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Citizen Petitioning of Federal Administrative Agencies - Domestic Infant Formula Misuse: A Case Study

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Can a product which requires clean water, good sanitation, adequate family income, and a literate parent to follow printed instructions be properly and safely used in areas where water is contaminated . . . poverty is severe and illiteracy is high?  

Is it appropriate for a seller to promote its products in a manner that will predictably lead a significant number of users to misuse or unnecessarily rely upon the product and suffer harm? What role do the pharmaceutical industry and the medical profession play in depriving women, particularly poor women, of the information necessary to facilitate informed choices about infant feeding and the type and quality of medical care they receive? These questions were squarely before the World Health Organization (WHO) on May 21, 1981 when it voted almost unanimously to endorse the International Marketing Code of Breastmilk Substitutes. The only nation to vote against the code was the United States. This vote was followed by strong statements by both the House and the Senate opposing the

4. On June 16, 1981, the House voted 301-100 to endorse the W.H.O. Code. H.R.
Reagan Administration's stance on the code.

At a time when breast-feeding is regarded as the medically preferred, superior method of infant feeding it is appalling that the Reagan Administration is placing a higher priority on profits than on the preservation of human life. The dangers associated with infant formula misuse are not limited to developing countries. Similar patterns of infant formula misuse, disease and death are rampant among low income and minority populations in the United States.

The decline in breast-feeding and the increase in infant formula misuse, like many other problems affecting the health of women and children in this country, is largely the product of a health care system where the primary incentive is profits and non-profitable concerns such as preventive health care receive short-shrift. While our health care system is in large part oner-

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7. Statement of the Congressional Black Caucus, quoted in Asiaweek, supra note 3, at 23.
8. See infra text accompanying notes 46-65.


The power of the domestic infant formula industry and its lobby on the Infant Formula Council was clearly demonstrated by the Reagan administration's stance on the W.H.O. Code. While the government professed to investigate even-handedly the infant formula issue prior to its vote at the U.N., in actuality, industry influence was more pronounced than that of consumer activists. Richard Schwerker, Secretary of the Department of Health, Education and Welfare, refused to meet with Infant Formula and Action Coalition (INFAC) representatives but granted a meeting to Bristol Myers executives. Letter from Gary W. Mize (Vice President Mead Johnson Nutritional) to Richard S.

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ous and unresponsive to patient needs in general, women are significantly more “at risk” of medical abuse.10 The very organization of the health care system reflects and perpetuates the social ideology of women as sexual and reproductive objects.11

In developing legal solutions to the broad spectrum of problems associated with the health care of women and children there are several avenues available to practitioners. Legislative, judicial and administrative remedies can be explored. Administrative petitioning12 of federal agencies has been a particularly


10. G. ANNAS, supra note 9, at 145; BOSTON WOMEN’S HEALTH COLLECTIVE, supra note 9, at 337. S. RUZK, supra note 9, at 13, discusses why health care utilization patterns are significantly higher among women than men.

11. S. RUZK, supra note 9, at 11. Sexism, like racism, has become institutionalized and embedded in the fabric of our society, so much so that many accepted medical practices are actually based on myths about female character and personality. Id. at 102; BOSTON WOMEN’S HEALTH COLLECTIVE, supra note 9, at 351-52. Furthermore, medical myths about women are reinforced by medical school training. G. ANNAS, supra note 9, at 145. See also G. COREA, THE HIDDEN MALPRACTICE 80-83 (1977); Howell, What Medical Schools Teach about Women, 291 New Eng. J. Med. 304 (1974).

12. Informal rulemaking under the Administrative Procedure Act, 5 U.S.C. § 553 (1976) will be the focus of this Comment. Formal or on the record rulemaking under §§ 556 and 557 are beyond the scope of this Comment. For a good discussion see Pedersen, Formal Records and Informal Rulemaking, 85 Yale L.J. 38, 39-41 (1975).

The rulemaking section provides that:

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rulemaking shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rulemaking procedures;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorpo-
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effective method of fashioning and securing comprehensive remedies for a wide variety of health care and consumer issues.18

This Comment will demonstrate how to petition federal

rates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.
(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, Sections 556 and 557 of this title apply instead of this subsection.
(d) The required publication or service of a substantive rule shall be made not less than thirty days before its effective date, except—
(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
(2) interpretative rules and statements of policy; or
(3) as otherwise provided by the agency for good cause found and published with the rule.
(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.


13. Both Public Advocates, a San Francisco based public interest law firm, and Ralph Nader's various organizations in Washington have been particularly successful, on both state and federal levels, in using the petitioning process to redress a wide variety of harms and injustices.

Petitioning efforts include:
—Petition for Classification of IUD's as New Drugs and For Labeling. (U.S. Department of Food and Drug Administration, May 19, 1976).
—Petition for Regulation of Pap Smear Screening. (California Department of Health, 1974).
—Petition for Regulations Requiring Broader Disclosure of Ingredients on Food and Drink Labels. (Food and Drug Administration, Feb. 25, 1971).
—Inner City Food Petition. (State of California, Sept. 15, 1979; also filed with President Carter, October 1980).
—Petition to Prevent Dumping of Hazardous Exports. (Filed with President Carter, September 1980).

(All examples by Public Advocates unless otherwise indicated.)

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agencies, how administrative petitioning has been used to resolve women's health care problems and how it may be used to work on other women's health issues. The Petition to Alleviate Domestic Infant Formula Misuse and Provide Informed Infant Feeding Choice\(^\text{14}\) will serve as a case study for the petitioning process. Additionally, this Comment will explore the legal remedies petitioners have under the Administrative Procedure Act when federal agencies fail to act on a petition, as well as discuss the extent to which courts will order agencies to act responsibly.

I. THE ROLE OF WOMEN IN CHOOSING THE TYPE AND QUALITY OF HEALTH CARE THEY RECEIVE

The medical profession has consistently treated women in a manner which disregards women's needs, safety and self esteem.\(^\text{15}\) Lawmakers and physicians are presently seeking to restrict access to contraception and abortion for low income women without regard to women's welfare and right to control their own fertility.\(^\text{16}\) Women's health and safety are endangered

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14. A. Blackwell & L. Salisbury, Petition to Alleviate Domestic Infant Formula Misuse and Provide Informed Infant Feeding Choice (June 12, 1981) [hereinafter cited as Petition]. This Petition was compiled by Public Advocates and filed with the Department of Health and Human Services, the U.S. Department of Agriculture and the Food and Drug Administration. The author was involved in the primary research and writing of that Petition.

References are made throughout this Comment to the Petition and the 100 expert witness statements accompanying it. Copies of the Petition can be obtained from Public Advocates, 1535 Mission St., San Francisco, California 94103 for $7. All statements and unpublished materials referred to in this Comment are also on file at Public Advocates.


For a discussion of the over-prescription of psychotropic drugs to women, see S. RUZEK, supra note 9, at 12; Fee, Women and Health Care: A Comparison of Theories, in SIZING OUR BODIES 281 (C. Dreifus ed. 1978) [hereinafter cited as C. DREIFUS]; Cooperstock, Sex Differences in the Use of Mood-Modifying Drugs: An Explanatory Model, 12 J. HEALTH & SOC. BEHAV. 238, 238-42 (1971).

16. E.g., Family Protection Act, S1090, 97th Cong., 1st Sess. (1981). For a discussion of the medical profession's role in marketing and disseminating information about birth control methods, see BOSTON WOMEN'S HEALTH COLLECTIVE, supra note 9, at 185-86, 338; S. RUZEK, supra note 11, at 78-79, 139-47.

G. ANNAS, supra note 9, at 148-51, reviews the legal issues concerning abortion. See also Dreifus, Abortion: This Piece is for Remembrance, in C. DREIFUS, supra note 15, at 131; Paul & Schaap, Abortion and the Law in 1980, 25 N.Y.L. SCH. L. REV. 497 (1980);
by profiteering inventors,\textsuperscript{17} drug companies,\textsuperscript{18} and ineffective regulatory agencies which promote widespread use of hazardous drugs and devices that disproportionately affect women.\textsuperscript{19} Physicians perform an inordinate amount of unnecessary reproductive tract surgery and sterilization.\textsuperscript{20} Childbirth practices are tailored to the needs of physicians rather than patients—often to the detriment of both mother and child.\textsuperscript{21} Infant formula promotion often deprives women of the right to choose a feeding method which benefits their child rather than the infant formula industry. Faced with these realities women have begun to assert their


17. For a discussion of low-income and minority women as an uninformed experimental population, see G. \textit{Annas}, supra note 9, at 152-53; \textit{Boston Women's Health Collective}, supra note 9, at 337-38; S. \textit{Ruzeek}, supra note 9, at 44-46.

18. The marketing of Diethylstilbestrol (DES) is the best example of medical profession and drug industry promotion of a drug which had not been adequately tested, was likely to be ineffective and was given to women experimentally without explaining the risks and dangers and obtaining informed consent. S. \textit{Ruzeek}, supra note 9, at 39-42; D. \textit{Sculley}, supra note 9, at 18; Seaman, \textit{The Dangers of Sex Hormones}, in C. \textit{Dreifus}, supra note 15, at 167-76. For legal analyses see Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980) (market share liability introduced as an avenue of recovery for DES plaintiffs seeking redress for injuries resulting from drug exposure before birth); Note, \textit{DES and a Proposed Theory of Enterprise Liability}, 46 \textit{Fordham L. Rev.} 963 (1978).

The American pharmaceutical industry is too quick to sell doctors on prescribing drugs and American doctors are too quick to believe the drug houses. This situation provides the basis of the domestic infant formula industries' success. Spake, \textit{The Pushers}, in C. \textit{Dreifus}, supra note 15, at 177; see infra notes 114-165 and accompanying text.

19. For a discussion of issues surrounding the Dalkon Shield, see S. \textit{Ruzeek}, supra note 9, at 43; Seaman \& Seaman, \textit{Women and The Crisis in Sex Hormones} (1977); Dowie \& Johnston, \textit{A Case of Corporate Malpractice and the Dalkon Shield}, in C. \textit{Dreifus}, supra note 15, at 86.


21. Despite this, upper and middle income women are rapidly demanding control over the birthing process. S. \textit{Ruzeek}, supra note 9, at 47. See G. \textit{Annas}, supra note 9, at 151-53; S. \textit{Arms}, \textit{Immaculate Deception: A New Look at Women and Childbirth in America} (1975); Rich, \textit{The Theft of Childbirth}, in C. \textit{Dreifus}, supra note 15, at 146.

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right to make informed choices about their own health care and that of their children.

The legal requirement that patients must give informed consent\textsuperscript{22} to medical treatment has been a critical tool in breaking the physician's monopoly over medical knowledge. Until recently, physicians have had complete freedom to mandate "proper" treatment for individual women.\textsuperscript{23} The "good patient" in the eyes of the health system, is docile, trusting and uncursively obedient.\textsuperscript{24} Women are treated as children—persons to be sheltered and protected from unpleasant facts and relieved of responsibility for decision-making, ostensibly for their own good.\textsuperscript{25} Physicians typically withhold critical medical information on the ground that patients are incapable of understanding it.\textsuperscript{26} In actuality, this implied medical ignorance is a self-fulfilling prophecy. Such fostering of medical ignorance avoids troublesome or unmanageable reactions from patients who might not agree with the course of treatment the doctor has chosen for them.

Recently, however, educated middle and upper income women have begun asserting that they themselves are most competent to make decisions on contraceptives and sterilization; on whether to give birth at home or in a hospital attended by a physician, nurse-midwife or lay midwife; to accept a hysterectomy on the basis of a single physician's findings or insist on additional consultations; to choose minimal, radical or no surgery for breast cancer; and to choose whether or not to breastfeed their infants. In sum, these women are choosing what care is best for them.\textsuperscript{27}

In the United States however, health care is a dual system;

\textsuperscript{22} Simply stated, a physician may not render treatment without explaining to the patient the risks and material facts concerning the treatment and its alternatives, including non-treatment, and the relative probabilities of success. Once this information has been obtained, the physician must secure the patient's competent, voluntary and understanding consent to proceed. G. Annas, supra note 9, at 57-58. For a full discussion of the informed consent doctrine, see id. at 57-66; Comment, supra note 15, at 563-79.

\textsuperscript{23} S. RuzeK, supra note 9, at 3.

\textsuperscript{24} Boston Women's Health Collective, supra note 9, at 98.

\textsuperscript{25} S. RuzeK, supra note 9, at 33; D. Scully, supra note 9, at 19.

\textsuperscript{26} S. RuzeK, supra note 9, at 33; D. Scully, supra note 9, at 11.

\textsuperscript{27} S. Arms, supra note 21, at 175-280; S. RuzeK, supra note 9, at 1, 5, 36.
there is one type and quality of medical services for the middle
class and the wealthy, another for low income, minority and eld­
erly members of our society. The extent to which one actually
chooses medical care is limited by economic status, domicile, ed­
ucation, the degree of medical crisis and sex.

Low income and minority women typically have so little
health care information as to be totally at the mercy of their
providers. Reduced to using emergency rooms, inpatient and
outpatient clinics and hospital wards of large, publicly funded,
teaching hospitals, the indigent are treated almost exclusively by
residents, interns and medical students. It is in this context
that low income, minority and non-English speaking women be­
come infant formula users, victims of sterilization abuse, sub­
jects of medical demonstration and experimentation—almost
uniformly without their informed consent.

The problem of domestic infant formula misuse is represen­
tative of a wide variety of issues concerning women in our health
care system. The major factors contributing to the decline in
breast-feeding among America's low income mothers and the
concurrent rise in infant formula misuse—hospital practices,
physician attitudes and health care industry promotional prac­
tices—are the same factors which in a large part determine the
Infant Formula Misuse and Provide Informed Infant Feeding Choice with the Department of Health and Human Services, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration. This petition will provide a case study illustrating the manner in which petitioning can be used to solve women's health care problems. What follows is a digest of that petition which illustrates a microcosm of the issues affecting women in our health care system.

II. DOMESTIC INFANT FORMULA MISUSE AND THE DECLINE IN BREAST-FEEDING: AN OVERVIEW

Despite strong recommendations from major national and international medical associations that breast-feeding is the medically preferred, superior method of infant feeding, and despite the current self-initiated return of middle and upper income American women to this feeding mode, commercially prepared, inherently inferior formulas continue to be used widely in this country by low income women. The breast-feeding rate for

36. See supra note 14.
37. Breast-Feeding, supra note 6; DRAFT INT'L PEDIATRICS ASS'N, RECOMMENDATIONS FOR ACTION PROGRAMS TO ENCOURAGE BREAST FEEDING, 4 BULL. INT'L PEDIATRIC A. 19 (1975); WORLD HEALTH ORGANIZATION, INT'L CODE OF MARKETING OF BREASTMILK SUBSTITUTES (1981); APHA, supra note 6.


