county public health department reported these events to the Center for Disease Control (hereinafter C.D.C.) in Atlanta. After a nationwide survey of pediatric nephrologists, the C.D.C. contacted the FDA.[20]

On July 27, 1979, all involved parties began to seriously investigate the matter. Dr. Hurd, the plant manager of the Elgin, Illinois facility was notified by Syntex to stop distributing the product.[21] Representatives of the FDA met with Dr. Roy in Tennessee and Dr. James Mutch of Syntex in Palo Alto.[22] Syntex sent mailgrams to approximately 24,000 pediatricians and other physicians informing them of the reported cases and suggesting

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[15] *Gore Hearings, supra* note 10, at 6 (testimony of Shane Roy). Doctor Roy also checked the formula against the product information and the ingredients appeared adequate. *Id.* Product information is listed annually in the PHYSICIAN'S DESK REFERENCE.

[16] *Id.*

[17] *Id.* at 5-6. Testimony revealed, however, that Syntex had in fact received a phone call on July 2, 1979, from a physician. Because his call was in the nature of an "inquiry" rather than a "report," Syntex asked only for sample cans so that the lot numbers could be checked. There was no ingredient check made. *Id.* at 102-03 (testimony of Paul E. Freiman and Virgil Thompson, Vice-President of Corporate Regulatory Affairs, Syntex Laboratories, Inc.).

[18] *Id.* at 5-6 (testimony of Shane Roy). *See also* SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 96TH CONG., 2D SESS., REPORT ON INFANT FORMULA, at 5 (COMM. PRINT 96-IFC 42, 1980) [hereinafter cited as HOUSE SUBCOMM. REPORT].

[19] *Gore Hearings, supra* note 10, at 5-7 (testimony of Shane Roy).

[20] *Id.* at 9 (testimony of Jose Cordero). This survey ascertained that there were thirty-one reported cases. For twenty-seven of the cases, the type of formula was known: twenty-six of the twenty-seven were using Neo-Mull-Soy. *Id.*

[21] Bruederle & McCullough, *FDA Establishment Inspection Report,* Elgin, Ill. (Aug. 1, 2, 9, 1979) at 5.

[22] *Gore Hearings, supra* note 10, at 5, 7, 27, 46.

that they "maintain suitable viligance."[23] Dr. Roy and Dr. Cordero of the C.D.C. had several discussions about the C.D.C. survey and the results of laboratory analysis of the formula that had begun the previous day. The laboratory tests indicated that the chloride content of the formula was only two milliequivalents per liter, one-third of the product information claim (nine milliequivalents) and even less than the Committee on Nutrition of the American Academy of Pediatrics recommendation (eleven milliequivalents).[24] When Dr. Roy called Dr. Ingram at Syntex that evening to report that "the mechanism for the production of the metabolic alkalosis was directly attributable to [the] low chloride intake," Dr. Ingram replied that Syntex had also analyzed the formula and found that the chloride was low, but "not that low."[25]

By July 31, 1979, the San Francisco district office of the FDA recommended an agency-initiated recall.[26] Syntex had already organized a California meeting the next day to be attended by Dr. Roy, two other prominent pediatric nephrologists, a representative from the C.D.C. and Dr. Ingram of Syntex.[27] All of the information was reviewed at this meeting and the recommendation was made to recall the formula immediately.[28] Late on August 1st, Syntex made the decision to voluntarily recall the formulas. The FDA granted approval of the recall documents prepared by Syntex, and the announcements were made on August 2, 1979.[29]

Before turning to the recall and the medical evidence, it is appropriate to review the events which led to the reduction (or deletion?) of sodium and chloride levels in the formulas. It is clear now that it was not necessarily the original reductions which led to the infants' conditions, but the failure to monitor the nutrient levels thereafter.

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[23] *Id.* at 63, 67 (testimony of Paul E. Freiman); *see, e.g., FDA Mailgram* from John Ingram, M.D., to physicians (July 27, 1979), *reprinted in Gore Hearings, supra* note 10, at 67.

[24] *Gore Hearings, supra* note 10, at 7 (testimony of Shane Roy). *See* PHYSICIANS' DESK REFERENCE, 1711, 1717 (33d ed. 1979) (these ingredients are listed for Cho-Free at 1711, but not for Neo-Mull-Soy at 1717); Committee on Nutrition, American Academy of Pediatrics [A.A.P.], *Commentary on Breast-Feeding and Infant Formulas, Including Proposed Standards for Formula,* 57 PEDIATRICS 278, 278-85 (1976). These guidelines were updated as of February 1980. *See Infant Formula Act of* 1980; *Hearings on S.* 2490 *Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Labor and Human Resources,* 96th Cong., 2d Sess. 117 (1980) [hereinafter cited as *Senate Hearings*].

[25] *Gore Hearings, supra* note 10, at 5, 7 (testimony of Shane Roy). In fact, the Syntex assay of one-hundred lots revealed very low levels. Only four lots contained chloride in amounts close to the A.A.P. recommendations, 63% contained less than two milliequivalents per liter, and several contained no chloride whatsoever. Memorandum of Syntex Laboratories, Inc. from John Kjellstrand (Elgin, Ill.) to Jack Cohen (undated) (discussing analysis results in 1979 products), *reprinted in Gore Hearings, supra* note 10, at 91-92.

[26] *FDA San Francisco District Office Memo* from Edward Cassidy to all district offices (July 27, 1981).

[27] *Gore Hearings, supra* note 10, at 5, 7 (testimony of Shane Roy). The FDA was not invited to this meeting because of its "preliminary" nature and the concern that the agency's presence might inhibit the free flow of information. *Id.* at 88 (testimony of Virgil Thompson).

[28] *Id.* at 7 (testimony of Shane Roy).

[29] *Id.* at 5, 7, 64.

II. PRODUCT REFORMULATION AND PROBABLE LIABILITY

A key event prior to the reformulation of the products was the decision in December, 1977 to discontinue a routine assay for chloride levels.[30] The decision was allegedly made by a nutritionist at the Elgin, Illinois facility because he felt that the assay was elective. He neglected to inform anyone in the chain of command of the dropping of the assay.[31] The formulas were reformulated and salt was reduced (deleted?) on March 20, 1978.[32] This was in part based on the school of thought that hypertension and high blood pressure later in life were related to high levels of sodium chloride (salt) in foods.[33] They were again reformulated in September and October of 1978 when the soy protein isolates were changed.[34]

More than likely, Syntex will be held ultimately liable for the damages sustained by infants who ingested Neo-Mull-Soy and Cho-Free. The extent of that liability, of course, will depend on how many infants were harmed and the probability of permanent injury. "It has been conservatively estimated that more than 20,000 infants ingested defective soybean-based formulas during the critical first months of life."[35] Because of the large numbers of children affected by the same products, class actions have been filed in Cincinnati, Atlanta and other cities[36] but class status may not be granted in any of these cases because of the inconsistencies in injuries.

Remedies should be obtainable in individual actions under a variety of theories. Besides the traditional negligence and breach of warranty routes, a tort action against the manufacturer based on strict liability should

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[30] Bruederle & McCullough, *supra* note 21, at 17. *See, e.g., Gore Hearings, supra* note 10, at 51.

