Physicians, Formula Companies, and Advertising

A Historical Perspective

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• **The recent advent of new advertising campaigns for infant formulas aimed at the general public via television commercials, newspapers, free formula coupons, and lay periodicals has disrupted a comfortable symbiotic relationship between infant food manufacturers and the medical profession that has endured for more than 50 years. In the late 19th century, physicians were concerned about the advertising claims of these products and generally felt that indications and directions for their use should be the province of the physician. Between 1929 and 1932, the American Medical Association, through its Committee on Foods and "Seal of Acceptance," essentially required the entire formula industry to advertise only to the medical profession. Since 1932, the US formula industry has developed into a $1.6 billion market. In 1988, Nestlé (absent from the US infant formula industry since the 1940s) acquired the Carnation Company and launched an advertising campaign to the general public for its formula products. Bristol Myers/Mead Johnson, in cooperation with Gerber Products Company, quickly followed suit. These actions threaten to once again remove the realm of infant feeding from the exclusive supervision of the medical profession. The new multimedia public advertising campaigns may increase the cost of infant formula to the general public and have a negative impact on the incidence of breast-feeding. In addition, formula advertising campaigns will likely increase the danger of advertising hyperbole and affect the level of financial support by formula companies for scientific meetings, medical research, education, and social events at medical meetings.**

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In October 1989, millions of television viewers throughout the United States saw 30-second advertising spots extolling the advantages of Gerber Baby Formula. Earlier that year, Nestlé-Carnation launched a similar television advertising campaign to promote its formula product, Good Nature (the name was recently changed to Follow-up Formula). These commercial presentations conflicted directly with the medical profession's long-standing and effective opposition to the advertising of infant formula to the general public, and disrupted a comfortable symbiotic relationship between infant food manufacturers and the profession that had lasted for more than 50 years.

Since the early decades of this century, the formula companies have advertised to the medical profession by promoting their products extensively in professional journals and displaying them at state and national medical meetings, which they also financially supported. After 1960, they also supplied free formula to physician-dominated hospitals, including starter packs for new mothers to bring home. Additionally, during this period, infant formula manufacturers funded medical research in pediatric nutrition, particularly when the studies were related to product development.

The medical profession's negative response to the new advertising campaigns was swift. The American Academy of Pediatrics (AAP) announced a new policy refusing contributions from formula companies who marketed their products directly to the public rather than exclusively to health care providers, and the Executive Board of the AAP subsequently rejected $760 000 in pledged contributions from Mead Johnson Nutritionals and Gerber Products Company (written communication from Donald W. Schiff, MD, AAP president, to membership, September 27, 1989).[1] There were also scattered reports that Mead Johnson formula products had been stricken from hospital formularies. What were the events that led to the 50-year advertising understanding between formula companies and physicians? What factors precipitated its demise?

In the 1870s, the vast majority of American babies were fed human milk. Mothers were expected to breast-feed and the few available alternatives were considered poor and risky substitutes. During the next 75 years, however, the US infant food and formula industry developed rapidly, accompanying a dramatic shift from breast-feeding to artificial or bottle feeding. Developments in technology, science, and medicine, along with social and economic changes, fueled the transformation in infant feeding practices and established the infant formula industry. In the 1940s and 1950s, this now safe and alternative method to breast-feeding rapidly gained popularity among physicians and consumers.[2] Indeed, by 1958, 63% of all newborns were fed formula exclusively before being discharged from the hospital.[3]

Many proprietary infant foods appeared in the United States in the last decades of the 19th century. Early manufacturers usually produced a variant of the formula developed by Justus von Liebig in Germany in the 1860s.[4] In Switzerland, Henri Nestlé created his variant of Liebig's

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formula combining condensed milk, sugar, and wheat flour. The first Nestlé's Milk Food plant opened in 1868, and by 1873 the formula was sold in the United States and 16 other countries.[5] Companies also formed on this side of the Atlantic. James Horlick, a pharmacist, formulated another Liebig-type formula, Horlick's Malted Milk, in Racine, Wis, in 1882.[6] During the early years of the industry, manufacturers solicited the broadest audience possible, advertising both to the general public and to physicians. As is still the practice today, the inclusion of medical testimonials by the profession in the advertising copy added a veneer of "scientific" and medical respectability. In addition, the companies distributed brochures and free samples at medical conventions and advertised in medical journals.[2] During this early period, promotions in nonmedical journals advised mothers to write in for free samples and brochures.