39. The following figures demonstrate the low, even declining rates of breast-feeding
Blacks during the last thirty years has declined from nearly 80% to 20%, with a significant portion of that 20% representing upper income, educated Black women. The rate for Hispanics has

among Blacks, Hispanics, Native Americans and Indochinese immigrants. The statements were made in support of the Petition, supra note 14:

—Los Angeles, California: Between 5 and 15% of low-income Blacks and Hispanics breastfed in 1977. Statement No. 53.
—San Diego, California: Among Indochinese, breastfeeding declines to 20% after arrival in the United States. Statement No. 85.
—San Francisco, California: In Chinatown, 18% of clinic women planned to breastfeed. Statement No. 45.
—New Orleans, Louisiana: At Charity Hospital, 5% of low-income Blacks breastfed in 1981. Statement No. 68.
—Twin Cities, Minnesota: Upon arrival in the United States, Vietnamese breastfed at 71%; Hmong, 50%; and Laotian, 100%. After 6 months, only 25% breastfeed. Statement No. 83.
—Philadelphia, Mississippi: Ten per cent of Choctaw Indians breastfeed. Statement No. 86.

While 90% of middle and upper income women delivering in private hospitals elect to breast-feed, no more than 5% of the women in public hospital maternity wards breast-feed their infants. O'Toole, supra note 38.


Historically, black women breast-fed significantly more than white women (72.8% versus 50.2%). Id.; Rivera, The Frequency of Use of Various Kinds of Milk During Infancy in Middle and Lower Income Families, 81(2) Am. J. Pub. Health 277 (1977). The data shows that 73% of black women breast-fed their children in 1950 while only 56% of white women were breast-feeding. In 1960, black and white women were breast-feeding at an equal rate of approximately 42%. By 1974, 11% of black women were breast-feeding, in contrast to 30% of white women. Hirschmann & Hendershot, supra note 38, at 16. As educational and socio-economic levels increase for black women, and they gain access to quality prenatal care and information on the superiority of breast-feeding, their breast-

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dropped from 73% to 18%, with a substantial portion of the
18% representing recent immigrants who have not yet aban­
doned the breast-feeding tradition.41 The breast-feeding rate for
native Americans has declined from 73% to less than 10%.42 In­
dochinese immigrants arrive in the United States breast-feeding
at rates ranging from 51% to 100%, depending upon their tradi­tional culture. Within six months of their arrival their breast­feeding rates uniformly decline to 25%.43 This reliance upon in­fant formula by the poor is particularly alarming since it is they
who can least afford expensive formulas,44 and benefit most from
feeding rates increase. Letter from Mila Jasey, Leader of the only Black La Leche
League Chapter in the country, South Orange, New Jersey, to Leslye E. Orloff (April 24,

41. CENTER FOR DISEASE CONTROL, UNITED STATES-MEXICO BORDER SURVEY, FIGURE
13 (1980). Where rises in Hispanic breast-feeding rates can be documented, they are due
largely to an influx of new immigrants. Statement No. 5 in support of Petition, supra
note 14. As Hispanic women gain purchasing power in their communities, they try to
emulate American culture and breast-feeding rapidly declines. In 1977, a study of breast­feeding among Mexican migrant workers in Houston, Texas found 92% of the children
of migrant women from Mexico were breast-fed. Among Houston-born Mexican-Ameri­can infants, 30% were breast-fed, usually for only one to six months. C. Johnson, Breast·
feeding and Social Class Mobility; the Case of Mexican Migrant Women (1977)
(presented at AAA meetings).

42. B. BURKHALTER, C. RITENBAUGH & G. HARRISON, supra note 39, at 33-34; French,
Relationship of Morbidity to the Feeding Pattern of Navajo Children from Birth
through Twenty-four Months, 20 AM. J. CLIN. NUTR. 375, 377 (1967). See generally El­
estad-Syad, Coodin, Dilling & Haworth, Breastfeeding Protects Against Infection in In­
dian Infants, 120 CAN. MED. A.J. 295, 297 (1970); Maynard & Hammes, A Study of
Growth, Morbidity and Mortality Among Eskimo Infants of Western Alaska, 42 WHO
BULL. 613, 616 (1970); Van Duzen, Protein and Calorie Malnutrition Among Pre-school

Generally, traditional (in belief, dress, housing arrangements, language) native amer­
ican women tend to breast-feed more than their assimilated counterparts. B. Burkhalter,
C. Ritenbaugh, G. Harrison, Infant Feeding Among the Navajos 9-10 (Jan. 19, 1981)
(unpublished study, University of Arizona). See also Statement No. 15 in support of
Petition, supra note 14.

are heavily influenced by the medical profession, which presents bottle-feeding as the
American way. Statement No. 85 in support of Petition, supra note 14. Isolated from
other sources of information, Indo-Chinese refugees are very susceptible to the influence
of the small group of professionals with whom they interact. Indo-Chinese groups as a
whole show a strong desire to become part of their new society and to function normally
in this new home. Statement No. 12 in support of Petition, supra note 14.

The most overwhelming food habit change is the adoption of bottle-feeding and the
introduction of dairy products into the diet. This can lead to inappropriate use of this
new food to the exclusion of traditional nutritious foods. One Cambodian family used
milk exclusively to feed children up to three years of age because they perceived milk as
the American "secret" to healthy children. Statement No. 7 in support of Petition, supra
note 14.

44. While a nursing mother should consume extra nutrients and calories, the added
breast milk's superiority. Furthermore, it is they who are most

dietary expense is considerably less than the cost of infant formula. A 1976 study demonstrated that the lactating mother’s dietary supplements for one year would cost $167, while feeding her infant concentrated formula would cost $227, powdered, $247, or ready-to-feed, $276. This represents an additional feeding cost of $60–99. Lamm, Delaney & Dwyer, Economy in the Feeding of Infants, 24(1) PEDIATR. CLIN. N. AM. 71 (1977).

These figures are conservative, since some forms of formula—particularly ready-to-feed bottles—are significantly more expensive. July 1976 figures for Washington, D.C., showed the weekly cost ranging from $3 for the lactating mother following USDA’s thrifty food plan to $19.70 for a week’s supply of four-ounce ready-to-feed bottles. Peterkin & Walker, Food for the Baby . . . Cost and Nutritive Value Considerations, Fam. Econ. Rev., Fall, 1976, at 3. This translates into an additional $706.16 per year for parents using ready-to-feed formula.

Assuming half the nation’s annual 3,500,000 new mothers who could breast-feed are not, these studies project savings of $105,000,000 to $173,250,000. Petition, supra note 14, at 48–49.

45. Comparisons of infant formula and human milk have shown vast differences in protein composition, fat absorption, carbohydrates, minerals, and immunological effects. These differences have significant implications for infant health and development. For a general discussion of breastmilk’s superiority, see Breast-feeding, supra note 6, at 591-96; Cunningham, Breastfeeding and Morbidity in Industrialized Countries: An Update, in ADVANCES IN INT’L MATERNAL AND CHILD HEALTH 137-39. (D. & E. Jelliffe eds. 1981) [hereinafter cited as Breastfeeding Update]; D. & E. Jelliffe, Human Milk in the Modern World (1978) [hereinafter cited as HUMAN MILK]; R. Lawrence, Breastfeeding: A Guide for the Medical Profession 46-47 (1980); Petition, supra note 14, at Appendix A.

Additional benefits of breastfeeding include:

—Contraceptive effect of Lactation. Statement Nos. 9, 65.
—No exposure to the dangers inherent in poor quality control of infant formulas. Blackwell & Salisbury, Administrative Petition to Relieve the Health Hazards of Promotion of Infant Formulas in the U.S., 8(4) BIRTH & FAMILY J., Winter 1981, at 287. For example, in January 1982, Vitamin B-1 rather than Vitamin B-6 was added to a huge batch of nursery formula. Such a mistake is known to cause cerebral palsy or retardation. Goodman, Pro-Family Isn’t Always Pro-Baby, Los Angeles Times, March 21, 1982, pt. IV, at 5, col. 3.

Bottle-fed infants are more susceptible to the following illnesses:

—Otitis Media. See id. at 11-12.
—Sudden Infant Death Syndrome (SIDS). See id. at A-12.
—Baby bottle carries. See id. at 31-32.
—Obesity. See id. at 32.
—Severe reduction in maternal infant bonding. See id. at 29-31; M. Klaus, S. Kennell, Maternal Infant Bonding (1976).

A common concern for many women is that toxins they receive from the environment which are stored in their bodies will be passed on to their infants through breastfeeding. Actually these toxins are stored in the fatty tissues of the mother’s body and are released into her milk only if she loses a large amount of weight in a short period of time. In fact, nature uses the mother as a filter, storing toxins in her body and protecting her infant from these dangers. The benefits of this protective value of breast-feeding are amplified in light of the number of mothers who use concentrated formula which must be mixed with water, thus feeding possibly dangerous toxins directly to the infant. The

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susceptible to the severe risk of harms that can, and often do, result from improper use.

A. Near Epidemic Misuse

The key requirements for safe use of formula are proper mixture, proper sterilization where required, and proper refrigeration. For the majority of American women who live in homes with sanitized water, electricity and refrigeration, and who read English, following the necessary directions presents no problem. Formula, however, is aggressively marketed to low income, technologically poor, and non-English reading populations who lack facilities for proper sterilization and refrigeration of formula and who cannot always distinguish between concentrate and ready-to-feed formula, or understand label instructions.

Infant health problems caused by formula misuse have reached near epidemic proportions among our fast growing Hispanic population. Incorrect preparation and contamination of formula cause a major portion of the diarrhea and gastroenteritis which plague both rural and urban Hispanic infants. The only solution in danger areas is to use ready-to-feed formula in individual servings. This option is prohibitive for many low income women. Statement No. 89 in support of Petition, supra note 14.

46. If formula is purchased in a powdered or liquid concentrate form, it must be mixed with the proper amount of water before it is used. Depending on the quality of the water, it may require sterilization either before or after the mixture is prepared. The directions on the Similac can of liquid concentrate state: "Sterilization is recommended. Your physician will decide if it is not required."

47. Statement No. 41 in support of Petition, supra note 14.

48. Mothers are often not informed of the critical importance of washing bottles and nipples and using boiled water to prepare formula. Thus, very small children arrive at the hospital with severe diarrhea, frequently specific diarrhea like Shigella and Salmonella. The contents of one formula bottle was found capable of growing a full spectrum of bacteria, usually found in the stool. Id. Families in many regions of the United States can neither use their home water supply for human consumption, nor afford to purchase bottled water. In such instances infant formula use can be extremely dangerous. Statement No. 26 in support of Petition, supra note 14.

In rural Northern California, a number of wells have been found contaminated with DBCP. Statement No. 19 in support of Petition, supra note 14. Water on the Arizona Navajo reservation is contaminated with radioactive wastes.


50. Statement Nos. 41, 46, 47, 77 in support of Petition, supra note 14.

51. In Del Rio, Texas, near the Mexican border, infant mortality among the largely Hispanic population is very high; its number one cause is diarrhea. Breast-feeding is the rare exception rather than the rule in the Del Rio area, and the biggest single problem is contamination of formula due to lack of sterilization or refrigeration. R. Dellums, Report on Field Investigation of Infant Formula Promotion and Use 18-19 (March 30, 1979)
most severe problems develop when an infant is fed concentrated formula without dilution, which occurs often because of the mother's inability to read the instructions on the label. The high concentrations of salt and protein in undiluted formula can lead to dehydration, kidney damage and cerebral bleeding. 

Frequently, the expense of formula also leads many low income families to stretch the formula by over-dilution or to switch to using whole cow's milk at a very early age.

Among native Americans, poverty and lack of facilities such as plumbing and electricity make conditions on most reservations indistinguishable from those in developing countries. Since infant formula is virtually impossible to use safely on the reservation, its widespread use leads directly to high infant morbidity and mortality.

The newest of American immigrant populations, the Indochinese refugees, are beset by these same patterns of formula misuse. Despite generations of breast-feeding, and indeed breast-feeding of siblings born in Cambodia, Laos or Vietnam, the immigrant infant born here is often bottle-fed, frequently improperly. Here too the language barrier has been the most common problem. Due to the difficulty in conveying basic information, the finer points of breast- and bottle-feeding are often overlooked. Multiple cases of formula misuse result.

(unpublished research report).

52. At the Pediatric Clinic of Los Angeles County General Hospital, where the patient population is about 98% Hispanic, two or three cases a week come into the emergency clinic in which the baby has severe diarrhea caused by undiluted concentrated formula. Statement No. 77 in support of Petition, supra note 14.


54. This results in widespread iron deficiency anemia among non-breast-fed low income children. Iron deficiency anemia is rare among breast-fed infants. Statement No. 88 in support of Petition, supra note 14.

55. Ready-to-feed formula cannot safely be used on the reservation due to the lack of refrigeration in many areas. Concentrate cannot safely be used because the water is contaminated with arsenic and radioactivity which are concentrated, rather than removed, by boiling. Feeding undiluted concentrate is also prevalent. The results are predictable—chronic diarrhea, gastroenteritis, otitis media and baby bottle carries. Statement No. 20 in support of Petition, supra note 14.

56. Infant mortality among Native Americans is ten times the national average. Severe problems from infant malnutrition are estimated to affect as much as 70% of the population. Statement Nos. 15, 44 in support of Petition, supra note 14.

57. Statement No. 51 in support of Petition, supra note 14.


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Even when used properly, infant formula has been associated with increased infant morbidity and mortality. The medical profession’s endorsement of breast-feeding has been based on concrete evidence. Bottle-fed infants suffer two to three times more significant illness and are hospitalized three times more often than breast-fed infants. In the first month of life, artificially-fed infants have a 15-fold greater chance of hospitalization. The formula-fed baby is three times as likely to suffer otitis media, twice as likely to suffer either significant vomiting or diarrhea and more than five times as likely to suffer acute lower respiratory illness.

In low income settings the protection breast-feeding provides is even more pronounced. Native American bottle-fed infants have hospitalization rates ten times higher than breast-fed infants. Mortality predictions are even more chilling than the above figures. By universal breast-feeding in the United States, 5,000 infants might be saved yearly.


