United States Government Accountability Office

GAO

Report to Congressional Requesters

March 2006

FOOD ASSISTANCE

FNS Could Take Additional Steps to Contain WIC Infant Formula Costs

GAO-06-380

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Highlights

Highlights of GAO-06-380, a report to congressional requesters

Why GAO Did This Study

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) provides food, nutrition education, and health care referrals to close to 8 million low-income pregnant and postpartum women, infants, and young children each year. About a quarter of these participants are served using rebate savings from contracts with infant formula manufacturers. WIC is administered by the Department of Agriculture's Food and Nutrition Service (FNS). To better understand infant formula cost containment, this report provides information on: (1) factors that influence program spending on infant formula, (2) how the level of savings resulting from infant formula cost containment has changed and the implications of these changes for the number of participants served; and (3) steps federal and state agencies have taken to contain state spending on infant formula.

What GAO Recommends

GAO recommends that the Secretary of Agriculture consider providing guidance to help prevent infant formula costs from rising when manufacturers introduce more costly formulas during a contract, and that the Secretary consider ways to more effectively restrict use of non-rebated formulas by WIC participants.

www.gao.gov/cgi-bin/getrpt?GAO-06-380.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Cindy Fagnoni at (202) 512-7215 or fagnonic@gao.gov.

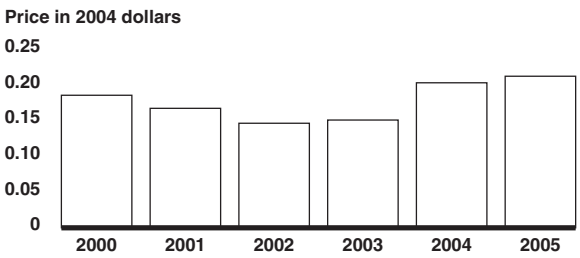
What GAO Found

Rebates drive state spending on infant formula but use of non-rebated formula increases state costs. In fiscal year 2004, states paid an average of $0.20 per can for milk-based concentrate formula, a savings of 93 percent off the wholesale price. However, states also allow some use of non-rebated formula that can cost states more than 10 times as much as contract formulas. For example, in 2004, 8 percent of infant formula provided to WIC participants was non-rebated.

Rebate savings from infant formula cost-containment contracts have allowed WIC to serve an additional 2 million participants per year, but recent increases in the cost per can of formula could lead to reductions in the number of participants served with rebates. Rebate savings have remained near $1.6 billion per year since 1997 after adjusting for inflation, but the amount states pay per can of infant formula has increased since 2002. We estimated that in 2004, if the cost per can of formula increased in every state by as much as it did in two states, approximately 400,000 fewer participants would have been able to enroll in WIC nationwide.

State and federal agencies have both taken steps to contain WIC infant formula costs, but FNS also focuses on sustaining the cost-containment system. States have sought to increase their costs savings through their infant formula contracts—for example, by joining coalitions to leverage greater discounts. Some also try to restrict the use of the more expensive non-contract formulas. FNS, in turn, helps states to contain costs through its review of contracts and through policy and guidance. For example, FNS reduced—but did not eliminate—the price increases that can result from the introduction of new, more costly formulas. FNS has also used its oversight authority to ensure that all interested manufacturers can compete for state infant formula contracts in an effort to maintain the long-run sustainability of the infant formula cost-containment system.

National average net price per can of milk-based concentrate, 2000-2005



Source: GAO.

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Abbreviations

ARA	arachidonic acid
DHA	docosahexaenoic acid
FNS	Food and Nutrition Services
FY	fiscal year
NEATO	New England and Tribal Organization coalition
USDA	United States Department of Agriculture
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

March 28, 2006

The Honorable Tom Harkin
Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Arlen Specter
United States Senate

The Honorable George Miller
House of Representatives

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) provides food, nutrition education, and health care referrals to close to 8 million low-income pregnant and postpartum women, infants, and young children each year. The 2 million infants who receive WIC benefits each year account for about half of infants born in the United States. Congress allotted just over $5.2 billion to fund the WIC program for fiscal year 2005, of which approximately 16 percent is typically used to purchase infant formula, the most expensive item supplied under the food grant. The U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) oversees and provides guidance to the state and local agencies that implement the WIC program.

States contain the cost of infant formula using a competitive bidding process that awards sole-source contracts to infant formula manufacturers. This competitive bidding process allows infant formula manufacturers to compete for the contracts by offering sizeable discounts to the states on the infant formula that WIC participants purchase. Three infant formula companies currently compete and serve WIC participants—Mead Johnson, Ross Laboratories, and Nestlé. With just three manufacturers competing for WIC contracts, infant formula is among the most concentrated markets in the United States.[1] State WIC agencies provide most of their WIC infants with one of the contract manufacturer's milk-based or soy-based infant formulas designed for healthy infants.

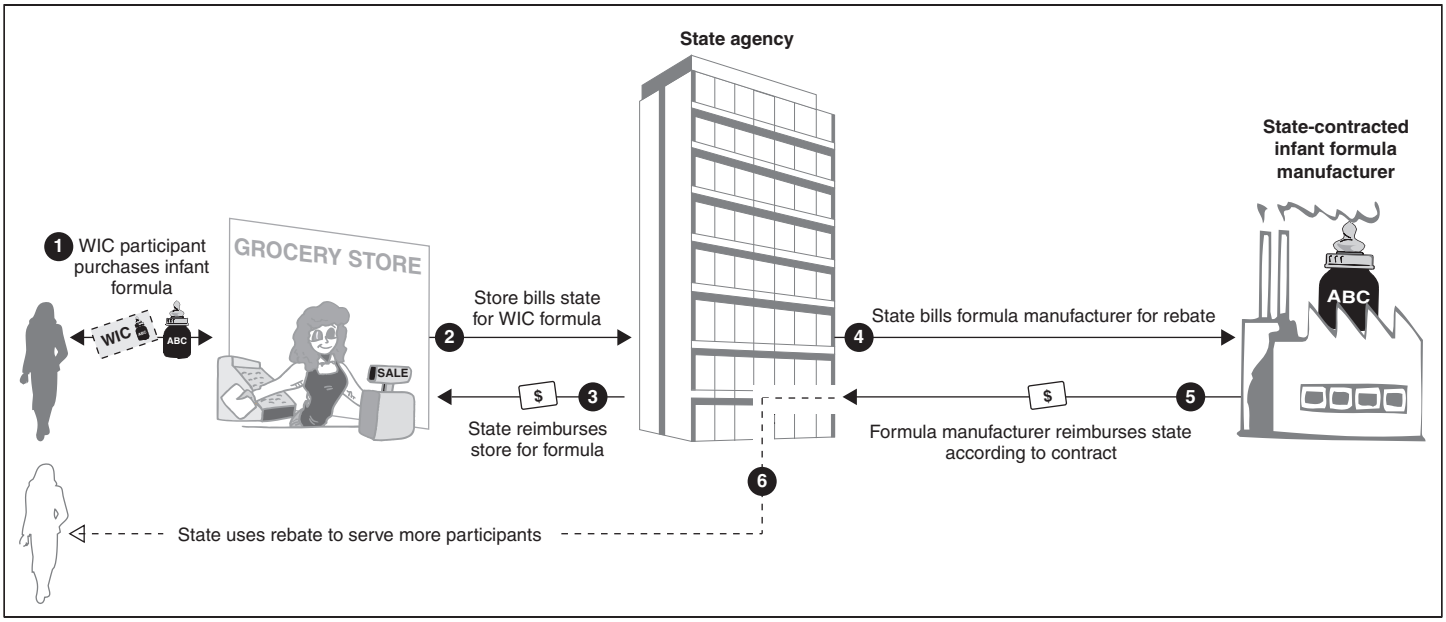
[1]A fourth manufacturer, PBM Nutritionals, manufactures infant formula for sale under store brands. PBM does not compete for WIC contracts.

Infants can also be provided with a "non-contract" infant formula if prescribed by a medical professional. There are two types of non-contract infant formula. "Exempt" infant formulas are designed for infants with specific medical or dietary problems, and "non-contract, non-exempt" infant formulas are designed for healthy infants but manufactured by a company other than the contract manufacturer. States do not receive rebates on non-contract infant formulas.

WIC participants typically purchase infant formula from stores at the full retail price using a voucher or coupon. The voucher specifies the brand and amount of infant formula the participant can purchase. The store then bills the state, and to obtain the price discounts, states then send the contract manufacturer an invoice listing the number of cans of contract brand infant formula purchased. The manufacturer, in turn, provides discounts to the state in the form of rebates for each can of infant formula purchased.

States use the savings generated by these cost-containment contracts to serve additional participants. Figure 1 depicts the transactions in the rebate process.

Figure 1: WIC Infant Formula Rebate Process



Sources: GAO (analysis); Art Explosion (images).