[31] *Gore Hearings, supra* note 10, at 89-90 (testimony of Paul E. Freiman).

[32] Vaundell & Scott, *supra* note 10, at 51-52. Dr. Sidney Saperstein, principal scientist for Syntex Laboratories, Inc., must ultimately approve any formula changes. *Id.* at 49. *See* Bruederle & McCullough, *supra* note 21, at 17.

[33] *Gore Hearings, supra* note 10, at 89-90. For commentators' views on the levels of salt in infant foods, *see generally* Filer, *Salt in Infant Foods,* 29 NUTRITION REV. 27 (1971); Foman, *Recommendations for Feeding Normal Infants,* 63 PEDRIATRICS 52 (1979); Foman, *What are Infants Fed?* 56 PEDIATRICS 350 (1975); STEWART, SALT IN THE INFANT DIETARY, EDITORIAL IN PEDIATRIC BASICS, (GERBER PRODUCTS CO. Issue 21 1978). These authors *did not,* however, urge the disregard of the A.A.P. recommendations.

[34] Vaundell & Scott, *supra* note 10, at 51-52. These changes probably had no causal relationship to the resultant metabolic alkalosis.

[35] Letter from James G. Butler, Esq. to the editor of the Research and Development Department of the Association of Trial Lawyers of America (Sept. 9, 1980) (discussing Syntex infant formulas and possible liability to Syntex).

[36] Letter from Sidney W. Gilreath, Esq. to the Products Liability-Medical Malpractice Exchange of the Association of Trial Lawyers of America (Dec. 27, 1979) (discussing class actions against Syntex). Over three billion dollars worth of lawsuits have been filed against Syntex, including a two-billion dollar class action in Memphis, Tennessee. Broadcast Excerpt from 20/20, Media Transcripts, Inc., March 13, 1980, at 15; Wash. Post, Dec. 10, 1979, at A4, col. 1. There have been no reported cases found at the time of this article's printing, however.

be available.[37] These product liability laws have favored maximum protection of human life by demanding that manufacturers be held liable for defective products, regardless of the exercise of due care in the production of the product.[38] And because Syntex failed to warn the ultimate consumers of the dangerous propensities of the formulas, an action in strict liability or negligence based on the breach of their "duty to warn" would also be appropriate.[39]

Although the Infant Formula Act was not in effect at the time of the Syntex formula deficiencies, violations of other laws could be litigated. Syntex's acts in relation to certain provisions of the Food, Drug and Cosmetic Act [hereinafter F.D.C.A.][40] were the subject of inquiry in many of the House and Senate hearings and reports.[41] The F.D.C.A. is primarily intended to promote the public health and welfare by preventing adulterated and misbranded substances from entering the marketplace.[42] Section 402 of the F.D.C.A. provides that "[a] food shall be deemed to be adulterated

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[37] Strict liability developed as an extension of negligence due to negligence theory's "roadblocks to recovery" which include: 1) limitations on the maker's duty of care, 2) the difficulty of satisfying the burden of proof as regards negligence (particularly because the product is under the manufacturer's control), 3) the rules pertaining to proximate cause, and 4) the defenses of contributory negligence and assumption of risk. Keeton *Manufacturer's Liability; The Meaning of "Defect" in the Manufacture and Design of Products,* 20 SYRACUSE L. REV. 559, 560 (1969). Problems with breach of warranty actions lie primarily in the notice requirements.

[38] The concept of strict liability most often used in the United States is set out in the RESTATEMENT (SECOND) OF TORTS § 402-A (1965). For the history of the development of strict liability in tort law *see* Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer),* 69 YALE L.J. 1099 (1960); Prosser, *The Fall of the Citadel,* 50 MINN. L. REV. 791 (1966).

[39] Liability based on negligent failure to warn is based on § 388 of the RESTATEMENT which provides that the supplier, in order to incur liability, must: (a) know or have reason to know that the chattel is dangerous; (b) have no reason to believe that the consumer will realize the condition; and (c) fail to inform the consumer of the chattel's dangerous condition. RESTATEMENT (SECOND) OF TORTS § 388 (1965). Strict liability, however, is not based on whether the seller had reason to know of the danger or reason to know that the buyer was unaware of the danger. Strict products liability is solely based on whether there was a defective product which was unreasonably dangerous. 2 L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY, § 16A[4][f][vi] (1981). Dean Prosser notes:

> [There] has [been] a general acceptance of the principle that in some cases the defendant may be held liable, although he is not only charged with no moral wrongdoing, but has not even departed in any way from a reasonable standard of intent or care . . . . This new policy frequently has found expression where the defendant's activity is unusual and abnormal in the community, and the danger which it threatens to others is unduly great — and particularly where the danger will be great even though the enterprise is conducted with every possible precaution.

W. PROSSER, HANDBOOK OF THE LAW OF TORTS, 494 (4th ed. 1971). *See* Comment, *The Case for Strict Liability in the Infant Formula Industry,* 6 BROOKLYN J. INT'L L. 89 (1980).

[40] 21 U.S.C. §§ 301-392 (1976 & Supp. IV 1980).

[41] *Gore Hearings, supra* note 10, at 62-104; *Senate Hearings, supra* note 24, at 42-48; HOUSE SUBCOMM. REPORT, *supra* note 18, at 14-30.

[42] S. REP. No. 712, 83d Cong., 1st Sess. 2 (1953), *reprinted in* [1953] U.S. CODE CONG. & AD. NEWS 2198. For an analysis of the history and purposes of the F.D.C.A. *see* Janssen, *The U.S. Food and Drug Law: How It Came; How It Works,* 35 FOOD DRUG COSM. L.J. 132 (1980); Hutt; *Food Legislation in Perspective,* 34 FOOD DRUG COSM. L.J. 590 (1979).

. . . if it is otherwise unfit for food; or . . . [i]f any valuable constituent has been in whole or in part omitted or abstracted therefrom. . . ."[43] The primary issue under section 402 would be whether chloride is a valuable constituent of infant formula or whether infant formula containing insufficient amounts of chloride is unfit as food.[44] In light of the report of the American Academy of Pediatrics Committee on Nutrition and the regulations of the Infant Formula Act,[45] *inter alia,* the House Subcommittee found that chloride "clearly is a vital ingredient,"[46] and, therefore, section 402 had been violated.

In addition, the Subcommittee believed other sections of the F.D.C.A. had been violated.[47] Section 403 proscribes misbranding which could occur through improper labeling or advertising.[48] After reviewing the claims made by labels, promotional literature and advertisements, and comparing them with the actual amounts of chloride contained in the formulas, the Subcommittee found a clear violation. They also cited the reply by Mr. Virgil Thompson (Vice-President, Corporate Regulatory Affairs, Syntex Laboratories, Inc.) to a query regarding the chloride concentration of Cho-Free: "There is no question but that there are lower chloride levels in there than are represented on the can . . . ."[49] Furthermore, section 301(a) which prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded"[50] was believed to be violated.