60. See supra note 38.


63. HUMAN MILK, supra note 45, at 147.

64. French, Relationship of Morbidity to the Feeding Pattern of Navajo Children from Birth Through Twenty-Four Months, 20 AMER. J. CLIN. NUTR. 375 (1967); Statement No. 44 in support of Petition, supra note 14.

65. Fifty years ago the post-neonatal mortality rate (deaths between one month and one year of age of breast-fed welfare infants) was 1.6/1,000. During the last decade the same rate in a socially comparable group of infants who were predominately bottle-fed was 10/1,000. In 1979 this rate for all U.S. infants (including those from middle and upper socio-economic groups) was 4.4/1,000. . . . Based on 1979 births about 5,000 U.S. infants might be saved yearly.

Statement No. 7 in support of Petition, supra note 14.
B. FACTORS WHICH DISCOURAGE BREAST-FEEDING AMONG LOW INCOME WOMEN

When human milk, an abundant low cost natural resource,66 is readily available, it is tragic that so many low income, minority and non-English speaking women are coerced into using infant formula. Although middle and upper income educated women generally enjoy extensive prenatal care,67 have access to counseling on infant feeding, and are demanding natural births and a say in their own medical care and that of their children,68 women who are educationally and economically disadvantaged do not have these advantages.69 Consequently, their infant feed-

66. See supra note 44. The greater morbidity and mortality rates for bottle-fed babies translate directly into greater expense for hospitalization, outpatient care, and emergency room services. If half the mothers who are presently bottle-feeding began breast-feeding national annual savings could be estimated at:

<table>
<thead>
<tr>
<th>Service</th>
<th>Estimated Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization</td>
<td>$117,342,000</td>
</tr>
<tr>
<td>Emergency Room</td>
<td>28,000,000</td>
</tr>
<tr>
<td>Outpatient Services</td>
<td>60,000,000</td>
</tr>
<tr>
<td>Extra Expense of Formula</td>
<td>173,250,000</td>
</tr>
<tr>
<td>Total Estimated Savings</td>
<td>$378,692,000</td>
</tr>
</tbody>
</table>

Petition, supra note 14, at 45-49.

67. Despite the critical nature of prenatal care, 25% of all pregnant women receive late, little or no such care. THE SELECT PANEL FOR PROMOTION OF CHILD HEALTH, BETTER HEALTH FOR OUR CHILDREN: A NATIONAL STRATEGY 166 (1980) (report to the United States Congress and the Secretary of Health and Human Services); R. Dellums, supra note 51, at 3, 18. For women who are very young, over 35, Black, poor, have little education or are unmarried, the percentage is significantly higher. Id. at 166. See generally DIVISION OF CONSUMER SERV., CALIFORNIA STATE DEP'T OF CONSUMER AFFAIRS, PERINATAL HEALTH CARE FOR THE POOR: A CONTINUING DEFICIENCY IN CALIFORNIA (1981) (G. Koehler & R. Deviers).

68. D. Scully, supra note 9, at 136-37; Jelliffe, Breast-feeding in the United States and the World, in SYMPOSIUM ON HUMAN LACTATION 1 (hereinafter cited as Jelliffe, LACTATION SYMPOSIUM).

69. As Blacks, Hispanics, Native Americans and Asians assimilate into the dominant Anglo-American society, specific cultural trends in breast-feeding are eventually abandoned and American society's inhibitions about breast-feeding are embraced. Of particular importance is the status of bottle-feeding, which is presented by the media and the medical profession as modern, scientifically approved, and the American way. A. ISENALUMNE, N.Y. Cty DEP'T OF PUB. HEALTH, A STUDY OF THE RELATIONSHIP BETWEEN BREAST-FEEDING AND FOUR SPECIFIC SOURCES OF INFORMATION ON INFANT FEEDING PRACTICES AMONG LOW SOCIO-ECONOMIC STATUS MOTHERS 87 (1979). Statement Nos. 51, 100 in support of Petition, supra note 14.

The elevated role of the breast as a sex symbol in Anglo-American society has also contributed to the decline in breast-feeding. Many women are led to believe that breast-feeding is incompatible with sexuality. They are told that their breasts are the sexiest part of their anatomy and consequently feel embarrassed or uncomfortable about breast-feeding. BOSTON WOMEN'S HEALTH COLLECTIVE, supra note 9, at 311; Mohrer, supra note 38, at 129; Winikoff & Baer, supra note 38, at 9-11.
ing decisions are significantly influenced by the treatment and advice they receive at the hospital. The formula companies, ac-
tutely aware of the critical influence hospitals have on infant feeding choices, particularly among the poor, have concentrated their promotional and advertising efforts on orienting medical professionals towards infant formula use and establishing a presence in the hospitals.

Most hospitals serving large, low income populations do not provide an atmosphere conducive to breast-feeding. They typically convey to low income mothers the view that bottle-feeding is safe, convenient and medically recommended as best for their

Infant formula is also viewed as “liberating.” Women believe it is easier, more convenient and does not “tie them down.” Ladas, supra note 38. There is a common misconception that many low income women choose not to breast-feed because they must work. Available data does not, however, support this contention. Winikoff & Baer, supra note 38, at 106; Domestic Use of Infant Formula: Hearings Before the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, 97th Cong., 1st Sess. 25 (1981) (hereinafter cited as Domestic Infant Formula Hearings) (statement of Angela Blackwell). When low income women are properly instructed on how to express and store milk at work, their efforts to breast-feed and work have been extremely successful. Id. at 25 (statement of Mercedes Salazar).

The concept of the modern woman who contributes to her family and society through work has had far-reaching effects on the role of women yet minimizes the value placed on her unique biological ability to breast-feed. This has been the most difficult issue for many feminists. Can women successfully debunk the definition of “woman-as-reproductive breast” and at the same time emphasize the value of female biology? Basically and most fundamentally, the feminist focus on health and body issues can be a strategy to subvert the ideology of sexism at its base, i.e., the social interpretation of biological difference. Marieskind & Ehrenreich, Toward Socialist Medicine: The Women’s Health Movement, 6 Soc. Pol., Sept./Oct. 1975, at 34, 38. Since the subservient position of women in society is socially conditioned, it, therefore, can be socially redefined. J. Hole, E. Levine, Rebirth of Feminism 171 (1971). Thus, rather than minimizing or ignoring their biology, women must begin to re-examine health and body issues so as to integrate the value of female biology into a redefined social self. If women are to truly gain equality in our society, their dual role—worker and mother—must be appreciated. The deterrents discussed above remained imbedded in American culture until the 1970s when significant numbers of well-educated, upper and middle income women returned to breast-feeding. Low income women, however, remain generally unaware that the “modern” woman of the 1980’s breast-feeds. More important, they remain in great part unaware of the significant benefits of breast-feeding. See O’Toole, supra note 39; S. Huffman, Trends in Breastfeeding in the U.S., Special Focus on the Practices of Low-Income Mothers (March 14, 1980) (unpublished study, Office of Policy Planning and Evaluation, Food and Nutrition Service, USDA, Washington, D.C. 20250).

70. See infra notes 84-113 and accompanying text for further discussion.

71. Statement No. 70 in support of Petition, supra note 14; see Petition, supra note 14, at 79-106; text accompanying notes 107-137.

children.73 For the low income and often non-English speaking mother, this could not be further from the truth.74

Detrimental Hospital Practices

Most first-time mothers, with little encouragement, express a desire to breast-feed, only to be defeated in a few days or weeks under the American system of hospital care.75 Over the past 20 or 30 years, childbirth has increasingly become a technical event. In recent years, while upper and middle income educated women have been demanding natural child birth and midwives, hospitals treating low income women have continued to place a higher priority on administrative and physical needs than on emotional needs which get in the way of efficiency.76 Common obstetrical practices, especially those to which poor women are subjected, fail to support the initiation and continuation of breast-feeding and actually physiologically obstruct the breast-feeding process.77 Such practices undermine any informed choice and predetermine that infant formula will be

[Notes and references]

73. Statement No. 100 in support of Petition, supra note 14.
74. See supra notes 46-58 and accompanying text for a discussion of hospital practices.
76. Morris, Psychological Miscarriage, An End to Mother Love, TRANSACTION, Jan./Feb. 1967, cited in BOSTON WOMEN'S HEALTH COLLECTIVE, supra note 9, at 308.
77. Breast-feeding functions on a supply and demand principle. Applebaum, The Modern Management of Successful Breastfeeding, 17(1) PED. CLIN. N. AM. 203 (1970). The establishment and maintenance of milk secretion depend ultimately on two interrelated reflexes—the infant's sucking reflex and the mother's letdown or milk ejection reflex. Lawrence, supra note 45, at 125-26; Newton, Physiology of Lactation, in SYMPOSIUM ON HUMAN LACTATION 17 (1976). A mother's milk supply is controlled by her baby's appetite. The infant's sucking at frequent intervals stimulates the secretion of prolactin, the hormone responsible for milk production in the mother. Id. The more the baby nurses, the more milk the mother will have. HUMAN MILK, supra note 45, at 14-15. Any decrease in suckling stimulus will result in a diminishing milk supply. Newton, supra at 27.

While the amount of milk produced is controlled by the baby's appetite, the availability of milk depends on the letdown or milk ejection reflex, which propels the milk into the ducts leading to the nipple. HUMAN MILK, supra note 45, at 20-21. The human letdown reflex can be markedly inhibited by psychological factors. Id. at 22-24. This is the secret to the infant formula industry's promotional successes. When a mother's confidence in her ability to breast-feed is undermined because she believes that her milk is not good enough or that her infant is not getting enough, her resulting anxiety or stress can block the reflex altogether, preventing the milk from reaching the baby. This situation is often characterized as the "insufficient milk syndrome." Id. at 22-24; R. LAWRENCE, supra note 45, at 127-128; Appelbaum, supra, at 233.

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used—unless, of course, a woman has the education and determination to demand treatment which overcomes such impediments.

Hospital practices which inhibit lactation may be outlined as follows:

[1] *Lack of prenatal care and education* prevents women from understanding and overcoming hospital practices which undermine successful lactation.


[3] *Lactation suppressants* are administered without adequate explanation of the drug, its side effects, its purpose, or obtaining informed consent.

[4] *Separation of mother and infant at birth*, often for as long as twelve to twenty-four hours, undermines breast-feeding by restricting contact when the infant’s suckling reflex is at its height. Moreover, denial of skin to skin contact immediately following delivery delays the psychological bonding process.

78. Petition, supra note 14, at 70-73, 78.

79. Breast-feeding is undermined in the hospital even for educated women. To be successful a woman must be very motivated, know what she wants, and be willing to fight the staff to ensure that her wishes are carried out. Statement Nos. 43, 73 in support of Petition, supra note 14.

80. The American Academy of Pediatrics Committee on Nutrition urges that efforts be made to change obstetrical ward and neonatal unit practices to increase the opportunity for successful lactation. Breast-feeding, supra note 6, at 597.

81. Winikoff & Baer, supra note 38, at 107.


86. Statement No. 65 in support of Petition, supra note 14. See Klaus & Kennell, supra note 45.
Typical hospital floor plans, especially public hospitals, encourage the routine and lengthy postpartum separation of mother and infant.87 Mothers are placed in large, multi-bed wards81 and the infants remain in nurseries where they are often bottle-fed regardless of the mother's wishes.88 Nurseries are separated physically and have separate staffs from the wards, so that the mothers are doubly divided from their infants.89 Babies are brought to their mothers only for a few minutes a day,81 if at all.82 The prevalence of central nurseries reflects the formula-feeding orientation of many American hospitals. Central nurseries provide a layout in which the hospital staff can feed many babies formula efficiently and conveniently.83 Rooming in,84 on the other hand, is ideally suited to the needs of the breast-feeding couple.85

Rigid four hour feeding schedules prevent demand feeding of breast-fed infants.86

91. Engel, supra note 88, at 1; R. Dellums, supra note 51, at 3.
92. Baumslag & Walker, supra note 88, at 1. At Charity Hospital in New Orleans, the third largest hospital in number of births per year, mothers are not permitted to handle their children until after discharge. They may view their infants for five minutes a day through a window. Id.
93. Statement No. 100 in support of Petition, supra note 14.
94. Rooming-in allows the mother and infant to remain together in the same room throughout the hospital stay. The mother becomes the primary care giver during this critical period and she can breast feed her infant on a demand basis whenever the infant is hungry.
95. CURRENT KNOWLEDGE OF BREASTFEEDING, supra note 89, at 18; Klaus & Kennel, supra note 45, at 95, 96; Mandik-Hall, supra note 84, at 31-32.

Formula takes longer to digest than breast milk enabling artificially-fed infants to go four hours between feedings. Each breast-fed baby, on the other hand, will nurse according to its own schedule. It is not unusual for a breast-fed baby to nurse every two hours

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[7] Supplemental glucose and formula feeds in the nursery, at staff convenience, delay the onset of a strong milk supply and deprive the infant of colostrum, the early milk, which is rich in critical nutrients and immunoglobulins. Furthermore, these supplemental feedings convey to the mother that her milk is inadequate and formula is necessary.

[8] Infant formula discharge packs are routinely distributed to all new mothers. These samples adversely affect lactation. The issuing of free formula through the hospitals conveys a very strong message, especially to the non-English speaking patient. In this context infant formula receives a seal of approval. It is interpreted as a prescription.

and sometimes even more frequently. Kemberling, Supporting Breastfeeding, 63(1) Pediatrics, 60, 69 Jan. 1979; Statement No. 91 in support of Petition, supra note 14.

97. R. Lawrence, supra note 45, at 46, 132. Supplemental feedings interfere with the delicate supply and demand balance needed for successful lactation. Women who supplement breast-feeding in the early weeks postpartum usually experience a drastic decrease in their milk supply and are more likely to fail at lactation, believing they had insufficient breast milk.

98. Petition, supra note 14, at 64. Each package contains a few bottles of ready-to-feed formula in four ounce bottles, one can of concentrated formula, and promotional literature. According to a Mead Johnson spokesman, 90% of all new American mothers receive a formula gift package upon discharge from the hospital, regardless of whether they are breast-feeding or bottle-feeding. Interfaith Council for Corporate Responsibility, Infant Formula Use in the United States (1979) (shareholder resolutions). Nearly 98% of the hospitals dispense discharge kits. Minnesota Public Interest Research Foundation, Minnesota Hospital Study, 4 (Spring, 1980). [hereinafter cited as Minnesota PIRF].

