

The Effects of Bundled Discounts on Entry in the Market for Pediatric Vaccines

by

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Abstract: The market for pediatric vaccines is unusual in that more than half are publicly provided through the federal Vaccines for Children (VFC) program. The CDC negotiates with vaccine manufacturers for the purchase of all pediatric vaccines supplied under the program, and given the size of its purchases buys at significant discounts off of list prices on a per-dose basis. In contrast, bundled discounts are in widespread use by multi-vaccine manufacturers for pediatric vaccines sold for private use. In this paper, we consider the competitive implications of the use of these bundled discounts, and whether the practice is at odds with the public health goals of ensuring a stable vaccine supply and encouraging the development of new and improved pediatric vaccines.

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I. Introduction

The development and widespread use of safe and effective vaccines has helped eradicate numerous once-common diseases in the U.S., including smallpox, polio, measles and rubella. A child today can be vaccinated against 17 diseases and conditions compared to a child born in 1995 who could only be vaccinated against nine (National Vaccine Plan 2010).¹ Instrumental in this success has been the Vaccines for Children (VFC) program implemented by the federal government in 1994 to provide pediatric vaccines at no charge to children who would otherwise not receive them due to the expense. Today, over half of all pediatric vaccines administered in the U.S. are purchased with public funds through the VFC program. The remainder is administered privately through physicians' offices and clinics, and the cost of the vaccines is typically covered by patients' health insurance plans.

Alongside this growth in the number of pediatric vaccines over the past several decades has been a dramatic change in the structure of the pediatric vaccine industry. Thirty years ago there were around 25 companies producing vaccines, while today supply is concentrated in a small number of producers (The Lancet Infectious Diseases 2004). For pediatric vaccines, there are only five FDA-approved suppliers in the U.S. Three (GSK, Sanofi, and Merck) supply a portfolio of pediatric vaccines, while two (Novartis and Pfizer) supply only one each. Sanofi's pediatric vaccine portfolio is largely complementary with Merck's portfolio, and together the two portfolios effectively mirror GSK's vaccine portfolio with the exception of Merck's sole-source Varicella and MMR vaccines. Novartis's Menveo competes with Sanofi's Menactra, while the Pfizer's vaccine is sole-source.

Largely owing to a number of pediatric vaccine shortages over the past decade, some concern has been raised that the small number of suppliers has put at risk the stability of U.S. vaccine supply (Sloan et al. 2004; Coleman et al. 2005). Acknowledging the possible link between vaccine shortages and the relatively small number of vaccine suppliers, the 2010 National Vaccine Plan gives as a policy goal the identification of the barriers that exist to having multiple suppliers for each vaccine licensed and recommended for use in the United States. Also identified as goals in the 2010 Plan are (1) to ensure the stable supply of, access to, and better use of recommended vaccines, and (2) the development of new and improved vaccines.²

In this paper we examine the widespread practice of offering bundled discounts to private purchasers of pediatric vaccines and the effects of this practice on competition in the supply of

¹ The National Vaccine Plan is developed under the National Vaccine Program, which was created by Congress in 1986 to coordinate vaccination activity within the U.S. with the purpose of preventing infectious diseases. The first plan was completed in 1994 and the 2010 version is the first update since then.

² The other goals identified are to enhance the vaccine safety system, support communications to enhance informed vaccine decision-making, and increase global prevention of death and disease through safe and effective vaccination.

pediatric vaccines. While public purchases account for over half of pediatric vaccine purchases, private purchases are a significant source of sales for vaccine suppliers and can influence physicians' choice of vaccines purchased through the VFC program. Multi-vaccine suppliers typically offer discounts on pediatric vaccines that are dependent on physicians' purchasing all or a number of the supplier's pediatric vaccines and meeting specific percentage of requirement targets. These bundled discounts may benefit physicians by lowering the price paid by the physician in the short-term, but in the long-run, they make entry and expansion by rival vaccine suppliers more difficult. This outcome may contribute to the highly concentrated supply of pediatric vaccines, and hamper the development of competing as well as new and improved vaccines; thus putting the practice at odds with public health goals.

Section II discusses public and private demand for pediatric vaccines. In Section III, we discuss the economic theory of bundling. Section IV discusses the structure of bundled discounts offered by pediatric vaccine suppliers. In Section V, we discuss the rationale for bundling in the market for pediatric vaccines, and in Section VI we discuss the implications of pediatric vaccine bundling. We summarize our observations and conclusions in Section VII.

