

Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines

by

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Abstract: Bundling by a firm with monopoly power can be shown to reduce consumer welfare in one of two ways. First, by applying the “discount attribution standard,” bundling can be shown to exclude or impair equally efficient rivals in ancillary or “tied” markets. Second, by comparing the penalty price of the monopolized or “tying” product when purchased separately with its “independent monopoly price,” bundling can be shown to reduce consumer welfare directly. This paper examines both approaches in the sale of pediatric vaccines in the United States. Analysis of contractual terms imposed by incumbent vaccine manufacturers implies large non-compliance penalties, such that there is no positive price at which a hypothetical rival could induce an otherwise indifferent buyer to “break the bundle.” Furthermore, an analysis of pricing benchmarks indicates that incumbents’ bundled discounts successfully leverage market power from the tying market to the tied market, and observed rival penetration rates indicate that incumbent manufacturers have induced significant foreclosure of rivals. Finally, we analyze the role of Physician Buying Groups (PBGs) in the U.S. pediatric vaccine market, demonstrating that PBGs’ compensation structure distorts their incentives to secure the best prices for healthcare providers.

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I. INTRODUCTION

Bundling by a firm with monopoly power can be shown to reduce consumer welfare in one of two ways.³ First, by applying the “discount attribution standard,” bundling can be shown to exclude or impair equally efficient rivals in ancillary or “tied” markets for products that would otherwise be supplied competitively. Second, by comparing the penalty price of the monopolized or “tying” product when purchased separately with its “independent monopoly price,” bundling can be shown to reduce consumer welfare directly. This paper examines both approaches in the sale of pediatric vaccines in the United States, focusing on the market for Meningitis vaccines. Pediatric vaccines are produced almost exclusively by incumbents, who bundle their vaccines in conjunction with other products; however, meningitis vaccines are manufactured by both an incumbent (Sanofi Pasteur) and Novartis—the first competitive rival to enter the domestic pediatric vaccine market in over a decade.⁴

With respect to the discount attribution standard, we analyze actual contractual terms used by incumbent vaccine makers to estimate the “imputed price” of the Meningitis vaccine in a bundle of vaccines after allocating the forgone discounts on the incumbent-dominated (or “tying”) products to the competitive (or “tied”) product (the Meningitis vaccine). We demonstrate that

3. Bundling practices in the pharmaceutical industry have been challenged in at least two high-profile cases. In *SmithKline*, the district court found that SmithKline could not match Lilly's bundled rebates without incurring losses, and that Lilly had willfully maintained monopoly power under Section 2 of the Sherman Act. See *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp 1089, 1094 (E.D. Pa 1976). More recently, in *Meijer et. al. v. Abbott*, the district court denied in part Abbott's motion for summary judgment, and allowed the case to “go forward on the theories that Abbott engaged in predatory pricing...and violated its antitrust duty to deal.” See *Order Granting In Part And Denying In Part Defendant Abbott Laboratories' Motions For Summary Judgment On Direct Purchasers' Claims (Docket No. 232) and on GSK's Claims (Docket No. 227), Meijer, Inc., et. al. v. Abbott Laboratories*, Case No. C 07-5985 CW (N.D. Ca), (Jan. 14, 2011). One of the authors (Dr. Singer) served as the direct purchasers' economic expert in that matter.

4. As discussed below, the only incumbent in the industry that cannot offer bundles is Wyeth/Pfizer, whose Prevnar franchise represents its only significant vaccine offering and for which it is a sole-source provider.

single-product entrants attempting to penetrate a market dominated by multi-product incumbents are placed at a significant competitive disadvantage by incumbents' bundled pricing schemes.

Specifically, existing contractual terms impose sufficiently large non-compliance penalties such that there is no positive price at which a hypothetical rival could induce an otherwise indifferent buyer to "break the bundle." In other words, even if a competitive entrant were to give away Meningitis vaccines for free, a buyer opting to defect would still incur losses, owing to the penalties associated with foregone discounts on the tying products. Because the avoidable cost of producing and distributing Meningitis vaccines is necessarily positive, such a bundle would be considered anticompetitive under the *Cascade* standard. We also show that additional incumbent combination vaccines for which regulatory approval is still pending would present an opportunity for further rival impairment in the future.

Even when the discount-allocation test is not triggered, bundled discounts can be an effective anticompetitive mechanism for leveraging market power: If the incumbent sets an unbundled penalty price in the tying market in excess of the independent monopoly price (defined as the but-for price that a single-product profit-maximizing firm would choose), then bundled discounts can produce anticompetitive effects. In contrast, an incumbent might choose a standalone price in the tying market no greater than the IMP, and allow committed customers to pay less than the IMP. Under the first scenario, consumer welfare is reduced; under the second, it is not. Empirical evidence based on cross-sectional data indicates that pricing behavior by incumbents in the relevant vaccine markets is more consistent with the welfare-reducing scenario.

