COMMENTS

Infant Formula: An Exploration of Administrative, Judicial, and Legislative Avenues to Recovery for Formula Associated Injuries in the United States

This comment examines administrative, judicial, and legislative approaches to the regulation of infant formula marketing and production in the United States. It analyzes the applicability of traditional malpractice and products liability theories to formula associated injuries. The comment proposes a model statute that imposes a duty on hospitals to instruct and warn new mothers in formula use, modifies hospital participation in formula marketing practices, and provides a civil remedy for formula associated injuries.

INTRODUCTION

Widespread use of infant formula[1] is associated with increased infant mortality and illness in the United States and abroad.[2] Safe use of in-

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[1] "Infant formula" is a general term referring to a variety of human milk substitutes. Starting formulas (Similac® and Enfamil®) are constituted to meet all the nutritional requirements of the healthy infant up to the age of six months. Adapted formulas, or humanized formulas (SMA® and Similac 60/40®), are formulas whose composition is closer to human milk than starting formulas. Medical or therapeutic formulas (soy isolate based Isomil® and Prosobee®) are recommended for specific disorders such as cow's milk intolerance, prematurity, and congenital metabolic anomalies. Brostrøm, *Human Milk and Infant Formulas: Nutritional and Immunological Characteristics* in TEXTBOOK OF PEDIATRIC NUTRITION 41-43 (R. Suskind ed. 1981) [hereafter Suskind].

[2] Generally, babies fed infant formula have higher rates of illness and death than breast-fed infants. Petition to Alleviate Domestic Infant Formula Misuse and Provide Informed Infant Feeding Choice: An Administrative Petition to the United States Food and Drug Administration and Department of Health and Human Services 22-28 (1981) [hereafter FDA Petition] (filed by Lois Salisbury and Angela Blackwell, Public Advocates, Inc., San Francisco, California, on Behalf of Petitioners) (petition has been pending without action since June 17, 1981) (copy on file at U.C. Davis Law Review office). *See* notes 23-39 and accompanying text *infra*.

fant formula requires proper mixing, sterilization, and refrigeration.[3] These prerequisites present significant obstacles to safe use for low income, technology-poor, non-English speaking populations[4] among whom formula use is most prevalent.[5] Infant health problems caused by formula misuse have reached epidemic proportions among certain of these groups.[6]

Although infant formula use may be appropriate in some circumstances, breast-feeding is the medically preferred mode of infant feeding and is recommended by the American Academy of Pediatrics.[7] The World Health Organization encourages breast-feeding[8] and has promulgated guidelines for international marketing of infant formula.[9]

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[3] FDA Petition, note 2 *supra*, at 35-36.

[4] *Id.* at 35. One pediatric clinic with a large number of undocumented Hispanic patients reports that inability to sterilize or refrigerate formula is a major cause of infant diarrhea and gastroenteritis. The most severe problems develop when infants are fed undiluted concentrate formula because of the mothers' inability to read the label. *Id.* at 36. Native Americans living on reservations experience similar problems with formula use. A number of physicians working on the Navajo Indian reservation have stated that "formula is virtually impossible to use safely there." *Id.* at 41. Ready-to-feed formula cannot be used safely in many areas "because the water is contaminated with arsenic and radioactivity which are *concentrated* rather than removed, by boiling." *Id.* at 41. Further, inability to distinguish the labels of ready-to-feed from concentrate formula results in the feeding of undiluted concentrate, causing severe health problems including chronic diarrhea (the primary cause of infant mortality on the reservation). *Id.* at 41-42.

[5] Statistics show that formula feeding is declining among the middle class at the same time it is rising among low income minority groups. *Id.* at 35. According to Dr. Buford Nichols, Professor of Pediatrics at Baylor College of Medicine, "More than 90 percent of the women having babies in the private hospitals of Houston are breast-feeding their infants." Similar figures are reported for private hospitals in Denver, San Francisco, Connecticut and New York. *Id.* at 7-8. A 1978-1979 reservation-wide study of Navajo infant feeding patterns disclosed that only 17.3% of the women breast-fed for two months or longer. *Id.* at 15. According to the Center for Disease Control's United States-Mexico Border Survey, breast-feeding among Mexican-Americans dropped from 30% to 18% between 1971 and 1979. *Id.* at 13.

[6] *Id.* at 36.

[7] The Committee on Nutrition of the American Academy of Pediatrics strongly recommends breast-feeding whenever possible. *New Views on Feeding Babies*, HARV. MED. SCH. HEALTH LETTER Aug. 1982, at 3.

[8] WORLD HEALTH ORGANIZATION, INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES (1981). The Code affirms the right of every child to be nourished adequately and recognizes "that breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants . . . ." *Id.* at 10.

[9] *Id.* at 16-17. The Code directs governments to objectively inform families and health practitioners about modes of infant feeding. *Id.* at 15. In addition, it prohibits both direct advertising or promotion of formula and distribution of samples, products,

Many of the health problems associated with infant formula use in developing nations are also present in the United States,[10] but no domestic marketing guidelines exist.[11]

In the United States, the marketing and promotional policies of the formula industry play a significant role in the adoption of formula feeding, particularly among low income mothers.[12] Infant formula is indirectly advertised to consumers;[13] the industry promotes the product through the auspices of hospitals.[14] In exchange for free formula and other services, hospitals agree to distribute formula discharge packs to new mothers.[15] The "gift" of free formula is often viewed by the mother as a physician's prescription for optimum infant health.[16] Consequently, most new mothers continue to feed their infants the brand of formula given to them by the hospital.[17] Because of this marketing

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and utensils that may encourage bottle-feeding. *Id.* at 16-17. Health care systems are prohibited from using the services of formula manufacturers. *Id.* at 17. Health workers are directed to encourage breast-feeding. *Id.* at 18. Employees of formula manufacturers are prohibited from educating new mothers on the use of infant formula. *Id.* at 19-20. In addition, it requires clear, easily readable labels on infant formula that must: (a) inform the consumer that breast-feeding is superior; (b) state that formula should only be used upon the advice of a health care worker; and (c) give adequate instructions for use and a warning about the hazards of infant formula use. *Id.* at 20-21.

Implementation and monitoring of the Code is achieved by individual nations through their own national policies, including laws and regulations. Manufacturers and distributors of the products are responsible for monitoring their marketing practices in accordance with the Code. *Id.* at 21-22.

The World Health Assembly adopted the Code in May 1981 with 118 votes in favor, 3 abstentions, and 1 against. *Id.* at 7. The dissenting nation was the United States. N.Y. Times, May 21, 1981 at 1, col. 3.

[10] D. JELLIFFE & E. JELLIFFE, HUMAN MILK IN THE MODERN WORLD: PSYCHOSOCIAL, NUTRITIONAL, AND ECONOMIC SIGNIFICANCE 241-99 (1978) [hereafter JELLIFFE & JELLIFFE]. *See also* notes 27-40 and accompanying text *infra*.

[11] An administrative petition to the United States Food and Drug Administration and the Department of Health and Human Services proposing marketing guidelines has been pending without action since June 17, 1981. FDA Petition, note 2 *supra*.

[12] *Id.* at 79-101. *See also* notes 46-48 and accompanying text *infra*.

[13] *See* FDA Petition, note 2 *supra*, at 79-106.

[14] *Id.*

[15] *Id.* at 82-84. *See also* note 46 *infra*.

[16] *Id.* at 96. When infants are discharged with a particular type of formula, low-income mothers assume it is "what the doctor wants them to have . . . ." According to the New York City Bureau of Maternity Services and Family Planning, giving free samples of formula upon discharge "implies that the hospital endorses the product . . . ." N.Y. Times, Oct. 27, 1981, at C6, col. 2. *See also* note 47 *infra*.

[17] FDA Petition, note 2 *supra*, at 95. "Ninety-three percent of the infants discharged on a particular brand remain on that brand for at least six months." *Id.*

practice, low income women, who are least able to afford formula and whose children are nutritionally most at risk, provide the dominant market for infant formula.[18]

This comment examines administrative, judicial, and legislative approaches to the regulation of infant formula marketing practices. It begins by describing the development of infant formula, the harms associated with its indiscriminate use, and federal regulation of the product. Next, it analyzes the applicability of traditional tort theories of malpractice and products liability to formula associated injuries. Finding these remedies inadequate, this comment proposes a model statute. The model statute imposes an affirmative duty on hospitals to instruct medical personnel and new mothers in the proper use of infant formula and warn them of the health consequences of improper use. The model statute also modifies hospital participation in infant formula marketing and provides a civil remedy for infant formula associated injuries.

I. SCOPE OF THE PROBLEM

Infant formula, a manufactured substitute for human milk, was first introduced for use by infants who could not be breast-fed.[19] For other infants, breast-feeding is the medically preferred mode of feeding because the nutritional and immunologic benefits of human milk cannot be duplicated by artificial milks.[20] Furthermore, unless artificial milks are used as medically advised and prepared as directed, side effects may endanger infant health and development.[21]

Early in this century, health professionals voiced concern about the effect of bottle-feeding on infant health.[22] Studies comparing the mor-

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[18] FDA Petition, note 2 *supra*, at 7-9. Studies indicate that economically and educationally disadvantaged women are substantially less likely to breast-feed than their upper and middle income counterparts. In a 1979-1980 New York City Department of Health study of women giving birth in New York City hospitals, 82% of low income women planned to use infant formula. N.Y. Times, Oct. 27, 1981, at C6, col. 2. Ironically, a 1976 study reported that a lactating mother's dietary supplements for one year would cost $167, whereas feeding concentrated formula would cost $227; powdered formula, $247; and ready-to-feed formula, $276. FDA Petition, note 2 *supra*, at 48-49.

[19] *See* FDA Petition, note 2 *supra*, at 80; J. GOLDFARB & E. TIBBETTS, BREASTFEEDING HANDBOOK: A PRACTICAL REFERENCE FOR PHYSICIANS, NURSES AND OTHER HEALTH PROFESSIONALS 19-20 (1980) [hereafter GOLDFARB & TIBBETTS].

[20] TEXTBOOK OF PAEDIATRIC NUTRITION 49-59 (D. McLaren & D. Burmen eds. 1982). *See generally* JELLIFFE & JELLIFFE, note 10 *supra*; HARV. MED. SCH. HEALTH LETTER, note 7 *supra*, at 3 (recommends breast-feeding in first 24 hours after delivery so that infant will benefit from immunologic factors in mother's pre-milk colostrum).

[21] *See* notes 27-39 and accompanying text *infra*.

[22] FDA Petition, note 2 *supra*, at 22-24. Scientific journals published mortality and

tality rates of breast-fed, partially breast-fed, and wholly bottle-fed infants found that bottle-fed infants had mortality rates three to six times higher than partially or wholly breast-fed infants.[23] Similarly, recent morbidity studies have found the incidence of illness and hospitalization among bottle-fed infants in middle income populations to be two to three times higher than that of breast-fed infants.[24] Among low income groups the incidence of harm was as much as ten times higher.[25] This section describes some of these harms and discusses the role of infant

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morbidity studies. *See, e.g.*, Davis, *Statistical Comparison of the Mortality of Breast-fed and Bottle-fed Infants*, 5 AM. J. DISEASES OF CHILDREN 234 (1913); Woodbury, *The Relation Between Breast and Artifical Feeding and Infant Mortality*, 2 AM. J. HYGIENE 668 (1922).