II. Public v. Private Demand

The federal government created the VFC program in the Omnibus Budget Reconciliation Act of 1993 as a new Medicaid entitlement program. Under the program, implemented in 1994, pediatricians and clinicians are able to obtain pediatric vaccines at no charge to vaccinate children who are uninsured, Medicaid eligible, American Indian or Alaska Natives, or underinsured (Lindley, et al. 2009).³ The vaccines provided under a VFC resolution are those recommended (either routinely or permissively) by the Advisory Committee on Immunization Practices (ACIP) to the CDC. So-called "Universal" states may utilize state monies to purchase vaccines under the CDC-negotiated contracts for non-VFC eligible children residing in their state (Linley, et al. 2009). For example, through the VFC program, Massachusetts supplies most recommended pediatric vaccines free of charge to all 0-18 year olds residing in the state. Other states participating in this enhanced program include Connecticut, Rhode Island, Vermont and New Hampshire. The Universal states were grandfathered in when the VFC program was implemented to allow them to purchase vaccines for their non-VFC populations at CDC-negotiated rates.

Through the VFC program, the government purchases from vaccine manufacturers over half of the pediatric vaccines purchased in the United States (Jacobson, et al. 2006). The CDC negotiates contracts with pediatric vaccine suppliers on a per-dose basis, and given the volume it purchases, receives significant discounts over the prices paid by private purchasers. For example, the CDC price (as of April 11, 2011) for Sanofi's Pentacel vaccine is \$52.55/dose versus the

³ Underinsured children can only obtain VFC doses at a Federally Qualified Health Center or Rural Health Clinic. States can also use Section 317 federal grants and state discretionary funds to pay for pediatric vaccines.

private sector cost of \$77.48/dose.⁴ Even though the CDC obtains lower prices based on its purchase volumes, vaccine suppliers receive some off-setting cost benefits through (1) lower transport costs (shipments only have to be made to two warehouses), (2) sales force cost savings, and (3) prompt and assured payment. Physicians registered as VFC providers obtain vaccines administered through the VFC program at no cost and receive an administrative fee from Medicaid for each vaccine administered.

On the private side, there are a number of large buyers, such as health maintenance organizations (HMOs), independent health networks (IHNs) and group purchasing organizations (GPOs). The remainder of private demand consists of smaller buyers, including members of physician buying groups (PBGs), individual physicians, hospital clinics, and wholesalers.⁵ While no single PBG represents a large portion of demand, collectively PBGs account for a significant portion of private demand.⁶ Due to their size, HMOs, IHNs and GPOs are in a stronger position to negotiate with suppliers compared with the remainder of the market, which is highly fragmented. No single entity likely has any significant buying power in negotiating price with vaccine suppliers (Coleman, et al. 2005).⁷

The costs of private-stock pediatric vaccines can be one of the largest expenses for pediatric practices and physician clinics after staff salaries (Coleman, et al. 2009). Health insurance companies typically reimburse a pre-set amount only after a vaccine is administered, specified by a current procedural terminology (CPT) code, which is usually not specific to the particular brand of vaccine used.⁸ Insurance providers reimburse physicians the same amount regardless of the actual price paid by the physician for the vaccine. This payment structure places the risk of inventory management on physicians and provides them with an economic incentive to obtain the lowest price possible for the particular brand of vaccine used. The difference between the amount the insurance company reimburses for the vaccine and the price the physician pays for the vaccine is a margin that the physician can use to defray other costs of the physician's practice. For example, assume that a physician is reimbursed \$100 for each DTaP vaccine administered; if GSK's DTaP vaccine costs \$85 and Sanofi's costs \$90, a physician would earn a higher margin by using GSK's vaccine (\$15) than she would by using Sanofi's vaccine (\$10). For a small number of physicians, the reimbursement amounts for administering vaccines may not be sufficient to cover the cost of the vaccine, and the physicians incur a loss on

⁴ Prices paid for older recommended vaccines were limited by congressional price caps, but these have since been removed for all but two vaccines. Newer pediatric vaccines are not subject to any price caps.

⁵ PBGs negotiate prices with vaccine manufacturers on behalf of member physician practices which then purchase vaccines directly from the manufacturers at the prices negotiated by the PBG.

⁶ Data on Novartis's Menveo vaccine, show members of PBGs as the largest type of non-government customer, representing approximately one-third of non-CDC purchases of Menveo.

⁷ Although the HMO Kaiser negotiates per-dose prices with pediatric vaccine suppliers, we are not aware of any other private buyers that do so.