A penalty price in excess of the IMP distorts buyers' incentives towards accepting bundles combining the (otherwise competitively supplied) tied product in conjunction with the tying

product. We test for evidence of these distortions empirically, and the results indicate that observed rival penetration rates are consistent with the hypothesis that incumbent manufacturers positioned to leverage their market power to impair rivals have done so, inducing significant foreclosure of rivals from the relevant market segments. In addition, we estimate the degree to which incumbents' bundling practices have foreclosed the Meningitis vaccine market from competition, and find that the estimated foreclosure shares significantly exceed the presumptively anticompetitive threshold of 20 percent.

We also analyze the role of Physician Buying Groups (PBGs) in the U.S. pediatric vaccine market. Drawing on research on Group Purchasing Organizations in the medical supply industry, we demonstrate that the PBGs' compensation structure distorts incentives to secure the best prices for healthcare providers.

These findings have significant implications for public policy and antitrust enforcement. The cost structure governing vaccine production is characterized by high barriers to entry (both regulatory and technical), high sunk and fixed costs, low marginal costs, and significant scale economies, all of which have contributed to the development of an industry dominated by large incumbents that have achieved the requisite scale economies to remain viable, with extremely limited entry by competitive rivals. Moreover, the biological processes utilized for vaccine production leave virtually no pathway for generics, which—although common in other pharmaceutical industries—are nonexistent in the US pediatric vaccine market. Given this industry structure, anticompetitive conduct may reduce consumer welfare substantially. The most obvious potential for consumer harm comes in the form of higher prices, leading to reduced vaccination rates both in the private sector, which is directly affected by the conduct noted above, and in the public sector through the Vaccines For Children (VFC) program, whose prices

are subject to spillover effects. Consumers would incur additional harm to the extent that anticompetitive conduct stifles investment and/or innovation in the industry, ultimately resulting in diminished manufacturing capacity, an increased likelihood of vaccine shortages, and a degradation in the quality, reliability, and availability of existing and future pediatric vaccines, relative to what would otherwise prevail.

II. BACKGROUND ON PEDIATRIC VACCINES

The U.S. vaccine industry can be divided into different components: pediatric/adolescent, adult, and travel/specialty vaccines. As with most pharmaceutical products, the U.S. pediatric vaccine market consists of a private sector and a public sector. In the private sector, physicians purchase vaccines directly from a manufacturer or distributor and administer them to their patients, with drug makers free to price their vaccines at the level the market will bear.⁵ Physicians are financially at risk for purchases in the private sector, and, with the exception of travel vaccines, generally rely on insurance companies for reimbursement. Vaccinations pose significant financial challenges for pediatric practices, making any increases in costs difficult to manage. For instance, Coleman et. al. (2009) found that most private pediatric practices incur losses as a result of the time and resource investments required to vaccinate their patients.⁶

In the public sector, which accounts for the remainder of the U.S. market, vaccines are provided to physicians and clinics free of charge through the Vaccines For Children program. VFC provides vaccines for uninsured, underinsured, Eskimo, or Native American children under the age of 18. VFC is administered by the Centers for Disease Control (CDC), which procures

5. R. Gordon Douglas, Jerald Sadoff & Vijay Samant, *The Vaccine Industry* in VACCINES (Stanley A. Plotkin, Walter A. Orenstein, Paul A. Offit eds.) (Elsevier 5th ed. 2008) [hereinafter *Vaccine Industry*] at 43.

6. Margaret Coleman, Megan Lindley, John Ekong, & Lance Rodewald, *Net financial gain or loss from vaccination in pediatric medical practices*, PEDIATRICS 124 Suppl 5:S472-91 (December 2009).

vaccines directly from manufacturers based on aggregate orders from state immunization projects. The Department of Health and Human Services negotiates vaccine prices under VFC, and pays the full cost of vaccines ordered by state and local governments. Therefore, public sector pricing is available only to specified government entities purchasing under defined circumstances.

Price negotiations in the public and private sectors are ultimately endogenous to one another. Fundamentally, this is due to the fact that vaccines sold in the two sectors are perfect functional substitutes. On the demand side, pediatric practices face clear incentives to stock and administer the same vaccine brands for both their public patients and their private patients, because doing so simplifies training requirements for staff, reduces the probability of administration errors, maintains a single standard of care for all patients, and allows for occasional substitution across public and private inventories to avoid shortages. On the supply side, the cost of manufacturing vaccines for use in either sector is identical, and output can be shifted freely from one sector to another. All else equal, manufacturers should be less willing to offer pricing concessions in their negotiations with government purchasers if demand in the private sector is strong, and vice-versa. It is therefore unsurprising that there appear to be strong spillover effects between public and private sector vaccine prices.⁷

In the United States, pediatric vaccines purchased at the public sector price account for approximately 57 percent of total pediatric vaccine purchases by volume.⁸ As such, the CDC

7. For example, the correlation coefficient between the public and private sector prices of Sanofi's Menactra exceeds 98 percent. See CDC, *VFC: CDC Vaccine Price List Archives*, available at <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list-archives.htm>.