In recent years, some states have seen their savings from cost-containment efforts decline, raising concern about the implications that reduced rebates might have on the WIC program since more than one-quarter of WIC participants are served with rebates. To better understand factors that affect state spending on infant formula and the implications of infant formula cost containment for the WIC program, this report will provide information on: (1) factors that influence program spending on infant formula, including the role of rebate savings that states receive through infant formula cost-containment contracts; (2) how the level of savings resulting from infant formula cost containment has changed over the past 5 years and the implications of these changes for the number of participants served; and (3) steps federal and state agencies have taken to contain state spending on infant formula.

To address these research objectives, we analyzed administrative data on program participation, food costs, and total rebates provided to us by FNS for the years 1999 through 2004, and information on rebates obtained by individual states per can of milk-based concentrate infant formula for fiscal years 2000 through 2005. Using FNS data, we calculated trends in the average per-can cost of milk-based concentrate infant formula in the 50 states plus the District of Columbia between 2000 and 2005, as well as

trends in total rebates, and trends in the share of participants served using rebate savings. We also used this data to estimate the potential impact of reduced rebates on program participation under three alternate scenarios. To better understand the factors that affect program spending on infant formula, we surveyed 50 state WIC programs and the District of Columbia to obtain additional information about their infant formula contracts. We achieved a 100 percent response rate. We also reviewed literature on factors that influence infant formula spending, and interviewed several state and local WIC directors, all three infant formula manufacturers currently participating in the WIC market, and policy experts with an interest in WIC infant formula cost containment. We performed this work between April 2005 and March 2006 in accordance with generally accepted government auditing standards. See appendix I for additional information on scope and methodology.

Results in Brief

State spending on infant formula is determined primarily by the discounts, in the form of rebates, that manufacturers offer, but the use of infant formula not covered by contracts with manufacturers can also affect state spending on infant formula. Over 90 percent of infant formula provided through the WIC program is covered by cost-containment contracts with manufacturers. In fiscal year 2004, states paid, on average, $0.20 after rebates per can for milk-based concentrate infant formula with a wholesale price of $2.60 to $3.57. The amount states pay can vary significantly—from as low as $0.07 per can of milk-based concentrated infant formula to as high as $0.80 per can. The amount of rebate savings depends primarily on the rebates offered to states by manufacturers. The rebates manufacturers offer, in turn, can be affected by factors that states have some control over, including the extent to which a WIC contract will help a manufacturer market its products to non-WIC consumers and the accuracy of state systems used to bill manufacturers for infant formula purchased by WIC participants. State spending on infant formula is also affected by spending on non-contract infant formulas for which states do not receive rebates, including exempt infant formulas and non-exempt infant formulas produced by another manufacturer. Non-contract infant formulas can cost states more than 10 times as much as contract infant formulas; therefore, even modest use can drive up state costs. Over the past 5 years, the use of non-contract, non-exempt infant formulas has fallen somewhat, but use of exempt infant formulas has risen.

The total amount of money state WIC agencies have saved on infant formula through their cost-containment contracts has been relatively stable since 1997, but if recent increases in the average price states pay per

can of infant formula continue, the number of participants that can be served with rebate savings is likely to fall. Total savings from rebates, which increased from about $800 million in 1990 to more than $1.6 billion in 1997, have remained near $1.6 billion per year since that time after adjusting for inflation. In 2004, rebate savings enabled the WIC program to serve an additional 2 million people—about a quarter of all participants. In recent years, the average amount states pay per can of infant formula purchased through WIC increased as the rebates manufacturers offered declined and manufacturers introduced new, more expensive infant formulas. Both of these trends contributed to an increase in the price states pay for a can of milk-based concentrated infant formula from $0.15 per can in 2002 to $0.21 per can in 2005, on average, even after adjusting for inflation. When states pay more per can, they cannot serve as many participants. We estimated that if the average rebate states received per can had fallen to 75 percent of wholesale price in 2004—requiring states to pay approximately $0.89 for a can of milk-based concentrate with a wholesale price of $3.57—approximately 400,000 fewer participants would have been able to enroll in WIC nationwide.

State and federal administrators have taken steps to contain the costs of infant formula, but federal efforts also focus on maintaining the long-run sustainability of the competitive bidding system by ensuring that all interested infant formula manufacturers can compete for WIC contracts. States have sought to minimize the cost of infant formula through their contracting and infant formula provision practices. For example, 30 states[2] have joined coalitions made up of two or more state WIC agencies in an effort to maximize cost savings by sharing the costs of administering WIC contracts and leverage greater discounts. In addition, recognizing the high cost of non-rebated infant formula, 12 states do not provide non-contract, non-exempt infant formula to WIC participants. Other states rely on the federal regulation requiring medical documentation to limit the use of these more expensive infant formulas. Despite these efforts, use of non-rebated infant formulas varies significantly by state, from a low of 0 to a high of 25 percent. FNS has also taken steps to contain infant formula costs. For example, FNS established a regulation requiring manufacturers to provide states with the same percent discount on all infant formulas covered by the contract, even new, more costly infant formulas introduced while a contract is in effect. This requirement helps, but does not entirely

[2]The 30 states includes the District of Columbia, but does not include Indian Tribal Organizations.

prevent states from incurring cost increases when manufacturers introduce infant formulas with higher wholesale prices. Because infant formulas with higher wholesale prices continue to cost more per can, state costs can escalate if manufacturers replace more commonly used infant formulas with more expensive ones during a contract as they did in some states and localities according to state and local WIC directors. To ensure the long-run sustainability of the cost-containment system, FNS has also used its oversight authority to ensure that all manufacturers can compete for state infant formula contracts regardless of their share of the market. For example, FNS does not approve contract provisions designed to increase state cost savings when it concludes that the provisions could limit competition by giving one or more companies a competitive advantage.

To help states preserve rebate savings generated through infant formula cost containment, we recommend that the Secretary of the Department of Agriculture consider providing guidance related to product changes to ensure that state costs do not increase when infant formula manufacturers replace the most commonly used infant formulas with new, more expensive infant formulas during a contract. In addition, we recommend that the Secretary consider ways to more effectively restrict issuance of non-rebated infant formulas to WIC participants.

Background

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) was established in 1972 to provide food, nutrition education, and health care referrals to low-income pregnant and postpartum women, infants, and young children. The program is administered by FNS in conjunction with state and local health departments and related agencies. WIC is almost entirely federally funded. WIC is not an entitlement program; Congress does not set aside funds to allow every eligible individual to participate in the program. Instead, WIC is a federal grant program for which Congress authorizes a specific amount of funds each year. USDA provides funding for food and nutrition services and administration. Both funding and participation have increased each year since fiscal year 2000. Congress also typically provides for a contingency fund to ensure that adequate resources are available for the program if unanticipated costs arise.

Infant Formula Rebate Savings

WIC participants typically receive food benefits in the form of vouchers or coupons that they redeem at authorized retail vendors to obtain, at no cost to the participants, certain approved foods, including infant formula.[3] State WIC agencies then reimburse the retail vendors for the food purchased by WIC participants. Since 1989, state WIC agencies have been required by law to contain the cost of infant formula using a competitive bidding process to award sole-source contracts unless they can demonstrate that an alternative method would yield the same or greater cost savings.[4] Manufacturers agree to provide a rebate to the state WIC agency for every can of infant formula purchased under the WIC contract, and the state awards the contract to the bidder offering the lowest net wholesale price after subtracting the rebate from the cost of infant formula.[5] In exchange, the state provides the contract brand of infant formula to most infants enrolled in the program except those that are breastfeeding exclusively and those with a medical condition that requires the use of a non-contract infant formula. Rebates have become an important source of funding for the WIC program. In 2004, rebates totaled more than $1.6 billion and funded the benefits provided to about a quarter of WIC participants.

FNS Review of Contracts

Contracts for WIC infant formula are between states and infant formula manufacturers. States are responsible for issuing requests for bids and drafting contract provisions according to state contracting requirements. Typically, a WIC agency will draft a bid solicitation and obtain state approval for the contract language. Once the state approves the

[3]Two states, Vermont and Mississippi, operate a direct distribution system whereby WIC supplemental foods are distributed directly to participants from state-operated warehouses. In these two states, WIC participants do not use the retail system. These states do, however, negotiate sole-source contracts with infant formula manufacturers and purchase WIC infant formula from the manufacturer at a discounted price.

[4]Pub. L. No. 101-147 (1989). Under the law, state agencies are required to procure infant formula using a competitive bidding system or an alternative method of cost containment that yields savings equal to or greater than those produced by a competitive bidding system.

[5]The net wholesale price is calculated by subtracting the rebate per can from the lowest national wholesale cost per unit for a full truckload of infant formula. The net wholesale price of the primary contract infant formula remains fixed over the contract period. The net wholesale price does not reflect any additional mark-ups imposed by retailers. Because state WIC agencies reimburse WIC vendors for the full retail price of infant formulas sold to WIC participants using WIC vouchers, the actual cost to the state for each can of infant formula is the "net retail price," or the retail price charged by the vendor less the rebate provided by the manufacturer. States generally do not track retail prices of infant formula. In this report, we use the term "net price" to refer to the net wholesale price.

solicitation, the WIC agency will submit it to the FNS regional office for review. The regional office ensures that the contract adheres to all federal requirements and may suggest ways to improve the contract. FNS headquarters reviews the contract for final approval. After approval, the contracting process is conducted by the state.

