

The Domestic Infant Formula Market

The development of the infant formula market has been greatly influenced by the demand for infant formula. This section describes some of the major factors that have impacted the demand for formula and the structure of the infant formula market in the United States.

Demand for Infant Formula

Commercially prepared infant formulas in powdered form have been available in the United States since the late 1800s (Fomon, 2001).¹ Prior to 1930, most infants were breastfed through their first year, although many were fed some formula as well, most of which was made in the home from cow's milk or, starting in the 1920s, from evaporated milk. Powdered formulas were appreciably more expensive than these home-prepared formulas and, as a result, the use of commercially prepared formulas was low at the time.

From 1930 to the 1970s, the percentage of breastfed infants in the United States declined and most children were fed cow's milk after 6 months of age (Fomon, 2001).² During the early portion of this period, the use of home-prepared formulas exceeded that of commercially prepared formulas. However, the use of commercially prepared formulas increased dramatically after the introduction of concentrated liquid formulas in 1951, when convenience considerations began to outweigh cost considerations. By the late 1950s, liquid concentrate had become the predominant form of commercially made formula (it would remain the predominant form of commercially made formula until the 1990s when powdered formula became predominant).³ During the early 1960s, commercially prepared formulas replaced home-prepared formulas as the predominant source of infant formula, due in part to the introduction of iron-fortified formulas in 1959 and the promotion of these formulas by the infant formula industry and pediatricians.

The downward trend in breastfeeding reached its nadir in 1971 when fewer than 25 percent of infants in the United States were breastfed while in the hospital, and fewer than 6 percent were breastfed at 5 to 6 months (Martinez and Krieger, 1985). At this time, most of the infants not breastfeeding were fed commercially prepared formulas until they reached 4 to 6 months of age and then they were fed cow's milk, which was considerably less expensive and more convenient to use than formula (Fomon, 2001). Breastfeeding rates increased during the rest of the 1970s. The increase in breastfeeding decreased the use of commercially prepared formulas among infants younger than 4 months of age. However, the use of commercially prepared formulas among infants older than 4 months of age rose as cow's milk was increasingly being introduced to infants at later ages, thereby extending the duration of formula use.

Although breastfeeding rates dipped slightly in the 1980s, they increased again during the 1990s. By 2000, 68 percent of mothers initiated breastfeeding in the hospital, and 31 percent of mothers

¹ The early commercially prepared formulas were milk-based. The first soy-based infant formulas, developed for infants allergic to cow's milk, were introduced in 1929 (Fomon, 2001).

² This decline in breastfeeding has been widely attributed, at least in part, to the concurrent increase in maternal employment.

³ Prior to the early 1970s, the physical properties of powdered formulas were such that they were less readily suspended in water than today's powdered form of formulas (Fomon, 2001).

were breastfeeding at 6 months, the highest rates since data were first collected in 1955 (see box “Breastfeeding Rates Among WIC Participants”) (Abbott Laboratories, 2001).⁴ Although breastfeeding rates have increased in recent years, breastfeeding duration is still generally short—only a minority of children in the United States are still being breastfed by the time they are 6 months old. At the same time, the feeding of cow’s milk continues to occur at later ages (Fomon, 2001). As a result, a large majority of infants in the United States are fed at least some formula.⁵

Structure of the Infant Formula Market

Although a number of firms manufacturing infant formula appeared during the early 1900s, their ranks were reduced considerably during the 1930s depression (Post and Wubbenhorst, 1989). It was not until the baby boom following World War II that the large-scale manufacture of infant formula appeared.

The Infant Formula Act of 1980 (the amendment of the Federal Food, Drug, and Cosmetic Act) had a significant impact on the manufacture of infant formula. The Act provided the legislative basis for greater regulatory control over the production of infant formula.⁶ Provisions of the Act (along with 1986 amendments) established minimum (and in some cases maximum) nutrient levels for infant formula, thereby standardizing its nutritional content to a large degree. The Act also provided the legislative basis for quality control procedures for producing infant formula and gave the Food and Drug Administration (FDA) the authority to enforce standards for infant formula marketed in the United States.