From the beginning of the infant food industry, physicians expressed concern about direct advertising to the public. Dr Thomas Morgan Rotch, on the staff of Harvard Medical School, believed that infant foods produced and advertised by "commercial men" rather than the medical profession contributed to the high infant mortality rate.[7] Dr Rotch demanded that pediatrics "rescue" infant feeding from "the pretensions of proprietary foods."[7] Thus, despite the 19th-century manufacturers' attention to physicians, the medical profession resisted and debated the use of infant formula products and opposed their direct advertisement to laypersons. Undoubtedly, these physicians believed that the indications and guidelines for the use of these products were the province of the medical profession.

An 1888 American Medical Association (AMA) Subcommittee on Infant Feeding clearly documented a lack of uniformity among physicians regarding infant feeding,[8] but most physicians unquestionably preferred breast-feeding, with bottle feeding being strongly associated with the high infant mortality rates. In fact, the ward for artificially fed infants of the New York (NY) Foundling Asylum was known as the "ward of the dying babies."[4] During this period, a growing proportion of general medical practice concerned the safe feeding of infants and the specialty of pediatrics emerged as a group of physicians particularly interested in promoting good infant nutrition and hygiene.

Between 1890 and 1910, these early pediatric researchers advocated the cleanup of infant milk supplies, including improving the quality and care of dairy herds, the establishment of infant milk depots and clinics for the distribution of "clean milk" to the public, and the founding of milk laboratories.[2] The latter change was a direct result of the dominant theory of infant feeding of the period, Rotch's percentage method.[9] He insisted that infants were to be fed a certain percentage of each known food element (ie, fat, protein, and carbohydrate) in proportions dictated by the individual's needs. Rotch believed that minute variations (as little as 0.1%) in the composition of the food could make a difference in its digestibility and healthfulness. As many as 19 formulations were recommended for healthy infants during the first year of life. Minute changes were made on weekly and even daily bases and elaborate tables and mathematical formulas were published to optimize Rotch's principles. Therefore, the need for laboratories to compound the required formulations developed. By 1910, growing numbers of studies in infant nutrition demonstrated the inadequacy of the percentage method. The most important data of this research supported the caloric method of infant feeding, the method that persists to this day.[10]

Despite continued medical criticism of commercial foods, a significant and increasing number of physicians did advise their patients to use these products. Physicians, rather than ignoring all commercial foods, became mediators between manufacturers and consumers. Henry Tuley, MD, writing in *JAMA* in 1899, concluded, "The method of artificial feeding which will prove most popular with the laity must embody two requisites: cheapness and ease of preparation. On the physician devolves the great burden of educating people beyond the indiscriminate use of proprietary foods, and the importance of accuracy in the preparation of the food prescribed."[11] Thus, given the complexities inherent in these early infant "percentage" formulas, both for the physician to calculate and for the mother to prepare, it was easier for busy practitioners to give up the whole program in despair and "resort to the use of the patent baby foods as the easiest way out of the difficulty," opined Eugene Darling, MD, in 1911.[12] Unfortunately, once this occurred, the mother could follow the printed instructions on the product and did not need to return to the physician for further supervision. Such a situation could be physically unhealthy for the infant and potentially economically harmful to the physician.

In 1910, J. S. Leopold, MD, returning to New York City from Germany, reported that the German use of dextrin and maltose in infant formulas resulted in improved tolerance and digestibility. Unable to find a source of this sugar in the United States, he convinced the Mead Johnson Company to manufacture and distribute Dextri-Maltose.[13] Dextri-Maltose was evaluated at the Babies Ward of New York (NY) Postgraduate Hospital, and was the first example of an infant food product developed through the cooperation of an investigative pediatric researcher and a private company. With its initial promotional efforts, Mead Johnson began a trend in the industry by deciding that gaining the respect and goodwill of the medical community could be potentially more profitable than marketing the product directly to the public.