99. Written Testimony of K. Frantz, D. Jelliffe, presented to California State Dep’t of Consumer Affairs, Div. of Consumer Services, Perinatal Health Care Hearing (April 10, 1981). At Los Angeles County USC, 63% of the breast-feeding mothers who went home with discharge packs were supplementing at one to two weeks, versus 25% of mothers who went home without them. Y. Bergevin, M. Kramer, & C. Dougherty, Do Infant Formula Samples Affect the Duration of Breast Feeding? A Randomized Controlled Trial (May 1, 1981) (paper presented to Ambulatory Pediatric Association). This study found conclusively that samples adversely affected the duration of breast-feeding.

100. Mercy Salazar, a community worker at Los Angeles County General Hospital, relates that:

[M]any mothers don’t breast-feed because they are given formula in the hospitals and given the packets, and they say, “This is what I’m going to feed my child.” So they stop breast feeding. It is the gift that is the key. Someone has given them a gift—you must understand that many of these women probably never receive a gift in their life. And because it is from the hospital, from some nurse, it is like a seal of approval. They may have thought they would breast feed, and then they
Indeed, the discharge pack phenomenon adds an even more insidious dimension to the substandard care received by indigents. Hospitals become the infant formula industry’s sales force in much the same way drug pushers operate. Potential customers are given free samples in small quantities, ready-to-use, and encouraged to use it whenever they like. They soon become hooked on it altogether, because of the failure of breast-feeding. When viewed in this light, the serious repercussions of discharge packs, and of the hospital practices which tend to discourage initial breast-feeding and encourage bottle-feeding, become quite clear.

Medical Professionals’ Indifference

While middle and upper income families who want to breast-feed will search for a sympathetic physician and will demand hospital treatment conducive to breast-feeding, low income mothers have less opportunity to do so. Their health think, “This is what the hospital gave me,” so they use it.

Statement No. 77 in support of Petition, supra note 14, at 64.

101. The Similac Sales Manual instructs:

... A nurse who supports Ross Laboratories is like an extra salesperson. She sees the doctor every day and can influence his/her choice of formula. There is more than one story of a nurse being the key to our getting new hospital business. Get to know all the nurses. Occasionally visit the 3 to 11 and 11 to 7 shifts. The gals on those shifts will appreciate the attention.”


102. Statement No. 24 in support of Petition, supra note 14; A. Isenalmne, supra note 69, at 82; R. Lawrence, supra note 45, at 35.

When mothers experience any breast-feeding difficulties, they often seek advice from doctors who have not been trained to resolve nursing problems. Problems such as engorgement, inhibited letdown and infants with poor suck are easily diagnosed by knowledgeable health professionals. But such knowledge is rare and mismanagement of the breast-feeding mother is widespread. Human Milk, supra note 45, at 204, 208; R. Lawrence, supra note 45, at 109, 117, 118, 132; A. Naylor, Assessment of Advice Offered for Breast Engorgement 7 (April 1980) (unpublished study, U.C. San Diego Medical School).

103. Statement No. 24 in support of Petition, supra note 14.

104. Statement No. 26 in support of Petition, supra note 14.

Hospital staff often advise women not to breast-feed. As these low income mothers relate:

[I] wanted to breast feed very badly, but [I] didn’t know how and the nurses told [me I] couldn’t because I hadn’t done the exercises or taken breast feeding classes.

I thought it would be better for the baby. The people in the

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care needs are served by residents in large, public or teaching hospitals who are trained to recognize illness, not normalcy. Breast-feeding is neither understood nor valued.

hospital told me I might not have enough milk, and that the baby would be healthier if I fed with a bottle.

Statement No. 13 in support of Petition, supra note 14.

105. Few women ever see the same doctor twice. Of women receiving continuity of care, 59% breast-feed, while only 32% of women receiving fragmented care do so. Burne, Breast-feeding, 2 LANCET 261 (1976).

106. Most women use the medical care system for maintaining their health when they are essentially normal. BOSTON WOMEN'S HEALTH COLLECTIVE, supra note 9, at 344. Obstetrics and gynecology are surgical specialties; doctors are taught to seek out illness. Because of this, and rampant medical sexism, doctors either fail to diagnose or misdiagnose organic conditions, seeking emotional causes or diagnosing a normal condition as an illness. S. RUZEX, supra note 9, at 78; Weiss, What Medical Students Learn About Women, in SEIZING OUR BODIES 212 (C. Dreifus ed. 1978).

When lack of medical school education on nutrition and breast-feeding is added to this background, widespread mismanagement of lactation results. Naylor, supra note 102; C. Marion, The Role of Medical School Training and Textbooks in Acquiring Knowledge of Breastfeeding (1979) (unpublished study, La Leche League).

107. Most medical professionals lack basic understanding of the fundamental principles of anatomy and physiology of breast structure and function. Applebaum, supra note 77; Naylor, supra note 102, at 7.

A U.C. San Diego Medical Center survey assessing advice offered for breast engorgement by medical professionals in California, Colorado and Massachusetts found 53% of the physicians and 32% of the nurses offered inappropriate advice to solve common, usually simply treated, breast-feeding problems. Naylor, supra note 102, at 7.

Since the lactation process is a sensitive one, any advice that interferes with the biologic interdependence of the mother-infant dyad is damaging. Incomplete, misleading and inappropriate advice provided by health professionals has been cited as a primary contributor to lactation failure and early weaning among American women. R. LAWRENCE, supra note 45, at 132; Ladas, supra note 38, at 342.

There are very few contraindications to breast-feeding. They include: hepatitis B virus, cytomegalovirus, breast cancer, B-streptococcal disease. R. LAWRENCE, supra note 45, at 104-07.

108. Hollen, Attitudes and Practices of Physicians Concerning Breast Feeding and Its Management, 22(6) ENVTL. CHILD HEALTH 288, 289-90 (1976), found only 24% of obstetricians routinely encourage their patients to breast-feed; 47% said they would encourage it only after the woman has expressed an interest, and 20% said they would never persuade a woman to breast-feed. In fact, 27% of the obstetricians had actively discouraged mothers from breast-feeding. Id.

THE NATIONAL COUNCIL OF CHURCHES OF CHRIST/INTERFAITH CENTER ON CORPORATE RESPONSIBILITY, PRELIMINARY REPORT: A SURVEY OF INFANT FEEDING PRACTICES AMONG LOW INCOME WOMEN IN THE UNITED STATES (1981), disclosed that of the 1,300 Black, Hispanic, White and Native American women surveyed, 59.4% of their obstetricians, 69.3% of their nurses, and 71.7% of their pediatricians had expressed no opinion on infant feeding to them. Id. at 7. At the hospital, the advice offered was even more sparse. During the first two days after delivery, only 13.7% of the physicians and 24.3% of the nurses provided any advice on infant feeding. For those few who did receive advice from hospital staff, only approximately 10% of the physicians and 20% of the nurses advised breast-feeding. The majority advised bottle-feeding, with a smaller number advising mixed feeding. Id. at 8.
Despite this atmosphere, mothers, particularly the less educated, put great credence in the advice of health professionals on infant nutrition, whatever that advice may be. The lower literacy of many low income women makes them even more dependent upon observations and verbal interactions in the hospital setting. Women see formula in use everywhere in the hospital and assume it must be better for their babies. It is not surprising that mothers who rely mostly on the medical establishment for infant feeding information are less likely to breast-feed.

Parents should know about the important benefits of breast-feeding. Most mothers who do not breast-feed are acting out of ignorance rather than intent. For them, the decision on how to feed their babies should be a conscious choice. Education should be mandatory at each step in the postnatal process.

Data and numerous accounts by patients, doctors and other informed observers of medical practices portray a profession whose words and deeds contravene the American Academy of Pediatrics' strong endorsement of breast-feeding. While many educated women choose to breast-feed despite this contradiction, the low income, less educated woman remains uniquely vulnerable to and unserved by the medical profession as she makes her infant-feeding decision. In effect, it is made for her by its indifference.

**Infant Formula Industry Promotional Practices**

Medical and hospital channels are practically the exclusive

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focus of the domestic infant formula industry's promotional efforts.114 The infant formula industry in the United States is highly concentrated,115 three major competitors accounting for approximately ninety-eight percent of the $700 million in annual sales.116 These firms, Abbott Laboratories (Ross Laboratories subsidiary), Bristol-Myers (Mead Johnson subsidiary) and American Home Products (Wyeth Laboratories subsidiary), have market shares of fifty-five, thirty-five117 and nine percent, respectively.118 Despite increased breast-feeding and a stable birth rate, profits on domestic infant formula sales have continued to rise throughout the 1970s119 and into the 1980s.120

Infant formula sales are a function of medical detailing. The magnitude of the three major formula companies’ promotional activities is indicated by the estimated 1,500 detail persons they employ domestically.121 Detail persons go through four-week training sessions which transform them into “undisputed experts” on infant nutrition to service the medical and nursing professions and hospitals.122 They call upon medical institutions, doctors, nurses, nurse practitioners, dieticians, childbirth educators, retail and wholesale drug and food outlets, the Women, Infants and Children Program (WIC)123 and other pediatric clinics as often as once a week.124 They distribute free samples, volumi-

114. See Petition, supra note 14, at 81-82, 104-106.
115. For a complete history of the infant formula industry see Petition, supra note 14, at 79-80; J. Post, INFANT FORMULA INDUSTRY: STRATEGY, STRUCTURE AND PERFORMANCE (1977) (Management & Public Policy Research Program, School of Management, Boston University).
120. Statement No. 70 in support of Petition, supra note 14.
123. WIC is a supplemental food program run by the U.S. Department of Agriculture.
124. Everdell, supra note 121, at 7; Ross Sales Manual, supra note 101, at 44.
nous literature and gifts for both professionals and patients. These materials are ubiquitous in hospital clinics and private offices.

Infant formula industry representatives provide the medical profession with extensive free services and products. These include but are not limited to:

1. Free infant formula for both in-hospital use, the medical professions’ private use and discharge packs for new mothers;
2. Free equipment, including isolators, incubators, respirators, growth charts, disposable gavage sets and myriad other items;
3. Architectural planning and consultation (Ross Laboratories designs about 200 intensive care units per year);
4. Funding for research;
5. Cash grants for projects and meetings;
6. Printing services for hospital literature, booklets, organizational newsletters, conference programs and periodicals;
7. Advertising gimmicks, and gifts such as posters, pens, note pads, flashlights and calendars;
8. Cocktail parties, meeting sponsorship, research

126. A. ISENALUMNE, supra note 69, at 41, 75-76.
127. Infant formula manufacturers often sell physicians on the similarity of their product to human milk and its convenience, not by providing nutritional or scientific data, but providing services. An ex-sales representative from Ross said that she “often felt [she] was giving bribes to get business.” Statement No. 17 in support of Petition, supra note 14.
128. See Petition, supra note 14, at 2-97 for details on any particular service.
129. Surveys of hospitals have found that in 1976, 84%, and in 1980, 80-90%, of American hospitals received free formula from the manufacturers. HUMAN MILK, supra note 45, at 338; MINNESOTA PIRF, supra note 98, at 3; Everdell, supra note 114, at 7.
130. This enables the companies to keep abreast of the organizations’ activities and to oversee the newsletters’ content before distribution. Statement No. 79 in support of Petition, supra note 14.
131. A program committee of the American Academy of Pediatrics which includes two formula companies’ representatives is responsible for selecting convention topics.

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grants, fellowships, awards, and free tickets;

[9] Underwriting professional journals with printing and advertising;\textsuperscript{138} publishing organizational mailing lists, and mailing out organizational newsletters.

The infant formula industry has in fact become the major source of medical information on infant feeding,\textsuperscript{139} selling its products subliminally and directly through the health care system. Most medical professionals remain unaware that their attitudes and patient care are substantially influenced by infant formula company promotional practices\textsuperscript{140} in at least three ways. First, such services provide tangible incentives and intangible encouragement for clinics and hospitals to promote bottle-feeding through free samples and promotional literature.\textsuperscript{141} Second, the seemingly innocent minor gifts showered by detail persons on individual health personnel, ostensibly to generate goodwill and information, also serve to keep the name of the company in constant view and play a critical role in molding opinion and influencing decisions.\textsuperscript{142} Finally, the financial underwriting and extensive services the formula companies provide professional organizations, national advisory committees and journals often yield concomitant product involvement or endorsement.\textsuperscript{143}

\textsuperscript{132} In 1974, the president of the AMA suggested dropping advertising from all of its publications because dependence on such advertisements strained the association's credibility and influence. While the legitimacy of this relationship has been questioned, little has been done to alter it. Human Milk, supra note 45, at 315.

\textsuperscript{133} The industry is acutely aware that medical and professional schools place little if any emphasis on teaching infant nutrition. Thus, the infant formula manufacturers' advertising and educational literature fills an educational vacuum on infant nutrition for both physicians and parents. Detail persons are trained to play the roles of educator and undisputed expert. A. Isen~ulumne, supra note 69, at 41, 76, 92; Ross Sales Manual, supra note 101, at 13.

\textsuperscript{134} Jelliffe, LACTATION SYMPOSIUM, supra note 10, at 202; Jelliffe, LACTATION SYMPOSIUM, supra note 68, at 10.

\textsuperscript{135} Human Milk, supra note 45, at 202; Peters, supra note 111, at 47; Statement No. 70 in support of Petition, supra note 14.

\textsuperscript{136} Human Milk, supra note 45, at 318; Jelliffe, LACTATION SYMPOSIUM, supra note 68, at 10.

\textsuperscript{137} P. Fleiss, & D. Jelliffe, The Taboo Zone: Health Professionals and the Infant Food Industry (Dec. 7, 1979) (unpublished study, UCLA School of Public Health), reprinted in Jelliffe & Jelliffe, The Taboo Zone, 65 Pediatrics 814, 821 (1981). An excellent way to become aware of the influence of marketing and advertising in medicine is to scan the medical journals. Drug ads in these journals generally portray helpless, passive women as nuisances to be managed via drugs. Boston Women's Health Collective, supra note 9, at 341-43.
The formula industry's promotional expenditures are considerable. Free formula alone represents a substantial financial investment. Hospitals which do not provide all mothers with discharge packs jeopardize this free formula, and numerous other valuable services provided by manufacturers.

Discharge packs are the fulcrum of infant formula advertising. The 1975 Ross Sales Manual states:

Hospitals represent one of the most critical markets in which Ross Laboratories competes for infant formula. . . . For every 100 infants discharged from the hospital with a particular brand, approximately 93 remain on that brand.

Gift packages have proven to be an extremely effective marketing tool, returning a six to one profit ratio on each sample. Efforts to halt the distribution of discharge packs have met with tough resistance.

