

Domestic Infant Formula Market

Infant formula was introduced in the United States in the early 1900s primarily to feed infants whose mothers had died during childbirth. The large-scale manufacture of infant formula did not appear until after World War II. Although breastfeeding is widely acknowledged as the best method of feeding most infants, many women do not breastfeed their infants (see box on breastfeeding rates in the 1990s).¹² In 1979, Congress recognized the critical importance of the availability of infant formula that is safe and nutritious. In order to improve protection of infants consuming commercial infant formula, Congress passed the Infant Formula Act of 1980, which provided the legislative basis for greater regulatory control over the production of infant formula.¹³ Provisions of the Act (along with 1986 amendments) established minimum (and in some cases maximum) nutrient levels for infant formula, thereby ensuring that it had adequate known nutrients and, in certain respects, standardizing its nutritional content. 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.

A wide variety of infant formulas are available. Conventional milk-based infant formula (containing lactose and cow's milk proteins) is the most widely used.¹⁴ Soy-based formulas are available as one alternative for infants who do not tolerate cow's milk-based formula well. According to FNS, "the best impartial medical evidence strongly demonstrates that milk-based, lactose-containing and soy-based, lactose-free

¹²The 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 breastmilk diet. Breastfeeding is recommended for at least 12 months and thereafter for as long as mutually desired.

¹³Congress passed the Act in response to a substantial number of infants having been made seriously ill in 1979 by the inadvertent omission of chlorides (essential nutrient for growth and development) in some infant formula when a manufacturer reformulated several of its infant formula products (61 FR 36153-36219, July 9, 1996).

¹⁴Lactose is a carbohydrate found in cow's milk.

infant formulas meet the nutritional needs of almost all infants" (65 FR 51213-51229, August 23, 2000). However, other types of infant formulas, including hypoallergenic and milk-based lactose-free, as well as formulas for infants with special nutritional needs, are also available. Infant formula is available in three different physical forms (liquid concentrate, powder, and ready-to-feed), in two different iron levels (added iron and low iron), and in a wide variety of package sizes.

Historically, the infant formula industry has been highly concentrated, with a small number of manufacturers. The manufacturers are usually owned by pharmaceutical companies, and those companies produce the vast majority of infant formula sold in the United States. In 1987 (i.e., before WIC's infant formula rebate programs were widely implemented), 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 (GAO, 1990) (table 2).

The fact that only a few firms produce infant formula for the U.S. market suggests that the costs of entering the market are high. It may be difficult for new firms, especially nonpharmaceutical firms, to enter because medical detailing is costly. According to the U.S. General Accounting Office, the practice of medical detailing by the pharmaceutical manufacturers of formula may have limited the ability of nonpharmaceutical companies to compete in the domestic infant formula market (GAO, 1990). 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 (GAO, 1990). Medical detailing also includes providing hospitals with "discharge packs" containing formula samples, 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. Other types of companies do not have the personnel (especially personnel with physician contacts) to compete.

Breastfeeding Rates in the 1990s

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 1998, the initiation of breastfeeding (i.e., breastfeeding while in the hospital) increased by almost 25 percent (table 1). By 1998, 64.3 percent of women were initiating breastfeeding, the highest rate ever recorded. Rates of breastfeeding infants at 6 months of age increased by almost 63 percent over the same period, from 17.6 to 28.6 percent (breastfeeding women included those who breastfed exclusively as well as those who supplemented breast milk with infant formula or milk from other sources).

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 over 50 percent from 1990 to 1998, while the percentage who were breastfeeding at 6 months

increased by over 130 percent. Despite these gains, WIC participants are still less likely to breastfeed (both in the hospital and at 6 months) than non-WIC participants. 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).

Through its nutrition education and breastfeeding promotion programs, the WIC Program encourages mothers to breastfeed their infants if possible. In addition, breastfeeding women 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. The quantity and variety of food in the WIC supplemental food package for breastfeeding women are also greater than that for nonbreastfeeding women. Women who exclusively breastfeed their infants may receive an enhanced WIC food package.

Table 1—Breastfeeding rates by WIC status, 1990-98

WIC status	1990	1991	1992	1993	1994	1995	1996	1997	1998
	<i>Percent</i>								
In hospital:									
All infants	51.5	53.3	54.2	55.9	57.4	59.7	59.2	62.4	64.3
WIC	33.7	36.9	38.8	41.6	44.3	46.6	46.6	50.4	52.6
Non-WIC	62.9	65.2	66.4	67.9	68.8	71.0	70.8	73.4	75.2
At 6 months:									
All infants	17.6	18.2	18.9	19.0	19.7	21.6	21.7	26.0	28.6
WIC	8.2	9.0	10.1	10.8	11.6	12.7	12.9	16.5	18.9
Non-WIC	23.6	24.6	25.6	25.8	26.5	29.2	29.5	35.5	38.5

Source: Abbott Laboratories, 1998.