8. W. A. Orenstein, R. G. Douglas, L. E. Rodewald, & A. R. Hinman, *Immunizations in the United States: Success, Structure, And Stress - A complex collaboration involving government, industry, providers, academe, professional societies, and third-party payers*, 24(3) HEALTH AFFAIRS 599, 610 (May/June 2005).

accounts for a significant portion of US vaccine demand.⁹ By comparison, on a global basis, the public purchase of vaccines (through immunization programs and government stockpiles) accounts for 90 percent of the volume and 40 percent of the revenues, while the private market accounts for 10 percent of the volume and 60 percent of the revenues.¹⁰

Along with the CDC, the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) recommend proper use of the vaccines. In practice, these ‘recommendations’ translate into a set of binding supply requirements for providers, who are obligated (by regulatory requirements and/or acceptable standards of medical care) to maintain inventories of all standard vaccines on the infant schedule.

Roughly three quarters of U.S. children ages 24-36 months have received all their vaccines.¹¹ Because the epidemiology of viral and bacterial infectious disease, as well as organism strains, vary across the globe, many vaccines are country- or region-specific. For example, the incidence and strains of meningococcal meningitis vary globally.¹²

There is also regional variability in market size and pricing. According to Frost & Sullivan, although Europe serves as a manufacturing hub for vaccine development, many of the vaccines are exported to North America “due to its consistent demand and higher price-points in the local market.”¹³

There are many different vaccines offering protection against organisms responsible for a range of formerly common childhood diseases, including: Hepatitis B virus (HepB), Rotavirus (RV),

9. *Vaccine Industry, supra*, at 43.

10. Frost & Sullivan, *Global Vaccines Market*, Dec. 7, 2009, at 8 [hereinafter Frost & Sullivan].

11. Cowen & Company, *Pediatric Vaccines Provide Opportunity, Risk*, May 11, 2010, at 3 [hereinafter Cowen & Company].

12. Raymond James, *Third Vaccines Seminar*, Oct. 7, 2009, at 10 [hereinafter Raymond James].

13. Frost & Sullivan at 5.

Diphtheria, Tetanus and Pertussis (DTaP), Haemophilus influenzae type B (Hib), Streptococcus Pneumoniae (PCV13), Polio virus (IPV), Influenza virus (TIV, LAIV), Measles, Mumps and Rubella (MMR), Varicella virus (Varicella), Hepatitis A virus (HepA), and Neisseria meningitidis (MCV4). The recommended immunization schedule for children six and under in the United States is provided in Appendix I. Table I shows the types of pediatric vaccines offered in 2011 in the United States by manufacturer.

TABLE I: TYPES OF PEDIATRIC/ADOLESCENT VACCINES, BY TYPE AND BY MANUFACTURER (2011)

Brandname/Tradename	Vaccine	Manufacturer
Tripedia/ Daptacel	DtaP	Sanofi Pasteur
Infanrix	DtaP	GlaxoSmithKline
Kinrix	DTaP- IPV	GlaxoSmithKline
Pediarix	DTaP-Hepatitis B-IPV	GlaxoSmithKline
Pentacel	DTaP-IPV-Hib	Sanofi Pasteur
IPOL	IPV	Sanofi Pasteur
Comvax	Hepatitis B-Hib	Merck
Vaqta	Hepatitis A Pediatric	Merck
Havrix	Hepatitis A Pediatric	GlaxoSmithKline
Twinrix	Hepatitis A-Hepatitis B 18 only	GlaxoSmithKline
Engerix B	Hepatitis B	GlaxoSmithKline
Recombivax HB	Hepatitis B	Merck
PedvaxHIB	Hib	Merck
ActHIB	Hib	Sanofi Pasteur
Hiberix	Hib	GlaxoSmithKline
Gardasil	HPV - Quadrivalent Human Papillomavirus Types 6, 11, 16 and 18	Merck
Cervarix	HPV -Bivalent Human Papillomavirus Types 16 and 18	GlaxoSmithKline
ProQuad	Measles, Mumps, Rubella and Varicella (MMR-V)	Merck
Menactra	Meningococcal Conjugate (Groups A, C, Y and W-135)	Sanofi Pasteur
Menveo	Meningococcal Conjugate (Groups A, C, Y and W-135)	Novartis
MenHibrix*	Meningococcal Conjugate (Groups C and Y) – Hib	GlaxoSmithKline
MMRII	Measles, Mumps and Rubella (MMR)	Merck
Prenar 13	Pneumococcal 13-valent (Pediatric)	Pfizer/Wyeth
Pneumovax	Pneumococcal Polysaccharide (23 Valent)	Merck
RotaTeq	Rotavirus, Live, Oral, Pentavalent	Merck
Rotarix	Rotavirus, Live, Oral	GlaxoSmithKline
Decavac	Tetanus & Diphtheria Toxoids	Sanofi Pasteur
MassBiologics	Tetanus & Diphtheria Toxoids	MassBiologics
Boostrix	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis	GlaxoSmithKline
Adacel	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis	Sanofi Pasteur
Varivax	Varicella	Merck

Source: CDC.