138. $200 million dollars per year is a "reasonable starting point for discussing promotional expenses." Domestic Infant Formula Hearings, supra note 69, at 85 (statement of James Post).
139. $120 million to $150 million of the total $200 million spent on advertising and promotion, goes to providing free samples, free gifts, equipment, cash grants and other services to hospitals. Id. A 1980 survey of only 55% of Minnesota's hospitals found the dollar value of formula donated to those hospitals to be at least $1,500,000 a year. These figures exclude discharge packs. MINNESOTA PIRF, supra note 98, at 3-4.
140. Petition, supra note 14, at 83, 96-97; Statement Nos. 10, 75 in support of Petition, supra note 14.
141. MINNESOTA PIRF, supra note 98, at 4; Statement No. 14 in support of Petition, supra note 14.
143. R. Dellums, supra note 51, at 3.
144. The American Academy of Husband-Coached Childbirth explains:

It has been our policy to advise prospective parents of the dangers of offering a new baby ANY formula at all. We advise new parents that the "starter-packs" formula companies "give away" in the hospital are traps, in that they encourage parents to interfere with the supply-demand relationship that is the foundation of breastfeeding. We were contacted by a formula sales representative and asked to stop this practice. They felt that our couples were setting a bad example for many other mothers in the hospital, and were insistent that our mothers be told to take the packs home, even to the extent that they advised feeding their junkfood to "the cat" . . . . Then they insisted that you could use the samples to make pancakes, and even sent a receipt for "Similac pancakes."

Statement No. 36 in support of Petition, supra note 14, at 7.

Los Angeles County USC at one point stopped giving out samples but reinstituted...
Infant Formula Promotion to Mothers

Since the American Academy of Pediatrics' official endorsement of breast-feeding as the ideal feeding method for the first six months of an infant's life, the domestic infant formula industry has been promoting formula as a supplement to breast-feeding. The promotion of supplemental feeds as a panacea for mothers who wish to be freed temporarily from breast-feeding, who must be away from their babies, or who are unsure if their infants are getting enough food undermines breast-feeding by eroding parents' confidence. Such promotion causes mothers to turn to infant formula immediately or eventually, and, even in the face of rising breast-feeding rates, promotion of the mixed feeding concept has increased industry revenues.

In addition to providing discharge packs, industry "educational" literature on breast-feeding, formula feeding and infant care is widely available in all hospital clinics and wards. Since there are no widely available, well done, unbiased publications to fill this need, industry materials constitute the only information low income women receive on infant nutrition.

distribution approximately a month later. At approximately the same time, the APA committee on which the Chief Pediatrician at Los Angeles County General Hospital sat received a renewable $1,000,000 grant from Ross. Education Grant, Cal. Ped., Winter 1981.

145. Petition, supra note 14, at 98-101; Domestic Infant Formula Hearings, supra note 69, at 73, 80 (statement of James Post).
146. Statement No. 70 in support of Petition, supra note 14.
147. See supra notes 77, 97 and accompanying text.
150. INTERFAITH COUNCIL FOR CORPORATE RESPONSIBILITY, supra note 98, at 14; Ross Cassette Information Program, Perspectives in Selling—2nd Period, 1978 (AH 454).
152. A. Isenialumne, supra note 69, at 41, 75, 82, 92, 94, 98. More than 80% of the educational materials available on breast-feeding and infant feeding in two large representative New York City hospitals serving low income populations were produced by commercial sources. Id. at 76. This literature was supplied to the hospitals free and in
Breast-feeding is subtly sabotaged in the promotional literature produced by infant formula manufacturers. These publications exploit the mother's fears and her eagerness to ensure that her infant is getting enough food. Breast-feeding is presented as complicated, tiring, requiring a special diet and likely to result in nipple soreness and breast infections. In contrast, formula feeding is presented as supported by medical experts and science, producing healthy babies, and used by beautiful, loving, smiling mothers.

Overall, today's infant formula promotional strategy is aimed at low income mothers, particularly those served by public clinics and the WIC program. The United States government through WIC is the largest single purchaser of infant formula in the world. Children can be formula fed for up to two years under the program and the government picks up the bill at full market price.

There is a high correlation between bottle-feeding among low income populations in the United States and increased infant morbidity and mortality. The central question is whether it is appropriate for a seller to promote its products in a manner that will predictably lead a significant number of users to misuse large quantities. AMERICAN HOME PRODUCTS, supra note 118, at 1; A. ISENALUMNE, supra note 69, at 76; Statement No. 79 in support of Petition, supra note 14. Virtually all American hospitals (96%) receive free educational materials from the industry. Baunslag & Walker, supra note 88, at 2; see also MINNESOTA PIRF, supra note 98, at 3.

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The extensive misuse of infant formula and concomitant harms suffered by low income populations have been documented. While most would agree that infant formula should not be promoted to women who through no fault of their own may feed their infants undiluted concentrate or may mix formula with an unsanitary water supply, formula companies claim that they should not have to bear the responsibility for use and distribution of their product.

The industry's stance can be summarized by the following excerpt. Journalist Barbara Garson described an interview with a Bristol-Myers representative:

"Tell me, if you stop selling to people who are too poor to use the product safety, will you still make a profit?"

"There was absolute silence. It must have been a full minute."

"Finally one of the corporate executives picked it up and said, "That is the crux of the problem.""

Summary

Professional indifference has, over time, left a void of information and support for breast-feeding. The formula companies have expended impressive resources to foster and then fill this void. Their success can be measured by their increasing profits—even in the face of breast-feeding's renewed popularity, by common hospital practices which facilitate bottle-feeding and undermine breast-feeding, and by the overwhelming market share formula companies have maintained among low income women. Across the country, however, concerned health workers are successfully breaking this cycle, permitting an informed in-
fant feeding choice by the low income families they serve. Once presented with the information, substantial numbers of low income mothers, like their middle and upper income counterparts, are choosing what is best for their infant’s health and well-being: breast-feeding. This movement of low income women toward breast-feeding can be hastened substantially if relevant government agencies take swift and appropriate action.

III. PETITIONING FEDERAL AGENCIES

A. PETITIONING AS AN ADVOCACY TOOL

When seeking resolution of women’s health problems or other problems of great public concern, like infant formula misuse and the decline of breast-feeding among low income women, there are several avenues one can choose. A lawsuit may be brought against the appropriate industry or responsible agency,\textsuperscript{166} legislators or members of Congress may be receptive to formulating and presenting appropriate legislation,\textsuperscript{167} community organizing can educate people about the problem and in some cases bring about an adequate solution.\textsuperscript{168}

\textsuperscript{166} Tort action against an agency can be costly and the available remedies limited. Action would be aimed at obtaining a court order forcing agency officials to solve the problem. If there is a clear legal basis for the suit, i.e., if the agency has failed to fulfill its statutory duty to act, petitioning would be a less expensive method of accomplishing this goal. C. OSHIRO & H. SNYDER, \textit{GETTING ACTION: HOW TO PETITION STATE GOVERNMENT} (1980).

Exhaustion of administrative remedies is a prerequisite to suing an agency. The courts require that agencies be given an opportunity to take corrective action before they will hear the case. Petitioning fulfills both these requirements. Oljato Chapter of the Navajo Tribe v. Train, 515 F.2d 654, 666 (D.C. Cir. 1975) (challenging the refusal of the Environmental Protection Agency to revise previously promulgated standards of performance for new coal-fired power plants in light of new information); Schuck v. Butz, 500 F.2d 810, 812 (D.C. Cir. 1974) (order directing the Secretary of Agriculture to repeal regulations authorizing the use of sodium nitrates and nitrites in meat products could be granted only through rulemaking, and the agency had to be given the opportunity to evaluate any repeal).

Lawsuits and petitioning are not mutually exclusive; pursuing the two in tandem is also possible and may force the industry voluntarily to make some of the changes requested.

\textsuperscript{167} Where new legislation is not required because the particular agency is already under a duty to act, legislators can be encouraged to hold fact-finding hearings to determine why the agency has failed to take necessary action. C. OSHIRO & H. SNYDER, \textit{supra} note 166, at 14. For a discussion of how lobbying is being used to solve women’s health issues see S. RUZEK, \textit{supra} note 9, at 152-57, 226, and COMMITTEE FOR ABORTION RIGHTS AND AGAINST STERILIZATION ABUSE, \textit{supra} note 16, at 52-55, 60-62.

\textsuperscript{168} The personal time and effort involved in community organization cannot be overestimated. This usually entails extensive use of media, canvassing, networking, and

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The administrative petitioning process differs from the above courses of action in several respects. It is faster, less expensive and allows for more creative, effective solutions than lawsuits. Petitioning can be more effective than legislation because it insures implementation as well as the issuance of the necessary rule. Finally, when an agency has received a clear, statutory mandate to act or when the harm complained of will be egregious or imminent if action is not taken immediately, petitioning can resolve the problem more effectively and with less personal effort than any other action. In fact, the petitioning process, in conjunction with litigation, legislation and community organizing, can produce the most effective solution in any particular case.

Until recently, women have constituted the most uninformed medical consumer group in our society. The rise of the women's health movement in response to this problem has succeeded in making individual women aware that their problems are shared by others. The women's health movement has taken an active role in influencing health legislation public policy and in pressing for enforcement of existing laws and regula-


Local organizing and petitioning of state and local governments can bring about substantial changes in health care in particular communities. Patient's Bills of Rights can be adopted by individual hospitals. G. Annas, supra note 9, at 152; D. Scully, supra note 9, at 137. Public Advocates and the Coalition for the Medical Rights of Women have successfully petitioned the State of California for regulation of IUD's, pap smears and sterilization.

169. See infra note 223 and accompanying text for a discussion of the differing factual situations in which petitions can be used. See infra notes 225-236 for a discussion of available administrative remedies.


171. Public Advocates' Petition to Free Surplus Cheese provides an excellent example. Petitioners asked the U.S. Department of Agriculture and the President to release a 225,000,000 pound surplus of cheese which had been paid for by a multi-billion dollar dairy subsidiary. After about two weeks work they succeeded in getting a portion of that cheese released to the poor before Christmas 1981.

172. See supra notes 59, 166 and infra notes 177, 194-197 and accompanying text.

173. G. Annas, supra note 9, at 146.

174. D. Scully, supra note 9, at 255-56.
tions through legal action. Patient education, legislative and lobbying efforts, judicial measures and direct pressure through community organizing and the press have been used to cut back on the abuse of women. The right to petition federal agencies plays an important role in furthering these objectives.

Petitions can fulfill several functions simultaneously. They focus agency attention on the particular problem, provide a rallying point around which community organizing can generate mass support, educate the press and the public about a harm which is occurring, and can spur legislators to act on the problem even if regulators do not. Women's health issues generally lend themselves well to petitioning. They are by their very nature the types of issues for which public consumer education is a primary goal. Furthermore, since most issues evolve around health and safety, agency authority is derived from general enabling statutes. The domestic infant formula petition provides an excellent example of how the petitioning process unites these various vehicles in an effort to force regulatory resolution of one very serious women's health issue.

B. THE REAGAN ADMINISTRATION'S REGULATORY PROGRAM

President Reagan, in the name of "regulatory relief" and getting government "off the backs" of the people, has departed on a program of regulatory reform which seeks to impair meaningful citizen participation in the administrative decision making process. His program may also undermine the integrity of

175. Id. at 253. For an overview of the legislative and judicial efforts of women's health groups, see S. RUZIK, supra note 9, at 152-161.
176. Id. at 235, and 147-152.
177. While often factually complex, these issues provide an opportunity for practitioners to gain expertise which can be very persuasive before the agencies.
178. See, e.g., infra notes 206-219 and accompanying text.
179. President Reagan's Exec. Order No. 12291, 46 Fed. Reg. 13,193 (1981), reprinted in 5 U.S.C. § 601 Supp. at 199-202 (1982), [hereinafter cited as Executive Order 12291] establishes for the first time a centralized mechanism for presidential management of agency rulemaking activities. The order creates a formal, comprehensive, centralized and substantially oriented system for control and direction of informal rulemaking at all stages of the process. HOUSE COMM. ON ENERGY AND COMMERCE, 97TH CONG., 1ST SESS., PRESIDENTIAL CONTROL OF AGENCY RULEMAKING: AN ANALYSIS OF CONSTITUTIONAL ISSUES THAT MAY BE RAISED BY EXECUTIVE HOUSE ORDER 12291, at 1-3 (Comm. Print 1981) [hereinafter cited as PRESIDENTIAL CONTROL]. The provisions of this order can be summarized as follows:

1. Substantive control over all agency rulemaking is centralized in the Office of

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the regulatory system by doing away with the important proce-
dural guarantees adopted over the last forty years, which in-
sure fairness to all citizens in dealing with the government.

A brief description of the procedural protections Congress
has imposed to prevent abuse within the regulatory process will
highlight the dire threat imposed by the administration’s poli-
cies. Regulations are the principal means by which govern-
ment acts. Simply stated, a “regulation” is a legally binding
statement by an administrative agency implementing a law en-
acted by Congress. When Congress sets national policy by
statute it does not spell out the details for achieving this goal.
Instead it addresses these major problems by delegating author-
ity to administrative agencies which implement the law by regu-
lation. Therefore, control of the regulation writing process
means effective control over the extent to which a law is or is
not implemented.

Budget and Management. OMB must review, approve and authorize for pub-
lication any agency action involving the promulgation of new rules, review of
old rules or the development of legislative proposals concerning regulations.

[2] The OMB is given complete discretion to determine which rules will be sub-
ject to their scrutiny, thus giving the OMB the ability to determine which
laws or congressional mandates it will implement.

[3] The OMB’s activities are subject to review by the Presidential Task Force on
Regulatory Relief and final appeal to the President.

See C. LUDLAM, UNDERMINING THE INTEGRITY OF GOVERNMENT: THE REAGAN ADMINIS-

180. The legal authority for Executive Order 12291 is seriously in doubt. First, cre-
ating a central coordinating agency with the power to substantively direct and control
the informal rulemaking process conflicts with Congressional intent behind the Adminis-
trative Procedure Act. Second, the OMB’s exercise of powers granted can effectively
usurp congressionally delegated discretionary agency rulemaking authority. PRESIDENTIAL
CONTROL, supra note 179, at 42-54. Finally, establishing OMB as the sole clearinghouse
for all rules could violate due process by creating a critical access point to agency deci-
dion-making without procedural safeguards against secret, undisclosed and unreviewable
contacts with nongovernmental interests who seek to influence the substance of agency
action. Id. at 3, 54-62. See generally C. LUDLAM, supra note 179; Edelman, REAGAN’S
ATTEMPT TO CONTROL THE FEDERAL ADMINISTRATIVE PROCESS IS UNCONSTITUTIONAL, 15(8)
CLEARING HOUSE REV. 646 (1981).