Even before the WIC infant formula rebate program was implemented, the infant formula industry was highly concentrated. A small number of manufacturers, usually owned by pharmaceutical companies, produced the vast majority of the infant formula sold in the United States. In 1987, three manufacturers, all owned by pharmaceutical companies, accounted for 99 percent of the total U.S. market share of infant formula:

- Ross Labs, owned by Abbott Laboratories,
- Mead Johnson, owned by Bristol-Myers, and
- Wyeth-Ayerst Laboratories, owned by American Home Products (table 4-1).⁷

The fact that only a few firms were producing infant formula for the U.S. market suggests that the costs of entering the market were high. One factor that may have contributed to the high cost of entry is medical detailing. Medical detailing is the manufacturer’s practice of contacting hospitals and medical practitioners directly, providing them with free or discounted infant formula, and encouraging physicians to recommend one particular brand of formula (U.S. GAO, 1990). Medical detailing also includes providing hospitals with “discharge packs” containing formula samples,

⁴ Reasons cited for the continued increase in breastfeeding initiation rates since the early 1970s include the publication of numerous reports documenting the advantages of breastfeeding, recognition of breastfeeding as the preferred method of infant feeding from a number of professional societies, the influence of the natural childhood movement which emphasized breastfeeding, and increased breastfeeding promotion efforts, particularly those conducted through the WIC program (American Dietetic Association, 1997; Wright and Schanler, 2001).

⁵ Over 80 percent of infants ages 3-11 months of age in 1998 were estimated to be fed at least some formula (includes infants who were also breastfed) (Fomon, 2001).

⁶ Congress passed the Act in response to a substantial number of infants having been made seriously ill in 1979 due to the inadvertent omission of chlorides (an essential nutrient for growth and development) in some infant formula when a manufacturer reformulated several of its infant formula products (FR, Vol. 61, No. 132).

⁷ All three of these companies entered the infant formula market in the 1920s (Post and Wubbenhorst, 1989).

Breastfeeding Rates Among WIC Participants

The American Academy of Pediatrics (AAP) recognizes breastfeeding as the ideal method of feeding infants and achieving optimal infant and child health, growth, and development (American Academy of Pediatrics, 1997). AAP recommends exclusive breastfeeding for approximately the first 6 months after birth and the gradual introduction of iron-enriched foods in the second half of the infant's first year to complement the breast milk diet. Breastfeeding is recommended for at least 12 months and thereafter for as long as mutually desired. Despite the wide acknowledgement of breastfeeding as the best method of feeding most infants, many women do not breastfeed their infants.

Since 1955, the Ross Laboratories Mothers Survey, a large national mail survey of infant feeding practices conducted by the infant formula manufacturer, has been used to monitor breastfeeding trends in the United States. From 1990 to 2000, the initiation of breastfeeding (i.e., breastfeeding while in the hospital) increased by almost 33 percent (see table below). By 2000, 68.4 percent of women were initiating breastfeeding, the highest rate ever recorded. Rates of breastfeeding infants at 6 months of age increased by 78 percent over the same period, from about 18 to 31 percent (breastfeeding women included those who breastfed exclusively as well as those who supplemented breast milk with infant formula or milk from other sources). Despite the recent increases in breastfeeding rates, they remain far below the Healthy People 2010 target that 75 percent of mothers breastfeed their babies during the early postpartum period, 50 percent of mothers breastfeed their babies at 6 months of age, and 25 percent of mothers breastfeed their babies at 1 year (U.S. Department of Health and Human Services, 2000).

WIC participants showed even greater increases in the prevalence of breastfeeding during the 1990s (mothers who, since the birth of their child, participated in WIC themselves, or whose child participated in the program, were considered to be WIC participants). The percentage of WIC participants who initiated breastfeeding increased by 69 percent from 1990 to 1998, while the percentage who were breastfeeding at 6 months increased by 145 percent. Despite these gains, WIC participants are still less likely to breastfeed (both in the hospital and when the infants reach 6 months) than non-WIC participants.

Some have questioned whether WIC, by supplying free infant formula, provides an incentive not to breastfeed (the average cash value of the WIC food package received by a nonbreastfeeding postpartum woman and her formula-fed infant is more than three times that received by a breastfeeding woman whose infant does not receive formula through WIC) (Rossi, 1998). However, historically, the more vulnerable and less affluent groups of mothers who are more likely to participate in WIC, including mothers who are Black, poor, and have low education levels, have been less likely to breastfeed their children (Ryan, 1997). Furthermore, through its nutrition education and breastfeeding promotion programs, the WIC program encourages mothers to breastfeed their infants if possible. Breastfeeding women also have a higher priority for certification into the program than nonbreastfeeding postpartum women and they are eligible to receive program benefits for up to 1 year postpartum (as long as they continue to breastfeed), as opposed to only 6 months of postpartum benefits for nonbreastfeeding women.