Accordingly, the company unveiled Dextri-Maltose at the 1912 AMA convention and promoted this milk modifier, as well as its later infant feeding products, exclusively to the medical profession. No directions appeared on the package. Wheel "feeding calculators" and formula prescription blanks imprinted with the physician's name and address were supplied to physicians. Such prescriptions told the mother how to mix the formula and feed it to her child, and reminded her to bring the baby back to the physician for a checkup and new formula on a specified date. Mead Johnson announced its policy in many of its advertisements and brochures for physicians, frequently stressing that "when Dextri-Maltose is used as the added carbohydrate of the baby's food, the physician himself controls the feeding problems."[14]

Following Mead Johnson's success, other companies emulated the company's so-called "ethical" policy of infant food advertising. In 1915, H. J. Gerstenberger, MD, of Western Reserve University, Cleveland, Ohio, formulated an infant milk food that was closer to human milk than any other popular artificial feeding product of its day. In this product, human milk fat was approximated for the first time by a blend of homogenized vegetable and animal fats. Gerstenberger presented this infant food at the 1915 meeting of the American Pediatric Society after testing it at the Babies Dispensary and Hospital in Cleveland.[15] The Laboratory Products Company (eventually bought by

Wyeth Laboratories) subsequently produced and distributed Gerstenberger's formulas under the name S.M.A. (Synthetic Milk Adapted) and directed its advertising campaign primarily toward physicians. Although a few advertisements did appear in the early years in lay journals such as *Hygeia*, actually published by the AMA, the advertising copy typically stated that S.M.A. was "to be used only under the direction of the physician."

The commercial success of Dextri-Maltose and S.M.A., both produced by companies new to the infant feeding industry, demonstrated to other companies that such advertising policies could result in a satisfactory compromise between the needs of the manufacturers to sell their products and the desires of physicians to control the distribution and use of infant foods. Although the Nestlé Company, unlike Mead Johnson and Laboratory Products, continued to advertise its milk food in lay journals and to offer mothers free samples and booklets, the company announced a new product, Lactogen, in 1924 "sold only on the prescription or recommendation of a physician. No feeding instructions appear on the trade package." At about the same time, the Horlick Company developed its Horlick's Milk Modifier, which was "offered for sale on physician prescription only."[2]

Another aspect of the infant food industry, the manufacture and promotion of evaporated milk formulas, showed a similar pattern. In 1929, W. M. Marriott, MD, of Washington University, St Louis, Mo, published a controlled study comparing evaporated milk formula, human milk, and bottled cow's milk formula.[16] The infants fed evaporated cow's milk formula showed better weight gain during the first week of life than the other infants; moreover, over the long term, those infants fed evaporated cow's milk formula grew as well as those fed human milk or bottled cow's milk formula. The evaporated milk industry quickly cited Marriott's studies in advertising and informational brochures for physicians. The Pet Milk Company even hired Marriott as a consultant to show the company's sales personnel the right and wrong ways to contact physicians.[17] By 1935, evaporated milk formulas dominated infant feeding and as late as 1956, 80% of all formulas used in hospital nurseries in the United States were some dilution of evaporated milk.[18]

Clearly, the apparent success of companies such as Mead Johnson and Laboratory Products resulted in the willingness of the infant food manufacturers to forego public advertising and to direct their attention to the medical profession. Additionally, direct pressures from the medical profession spurred the demise of promotions to the laity. In 1923, the Philadelphia Pediatric Society urged the AMA to halt infant food advertising in its lay journal *Hygeia*. Such advertising, the society contended, implied recommendations by the members of the American Medical Association "[which] will tend to undo all the work which thousands of members of the medical profession have been trying to accomplish in the education of the public to the fact that infants cannot be fed in this indiscriminate manner."[19]

Although advertisements continued to appear, in 1924 the Section on Diseases of Children of the AMA established a committee "to investigate the general question of advertising of proprietary foods in medical journals and to the laity."[20] In its 1925 report, the committee acknowledged the significance of infant food products in medical practice and concluded that "it is impractical at the present time to dispense entirely with all proprietary foods." While stressing the nutritional importance of breast-feeding and "the dangers of artificial feeding of infants, particularly when carried out without supervision of medical men," it found heartening the "disposition on the part of many manufacturers of proprietary foods to cooperate with the medical profession and its medical journals."[21]