It appears that it was not necessarily the reformulation of the products that was harmful, but the failure to test the formulas and discover the inadequate amounts of chloride following reformulation. Even though

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[43] 21 U.S.C. § 342(a)(3), (b)(1) (1976). Ohio's analogous provisions appear at OHIO REV. CODE ANN. § 3715.59(C), (G) (Page 1980). Violations of Ohio's food and drug laws making it a crime to sell adulterated food have been held to constitute negligence per se. Allen v. Grafton, 170 Ohio St. 249, 164 N.E.2d 167 (1960); Kurth v. Krumme, 143 Ohio St. 638, 56 N.E.2d 227 (1944); Portage Markets Co. v. George, 111 Ohio St. 775, 146 N.E. 283 (1924).

[44] HOUSE SUBCOMM. REPORT, *supra* note 18, at 14.

[45] 21 U.S.C. § 350a(g) (Supp. IV. 1980). *See infra* note 103 and accompanying text.

[46] HOUSE SUBCOMM. REPORT, *supra* note 18, at 14, 15.

[47] *Id.* at 15-17.

[48] Two sections of the F.D.C.A. must be considered: § 403(a) provides that food shall be deemed to be misbranded if: 1) its labeling is false or misleading in any particular, or 2) in the case of a § 411 food, its advertising is false or misleading in a material respect or its labeling is in violation of § 411(b)(2). Section 201(n) provides factors to be considered in determining whether labeling or advertising is misleading: representations made or suggested by statement, word, design, device, or any combination thereof, and the extent to which the labeling or advertising fails to reveal material facts are all considerations to be taken into account. These factors must be weighed against resulting consequences of proscribed or customary use. 21 U.S.C. §§ 343(a), 321(n) (1976). Ohio's provisions are found at OHIO REV. CODE ANN. § 3715.60 (Page 1980).

[49] HOUSE SUBCOMM. REPORT, *supra* note 18, at 16.

[50] 21 U.S.C. § 331(a) (1976).

Syntex admitted the error[51] and reacted quickly once the problem was discovered, a majority of the Subcommittee felt so strongly about the situation that the matter was referred to the Justice Department for criminal prosecution.[52] Because the F.D.C.A. imposes strict liability for violations, some Subcommittee members "strenuously" dissented insofar as the report referred the investigation to the Justice Department.[53] They stressed the corporation's lack of knowledge that the formula was deficient,[54] their cooperation with the FDA,[55] possible due process violations,[56] and most importantly, that the FDA had no regulations in effect governing the levels of sodium and chloride.[57]

Despite seemingly overwhelming evidence establishing statutory violations on the part of Syntex, proving that those violations caused a child's injuries is another matter. "The question of causation has always been paramount in food cases."[58] Because this was the first time that chloride defi-

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51 Mr. Gore: You reformulated your product after the testing for chloride was stopped. Is that correct?
Mr. Freiman: That is correct.
Mr. Gore: And you didn't test for chloride after the reformulation. Is that correct?
Mr. Freiman: That is correct.
Mr. Gore: Another mistake, wasn't it?
Mr. Freiman: Yes.
Gore Hearings, supra note 10, at 90.

52 HOUSE SUBCOMM. REPORT, *supra* note 18, at 18. "Any person who violates a provision of section 331 . . . shall not be imprisoned for more than one year or fined not more than $1,000.00, or both," 21 U.S.C. § 333 (1976). Ohio's penalty provisions are set out in OHIO REV. CODE ANN. § 3715.99 (Page 1980).

53 HOUSE SUBCOMM. REPORT, *supra* note 18, at 22. "[A] recommendation of criminal prosecution . . . represents a quantum leap beyond the facts herein, and beyond what is necessary to achieve the goal of safe and effective formulas." *Id.* The FDCA has withstood several congressional challenges. Subsequent to the Act's passage, a proposed amendment that would have imposed criminal liability only for violations committed willfully or as a result of gross negligence died in a House-Senate conference. 44 CONG. REC. 8551, 8838 (1948). In United States v. Park, 421 U.S. 658 (1975), the Supreme Court ruled that corporate officers could be held criminally liable for virtually any preventable violation by subordinates. This decision confirmed the conviction of the president of a large food chain for the offense of permitting food to be exposed to rodents. 421 U.S. at 660. Liability was predicated on the degree of responsibility borne by the officer, rather than on personal participation in the violation itself. Therefore, the Court inferred that responsible corporate officials are required not only to remedy violations when they occur, but to institute procedures to prevent their occurrence. 421 U.S. at 672. Following this decision, legislation seeking to limit vicarious liability by establishing a negligence standard for the criminal liability of corporate officers was proposed, but has not passed Congress. 122 CONG. REC. 7204-37 (1976). *See* Survey, *White-Collar Crime: Food and Drug*, 18 AM. CRIM. L. REV. 336 (1980).

54 HOUSE SUBCOMM. REPORT, *supra* note 18, at 22.

55 *Id.* at 24-27. *But see id.* at 13, and *Gore Hearings, supra* note 10, at 55-56.

56 HOUSE SUBCOMM. REPORT, *supra* note 18, at 28-29 (citing the Act's notice and hearing procedures). 21 U.S.C. § 335 (1976).

57 HOUSE SUBCOMM. REPORT, *supra* note 18, at 14, 30. FDA requirements for infant foods are codified at 21 C.F.R. § 105.65 (1981). They were updated in 1971, but never adopted the 1976 A.A.P. recommendations. HOUSE SUBCOMM. REPORT, *supra* note 18, at 14-15. Nevertheless, the industry was aware of the updated guidelines. *See Senate Hearings, supra* note 24, at 111-16. Although the FDA proposed to change their regulations to approximate those of the A.A.P., their offer became moot when the Infant Formula Act established nutritional requirements based on the A.A.P. recommendations. 21 U.S.C. § 350a(g) (Supp. IV 1980).

58 Condon, *Products Liability - 1979*, 35 FOOD DRUG COSM. L.J. 404, 412 (1980).

ciencies and associated developmental problems have appeared in humans,[59] the medical profession has responded with numerous case studies, articles and reports to document the correlation between the ingestion of defective formulas and the incidence of metabolic alkalosis.

III. MEDICAL EVIDENCE

As previously stated, Dr. Shane Roy was the physician who brought the infant formula problems to the attention of the public. Following his discovery, nearly every medical commentator who has written on the subject has concluded that there exists some correlation between ingesting the formula for a month or more and similar physical symptoms.[60] Generally, each investigation began with infants showing signs of failure to thrive which may include weight loss or failure to gain weight, diarrhea, lethargy, refusal to take other foods, dehydration, blood in the urine, and spitting-up. Their growth rates were usually in the twenty-fifth percentile or below and some even developed seizures and kidney problems.[61] The symptoms appeared very similar to Bartter's syndrome, a rare situation where there is a failure by the kidneys to absorb chloride into the body[62] causing chloride to be readily detectable in the urine and stools. In all of the case reports, how-

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[59] *See* Grossman & Hellerstein, *The Dietary Chloride Deficiency Syndrome*, 66 PEDIATRICS 366 (Sept. 1980). *Cf.* Kassirer, *The Critical Role of Chloride in the Correction of Hypokalemic Alkalosis in Man*, 38 AM. J. MED. 172 (1965) (discussing the vital role of chloride in the renal handling of sodium). *See infra* note 116.