[23] A descriptive (i.e., not controlled) study of mortality rates in eight American cities between 1911 and 1916 found mortality rates of exclusively bottle-fed infants to be four times higher than among exclusively breast-fed infants. Socio-economic status affected the mortality rates: lowest income bottle-fed infants had a 50% higher mortality rate than highest income bottle-fed infants. Woodbury, note 22 *supra*, at 686. *See also* Howarth, *The Influence of Feeding on the Mortality of Infants*, 2 LANCET 210 (1905) (three times higher mortality rate among wholly bottle-fed infants, 1900-1903). This study did take into account factors unrelated to feeding that caused early death in some infants.

[24] Two studies of normal infants examined regularly at a pediatric clinic in upstate New York found the incidence of significant illness to be two to three times higher among bottle-fed infants than among breast-fed infants. Hospital admissions for the bottle-fed infants were also three times higher. In addition, serious illness seldom occurred among the breast-fed infants. Cunningham, *Morbidity in Breast-fed and Artificially Fed Infants*, 90 J. PEDIATRICS 726, 727 (1977); Cunningham, *Morbidity in Breast-fed and Artificially Fed Infants II*, 95 J. PEDIATRICS 685, 686-89 (1979). A British study of mortality rates of infants served by a welfare clinic found mortality rates six times higher among minimally breast-fed infants compared to a maximally breast-fed group. Robinson, *Infant Morbidity and Mortality, A Study of 3,266 Infants*, 1 LANCET 788, 788 (1951). *See also* Fallot, Boyd & Oski, *Breastfeeding Reduces Incidence of Hospital Admissions for Infection in Infants*, 65 PEDIATRICS 1121, 1121 (1980) (hospital admissions of breast-fed infants were 11.0% instead of expected frequency of 25.2%); Larsen & Homer, *Relation of Breast Versus Bottlefeeding to Hospitalization for Gastroenteritis in a Middle-Class U.S. Population*, 92 J. PEDIATRICS 417, 418 (1978) (of 107 infants admitted to California hospital for acute gastroenteritis with symptoms including diarrhea, weight loss, and vomiting, less than 1% were being breast-fed, although incidence of breast-feeding in community was 28%).

[25] French, *Relationship of Morbidity to the Feeding Patterns of Navajo Children from Birth Through Twenty-Four Months*, 20 AM. J. CLINICAL NUTRITION 375, 382 (1967) (on Navajo Reservation in New Mexico and Arizona, bottle-fed infants were hospitalized ten times more frequently than breast-fed infants); Schaefer, *Otitis Media and Breastfeeding*, 62 CAN. J. PUB. HEALTH 478, 488 (1971) (among Eskimo population of Canadian Northwest, bottle-fed infants were nine times more likely to incur otitis media). *See also* studies cited in FDA Petition, note 2 *supra*, at 27-28.

formula manufacturers in promoting formula feeding in the United States.

A. Physiological and Psychological Harms

Substituting the use of infant formula for breast-feeding may cause children substantial physical and psychological harms. These harms are extensively documented.[26] The range of physical illnesses includes severe diarrhea (often resulting in death),[27] severe dehydration,[28] gastroenteritis,[29] allergy related vomiting,[30] otitis media,[31] lower respiratory infections and colds,[32] dental caries,[33] obesity,[34] milk intolerance,[35] necrotizing enterocolitis,[36] and impaired physical growth[37] and brain development.[38] Equally important, breast-feeding fosters mother-infant

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[26] *See* notes 27-39 and accompanying text *infra*.

[27] JELLIFFE & JELLIFFE, note 10 *supra*, at 262. For a discussion of the preventive effects of human milk, see P. Sunshine, *Use of Human Milk in the Treatment of Patients with Intractable Diarrhea of Infancy and the Short Gut Syndrome*, in HUMAN MILK: ITS BIOLOGICAL AND SOCIAL VALUE 214 (S. Freier & A. Eidelman eds. 1980) [hereafter Freier & Eidelman].

[28] Picon, *Evaluation and Treatment of the Malnourished Child* in Suskind, note 1 *supra*, at 218-219. *See* GOLDFARB & TIBBETTS, note 19 *supra*, at 63.

[29] Gastroenteritis is an "inflammation of the stomach and intestines." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 635 (25th ed. 1974) [hereafter DORLAND'S]. *See* JELLIFFE & JELLIFFE, note 10 *supra*, at 263; Larsen & Homer, note 24 *supra*, at 417.

[30] *See* GOLDFARB & TIBBETTS, note 19 *supra*, at 63.

[31] Otitis media is an "inflammation of the middle ear" which "may be marked by pain, fever, abnormalities of hearing, deafness, tinnitus, and vertigo." DORLAND'S, note 29 *supra*, at 1109. *See* Beauregard, *Positional Otitis Media*, 70 J. PEDIATRICS 294 (1971); JELLIFFE & JELLIFFE, note 10 *supra*, at 291; Schaeffer, note 25 *supra*, at 478.

[32] JELLIFFE & JELLIFFE, note 10 *supra*, at 245.

[33] Dental caries, commonly known as "cavities," is "a disease of the calcified tissues of the teeth." DORLAND'S, note 29 *supra*, at 265. *See* JELLIFFE & JELLIFFE, note 10 *supra*, at 110; Tank & Storvick, *Caries Experience of Children One to Six Years Old in Two Oregon Communities*, 70 J. AM. DENTAL A. 394, 395 (1965) (breast-feeding for more than three months resulted in statistically significant reduction of 46-59% in caries activity).

[34] GOLDFARB & TIBBETTS, note 19 *supra*, at 62-63.

[35] *Id.* at 62.

[36] Necrotizing enterocolitis is "an acute superficial necrosis of the mucosa of the small intestine and colon." DORLAND'S, note 29 *supra*, at 523. Infants who are especially susceptible to this disease (e.g., premature infants) may benefit from the preventive effect of breast milk. Brostrøm, *Human Milk and Infant Formulas: Nutritional and Immunological Characteristics*, in Suskind, note 1 *supra*, at 57.

[37] Viteri, *Primary Protein-Energy Malnutrition: Clinical, Biochemical, and Metabolic Changes* in Suskind, note 1 *supra*, at 213.

[38] *Id.* For a discussion of the effect of nutrition on brain development, see MALNU-

bonding in a mutually interactive and nurturant mother-child relationship.[39] Artificial feeding may disrupt this vital developmental process, resulting in far reaching consequences for both mother and child. In many areas of the country, more than eighty percent of low income mothers feed their babies infant formula;[40] hence the public health problem is widespread.

B. Domestic Marketing Practices

As a result of the public acceptance of infant formula, sales in the United States amount to more than one-half billion dollars annually.[41] Three major competitors share these sales: Abbott Laboratories (a Ross Laboratories subsidiary) with fifty-five percent of the market; Bristol-Meyers (a Mead Johnson subsidiary) with thirty-five percent; and American Home Products (a Wyeth Laboratories subsidiary) with nine percent.[42]

The infant formula industry's domestic marketing and promotional policies greatly contribute to demand for the product. The manufacturers indirectly promote their products to consumers[43] by developing cooperative relationships with hospitals and hospital personnel.[44] The manufacturers hire and train an estimated fifteen hundred detail personnel to call upon hospitals and health professionals as often as once a week.[45] The detail person offers numerous free services, equipment and supplies (including incubators, architectural planning, research funds, and medical information for hospital use), in addition to discharge packs of formula for distribution to departing mothers.[46] Because the

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TRITION AND INTELLECTUAL DEVELOPMENT (J. Lloyd-Still ed. 1976).

[39] GOLDFARB & TIBBETTS, note 19 *supra*, at 68. *See also* Blumen, *Maternal-Infant Bonding*, in Freier & Eidelman, note 27 *supra*, at 277; Los Angeles Dept. of Health, Morbidity and Health Statistics, MATERNAL-INFANT BONDING, BREAST-FEEDING, AND OTHER IMPORTANT COMPONENTS IN THE PREVENTION OF CHILD ABUSE (June 1978).

[40] FDA Petition, note 2 *supra*, at 7-18. For example, in Durham, North Carolina, 1-1.5% of low income Blacks breast-fed in 1980; in Los Angeles, California, 5-15% of low income Hispanics and Blacks breast-fed in 1977; in Wichita, Kansas, under 10% of low income Blacks breast-fed in 1980; in Del Rio, Texas, 1% of Mexican-Americans breast-fed in 1980.

[41] *Id.* at 79.

[42] *Id.*

[43] *Id.* at 81. Promotional efforts focus almost exclusively on hospitals and medical professionals.

[44] *Id.* at 81-93.

[45] *Id.* at 81-82.

[46] *Id.* at 82-98. Many hospitals are under pressure to accept these offers because the drug companies are major resources for research, printing services, equipment, and ar-

formula is distributed by the hospital, new mothers may reasonably infer that formula is the medically preferred mode of infant nutrition.[47] This assumption is particularly prevalent among new mothers who do not speak English or who lack the educational background to make an informed choice.[48]

II. ADMINISTRATIVE REGULATION

A recent rulemaking petition[49] filed with the United States Food and Drug Administration and the Department of Health and Human Services[50] documents the intensive marketing and promotional policies of the major infant formula producers which influence hospitals, health

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chitectural planning. Frequently, these services redound, directly or indirectly, to the benefit of the drug companies. For example, architectural advice may be aimed at a building design featuring a central nursery that facilitates bottle-feeding and makes breast-feeding institutionally inconvenient. Ross Laboratories designs approximately 200 facilities a year. *Id.* at 84.

[47] Distribution of free formula discharge packs by the hospital conveys a strong message, especially to the non-English speaking patient; it is interpreted as something she *should* do. FDA Petition, note 2 *supra*, at 63-68. One 17-year-old woman interviewed at New York's Metropolitan Hospital said she would use Similac because "[t]he doctor here picks the milk for the baby." N.Y. Times, Oct. 27, 1981, at C6, col. 2.

[48] FDA Petition, note 2 *supra*, at 63-68.

[49] FDA Petition, note 2 *supra*.