Four years later, the AMA established its Committee on Foods, within the Council on Pharmacy and Chemistry, to approve the composition and advertising claims of food products in general. Infant food companies, including evaporated milk producers, quickly presented their products for AMA approval and its "Seal of Acceptance." In 1932, the committee published specific advertising guidelines for infant foods. These insisted that "every infant, breast-fed, and doubly so, the artificially fed should be under the supervision of the physician who is experienced and skilled in the care and feeding of infants."[22] The new rules sought to restrain manufacturers from distributing directions for formulas to nonmedical personnel, reasoning that "The feeding of an infant by routine feeding formulas and instructions distributed by food manufacturers, or according to directions, printed material, or advice of any person other than the attending physician who can personally observe the condition of the baby, may seriously endanger the health of the infant. The promulgation of feeding formulas in advertising to the laity is considered to be in conflict with the best experience, authoritative judgment, and basic principles in infant feeding, and is not permissible."[22]

Nestlé did not have to change its Lactogen promotions, but the company did stop advertising Nestlé's Milk Food to the general public and limited distribution of feeding directions to physicians only.[2] Most, but not all, other companies and evaporated milk producers followed suit. The labels and advertising for Horlick's Malted Milk continued to "present explicit infant feedings formulas for infants age one week to 12 months." Despite the committee's recommendation that the company alter its advertising copy, Horlick's refused. The committee stated, "The manufacturer when informed of these opinions expressed himself unwilling to remove the feeding formulas from advertising addressed to the public for merchandising reasons. The acceptance of Horlick's Malted Milk is being withdrawn for the preceding reasons; the product will therefore no longer be listed among the committee's accepted foods."[23]

The withdrawal of the AMA's previous acceptance of Horlick's Malted Milk meant that the company could no longer advertise in AMA publications or participate in AMA meetings. Furthermore, many medical journals, such as the *New England Journal of Medicine*, received advertising contracts through AMA's Cooperative Medical Advertising Bureau.[24] This group would approve copy only for "drugs, therapeutic agents and food which are acceptable to the respective approving committees of the American Medical Association." As a result, withdrawal of the Committee on Foods' acceptance further limited Horlick's promotional activities by preventing the company from advertising in other major medical journals.

The subsequent demise of Horlick's in the United States is more complex than this analysis suggests, but it is true that the action of the committee significantly lessened the use of Horlick's products in infant feeding. Companies that allowed the AMA committee to approve their promotional material fared much better. As Mead Johnson cogently explained, "When mothers in America feed their babies by lay advice, the control of your pediatric cases passes out of your hands, doctor. Our interest in this important phase of medical economics springs, not from any motive of altruism, philanthropy or paternalism, but

rather from a spirit of enlightened self-interest and cooperation because [our] infant diet materials are advertised only to you, never to the public."[25]

By the 1930s, simplified, standardized, and inexpensive artificial infant food products were widely available in this country. They contained appropriate amounts of nutrients, were free of pathogenic bacteria, and were generally accepted by the medical profession as a safe alternative to breast-feeding. Also, by this time, physicians and infant food companies had established a beneficial, reciprocal relationship.[26] In 1933, a Pennsylvania practitioner counted no fewer than 17 advertisements for infant foods in a single issue of *JAMA*.[27] Elaborate presentations by infant food manufacturers appeared at medical conventions. Ties between the formula companies and academic medicine were also well established through the funding of scientific meetings and the open support of published infant nutritional research. What happened to change this advantageous 50-year association between physicians and the formula companies?

In the late 1960s and 1970s, world attention was focused on the declining incidence of breast-feeding and the associated increasing infant mortality in some third world countries. This decline was in part attributed by physicians and laypersons to the marketing and advertising of infant formulas by international companies to the mothers in these countries. Families were often unable to maintain adequate supplies of formula without making severe economic sacrifices and lacked the necessary sanitary facilities for formula preparation and storage. Furthermore, many mothers were unable to read and/or follow the directions for safe formula preparation. In truth, no scientific data were ever presented that could separate the effects of marketing infant formulas from other causes for the decline in breast-feeding in these countries. These factors included the negative overall influence of western culture with its acceptance of formula feeding, the increasing urbanization of the population, the economic necessity for mothers to work outside the home in urban areas, and the negative effects of government health services in those countries distributing free milk powder and Western ways of infant medical care in general.[28]

Ultimately, Nestlé was singled out and an international boycott of its products was organized by INFACT (Infant Formula Action Coalition), a group that drew on existing organizations committed to curbing infant formula promotions in third world countries.[29] The controversy led to US Senate hearings in 1978, chaired by Sen Edward Kennedy (D, Mass), on the subject.[29] The World Health Organization became involved and adopted its *International Code of Marketing of Breast-Milk Substitutes* in 1981.[30] Article 5.1 of the code stated that "There should be no advertising or other form of promotion to the general public of products within the scope of this Code." Subsequently, the formula companies largely complied with these guidelines for marketing their products in third world countries. Ironically, all countries endorsed this code except the United States, citing concerns about possible restraint of trade infringements and violations of the US Constitution.