[60] *See* Barness, *Formula Manufacture and Infant Feeding*, 243 J. AMER. MED. ASSOC. 1075 (March 14, 1980); Committee on Nutrition, American Academy of Pediatrics, *Commentary on Breast-Feeding and Infant Formulas, Including Proposed Standards for Formula*, 57 PEDRIATRICS 278, 278-85 (1976); Garin, *Soybean Formula (Neo-Mul-Soy) Metabolic Alkalosis in Infancy*, J. OF PEDIATRICS 985 (Dec. 1979); Grossman & Hellerstein, *The Dietary Chloride Deficiency Syndrome*, 66 PEDIATRICS 366 (Sept. 1980); Hellerstein, *Metabolic Alkalosis and Neo-Mull-Soy*, J. OF PEDIATRICS 1083 (Dec. 1979); Holliday, *Alkalosis in Infancy and Commercial Formulas*, 65 PEDIATRICS 639 (March 1980); Letter, *Withdrawal of Two Soy-Based Infant Formulae*, THE LANCET 462 (Sept. 1, 1979); Linshaw, *Hypochloremic Alkalosis in Infants Associated with Soy Protein Formula*, J. OF PEDIATRICS 635 (April, 1980); Report, *Infant Metabolic Alkalosis and Soy-Based Formula*, MORBIDITY AND MORTALITY WEEKLY REP. 358 (Aug. 3, 1979); Report, *Follow-up on Formula-Associated Illness in Children*, MORBIDITY AND MORTALITY WEEKLY REP. 124 (March 21, 1980); Report, *Follow-up on Infant Metabolic Alkalosis*, MORBIDITY AND MORTALITY WEEKLY REP. 364 (Aug. 10, 1979); Report *Follow-up Study of Infants Fed Soybean-Based Formulas*, 96 PUB. HEALTH REP. 93 (Jan.-Feb. 1981); Reznik, *Neo-Mull-Soy Metabolic Alkalosis: A Model of Bartter's Syndrome?*, 66 PEDIATRICS 784 (Nov. 1980); Roy & Arant, *Alkalosis From Chloride-Deficient Neo-Mull-Soy*, 301 NEW ENG. J. MED. 615 (1979); Simopoulos and Bartter, *The Metabolic Consequences of Chloride Deficiency*, 38 NUTRITION REV. 201 (June 1980); Wolfsford & Senior, *Failure to Thrive and Metabolic Alkalosis*, 243 J. AMER. MED. ASSOC. 1068 (March 14, 1980).

[61] *Id. See, e.g.*, correspondence and questionnaire from Formula (a group organized by two Washington, D.C. parents of affected children, Carol Laskin and Lynne Pilot) to requesting parents (Formula, P.O. Box 39051, Washington, D.C. 20016); Wash. Post, Dec. 10, 1979, at A5.

[62] Report, *Infant Metabolic Alkalosis and Soy-Based Formula*, MORBIDITY AND MORTALITY WEEKLY REP. 358 (Aug. 3, 1979); Reznick, *supra* note 60, at 785.

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ever, none of the infants revealed chloride in their urine or stools.[63] Normal electrolyte levels in the sweat ruled out cystic fibrosis.[64] The obvious next step was to determine if the infants were in fact *receiving* the necessary levels of chloride.

Although all of the published case reports resulted in solving the problem, the methods of detection differed. Some physicians went directly to the formula, analyzed it, and discovered the problem.[65] Others used an elimination technique to either supplement the defective formula or use a different formula when the symptoms caused by the defective formula did not abate. Some physicians used both the formula analysis and elimination techniques.[66] Generally, the physicians who went directly to the defective formula to analyze it were in a situation where they had two or more patients with similar symptoms and the defective formula was the common denominator. Despite the fact that none of the case histories revealed exactly the same symptoms,[67] all the infants had some form of metabolic alkalosis and all had been taking Cho-Free or Neo-Mull-Soy for a month or more.[68]

Clearly, the evidence indicates a direct causal relationship between the low chloride levels of Neo-Mull-Soy and Cho-Free and the resultant metabolic alkalosis described in the literature. Many infants who ingested these formulas and did not develop metabolic alkalosis either did not take enough of it for a long enough period of time or, more likely, had their diets supplemented so as to receive necessary nutrient levels from other sources.[69] But, "infants receiving a diet consisting *almost exclusively* of Neo-Mull-Soy [or Cho-Free] developed the dietary chloride deficiency syndrome because the manufacturer, Syntex Laboratories, Inc., failed to maintain proper quality control in the preparation of their infant formulas."[70] Unfortunate-

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[63] Garin, *supra* note 60, at 986, Grossman & Hellerstein, *supra* note 60, at 367-70; Hellerstein, *supra* note 60, at 1083-84; Linshaw, *supra* note 60, at 639; Reznick, *supra* note 60, at 785; Simopoulos & Bartter, *supra* note 60, at 202; Wolfsford & Senior, *supra* note 60, at 1069.

[64] Simopoulos & Bartter, *supra* note 60, at 202; Wolfsford & Senior, *supra* note 60, at 1069.

[65] Hellerstein, *supra* note 60, at 1084. Dr. Hellerstein was one of the physicians who attended the Aug. 1, 1979 meeting in California and urged Syntex to recall the product. Roy & Arant, *supra* note 59, at 615; Wolfsford & Senior, *supra* note 60, at 1069.

[66] Garin, *supra* note 60, at 985-86; Grossman & Hellerstein, *supra* note 60, at 366-67; Holliday, *supra* note 60, at 640 (Dr. Holliday was another participant at the August 1, 1979 meeting.). Linshaw, *supra* note 60, at 637; Reznick, *supra* note 60, at 785; Roy & Arant, *supra* note 60, at 615.

[67] *Compare* Report, *Infant Metabolic Alkalosis and Soy-based Formula,* MORBIDITY AND MORTALITY WEEKLY REP. 358, at 358 (Aug. 3, 1979) (where one of the three infants had constipation and the other two had diarrhea) *with* Grossman & Hellerstein, *supra* note 60, at 369 (where four of twelve infants were dehydrated but the other six were not).

[68] Following one infant's switch to Neo-Mull-Soy at age five months, the typical symptoms began to appear four to six weeks later. Reznick, *supra* note 60, at 784. Other case histories indicated that the symptoms did not appear until an infant had been on the defective formula for three to five months. Grossman & Hellerstein, *supra* note 60, at 366.

[69] *See* Garin, *supra* note 60, at 987; Grossman & Hellerstein, *supra* note 60, at 372.