181. C. LUDLAM, supra note 179, at 67; see PRESIDENTIAL CONTROL, supra note 179,
at 3-4 for a discussion of the purpose of the Administrative Procedure Act.

182. C. LUDLAM, supra note 179, at 3-4.

183. Regulatory agencies have become captives of the industries they regulate. J.

At least one court has recognized that there is an excess of solicitude toward indus-
(after four years delay, FDA gave drug manufacturers more time to supplement the
rulemaking record; the court denied this extension). Since regulated interests commit
To ensure that laws are implemented effectively, in accordance with congressional intent, and to preserve openness and fairness, Congress has adopted strict substantive and procedural standards for issuance of regulations,\textsuperscript{184} codified in the Administrative Procedure Act (APA).\textsuperscript{185} Among the most important rights guaranteed by the Constitution and the APA is the right of every citizen to petition the government for redress of grievances,\textsuperscript{186} which facilitates increased public participation in great resources to participation before regulatory agencies it is extremely important to facilitate public interest representation to counter-weight this influence. Petitioning is one mechanism for achieving this goal. \textit{Administrative Conference of the United States, 1971-72, Report 11-2, at 37-18 (1972)}; \textit{K. Davis, Administrative Law of the Seventies 602 (1976)}; Chambers, \textit{Increasing Citizen Participation in Administrative Proceedings: Can Federal Financing Bridge the Costs Barrier,} 30 \textit{Case W. Res. L. Rev.} 33, 34 (1979); Cramton, \textit{The Why, Where and How of Broadened Public Participation in the Administrative Process,} 60 \textit{Geo. L.J.} 525, 529 (1972). Regulated industries spend much more on regulatory participation than their public interest counterparts who lack the resources to participate effectively. \textit{See generally Lenny, The Case for Funding Citizen Participation in the Administrative Process, 28 Ad. L. Rev. 483 (1976); Public Participation in Federal Agency Proceedings Act of 1977: Hearings on S270 Before The Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary (pt. 1), 95th Cong., 1st Sess. 4 (1977) [hereinafter cited as \textit{Hearings I}] (statement of Calvan J. Collier).}

\textsuperscript{184} Regulatory protections can be outlined as follows. Congressionally confirmed agency officials must:

3. Evaluate and respond to these comments. \textit{Id}.
4. Explain the regulation that is finally issued. \textit{Id}.
5. Support the decision with information in the rulemaking record. Rodway v. USDA, 514 F.2d 809, 816-18 (D.C. Cir. 1975) (members of low income households challenged the coupon allotment system under the Food Stamp Act, claiming that the averaging system denied them a nutritionally adequate diet).
6. Refrain from ex-parte contacts. Home Box Office, Inc. v. FCC, 567 F.2d 9 (D.C. Cir. 1977) (ex parte communications in informal rule-making under § 553 are prohibited since they lead to undue industry influence over the agency).

\textsuperscript{186} See 5 U.S.C. § 553(e) (1976) ("Each agency shall give an interested person the right to petition for issuance, amendment or repeal of a rule."). This right is particularly effective when an agency adopts a rule without allowing public participation either through hearings or notice and comment procedures. A petition in such instances forces the agency to consider and answer to petitioner's comments. Guardian Fed. Sav. & Loan v. Federal Sav. & Loan Corp., 589 F.2d 658, 668 (D.C. Cir. 1978) (regulation, issued without prior notice and comment qualified as general policy statement when the regulation promulgated reiterated existing guidelines).
agency rulemaking and forces agencies to consider views and issues they might otherwise ignore. 187

Public participation figures heavily among the essential procedural protections imposed upon the administrative agencies by the APA. The primary purpose behind requiring publication of a proposed rule in the Federal Register is to increase public participation in the regulatory decision-making process. 188 Agencies draft proposals to educate the public and elicit comments which in turn will enlighten the agency with regard to aspects of the proposal it may not have understood fully. Because agencies supposedly make no key decisions during the pre-proposal drafting stage, they traditionally have been allowed to consult a wide range of parties without any formal requirements to reveal the nature of those contacts or to compile a formal record. 189 Publication of the proposed regulation provides the procedural check

187. One objective of § 553(e) is to provide an opportunity for interested persons to correct agency error or inaction. Tabor v. Joint Bd. for Enrollment of Actuaries, 566 F.2d 705, 711 (D.C. Cir. 1977) (challenging regulations under the Employee Retirement Income Security Act for failure to incorporate in the rules adopted a concise general statement of their basis and purpose). See also 5 U.S.C. § 555(b) (1976) (requiring prompt written notice of reasons for denying applications, petitions and other requests).

188. The benefits of increased public participation in all agency rulemaking are numerous. They include greater agency responsiveness to the public, well-balanced administrative decisions, strong advocacy of currently unrepresented interests, early citizen input into decisions which will have a substantial impact on their lives, education of the agency, greater assurance of fairness and mature consideration prior to promulgation of a rule of regulation and more diligence by the agencies themselves. Lenny, The Case for Funding Citizen Participation in the Administrative Process, 28 Admin. L. Rev. 483, 491-94 (1976).

189. PRESIDENTIAL CONTROL, supra note 179, at 3-4, 37, 55-62.
necessary to safeguard the right to public input. Furthermore, Congress, the public and the courts rightfully expect that agencies will be held accountable for decisions concerning the implementation of any particular law. 190

Today the Office of Budget and Management (OMB) clearance process for proposed regulations subverts effective public participation by allowing OMB the discretion to prevent solicitation of public comment on a proposal and censoring the proposal before debate begins. 191 This also means that the real decisions on a regulatory issue are often made during the pre-proposal clearance and not on the basis of public comments. 192 Even more troublesome is that lax procedural protections at this stage of the administrative proceedings provide a fruitful arena for economically interested parties to compromise the intent of a rule through negotiations or to kill a controversial proposal before it even becomes public. 193

190. See infra notes 271-285 and accompanying text.
191. C. LUDLAM, supra note 179, at 31-32.
192. This particular grant of power to OMB is in clear and direct opposition to the legislative history of the APA in general and § 553(e) in particular. See, PRESIDENTIAL CONTROL, supra note 172, at 50-54 for a decision on the conflict between Executive Order 12291 and 5 U.S.C. § 553(e).
193. The mere fact that one agency of government, OMB, now possesses the power of life or death over the activities and decisions of every other agency must itself arouse grave concern. OMB's seemingly limitless powers create a substantial potential for abuse and mischief including potential for outright corruption. OMB is likely to view an issue from a political or ideological perspective, relying on the arguments of White House political advisors or special interest lobbyists. This danger is even greater when major political supporters of the White House become interested in a particular proceeding. C. LUDLAM, supra note 179, at 33-35; PRESIDENTIAL CONTROL, supra note 179, at 4-5. See Project, Due Process and Ex parte Contacts in Informal Rulemaking, 89 YALE L.J. 194 (1979).

When the pending regulations relate to issues of public health and safety the results of delay or non-issuance of regulations can be disastrous. The Infant Formula Act of 1980 included a provision requiring FDA to promulgate regulations for recall of defectively manufactured infant formulas. These regulations could legally have gone into effect anytime after the comment period ended in May, 1981. Instead, the cost benefit analysis required under Executive Order No. 12291, supra note 179, provided an opportunity for industry influence and interference which delayed issuance of these regulations. The cost benefit analysis was not completed until February, 1982 and another six months will lapse before the regulations finally go into effect.

In the meantime, Wyeth Laboratories produced two batches of defective formula—one lacking Vitamin B-6 totally and the other containing deficient amounts of B-6. The first batch, manufactured in January, 1982, went undetected by the FDA until March, 1982. Following discovery, Wyeth refused to initiate high priority recall and effectively delayed any recall action until the House Commerce Subcommittee on Over-
Petitioning can be the ideal weapon to combat these practices. Especially when combined with community organizing and press coverage, it can be used to focus attention on exactly those regulatory issues which the administration wishes to ignore. The right to petition for issuance, amendment or repeal of a rule and to receive a reasoned response thereto is the key to assuring sound government. The concerned public can, through petitioning, force agencies to implement congressional mandates. Additionally, petitioners can insist that administrators, satisfied with the status quo, consider action in new areas or re-examine their position on a particular problem in light of information that becomes available. Petitioning provides interested persons an opportunity to research, gather and present new data in a manner which compels agencies to reconsider their present stance on existing or proposed regulations. In this manner women's and consumer groups can force government to respond to their particular needs.

C. THE PETITIONING PROCESS

Petitioning the federal government can be a significant undertaking. To use this process most effectively, one must acquire expertise in the issue of concern, prepare a competent and
well-documented petition, and persuade others to support the petition. An administrative petition must contain the substance and nature of the rule or other action being requested, the reasons for the request, the petitioner’s interest in the request and reference to the agency’s authority to take the requested action. Throughout this section, the Petition to Alleviate Domestic Infant Formula Misuse and Provide Informed Feeding Choice prepared by Public Advocates in San Francisco detailed scientific research is needed. Another type of petition is one in which an existing phenomenon must be documented to convince the agency that a problem in fact exists. Petition for Immediate Executive Action to Alleviate the Nationwide Inner City Food Crisis, filed by Public Advocates, October 23, 1980, described the exodus of supermarket chains from the inner cities and requested alternatives to remedy this food crisis.

The petition should be written in a simple, straightforward style, especially if it involves complex or technical facts. It should present the issues and data objectively as possible while still advocating the cause. Jargon, sensationalism and accusations should be avoided wherever possible. It should reflect that petitioners are concerned people attempting to work with the government to solve an important problem. C. OSHIRO & H. SNYDER, supra note 166, at 15.

Gathering support for the petition is crucial. The Infant Formula Petition sought to bring together as broad a group as possible. Petitioning organizations included American Medical Students Association; American Public Health Association (Women’s Caucus); Coalition to Fight Infant Mortality; Infant Formula Action Coalition (INFAC); Interfaith Center on Corporate Responsibility (Infant Formula Work Group); International Childbirth Education Association (ICEA); Mexican American Legal Defense and Education Fund (MALDEF); National Association for Parents; National Council of Negro Women; National Council of Jewish Women; National League of United Latin American Citizens (LULAC); National Women’s Health Network; Professionals for Safe Alternatives in Childbirth (NAPSAC); and Women of All Red Nations (WARN).

The petition should discuss why the petitioned agency is responsible for correcting the situation and identify the actions which need to be taken. ATTORNEY GENERAL’S MANUAL ON ADMINISTRATIVE PROCEDURE ACT 38-39 (1947) [hereinafter cited as ATTORNEY GENERAL’S MANUAL].

An explanation of the problem and a description of how and why it is hurting the public should be included. Id.

It is important to identify each of the petitioners or petitioning organizations and describe how they are affected by the problem. Id.

will be used as an example of the petitioning process.\footnote{205}

1. \textit{Researching the Issue}

\textit{Factual research}

A petition for rulemaking must disclose sufficient reasons to justify the institution of a rulemaking proceeding.\footnote{206} In developing the factual basis for a petition it must be kept in mind that the petition will become part of the administrative record for purposes of judicial review.\footnote{207} Therefore, the more specific the examples of harm and the more detailed the data collected, the better the case can be made that the agency \textit{must} take the action requested. The complexity and substantiality of the issues and data presented by petitioners in support of their claim will determine the expansiveness of the response the courts will demand of the agency.\footnote{208} For example, on at least two occasions administrators sought to deny petitions which failed to present "the sound, scientific, and convincing evidence needed to make a final determination"\footnote{209} or failed to "contain any evidence that aid[ed the agency] in making [its] judgment."\footnote{210} On both occasions the reviewing courts found an existing harm which the agency had jurisdiction to prevent.\footnote{211} The petition need not present in exhaustive detail every view presented on the particular issue, but should cover all relevant aspects of the problem.

The first step towards developing an administrative petition is field research—a careful accumulation and documentation of the problem.\footnote{212} In the case of the infant formula petition this stage of research took about six months. At the outset, profes-

\begin{itemize}
  \item \footnote{205} Petition, \textit{supra} note 14.
  \item \footnote{206} This is the standard used by the Federal Commerce Commission, and should be the minimum standard for any rulemaking petition. See F.C.C. Petitioning Guidelines, 47 C.F.R. § 1.406 (1981).
  \item \footnote{207} Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031, 1047 (D.C. Cir. 1979).
  \item \footnote{208} See Oujato Chapter of the Navajo Tribe v. Train, 515 F.2d 654, 666-67 (D.C. Cir. 1979).
  \item \footnote{209} Shuck v. Butz, 500 F.2d 810, 812 (D.C. Cir. 1974).
  \item \footnote{210} Geller v. FCC, 610 F.2d 973, 979 (D.C. Cir. 1979) (FCC rules reflecting consen-
sus agreement by affected parties seeking modification of copyright laws cannot be ad-
hered to without a showing that they serve the public interest).
  \item \footnote{211} \textit{Id.}
  \item \footnote{212} See C. OSIRO \\& H. SNYDER, \textit{supra} note 166, at 21-22, 51-52 which outlines a step-by-step approach for petitioning state agencies.
\end{itemize}
sionals and organizations who shared an interest in the problem of infant formula misuse were contacted. These persons referred the researchers to other individuals, beginning a process which resulted in 100 expert witness statements from interested individuals throughout the country. An extensive literature search was also conducted, including unpublished research and research in progress.

Once an overview is gained, potentially unsympathetic sources of information should also be approached. Many of these may actually provide important information. Speaking with unsympathetic persons not only insures objectivity but helps refine your argument, test your confidence and grasp of the problem and gain insight into potential counter arguments.

**Legal research**

Once the problem has been identified and defined through field research, the next step is to research those agencies which can best provide solutions. The fundamental authority for

213. Prior to the initial conversation it is useful to make a list of various aspects of the problem and information, including research sources, sought. Infant formula project topics included: Trends, harms of infant formula use, misuse, hospital practices, attitudes of professionals, industry practices, programs to enhance breast-feeding, articles, unpublished research, and other contacts. Each contact was asked to make an expert witness statement.

214. It is helpful to request recommendations and citations to important, definitive articles in each expert's field. The petition will necessarily reflect that expertise and be all the more effective.