Types of Infant Formula

Infant formula comes in three physical forms: liquid concentrate, powder, and ready-to-feed. Infants may receive up to 31 13-ounce cans of liquid concentrate per month through WIC, or roughly the equivalent amount of powdered or ready-to-feed infant formula. Most infants are provided an infant formula that is covered by the state's cost-containment contract. There are three categories of infant formula provided to WIC participants:

- Contract brand infant formula is produced by the contract manufacturer and is suitable for routine use by the majority of healthy full-term infants. These include milk-based and soy-based infant formulas and could include milk- and soy-based infant formulas enhanced with DHA and ARA,[6] lactose-free infant formula, added-rice infant formulas, and easy-to-digest infant formulas.[7] "Contract brand infant formula" also includes new infant formulas introduced by the contract manufacturer after the contract is awarded, with the exception of infant formula under the following "exempt" category.

- Exempt infant formula is represented and labeled for use by infants with medical conditions such as inborn errors of metabolism, low birth weight, or other unusual medical or dietary problems that require that they use a more specialized infant formula.[8]

[6]Docosahexaenoic acid (DHA) and arachidonic acid (ARA) are fatty acids found in breastmilk.

[7]If a state agency elects to solicit separate bids for milk-based and soy-based infant formulas, all infant formulas issued under each contract are considered the contract brand infant formula (see 7 C.F.R. §246.16a(c)(1)(ii)). For example, all of the milk-based infant formulas issued by a state agency that are produced by the manufacturer that was awarded the milk-based contract are considered contract brand infant formulas. Similarly, all of the soy-based infant formulas issued by a state agency that are produced by the manufacturer that was awarded the soy-based contract are also considered to be contract brand infant formulas.

[8]See 21 U.S.C. §350a(h)) and the regulations at 21 C.F.R. parts 106 and 107.

- Non-contract brand non-exempt infant formula is all infant formula produced by a manufacturer other than the contract manufacturer that is suitable for routine use by the majority of healthy full-term infants.

FNS regulations require local WIC agencies to obtain medical documentation to provide all exempt infant formulas and all non-contract, non-exempt infant formulas.[9] Medical documentation, for these purposes, is a determination by a licensed health care professional authorized to write medical prescriptions under state law. A licensed health care professional must make a medical determination that an infant has a medical condition that dictates the use of these infant formulas.

Rebates Drive WIC Infant Formula Costs More Than Any Other Factor, but Use of Non-Contract Infant Formulas also Plays a Role

State spending on infant formula depends on the discounts, in the form of rebates, that states receive from manufacturers, and use of non-contract infant formula. Rebates are the most important factor driving state spending on infant formula because such a large proportion of WIC infant formula is purchased under cost-containment contracts with manufacturers. According to infant formula manufacturers, the attractiveness of a WIC contract depends, at least in part, on factors over which states have some control, including the extent to which a WIC contract will help a manufacturer market its products to non-WIC consumers; state-level administration of WIC contracts; and the provision of powder, concentrate, and ready-to-feed infant formula to WIC participants. These factors, in turn, could affect whether or not a manufacturer bids on a contract and the level of rebates offered by the manufacturers. The provision of non-rebated infant formula also affects state spending.

States Receive Rebates on Most Infant Formula Purchased through WIC

In 2004, states received rebates on approximately 92 percent of the infant formula provided to WIC participants, and saved, on average, 93 percent off the wholesale price. As a result, states paid an average of $0.20 per 13-ounce can of milk-based infant formula with a wholesale price of $2.60 to $3.57. However, while average rebates were high, rebate levels varied significantly by state. For example, in 2004, Virginia and South Carolina were paying as little as $0.07 per can of milk-based concentrate after rebates, while New York was paying $0.80 per can after rebates.

[9]Participants must also provide medical documentation to receive certain types of contract brand infant formulas such as low-iron infant formula.

Representatives of the three infant formula manufacturers identified several factors that influence how "attractive" they find a state contract. The attractiveness of a contract, in turn, could influence whether a manufacturer bids on a contract and the size of the rebate offered. Many of the factors cited by manufacturers are things over which states have at least some control.

Shelf space and product placement: WIC-brand infant formulas may get more shelf space than competing brands, particularly in stores that serve areas with large concentrations of WIC participants. Because WIC participants purchase such a large share of infant formula in some stores, retailers tend to stock more of the WIC brand of infant formula. In addition to shelf space, WIC-brand products may be placed at eye level so that they are easy to spot.

All three infant formula manufacturers noted the importance of shelf space and product placement to their marketing strategies. In addition, 31 of the 51 state WIC directors that responded to our survey felt that shelf space was moderately, very, or extremely important to manufacturers in determining how much they bid on an infant formula contract. While WIC agencies do not have direct control over shelf space and product placement, some include stocking requirements in their contracts with vendors.

State policies regarding authorization of WIC vendors can also impact manufacturers' access to non-WIC consumers. Some states have authorized WIC vendors that sell exclusively or primarily to WIC participants. Manufacturers have less access to non-WIC consumers if more WIC participants purchase their infant formula at these "WIC-only" stores. In those cases, retailers that serve the non-WIC population in the area may be less likely to focus on product placement or devoting shelf space to the WIC brand—two factors that benefit manufacturers in their drive to reach non-WIC consumers.

Physician and Hospital Recommendations: Having WIC contracts could also benefit manufacturers through physician recommendations. State WIC programs often work with physicians to educate them about the program and the requirement that most WIC participants use the contract brand of infant formula. Physicians may decide to recommend the WIC brand of infant formula to all patients to avoid having to differentiate between those enrolled and not enrolled in WIC. Similarly, some hospitals agree to provide WIC-brand infant formula to new mothers so that they won't have to switch infant formulas after they leave the hospital. It may

be easier for hospitals to provide the WIC-brand infant formula to all new mothers. Moreover, two of the infant formula companies that participate in the WIC market are divisions of pharmaceutical companies that primarily market their products directly to physicians and hospitals while also marketing, though to a lesser extent, directly to consumers. States vary in the extent to which they emphasize doctor and hospital outreach.

Product Innovation: All three manufacturers cited the central role of product innovation in their business strategies. Manufacturers seek to compete on the basis of product innovation and product quality despite the fact that infant formula is a relatively homogeneous product.[10] Manufacturers said that certain state practices could make it more difficult to pursue their core strategy of innovation, and the development, distribution, and marketing of new products. These practices include the use of long-term contracts, requirements that manufacturers notify states of product changes in advance of introducing new products into the market, provisions that allow states to unilaterally extend contracts without requesting the consent of the manufacturer, state restrictions on the ways in which manufacturers market their infant formula, and restrictions on their interactions with physicians. While these state practices could inhibit innovation, many are put in place to protect states from increases in infant formula costs.

State Billing Systems: All three manufacturers cited the accuracy of state billing systems as a key factor they consider when developing bids, and all stated that the vast majority of state billing systems need improvement. One manufacturer said that most states rely on antiquated information technology that is prone to costly billing errors. According to FNS officials, disputes over billing for infant formula rebates have long been a problem in the WIC program. In the past, some states requested reimbursement from infant formula manufacturers for every can of infant formula listed on redeemed vouchers. However, some WIC participants did not purchase every can of infant formula listed on the voucher. In these instances, the manufacturers claimed they were being billed for purchases that were never made. Partly in response to these disputes, a new provision was included in the Child Nutrition and WIC

[10]The Infant Formula Act of 1980 requires infant formula manufacturers to follow specific guidance on quality, manufacturing practices, and nutrient requirements See 21 U.S.C. §350a.

Reauthorization Act of 2004 that requires states to bill only for infant formula actually purchased.

Contract size: State WIC directors said they believe that contracts that cover more infants yield higher rebates; however, the manufacturers said that the largest contracts may not draw their highest bids. A few state WIC directors expressed concerns that new provisions in the Child Nutrition and WIC Reauthorization Act of 2004 limiting the size of state coalitions and requiring separate contracts for milk-based and soy-based infant formula could reduce the size of contracts and the size of rebates. However, manufacturers noted that costly shifts in demand occur when very large states or coalitions change contractors. Manufacturers must be able to respond to these shifts by quickly increasing or decreasing production, and must, therefore, consider their own production capacity when they bid on very large contracts.

Contract Provisions: Manufacturers noted that states sometimes include contract provisions that manufacturers consider complex, ambiguous, and extraneous and inclusion of these provisions could affect rebates. For example, manufacturers cited provisions that increase the potential liabilities of manufacturers, give states control over manufacturer activities, or require manufacturers to provide products or services not directly related to the sale of infant formula—such as sponsoring conferences, providing literature on nutrition education, or providing free infant formula—as particularly unattractive. Because states rarely modify contract provisions in response to manufacturer concerns, manufacturers may respond to these provisions by either not bidding on contracts or offering lower rebates.