[70] Grossman & Hellerstein, *supra* note 60, at 374 (emphasis added).

ly, for Syntex Laboratories, as well as the infants affected, this opinion is virtually unanimous. There are also indications that many infants developed these same problems while using Neo-Mull-Soy or Cho-Free *before* the March, 1978 product reformulation.[71]

IV. THE RECALL

The greatest controversy of the entire formula episode was generated after the medical investigators pursuaded Syntex to recall its products. "Recalls are undertaken voluntarily by manufacturers and distributors, or at the request of the FDA, when the agency considers a product to be in violation of the laws it administers. The FDA does not have the authority to mandate product recalls."[72] Following the August 1, 1979 decision to recall its formulas, Syntex repeated the mailgram to the initial 24,000 physicians it sent warnings to the week before — only this time, it was for a complete recall.[73] That same day, Syntex also mailed a first class letter, marked on the envelope with the words in red: "Urgent: Product Recall," to over 100,000 physicians and pediatric nurses.[74] In addition to press statements that were carried by radio, television and newspapers, Syntex sent similar first class letters to all direct customer wholesalers, hospitals, food markets, drug stores and food brokers. These were followed with additional letters and phone calls.[75] Salesmen were ordered to go beyond their normal

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[71] Formula correspondence and questionnaire, *supra* note 61 (emphasis added); Broadcast Excerpt from 20/20, Radio TV Reports, Inc., Jan. 15, 1981, at 3-4. This could be attributed to the formulas if they were deficient in the A.A.P. nutrient recommendations prior to the reformulation.

[72] *House Subcomm. Report, supra* note 18, at 6. *See* 21 C.F.R. §§ 7.1-7.59 (1981) for the FDA's enforcement and recall policy.

[73] *Gore Hearings, supra* note 10, at 64.

[74] *Id. FDA Memo* from Edward Cassidy to all district offices (Oct. 24, 1979).

[75] *Gore Hearings, supra* note 10, at 64-79. All the letters contained basically the same information as set out below, with any differences characteristic of the recipient's obligations:

> Dear Doctor: Syntex is initiating a recall of its current stocks of Neo-Mull-Soy and Cho-Free soy formulas because the products were believed to be manufactured with chloride levels that were too low.
>
> Infants primarily at risk are those who are essentially dependent on these soy formulas for their overall nutrition as well as those subject to unusual stresses leading to chloride loss such as vomiting, diarrhea, severe anorexia and/or extreme sweating. When signs of failure-to-thrive anorexia, lassitude, or failure to gain weight are seen, physicians are urged to check whether Neo-Mull-Soy and/or Cho-Free products may have been used. If so, blood electrolyte levels, including chloride levels, should immediately be obtained.
>
> If electrolyte abnormalities such as hypokalemia, hypochloremia, and increased bicarbonate are evident, the child should be further evaluated for additional signs such as urinary levels of chloride less than 10 milliequivalents per liter, elevated BUN, or microhematuria.
>
> A panel of experts convened by Syntex has recommended that an individualized management program for this type of metabolic alkalosis should include immediate discontinuance of Neo-Mull-Soy or Cho-Free formulas, and appropriate corrective measures. These may include restoration of fluid and electrolyte balance.
>
> If you have any inventory of Neo-Mull-Soy or Cho-Free samples, please quarantine them until a Syntex representative contacts you regarding their disposition. Also, please

rounds to effectuate the recall — over 26,000 visits were made in an attempt to clear territories of Neo-Mull-Soy and Cho-Free by September 15th.[76] By November 1st, over two million cans of the product were destroyed in a recall that cost over four million dollars.[77]

The recall, notwithstanding the good faith efforts accompanying it, was not totally successful. Through a variety of communication mix-ups and misinterpreted instructions dealing with the monitoring of the recall, there were reports of defective formula being available on store shelves the same day as Representative Gore's Subcommittee Hearing, November 1, 1979 — nearly three months after the recall began.[78] Mr. Gore indicated that the General Accounting Office found 132 cans in a spot check, NBC affiliates found cans in several cities and his own staff found it in his congressional district. "People have called in saying they found it on the shelves. It is still on the shelves. The recall was not effective."[79]

Syntex countered with evidence indicating the practical difficulties of coordinating such an extensive recall.[80] Other factors contributing to the problem were: 1) some merchants not receiving direct communication from Syntex were not direct customers and 2) Syntex also reformulated the products to contain adequate levels of sodium chloride, then shipped them before the FDA requested that they cease and desist.[81] From Syntex's and

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complete the enclosed business reply card indicating the quantity on hand and return it to the Syntex Director of Quality Control.

For the present, physicians are advised that other soy formulas should be used. Syntex will inform you concerning the future availability of its soy-formula products.

Very truly yours, John S. Ingram, M.D., Director, Medical Services, Syntex Laboratories, Inc. (Enclosure)

Id. at 68.

[76] *Id.* at 65; *See, e.g., FDA Memo* from Rick Casey to all field personnel (Aug. 6, 1979) (discussing corporate standards for carrying out the recall).

[77] *Gore Hearings, supra* note 10, at 65, 97. "Syntex has spared no expense and has made every effort to inform wholesalers, retailers, and consumers of the recall and to remove the product from the market." *Id.* at 65 (testimony of Paul E. Freiman). By February of 1980, Syntex had destroyed over eight million cans of formula. HOUSE SUBCOMM. REPORT, *supra* note 18, at 23 (dissenting views of Representative Lent).

[78] *Gore Hearings, supra* note 10, at 80-84, 103-04. *FDA Memo* from Edward Cassidy to Syntex and to all district offices (Oct. 26, 1979) (discussing recall procedures). The furor was originally sparked by Washington reporter, Lea Thompson of television station WRC. In a series of broadcasts that began in September, she brought the entire tragedy to the public's eye — and to Congress'. *See* transcript of Lea Thompson, WRC-TV (Wash. D.C.), Oct. 25, 1979; broadcast excerpt from *Today*, Radio TV Reports, Inc., Oct. 29, 1979. Her perseverence paid off when she joined mothers and congressmen in the Oval Office to receive congratulations from President Jimmy Carter and to witness the signing of the Infant Formula Act. Infant Formula Act of 1980, 16 WEEKLY COMP. PRES. DOC. 1936, 37 (Sept. 26, 1980).

[79] *Gore Hearings, supra* note 10, at 103.

[80] Of the 1000 direct account pharmacies that Syntex sold to in the Washington, D.C. area, the product was found in only fourteen stores; only two of those actually had products on the shelves. In addition, Syntex dealt with over 100,000 accounts annually. *Id.* at 83, 98.