⁸ Health insurance companies typically reimburse physicians by CPT code. Physicians submit reimbursement claims to insurance companies based on the CPT codes (treatments) a patient received, and the insurance company pays a pre-fixed amount for each CPT code. A CPT code for a vaccination is not specific to the brand of vaccine used, only the type vaccine administered (e.g., a meningococcal vaccine).

each vaccine administered.⁹ Given the economic incentives physicians face, it is likely that they are price sensitive when it comes to purchasing pediatric vaccines. This means that for a physician, price may be the primary driver of the purchase decision, outweighing any preference for a particular vaccine brand.¹⁰

Even though physicians administering pediatric vaccines both privately and under the VFC program must maintain separate stock records for the VFC-provided and privately purchased vaccines, there are numerous economic incentives that make it rational for physicians to use the same brand for both publicly and privately administered vaccinations. These incentives include (1) simplifying inventory management, (2) reducing the chance of medical errors, (3) reducing confusion among office staff as to which vaccine treatment should be used, (4) avoiding the perception that there are different standards of care for the two populations, and (5) allowing for the possibility of “borrowing” between VFC and private stock in limited circumstances (VFC Operations Guide, Section M-3). Given these incentives, pediatric vaccine purchases for private use, which depend on the prices physicians have to pay, will influence which vaccines physicians use under the VFC program (where they have choice under the program). For example, if a physician’s practice uses Sanofi’s Pentacel vaccine for private vaccinations because it obtains a better price for that vaccine over GSK’s competing Pediarix vaccine, it may also use Pentacel for any VFC-provided vaccines. This enables the physician to stock only one vaccine for most of their DTaP vaccinations and limits the number of complementary antigens needed to complete each series.

The implication of this is that the private-stock vaccine choice may drive VFC vaccine choice.¹¹ In other words, the quantity demanded for a particular brand of VFC vaccine is not determined independently of the quantity demanded for privately administered brands of pediatric vaccines. Indirectly, the price of privately administered pediatric brand vaccines also determines the quantity demanded for publicly administered brands of vaccines. This relationship becomes an important consideration in assessing the economic impact of bundled discounts for privately administered pediatric vaccines.

III. The Economics of Bundling

Product bundling typically falls into one of three types: pure bundling, mixed bundling, and tying (Nalebuff 2003). Pediatric vaccine suppliers typically employ a mixed bundling

⁹ Research on reimbursements for pediatric vaccines shows that private pediatric practices on average break even or achieve only a slight gain from administering vaccines (Coleman, et al. 2009).

¹⁰ We recognize that there may be clinical differences between vaccines which will drive physician choice; however, if a physician perceives there to be no material clinical difference between two (or more) vaccines, price likely will be the primary driver of the purchase decision.

¹¹ Since some states are involved in the decision of which pediatric vaccines are used in the state under the VFC program, the reverse may also be the case in states that restrict which vaccine brands they are willing to pay for under the VFC program – if a physician can only use one particular brand under the VFC program, she may choose to use that brand for privately administered vaccinations. An example of a state that restricts which vaccines it purchases under the VFC program is Mississippi.

pricing strategy, which occurs when a manufacturer offers two or more products in a package at a discounted price and offers the products for sale individually but at higher prices. Another example (this and the following examples are similar to those used in Nalebuff 2003) would be a restaurant offering a prix fixe menu in which it offers an appetizer, entrée and dessert at a discount to the à la carte prices. Pure bundling is similar to mixed bundling but the manufacturer offers the products *only* as part of a package in fixed portions. The supplier does not sell the products for individual purchase. An example would be an airline that includes a meal with the purchase of an airline ticket; the airline meal cannot be purchased without the flight, and vice-versa. Pure bundling is often included under the category of mixed bundling since mixed bundling can effectively be pure bundling when the prices for the individual products are so high that separate purchase is not rational.

Tying is a form of bundling where the purchase of one product (the tying product) is conditional on the purchase of another (the tied product). Tying can be static or dynamic. In a static tie, a customer must buy product A with the purchase of product B, but it is possible to buy product A without product B. An example would be Apple's former exclusive deal with AT&T for the iPhone: to buy the iPhone (product B), a consumer also had to purchase service from AT&T (product A), but service could be purchased without the iPhone (another compatible mobile device would, however, be needed). In a dynamic tie, for a consumer to purchase product A, he must also purchase product B, but the amount of product B purchased may vary. An example would be a photocopier (product A) that could only be used with a specific type of paper (product B); the consumer would not need to buy a specific quantity of paper, but whatever paper they used would have to be of the specific type.

Product bundling with price discounts or rebates can either raise or lower consumer welfare. Generally, bundled pricing may be motivated by efficiency or strategic reasons. Customers may reap the benefits of scope economies, efficiencies, and price competition. Alternatively, bundled discounts may adversely harm rivals' ability to compete or be a form of predatory pricing that results in effective foreclosure of rivals, thereby dampening competition that otherwise would have occurred. We discuss these in more detail.

Efficiency Motivations for Bundling

Companies often bundle their product offerings as a means of lowering the costs of supply or of providing a more convenient or higher quality (combined) product to consumers. An example of such product bundling would be automobile manufacturing: a car is essentially a bundle of components (engine, body, wheels, etc.) that can be put together at lower cost, at greater convenience and to a higher quality by an auto company than by a consumer. Given the cost efficiencies and quality improvements that can be gained from this type of product bundling it is beneficial to consumers.