[50] The Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and the Department of Agriculture possess the statutory authority to regulate the labeling of infant formula, its use in government nutrition programs, and its use in hospitals receiving federal Medicaid funds. HHS is the principal executive agency responsible for administrating the nation's health, social service, and income maintenance programs. UNITED STATES GOVERNMENT MANUAL 257 (1982-1983). The FDA is an agency within HHS specifically responsible for regulating food and drug safety. *Id.* at 265. The Department of Agriculture administers the Special Supplementation Program for Women, Infants and Children (WIC). This program provides specified nutritious food supplements to pregnant and nursing women up to six months postpartum and to children up to five years of age. Program participants are determined by competent health professionals to be health risks because of inadequate nutrition and low income. *Id.* at 109. The FDA has authority under 21 U.S.C. § 371a (1976 & Supp. V 1981) to promulgate regulations to implement the Food, Drug, and Cosmetic Act and authority under 15 U.S.C. §§ 1451-1454 (1976 & Supp. V 1981) to fully implement the Fair Packaging and Labeling Act. The Secretary of HHS has authority to prescribe standards to ensure adequate education in nutrition, and to issue educational materials for use in the WIC program. The Secretary of HHS has broad discretionary authority under 42 U.S.C. § 3501 (1976 & Supp. IV 1980) to guide national health policies. Under the Social Security Act, 42 U.S.C. § 1396(a)(4) (1976 & Supp. IV 1980) the Secretary may impose conditions of participation on hospitals before federal funds are disbursed under the Medicaid Program.

care professionals, and new mothers to adopt the practice of infant formula feeding.[51] The administrative relief proposed by the petition addresses the problems posed by indiscriminate formula distribution and inadequate labeling.[52] The current administration, however, op-

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[51] The promotional practices of the formula manufacturers and the acquiescence of many hospitals to these practices are major obstacles to the adoption of breast-feeding by new mothers. The Secretary of Health and Human Services (HHS) has the authority to eliminate that obstacle in all hospitals receiving federal funds. The petition urges HHS to require each hospital receiving Medicaid funds to certify that 1) it does not dispense free formula gift packages; 2) it administers an educational and support program which encourages women to breast-feed; 3) it provides instruction regarding the proper use of infant formula to women who choose bottle-feeding, or must do so for medical reasons; and 4) it provides in-hospital support for the lactating woman. FDA Petition, note 2 *supra*, at 134-37.

[52] Many parents cannot distinguish the ready-to-use formula from the concentrate because of illiteracy or lack of labeling in their native tongue; most infant formula cans appear similar. Feeding of undiluted concentrate formula may cause gastroenteritis, long-term kidney damage and bleeding to the brain. FDA Petition, note 2 *supra*, at 36. *See* notes 106-08 and accompanying text *infra*. In response to these problems, the Petitioners request the Commissioner to issue the following regulation:

Chapter IV of the Federal Food, Drug, and Cosmetic Act Section 403 (21 U.S.C. § 343) shall be enforced through a regulation which reads:

> [Sec. 403. A food shall be deemed to be misbranded . . . .]
> if it is an infant formula as defined in Section 201(aa) of this Act unless,
> (1) its labeling bears
> (A) the color assigned to that particular type of formula in an industry-wide color coding system to be prescribed by the Secretary, and
> (B) bilingual descriptions of the type of formula, instructions as to its use and warnings if the formula is to be sold in areas with significant non-English speaking populations, and
> (C) a prominent endorsement of breastfeeding [sic] as the superior form of infant feeding emphasizing the immunological and nutritional benefits of human milk, and
> (D) a warning indicating that infant formula should be used only when breast-feeding is not feasible, and
> (E) a warning as to possible health hazards associated with improper use of infant formula, and
> (F) graphic instructions illustrating clearly
> (i) the need for dilution of concentrated formula; and
> (ii) the proper proportions of formula and water required; and
> (iii) the need for sterilization of any equipment coming into contact with the infant formula;
> (iv) the need for cooling the boiled formula before feeding; and
> (v) the need to refrigerate any excess formula for later use, and

poses federal regulatory intervention in favor of marketplace adjustments.[53] Because the administrative agencies are headed by presidential appointees, the regulatory process is responsive to the views of the executive branch of government.[54] As a result of aversion to federal regulation, promulgation of administrative solutions to the infant formula problem is unlikely at the present time.[55]

Although future administrations may regard administrative regulation more favorably, the political nature of the regulatory process itself raises a barrier to effective action.[56] Administrative agencies are subject to organized pressure from the groups they regulate.[57] As a result, the agencies develop political ties to their constituencies[58] that greatly influence whether or not regulation will be forthcoming and what form it will take. Thus, even if the President were more favorably disposed toward regulation, actual promulgation of administrative rules would probably face intense opposition from the formula industry. Therefore, it is necessary to explore other avenues of regulating formula distribution and preventing infant formula injuries.

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(2) it is packaged in such a manner that concentrate, ready to feed and powder are easily distinguishable by their differently-shaped packaging.

Id. at Appendix B-1 to B-2.

[53] Estimating that it costs business $100 billion a year to comply with federal regulations, President Reagan has selected a sweeping approach to regulatory reform. Weiss, *Reagan, Congress Planning Regulatory Machinery Repair*, CONG. Q., March 7, 1981 at 409. *See also* N.Y. Times, Jan. 23, 1982, at 1, col. 3 (discussion of President Reagan's efforts to deregulate industry in his first year).

[54] "The agency head who disagrees with the task force [Presidential Task Force on Regulatory Relief] about a proposed rule has the authority to issue it. . . . [b]ut that action could be risky, meaning that the President of the United States might decide to remove such a person from office." James C. Miller, III, Executive Director of the Task Force, in *Deregulation HQ, An Interview on the New Executive Order with Murray L. Weidenbaum and James C. Miller III*, 5 REGULATION, Mar.-Apr. 1981, at 16.

[55] FDA Petition, note 2 *supra*, has been pending without action since June 17, 1981.

[56] Administrative agencies must respond to at least two constituencies for every regulated activity: the producers of the regulated product and those seeking regulation to further what they perceive to be the "public interest." The extent to which administrative agencies have been "captured" by the clientele they regulate has been the subject of much scholarly commentary. *See, e.g.*, L. DODD & R. SCHOTT, CONGRESS AND THE ADMINISTRATIVE STATE (1979); G. MCCONNELL, PRIVATE POWER AND AMERICAN DEMOCRACY (1966).

[57] G. MCCONNELL, PRIVATE POWER AND AMERICAN DEMOCRACY 162 (1966).

[58] *Id.* at 162-65.

III. TORT LIABILITY

Injuries caused by infant formula may be compensable under traditional tort theories of malpractice and products liability. Plaintiffs[59] may bring suit against manufacturers for supplying a defective product[60] or against hospitals for providing formula to new mothers without adequate warnings and instructions for use. This section analyzes civil remedies for infant formula injuries.

A. Malpractice Liability

Theories of hospital tort liability have evolved to keep pace with the expanding role of the modern hospital.[61] At early common law, a hospital was not liable for the negligent acts of its physicians and nurses.[62] Today, liability of a hospital is premised upon the doctrines of *respondeat superior* and corporate negligence.[63] Under *respondeat superior*,

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[59] An infant who becomes ill from the use of infant formula may bring suit for his own injuries. His parents may also have a cause of action for expenses, wrongful death, and loss of services. *See generally* W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 125 (4th ed. 1971) [hereafter W. PROSSER].

[60] A few plaintiffs will trace their injuries to defectively manufactured formula. For example, in 1979, SMA was recalled for improper homogenization that caused gastrointestinal injuries. In the same year, Syntex Laboratories recalled two soybean-based formulas that were deficient in chloride. Chloride deficiency may cause metabolic alkalosis in infants, a condition characterized by inability to gain weight, diarrhea or constipation, and lethargy. Infants injured by such a deficiency might have a cause of action in negligence or strict products liability. Instances of defectively manufactured formula are relatively rare, however, and unrelated to the numerous injuries resulting from improperly prepared and stored formula. FDA Petition, note 2 *supra*, at 33-44.

[61] A. SOUTHWICK, THE LAW OF HOSPITAL AND HEALTH CARE ADMINISTRATION, 347-58 (1978) [hereafter SOUTHWICK]. For a discussion of a hospital's expanding duty to treat in emergency medical situations, see Comment, *To Treat or Not to Treat: A Hospital's Duty to Provide Emergency Care*, 15 U.C. DAVIS L. REV. 1047 (1982).

[62] *See, e.g.*, Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 105 N.E. 94 (1914) (hospital not vicariously liable for physicians' and nurses' negligence because they employ special knowledge and skills and are not controlled by hospital). For a discussion of hospital liability, see HOSPITAL LIABILITY: LAW AND TACTICS, 532-34, 682 (M. Bertolet & L. Goldsmith eds. 1980) [hereafter Bertolet & Goldsmith].

[63] Bing v. Thunig, 2 N.Y.2d 656, 667, 143 N.E.2d 3, 8, 163 N.Y.S.2d 3, 11 (1957) (rejected professional skill theory in favor of applying *respondeat superior* to all negligent employees of hospital); Darling v. Charleston Community Memorial Hosp., 33 Ill. 2d 326, 333-34, 211 N.E.2d 253, 255-58, *cert. denied*, 383 U.S. 946 (1966) (hospital owed non-delegable duty of care directly to patient; duty was breached by its failure to require consultation or review of attending physician's work when patient's leg became gangrenous). The term "corporate negligence" was not used by the court; it was affixed by commentators. *See generally* SOUTHWICK, note 61 *supra*, at 358; Bertolet &

the hospital is liable when an employee acts negligently within the scope of employment even though the hospital itself has not violated a duty owed to the patient.[64] Corporate negligence, on the other hand, is the breach of a duty owed directly to the patient by the hospital.[65] Regardless of the theory asserted by the plaintiff, liability may be found by establishing a breach of the institutional or professional standard of care.[66]

Goldsmith, note 62 *supra*, at 532-34, 562-65; W. PROSSER, note 59 *supra*, § 69 at 458.

[64] Beeck v. Tucson Gen. Hosp., 18 Ariz. App. 165, 167, 500 P.2d 1153, 1155 (1972) (rejected *Schloendorff* rule); Bing v. Thunig, 2 N.Y.2d 656, 667, 143 N.E.2d 3, 8, 163 N.Y.S. 2d 3, 11 (1957) (applying *respondeat superior* to negligent hospital employees); Rabon v. Rowan Memorial Hosp., Inc., 269 N.C. 1, 9-12, 152 S.E.2d 485, 491-92 (1967) (rejecting implied waiver theory and professional skill theory) *See also* Brown v. La Societé Française de Bienfaisance Mutuelle, 138 Cal. 475, 476, 71 P. 516, 516-17 (1903) (*respondeat superior* applied to salaried physician treating hospital's patient); Bowers v. Olch, 120 Cal. App. 2d 108, 116, 260 P.2d 997, 1002 (2d Dist. 1953) (hospital liable for resident surgeon's negligence); Bernardi v. Community Hosp. Ass'n, 166 Colo. 280, 285, 443 P.2d 708, 713 (1968) (hospital liable for nurse's negligent administration of injection); Gilstrap v. Osteopathic Sanitorium Co., 224 Mo. App. 798, 811, 24 S.W.2d 249, 256 (1929) (hospital liable for staff physician's negligence in performing tonsilectomy); Sepaugh v. Methodist Hosp., 30 Tenn. App. 25, 37, 202 S.W.2d 985, 990 (1946) (hospital liable for negligent acts of its interns).

[65] Darling v. Charleston Community Memorial Hosp., 33 Ill. 2d 326, 333-34, 211 N.E.2d 253, 258, *cert. denied*, 383 U.S. 946 (1966). Hospitals have a duty to select their employees with reasonable care. Mitchell County Hospital Authority v. Joiner, 229 Ga. 140, 143, 189 S.E.2d 412, 414 (1972); Hoke v. Glenn, 167 N.C. 594, 598, 83 S.E. 807, 808 (1914). They must also supervise everyone who practices medicine on their premises. Darling v. Charleston Community Memorial Hosp., 33 Ill. 2d at 333-34, 211 N.E.2d at 258.