215. Unpublished research, both local and national, conducted by universities, students, individual clinics, hospitals, etc., can be a valuable source of information critical to any project. Much of the documentation in the Infant Formula Petition came from unpublished sources. Often issues which are the subjects of petitions have either just recently been investigated or are in areas in which large scale research funding has been unavailable. When large national studies are available they are often four to five years old. Unpublished research fills this gap and brings the research up-to-date. Furthermore, the most up-to-date nationwide data often is gathered by the industry itself.

216. The federal agencies addressing areas of concern are:
   - Consumer Protection: Federal Trade Commission (FTC); Consumer Product Safety Commission (CPSC); Food and Drug Administration (FDA); National Highway Traffic Safety Administration (NHTSA).
   - Education: Department of Education.
   - Energy and Utilities: Department of Energy (DOE); Federal Communications Commission (FCC); Interstate Commerce Commission (ICC); Civil Aeronautics Board (CAB); Federal Aviation Administration (FAA); Nuclear Regulatory Commission (NRC).
   - Food: U.S. Department of Agriculture (USDA); Food and Drug Administration (FDA).

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each agency is either a statutory mandate to take a particular action\textsuperscript{217} or an enabling statute. The Secretary of Health and Human Services (HHS), for example, has general authority under the Social Security Act to mandate rules and regulations necessary to the efficient administration of the functions of the Act.\textsuperscript{218} This enabling statute provided sufficient authorization for the issuance of the comprehensive informed consent procedures for sterilization.\textsuperscript{219} This is also the authoritative basis for HHS action on the infant formula petition.

Once the authorizing statutes are identified, a thorough review of agency regulations is necessary. In reading the relevant regulations special attention should be paid to regulations which delineate each agency's particular petitioning requirements, regulations which mandate agency action to be taken on citizen petitioning,\textsuperscript{220} rules which are directed or could be interpreted in favor of alleviating the problem being researched,\textsuperscript{221} and agency waivers of APA exceptions.\textsuperscript{222} Additional sources of useful infor-

\begin{itemize}
  \item Health Care: Department of Health and Human Services (HHS).
  \item Housing: Department of Housing and Urban Development (HUD).
  \item Labor: Department of Labor; Occupational Safety and Health Administration (OSHA); Equal Employment Opportunity Commission (EEOC); National Labor Relations Board (NLRB).
  \item Natural Resources: Environmental Protection Agency (EPA); USDA; Department of the Interior.
  \item Welfare: Social Security Administration (Aid to Families with Dependent Children; Supplemental Security Income); USDA (Food Stamps; Women, Infants, and Children Program; Commodity Supplemental Food Program); Administration on Aging (National Nutrition for the Elderly); Office of Child Development (Head Start).
\end{itemize}

\textsuperscript{217} \textit{E.g.}, \textit{15 U.S.C. § 52 (1976)} (FTC statutory mandate to act against deceptive advertising practices).

\textsuperscript{218} \textit{42 U.S.C. § 1302 (1953)}.


\textsuperscript{220} \textit{ATTORNEY GENERAL'S MANUAL}, supra note 194, at 38-39 states that "every agency with rulemaking powers subject to Section 4 should establish, and publish under Section 3(a)(3), procedural rules governing the receipt, consideration and disposition of petitions filed pursuant to Section 4(d)." \textit{See PRESIDENTIAL CONTROL}, supra note 179, at 51.

\textsuperscript{221} \textit{See e.g.}, \textit{7 C.F.R. § 246.9 (1981)} (nutrition education must be provided at WIC certification); \textit{7 C.F.R. § 247.8 (1981)} (nutrition education is encouraged at all stages of the WIC program); \textit{42 C.F.R. § 405.1021 (1981)} (delineates conditions for participating hospitals); \textit{42 C.F.R. § 431.107 (1981)} (delineates provider requirements under Medicaid); \textit{42 C.F.R. § 431.610(f)-610(g) (1981)} (Medicaid eligibility includes provider standards and service standards); \textit{see also supra note 204}.

\textsuperscript{222} The Administrative Procedure Act, \textit{5 U.S.C. § 553 (1976)} contains numerous exceptions to its minimum procedural requirements. The two exceptions relevant to the infant formula case are the exceptions relating to public property, loans, grants, benefits.
information include testimony before congressional committees and government research on the topic. In short, you are seeking any legal authority which will support your argument that the agency has a statutory duty or an obligation to use its discretionary powers to remedy the specified harm.

2. Developing Administrative Remedies

Remedies available through an administrative petition are broader and more flexible than those awarded by the courts. To design appropriate administrative remedies one must carefully delineate the problem and examine effective, workable solutions. While developing solutions to the problem of infant formula misuse it was helpful to focus on those points of intervention at which agency action could simply, yet profoundly, benefit mothers and children who have fallen victim to the abusive marketing practices of the infant formula industry.

Research revealed that several factors play an important role in significantly increasing breast-feeding rates and duration among low income women: education of both the health professional and the mother; individual lactation instruction or contracts, id. § 553(a)(2) (1976), and the public policy exception, id. § 553(b)(3)(A) (1976). Agencies may, at their discretion, waive these exceptions. Annot., 45 A.L.R. FED. 12 (1979).

223. The easiest case for petitioning is when an agency has a specific duty to promulgate a regulation. Consumers, aware that Congress has passed a law in their favor, should petition for the promulgation of rules under that statute. This would effectively prevent the OMB from stalling implementation of congressional mandates.

224. When filing a petition for exercise of a discretionary power, it is helpful to investigate previous similar exercises of agency discretion in related areas. An example is the mandate that informed consent be obtained prior to sterilization in all family planning programs paid for in part by HHS through Medicaid. See supra note 219. The sterilization regulation included a model instruction pamphlet which would meet HHS guidelines. These regulations were issued under the same sections that authorized the actions requested in the Infant Formula Petition.

225. For the most part, solutions proposed in a petition are only recommendations. The agency can fashion any remedies it desires provided it complies with the APA notice and comment publication requirements. Even so, suggested remedies can provide concrete solutions.

226. See Petition, supra note 14, at 108-11, 113-16, 118-20, 126.

227. Winikoff & Baer, supra note 38, at 105. See generally Petition, supra note 14, at 126.

228. Harfouche, The Importance of Breastfeeding, J. TROP. PED., Sept. 1970, at 133, 159; Statement No. 28 in support of Petition, supra note 14. Most mothers make infant feeding decisions pre-natally, based on whatever nutritional information they receive at that time. Peters, supra note 121, at 83; Winikoff & Baer, supra note 38, at 109. It is

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for mothers who experience breast-feeding problems; changes in hospital protocol, including the discontinuance of the discharge pack, and changes in the labeling of infant formula cans. The next step was to determine how the government could effectuate these solutions and whether or not the agency has legal authority to do so. Where possible, examples of programs which have successfully implemented any of the proposed solutions should be included in the petition.

Often government agencies can play a leading role in implementing solutions. Therefore, it is imperative that accurate, consistent nutritional information be provided to all pregnant women. Id. at 107.

A lactation counselor or postpartum division nurse can act as teacher, imparting practical knowledge and assistance. Small informal classes for nursing mothers enable nurses to instruct several women at once while providing mothers with peer support. See Bird, Breastfeeding Classes on the Postpartum Unit, Am. J. Nursing 456 (1975). In hospitals, information can be provided to mothers through closed circuit television, slide tape, and cassette tape, presentations and unbiased educational literature, which are available ad libitum. This allows the nurse/counselors, or lactation specialists, to devote more of their time assisting each mother with her particular needs. Petition, supra note 14, at 125-26.

See supra notes 80-100 and accompanying text for an outline of detrimental hospital practices.

Necessary changes include: color coding, changes in package size, bilingual labeling, warnings emphasizing the superiority of human milk and indications of misuse, and graphic preparation instructions.

This often requires a good deal of creative lawyering. Once solutions and authority are decided upon, agency regulations reveal instances in which the agency has granted similar remedies. In 1978, for example, the Department of Health and Human Services promulgated sophisticated informed consent procedures for sterilizations. Terminations and Abortions: Federal Financial Participation, supra note 219. These regulations provided impetus to the informed consent approach taken in the infant formula petition.

A number of successful efforts have demonstrated that enlightened medical practice can substantially increase the prevalence and length of successful lactation. They include:


Canadian In-Service Information Packet: (conceived and produced by the Canadian Department of Health and Welfare, the La Leche League, and the Canadian Pediatric Society).

Women's Breastfeeding Support Group, Oakland, California.

Lactation Clinic, University of California, San Diego.

Promotion of Breastfeeding, Window Rock, Arizona.

One Support Person Increased Breastfeeding Rate, Mississippi.

Breastfeeding Intervention Clinic LA/USC, Los Angeles, California; Petition, supra note 14, at 108-20.
menting these necessary changes. In the case of the infant formula petition, government agencies were requested to develop unbiased materials on breast-feeding and infant nutrition aimed at educating both health professionals and new or expectant mothers. Government funding was to be restricted to those institutions which encourage breast-feeding, have a lactation consultant on staff and do not distribute discharge packs or formula company promotional literature. The WIC program was asked to play a more critical role in encouraging breast-feeding prenatally and assisting women toward successful periods of lactation. The FDA was requested to change packaging and labeling requirements to alleviate the formula misuse presently rampant among our low income and minority populations. Finally, all agencies were requested to hold hearings for consideration of these proposals. Ideally, hearings should be held in geographically diverse locations and, where appropriate, public participation funding should be provided.

3. The Actual Petitioning Process

Although an individual or group can petition a federal agency for relief on its own, there is a greater impact and a greater chance of success if others join in the petitioning effort. Agencies are less likely to overlook or deny a petition that has broad public support. In seeking petitioners it helps to join groups which represent a broad cross section of the Ameri-

235. Both Breastfeeding, supra note 6, at 597, and Recommendations for Action Programs to Encourage Breast Feeding, 4 BULL. INT'L PEDI., Oct. 1975, at 19, emphasize the need for health professionals to become much more knowledgeable about infant nutrition and the physiology, value, and technique of breast-feeding. In Canada, a nationwide educational campaign by the government and private sector groups for all health professionals associated with pregnant women and new mothers cost only $100,000 and was deemed an overwhelming success. Statement No. 61 in support of Petition, supra note 14.

Once professionals receive accurate information about the relative values of breast and bottle feeding to both mother and infant and instruction on how to treat minor breast-feeding problems, breast-feeding rates and duration among their patients improve. Winikoff & Baer, supra note 38, at 110-11.

236. While hearings are not required by statute, USDA/WIC in the past has held nationwide public hearings at which program officials received testimony from program recipients, welfare organizations, state and local officers, project directors and health professionals on the program's effectiveness. Recommendations for program improvement resulted from these hearings. COMMUNITY SERV. ADMIN., GOVERNMENT PRINTING OFFICE, CITIZEN PARTICIPATION, (1978).

237. C. OSHIRO & H. SNYDER, supra note 166, at 27.

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can public.\textsuperscript{238}

Once the petition has been written\textsuperscript{238} it should be filed with the appropriate agency.\textsuperscript{240} Unless there is a person who has been specifically designated to receive petitions, documents are best filed with the head of the agency.\textsuperscript{241} It is often helpful to telephone agency officials to inform them that a petition is being filed.

The media can perform an extremely important role in the administrative petitioning process by allowing petitioners to communicate with and educate broad segments of the public. The media also enables petitioners to mobilize public support for the petition.\textsuperscript{248} After the petition has been filed there are

\begin{itemize}
\item Large, nationally respected and community based organizations should be included if at all possible. See supra note 200, for examples.
\item The Petition should be structured as follows:
\begin{itemize}
\item (1) INTRODUCTION—Summarize key facts; identify petitioners and the responding agencies, the facts giving rise to the petition, action requested by the responding agency and why the action is necessary to protect the public interest.
\item (2) STATEMENT OF FACTS—Explain the current state of affairs, why current state of affairs is harming the public, why it is the agency's responsibility to take corrective action; discuss necessary corrective action.
\item (3) PETITIONERS—Identify petitioners, state briefly their interest in the action requested and give a brief description of the organization.
\item (4) JURISDICTION—Cite the relevant petitioning statute; identify the section containing the laws that give the agency authority to act.
\item (5) RELIEF—List all corrective actions requested. A draft of proposed regulations may be included, but it is not essential.
\item (6) CONCLUSION—Urge the agency to take prompt action. This should be followed by signatures of the petitioners or their representatives.
\item (7) EXHIBITS—This section can be used to highlight critical facts in the Petition and is very important. The infant formula petition was accompanied by one hundred expert witness statements as exhibits.
\end{itemize}
\item Timing of the filing can be critical. Relevant factors include: Conflict with other events which could cut back on press coverage, political campaigns and campaign issues, proximity in time to other events which could bear on the petition or which could enhance press interest in the topic. The Infant Formula Petition, supra note 14 was filed one day after the House voted to censure President Reagan's stance on the W.H.O. infant formula marketing code and one day before the Senate took a similar stance.
\item Filing means delivering the petition to the respective agencies. Some agency regulations specify a person other than the agency Secretary with whom petitions should be filed.
\item A contact list composed of media likely to reach populations affected by the problem, interested in the petition, or influential in the agency's decision should be prepared in advance. A brief press release should also be prepared in clear, straightforward and non-technical language. If a press conference is planned, this information should be included. See C. OSHIRO & H. SNYDER, supra note 166, at 34-42, 77-81 for an overview of methods and strategy for involving the press.
\end{itemize}
several avenues which may be pursued to keep the process alive. Community organizing efforts can serve the purpose of effectuating certain changes on a local level\(^\text{243}\) and keeping the issue alive in the press.

Another manner of pressing the agency into action is through Congress.\(^\text{244}\) Since all agencies derive their powers from Congress, they are subject to congressional scrutiny. This is the fundamental basis for congressional influence over agencies, but the day-to-day relationship is based on other powerful considerations as well. Congress has authority to investigate and review agency operations and require agencies to account for their action or inaction.

Although agencies ultimately depend on Congress as a body for their funding and existence, each agency has a direct relationship to a particular congressional committee. Oversight committees have jurisdiction over legislation involving the agency and can, if interested, ensure that the agency is giving your petition the treatment it deserves.\(^\text{245}\)

Prior to filing the Petition to Alleviate Domestic Infant Formula Misuse and Provide Informed Infant Feeding Choices, Public Advocates, attorneys for the infant formula petitioners, testified before the House Committee on Oversight and Investigation chaired by Congressman Dingell\(^\text{246}\) and the Subcommittee on Domestic Marketing, Consumer Relations and Nutrition chaired by Congressman Richmond.\(^\text{247}\) Both committees expressed grave concern over the very low prevalence of breastfeeding among low income women. Congressman Richmond’s committee advocated educational activities, improvement of prenatal services and hospital procedures to reverse this trend. His committee also recommended that the FDA issue guidelines for

\(^{243}\) On a local level, petitioning organizations encouraged their membership to refuse en masse to accept discharge packs at all local hospitals.