Breastfeeding rates by WIC status, 1990-2000

Item	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
In hospital:											
All infants	51.5	53.3	54.2	55.9	57.4	59.7	59.2	62.4	64.3	67.2	68.4
By WIC participation status:											
WIC	33.7	36.9	38.8	41.6	44.3	46.6	46.6	50.4	55.8	56.1	56.8
Non-WIC	62.9	65.2	66.4	67.9	68.8	71.0	70.8	73.4	75.2	76.9	77.8
At 6 months:											
All infants	17.6	18.2	18.9	19.0	19.7	21.6	21.7	26.0	28.6	30.7	31.4
By WIC participation status:											
WIC	8.2	9.0	10.1	10.8	11.6	12.7	12.9	16.5	18.9	19.9	20.1
Non-WIC	23.6	24.6	25.6	25.8	26.5	29.2	29.5	35.5	38.5	40.3	40.7

Source: Abbott Laboratories, 2001.

Table 4-1—Share of the U.S. infant formula market by company, 1987, 1994, and 2000

Company	1987	1994	2000
	<i>Percent</i>		
Ross	55	53	35
Mead Johnson	35	27	52
Wyeth	9	9	NA
Carnation	NA	7	12
Gerber (Mead Johnson)	NA	3	NA
PBM (Wyeth)	NA	NA	1

NA=Not applicable.

Notes: Market share was determined by volume of infant formula sold. Companies accounting for less than 1 percent of the market are not identified. Infant formula sold under the Gerber name was manufactured by Mead Johnson. Infant formula sold by PBM was manufactured by Wyeth.

Sources: Data for 1987 are from U.S. General Accounting Office, 1990. Data for 1994 and 2000 are from ERS analysis of InfoScan data.

cents-off coupons, and company advertising aimed at mothers when they leave the hospital with their babies; such activities may serve as implicit endorsement of a particular brand of infant formula by the hospital. To the extent that parents of formula-fed infants develop a strong brand loyalty, their responsiveness to price differentials across brands is reduced. Thus, medical detailing may provide some market power to pharmaceutical companies. According to GAO, the practice of medical detailing by the pharmaceutical manufacturers of infant formula may have limited the ability of nonpharmaceutical companies to compete in the domestic infant formula market (U.S. GAO, 1990).

The industry's high concentration may also have been a reflection of high costs due to regulatory requirements of the Federal Food, Drug, and Cosmetic Act. For example, the Act requires that manufacturers demonstrate that infant formulas new to the U.S. market provide nutrients to the infant in usable form, and testing of every batch of infant formula to ensure its nutrient composition. The costs associated with meeting these regulatory requirements may increase firm unit costs more for small firms than large firms.⁸

The U.S. infant formula market has undergone several changes since 1987, the most important of which has been the introduction of several lower priced infant formulas being marketed directly to consumers (a marketing strategy that shows that medical detailing is not a necessary condition to enter the infant formula market). For example, Carnation introduced their infant formula products into the U.S. market in 1988.⁹ Unlike the other major infant formula manufacturers, which are subsidiaries of pharmaceutical companies, Carnation is a subsidiary of Nestlé, a large Swiss-owned food company. Nestlé markets its formula directly to consumers rather than to medical professionals. Although the wholesale prices of infant formula charged by the other major manufacturers have historically been very similar, Carnation has offered its product at substantially lower wholesale prices (fig. 4-1). Carnation has steadily increased its share of the U.S. market over time: ERS analysis of scanner data indicates that in 2000, Carnation accounted for an estimated 12 percent of the market in volume sales.

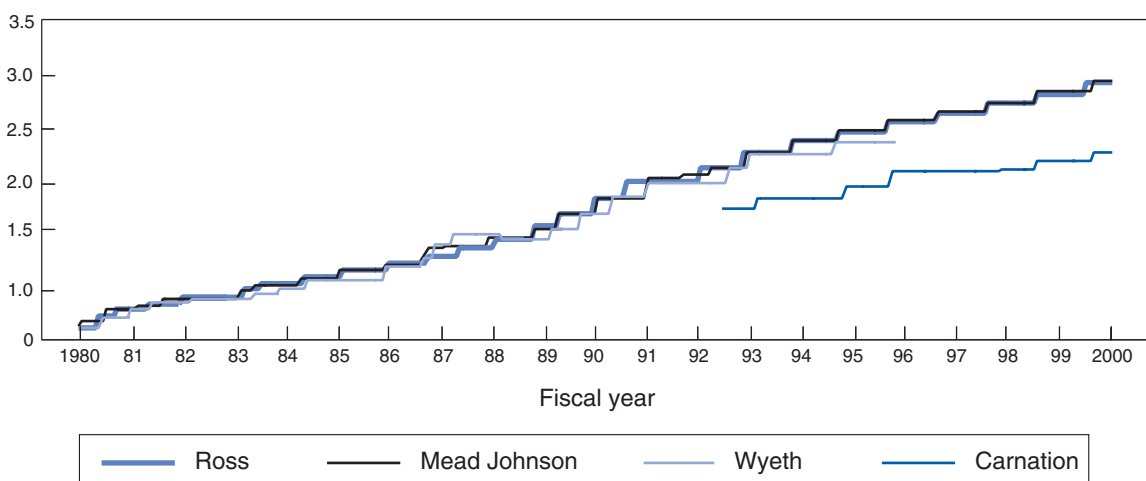
⁸ A technical point—even if all firms have identical unit cost curves and batch testing raised cost curves for all firms by the same amount, industry concentration may be increased by testing requirements if the higher level of costs, relative to a (fixed) product demand curve, means that the market could not support as many firms at minimum efficient scale.