Product bundling is also done to reduce price inefficiencies and increase sales. There are two main rationales for this type of bundling: to price discriminate and to remove the problem of double marginalization. Price discrimination is when a firm charges different prices for the same product to different consumers in order to increase sales (Adams and Yellen 1976). If a firm cannot charge different prices for a product when it is sold by itself, bundling it with another product can sometimes enable the company to effectively achieve the same result. For example, assume that consumer 1 values product A at \$5 and product B at \$1, while consumer 2 values product A at \$1 and product B at \$5; if the firm has to price each product the same, it would set a price of \$5, and sell one to each consumer (product A to consumer 1 and product B to consumer 2) generating revenue of \$10; however, if it were to bundle the products and charge a price of \$6 for the bundle, it would sell both products to each customer, generating a revenue of \$12. Bundling in this situation leads to higher sales and revenues for the firm. This type of bundling is most effective when consumers have divergent valuations of the products in the bundle.

The problem of double marginalization can occur when the consumption of one product influences the consumption of another product. For example, a ski lift ticket and ski equipment rental are complementary products typically used together, and the consumption of one will influence the consumption of the other; i.e., if more ski tickets are purchased, more ski equipment rentals can be made (a positive externality). In this situation, the price of the one product will affect the demand for that product and the demand for the complementary product (e.g., a lower price for a ski lift pass will increase its demand and increase the demand for ski equipment rentals). A pricing inefficiency arises when the prices for the two products are set separately because each price is set without taking into account the effect that it has on the demand for the other product. That is, when the prices are set separately they do not take into account the positive externality in the consumption of the two products. This inefficiency occurs from setting prices at a higher level for each product which lowers the demand below the level it would have achieved if the prices were set taking into account the positive externality. When the products are sold in a bundle, a price is set to optimize sales of the bundle, and in doing this, the effect of the positive externality between the two products is taken into account. Prices for the product will be lower and sales of the product higher.

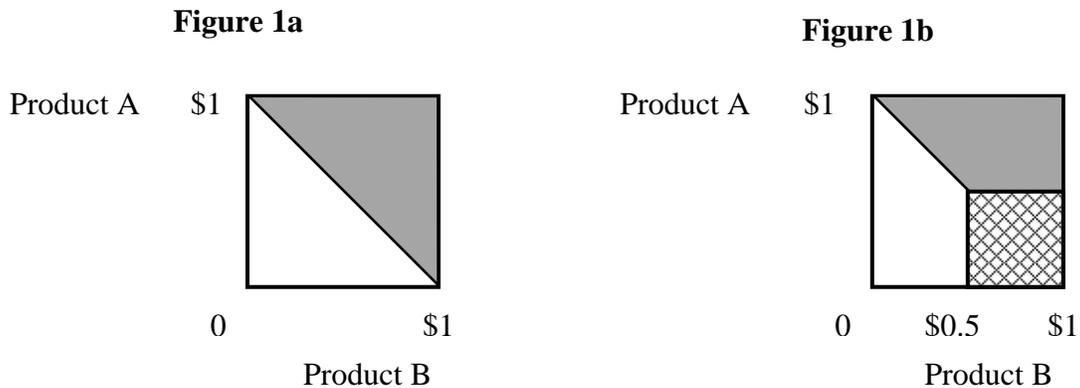
Strategic Motivations for Bundling

Bundling can also be used to gain competitive advantage over rivals. We discuss two bundling strategies that can be used for this purpose.¹² The first is the use of bundling to deter entry or expansion by rivals. This occurs when a firm that has two products sells them in a bundle to make it more difficult for a rival that sells only one of the products to enter or compete successfully in the market. The logic is that if a firm sells products A and B in a bundle rather

¹² There are more strategic reasons for product bundling beyond the two we discuss here, including, for example, using bundling as a means to obscure prices. The two strategic reasons we discuss here are two of the more widely-recognized strategic reasons for bundling, and of most relevance to the bundling that occurs in the supply of pediatric vaccines. (See Nalebuff 2003 for a further discussion.)

than individually, this pricing strategy will limit an entrant or existing rival that only sells product B to selling its product to those customers who value product B, but do not particularly value product A. Customers who also value product A will prefer to buy the A-B bundle. This strategy limits the available market for the one-product rival resulting in both a volume and price effect with ultimate adverse consequences on the rival's rate of return from entry or expansion.