Provision of Powder, Concentrate and Ready-to-Feed Infant Formulas: All three manufacturers cited the importance of state policies governing the provision of powder, concentrate, and ready-to-feed infant formulas. Historically, the WIC program has issued more concentrate than powder, but there has been an increase in the use of powder in the WIC program since 2000. Because ready-to-feed infant formula is the most expensive, WIC regulations allow WIC agencies to provide it only in certain circumstances[11] Twenty-nine states were able to provide us with

[11]Ready-to-feed infant formula can be provide when (1) the participant has unsanitary or restricted water supply or poor refrigeration; (2) the participant may have difficulty in correctly diluting liquid concentrate or reconstituting powder; or (3) ready-to-feed infant formula is the only form available.

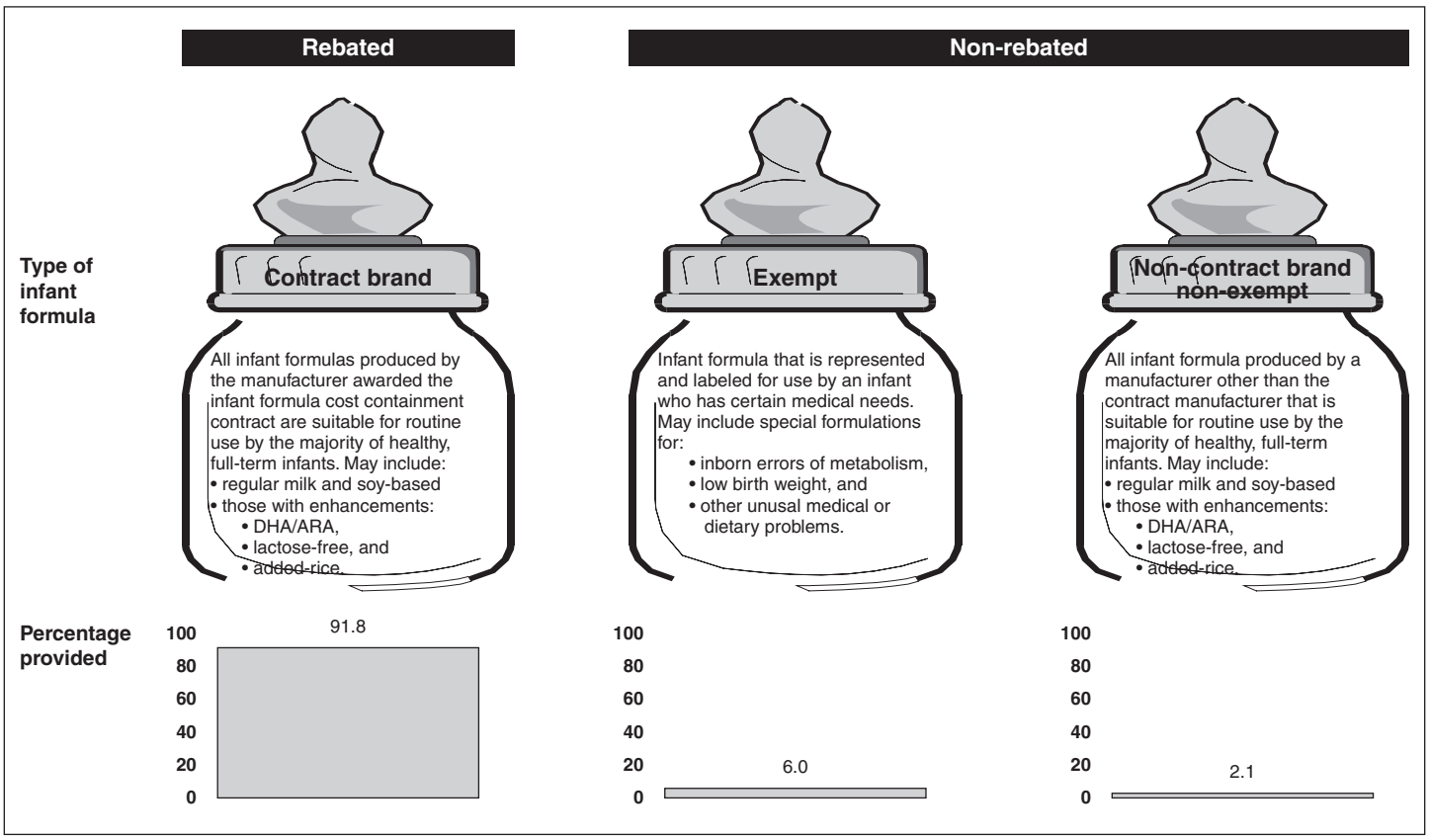
data on their use of the different forms of infant formula in both 2000 and 2004. In 2000, 55 percent of all infant formula issued in those states was in the form of liquid concentrate. By 2004, liquid concentrate represented only a third of all infant formula provided to WIC participants in those states. Powder use may have increased because it can be more convenient for mothers who are partially breastfeeding because mothers can reconstitute small amounts of powdered infant formula at a time, whereas liquid concentrate must be diluted all at once. Manufacturers did not provide information on how the provision of different forms of infant formula might affect their bids on infant formula contracts. However, if concentrate is more profitable, the shift to powder could reduce manufacturer profits—and the rebates they offer to states. Alternatively, if powder is more profitable or there are no differences in the profitability of different forms, the shift to powder might not affect rebates.

Use of Non-Contract Infant Formula Increases Formula Costs

Although non-contract infant formula, including both exempt and non-contract, non-exempt infant formula, accounts for less than 10 percent of infant formula purchased through WIC, its use can have a significant impact on total infant formula spending because it can cost as much as 10 to 20 times more per can than rebated formula. Among the 27 states that were able to provide us with data on their use of contract, exempt, and non-contract, non-exempt formulas in both 2000 and 2004, use of exempt formula increased and use of non-contract, non-exempt formula decreased over the 4-year period.[12] Figure 2 shows the average share of each type of formula provided to WIC participants in 43 states in 2004.

[12]These 27 states account for 62 percent of WIC participants.

Figure 2: Type of Infant Formulas and Percentage of All WIC Formula Issued FY 2004



Source: GAO survey of state WIC directors, based on responses from 43 states.

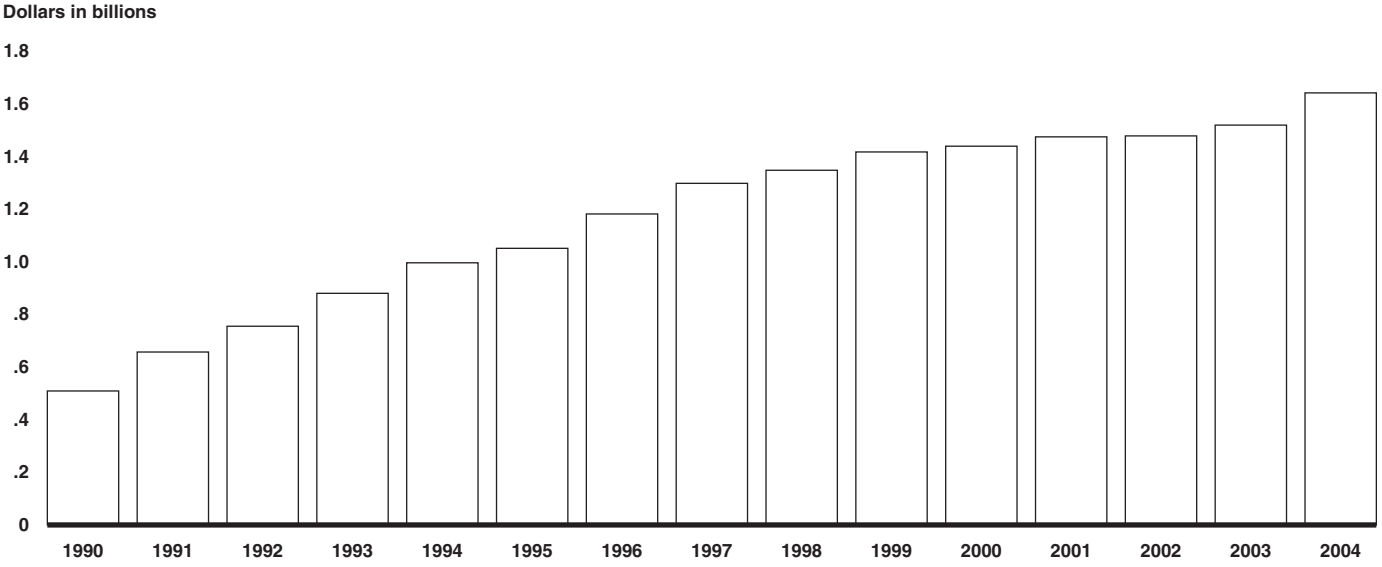
Rebate Savings Have Been Used to Serve about a Quarter of All Participants in Recent Years, but If Rebate Savings Continue to Decline, Fewer People Will Be Able to Participate

Rebate savings have remained relatively stable since 1997 after adjusting for inflation, but if recent increases in the amount states pay for each can of infant formula they purchase through WIC continue, fewer participants will likely be served with rebates in the future. About a quarter of all WIC participants are served using rebate savings. However, over the past 5 years, the amount states pay for infant formula has increased somewhat, particularly among states that have awarded new contracts. There is some concern that if the price states must pay for infant formula continues to increase, fewer participants will be served using rebates. We estimated that in 2004, if all states had paid as much per can of infant formula as the two states with the lowest rebates, approximately 400,000 fewer children would have been able to enroll in WIC nationwide.