Closer to home, by the 1970s and 1980s, notwithstanding the nationwide surge in the incidence of breast-feeding, the vast majority of infants aged 3 months and older were receiving commercial formula preparations as the US infant formula industry evolved into a $1.6 billion market. In 1988, Abbott Laboratories (parent company of Ross Laboratories) and Bristol Myers (parent company of Mead Johnson Nutritionals) had a virtual lock on this lucrative market. Nestlé, absent from the United States since the 1940s, was poised to reestablish its presence. As a first step, the company acquired the Carnation Company and its image of the "Carnation baby," familiar to millions of Americans who had been fed Carnation evaporated milk formula in the 1940s and 1950s (*Wall Street Journal*. February 16, 1989:A-1).

In June 1988, Nestlé-Carnation introduced two infant formulas to the United States market. The first, Good Start H.A., was a "hypoallergenic" product for the sensitive, colicky newborn. Its advertising, which the company called an "informational campaign," was directed to the general public and made no specific mention of the formula, yet its scientific benefits were pushed vigorously to the medical profession. The second formula, Good Nature (now Follow-up Formula), was designed for older infants weaned from the breast and would, in theory, not discourage breast-feeding. It became the first infant formula marketed directly to the public on US television. Additionally, for the first time in half of a century, an infant formula, Good Nature (Follow-up Formula), was widely advertised in lay journals and newspapers. Within a short time, Nestlé-Carnation captured between 2% and 4% of the US formula market, although its proportion has since fallen somewhat (*Wall Street Journal*. June 15, 1989:B-3).[1]

Subsequently, Good Start H.A. has fallen on hard times. Public advertising has been discontinued since the product was found to be not so "hypoallergenic," and reports of severe allergic reactions to the formula appeared in the press. However, although the company has discontinued television advertising and despite extensive pressure from the medical profession and most prominently the AAP, Follow-up Formula continues to be advertised in lay journals.

With the sudden success of Nestlé-Carnation in the United States, Bristol Myers entered into an agreement with Gerber Food Company to produce Gerber Baby Formula and to market it directly to the public (*Wall Street Journal*. June 15, 1989:B-3). Not only was the product promoted on US television, but free formula coupons and free formula samples were mailed to 1.6 million new mothers throughout the United States.[31] The company argued that this was no different from supplying mothers with take-home samples of their competitors' products at the time of discharge from the hospital. Interestingly, the Gerber Baby Formula is a former Mead Johnson product that was discontinued in the early 1980s in favor of a new "superior" and heavily advertised product.

This new marketing strategy has resulted in strong reactions from the American medical community. Although the AMA has a smaller role in setting infant nutrition policies than it did 50 years ago, it recently confirmed its opposition to the direct advertising of infant formula in the United States.[32] An official statement was made by the AAP before the US Senate Judiciary Subcommittee on Antitrust, Monopolies and Business Rights at its May 29, 1990, hearing on "Advertising of Infant Formula." In this statement, the academy officially opposed any form of direct advertising to the public for the following reasons: (1) negative effect on breast-feeding; (2) interference with the patient-physician relationship regarding nutritional advice; (3) advertising hyperbole leading to consumer confusion; and (4) the impact of large-scale public advertising on the cost of infant formula.[33] The AAP did not comment, however, on the negative impact that large-scale advertising might have on the financial support that the formula industry has made available to physicians for scientific meetings, medical research, education, and social events.

It does not take a crystal ball to predict that if Gerber, Bristol Myers, and Nestlé-Carnation are successful with their new marketing strategies, then other infant formula manufacturers may follow with direct public advertising. This will once again remove the realm of infant feeding from the supervision of the physician and will likely have a negative impact on the incidence and duration of breastfeeding. Of importance economically is the potential effect of new multimedia, public advertising campaigns on the cost of infant formula. Although the new marketing strategy will not have the economic impact on medical practice it would have had 50 or more years ago, it will permanently alter the mutually beneficial relationship between the medical profession and the infant formula industry.

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