Nalebuff (2003) illustrated this concept graphically. In Figure 1a, consumers are distributed uniformly in the box based on their valuations of products A and B. Consumers with a high valuation of product A are located at the top of the box and those with a high valuation of product B are located to the right. The only firm selling both products A and B offers the two products in a bundle for a price of \$1, and sells the bundle to the consumers – those whose combined value of the two products is \$1 or greater – shown in the upper right portion of figure.



If a firm enters the market with only product B, then it can only attract those customers who are willing to pay its price for product B and give up buying product A or pay a higher price for product A. These are the customers in the lower right corner of the box. Figure 1b illustrates the size of the market that would be available to an entrant selling only product B at a price of \$0.50 against a firm selling an A-B product bundle at a price of \$1. Only those consumers who value product B at a price greater than \$0.50 will consider purchasing the product. However, since the incremental price of purchasing the incumbent firm's A-B product bundle is only \$0.50, consumers who value product A at more than \$0.50 will purchase the bundle. This leaves the entrant firm with only those customers in the lower right shaded corner in Figure 1b, which is half the number of customers it could attract if it did not have to compete against the bundle.

Any customer who is not willing to give up product A, or pay a higher price for product A, will buy the bundle, and will receive product B in the process. These customers will not be interested in the entrant firm's product B or will only be interested to the extent they are willing to pay on top of what they have already paid to receive the incumbent firm's product B. The effect of this type of bundling will be greater when customers' values of products A and B are positively correlated. The reason is that there will be even fewer customers who value only one

product but not the other when customer valuations are positively correlated. An example of products with positively correlated customer values would be Microsoft’s Office suite.

A second use of bundling is to mitigate competition. To this end, firms bundle to differentiate their product offerings and reduce the intensity of competition they face. To illustrate this effect, assume that one firm produces both products A and B, while a rival produces only product B. If the first firm producing both products sells them separately, the profits on product B will be competed away through competition with the rival firm, and the first firm only earns profits on product A. However, if the first firm only sells A and B as a bundle, it captures those customers who place a higher value on product B, thereby leaving the rival firm to capture the customers who value product B less.

IV. The Structure of Pediatric Vaccine Discounts

As discussed above, three manufacturers supply multiple pediatric vaccine products. These manufacturers commonly employ bundled discounts in which the size of the discount on one of their products is predicated on the purchase of their other products. For example, Sanofi offers additional discounts that require physicians to purchase at least three different pediatric vaccine products from Sanofi’s portfolio. The following table shows the discounts Sanofi offers to IHNs, depending on whether the IHN purchases three or four vaccine products from Sanofi’s portfolio. On a per patient basis, the recommended dosage for these products (excluding influenza), which is four doses of the combined DTaP, IPV, HIB, one dose of TdaP, and one dose of MCV4, would lead physicians to order these products in a 4:1:1 ratio.

Vaccines (Brand)	3-Product Discount	4-Product Discount
DTaP, IPV, HIB (Pentacel)	--	29%
TdaP (Adacel)	12%	14%
MCV4 (Menactra)	3%	5%
Influenza (Fluzone)	Variable	Variable

Source: Novartis Vaccines and Diagnostics (representative 2010 contract structure)

As Table 1 shows, if an IHN purchases the three-product bundle, it receives a discount of 12% on Adacel, 3% on Menactra, and a variable discount on Fluzone; if it purchases the four-product bundle, it receives a discount of 29% on Pentacel, and discounts of 14%, 5% and a variable discount, respectively, on the other three products. If the IHN were not to purchase all of the products in the bundle it selects, it would not receive the discounts on any brands. The economic incentive to purchase the bundle of four Sanofi pediatric vaccines is apparent. Substantial

additional margin is available to the physician if the physician chooses the larger bundle of vaccine products. To qualify for the discounts, the IHN also must typically purchase at least 90% of its quantity requirements for each vaccine from Sanofi.¹³ The purchase requirements are typically based on purchases made within a year, and Sanofi actively monitors compliance with the requirements. A purchaser's failure to adhere to the requirements commitment may risk losing discounts on all future vaccines purchased, pending rebates, and/or removal from the contract.

Sanofi has a similar four-product discount structure (there is no three-product option) for PBG members with slightly lower discount rates. For both IHNs and PBGs, Sanofi also offers additional discounts that are unrelated to the purchase of the product bundles: a rebate discount (dependent on the IHNs' or PBG members' meeting the share of requirements target), and discounts for prompt payment and on-line ordering, which are typical in the industry.¹⁴

In contrast to Sanofi's discount schedule, suppliers of a single pediatric vaccine in the United States usually offer only the more typical price discounts based on (1) the volume purchased (the more of the product the customer purchases, the higher the discount given, plus additional rebates if the customer purchases a high percentage (e.g., 90%) of its requirements), and (2) prompt payment and on-line ordering.