[81] *Id.* at 65, 83, 99, 104. This cease and desist order was following an original clearance by the FDA for Syntex to market its reformulated product. *See* HOUSE SUBCOMM. REPORT, *supra* note 18, at 23.

the FDA's point of view, the recall was ninety-five percent effective as of November 1, 1979.[82]

There is no doubt that some of the recall confusion was generated by the FDA itself. In addition to reversing the decision to allow Syntex to market Neo-Mull-Soy once the nutrient levels were corrected, attaching the proper class designation to the recall proved to be controversial.[83] On the day that Syntex announced the recall, the FDA Health Hazard Evaluation Board convened and unanimously declared the products as potential "life threatening, subacute" hazards.[84] The Division of Regulatory Guidance then classified the recall as Class II, as opposed to the recommended Class I.[85] Although it was a close call, Commissioner Jere E. Goyan of the FDA testified that he would "make it a Class I today."[86]

Another source of embarrassment was the recall monitoring by the FDA. "FDA's Bureau of Foods intended its instructions to require a certain level of audit on the part of the FDA; the instructions were, however, interpreted by [the] San Francisco office to refer to the minimum level to be undertaken by the firm."[87] The FDA actually intended Syntex to conduct a Level A effectiveness check — requiring one hundred percent contact with consignees — whereas the FDA would then conduct their own Level C effectiveness check — requiring only ten percent contact with consignees.[88] Through the misinterpretation by the San Francisco office, Syntex only carried out a ten percent check. The FDA made no effectiveness checks until a week before the House Subcommittee Hearing.[89]

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[82] *Gore Hearings, supra* note 10, at 24; HOUSE SUBCOMM. REPORT, *supra* note 18, at 12.

[83] Once a decision is made to follow the voluntary process, FDA regulations require the establishment of a recall strategy. The recall strategy addresses three elements regarding the conduct of the recall: 1) depth of the recall, 2) public warning, and 3) effectiveness checks. 21 C.F.R. § 7.42 (1981). In addition, an ad hoc committee evaluates the health hazard. HOUSE SUBCOMM. REPORT, *supra* note 18, at 8.

[84] Health Hazard Evaluation Form, *reprinted in Gore Hearings, supra* note 10, at 35 and HOUSE SUBCOMM. REPORT, *supra* note 18, at 8.

[85] HOUSE SUBCOMM. REPORT, *supra* note 18, at 9. The difference between the recall classes is as follows:

> 1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
> 2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
> 3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

21 C.F.R. § 7.3(m)(1)-(3) (1981).

[86] *Gore Hearings, supra* note 10, at 43.

[87] *Id.* at 30 (statement by Jere E. Goyan, Commissioner of the FDA).

[88] HOUSE SUBCOMM. REPORT, *supra* note 18, at 11-13. Recall strategy and descriptions of the various effectiveness checks are codified at 21 C.F.R. § 7.42 (1981).

[89] HOUSE SUBCOMM. REPORT, *supra* note 18, at 12. The evolution of the FDA's recall and seizure powers has taken an interesting course since its inception in the 1950's. It is true that there is no explicit statutory authority for FDA mandated recalls; the courts have so held, allowing only seizure proceedings and requests for voluntary recalls. United States v. C.E.B.

V. THE INFANT FORMULA ACT

The Subcommittee presented their recommendation to Congress in February of 1980 that legislation be enacted requiring testing of infant formulas before marketing and after any reformulation.[90] The House considered four bills over the next few months[91] and the Senate considered one, while continuing to hold hearings over the early part of the summer.[92] A compromise House bill[93] incorporating the language of the Senate bill was ultimately passed by both houses.[94] It was signed into law by President Jimmy Carter on September 26, 1980,[95] and codified as new section 412 of the F.D.C.A.[96]

The Infant Formula Act "creates a separate category of food designated 'infant formula' and requires that formula meet specified standards of quality and safety."[97] It also grants authority for the Secretary of the FDA "to

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Products, Inc., 380 F. Supp. 664 (N.D. Ill. 1974). *But see* United States v. K-N Enterprises, Inc., 461 F. Supp. 988 (N.D. Ill. 1978) which directly conflicts with the earlier district court opinion in granting a preliminary injunction and a prayed-for recall of the manufacturer's violative products. *See* Comment, *Mandatory Food and Drug Recalls — An Analysis of a Developing FDA Enforcement Tool*, UTAH L. REV. 809 (1980). Although this comment makes reference to some of the early newspaper articles concerning the instant defective formula situation to support her argument in favor of mandatory FDA recalls, examination of all the facts at this point does not seem to support adoption of that position. Despite some beliefs that Syntex did not cooperate with the FDA, the more reasonable view is that they did. Recall *orders* are usually unnecessary. If a company does refuse to cooperate, the equitable power of the courts to grant the prayed-for recall would be adequate where the protection of the public was at stake. The FDA itself does not feel that mandatory recall authority is necessary: "It is far more important to have improved record keeping by firms, inspectional authority for those records, product coding, and plans to implement recalls, than to have mandatory recall authority." Statement by Jere E. Goyan, *reprinted in Nutritional Quality Hearings, supra* note 3, at 76 and *Senate Hearings, supra* note 24, at 86. *See infra* note 109 and text accompanying notes 106-109. Furthermore, S. REP. No. 96-916, 96th Cong., 2d Sess. 9 (Aug. 26, 1980), *reprinted in* [1980] U.S. CODE CONG. & AD. NEWS 2858 [hereinafter S. REP. No. 96-916] recognizes the *K-N Enterprises* decision and expressly provides for the Secretary to request an injunction from a federal court (to order a recall) pursuant to 21 U.S.C. § 332 (1976). The "Court may or may not exercise their *statutory authority* and order the recall." S. REP. No. 96-916 *supra*, at 2866 (emphasis added). *See infra* note 102 and accompanying text.

[90] HOUSE SUBCOMM. REPORT, *supra* note 18, at 20. Their specific recommendations are set out in S. REP. No. 96-916, *supra* note 89, at 2861-71.

[91] The four bills under consideration were: H.R. 6590, 96th Cong., 2d Sess. (1980); H.R. 6608, 96th Cong., 2d Sess. (1980); H.R. 5836, 96th Cong., 2d Sess. (1980); and H.R. 5839, 96th Cong., 2d Sess. (1980).

[92] The bill considered was: S. 2490, 96th Cong., 2d Sess. (1980). *See Senate Hearings, supra* note 24.

[93] H.R. 6940, 96th Cong., 2d Sess. (1980). *See* S. REP. No. 96-916 *supra* note 89, at 2859-60.

[94] The House considered and passed the bill on May 20th and September 9, 1980. The Senate considered and passed the bill on September 8, 1980. *See* S. REP. No. 96-916, *supra* note 89, at 2858.

[95] Infant Formula Act of 1980, 16 WEEKLY COMP. PRES. DOC. 1936-37 (Sept. 26, 1980).

[96] 21 U.S.C. §§ 301, 321, 331, 350a, 374 (Supp. IV 1980) and 21 U.S.C.A. §§ 830, 841-43, 873 (West 1981). Sections 830, 841-43, and 873 were actually riders to the Infant Formula Act relating to drug law enforcement, piperidine (PCP) reporting, and marijuana trafficking penalties, and therefore, are not dealt with in this comment.