[66] Kastler v. Iowa Methodist Hosp., 193 N.W.2d 98, 103 (Iowa 1971) (hospital negligent for allowing epileptic psychiatric patient to take shower unassisted); Burks v. Christ Hosp., 19 Ohio St. 2d 128, 131, 249 N.E.2d 829, 831 (1969) (reversing directed verdict for hospital and remanding for jury to determine whether failure to raise bedrails on heavily sedated patient was negligence); Johnson v. Grant Hosp., 31 Ohio App. 2d 118, 122, 286 N.E.2d 308, 311 (1972) (hospital must exercise reasonable care to prevent suicide of patient with known suicidal tendencies).

Some courts have carefully considered whether providers of medical services should be strictly liable for "defective" medical services. In Hoven v. Kelble, 79 Wis. 2d 444, 256 N.W.2d 379 (1977), the court concluded that moving from the malpractice concept to a strict liability system would be "dubious" because unknown costs are involved. *Id.* at 471, 256 N.W.2d at 392. The court noted that strict liability has not been a panacea in products cases. *Id.* at 471, 256 N.W.2d at 392. Other courts have refused to extend principles of strict liability to medical services. *Id.* at 464, 265 N.W.2d at 389. *See, e.g.*, Barton v. Owen, 71 Cal. App. 3d 484, 498, 139 Cal. Rptr. 494, 502 (2d Dist. 1977) (rejected *Helling* standard of reasonable prudence). *Cf.* Helling v. Carey, 83 Wash. 2d 514, 520, 519 P.2d 981, 989 (1974) (Utter, J., concurring) (ophthalmologists negligent in not performing simple, inexpensive, risk-free test for glaucoma). *See* notes 80-82 and

To recover under either negligence theory, the plaintiff must be able to show that the breach of the applicable standard of care was the cause in fact and proximate cause of the injury.[67] Even when causation in fact is provable, the standard of care presents obstacles to recovery against hospital employees or the institution itself for formula associated injuries.

1. Standard of Care

The standard of care for hospitals is similar to that required of physicians and nurses. Both have a legal duty to act in accordance with standards that will not subject their patients to unreasonable risk of harm.[68] For medical professionals, the standard requires that care be consistent with the level of knowledge and skill commonly possessed by members of the profession in good standing.[69] For hospitals, the standard of care requires exercise of the degree of care, skill, and diligence generally used by hospitals in the community and such reasonable care and attention to the safety of patients as the patients' mental and physical conditions, if known, may require.[70]

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accompanying text *infra*. One court has extended strict liability to the "mechanical and administrative services" of hospitals. *See* Johnson v. Sears, Roebuck & Co., 355 F. Supp. 1065, 1067 (E.D. Wis. 1973); Recent Developments, 41 TENN. L. REV. 392 (1974). Conceivably, hospitals might be strictly liable for providing formula to infants without obtaining parental consent. *Cf.* Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (negligence not to obtain informed consent).

[67] Hicks v. United States, 368 F.2d 627, 633 (4th Cir. 1966) (when prompt surgery would have saved patient's life, physician's negligent diagnosis was proximate cause of death); Kuhn v. Baker, 13 N.E.2d 242, 247 (Ohio 1938) (despite evidence of negligent treatment, directed verdict was proper in absence of evidence that physician's negligence was proximate cause of patient's death). *See* W. PROSSER, note 59 *supra*, § 30 at 143.

[68] *See, e.g.*, Fitzgerald v. Manning, 679 F.2d 341, 346 (4th Cir. 1982) (physician must exhibit degree of skill and diligence of ordinary, prudent practitioner in his field and community). *See also* W. PROSSER, note 59 *supra*, § 31 at 145; RESTATEMENT (SECOND) OF TORTS § 282 (1965).

[69] *See, e.g.*, Ayers v. Parry, 192 F.2d 181, 184 (3d Cir. 1951) (in practice of medicine, physician impliedly promises that he possesses a degree of knowledge and skill comparable to that held by other members of profession); Adkins v. Ropp, 105 Ind. App. 331, 334, 14 N.E.2d 727, 728 (1938) (physician assuming treatment of patient impliedly contracts that he possesses and will exercise reasonable and ordinary skills of profession). *See also* W. PROSSER, note 59 *supra*, § 32 at 162-65.

[70] *See, e.g.*, Garfield Memorial Hosp. v. Marshall, 204 F.2d 721, 726 (D.C. Cir. 1953) (hospital breached its duty to give maternity patient in premature labor such reasonable care as her known condition required); Marks v. St. Francis Hosp. and School of Nursing, 179 Kan. 268, 273, 294 P.2d 258, 261 (1956) (in action for wrongful death of hospitalized psychiatric patient, no liability when hospital authorities knew patient was suffering from a mental disorder but were not expressly informed of pa-

Lacking training in medical science, courts hesitate to substitute their judgment of reasonable medical care for the medical community's judgment.[71] Thus, determination of a standard of care for hospitals and medical professionals relies to a great extent on customary practice, as determined by expert testimony.[72] In principle, customary practice within the profession is strongly suggestive but not dispositive of a standard of care.[73] It is not to be regarded as the equivalent of due care.[74] Nevertheless, customary practice is usually held to be controlling; juries

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tient's suicidal tendencies or need for physical restraint).

[71] "Doctors — or at least the Legislature — rather than judges are in the best position to balance the professional relationship between doctor and patients . . . ." Truman v. Thomas, 27 Cal. 3d 285, 299, 611 P.2d 902, 910, 165 Cal. Rptr. 308, 316, (1980) (Clark, J., dissenting). *See also* Barton v. Owen, 71 Cal. App. 3d 484, 494, 139 Cal. Rptr. 494, 499 (2d Dist. 1977) (general rule concerning medical negligence is that liability may not be imposed as a matter of law); Swanson v. Brigham, 18 Wash. App. 647, 651, 571 P.2d 217, 219 (1977) (plaintiff has burden of establishing standard of professional practice at time of injury and violation of standard by testimony of professional peers of defendant).

[72] *See, e.g.*, Boyce v. Brown, 51 Ariz. 416, 420-21, 77 P.2d 455, 457 (1938) (standard of medical practice in community must be shown by affirmative evidence; no liability unless physician breaches recognized standard of good medical practice); Trindle v. Wheeler, 133 P.2d 425, 427-29 (4th Dist. 1943) (officially depublished), *rev'd on other grounds*, 23 Cal. 2d 330, 143 P.2d 932 (1943) (standard of good medical practice is solely within knowledge of physicians and surgeons and must be established by expert testimony; in absence of expert testimony, presumption is that physician exercised ordinary care and skill); Adkins v. Ropp, 105 Ind. App. 331, 335, 14 N.E.2d 727, 729 (1938) (expert testimony required to determine the standard of care because of scientific nature of issues; jury cannot set standards of care and skill). For a discussion of the medical profession's unique privilege of setting its own legal standards of conduct, see W. PROSSER, note 59 *supra*, § 32 at 164-65.

[73] Texas & Pacific Ry. v. Behmer, 189 U.S. 468, 470 (1903) ("What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not.") (Holmes, J.). *See also* The T. J. Hooper, 60 F.2d 737, 740 (2d Cir.), *cert. denied*, 287 U.S. 662 (1932) ("A whole calling may have lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.") (Hand, J.). For further discussion regarding custom, see RESTATEMENT (SECOND) OF TORTS, § 295A comments b and c (1965); James, *Particularizing Standards of Conduct in Negligence Trials*, 5 VAND. L. REV. 697, 709-14 (1952); Comment, *Custom and Negligence*, 42 COLUM. L. REV. 1147 (1942). *See also* discussion in notes 79-86 and accompanying text *infra*.

[74] Leonard v. Watsonville Community Hosp., 47 Cal. 2d 509, 519, 305 P.2d 36, 42 (1956) (custom is some evidence of what should be done but it does not conclusively establish standard of care); Ales v. Ryan, 8 Cal. 2d 82, 100, 64 P.2d 409, 418 (1936) ("General negligence cannot be excused on the ground that others in the same locality practice the same kind of negligence.").

are instructed that a plaintiff cannot recover unless she can prove the defendant's conduct was not in accordance with recognized medical practice.[75] If the action alleged to be negligent is widely practiced, it will be extremely difficult to demonstrate breach of the standard of care because courts will not usually disregard custom.

This judicial reliance on custom presents a difficult hurdle for infant formula plaintiffs. Ninety percent of American hospitals receive free infant formula from manufacturers for distribution to hospital patients.[76] It is precisely this customary practice that contributes to infant morbidity and mortality[77] and which plaintiffs must allege to be negligent.

Judicial reluctance to depart from the standard of care customary in the medical community is understandable when complex medical problems are involved. It is less appropriate in the infant formula context because the need for a higher standard of care to protect patients from foreseeable injury is apparent to lay persons without medical expertise.[78]

One of the few cases to disregard medical custom and judicially impose a standard of care is *Helling v. Carey*.[79] The defendant ophthalmologists were held to be negligent as a matter of law for failing to administer a simple glaucoma test to a twenty-three year old patient despite uncontradicted expert testimony that it was the universal prac-

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[75] *See* cases cited in note 72 *supra*; *see also* Hallinan v. Prindle, 17 Cal. App. 2d 656, 662, 62 P.2d 1075, 1078 (1936) (evidence showed it was customary practice for physicians not to examine medications prepared by nursing staff; physician not liable for injecting surgical patient with disinfectant instead of anesthetic); Hunt v. Bogalusa Community Medical Center, 289 So. 2d 219, 220-21 (La. 1973) (as matter of law, hospital breached duty of care to 65 year old post-operative patient when it failed to provide full guardrails and patient fell from bed; reversed on showing by expert testimony that partial rails were standard practice of area hospitals). *See also* Comment, *Custom and Negligence*, 42 COLUM. L. REV. 1147, 1163 (1942) ("[I]n medical malpractice cases, failure to establish non-conformity [with custom] is fatal to the plaintiff, and the defendant who establishes conformity is entitled to a directed verdict.").

[76] *See* FDA Petition, note 2 *supra*, at 82. *See also* note 46 and accompanying text *supra*.

[77] *See* FDA Petition, note 2 *supra*, at 22-34, 63-66.

[78] Some cases have held that lay knowledge is sufficient to establish negligence of medical practitioners. Leonard v. Watsonville Community Hosp., 47 Cal. 2d 509, 514, 305 P.2d 36, 39 (1956) (surgical clamp left in abdomen obviously negligent, even to lay persons); Ybarra v. Spangard, 25 Cal. 2d 486, 494, 154 P.2d 687, 691 (1944) (shoulder injury during appendectomy raised inference of negligence under doctrine of *res ipsa loquitur*). For a discussion of jury's competence to find medical custom negligent, see W. PROSSER, note 59 *supra*, § 32 at 165.