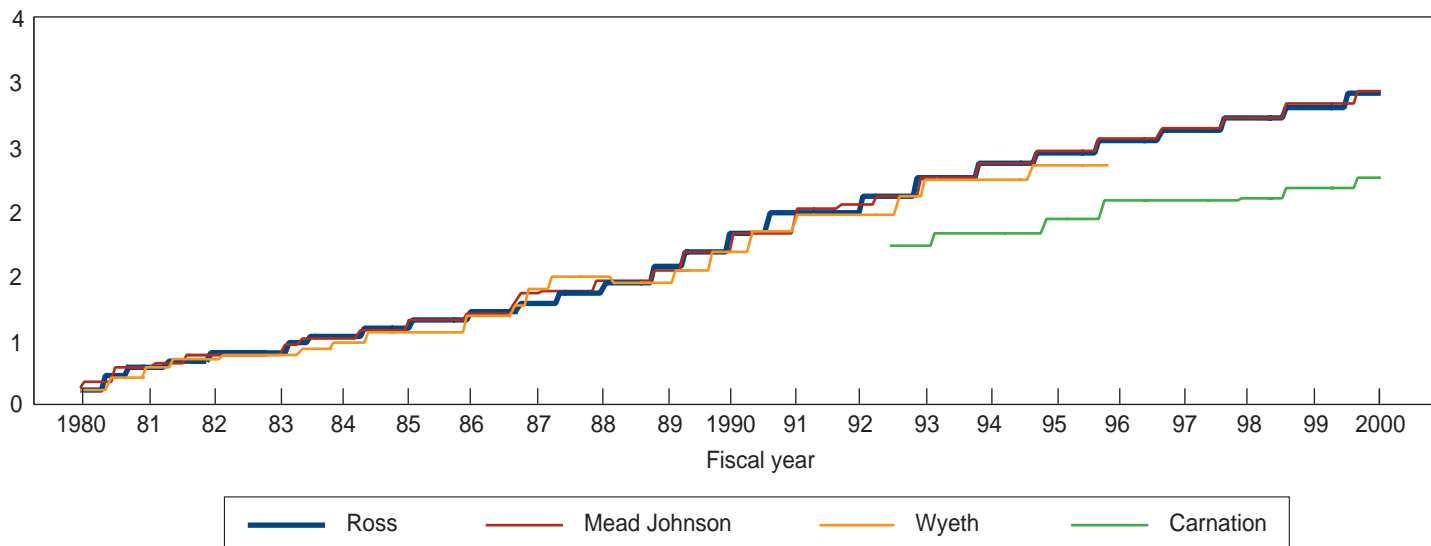
The industry's high concentration may also be a reflection of costs due to regulatory requirements. For example, the Infant Formula Act of 1980 requires demonstrating that infant formulas new to the U.S. market provide nutrients to the infant in usable form, and test-

ing of every batch of infant formula to ensure its nutrient composition. Finally, through a variety of practices, firms in concentrated markets are often able to charge higher prices, relative to production costs, than firms in less concentrated markets.

Figure 2

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.

Table 2—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 GAO, 1990. Data for 1994 and 2000 are from ERS analysis of InfoScan data.

As large buyers, WIC State agencies can use their market power to obtain lower prices. In order to win a WIC contract, infant formula manufacturers may choose to sell infant formula at a loss in the WIC market. To be profitable, such a strategy requires that increased sales in the non-WIC market offset the loss in the WIC market. An increase in non-WIC market sales could take place if retail stores give more shelf space to the WIC brand of infant formula (since, on average, over half of all sales are through WIC) or if physicians or hospitals become more likely to recom-

mend the WIC brand of infant formula to non-WIC consumers. GAO concluded that since WIC comprises over half of the market, it is unlikely that infant formula manufacturers sell their product at a loss in the WIC market (GAO, 1998).

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. For example, Carnation introduced their infant formula products into the U.S. market in 1988.¹⁵ Unlike the other major infant formula manufacturers, who are subsidiaries of pharmaceutical companies, Carnation is a subsidiary of Nestle, a large food company. It 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. 2). Carnation has steadily increased its share of the U.S. market. ERS analysis of scanner data indicates that in 2000, Carnation accounted for an estimated 12 percent of the market in volume sales.

¹⁵Carnation had been producing infant formula for the international market for many years prior to this time.

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), in which the formula was manufactured by Bristol-Myers but marketed under the Gerber name (Gerber, 1989).¹⁶ Gerber infant formula was generally priced below the leading brands and was marketed directly to consumers. The agreement ended in 1997 and the production of Gerber brand infant formula ceased (Mead Johnson, 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 1996.¹⁷ 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 reentered 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 such chains as Wal-Mart and Target at prices below the major brands (*Washington Post*, Sept. 11, 1999). Product marketing is aimed at consumers rather than the medical community (PBM does no medical detailing). Infant formula sold by PBM Products (virtually all of it in powdered form) accounted for just over 1 percent of the domestic market in 2000.¹⁸

¹⁶This was Gerber's second attempt to enter the infant formula market. Gerber produced an infant formula from 1967 until it was discontinued in 1972 (*New York Times*, 1989).

¹⁷Wyeth continued to manufacture infant formula for the international market.

Another change in the infant formula market has been the switch in market shares between Mead Johnson and Ross. Mead Johnson's share increased from 35 percent in 1987 to 52 percent in 2000 as their share of the WIC infant formula market almost tripled from 23 percent to 68 percent over the same period (see Appendix A). Meanwhile, Ross's share of the market declined from 55 percent in 1987 to 35 percent in 2000.

Since 2000 (the last year for which retail price data were analyzed), other changes have occurred in the infant formula market that are not captured in the study. Anecdotal evidence suggests that PBM continues to gain market share. In recent months, 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, is positioned to compete with PBM and Carnation products.¹⁹

¹⁸According to ERS tabulations, PBM infant formula accounted for over 1 percent of all infant formula and 2 percent of powdered formula sold in 2000.

¹⁹In addition, in the summer of 2001, the U.S. Food and Drug Administration (FDA) approved the use of DHA (docosahexaenoic acid) in domestic infant formula (*New York Times*, 2001). Manufacturers that choose to add the fatty acid to their formula are required to do postmarketing surveillance. The costs of postmarketing surveillance, which helps ensure that infants consuming the product do not experience bad effects, may lead to higher infant formula prices.