Total Rebate Savings Have Been Stable but the Amount States Pay Per Can of Infant Formula Has Increased Since 2002

After increasing substantially in the years prior to 1997, the total amount that states received from manufacturers in infant formula rebates has remained relatively constant since that time. As shown in figure 3, rebate savings have remained at about $1.6 billion per year after adjusting for inflation.

Figure 3: Total Rebate Savings, 1990-2004



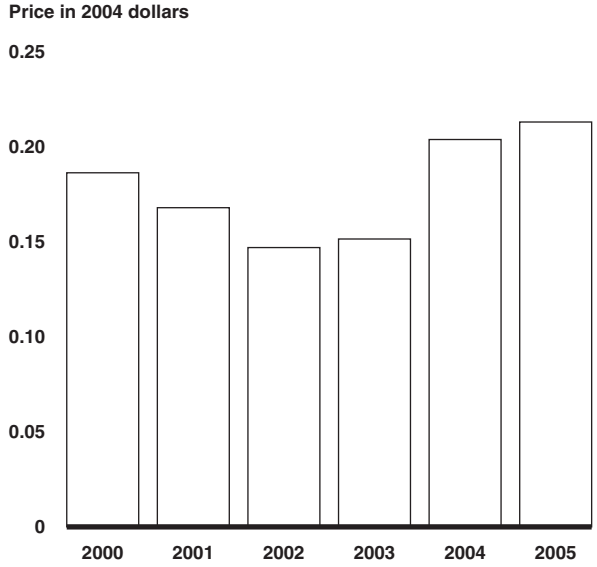
Source: FNS, Bureau of Labor Statistics.

The percent of participants that have been served using rebates has also remained relatively stable over the past 5 years, at about 25 percent. In 2004, some 2 million participants were served using rebate dollars.

Although both total rebate savings and the share of participants served using rebate savings has changed little in recent years, we found that the amount states pay per can of infant formula, after taking rebates into account, has increased over the past few years. The average net price states paid per can of milk-based concentrate infant formula increased from $0.15 in fiscal year 2002 to $0.21 in fiscal year 2005 after adjusting for inflation.[13]

[13]These figures are adjusted for inflation using the Producer Price Index for drugs and pharmaceuticals.

Figure 4: National Weighted Average Net Price per Can of Milk-Based Concentrate

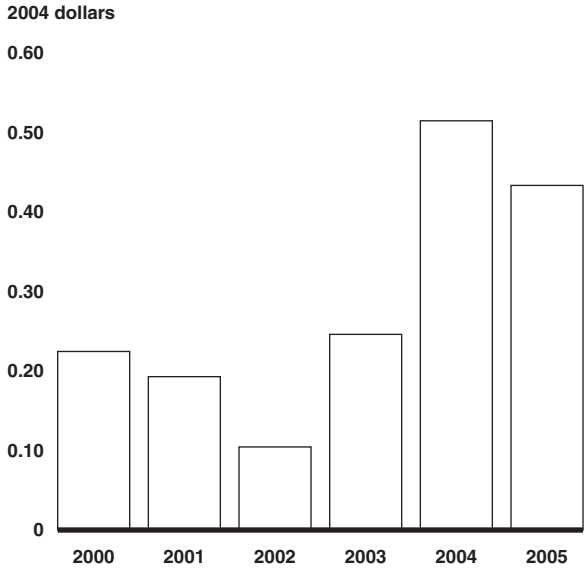


Source: GAO analysis of FNS data.

Because most contracts lock in the price states pay for infant formula for up to 5 years, average prices tend to move slowly. The price increases are more apparent among contracts that were newly awarded each fiscal year. Among newly awarded contracts, there was a fourfold increase in the average net price of a can of infant formula over the 3-year period, from $0.10 in 2002 to $0.43 in 2005. Figure 4 shows rebates for newly awarded contracts between fiscal year 2000 and fiscal year 2005.[14]

[14]Because the number of states implementing new contracts is different each year, the figures shown reflect a simple, not a weighted average for each fiscal year.

Figure 5: Change in Net Price Paid under Newly Awarded Contracts



Source: GAO analysis of FNS data.

Although the amount states pay for infant formula varies by state, the increases in the average net price were not driven by large increases in just a few states, but reflect higher wholesale prices and lower rebates nationwide. Eight of the 9 states that implemented a new contract in 2002 did so at either the same net price as under their previous contract or at a lower net price. This trend shifted over the next few years. By 2004, a majority of states implementing new contracts saw their net price increase, and in 2005, every state that implemented a new contract did so at a higher net price than under its previous contract.

The extent to which net prices increased among newly awarded contracts varied, but most states did not experience significant price increases. Among states that implemented new contracts in 2005, the average net price for a can of milk-based concentrate was $0.43 after rebates. This represented a discount of about 87 percent off the wholesale price. In a few states, however, the net price states paid for milk-based concentrate under their contracts was significantly higher than the average. New York implemented a contract in 2004 that provided milk-based concentrate for a net price of $0.80 per can, a discount of 75 percent off the wholesale price.

Similarly, North Dakota implemented a contract in 2005 that provided a net price of 0.83 per can, a discount of 77 percent off the wholesale price.[15]

The impact of reduced rebates per can of infant formula was exacerbated by an increase in the use of more expensive types of infant formulas. Since the early 1990s, infant formula manufacturers have diversified their product lines to include a greater number of infant formula types, all of which have higher wholesale prices than traditional unenhanced milk- and soy-based infant formulas. The most significant change in infant formulas came with the introduction of DHA and ARA enhanced infant formulas starting in 2002. All three manufacturers have introduced DHA and ARA enhanced infant formulas at prices that are higher than the unenhanced versions. At the time of our survey in mid-2005, 23 states reported that they issue enhanced infant formula as their primary contract brand; only 8 states reported that they do not approve enhanced infant formula.[16] In addition, four of the five most recent contracts to be awarded specified the enhanced infant formulas as the primary contract brand.[17] The increased use of infant formulas with a higher wholesale price may have contributed to the increase in the net price of infant formula under new cost-containment contracts if infant formula companies sought higher compensation for their more expensive products.

Higher Infant Formula Costs Could Reduce Participation by Nearly 400,000

Increases in the cost of infant formula have not yet had a significant impact on the share of participants served with rebate savings, but if infant formula costs were to continue to increase, it is likely that fewer participants would be served using rebate savings in the future absent funding increases. To illustrate how infant formula prices can affect WIC

[15]At the beginning of fiscal year 2006, Vermont implemented a new contract under which the state is paying $1.11 per can of milk-based concentrate. Vermont operates a home delivery system. As a result, the state does not receive rebates from the manufacturer. It purchases infant formula directly from the manufacturer at a reduced price.

[16]Twenty-three states reported that they provided enhanced infant formula to all participants, or provide it to all participants unless non-enhanced infant formula is requested. The remaining states provide enhanced infant formula under certain circumstances such as when a prescription is provided or when other non-enhanced infant formulas are not available in retail outlets.

[17]The Child Nutrition Act and WIC Reauthorization Act of 2004 requires state agencies to provide, as the infant formula of first choice, the primary contract infant formula specified in the manufacturer's bid. As a result, state agencies have no choice but to issue the higher-cost DHA/ARA enhanced infant formulas if manufacturers identify these as their primary contract infant formulas.

participation, we considered how three different scenarios would have affected participation in WIC during fiscal year 2004. We estimated the number of WIC participants that would have been served using rebate savings if the average rebate in 2004 had been 90 percent of the wholesale price of infant formula—slightly less than the actual discount of 93 percent. We also considered scenarios reflecting larger reductions in rebates, to 85 percent and 75 percent of the wholesale price of infant formula.[18] We compared our estimates to the actual number served using rebates in fiscal year 2004.[19]

We found that with even a modest reduction in rebates across all states, fewer participants could be served:

- If rebates were equal to 90 percent of the wholesale price in all states in 2004, about 70,000 fewer participants would have received WIC benefits.
- If rebates were equal to 85 percent of the wholesale price in all states in 2004, about 175,000 fewer participants would have received WIC benefits.
- If rebates had fallen to 75 percent of the wholesale price in all states in 2004, the program would have been able to serve about 400,000 fewer participants.