[79] 84 Wash. 2d 514, 519 P.2d 981 (1974).

tice of the profession not to administer the test to patients under the age of forty.[80] The Washington Supreme Court held that reasonable prudence may require a standard of practice that is higher than that exercised by the relevant professional community.[81] The case is controversial and has not been followed in other jurisdictions.[82]

The medical procedure mandated by the *Helling* court is simple, in-

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[80] *Id* at 519, 519 P.2d at 983.

[81] *Id.* The standard of reasonable care should have been followed as a matter of law rather than following the standard of the profession of ophthalmology. In response, the state legislature enacted a statute abolishing the *Helling* rule and expressly requiring proof of departure from the standards of the medical profession in order to sustain recovery in medical malpractice actions:

> In any civil action for damages based on professional negligence against a hospital . . . or against the personnel of a hospital . . . or a member of the healing arts including, but not limited to, a physician . . . an osteopathic physician . . . a chiropractor . . . a dentist . . . a podiatrist . . . or a nurse . . . the plaintiff in order to prevail shall be required to prove by a preponderance of the evidence that the defendant failed to exercise that degree of skill, care and learning possessed by other persons in the same profession and that as a proximate result of such failure the patient suffered damages.

WASH. REV. CODE § 4.24.290 (1975). The Washington Supreme Court subsequently held that the statute did not abolish the *Helling* rule of reasonable prudence as a standard of medical care. Gates v. Jensen, 92 Wash. 2d 246, 253, 595 P.2d 919, 924 (1979) (instruction on *Helling* rule should have been given when plaintiff alleged facts similar to *Helling*; ophthalmologist failed to administer a visual field test which could have shown existence of open angle glaucoma, although test was simple, inexpensive, risk free, and conclusive). The *Helling* rule has been affirmed in subsequent Washington state cases. *See* Harbeson v. Parke-Davis, Inc., 98 Wash. 2d 460, ____, 656 P.2d 483, 489-93 (1983) (wrongful birth action affirming but not applying *Helling* rule because physician's alleged negligence occurred before formulation of *Helling* standard); Keogan v. Holy Family Hosp., 95 Wash. 2d 306, 328, 622 P.2d 1246, 1260 (1980) (affirming *Helling*; failure of emergency room physician to administer an EKG to middle-aged man with chest pain rushed to hospital by ambulance in middle of night was negligent as matter of law); Harris v. Groth, 31 Wash. App. 876, ____, 645 P.2d 1104, 1107-08 (1982) (affirms *Helling* rule in glaucoma cases); Meeks v. Marx, 15 Wash. App. 571, 577, 550 P.2d 1158, 1162 (1976) (limiting *Helling* to "its own unique facts, i.e., cases in which an opthalmogist [sic] is alleged to have failed to test for glaucoma under the same or similar facts").

[82] Truman v. Thomas, 27 Cal. 3d 285, 295, 611 P.2d 902, 908, 165 Cal. Rptr. 308, 314 (1980). The *Truman* court distinguished *Helling*, which found negligence as a matter of law for failure to recommend a glaucoma test. In *Truman*, a physician recommended pap smear but failed to inform the patient of the risks of declining test. Barton v. Owen, 71 Cal. App. 3d 484, 498, 139 Cal. Rptr. 494, 502 (2d Dist. 1977) ("We thus disapprove of the Washington case of *Helling v. Carey* . . . . It does not state the law in California.").

expensive, risk free, and conclusive.[83] It is analogous to the measures needed to enable patients to make an informed choice about formula feeding and to ensure safe formula preparation and use.[84] Informing mothers of the health consequences of formula use and the hazards arising from improper use is simple, risk free, and effective. Although such instructions and warnings are not routinely given by medical professionals or hospitals, the need for such measures is reflected in the large number of infants injured by improper formula use.[85] Thus, the *Helling* approach could be used when the standard of the profession does not offer reasonable protection to the patient. Yet, given the judicial response to *Helling*,[86] it is unlikely that courts will resolve the formula problem by judicially declaring the standard of care. Thus, plaintiffs would be restricted to actions against the manufacturers of infant formula.

B. Products Liability

The plaintiff injured by infant formula may be able to sue manufacturers and distributors under products liability theories that protect consumers from hazards caused by defects in the design, manufacture, and marketing of commercial products.[87] Design defects are often deter-

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[83] Helling v. Carey, 83 Wash. 2d 514, 519, 519 P. 2d 985, 981 (1974) (intraocular pressure test with Schiotz tonometer and Goldman applanometer is quick and involves no damage to patient).

[84] *See* note 90 and accompanying text *infra*.

[85] *See* notes 23-39 and accompanying text *supra*.

[86] *See, e.g.*, Barton v. Owen, 71 Cal. App. 3d 484, 139 Cal. Rptr. 494 (2d Dist. 1977).

[87] A manufacturing defect is present when a product comes off an assembly line in a substandard condition. *See, e.g.*, Lewis v. American Hoist Derrick Co., 20 Cal. App. 3d 570, 580, 97 Cal. Rptr. 798, 804 (2d Dist. 1971) (manufacturer mistakenly furnished rope too small for its crane). Products with design defects have been manufactured as intended, but the design is excessively dangerous. *See, e.g.*, Barker v. Lull Engineering Co., 20 Cal. 3d 412, 429-32, 573 P.2d 443, 454-56, 143 Cal. Rptr. 225, 236-38 (1978) (defective loader). A product may be created exactly as intended by the manufacturer yet still be unduly hazardous as a result of a marketing process which does not adequately warn or instruct users. *See* RESTATEMENT (SECOND) OF TORTS, § 388 (1965).

The standard of care has traditionally been higher than ordinary in the manufacture of food products. Eisenbeiss v. Payne, 42 Ariz. 262, 270, 25 P.2d 162, 166 (1933) ("highest duty known to the law"). According to the doctrine of privity, only parties in privity of contract had a cause of action for negligence against a vendor or manufacturer. Winterbottom v. Wright, 10 M. & W. 109, 115, 152 Eng. Rep. 402, 405 (Ex. 1842) ("The only safe rule is to confine the right to recover to those who enter into the contract.") (Anderson, J.). However, food was among products considered inherently

mined by either a consumer expectations test or a risk-benefit analysis.[88] Plaintiffs may argue that infant formula is defective in design because it does not duplicate the nutrients and immunologic factors found in human milk.[89] Formula, however, is a relatively nutritious substitute for human milk when properly used,[90] and it is lifesaving for infants who cannot be breast-fed.[91] Thus, if a risk-benefit test were applied to the design of formula, its general safety and usefulness would probably outweigh the risk of injury.[92]

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dangerous and thus exempted from the doctrine in the early twentieth century. Huset v. J. I. Case Threshing Mach. Co., 120 F. 865, 870 (8th Cir. 1903) (third parties suffering injury from products "imminently dangerous to the life or health of mankind" have cause of action in negligence against the manufacturer or vendor). *See also* RESTATEMENT (SECOND) OF TORTS § 395 comment a (1965).

[88] According to the consumer expectations test, a product with an obvious (patent) defect is not defective in design if the consumer may reasonably anticipate and appreciate the dangerous condition of the product. Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 69 Wis. 2d 326, 332, 230 N.W.2d 794, 798 (1975). A product is "unreasonably defective" when "it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." RESTATEMENT (SECOND) OF TORTS § 402A comment g (1965). To be "unreasonably dangerous . . . . [t]he article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." RESTATEMENT (SECOND) OF TORTS § 402A comment i (1965).

A risk-benefit analysis weighs the probability and gravity of injury inherent in a product's design against the interest that must be sacrificed to avoid the risk of injury. *See* United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) (duty of barge owners to prevent barge from breaking free of its moorings); Conway v. O'Brien, 111 F.2d 611, 612 (2d Cir. 1940), *rev'd on other grounds*, 312 U.S. 492, 493 (1941) (automobile driver's duty of care).

[89] Brostrøm, *Human Milk and Infant Formulas: Nutritional and Immunological Characteristics*, in Suskind, note 1 *supra*, at 41; Gaull, *What is Biochemically Special About Human Milk?*, in BREASTFEEDING AND FOOD POLICY IN A HUNGRY WORLD 217 (D. Rafael ed. 1979); HARV. MED. SCH. HEALTH LETTER, note 7 *supra*, at 3.

[90] Proper use requires dilution of formula with uncontaminated water, sterilization of bottles and equipment, and refrigeration of leftover formula. FDA Petition, note 2 *supra*, at 34-38. The person preparing the formula must be able to read and comprehend the instructions in English on the cans. *Id.* Any or all of these requisites for safe use is likely to be absent in low income populations, which suffer disproportionately high rates of infant mortality and morbidity. *Id.* at 22-28. The public health problem is significant since in many areas of the country more than 80% of low income mothers feed their babies infant formula. *See* note 40 *supra*.

[91] *See* studies cited in note 89 *supra*.

[92] It may be useful to view infant formula as if it were an unavoidably unsafe product which cannot be made completely safe in the current state of the art. *See* RESTATEMENT (SECOND) OF TORTS § 402A comment k.

Further, the deficiencies of artificial milk substitutes have only recently been identi-

Plaintiffs tracing their injuries to defectively manufactured formula have a cause of action in negligence[93] or strict liability.[94] They may also have causes of action for breach of express[95] and implied[96] warranties. Express warranty, for example, may apply to statements on labels saying infant formula is "for baby's first 12 months."[97] Breach of implied warranty, which is similar to strict liability in tort,[98] may be advanced

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fied as a result of advances in biology and biochemistry. Thus, infant formula manufacturers may not be liable for design defects in the product because the deficiencies were unknown at the time of product design. *Cf.* Bruce v. Martin-Marietta Corp., 544 F.2d 442, 447 (10th Cir. 1976) (ordinary consumer would not expect aircraft made in 1952 to have safety features of one made in 1970); Pontifex v. Sears, Roebuck & Co., 226 F.2d 909, 910 (4th Cir. 1955) (power mower not defective in design because it does not have safety features of later models).

[93] *See, e.g.*, Haynes v. Coca Cola Bottling Co., 39 Ill. App. 3d 39, 45, 350 N.E.2d 20, 25 (1976) (quality control system held to be so inadequate as to be negligent). *See also* RESTATEMENT (SECOND) OF TORTS § 395 (1965).

[94] *See, e.g.*, Greenman v. Yuba Power Products, Inc., 59 Cal. 2d 57, 64, 27 Cal. Rptr. 697, 701, 377 P.2d 897, 901 (1963) (power tool manufacturer held strictly liable in tort for injury to consumer-purchaser). *See also* RESTATEMENT (SECOND) OF TORTS § 402A (1965) ("[o]ne who sells any product in a defective condition unreasonably dangerous to property is subject to liability for physical harm thereby caused to the ultimate user or consumer"). California requires only that the product be "dangerous." Barker v. Lull Engineering Co., 20 Cal. 3d 413, 435, 573 P.2d 443, 457-58, 143 Cal. Rptr. 225, 239-40 (1978).

[95] *See* U.C.C. § 2-313 (protects consumers who buy products in reliance on seller's affirmation, promise, description, or sample and later suffer injury because the product is defective). *See, e.g.*, Dessert Seed Co. v. Drew Farmers Supply, Inc., 248 Ark. 858, 861-62, 454 S.W.2d 307, 310-11 (1970) (express warranty created when seller's tags on bags of tomato seeds described them as "Pink Shipper" variety).