⁹ Carnation had been producing infant formula for the international market for many years prior to this time.

Figure 4-1

Wholesale prices of selected infant formula by manufacturer, 1980-2000

Dollars per can of 13-ounce milk-based liquid concentrate



Source: Data provided by USDA's Food and Nutrition Service.

In 1989, Bristol-Myers, the parent company of Mead Johnson, entered into a marketing agreement with a nonpharmaceutical company—Gerber Products Company (a large baby food producer)—to manufacture formula to be marketed under the Gerber name (Gerber, 1989).¹⁰ Gerber infant formula was generally priced below the leading brands and, like Carnation formula, was marketed directly to consumers. The agreement ended in 1997, and the production of Gerber brand infant formula ceased (Mead Johnson Nutritionals, 1997).

After many years of producing infant formula for the U.S. market, Wyeth phased out production of its infant formulas for the U.S. market during 1996.¹¹ Among the reasons the company cited for its exit from the domestic market were the increasing costs of competing in the overall nutrition market and the spiraling growth of the WIC program (Wyeth-Ayerst Laboratories, 1996). In 1997 Wyeth re-entered the domestic infant formula market, not as a distributor of infant formula but as a producer for PBM Products. PBM Products markets the formula under its own label as well as under private-label brands in supermarkets and mass merchandiser chains such as Wal-Mart and Target, at prices below the major brands (*The Washington Post*, Sept. 11, 1999). PBM product marketing is aimed at consumers rather than the medical community (PBM does little medical detailing). ERS analysis of retail scanner data from supermarkets, mass merchandisers, and drugstores, indicates that in 2000, infant formula sold by PBM Products (virtually all of it in powdered form) accounted for just over 1 percent of all infant formula sold and 2 percent of all powdered formula sold.

Another recent change in the infant formula market has been the switch in market shares between Mead Johnson and Ross. Mead Johnson's share of the national market increased from 27 percent in 1994 to 52 percent in 2000 (table 4-1). During this period, Mead Johnson was successfully bidding for new WIC contracts as its share of the WIC infant formula market almost tripled from

¹⁰ This was Gerber's second attempt to enter the infant formula market. Gerber produced an infant formula from 1967 until the formula was discontinued in 1972 (*The New York Times*, 1989).

¹¹ Wyeth continued to manufacture infant formula for the international market.

23 percent to 68 percent.¹² Meanwhile, Ross's share of the national market declined from 53 percent in 1994 to 35 percent in 2000 as its share of the WIC market fell from 54 to 27 percent.

Since 2000 (the last year for which retail price data for this report were analyzed), other changes have occurred in the infant formula market. Anecdotal evidence suggests that PBM continues to gain market share. Recently PBM has introduced both liquid concentrate and ready-to-feed versions of infant formula into the market. In the spring of 2001, Abbott Labs, the parent company of Ross, began producing a private label infant formula for sale in Costco stores. This product, priced well below the Ross brand of formula, will compete with other brands—including Ross products—in the infant formula market. Lastly, in the summer of 2001, the U.S. Food and Drug Administration (FDA) approved the use of the fatty acids docosahexaenoic acid (DHA) and arachidonic acid (ARA) in domestic infant formula (*The New York Times*, 2001). Manufacturers that choose to add the fatty acids to their formula are required to do postmarketing surveillance, to ensure that infants consuming the product do not experience bad effects, that may result in higher costs.¹³

¹² Much of this dramatic shift occurred between fiscal years 1995 and 1996 when Mead Johnson's share of the WIC market increased from 33 percent to 62 percent (appendix table A-1).

¹³ Mead Johnson, Ross, Carnation, and PBM have all introduced formula containing DHA and ARA into their product line while continuing to offer formula without the fatty acids as well.