V. The Rationale for Bundling in the Pediatric Vaccine Market

By offering higher discounts on pediatric vaccines when physicians purchase bundled pediatric vaccines, suppliers are essentially offering a lower price for the bundle of pediatric vaccines. There do not appear to be lower costs associated with supplying pediatric vaccines in a bundle, which would be a rationale for offering discounts on a bundled purchase basis. Each manufacturer produces each pediatric vaccine using a separate production process regulated by the Federal Drug Administration (FDA). The FDA licenses each product based on clinical data generated in human subjects using the vaccine made by a particular production process, typically in a dedicated facility and governed by particular facility practices. Any changes to any aspects of production require significant testing and validation, regulatory approval, and possibly costly clinical bridging studies. These restrictions are not conducive to lower-cost goals through bundling. In terms of packaging and delivery, suppliers package and deliver pediatric vaccines separately. The ages at which physicians administer each vaccine and the number of doses to be administered are dictated by the U.S. Recommended Immunization Schedules, and vary by product. As a result, each bundle of vaccine is used across multiple patients over an 18-year period of time. Although there may be some efficiency in the logistics of delivering multiple

¹³ Sanofi's quantity requirement for the influenza vaccine is typically lower at 85%.

¹⁴ We understand that some PBGs also offer contracts that provide discounts based on combined purchases of Sanofi and Merck vaccines. The combination of these two suppliers' pediatric vaccine products provides physicians with virtually all of their pediatric vaccination needs.

vaccines simultaneously, we have seen no indication that such logistics would account for the size of the discounts offered through bundling.¹⁵

Moreover, suppliers do not appear to be using product bundling as a means to address price inefficiencies. Expanding the market through price discrimination does not seem applicable to the pediatric vaccine market. Consumers are not likely to have widely different valuations of different vaccines. For example, there is no indicator suggesting that consumers place a higher value on DtaP vaccines and a lower value on HepB vaccines such that a supplier would use bundling to price discriminate in order to increase sales, i.e., by offering a lower price for HepB vaccines to those customers with a lower valuation and a higher price for DTaP vaccines to those customer with a high valuation of DTaP. This outcome is consistent with consumers' generally high level of acceptance of routine pediatric vaccine recommendations by the ACIP.

We find no indication that multi-vaccine manufacturers have complementary product externalities to internalize by selling pediatric vaccines in a bundle. Pediatric vaccines are not complementary in that having one vaccine does not increase the effectiveness of having another vaccine. This compares to complementary products, such as ski lift tickets and ski equipment rentals, discussed above, where the purchase of one product generates a demand for the other (a positive externality), the value of which can be internalized by pricing the products in a bundle. That pediatric vaccines are not complementary is not to say that consumers' valuations of pediatric vaccines are not positively correlated – consumers are likely to value having all vaccines, i.e., their valuations of them are correlated, to protect against a range of diseases.

A logical economic reason for product bundling by pediatric vaccine suppliers is to attempt strategically to make entry by rival suppliers more difficult. The demand for pediatric vaccines is inelastic—lowering the price of vaccines will not increase the quantity demanded of any particular pediatric vaccine product, at least within the United States, since the VFC program guarantees access to vaccines regardless of ability to pay and insurance companies routinely follow ACIP recommendations for routinely recommended vaccines. Pediatric vaccine suppliers use a discounting structure that effectively bundles the vaccine products together to discourage physicians from purchasing products separately, which would increase the likelihood that the physician would chose a competing brand. By doing this, a supplier with only one vaccine product is limited to marketing to those customers who value the vaccine product it sells, but have low valuations of the other vaccine products in the competitor's bundle such that purchasing the bundling is not economically advantageous. This restricts the size of the market for the entrant, first by affecting the quantity demanded of the single vaccine product, and secondly, by necessitating the single product supplier to heavily discount its single brand to compete against the larger bundled discount. This strategy increases the likelihood that the single

¹⁵ We offer no analysis or conclusions on whether bundled discounts for pediatric vaccines offered by multi-vaccine manufacturers lead to post-discount prices that are below cost, which may potentially raise antitrust concerns, only that the bundled discounts are being used for reasons other than the cost efficiencies product bundling may generate.

vaccine product supplier will be unable to make a return on its investment sufficient to encourage expansion of its existing vaccine portfolio. Moreover, the bundled discount strategy will also decrease the likelihood of de novo entry into pediatric vaccines. A new entrant with a competitive vaccine would either have to offer a price for its single vaccine product that is sufficiently low as to compensate the buyer for the additional discount he would lose by not buying the bundle, or engage in a multi-product entry strategy sufficient to offer a similar bundle to compete with the existing discounted bundled product offering.