* As of May 2011, MenHibrix was not yet approved for use in the United States but is included in Table I due to its relevance in the discussion herein.

As Table I shows, some suppliers offer a wider array of pediatric vaccines than others. For example, Merck (the sole U.S. supplier of MMR and Varicella vaccines) offers 10,

GlaxoSmithKline (GSK) offers 10, and Sanofi Pasteur (Sanofi) offers seven separate pediatric vaccines. In contrast, Novartis and Pfizer each offer only one pediatric vaccine.¹⁴

Table I also shows that as of May 2011 there were only two meningococcal conjugate vaccines offering protection against serogroups A, C, W, and Y for individuals between two and 55 years of age in the United States: Sanofi's Menactra and Novartis's Menveo. (GSK is developing an alternative with more limited coverage, reviewed below.) ACIP recommends routine immunization for children between 11 and 12 years of age and a booster dose at 16 years, making the meningococcal conjugate vaccine part of the routine childhood immunization schedule.

Currently, serogroup A disease is exceedingly uncommon in the United States, while serogroup Y disease has emerged in importance. The proportion of meningococcal disease caused by serogroup Y increased from 2 percent during 1989–1991 to 37 percent during 1997–2002. More than 98 percent of meningococcal disease cases in the United States are sporadic, while the other 2 percent are associated with outbreaks. Compared with the 1980s, the frequency of meningococcal outbreaks has increased. The majority of outbreaks have been caused by serogroup C, although the incidence of serogroup Y outbreaks has increased as well.¹⁵

Serogroups B, C and Y each cause approximately one-third of meningococcal disease cases in the United States. The proportion of cases caused by each serogroup varies by age; serogroup B causes over 50 percent of cases in infants younger than 1 year of age, while serogroups C, Y, and

14. Although Novartis—in addition to Sanofi, GSK, Merck (via a marketing agreement with CSL), and others—does offer a seasonal influenza vaccine, note that these products occupy a market segment separate from other pediatric vaccines, and typically do not represent a significant component of incumbents' bundled pricing schedules for pediatric vaccines.

15. CDC, *Prevention and control of meningococcal disease* MMWR 2005;54 (No. RR-7):1–17.

W135 cause 75 percent of meningococcal disease in those 11 years and older. There is currently no vaccine approved for use in the US for protection against serogroup B.¹⁶

According to Cowen & Company, growth in the meningococcal A, C, W, and Y segment has likely approached the rate of the birth cohort in the United States, because the catch-up cohort has been vaccinated.¹⁷ According to Frost & Sullivan, however, “[r]egulatory approval extending age indications, expanding licensures into other countries, and new product approvals in the meningitis segment are expected to contribute significantly to the overall growth of the [global] vaccines market during the forecast period.”¹⁸ Frost & Sullivan predicted global sales of meningococcal meningitis vaccines to have reached \$1 billion by 2010, with the potential to double by 2015.¹⁹

A. Market Shares

Pediatric vaccines are a “key component of revenue” for GSK, Merck, and Sanofi.²⁰ In contrast, pediatric vaccines are a “potential source of growth” for Novartis.²¹ The supply of pediatric vaccines in the United States is highly concentrated, as a relatively small number of pharmaceutical firms engage in research, development, manufacture, sales, marketing, and distribution.²²

16. CDC, *Manual for the Surveillance of Vaccine-Preventable Diseases* (4th ed.), Chapter 8 (Meningococcal Disease), available at <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.htm>.

17. Cowen & Company, at 5.

18. Frost & Sullivan, at 10. Note also that the ACIP recently approved updated recommendations for the use of meningococcal conjugate vaccines, adding a booster dose to the adolescent vaccination schedule. See CDC, “Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010,” available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm?s_cid=mm6003a3_w.

19. Frost & Sullivan, at 10.

20. Cowen & Company, at 1.

21. *Id.*

22. *Id.*

Sanofi, Merck, GSK, and Wyeth/Pfizer are the primary suppliers in the domestic vaccine market. Top selling vaccines in the U.S. include Wyeth/Pfizer's Prevnar-7/-13,²³ Merck's Gardasil, MMR-II ProQuad, Recombivax, RotaTeq, and Varivax,²⁴ Sanofi's ActHIB, Adacel, Daptacel, IPOL, Menactra, and Pentacel²⁵ as well as several GSK vaccines, including Boostrix, Ceravix, Energix, Havrix, Infanrix, Pediarix, and Twinrix.²⁶

As seen in Figure I, Sanofi and Merck have a combined market share of approximately 58 percent in domestic vaccines overall. The next largest shares are those of Wyeth/Pfizer (21 percent), and GSK (13 percent). Novartis' share of approximately four percent is by far the lowest. It bears emphasis that these statistics overstate Novartis' relative market share in pediatric vaccines, because influenza vaccine sales make up a relatively large proportion of Novartis' total vaccine sales, whereas other manufacturers are concentrated more heavily in pediatric offerings.