[96] *See* U.C.C. § 2-314 (implied warranty of merchantability assures consumers that goods bought from merchants will meet acceptable trade standards). *See, e.g.*, Kassab v. Central Soya, 432 Pa. 217, 226, 246 A.2d 848, 852 (1968) (injury caused by defective cattlefeed breached implied warranty of merchantability).

[97] If a formula injures an infant in the first 12 months it may be in breach of the warranty arising from the statement on the label. *See* U.C.C. § 2-313. *Cf.* Dessert Seed Co. v. Drew Farmers Supply, Inc., 248 Ark. 858, 454 S.W.2d 307 (1970).

[98] An injured consumer need not prove negligence under either strict liability or implied warranty. The latter, of course, imposes conditions of privity and notice not required in strict liability. *See* Greeno v. Clark Equipment Co., 237 F. Supp. 427 (N.D. Ind. 1965) (defective fork-lift truck caused personal injuries); Greenman v. Yuba Power Products, Inc., 59 Cal. 2d 57, 64, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1962) (power tool manufacturer held strictly liable in tort for injury to consumer-purchaser); Escola v. Coca Cola Bottling Co., 24 Cal. 2d 453, 461-68, 150 P.2d 436, 440-44 (1944) (setting forth doctrine of strict liability) (Traynor, J., concurring); RESTATEMENT (SECOND) OF TORTS § 402A (1965); J. WHITE & R. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE 325 (2d ed. 1980).

The tort standard requires the product to be "unreasonably dangerous," making it

as an alternative cause of action.[99]

Liability may also arise from a failure to warn of hazards incident to a product's use.[100] This cause of action stems from negligence[101] and strict liability[102] theories. A product is unduly hazardous to consumers who are inadequately warned of its potential or hidden dangers,[103] or

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narrower than the contract standard. RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965). The California Supreme Court, however, has held that plaintiff need only prove that the product is "dangerous." Barker v. Lull Engineering Co., 20 Cal. 3d 412, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).

[99] *See* note 98 *supra*.

[100] Burch v. Amsterdam Corp., 366 A.2d 1079, 1080 (D.C. App. 1976) (personal injuries resulted from use of flammable floor tile adhesive); W. PROSSER, note 59 *supra*, at § 96; RESTATEMENT (SECOND) OF TORTS § 388(c) (1965). Warnings of the hazards from normal use may be inadequate if the information given is incomplete. Dougherty v. Hooker Chemical Corp., 540 F.2d 174, 181-82 (3d Cir. 1976) (jury could find that magnitude of risk with normal use was not set forth). Hazards of misuse must be pointed out. Bean v. Ross Mfg. Co., 344 S.W.2d 18, 24 (Mo. 1961) (sufficient evidence for finding of negligence based on inadequacy of warning). Especially dangerous misuse must also be pointed out. Hill v. Husky Briquetting, Inc., 54 Mich. App. 17, 25, 220 N.W.2d 137, 141 (1974) (sufficiency of warning regarding risk of asphyxiation when product used for indoor heating purposes is jury question).

[101] *See, e.g.*, Rawlings v. D. M. Oliver, Inc., 97 Cal. App. 3d 890, 896, 159 Cal. Rptr. 119, 121 (4th Dist. 1979) (negligence when manufacturer knows or should know product is dangerous and fails to use due care in warning); Casetta v. United States Rubber Co., 260 Cal. App. 2d 792, 818, 67 Cal. Rptr. 645, 661-62 (1st Dist. 1968) (negligent failure to warn renders product defective); Gherna v. Ford Motor Co., 246 Cal. App. 2d 639, 651, 55 Cal. Rptr. 94, 102 (1st Dist. 1966) (negligent not to warn of known danger); Reynolds v. Natural Gas Equipment, 184 Cal. App. 2d 724, 737-38, 7 Cal. Rptr. 879, 887-89 (1st Dist. 1960) (failure to warn of possible explosion if gas burner used with air cap shut).

[102] *See, e.g.*, Barker v. Lull Engineering Co., 20 Cal. 3d 412, 428, 573 P.2d 443, 453, 143 Cal. Rptr. 225, 235 (1978) (manufacturer of defective loader held strictly liable in tort). *See also* Kay v. Cessna Aircraft Co., 548 F.2d 1370, 1372 (9th Cir. 1977) (manufacturer may be held liable for injuries proximately caused by failure to warn); Dimond v. Caterpillar Tractor Co., 65 Cal. App. 3d 173, 181 n.6, 134 Cal. Rptr. 895, 900 n.6 (4th Dist. 1976) (non-defective product may become defective by failure to warn); Midgley v. S. S. Kresge Co., 55 Cal. App. 3d 67, 74, 127 Cal. Rptr. 217, 221 (3d Dist. 1976) (inadequate instructions and warnings made product defective); Canifax v. Hercules Powder Co., 237 Cal. App. 2d 44, 53, 46 Cal. Rptr. 552, 558 (3d Dist. 1965) (product otherwise free of defect may become defective when placed in hands of user without suitable warning). *See also* RESTATEMENT (SECOND) OF TORTS § 402A comment j (1965) (product may be defective if proper instructions and warnings omitted).

[103] Phillips v. Kimwood Machine Co., 269 Or. 485, 496-97, 525 P.2d 1033, 1038 (1974) ("failure to warn may make a product unreasonably dangerous"). *See also* Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 88 (4th Cir. 1962) (hidden danger in ingesting furniture polish); Boyl v. California Chemical Co., 221 F. Supp. 669, 675-76

who are inadequately instructed in its use.[104] The directions for use on infant formula cans may be inadequate. For example, only one of three major companies marketing formula in the United States warns users that improperly prepared formula may cause illness.[105] None of the

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(D. Or. 1963) (failure to warn that weed killer contained long lasting, earth contaminating poison); Crane v. Sears Roebuck & Co., 218 Cal. App. 2d 855, 859-60, 32 Cal. Rptr. 754, 756-57 (4th Dist. 1963) (failure to warn that product was combustible); Moran v. Faberge, Inc., 273 Md. 538, 554, 332 A.2d 11, 21 (1975) (failure to warn of hidden danger of igniting perfume); Incollingo v. Ewing, 444 Pa. 263, 291, 282 A.2d 206, 220 (1971) (no warning of possible side effect of drug); Rumsey v. Freeway Manor Minimax, 423 S.W.2d 387, 393 (Tex. App. 1968) (failure to warn of no antidote for roach poison). *See generally* W. PROSSER, note 59 *supra*, § 98.

[104] *See, e.g.*, Harp v. Montgomery Ward & Co., 336 F.2d 255, 258-59 (9th Cir. 1964) (necessity of ground for electric clothes drier); Boyl v. California Chemical Co., 221 F. Supp. 669, 675-76 (D. Or. 1963) (consumer not warned of long lasting contamination of earth used for disposal of weed killer); Michael v. Warner/Chilcott, 91 N.M. 651, 653-55, 579 P.2d 183, 185-87 (1978) (consumers not adequately warned against excessive use of over-the-counter drug); McCully v. Fuller Brush Co., 68 Wash. 2d 675, 679-81, 415 P.2d 7, 10-11 (1966) (instructions failed to warn that cleaning solution may be harmful after prolonged contact with skin). Manufacturers are generally required to give both directions for use and warnings. Hubbard-Hall Chemical Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965) (inadequacy of label instructions and warnings on poisonous insecticide); Burch v. Amsterdam Corp., 366 A.2d 1079, 1084 (D.C. App. 1976) (instructions did not warn users of product's combustibility); Rawlings v. D. M. Oliver, Inc., 97 Cal. App. 3d 890, 896, 159 Cal. Rptr. 119, 121 (4th Dist. 1979) (manufacturer negligent when he knows or should know product is dangerous and fails to use due care in warning); Midgley v. S. S. Kresge Co., 55 Cal. App. 3d 67, 71-74, 127 Cal. Rptr. 217, 219-21 (3d Dist. 1976) (inadequate instructions and warnings made product defective); RESTATEMENT (SECOND) OF TORTS § 388 and § 402A comment j (1965); W. PROSSER, note 59 *supra*, at § 96. For a more detailed discussion, see Keeton, *Products Liability — Inadequacy of Information*, 48 TEX. L. REV. 398 (1970); Kidwell, *The Duty to Warn, A Description of the Model of Decision*, 53 TEX. L. REV. 1375 (1975); Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW. L.J. 256 (1969); Noel, *Recent Trends in Manufacturers' Negligence as to Design, Instructions or Warnings* 19 SW. L.J. 256 (1965); Noel, *Manufacturer's Negligence of Design or Directions for Use of a Product*, 71 YALE L.J. 816 (1962); Twerski, Weinstein, Donaher, & Piehler, *The Use and Abuse of Warnings in Product Liability — Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495 (1976); Note, *Products Liability — Prescription Drugs — Manufacturer's Liability for Failure to Warn the Medical Profession of Possible Side Effects*, 52 IOWA L. REV. 1213 (1967); Note, *The Manufacturer's Duty to Warn of Dangers Involved in Use of a Product*, 1 WASH. U.L.Q 206 (1967); Annot., *Failure to Warn as Basis of Liability Under Doctrine of Strict Liability in Tort*, 53 A.L.R. 3d 239 (1973).

[105] The labels on Similac® (manufactured by Ross Laboratories) warn that "[r]epeated use of formula prepared following improper dilution instructions could cause illness."

other manufacturers warn against the serious hazards of feeding infants overly diluted or concentrated formula.[106] Further, instructions are printed only in English, but many purchasers in the United States cannot speak or read English.[107] It is foreseeable, therefore, that some consumers may prepare the formula incorrectly.[108] Consequently, their in-

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[106] Because human infants begin life *ex utero* in an extremely rapid phase of growth (doubling their birth weight in five months), malnutrition resulting from too much, too little, or the wrong kind of food at this stage of life may have significant short and long term effects. Breast milk is species specific for human infants, and even the best artificial milks are not entirely satisfactory. Gaull, *What is Biochemically Special About Human Milk?*, in BREASTFEEDING AND FOOD POLICY IN A HUNGRY WORLD 217 (D. Rafael ed. 1979). *See also* Brostrøm, *Human Milk and Infant Formulas: Nutritional and Immunological Characteristics*, in Suskind, note 1 *supra*, at 41. Feeding of undiluted concentrate formula may cause gastroenteritis, possible long term kidney damage and bleeding to the brain. FDA Petition, note 2 *supra*, at 36.

[107] FDA Petition, note 2 *supra*, at 138. *Cf.* Hubbard Hall Chemical Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965). In *Hubbard*, two Spanish speaking farmworkers died from inhalation of insecticide dust; they could not read the English language warnings on the insecticide bag. The court held that written warnings may be inadequate, if it is foreseeable that the information would be needed by persons of limited education, and that pictographic warning symbols might be required instead.