\(^{244}\) J. MICHAEL, supra note 183, at 31-32.

\(^{245}\) PRESIDENTIAL CONTROL, supra note 172, at v. (statement of John D. Dingell); see generally Ribicoff, Congressional Oversight and Regulatory Reform, 28 AD. L. REV. 415 (1976).


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labeling of infant formulas to differentiate the various forms of preparation.  

D. Obligations of the Agency to Act on the Petition

Section 4(a) of the Administrative Procedure Act provides that each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule. The legislative history accompanying section 4(a) states that this section "requires agencies to receive and consider requests" for rulemaking. The agency must act on the petition in accordance with its procedures and may grant such a petition or undertake public rulemaking proceedings in relation to it, or may deny the petition.

If an agency grants a petition it must comply with APA informal rulemaking requirements. The Act imposes minimum notice requirements in addition to requirements that "interested persons" be given an opportunity to submit comments, and that the agency incorporate in any rules adopted a "concise general statement of their basis and purpose."

The chief practical significance of the express right to petition is the requirement that the denial of a section 553(e) peti-

248. Letter from Congressman Fred Richmond to Public Advocates (July 8, 1981).
252. Granting a petition means only that the agency will incorporate the general proposal of the petition in its own notice of proposed rulemaking, or use the ideas as a point of departure for the rule. J. MICHAEL, supra note 183, at 740. An agency grant of a petition means the proposed rules are sufficiently meritorious to warrant further investigation through rulemaking, and notice and comment proceedings. Such action results in the ultimate decision of whether or not to promulgate a rule subject to broader judicial review on the merits. WWHT, Inc. v. FCC, 656 F.2d 807, 817 (D.C. Cir. 1981) (Subscription television broadcasters sought review of FCC orders which excluded scrambled signals of local subscription television stations from mandatory carriage requirements of local cable television operators.).
255. Id. § 553(b).
256. Id. § 553(c).
tion requires a prompt notice of the denial "accompanied by a brief statement of grounds." Administrators must articulate the specific factors on which they base their decisions; the extensiveness of the articulation required depends on the depth and breadth of the petition.

Before turning to the reviewability of denials of section 553(e) petitions, it is important to realize that courts have held that unreasonable delay is tantamount to agency denial. Interests and concerns of little importance to the agency may require judicial help to exert leverage on recalcitrant agencies. Section 706(1) of the APA provides that a reviewing court "shall compel action unlawfully withheld or unreasonably delayed." Section 555(b) provides that "within a reasonable time each agency shall proceed to conclude a matter presented to it." Courts have relied on these sections to accelerate protracted agency proceedings and to compel agency decisions. Judicial review serves as an effective means of insuring agency compliance with statutory deadlines. The reality of a lawsuit, the fear of unfavorable publicity, and the possibility of a contempt citation combine to compel agencies to commence unlawfully postponed actions.

257. See note 194 supra.
258. Oujo Chapter of the Navajo Tribe v. Train, 515 F.2d 654, 666 (D.C. Cir. 1975); Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 597 (D.C. Cir. 1971) (Where the Secretary finds substantial question concerning safety of a pesticide he is required by statute to commence formal administrative proceedings to determine whether registration should be cancelled.).
260. Id.
261. Nader v. FCC, 520 F.2d 182, 205-06 (D.C. Cir. 1975) (10-year delay in investigating utility rate increases was unreasonable; expeditious resolution of the matter and issuance of regulations was ordered).
262. Home Box Office, Inc. v. FCC, 567 F.2d 9 (D.C. Cir. 1977) (where 18 months elapsed since the notice of proposed rule-making and 12 months since the comment period had closed, FCC was ordered to complete proceedings within 180 days); B.F. Goodrich Co. v. Department of Transp., 541 F.2d 1178 (6th Cir. 1976) (after 9 years of delay, consumer organizations sued to force promulgation of regulations on a quality grading system for tires); North American Van Lines, Inc. v. United States, 412 F. Supp. 782 (N.D. Ind. 1976) (ICC ordered to act within 160 days after practice of flagging carrier applications were found unlawfully delay actions); Booth American Co. v. FCC, 374 F.2d 311 (D.C. Cir. 1970) (17-month delay on an application for emergency license demand inordinate; agency ordered to act within 15 days); Adams v. Richardson, 351 F. Supp. 636 (D.D.C. 1972) (ordering enforcement of school desegregation plan after HEW failed to induce voluntary compliance with Title VI of the Civil Rights Act); PROD v. EPA, No. 7499 (D.D.C. 1974) (delayed EPA noise regulations issued within 4 months of truck-drivers' suit); Public Citizen v. Cook, No. 743-73 (D.D.C. 1973) (forcing SEC rulemaking...
Agency delay may take one of the two forms. One is an endless series of hearings, "repetitive, purposeless and oppressive, without final decision." A second form of delay occurs when an agency refuses to act on a matter before it. Judicial intervention is called for in both situations since delay is a weapon that can be, and has been, used by an agency to exhaust private parties and consumer groups.

By its very nature unreasonable delay constitutes final agency action. Even when the action petitioned for is a matter of agency discretion, discretion is not a license for lethargy; judicial review may extend to failure to act as well as abuse in acting. Too often delay tactics are encouraged by regulated industries which have much to gain from inaction. Courts will step in to prevent such abuses.

If an agency denies a petition, the petitioners are not entirely without recourse. They may (1) re-petition the agency if there has been a change in the facts, law or government policy; (2) seek assistance from the Congressional Oversight Committee for the particular agency as well as try to get legislation intro-
duced; (3) seek judicial review of the agency's decision.269 Except where there is evidence of a clear and convincing legislative intent to negate review, an agency's denial of a rulemaking petition is subject to judicial review.270 Section 701(a) creates a strong presumption of reviewability, rebuttable only by a clear showing that judicial review would be inappropriate.271

Section 701(a)(2) construed in conjunction with section 706(2)(A) confers jurisdiction on the court to review actions allegedly subject to agency discretion.272 Courts are to review and set aside any agency action that "infringes upon some legal mandate and thus is 'arbitrary, capricious, [or an] abuse of discretion, or otherwise not in accordance with law.' "273 Review is expressly provided when there is an abuse of discretion.274

While it is clear that the applicable scope of review of discretionary agency decisions not to promulgate certain rules can be found under section 706(2)(A), the limits of the arbitrary and capricious standard of review will vary with the context of the case.275 The agency's decision that public interest, health and welfare do not require the promulgation of specific rules will probably be sustained if it violates no law, is accompanied by an articulated justification that makes a rational connection between the facts found and the choice made, and follows a careful examination of the relevant issues.276 The agency, however, must have acted in a manner calculated to negate the dangers of arbitrariness and irrationality.277

269. C. OSHIRO & H. SNYDER, supra note 166, at 47-48.
271. Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031, 1043 (D.C. Cir. 1979). Section 701 provides for review except to the extent: "(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701 (1976).
On review, the court may examine both procedural and substantive abuses of discretion. Denial of a petition at this early stage is aimed at weeding out "obviously frivolous or unworkable proposals." Due to the broad discretionary powers possessed by administrative agencies and the narrow scope of review, few courts have forced agencies to institute rulemaking procedures after an agency has declined to do so. However, under the Reagan Administration, the expectation that agency officials will diligently review meritorious proposals without undue industry influence is rapidly vanishing. As this occurs the courts' role in protecting the public interest and ensuring that APA and constitutional procedural protections are actually preserved will become increasingly critical.

The purposes of judicial review of agency decisions both as to rules they promulgate and petitions they deny are multi-fold. Review insures impartiality in agency decision-making, forces agencies to consider all relevant factors in making decisions, avoids undue influence by and bias towards regulated industries, disallows procedurally unfair and unauthorized

278. The procedural aspects are clearly reviewable. The court must determine whether or not the agency's decision not to grant the petition was an abuse of discretion or was arbitrary or capricious. Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031, 1045 (D.C. Cir. 1979).

Substantive review is intertwined in many respects with the procedural issues. The greater and more persuasive the administrative record before the court, the better the chances the court will subject the record substantively to at least a minimum level of judicial scrutiny. WWHT v. FCC, 656 F.2d 807, 816 (D.C. Cir. 1981). If in fact the OMB and the agencies are basing their procedural decisions on political criteria, the case for substantive reviewability will be even stronger.


280. Geller v. FCC, 610 F.2d 973, 979 (D.C. Cir. 1979); NAACP v. FPC, 520 F.2d 432, 446-47 (D.C. Cir. 1975) (Federal Power Commission claim that it lacked jurisdiction to consider and write regulations concerning employment discrimination was unfounded); National Org. for Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654, 657-59 (1974) (petition to reclassify marijuana under the Controlled Substances Act must be given appropriate consideration and cannot summarily be rejected as in conflict with treaty obligations); see supra note 263 and accompanying text.


283. Shell Oil Co. v. Department of Energy, 477 F. Supp. 413, 425 (D. Del. 1979) (eight energy producers challenged order of the Energy Information Administration directing the companies to file reports on company financial and operational data); Knickerbocker v. TVA, 348 F. Supp. 230, 233 (E.D. Ill. 1972) (action seeking recovery from
techniques, and assures that the agency's decision has a nexus with the public interest. Judicial review of agency decisions not to adopt rules insures that the agency gives due consideration to citizen participation, and in this sense might actually enhance the agency's effectiveness in furthering the public interest. It is only through such review that a court can pierce the veil of agency discretion and assure itself that the underlying agency decisions are in fact rational.

IV. CONCLUSION

There is a substantial public interest in having questions which directly affect the health and welfare of women, and indeed the nation as a whole, raised before the relevant federal agencies and the courts. Acting on rights afforded by the Constitution and the Administrative Procedure Act, citizens, public interest organizations and women's groups have successfully challenged arbitrary government action and inaction, secret influence peddling by special interest lobbyists, and failure of government agencies to take effective and timely action to protect the public interest, health and welfare. Parties and organizations who utilize the petitioning process are performing a valuable public service by forcing agencies to examine issues of national concern in light of the agencies' ability to significantly

Tennessee Valley Authority, after administrative procedures had been exhausted, for breach of contract disputes clause).


287. Barr, supra note 281, at 791.

288. Certainly the problem of domestic infant formula misuse and the infant formula industry's heightened role in marketing its product to women who cannot afford it and are highly likely to misuse the product is a problem of dire proportions affecting low income families nationwide. The agencies can substantially reduce illnesses resulting from infant formula misuse. However, as witnessed by the controversy over the World Health Organization's Marketing Code, the infant formula industry wields a powerful lobby. Its influence on HHS, FDA and USDA may determine those agencies' actions on the Petition. If this occurs, the Infant Formula Petition will provide an ideal vehicle for exposing the increased industry input allowed in agency decision-making under the present administration and the possibly unconstitutional interference by the executive branch (particularly through the OMB) in administrative agency decisions.

289. See J. Michael, supra note 190; C. Oshiro & H. Snyder, supra note 166; S. Ruzeck, supra note 9, at 152-61.

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alleviate these problems.\textsuperscript{290}

Under the Reagan Administration, crucial decisions affecting public health and safety, women, the environment, consumer and civil rights are being made in secret before there is any opportunity for public participation, on the basis of closed door ex parte communications\textsuperscript{291} with industry representatives, or on the basis of irrelevant and biased cost-benefit criteria. Today the heightened level of interference by industry and other regulated interests in agency decision-making and the increased role of the OMB, which is likely to view an issue from the Administration's political perspective, create a regulatory atmosphere which the increased use of citizen petitioning is best able to combat.

Women's groups, feminist advocates, and community-based organizations concerned with health care issues, must band together to begin asserting consumer rights for women and minorities in our health care system. All patients, male, female, rich, poor, educated, illiterate, young, old, English-speaking or not, must have the right to make informed decisions about the type and quality of health care they will receive. Citizen petitioning, especially when combined with legislative lobbying, community

\textsuperscript{290} Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031, 1046 (D.C. Cir. 1979).

\textsuperscript{291} Those cozy, one-sided ex parte "hearings," if you can call them that, are not in the public interest. Unless ex parte contacts during rulemaking are avoided, in addition to keeping the public and other parties in the dark, the reviewing court is denied access, not only to the contents of the contacts, but also to whatever response those contacts would have triggered were their contents known. How is a court to make in-depth review of the record when some parts, perhaps some important parts, have been withheld—from it, from the public, and from other interested parties? How is a court to know—how is anyone to know—whether an undisclosed ex parte contact with the decisionmaker tilted his decision one way or another?

Whatever the law was with respect to ex parte contacts during informal rulemaking proceedings before Overton Park, in my judgment a reviewing court acting under the mandate of Overton Park can no longer accept a record flawed by such practices. And, in the present atmosphere, when the issue is properly preserved for judicial review, I suggest to you that it will be difficult for Commission counsel to defend ex parte contacts with a straight face. For the courts, supported by the public interest, will insist on an acceptable answer to this question: Why—why the ex parte contacts?"

organizing, media publicity, consumer education and judicial action, can be a powerful tool to be used toward the accomplishment of this goal. The petition, is in essence, the catalyst.

Leslye E. Orloff

292. In March, 1982, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) responded jointly to the Petition to Alleviate Infant Formula Misuse and Provide Informed Infant Feeding Choice. The HHS and FDA combined response indicates a significant consensus on three of Petitioner's central concerns: (1) the superiority of breast-feeding for all infants; (2) the serious risk of infant formula misuse among low income families in the United States; and (3) the absence of informed infant feeding choices in American hospitals.

Accordingly, the agencies plan to proceed to rulemaking on petitioners' proposed labeling changes and on the national breast-feeding campaign urged by petitioners. Specifically, HHS is committed to achieving, by 1990, a goal of 75% of mothers breast-feeding at hospital discharge and 35% continuing through six months.

Despite this commitment, HHS was reluctant to consider petitioners' proposals to tie federal health care financing to clinic and hospital assurances that they provide all parents informed infant feeding choices and concomitant supportive practices. Petitioners have urged HHS reconsideration of this preliminary disinterest in conditioning federal financing on informed infant feeding practices and supportive procedures.

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