[97] S. REP. No. 96-916, *supra* note 89, at 2858.

establish nutritional, quality control, record keeping, notification and recall requirements necessary to insure that infant formula is safe and will promote healthy development."[98]

The body of the Act which begins at section 2(a), establishes nutritional, quality and processing requirements that must be met for a formula to be considered unadulterated. These requirements are either set out in the Act or are established by the Secretary of the Department of Health, Education and Welfare.[99]

Rather than delegate to an administrative body the task of establishing a list of required nutritional ingredients for normal, full-term infants, Congress wisely chose to include one in the statute itself:[100]

> The Committee has elected to specify an initial list of ingredients in the statute to ensure that uniform standards for infant formula will be in place upon the effective date of the legislation [ninety days after September 26, 1980] . . . . [I]t would be irresponsible public policy to permit the effective establishment of formula safety and quality standards to be delayed one or two years due to the procedural requirements of the rule making process.[101]

The table of ingredients, which includes minimum (and a few maximum) requirements for protein, vitamins and minerals, reflects the recommendations of the American Academy of Pediatrics.[102] Flexibility is accomplished by empowering the Secretary to revise the nutrient list as well as the nutrient levels.[103] In addition, the Secretary may establish quality factors and quality control procedures to ensure the Act's effectiveness.[104]

Notice provisions are found in section 2(b). Manufacturers must notify the Secretary that their products are in compliance with the Act: 1) ninety days before the first processing of a formula intended for commercial or charitable distribution, and 2) any time before the first processing of a reformulation or reprocessing, where the manufacturer reasonably believes

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[98] *Id.* at 2874.

[99] 21 U.S.C. § 350a(a) (Supp. IV 1980).

[100] *Id.* § 350a(g).

[101] S. REP. No. 96-916, *supra* note 89, at 2862.

[102] *Id.* at 2867.

[103] 21 U.S.C. § 350a(a)(2) (Supp. IV 1980). Note that by adopting these recommendations as law — including those for sodium, potassium, and chloride — the FDA was relieved of the responsibility of establishing guidelines for 21 C.F.R. § 105.65(c) (1981). Realistically, though, the revision authority granted to the Secretary most likely will be delegated to the FDA.

[104] 21 U.S.C. § 350a(a)(2) (Supp. IV 1980). Quality factors are those considerations pertaining to maintaining the potency of the nutrients during the product's expected shelf life. Quality control procedures, in addition to "good manufacturing practices" applicable to foods, are intended to ensure that safety and quality are "built into" the formula manufacturing process. Quality control procedures include the periodic testing of infant formulas. S. REP. No. 96-916, *supra* note 89, at 2862-63.

that such reformulation may affect the product's status as unadulterated.[105] Section 2(c) places an additional prompt notification requirement on the manufacturer who has knowledge which "reasonably supports the conclusion" that the formula may present a risk to human health or may be otherwise adulterated.[106]

Although the FDA does not have the power to order a recall,[107] section 2(d) authorizes the Secretary to become actively involved through regulation of the scope and extent of a recall.[108] The Act also requires him to review (every fifteen days) actions taken under the recall while mandating that a manufacturer submit status reports (every fourteen days from the beginning of the recall) on all actions to implement the recall.[109] These review and reporting requirements end only upon the termination of the recall.[110]

Section 2(c) requires manufacturers to make and retain distribution records, for up to two years, to improve the monitoring and effectiveness of recalls.[111] Although the Senate Subcommittee report concurs with this requirement, their statement that this subsection would also provide the Secretary with authority to inspect those records could be open to controversy.[112] There is no express authority in this provision to inspect factories or records. In order to carry out the purpose of section 2(c), however, the authority might be inferred from the power granted to regulate the making of those records (which was required to enable an effective monitoring of a recall),

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[105] 21 U.S.C. § 350a(b) (Supp. IV 1980). A manufacturer does not need any preclearance or approval to market a formula, however. All that is required is formal notification. *See* S. REP. No. 96-916, *supra* note 89, at 2863.

[106] 21 U.S.C. § 350a(c)(1) (Supp. IV 1980). "Knowledge" is defined as "(A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care." *Id.* § 350a(c)(2). By combining a subjective standard with a liberal objective standard, Congress intended to provide the Secretary with a timely opportunity to review any potential health risks that might result from the use of an infant formula. The Senate Report approached understatement when they noted that many other products are subject to similar consumer protection statutes: "The Committee believes the protections provided consumers of infant formula should at least be equivalent to that already available to purchasers of snowmobiles and hairdryers." S. REP. No. 96-916, *supra* note 89, at 2864.

[107] *See supra* note 89.

[108] 21 U.S.C. § 350a(d) (Supp. IV 1980).

[109] *Id.*

[110] *Id.* It is apparent that these measures, along with § 2(e) of the popular Act and § 274 of the codification, were in indirect response to FDA Commissioner Jere Goyan's testimony regarding the lack of power on the part of his agency to effectively regulate and monitor record keeping and recalls. *See supra* note 89 and text accompanying notes 82-88. Indeed, the Committee stated that "the events of [the summer of 1979] indicate the necessity of these requirements. Two chloride deficient formulas were left on the market fully three months after 'voluntary' recalls had been initiated." S. REP. No. 96-916, *supra* note 89, at 2865.

[111] 21 U.S.C. § 350a(e) (Supp. IV (1980).

[112] S. REP. No. 96-916, *supra* note 89, at 2866.

or from the power granted to regulate the retention of those records.[113] Section 2(c) alone seems inadequate to authorize the inspection of factories and records.

Express authority for the inspection of factories and certain records is found in section 4 of the Infant Formula Act which amended the general inspection provisions of the F.D.C.A.[114] This section provides that upon proper identification and with written notice, duly authorized persons may, at reasonable times and in a reasonable manner, enter establishments where infant formulas are manufactured or held.[115] Upon entrance the agents may verify records to confirm whether the formula meets the requirements of section 2 of the Act.[116] Certain exclusions provide exemptions for financial data, sales data (other than shipment data), pricing data and certain personnel and research data.[117] All inspections must be "commenced and completed with reasonable promptness."[118]

Because some infant formulas are manufactured for infants with inborn errors of metabolism, low birth weights or other unusual medical or dietary problems, Congress has exempted formulas for these infants (if properly represented and labeled) from the adulteration, new processing and reprocessing notice requirements of the Act.[119] The manufacturers are required, however, to provide the "reasonable knowledge" notice when it appears that the special formula may be adulterated or misbranded.[120] Congress recognized the need for formulas tailored to specific medical or dietary requirements. Concern that manufacturers would feel the regulations of the Act too cumbersome and therefore elect not to manufacture special formulas encouraged the exemption.[121] By providing the Secretary with discretion to regulate these formulas, Congress sought to ensure high standards for all formulas while not discouraging this essential service.[122]

Finally, section 7 of the Act requires reports to be submitted to Congress by the Secretary of Health and Human Services to study, *inter alia,* the

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[113] 21 U.S.C. § 350a(e)(2) (Supp. IV 1980).
[114] *Id.* § 374(a).
[115] *Id.* § 374(a)(1).
[116] *Id.* § 374(a)(3).
[117] *Id.* § 374(a)(1).
[118] *Id.*
[119] *Id.* § 350a(f)(1).
[120] *Id.*
[121] S. REP. No. 96-916, *supra* note 89, at 2867.
[122] *Id.* Additionally, the Secretary may withdraw this exemption if his prescribed regulations and conditions are not met. 21 U.S.C. § 350a(f)(2) (Supp. IV 1980). Questions remain, however, about whether a soy-based formula would fall into this category. Although the statute is silent on the matter and the Senate Report does not include soy-based formulas in the few examples that they provide, it seems tenable that they could fall under the category of providing nutrition to an infant with a "dietary problem."