[108] Manufacturers are often required to give warnings of the dangers of foreseeable misuse. *See, e.g.*, Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 88 (4th Cir. 1962) (foreseeable that infant may consume furniture polish). The California Supreme Court has found that there is no clear distinction between failure to warn and a design defect. Barker v. Lull Engineering Co., 20 Cal. 3d 413, 428, 573 P.2d 443, 453, 143 Cal. Rptr. 225, 235 (1978). Accordingly, the court formulated a two-pronged test. The first prong weighs the benefits of the design against the risk of danger in its use. Application of this test to infant formula might result in a conclusion that the product's general safety and usefulness outweigh the risk of injury. The second prong of the *Barker* test requires the plaintiff to prove "that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or *reasonably foreseeable manner.*" *Id.* at 432, 573 P.2d at 456, 143 Cal. Rptr. at 237 (emphasis added). Thus, according to the *Barker* test, manufacturers of infant formula may be strictly liable for failure to warn users of the defects of the product resulting from foreseeable misuse. *See also* Cavers v. Cushman Motor Sales, Inc., 95 Cal. App. 3d 338, 347-48, 157 Cal. Rptr. 142, 148 (1st Dist. 1979) (foreseeable that driver of golf cart might make sharp turn and cart would overturn); Moran v. Faberge, Inc., 273 Md. 538, 554, 332 A.2d 11, 20-21 (1975) (foreseeable that perfume might be ignited); Haberly v. Reardon Co., 319 S.W.2d 859, 864 (Mo. 1958) (foreseeable that paint might be splashed into eye of painter's helper); Martin v. Bengue, Inc., 25 N.J. 359, 372, 136 A.2d 626, 633 (1957) (foreseeable that bodyrub ointment could give off ignitable vapors). *See generally* W. PROSSER, note 59 *supra*, § 96 at 647-48.

Even warnings against foreseeable misuse may be inadequate if they fail to warn of the serious nature of the results. *See, e.g.*, Seible v. Symons Corp., 221 N.W.2d 50, 57 (N.D. 1974) (warning not to hang off end rail support rods inadequate because seriousness of danger was not conveyed).

fants would be exposed to risk of injury, and manufacturers could be held liable on this ground. Even if manufacturers do place warnings on cans, they may still be liable if the warnings are not reasonably calculated to reach the consumers who will foreseeably suffer injury.[109]

C. Causation in Fact

Under either a negligence or strict liability theory, the plaintiff must show by a preponderance of the evidence that infant formula caused his injuries. Thus, the infant formula plaintiff must show either that infant formula was a substantial and contributing factor to his injury, or that "but for" the use of the formula he would not have been injured.[110]

Causation of some formula related injuries may be proved directly. For example, medical investigation or prompt laboratory testing may link a child's illness with a particular batch of formula. Most cases will not be so simple, however, because many of the injuries associated with infant formula use also have natural causes.[111]

Epidemiologic evidence (circumstantial evidence) may be useful to distinguish formula related injuries from naturally occurring injuries.[112] For example, an injury may be known to occur naturally at a stable or background rate of 100 cases of injury per year in a designated region.[113] After a defendant releases a product or agent known to cause

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[109] Hubbard-Hall Chemical Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965) (pictographic warnings might be required if foreseeable users do not speak or read English).

[110] *See* W. PROSSER, note 59 *supra*, § 41 at 236-44.

[111] *See* notes 29-39 and accompanying text *supra*.

[112] Epidemiology is "the field of medicine concerned with the determination of the specific causes of localized outbreaks of infection, such as hepatitis, of toxic disorders, such as lead poisoning, or any other diseases of recognized etiology." DORLAND'S, note 29 *supra*, at 529. Epidemiologists use observational studies (in contrast to experimental tests which may be impossible to conduct ethically with human subjects) to gain evidence of causal relations. Tests are made to determine whether variation in frequency of disease in different groups is statistically significant. In addition to the estimate of probabilities, statistical techniques such as multiple linear regression are also used to estimate how much of the variation in a dependent variable is correlated with an independent variable. For example, an injury associated with infant formula could be accounted for by the action of the independent variable, mode of feeding. For a discussion of epidemiologic methods, see J. MAUSNER & A. BAHN, EPIDEMIOLOGY 94-140, 307-39 (1974); B. MCMAHON & T. PUGH, EPIDEMIOLOGY: PRINCIPLES AND METHODS 29-46, 47-72, 157-73, 210-32 (1970). *See also* G. FRIEDMAN, PRIMER OF EPIDEMIOLOGY 150-68 (1974).

[113] A similar hypothetical is discussed in Delgado, *Beyond Sindell: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs*, 70 CALIF. L. REV. 881, 884-86 (1982).

the same type of injury, the rate of injury increases to 200 cases per year. If expert testimony establishes that the defendant is the only possible source of the increased incidence, the injury to the class may be "statistically proved."[114]

Two problems confront an infant formula plaintiff attempting to use epidemiologic evidence. First, when the probability that infant formula is the source of the injury is less than fifty percent, the circumstantial evidence may not be sufficient to prove causation because the individual infants who are injured by formula cannot be identified; they are indeterminate.[115] Second, even when an identified (determinate) plaintiff

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[114] *Id.* at 886. Even when an infant formula plaintiff can prove, with probabilities greater than 50%, that the defendant caused her injuries, a clever defendant might challenge such proof by multiplying the probabilities of several elements of a cause of action to arrive at a figure which does not meet the burden of proof. For example, consider a plaintiff who can demonstrate a probability of 70% that her severe ear infection was caused by infant formula use. If she can also prove by statistical evidence that the probability is likewise 70% that the defendant is the correct manufacturer (e.g., based on a 70% share of the market), then the plaintiff might be successful because there is a 70% probability both that the defendant caused the injury and that this plaintiff incurred it.

The defendant manufacturer, however, might combine the probabilities and argue that the plaintiff did not prove her case at all. For example, if the probability that a formula-fed infant's permanent hearing loss resulted from infant formula use is 70%, and the probability that the defendant is the manufacturer is also 70%, then the combined probability of both events is 49% (just short of the 50% necessary for the civil preponderance of the evidence standard of probability). Hence, the infant would be unable to prove that this manufacturer probably injured her in a way that is legally compensable. One difficulty with this line of argument is that theoretically a defendant could multiply the probabilities for every element of a cause of action (duty, breach, causation, injury, damages) and arrive at probabilities of less than 50% in suitable cases. This would generally be considered absurd. It may not be so absurd, however, to combine the probabilities for a single element of the plaintiff's case, namely causation. If a court permitted defendants to take this approach, then many individual plaintiffs would not be able to successfully defend a summary judgment motion. Plaintiffs in class suits proceeding on both indeterminate plaintiff and defendant theories would also encounter difficulties. *See* note 115 *infra*. But unlike the single indeterminate plaintiff, class litigants might be able to preserve a cause of action by only seeking recovery proportional to the reduced (i.e., combined) probability that the members were injured by the defendant. Interview with Richard Delgado, Professor, U.C.L.A. School of Law, in Davis, California (June 26, 1982).

[115] For example, bottle-fed infants comprise a group of persons who suffer similar injuries, some from natural causes and some from infant formula feeding. Although it can be proved that the defendant is responsible for causing many of the victims harm, it is impossible to determine exactly which infants the defendant has harmed because the increased percentage of injury is less than 50%. In other words, potential plaintiffs harmed by the use of infant formula are not determinable under existing theories. Some

can prove causation statistically, she may have difficulty identifying the company that manufactured the formula she used. In the United States, there are three major manufacturers of infant formula, one of which (Abbott Laboratories) controls over fifty percent of the market.[116] In geographic regions where Abbott is the major seller of infant formula, a plaintiff may be able to prove by a preponderance of the evidence that Abbott is the correct defendant.[117] But where Abbott controls less than fifty percent of the market, an infant formula plaintiff faces a problem similar to that presented in *Sindell v. Abbott Laboratories*.[118]

In *Sindell*, the plaintiff could not identify which of eleven manufacturers produced the drug, diethylstilbestrol (DES), that caused her cancer.[119] Thus, under traditional tort theories, she could not prove causation. However, because the injury was so serious, the plaintiff was faultless, all the defendants were negligent, and the plaintiff could not reasonably be expected to identify which defendant had actually caused

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injuries caused by infant formula may be compensable, however, under a recently proposed theory of recovery which relaxes cause-in-fact rules for indeterminate plaintiffs. Delgado, *Beyond Sindell: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs*, 70 CALIF. L. REV. 881 (1982). When the plaintiff establishes a prima facie case, the burden shifts to the defendant to prove noncausation for each injury. *Id.* at 899.

Under the indeterminate plaintiff theory, the plaintiff class is represented by a class proxy who sues for the statistically provable number of claims attributable to the defendant's actions; the plaintiff distributes the amount recovered among the class. *Id.* at 900. Thus, the indeterminate plaintiffs receive a pro rata recovery based on the increased statistical incidence of injury to their class. *Id.* at 901. Hence, if the increase in injuries to the class were 40%, the class as a whole would recover 40% of the cost of the total injury. In sum, plaintiffs in the zone of risk who suffered injury are compensated, and tortfeasors pay only the amount for which they are liable.

The indeterminate plaintiff theory has only limited applicability to infant formula injuries. Its use is restricted to stable population groups with measurable and constant background rates of the disease or injury in question. Some of the population groups in which infant formula harms occur may meet these criteria. For example, potential classes might be formed within isolated communities of Native Americans, Blacks, and Hispanics. Even when a suitable class can be formed, however, the theory's requirement that the defendant be the only possible human cause of injury would limit application of the theory to injuries which are not related to consumer misuse. In addition, the indeterminate plaintiff theory has only recently been proposed and has not yet been tested in any court. For all these reasons, the theory is probably of little help to the majority of infant formula plaintiffs.

[116] *See* note 42 and accompanying text *supra*.

[117] *See* the market share approach to identifying defendants in Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 449 U.S. 912 (1980).

[118] *Id.*

[119] *Id.* at 593-94, 607 P.2d at 925, 136 Cal. Rptr. at 133.

her injury,[120] the court relaxed causation in fact requirements and shifted the burden of proof to the defendants to establish that they were not the cause in fact of the injury.[121]

Infant formula plaintiffs might argue that their situation is analogous to that of *Sindell* and, therefore, courts should relax the traditional standards for proof of causation. However, two distinctions between *Sindell* and infant formula plaintiffs may prevent recovery. First, the plaintiff and her parents in *Sindell* were faultless, contributing in no way to her injury.[122] In contrast, many infant formula injuries are associated with consumer misuse.[123] Second, in *Sindell*, the chemical composition of the drug administered to the plaintiff's mother did not vary with the manufacturer.[124] Infant formulas, however, vary considerably in composition.[125] Thus, because the infant formula plaintiff may not be faultless and because the product is not fungible, courts may be reluctant to apply the market share approach of *Sindell* to infant formula cases.

In summary, some infant formula injuries may be compensable under theories of malpractice and products liability. Most plaintiffs, however, will find it difficult to prove causation. In malpractice suits against hospitals and physicians, they will face an additional hurdle in proving that the customary standard of care has been violated. Therefore, the next section proposes a model statute to provide remedies for infant formula injuries and to prevent future injury.