Because most states are still under existing contracts negotiated in prior years, it would take some time for the impact of reduced rebates to be fully realized. Many states will be under their current contracts through 2006 and 2007 and many have contracts that continue through 2008 or 2009 if they opt to extend their contracts as permitted. State WIC directors in 45 of 51 states reported that their infant formula contracts allow for

[18]We selected these percentages based on rebates offered to states over the past 5 years and included scenarios representing a modest decrease (90 percent of wholesale price), a moderate decrease (85 percent of wholesale price) that was approximately equal to the discount offered on newly awarded contracts in fiscal year 2004, and a larger decrease (75 percent of wholesale price) that was similar to the discount received in two states during fiscal years 2004 and 2005.

[19]By confining our estimates to 2004, we were able assume that all else remained as it was in 2004 and thereby isolate the impact of rebates from other factors that can affect the number of participants served, such as changes in the retail prices of WIC foods, changes in breastfeeding rates, and changes in the size and composition of the caseload. These estimates do not take into consideration the availability of the WIC contingency fund that can be drawn down to maintain participation when food costs increase more quickly than anticipated. Similarly, the estimates do not take into account the possibility that supplemental appropriations could make up any funding shortfall to maintain participation.

extensions ranging from 1 year to 4 years. However, if the recent decline in rebates continues, there could be an impact on the number of participants served using rebates within the next few years.

State and Federal Agencies Take Steps to Contain Costs; however, FNS also Focuses on Sustaining the Competitive Bidding System

While both states and FNS try to contain costs, FNS also works to sustain the competitive bidding system while states work to maximize their own savings. State WIC agencies have taken a variety of actions to promote cost containment. For example, some have joined coalitions or barred the provision of non-contract, non-exempt infant formula. Similarly, FNS promotes cost savings through a requirement that infant formula manufacturers provide the same percent discount for all infant formulas, even new infant formulas introduced when a contract is already in effect.[20] However, FNS attempts to balance its efforts to promote cost containment with its larger goal of sustaining the competitive bidding system. For example, in some cases, FNS did not approve provisions in cost-containment contracts that would save states money if FNS believed these provisions would reduce competition.

States Have Taken Steps to Reduce Infant Formula Costs

Through their infant formula contract bid solicitations, states have taken steps to promote cost containment. For example, by including provisions they believe manufacturers might find favorable or by omitting provisions they believe would have a negative impact on their rebate savings, states have sought to maximize their savings. As other examples:

- Thirty states have joined coalitions in an effort to share streamline the bidding process and leverage greater bargaining power when negotiating contracts with manufacturers.
- Some states allow contract extensions only if both the state and the infant formula contractor agree, rather than providing for unilateral contract extensions at state option.

States have also taken steps to limit the amount they spend on non-contract infant formulas:

[20] 7 C.F.R. §246.16A(c)(5)(i).

- Sixteen states purchase some or all of the exempt infant formula that is provided to participants directly from manufacturers or from low-cost providers.

- Twelve states do not provide more expensive non-contract brand, non-exempt infant formula to WIC participants, and nine states limit statewide use of non-contract, non-exempt infant formula to a specified share of all infant formula provided. In addition, 27 states limit the amount of time that non-contract, non-exempt infant formulas can be issued to participants.

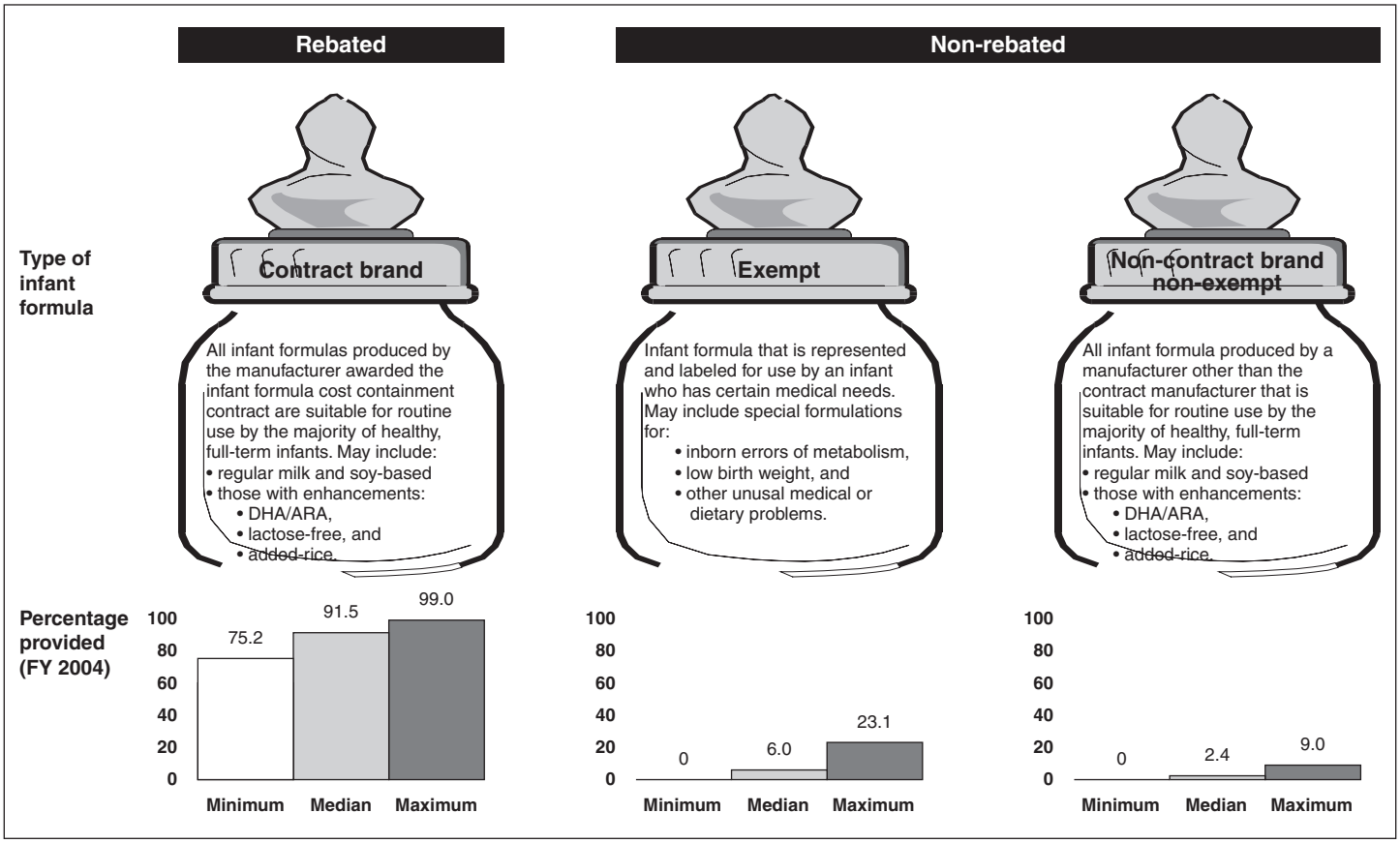
- Eight states do not provide more expensive enhanced infant formula.

Despite these state efforts to contain costs, opportunities remain for more states to further reduce the use of non-rebated infant formulas. Use of non-contract, non-exempt infant formula varies. Twelve states reported that they have policies in place not allowing the use of non-contract, non-exempt infant formula. Of the 43 states that provided complete information on their average monthly usage of contract, exempt, and non-contract, non-exempt infant formulas in 2004, 27 states reported that between 0.3 percent and 4 percent of infant formula provided is non-contract, non-exempt, and 8 states reported use between 4.5 percent and 9 percent.[21] As required by the Infant Formula Act, infant formula is a relatively homogeneous product. Consequently, it is unlikely that large discrepancies among states in the use of non-contract, non-exempt infant formulas designed for use by healthy infants can be explained by differences in health conditions of infants receiving WIC infant formula in these states. There are also large discrepancies in the use of exempt infant formula designed to treat infants' medical conditions. State provision of exempt infant formula ranges from a low of 0 percent to a high of about 23 percent. (See app. II for information on use of non-contract, non-exempt and exempt infant formula by state.) Again, as with non-contract, non-exempt infant formula, it is not clear how infants' medical needs could vary so significantly among states. Figure 6 shows the minimum, median, and maximum use of each type of infant formula in 2004.[22]

[21]Eight of the states with policies in place to not allow non-contract, non-exempt infant formula reported providing 0 percent of this type of infant formula. Three states with these policies indicated that they provided between 1.6 percent and 3 percent non-contract, non-exempt infant formula per month. One state with these policies did not provide data on use of non-contract, non-exempt formula.

[22]Forthy-three states provided information on their use of contract, exempt, and non-contract, non-exempt infant formulas in 2004.

Figure 6: Percentage Contract, Exempt, and Non-Contract, Non-exempt Infant Formula Provided



Source: GAO survey of state WIC directors, based on responses from 43 states.

Most states reported that they require participants to obtain medical documentation for non-rebated infant formula, as required by FNS. However, some local WIC directors said there are instances in which doctors do not diagnose a medical condition but still write a prescription at the request of the participant. Local WIC agency staff told us that they identify these cases only by confirming diagnoses with each physician which not all agencies have the resources to do. As a result, some WIC participants may be receiving non-rebated infant formula even though they do not have a medical condition requiring such infant formula.