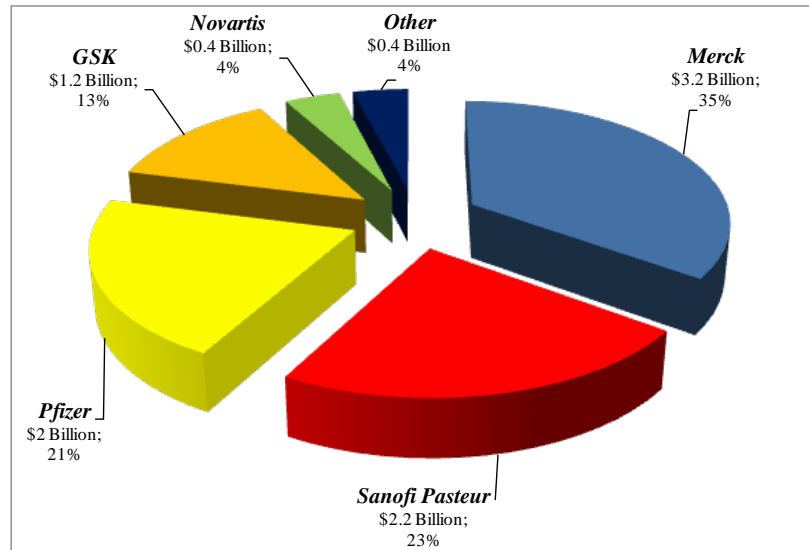
23. Sales of Prevnar-7/-13 were estimated at \$3.26 billion in 2010. *Id.* at 4-5.

24. Sales of Proquad/MMR-II/Varivax sales were estimated at \$1.35 billion in 2010. Rotateq sales were estimated at \$560 million *Id.* at 4. Merck's Gardasil is also a significant source of revenue, with annual revenues over \$1 billion. See Frost & Sullivan at 13.

25. Pentacel sales reached an estimated \$1.1 billion in 2008; Menactra's sales were estimated at \$694 million in that year. See Raymond James at 3.

26. GSK's sales of Infanrix/Pediarix were estimated at \$858 million as of 2008; sales of Energix, Twinrix, and Havrix were estimated at \$836 million. *Id.* at 3.

FIGURE I: MARKET SHARES IN THE DOMESTIC VACCINE INDUSTRY



Sources: SEC filings; investor analyst reports.

B. Entry Barriers

Some analysts have found that “current dynamics are not favorable” to entrants in vaccine markets such as Novartis.²⁷ According to Frost and Sullivan, the “threat of new entrants in this market is seemingly low as the barriers to entry when developing biological products like vaccines are quite high.”²⁸ Raymond James explains that “GSK and Sanofi-Pasteur do not appear to be at risk, even though Wyeth and Merck intend to remain influential players and Novartis has joined in the battle.”²⁹ Datamonitor notes the “high barrier to entry for smaller players, which usually have limited manufacturing capacity, and may also lack the resources and the distribution networks required for vaccine development.”³⁰

27. Cowen & Company, at 1.

28. Frost & Sullivan, at 4.

29. Raymond James, at 1.

30. Datamonitor, Vaccine Market Overview 2010, Dec. 1, 2010, available at http://www.tradingmarkets.com/news/stock-alert/gsk_mrk_nvs_vaccine-market-overview-2010-1339487.html.

1. High Fixed Costs and Economies of Scale

Vaccine development is extremely risky because most vaccine candidates fail in preclinical or early clinical development.³¹ The manufacturing process of a new vaccine involves two fundamental steps: 1) bulk manufacturing (which includes cell culture or fermentation-based manufacturing followed by separation/purification processes); and 2) finishing operations, which include formulation and the addition of an adjuvant (if required). These steps are followed by vial or syringe filling, then labeling and packaging. Infrastructure costs for vaccine manufacturing are significant; Douglas et al. (2008) estimate that the cost of a manufacturing plant ranges from \$50 to \$300 million, depending on the dose requirements and other complexities.³² Research and Development (R&D) is another critical cost driver; based on the experience of Aviron and Medimmune, the R&D expenditures of new vaccines are estimated between \$600 and \$800 million.³³ Thus, the vaccine industry resembles many other industries characterized by high sunk costs, high fixed costs, low marginal costs, and significant scale economies, giving rise to markets dominated by large incumbents that have achieved the requisite scale economies to remain viable. Such markets can be particularly difficult for new entrants to penetrate, given the high risk of failure, and the need to defray high fixed costs over a sufficiently large customer base.