The value of the overall bundled discount makes it highly unlikely that a new entrant would find it financially attractive to match the discount a purchaser would lose by not buying the bundled offering. For example, Table 2 illustrates the price Novartis would have to charge for its MCV4 vaccine to make a pediatric practice purchasing under a typical PBG contract financially indifferent between buying Sanofi’s four-product discounted bundle and buying three products from Sanofi at list price plus Novartis’s MCV4 vaccine (for purposes of this illustration, we ignore the other discounts, such as volume and prompt payment discounts, that are typically given).¹⁶

Vaccine (Brand)	Cost per Patient Treatment	
	Buy Sanofi Bundle	Buy Novartis Vaccine
DTaP, IPV, Hib (Pentacel)*	\$226.24	\$309.92
Tdap (Adacel)	\$34.17	\$38.83
MCV4 (Menactra)	\$102.23	---
Influenza (Fluzone)	\$12.50	\$13.16
MCV4 (Menveo) (List)	---	\$106.49
Total	\$375.14	\$468.40
MCV4 (Menveo) (Discounted)	---	\$13.23
Total (with discounted Menveo)	---	\$375.14

* Vaccination requires four doses of Pentacel; the discounted individual dose price is \$56.56

Table 2 shows that a pediatric practice purchasing Sanofi’s vaccine bundle under a typical PBG contract would pay a total of \$375.14 to treat a patient with the four vaccine products after the bundled discounts.¹⁷ If the PBG were to substitute Novartis’s Menveo vaccine for Sanofi’s

¹⁶ The prices a PBG member pays when it does not purchase the Sanofi bundle are taken to be the private sector prices on the CDC’s VFC price list; the prices a PBG member pays when it purchases the bundle are the private sector list prices less the discounts shown in Table 3. Absent additional information, we assume a 5% discount on Fluzone for purposes of the illustration; the Fluzone price is for the pediatric dose (age 6-35 months).

¹⁷ Vaccination with Pentacel requires the administration of four doses at the following ACIP-recommended intervals: two months, four months, six months, and 12-15 months. Influenza vaccines are annual, so treatment of a

Menactra, it would lose the bundled discounts on the three remaining Sanofi products and likely pay the list price. If the PBG were to pay the list price for Novartis's Menveo, it would end up paying \$468.40 for all four of the vaccines, which is a 24.9% increase over what it would pay for the Sanofi bundle. For the pediatric practice to substitute Menveo for Menactra and pay the same amount as it would for the balance of the Sanofi bundle under the PBG contract, the price of Novartis's Menveo product would have to be \$13.23. In other words, Novartis would have to offer an 87.6% discount on Menveo to entice the pediatric practice to switch from Menactra to Menveo. This type of discount would substantially affect the return on investment by Novartis and discourage further entry and expansion. Attempting to compete with an incumbent's product bundle by developing the products necessary to offer a comparable bundle is likely to be prohibitively expensive and in the vaccine industry, in particular, would take many years given the testing and certifications required to gain FDA approval.¹⁸

VI. The Implications of Pediatric Vaccine Bundling

The implications of bundling by multi-pediatric vaccine suppliers is that entry by rival vaccine suppliers without a portfolio of brands will likely be more difficult. Novartis's experience with its meningococcal vaccine, Menveo, highlights the effect bundling can have on an entrant. Novartis has achieved greater sales success with customers purchasing vaccines from GSK, which does not currently produce a competing meningococcal pediatric vaccine, than it has with customers who purchase vaccines from, or are considered loyal to, Sanofi, which sells a meningococcal vaccine in a bundle with its other pediatric vaccines.¹⁹ This effect is consistent with strategic bundling having the intent to affect entry and expansion by limiting the size of the market for entrants.

Firms have limited funds to invest in developing vaccines, and the major driver in choosing how to invest those funds will be the expected returns on investments (ROI) from the project.²⁰ With lower ROIs available to potential entrants in pediatric vaccines, owing to lower

child would technically require 18 doses; for purposes of the illustration here, we consider only the purchase of a single dose.

¹⁸ Research and development expenditures for a new vaccine have been estimated to be \$600 million to \$800 million, and the cost of building a manufacturing plant has been estimated to be \$50 million to \$300 million (Douglas, et al. 2008).

¹⁹ Novartis classifies its potential customers as being "GSK Loyal" (i.e., customers that tend to be loyal to buying GSK's vaccines), "Sanofi Loyal," and "Non Loyal." (Novartis also uses other customer classifications, such as "VFC with choice," and cannot classify all of its potential customers.) Novartis's sales penetration with its Menveo vaccine is much higher with GSK Loyal and Non-Loyal customers than it is with Sanofi Loyal customers. Novartis's sales penetration (number of customers to which it has sold Menveo as a percentage of the total number of customers with that classification) is approximately 45% to GSK Loyal customers, approximately 23% to Non Loyal customers, but only approximately 13% to Sanofi Loyal customers.