FNS Has Taken Steps to Reduce Infant Formula Costs

In its oversight capacity, FNS has helped states increase their cost-containment savings by providing technical assistance to states as they develop their cost-containment contracts, and by implementing regulations that help states achieve cost savings. For example, FNS requires manufactures to provide the same discount on all infant formulas after state costs rose with the introduction of a new infant formula. In 1993, one company introduced a lactose-free infant formula to accommodate infants with intolerance for milk-based infant formula.[23] When this company introduced its lactose-free infant formula, it provided a significantly lower rebate amount on this infant formula than it provided on its milk-based infant formula covered by the existing contract, even though the wholesale price of the new infant formula was higher per can. As a result, states received a much lower discount on the new infant formula than they received on the original contract infant formula. At the same time, prescriptions for the lactose-free infant formula increased because the company marketed the infant formula directly to doctors. The cost savings states achieved through rebates began to erode. To maintain competition by ensuring that all manufacturers could bid on contracts and to help preserve rebate savings, FNS in 2000 established the requirement that infant formula manufacturers provide the same percent discount for all infant formulas, even those introduced when a contract is already in effect.

The requirement that manufacturers provide the same percent discount for infant formulas introduced during a contract slows but does not completely stem increases in state spending on infant formula. Even with the requirement, states must still pay more for each can of newly-introduced infant formula when the wholesale price of the infant formula is higher. As a result, manufacturers still have a financial incentive to introduce and market more expensive infant formula because they charge a higher price per can.

By 2003, all three manufacturers introduced new infant formulas enhanced with the fatty acids DHA and ARA. Like other newly-introduced infant formulas, these enhanced infant formulas were more expensive. Two state officials told us that the manufacturers replaced the milk-based infant

[23]Until 1993, infants with intolerance for milk-based infant formula were provided with either soy infant formula or an exempt infant formula that did not contain lactose. Since the introduction of lactose-free infant formula, companies have further diversified the products they produce for healthy infants. New products include added-rice infant formula, DHA and ARA enhanced infant formula, and a variety of other infant formulas.

formula the state was providing to WIC participants in some parts of the state with the enhanced infant formula. Retail outlets stopped stocking the original milk-based infant formula; as a result, states had to purchase the enhanced infant formula. In contrast, when manufacturers introduced new infant formulas in the past, states had a choice not to provide the new infant formulas or to limit their use because the original milk-based infant formula was still available. At least one state has since introduced a contract provision that requires manufacturers to charge the same price per can for newly-introduced products when those products replace the primary contract infant formula.

FNS Promotes the Long-Run Sustainability of the Competitive Bidding System

Recognizing the history and dynamics of the infant formula market and the importance of competition to the cost-containment goals of the WIC program, FNS has attempted to ensure that all manufacturers can compete for state infant formula contracts regardless of their share of the market. Infant formula manufacturers operate within a highly concentrated industry. Beginning in the 1970s, three manufacturers—Wyeth-Ayerst, Mead Johnson, and Ross Laboratories—dominated the infant formula market. By the 1990s, the industry had shifted. Wyeth-Ayerst exited the domestic infant formula market in 1996. By then Nestlé had begun selling infant formula and had at least one state WIC contract. By 2000, Nestlé still had the smallest market share of the three companies.

In order to ensure the sustainability of competitive bidding, FNS has not allowed provisions in cost-containment contracts that would have boosted state savings when FNS believed those provisions would reduce competition:

- For example, during negations FNS held with New England and Tribal Organization (NEATO) coalition from January 1995 through February 1996, FNS disapproved a contract provision that would have required that manufacturers demonstrate that they had the production capacity sufficient not only to meet infant formula contract commitments they had with NEATO, but also commitments they had made with other states and those to be awarded. NEATO included this provision, in part, because its contractor at the time had run out of infant formula, and, as a result, smaller states in the coalition did not have enough infant formula. FNS rejected the requirement that manufacturers prove they could fulfill contracts commitments with others states, which it viewed as intrusive and which it felt hindered fair and open competition.

- Similarly, in 2005, FNS did not approve a contract provision that would have allowed Wisconsin to continue with its current contractor if the bids

it received differed by $10,000 or less. Under the provision, the state could have avoided expenses associated with switching contracts. FNS did not approve the provision because it believed it would give the current contract holder an advantage over the other two competitors.

Several state WIC directors we interviewed questioned FNS' role in the infant formula contracting process. Three state WIC directors pointed out that infant formula cost containment was initiated by states. In addition, a few state WIC directors noted that the manufacturers have stayed in the WIC market for years, even though some say that providing infant formula under these contracts is not profitable. FNS officials, however, pointed out that Wyeth stopped bidding on WIC contracts, and that competition would decrease if any other manufacturers stop bidding on WIC contracts.

The Child Nutrition and WIC Reauthorization Act of 2004[24] contained two provisions that promote competition among infant formula manufacturers by limiting the size of contracts and coalitions to ensure all manufacturers can bid on contracts regardless of their capacity:

- A requirement that states or coalitions serving more than 100,000 infants request separate bids for milk-based and soy-based infant formulas.
- Limits on the size of state coalitions.

The act also addressed manufacturers' concerns about how WIC agencies implement their infant formula contracts:

- A requirement that states provide participants, as the infant formula of first choice, the infant formula designated by the contract manufacturer as its "primary contract infant formula."[25]
- A requirement that manufacturers not only raise the rebates they provide to states in response to any increase in wholesale price, but also lower the

[24] Pub. L. No. 108-265.

[25] The primary contract infant formula is the infant formula on which contract bids are evaluated. Therefore, the bidder who offers the lowest net wholesale price on the infant formula they designate as their primary contract infant formula becomes the contract manufacturer, regardless of rebates provided for other infant formulas covered by the contract. The requirement that states offer the primary contract infant formula as their first choice ensures that the primary contract infant formula is provided before any other infant formula covered by the contract.

rebates they provide to states by an amount equal to any decreases in wholesale price.

- A requirement that states accurately account for the number of cans of infant formula purchased, not just the number of vouchers redeemed at retailers.

Conclusion

Although states developed and implemented measures to contain the cost of infant formula, FNS has played an increasingly important role in balancing the goals of containing infant formula costs and maintaining competition among infant formula manufacturers. FNS actions have not always maximized the cost savings of individual states, but by ensuring that all interested manufacturers can compete for WIC contracts, it has helped to ensure the long-run sustainability of the WIC cost-containment system. However, if manufacturers continue to emphasize a business strategy focused on innovation and product differentiation, WIC cost-containment savings are likely to erode further despite existing measures to protect state cost savings. By providing manufacturers with a higher per-can reimbursement for newly introduced, more expensive products, and by allowing states to issue non-contract, non-exempt infant formulas to participants with physician prescriptions, federal regulations encourage manufacturers to diversify their product lines and charge more for infant formula, even within a contract period. Unless FNS takes additional steps to safeguard rebate savings, total rebates could continue to erode and the number of participants who can be served by WIC will likely fall.

Recommendations for Executive Action

To help states preserve rebate savings generated through infant formula cost containment and reduce costs associated with the purchase of non-rebated infant formula, we recommend that the Secretary of the Department of Agriculture take the following two actions:

- Consider providing additional guidance related to product changes so that state costs do not increase when infant formula manufacturers introduce new or improved infant formulas by encouraging all states to include in their contracts a provision that requires manufacturers to provide new and improved products marketed under a different name at the net wholesale price specified in the contract when the new product replaces the product the manufacturer designated as its “primary contract infant formula.” We recommend that the Secretary consider implementing a regulatory provision if necessary to ensure that states implement the guidance.

- Provide guidance or technical assistance to state agencies on ways to reduce the use of non-rebated infant formulas in states where use of these infant formulas is high.

Agency Comments and Our Evaluation

On March 13, 2006, we met with FNS officials to discuss their comments. The officials said they generally agreed with our recommendations. They stated that they will provide guidance related to product changes to assist state agencies in minimizing cost increases when infant formula manufacturers introduce a new infant formula that replaces the primary contract infant formula. Officials agree that a regulatory change would be necessary to require that state agencies include provisions in their contracts to accomplish this goal. They cautioned, however, that they have limited influence over the recent increases in infant formula costs attributable to manufacturers' price and product changes. While we agree that FNS is constrained in its ability to affect manufacturer marketing and pricing decisions, we believe the agency should take any steps available to contain infant formula costs given the importance of cost-containment savings to serving as many eligible women, infants, and children as possible.

Agency officials also stated that they will continue to provide guidance to state agencies related to the issuance of non-contract infant formula for those states where the use of these infant formulas appears high. However, officials expressed concern that some states may have misreported their use of exempt and non-contract, non-exempt infant formulas due to confusion over terminology and interpretation of the survey instrument. Officials noted that since some state agencies may require the same medical documentation for exempt infant formulas, non-contract, non-exempt infant formulas, and certain contract infant formulas other than the primary contract brand, some states may have misunderstood the distinction between the three types of infant formula we identified and misreported use of the different types of infant formula. We believe that the survey provided sufficient examples to allow states to distinguish between the three infant formula types we identified. We pretested our survey with officials in five states, in which we discussed their understanding of each question and the terms we used, and all of the officials we spoke with understood the differences between the categories of infant formula we identified. However, we acknowledge that because states are not required to track infant formula use by the categories we used or by the technical categories defined in the Infant Formula Act, our estimates of the use of the three types of infant formula may not be consistent across all states.