Compared to other pharmaceutical products, incumbent vaccines are largely sheltered from competitive entry because access to proprietary cell lines and virus strains are more valuable than patent protection. The biological processes utilized for vaccine production are complex to

31. *Vaccine Industry, supra*, at 39.

32. *Id.* at 38.

33. *Id.* at 38.

manage, difficult to scale, and nearly impossible to duplicate, leaving no viable pathway for generics, which are nonexistent in the US vaccine market.³⁴ The Abbreviated New Drug Application (ANDA) process is not available for biologics in the U.S., which means that would-be competitors are obligated to duplicate the costly clinical studies performed for the original licensure.³⁵ For example, despite the four decades that have passed since the introduction of MMR vaccines, the sole supplier in the United States (Merck), has “yet to see competition.”³⁶ For other pediatric vaccines, there are generally only one or two sources of supply approved and recommended for use in the U.S., and periodic shortages of routinely recommended vaccines have occurred as a result of manufacturer stock-outs.

The number of suppliers in the U.S. vaccine industry has contracted significantly; 26 different companies held vaccine licenses in 1967 while only 12 companies held licenses in 2002.³⁷ The Immunization Action Coalition currently lists only 10 active US vaccine manufacturers.³⁸ While the number of pediatric vaccines available has expanded considerably primarily due to the licensure of new antigens, since 1990, there have been only two new entrants in pediatric vaccines: First, Certiva, a DTaP vaccine, was licensed in 1998 by North America Vaccines, only to be withdrawn two years later after Baxter’s purchase of North American Vaccines.³⁹ (Other notable firms that have exited the U.S. vaccine market include Eli Lilly & Co. and E.R. Squibb

34. *Id.* at 40.

35. *See* 21 U.S.C. § 355 (1994).

36. *Vaccine Industry, supra.* at 40.

37. *Id.* at 43.

38. *See* http://www.immunize.org/resources/manufact_vax.asp.

39. *Id.* at 40. North American Vaccines licensed and sold a DTaP vaccine, branded Certiva, for a brief period (from 1998-2000). North American exited from the US marketplace and discontinued sales of their lone pediatric product after only 2 years, having failed to achieve sufficient sales volumes. *See* FDA, *1998 Biological License Application Approvals*, available at <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicalApprovalsbyYear/ucm180084.htm>; *see also* CDC, “Notice to Readers: Update on the Supply of Tetanus and Diphtheria Toxoids and of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine,” (March 2001), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5010a3.htm>.

& Sons.⁴⁰) Second, Novartis, the first new entrant in over ten years to the U.S. pediatric vaccines market, introduced Menveo in 2010.

In contrast with the vaccine market, entry is much more common in the pharmaceutical industry generally. Since the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act streamlined the procedures for bringing generic drugs to the market,⁴¹ generic drugs have played an increasingly prominent role in the marketplace, accounting for a substantial fraction of prescriptions filled in the United States.⁴² Beyond generics, entry in pharmaceutical markets frequently takes the form of new drugs offering substantial improvements relative to incumbents in the same therapeutic class; one study analyzed over 140 new drugs introduced over a ten-year period, many of which delivered significant therapeutic gains.⁴³ Even in the absence of substantial therapeutic improvements, entry by branded substitutes (in the form of so-called “me-too” drugs) plays an important role in disciplining drug prices and maintaining competition in the marketplace.⁴⁴

2. Regulatory Barriers

Vaccine development and licensing must meet extremely stringent regulatory guidelines, a process that can take nearly 15 years to complete and can cost upwards of a billion dollars.⁴⁵ The FDA’s rigorous licensing and approval process is a requirement for vaccine use in the United States.

40. *Vaccine Industry*, *supra*, at 43.

41. *See* 21 U.S.C. § 355 (1994).

42. *See* Federal Trade Commission, *Generic Drug Entry Prior To Patent Expiration: An FTC Study* (July 2002).

43. *See, e.g.*, John Lu & William S. Comanor, *Strategic Pricing of New Pharmaceuticals*, *REV. ECON. STAT.* 110 (1998).

44. *See* U.S. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices And Returns In The Pharmaceutical Industry* (July 1998).

45. Frost & Sullivan, at 4.

Complying with these standards and proving that vaccines are effective and safe requires companies to expend significant resources on facilities, personnel, and processes to document and validate each step in vaccine development. In addition to conducting costly preclinical testing and large-scale safety and immunogenicity studies, companies must “perform supplemental research to ensure production consistency amongst batches, evaluating safety and immunogenicity in special populations, and, when necessary, formal post-marketing safety studies.”⁴⁶ Because of these significant costs of developing new vaccines, entrants often partner with incumbents to develop and market vaccines. Moreover, the FDA’s requirement that vaccines currently sold in other markets undergo costly additional clinical trials before entering the U.S. market (to meet potentially more stringent regulatory requirements) “often discourages manufacturers from launching vaccines in the U.S.”⁴⁷

3. Policy Barriers

Following FDA approval, a positive, ideally routine, ACIP recommendation is critical to the success of a pediatric vaccine, as recommendations by ACIP (as well as AAP and other bodies) influence and/or dictate the uptake of a particular vaccine. These organizations publish vaccination schedules for children, adolescents and adults, detailing which vaccines are to be used by which population(s), as well as the recommended number of doses, which becomes the medical standard of care. An ACIP recommendation is necessary to secure VFC funding, which is frequently followed, in the case of routine recommendations, by coverage by major insurers.