IV. PROPOSED MODEL STATUTE

The problems associated with infant formula use are susceptible of administrative, judicial, or legislative intervention. The improbability of administrative relief,[126] coupled with the inadequacy of existing tort law,[127] indicates the advisability of a legislative solution. Toward this end, a model statute is proposed below and set out fully in the appendix.

The health problems associated with infant formula are well docu-

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[120] *Id.*

[121] *Id* at 610-13, 607 P.2d at 936-37, 163 Cal. Rptr. at 144-45.

[122] *Id.* at 594, 607 P.2d at 926, 163 Cal. Rptr. at 133.

[123] *See* notes 105-09 and accompanying text *supra.*

[124] 26 Cal. 3d at 594, 607 P.2d at 926, 163 Cal. Rptr. at 134.

[125] *See* note 1 *supra.*

[126] *See* notes 53-58 and accompanying text *supra.*

[127] *See* Section III and accompanying text *supra.*

mented.[128] These problems are most severe within minority and low income population groups in which inadequate instruction in safe formula preparation and use can lead to injury and death in the neonate.[129] The model statute specifically addresses the needs of these high risk populations by requiring the state department of health to develop and implement an intensive educational program.

The educational program would be directed to two groups: medical professionals and nursing mothers.[130] Many medical professionals have not had adequate training in medical management of breast-feeding problems.[131] Consequently, inappropriate advice may be offered for common and easily remedied problems.[132] A recent study reported that fifty-three percent of the physicians and thirty-two percent of the nurses surveyed offered inappropriate advice for common breast-feeding problems.[133] Thus, a successful educational program should encompass health professionals as well as nursing mothers.

Accordingly, the proposed program has two components. The first would require the state department of health to develop and implement an educational program for hospital based medical professionals. This component would inform medical professionals that there are sound scientific bases[134] for promoting breast-feeding and instruct them in the management of routine breast-feeding problems. The second component proposes similar educational programs for new mothers. Equipped with the skills developed in the first component, hospital based medical professionals would implement the second component by informing all mothers of the benefits of breast-feeding and instructing women who

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[128] *See* notes 27-39 and accompanying text *supra*.

[129] *See* FDA Petition, note 2 *supra*, at 7-18, 22-28.

[130] An educational program similar to the one proposed by the model statute was enacted by the North Dakota legislature in response to another infant health problem, phenylketonuria (PKU). The statute required an educational program among medical professionals and the citizens of the state regarding the cause, prevention and treatment of PKU. *See* N.D. CENT. CODE § 25-17-01 (1978).

[131] *See* FDA Petition, note 2 *supra*, at 75-78.

[132] A recent survey noted, "[W]hen mothers report difficulties with breast-feeding such as an inadequate milk supply (the most frequent reason given for weaning), many pediatricians respond by suggesting solids . . . supplemental formula or even weaning, rather than encouraging . . . build up [of the] milk supply through more frequent nursing sessions and greater intake of fluids." Cole, *Breastfeeding in the Boston Suburbs in Relation to Personal-Social Factors*, 16 CLINICAL PEDIATRICS 352, 355 (1977).

[133] A. Naylor, *Assessment of Advice Offered for Breast Engorgement* (April 1980) (unpublished study, Univ. of Cal., San Diego Med. Sch.) (copy on file at U.C. Davis Law Review office).

[134] *See* FDA Petition, note 2 *supra*, at 34-44.

choose to bottle-feed in the proper use of infant formula.

Both components emphasize the special needs of high risk populations including non-English speaking patients,[135] low income patients,[136] and patients without access to refrigeration or uncontaminated water supplies.[137] Requiring education and instruction in proper formula use would eliminate many of the factors that contribute to infant morbidity and mortality.

An infant formula plaintiff's burden of proof with respect to the hospital's standard of care is virtually an impossible one;[138] plaintiffs are often unable to demonstrate breach of the duty of care when hospitals follow the customary practice giving rise to the injury.[139] Therefore, the proposed model statute imposes a statutory duty on hospitals to provide instructions and warnings regarding infant formula.

Imposition of a duty is warranted by the unique method of marketing infant formula.[140] Rather than advertising directly to the consumer, formula manufacturers promote their products directly to the hospital.[141] The hospital, in turn, distributes free infant formula to the mother,[142] leaving her to the reasonable assumption that formula is not only safe but also is the medically preferred mode of infant feeding.[143] When new mothers are neither instructed in proper formula use, nor warned of the dangers of improper use, the infant is subjected to a risk of serious injury.[144]

Because the hospital plays a prominent role in the distribution of infant formula to patients,[145] imposition of a duty to instruct and warn provides a reasonable and effective solution. The statute provides a civil remedy for breach of the duty; aggrieved persons would be able to sue in negligence to recover against the hospital for breach of the duty to

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[135] *Id.*

[136] *Id.*

[137] *Id* at 39-44.

[138] *See* notes 71-75 and accompanying text *supra.*

[139] In 1980, 89-90% of hospitals in the United States received free formula from the manufacturers. In return for the free formula, the hospital agrees to provide each departing mother with a free discharge pack. FDA Petition, note 2 *supra*, at 82-83.

[140] *Id.* at 80-81.

[141] *Id.* at 82-87.

[142] *Id.* at 82-84.

[143] *Id.* at 17-18, 63-65.

[144] *Id.* at 34-44.

[145] *See* notes 43-47 and accompanying text *supra.*

instruct and warn.

CONCLUSION

The newborn is biochemically and psychologically fragile. Failure to obtain adequate nutrients at this delicate stage may result in convulsions, brain damage, and other serious disorders. The risk of incomplete mother-infant bonding increases with formula feeding. Encouragement of formula feeding by hospitals, without adequate emphasis on instruction in safe preparation and use, creates a situation in which serious and tragic injuries to infants may occur. Those most likely to sustain injury from formula are infants of low income parents. Their parents are likely to be unaware of the source of the injury, and even if they are, existing tort law presents significant obstacles to recovery. The unwillingness of the federal government to provide administrative relief indicates that state legislatures must remedy the problem.

The model statute proposed in this comment would create an efficient educational mechanism for medical professionals and parents with respect to infant formula. Infant health would be improved as more mothers, presented with objective information on the benefits of breastfeeding, would be more likely to choose that mode of feeding. The statute encourages informed choice. Those mothers who choose to formula feed would be able to continue to do so. Most importantly, they would know how to prepare and store the product safely.

Imposition of a statutory duty to instruct and warn would ensure that hospitals provide patients with the required information. The statutory cause of action in negligence for failure to discharge the duty would provide an enforcement mechanism.

It has been said that the measure of a nation is the care that it affords its children and its elderly. Adoption of the proposed model statute is a simple, inexpensive, and effective way of demonstrating concern for the health of American children. That concern has already been demonstrated for the children of undeveloped nations. We should show no less for our own.

Helen Leskovac
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APPENDIX

Model Statute

Legislative Findings

Widespread use of infant formula has created a significant public health problem demonstrated by formula associated increases in infant morbidity and mortality. Marketing practices that utilize hospitals for promotion and distribution of infant formula contribute significantly to the problem of inappropriate formula use. The implied approval of infant formula by hospitals may inhibit the exercise of informed choice by some mothers, particularly among low income or non-English speaking population groups.

§ 1 *Purpose*

The purpose of this statute is to enhance maternal and child health by ensuring that women receiving infant formula in or from hospitals be instructed in its proper use, preparation, and storage, and be warned about the dangers to infant health resulting from improper use; and to afford a civil remedy when hospitals breach the statutory standard of care imposed herein.

§ 2 *Definitions*

For purposes of this section:

a) "Hospital" includes both public and private facilities.

b) "Medical personnel" are physicians, interns, residents, midwives, nurse practitioners, physician's assistants, and registered nurses.

c) "Patient" means the mother of a newborn infant or other legally designated caretaker.

§ 3 *Educational Program*

The State Department of Health shall develop and implement an intensive educational program regarding the medical and psychological benefits of breast-feeding. This educational program shall include two components. The first shall be designed for hospital based physicians, nurses, midwives, and other appropriate hospital personnel. The educational program shall include information about the scientific bases for encouraging breast-feeding; the health consequences of artificial milk substitutes; the dangers associated with improper formula use; the special educational efforts required for high risk

populations including, but not limited to, non-English speaking patients; training in the management of routine breast-feeding problems; and special instruction for working with low income patients and patients without access to refrigeration or uncontaminated water supplies.

The second component shall be designed to provide education about the benefits of breast-feeding to all mothers and instruction regarding proper use of infant formula to mothers who choose to formula feed. The second component shall be implemented by hospital based physicians, nurses, midwives, and other appropriate hospital personnel.

§ 4 *Duty of Hospital to Instruct and Warn*

a) All hospitals that dispense infant formula, or permit infant formula to be dispensed, to patients shall designate appropriate medical personnel to assume responsibility for disseminating the warnings and instructions contained in § 4(b) & (c).

b) *Instructions*

(1) Unless contraindicated for medical reasons,* designated medical personnel shall inform the patient that breast milk is the medically preferred source of infant nutrition.

(2) Hospitals that distribute promotional literature published or provided by formula manufacturers shall be required to furnish patients with independently produced educational materials. The accuracy of said materials must be reviewed and approved by the State Department of Health.

(3) Designated medical personnel shall provide comprehensive instruction in proper formula preparation, use, and storage to patients choosing to bottle-feed. Such instruction shall include but is not limited to information on how to distinguish concentrate from ready-to-feed formula; the importance of refrigeration and sterilization; and the dangers of formula dilution.

(4) Designated medical personnel shall be under an affirmative duty to reasonably inquire whether conditions exist that would contraindicate safe use of formula.† Such conditions include but

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* There are very few contraindications for breast feeding. They include: hepatitis B virus; cytomegalovirus; breast cancer; B-streptococcal disease. FDA Petition, note 2 *supra*, at 77.

† The general rule in hospital liability cases is that a patient is entitled to such reasonable care and attention as his known condition may require. Marks v. St. Francis Hosp. and School of Nursing, 179 Kan. 268, 273, 294 P.2d 258, 261 (1956). The minority rule holds that it is also the responsibility of the hospital to guard against conditions which it reasonably should be expected to discover. Foley v. Bishop Clarkson

are not limited to: lack of refrigeration, lack of access to uncontaminated water supplies, and lack of facilities to sterilize bottles.

In the event such conditions do exist, designated medical personnel shall develop alternatives in accordance with sound medical judgment.

c) *Warnings*

1) Designated medical personnel shall be under an affirmative duty to warn patients that improper use of infant formula may cause severe or fatal medical complications in the infant.

2) All instructions and warnings shall be given in "plain English" or the foreign language equivalent and tailored to the patient's level of understanding.

§ 5 *Civil Remedy*

Any aggrieved person or his or her representative may bring a cause of action in negligence against the hospital arising from breach of the duty to instruct and warn as contained in § 4. In addition to compensatory damages, punitive damages may be awarded in appropriate circumstances.

Memorial Hosp., 185 Neb. 89, 94-95, 173 N.W.2d 881, 884 (1970). The duty to reasonably inquire about patients' circumstances regarding access to refrigeration, uncontaminated water supplies, and facilities to sterilize equipment is based on the minority rule.