long-term health effects on infants who developed hypochloremic metabolic alkalosis.[123] These tests, along with independent medical research and the studies being conducted by the Center for Disease Control in Atlanta, will provide answers to the uncertainties surrounding the scope of injury to children who ingested Neo-Mull-Soy and Cho-Free.[124]

CONCLUSION

There are no definite answers for parents whose children developed metabolic alkalosis as a result of ingesting Neo-Mull-Soy and Cho-Free. It is clear that there is concern for the proper mental and physical development of the affected infants.[125] Legislative hearings and news reports are replete with statements by parents concerning their anger and frustration over the original problems as well as their deep-seated fear that their children will develop improperly.[126] Before discovery of the deficiencies, mothers had been consistently accused of being "overanxious."[127] Most physicians just did not make the connection between the formula and the symptoms.[128] Now parents find their children developing "improperly" and diagnosed as having "delayed gross motor development."[129] While most infants improved with a new formula or a chloride supplement, some did not.[130]

Future lawsuits are inevitable. Undoubtedly Syntex will use the defense in these suits that the children would have developed abnormally notwithstanding the defective formula.[131] A plaintiff will need to produce evidence tending to show that the child was not suffering from the symptoms of metabolic alkalosis before consuming the defective formula or that the formula was a substantial contributing factor to their conditions. The burden on the plaintiff will be difficult in view of the fact that even though physicians

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[123] S. REP. No. 96-916, *supra* note 89, at 2877. Section 7 is one of the uncodified sections of the Infant Formula Act.

[124] A team of investigators at the National Institute of Health has begun a five-year follow-up study in conjunction with the Center for Disease Control to examine infants who consumed a defective formula and subsequently developed metabolic alkalosis. Report, *Follow-up Formula-Associated Illness in Children,* MORBIDITY AND MORTALITY WEEKLY REP. 124 (March 21, 1980); Report, *Follow-up Study of Infants Fed Soybean-Based Formulas,* 96 PUB. HEALTH REP. 93, 94 (Jan.-Feb. 1981).

[125] "Infants grow most rapidly during the first 4 to 6 months of life. Nutrient requirements are most critical in this period during which nutritional deficiencies can have lasting effects on growth and development." *Nutritional Quality Hearings, supra* note 3, at 133. *See* Simopoulos & Bartter, *supra* note 60, at 204.

[126] *See generally, Senate Hearings, supra* note 23, at 49-71 (testimony of parents); *Nutritional Quality Hearings, supra* note 3, at 1.

[127] *Senate Hearings, supra* note 24, at 50 (testimony of Mrs. Barbara Gasper).

[128] *Id.* at 57 (testimony of Mrs. Janet Marcantonio).

[129] *Id.* at 49 (testimony of Mrs. Lynne Pilot).

[130] *Id.* at 65 (testimony of Mrs. Lynne Pilot).

[131] Although it is probably inadmissable evidence, it is interesting to note that due to adverse publicity, *inter alia,* Syntex discontinued production and distribution of Neo-Mull-Soy and Cho-Free as of March 31, 1981. *See* letter from Tom Guntly, Manager of Distributor Relations, Syntex Laboratories, Inc., to Syntex Customers, March 13, 1981.

suspect that delayed or improper development is linked to chloride deficiencies at an early age, there is as yet no conclusive medical evidence.[132]

The passage of the Infant Formula Act will tend to reduce the chances of a similar incident occurring in the future. Although many criticize increased government regulation in principle, Larry Pilot, a former FDA attorney and father of an affected child, has remarked that increased regulation does not necessarily mean that there cannot also exist excellent regulation.[133] In retrospect, he, along with many others, probably wishes that the Infant Formula Act had been in effect just a few years earlier.

RANDAL D. SHIELDS

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[132] Holliday, *supra* note 60, at 640; Linshaw, *supra* note 60, at 640; Simopoulos & Bartter, *supra* note 60, at 204. Children who suffered from pyloric stenosis, a chloride deficiency in infants caused by vomiting due to an obstruction at the outlet of the stomach, have been shown to have discrete learning disorders five to fifteen years later, primarily in tasks that require short-term memory or arithmetic. Holliday, *supra* note 60, at 640 (citing Klein, *Effects of Starvation in Infancy (Pyloric Stenosis) on Subsequent Learning Abilities*, 87 J. PEDIATRICS 8 (1975)). Also, studies with rats who were injected with angiotensin (a chemical that is increasingly produced in the presence of hypokalemic alkalosis) five minutes after they had learned a passive avoidance task, showed that the retention of that task was disrupted twenty-four hours later. Simopoulos & Bartter, *supra* note 60, at 204. These results are mentioned in a report by Dr. Shane Roy, who cogently summarizes the prognosis for children affected by the chloride-deficient formulas:

> The medical literature contains numerous references covering the long-term effects of protein-calorie malnutrition upon both experimental animals (rats, pigs, dogs) and upon human infants. The effects of chloride malnutrition (or deprivation) upon the developing human infant, however, has not been studied to my knowledge.
>
> There are 3 specific causes of chloride deficiency either from losses through the gastrointestinal tract or the genito-urinary system. These are 1) pyloric stenosis (vomiting from an obstruction at the outlet of the stomach), 2) congenital chloride diarrhea, and 3) Bartter's syndrome (chloride loss in the urine).
>
> Children with pyloric stenosis leading to significant malnutrition in the first few months of life when compared to their unaffected siblings at school age show a significant lack of short-term memory and an impairment of attention span. No differences in overall intelligence was appreciated between the groups. (Journal of Pediatrics, April 1975). Many children with Bartter's syndrome show significant degrees of mental impairment (Nephron 23:130, 1979).
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> Patients with chloride diarrhea (J. Pediatrics 91:738, 1977) (Acta Endocrinologica 55, 1967) or Bartter's syndrome (Pediatrics 46:344, 1970), which of course are lifetime illnesses, frequently have significant kidney damage and may, in fact, succumb to kidney failure.
>
> At the present time our infants affected by Neo-Mull-Soy® are being followed prospectively to gain data which will hopefully answer [the] question. I have noted developmental delay and significantly smaller head circumferences (indicating subnormal brain growth) in the majority of affected infants which I have examined. The degree of recovery, however, will take several years of testing and observation to come to a final conclusion . . .
>
> [M]ore questions than answers have been raised by this recent discovery. I am optimistic that answers can be obtained but I have occasional pangs of fear that there are not too many investigators who share my concerns for these affected infants. I also know that there are many infants who were surely affected by the formula but who have escaped medical detection just because the formula was changed and the infants were not critically evaluated medically.

Letter from Shane Roy, M.D. to Michael C. Jainchill, Esq. (Dec. 19, 1979) (submitted to the Medical Malpractice Exchange of the Association of Trial Lawyers of America).

[133] Pilot, *Regulatory Update—New Enforcement Approaches and International Device Regulation*, 34 FOOD DRUG COSM. L.J. 132 (1979). (Mr. Pilot's comment was not made in the context of the infant formula chloride deficiency problem.).