46. Frost & Sullivan, at 4.

47. *Id.* at 5.

4. Bundling Practices

In addition to high costs, technical barriers, and regulatory/policy impediments, the pricing schemes used by incumbent vaccine makers can create barriers to entry. Vaccine companies have long offered the best prices to customers who purchase a bundle of products, and key vaccines of incumbent manufacturers have been coordinated into bundles spanning broad offerings of pediatric and adolescent vaccines. Customers have evolved into three camps: (1) those that primarily purchase Sanofi/Merck vaccines to minimize expenditures (“Sanofi Loyalists”);⁴⁸ (2) those that purchase primarily GSK vaccines (“GSK Loyalists”); and (3) those attempting to toggle intermittently between incumbent suppliers, periodically replenishing their vaccine inventories from various manufacturers (“Non-Loyalists”).⁴⁹

Depending on how they construct their bundles, drug companies with a portfolio of vaccines can leverage their market power from one type of vaccine (or one group of vaccines), into another market segment. As noted above, Meningitis vaccines are sold by the only new competitive entrant to the industry in over a decade; as a consequence, below we focus on bundles that implicate these products. Bundled offerings from Sanofi explicitly incorporate Meningitis vaccines, and potential bundled offerings from GSK may soon do the same, pending regulatory approval of MenHibrix.

48. As noted below, Physician Buying Groups sometimes require that their members agree to purchase Sanofi and Merck vaccines exclusively. Note also that Merck’s Gardasil and RotaTeq are marketed under a joint venture with Sanofi Pasteur.

49. Wyeth/Pfizer accounts for a significant share of the U.S. pediatric vaccine market. However, although the company’s Prevnar franchise dominates the U.S. market for pneumococcal vaccines, Wyeth/Pfizer does not have significant offerings in other areas, and thus cannot offer bundles comparable to those of GSK or Sanofi/Merck. *See* Datamonitor, Vaccine Market Overview 2010, Dec. 1, 2010 (“Wyeth’s success in vaccines has been built largely on the back of a single product: the pneumococcal conjugate vaccine Prevnar.”).

GSK’s key pediatric vaccine offerings include Pediarix (DTaP-HepB-IPV), Rotarix (Rotavirus), Boostrix (TdaP), and Infanrix (DTaP); Sanofi’s “core franchises” within pediatric vaccines include Pentacel (DTP-IPV-Hib), Menactra (MenACWY), Daptacel (DTaP), Adacel (TdaP).⁵⁰ Figure II illustrates how pediatric vaccines manufactured by GSK, Sanofi, and Merck have been bundled, either contractually or physically, to span the relevant line of vaccines.

FIGURE II: BUNDLES IMPLICATING MENINGITIS VACCINES

Brand	Type	Maker	HepA	HepB	Rotavirus	MMR-V	HPV	TDAP	DTaP	IPV	Hib	MenACWY
Vaqta	Pediatric	Merck	Green									
Havrix	Pediatric	GSK	Yellow									
Recombivax HB	Pediatric	Merck		Green								
Energix B	Pediatric	GSK		Yellow								
RotaTeq	Pediatric	Merck			Green							
Rotarix	Pediatric	GSK			Yellow							
ProQuad	Pediatric	Merck				Green						
Gardasil	Adolescent	Merck					Green					
Cervarix	Adolescent	GSK					Yellow					
Boostrix	Adolescent	GSK						Yellow				
Infanrix	Pediatric	GSK							Yellow			
Pediarix	Pediatric	GSK		Yellow					Yellow			
Hiberix	Pediatric	GSK									Yellow	
MenHibrix*	Pediatric	GSK									Yellow	Yellow
Adacel	Adolescent	Sanofi						Green				
Daptacel	Pediatric	Sanofi							Green			
Pentacel	Pediatric	Sanofi							Green			
PedvaxHIB	Pediatric	Merck									Green	
Menactra	Adolescent	Sanofi										Green
Menveo	Adolescent	Novartis										Blue

Notes: TDAP is Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis. Hiberix approved as a booster dose for children 15 months through four years of age. Wyeth/Pfizer not included; it cannot offer bundles as its Prevnar franchise represents its only significant vaccine offering.

*MenHibrix protects against the C and Y serogroups only. As of July 2011, it had not been approved for use in the U.S.