²⁰ A typical approach used by firms in deciding which investments will generate the highest returns is to compare the present value of the expected net cash flows of their various investment project choices, and to choose the project with the highest present value. The expected future net cash flow of each project is discounted to the present time by a discount rate that reflects the expected risk associated with the investment. The net cash flow of a project with a higher risk will be discounted by a higher rate than a project with a lower risk. Thus, a more risky project has

expected sales because of competition with vaccine bundles from incumbent suppliers, the incentive of pharmaceutical firms to invest in new pediatric vaccines instead of investing in other vaccines or pharmaceutical treatments will decline.

Product bundling can therefore discourage new entry and expansion by rival competitors that are unable to offer a competing multi-product bundle in the market for pediatric vaccines. In addition to potentially increasing the risk of shortages in pediatric vaccine supply or hampering the development of improved vaccines, fewer competitors ultimately may lead to higher prices. There is notional evidence to suggest that entry by a supplier of a rival vaccine product may be associated with lower increases in vaccine prices. A comparison of the increases in vaccine product prices CDC negotiates for the VFC program before and after the entry of a competing supplier suggests that the price increases that occur after entry are lower than they are before entry. Table 3 shows the pre-entry and post-entry average annual price increases for three pediatric vaccines that faced entry over the past decade.²¹

Incumbent Brand	Competitor Brand	Entry Year	Pre-Entry Average Increase	Post-Entry Average Increase
Gardasil	Cervarix	2010	3.2%	0%
RotaTeq	Rotarix	2008	5.9%	1.5%
Menactra	Menveo	2010	4.1%	3.0%

Source: CDC Pediatric/VFC Price List; CDC Cost/Dose

The table shows that for the three pediatric vaccines where competing vaccines entered, the market benefited from lower annual increases in prices after entry occurred.²²

to have a higher net cash flow to have the same present value as a less risky project with a lower cash flow. Projects with the same expected risk would use the same discount rate, and a firm would simply choose to invest in the project with the higher cash flow value. In addition to expected ROI, pharmaceutical companies will also likely take into account the public health need for a vaccine or drug.

²¹ Pre-entry percentage increases are the compound annual growth rates from the year of entry of the first vaccine to the year of entry of the competing vaccine; post-entry percentage increases are the compound annual growth rates of the first vaccine from the year of entry of the competing vaccine to present.

²² We recognize that this analysis does not attempt to control for other factors that may have influenced the increase in prices over time. We consider the evidence indicative of the fact that entry is effective in creating price competition, as economic theory would anticipate. It is worth noting by way of comparison that the CDC/VFC price of Merck's varicella vaccine, Varivax, which launched in 2001 and has faced no direct competition, has increased by 5.9% on average per year.

VII. Conclusions

The market for pediatric vaccines is unusual in that the government is by far the largest single purchaser of pediatric vaccines through the VFC program, accounting for over half of purchases. The demand for private-stock pediatric vaccines by contrast is fragmented and no single purchaser (or group of purchasers) has buyer power comparable to that of the CDC in negotiating with pediatric vaccine suppliers. The use of bundled vaccine discounts by multi-pediatric vaccine suppliers on the private side as a means of offering lower prices is prevalent, while the CDC does not accept any product bundling. The reason for the product bundling appears to be the strategic goal of making entry by pediatric vaccine suppliers with a rival vaccine more difficult, rather than for any cost or pricing efficiency reasons. Novartis's experience entering the market with a competing meningococcal vaccine is consistent with this outcome.

Private-stock pediatric vaccines represent a significant cost for pediatrician practices and physician clinics. The increasingly challenging economic environment in which physicians operate makes them highly sensitive to the price of vaccines, and each has the economic incentive to take advantage of any discounts on vaccines that may be offered to them. These incentives mean that price will likely be the primary driver in their vaccine purchase decisions over any brand preferences or perceived non-material differences in clinical attributes. In spite of product bundling not being allowed for around half of the pediatric vaccine market, physicians have a rational economic incentive to use the same pediatric vaccine brands for both their VFC and private stocks. This means that their private-stock vaccine decisions will likely influence which vaccines they use through the VFC program. A single-vaccine supplier's inability to gain sales on the private side in the face of bundling by multi-vaccine suppliers, therefore, spills over to its ability to gain sales on the public side.

By making entry more difficult, the long-term effects of bundling on the market for pediatric vaccines is likely to be fewer new products developed and fewer suppliers in the market. The implications of this would be a decreased likelihood of improvements in vaccines, and a greater risk of supply shortages because of a dependence on a smaller number of vaccine suppliers. Such an outcome would be inconsistent with key goals of the National Vaccine Program and at odds with public health goals.

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