Agency officials also expressed concern over the fact that we requested data for non-contract and exempt infant formulas by the average monthly percentage of total cans issued rather than by average monthly percentage of participation. Agency officials stated that some state agencies capture their data in terms of percentage of participation and this may have contributed to misreporting. In our discussions with state officials, we were told that because information on the number of cans provided through WIC is usually used to bill manufacturers for infant formula rebates, most states track the number of cans of infant formula provided to WIC participants.

In 2003, GAO reported similar findings related to use of non-contract infant formula based on a survey that used different terminology and a different measure of use. The consistency between the findings in the two reports reinforces the ongoing importance of ensuring that states clearly understand the distinction between the different types of non-contract infant formula, monitoring the use of different types of infant formula, and providing technical assistance to state agencies where use of non-contract infant formula is high.

Agency officials also provided technical comments, which we incorporated into the report where appropriate. This included revising data that had been provided by two states that had reported particularly high use of non-contract, non-exempt infant formula.

We are sending copies of this report to the Secretary of USDA, relevant congressional committees, and others who are interested. Copies will be made available to others upon request, and this report will also be available on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me on (202)512-7215 or fagnonic@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

Cynthia M. Fagnoni
Managing Director, Education, Workforce,
and Income Security

Appendix I: Scope and Methodology

This appendix provides a detailed description of the scope and methodology we used to determine (1) what factors influence program spending on infant formula, including the role of rebates that states receive through infant formula cost-containment contracts; (2) how the level of savings resulting from infant formula cost containment has changed over the past 5 years and the implications of these changes for the number of participants served; and (3) how federal and state policies and guidance have influenced state spending on infant formula.

To assess what factors influence program spending on infant formula, including federal and state policies, we surveyed state directors of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in all 50 states and the District of Columbia. All 51 survey recipients responded to our survey, but not all respondents provided answers to every question. Where fewer than 51 responses were provided, we noted in the text the number of respondents on which the finding was based. We pretested the survey questionnaire with state WIC officials in five states. During these pretests, we administered the questionnaire and asked the officials to fill it out as they would if they had received it in the mail. After completing the questionnaire, we interviewed the respondents to ensure that the questions were clear and unbiased, the data we requested were feasible to collect, and the questionnaire did not place an undue burden on the agency officials completing it. To encourage respondents to complete the questionnaire, we sent one follow-up mailing containing the full survey instrument to nonrespondents approximately 3 weeks after the initial mailing and a second follow-up letter about 2 weeks later.

We also conducted a review of literature on infant formula cost containment and spoke with officials from the U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS); state WIC directors in Illinois, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, and Washington; and local WIC directors from Belford, New Jersey; Chicago, Illinois; Odessa, Texas; Salt Lake City, Utah; and Tempe, Arizona. These state and local WIC directors were selected based on recommendations of the National WIC Association and FNS and represent several different geographic areas. We included states that belong to contracting coalitions as well as those that contract themselves, and those that had rebid their infant formula contracts recently as well as those that last rebid their contracts several years ago. We also interviewed individuals with expertise related to WIC and infant formula cost containment from the National WIC Association and the Center on Budget and Policy Priorities. In addition, we interviewed representatives from

Nestlé, Mead Johnson, and Ross Products to understand the perspectives of the infant formula manufacturers.

To assess trends in rebate savings and in the number of participants served with rebate savings, we analyzed administrative data we received from FNS on WIC program participation, food costs, and total rebates from 1990 through 2005. We assessed the reliability of the data by reviewing existing information about the data and the system that produced them and interviewing agency officials knowledgeable about the data. We determined that the data were sufficiently reliable for the purposes of this report. We adjusted the rebate figures for inflation using the producer price index for pharmaceuticals. Infant formula is marketed in a way that is similar to pharmaceuticals.

To estimate the impact of reduced rebates on the number of participants served with rebate savings, we used data we received from FNS on total rebates for 2004. This allowed us to estimate the share of infant formula spending that was spent on rebated infant formula and the share that was spent on non-rebated infant formula including exempt and non-contract, non-exempt infant formulas. We then held spending on non-rebated infant formulas constant, and estimated the reduction in total rebates that would have resulted if the average rebate states received through their cost-containment contracts in 2004 had been lower than the actual average discount of 93 percent of the wholesale price of milk-based concentrate. We considered three scenarios to represent recent trends in infant formula rebates, either nationwide or in individual states:

- A reduction in rebates from 93 percent of the wholesale price of infant formula to 90 percent of the wholesale price of infant formula, a modest decrease to rebate levels experienced by states in 2000.
- A moderate decrease to 85 percent of the wholesale price of infant formula, the average rebate on newly awarded contracts in 2004.
- A larger decrease to 75 percent of the wholesale price of infant formula, a decrease similar to that experienced by two states.[1]

[1]Between 2004 and 2005, three states received rebate bids that were lower than those of most existing contracts. New York received a winning bid equal to 76 percent of the wholesale price of infant formula and North Dakota received a winning bid equal to 77 percent of the wholesale price of infant formula. Vermont received a winning bid equal to 66 percent of the wholesale price of infant formula.

To estimate trends in the per-can cost of infant formula, we also analyzed information we received from FNS on the rebates individual states received per can of milk-based concentrate infant formula from fiscal years 2000 to 2005. We used this data to calculate trends in state infant formula costs.

Appendix II: Use of Non-Contract, Non-Exempt and Exempt Infant Formula by State, Fiscal Year 2004

Table 1: Non-contract, Non-exempt Infant Formula as a Share of All Infant Formula Issued, Monthly Average, Fiscal Year 2004

State[a]	Non-contract Brand non-exempt infant formula (percent)
Virginia	0
Arkansas	0
District of Columbia	0
Louisiana	0
Mississippi	0
New Mexico	0
Pennsylvania	0
Vermont	0
Alaska	0.3
Arizona	0.4
Maryland	0.6
Massachusetts	0.8
Oklahoma	1.0
California	1.2
Texas	1.3
New Jersey	1.6
Ohio	1.7
New York	1.9
Nevada	2.0
Minnesota	2.3
Georgia	2.3
Iowa	2.4
Maine	2.4
Michigan	2.7
Hawaii	2.8
Alabama	3.0
Nebraska	3.0
North Carolina	3.0
Washington	3.0
Colorado	3.7
Illinois	3.9
Oregon	3.9
Delaware	4.0

State[a]	Non-contract Brand non-exempt infant formula (percent)
West Virginia	4.0
Wisconsin	4.0
Florida	4.5
Wyoming	4.7
Utah	5.0
Connecticut	6.0
Kansas	6.0
North Dakota	6.5
Kentucky	8.3
Idaho	9.0

Source: GAO survey of state WIC directors.

[a]The following states did not provide us with information on their use of non-contract, non-exempt infant formula: Indiana, Missouri, Montana, New Hampshire, Rhode Island, South Carolina, South Dakota, and Tennessee.

Table 2: Exempt Infant Formula as a Share of All Infant Formula Issued, Monthly Average, Fiscal Year 2004

State[a]	Exempt infant formula (percent)
District of Columbia	1.0
Nevada	1.0
California	1.7
Washington	2.0
Georgia	2.0
Vermont	2.5
Connecticut	3.0
Idaho	3.0
Kansas	3.0
Wisconsin	3.0
Arizona	3.4
New Jersey	3.6
Colorado	3.8
Texas	4.2
Iowa	4.6
North Carolina	5.0

State[a]	Exempt infant formula (percent)
Illinois	5.5
Hawaii	5.7
Oklahoma	6.0
Minnesota	6.5
Alaska	7.0
New Mexico	7.0
Maryland	7.4
Maine	7.5
Alabama	8.0
Mississippi	8.0
West Virginia	8.0
New York	8.2
Kentucky	8.3
Virginia	9.0
Oregon	9.1
Delaware	10.0
Nebraska	10.0
Louisiana	11.3
Utah	12.0
Massachusetts	16.5
Arkansas	17.3
Wyoming	20.1
Ohio	21.0
Pennsylvania	23.1

Source: GAO survey of state WIC directors.

[a]The following states did not provide us with information on their use of exempt infant formula: Florida, Indiana, Michigan, Missouri, Montana, New Hampshire, North Dakota, Rhode Island, South Carolina, South Dakota, and Tennessee.

Appendix III: GAO Contacts and Staff Acknowledgments

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Acknowledgments

Kay Brown, Assistant Director; Carol Bray; Kathryn Larin; Lise Levie; Lynn Milan; Marc Molino; Luann Moy; Susan Pachikara; Tovah Rom; and Daniel Schwimer made significant contributions to this report.

Related GAO Products

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