Of course, the mere bundling of products by itself is not exclusionary. To exclude rivals, a firm must establish a penalty price for the “tying” products (when purchased outside of the bundle) in a way that makes it impossible for equally efficient one-good rivals in the “tied” market to compete. Because Novartis offers only one vaccine (Menveo) in the routine child/adolescent immunization schedule, Novartis is properly considered a “one-good” rival.

50. See, e.g., Datamonitor, Vaccine Market Overview 2010, Dec. 1, 2010, available at http://www.tradingmarkets.com/news/stock-alert/gsk_mrk_nvs_vaccine-market-overview-2010-1339487.html.

In addition, the importance of Physician Buying Groups (PBGs) has expanded, as detailed in Section III. PBGs contract with manufacturers to get the best pricing for their members and act as enforcers requiring participants to comply with contractual agreements on market share. The emergence of bundling and the growth of PBGs has eroded the ability of physicians to make individual product choices based on performance characteristics or clinical data, as they are financially penalized for doing so. As noted above, vaccines frequently represent a significant financial burden for pediatric practices, making any increases in costs difficult to manage.

III. THE ROLE OF PHYSICIAN BUYING GROUPS

Physician Buying Groups are typically privately held, for-profit entities, with membership consisting of thousands of family practices, pediatricians, and other independent medical practices. PBGs perform various services on behalf of their members, including coordinating and aggregating member purchases of vaccines and other healthcare supplies through group purchasing contracts with major vaccine manufacturers and medical supply distributors. Because PBGs seldom charge membership dues or participation fees, most or all of their compensation typically comes in the form of rebates and administrative fees paid by vendors (based on PBG members' aggregate expenditures). To qualify for vaccine discounts, PBGs typically require that participating practices agree to contractual terms, such as manufacturer exclusivity. Manufacturers grant rebates to PBGs based on their success in enrolling practices and aggregating purchase volumes. PBGs may share some portion of these rebates with their members, and may also keep some portion for themselves, depending on the specifics of contractual terms and industry practice.

A partial list of PBGs and other buying groups that aggregate vaccine purchases is given in Table II. Although PBGs are typically organized as for-profit corporations, few (if any) are publicly traded. As such, the publicly available information on the contractual and financial structures of PBGs is limited. Nevertheless, the available information indicates that the typical PBG represents thousands of hospitals and practices, while maintaining contractual arrangements with a select set of vaccine manufacturers. In many cases, PBGs' public documentation specifies the administrative fees charged to vendors to finance their operations. But even in the absence of such documentation, the existence of vendor fees can be inferred, based on the absence of any revenues earned from members for participation.

TABLE II: CHARACTERISTICS OF SELECTED PHYSICIAN BUYING GROUPS

NAME	DESCRIPTION	MEMBERSHIP	FOR PROFIT/ PRIVATELY HELD?	VACCINE PURCHASING ARRANGEMENTS	SOURCE OF COMPENSATION
Atlantic Health Partners LLC	Physician Buying Group specializing in vaccines	“Leading physician vaccine buying group with Family Physicians across the country”	Y/Y	Sanofi/Merck. Participating practices agree to exclusivity.	Administrative vendor fees*
Child Health Corporation of America	Hospital-owned GPO; manages Child Health Advantage Program	Hospitals representing > 20,000 physicians, > \$14 billion in revenue	Y/Y	GSK/Merck/Novartis	Administrative vendor fees (up to 3%)
Kelson Physician Partners, Inc	Pediatric healthcare services provider with Vaccine Purchase Program	4,200 physicians in 38 states	Y/Y	Works with practices to "build the best purchasing strategy...which may include access to contracts with various vaccine manufactures"	Administrative vendor fees*
Main Street Vaccines	Nationwide physician GPO	Over 7,000 members	Y/Y	Exclusive to Merck/Sanofi. Member practices may not use competing vaccines except for explicit reasons of medical necessity or product unavailability.	Administrative vendor fees*
National Physician Care, Inc	GPO representing private practice physicians, non-governmental health clinics, corporate employee health clinics, and travel clinics	5,000 medical practices; 20,000 practitioners	Y/Y	GSK, Sanofi Pasteur, Novartis Vaccines, VaxServe, Crucell Vaccine, and MedImmune	Administrative vendor fees (1% to 3%)
Physicians' Alliance of America	Non-Profit Physician-Owned GPO	25,000 physicians	N/Y	Maintains vaccine contracts with GSK, Sanofi Pasteur, MedImmune, Novartis	Administrative vendor fees*
US Physicians Purchasing Group LLC	Physician-owned GPO exclusively partnered with GSK	Over 7,000 members nationwide	Y/Y	Contracts exclusively with GSK	Administrative vendor fees (up to 3%)

*Vendor fees inferred based on an absence of membership fees.

PBGs are closely related to, and in many cases indistinguishable from, Group Purchasing Organizations (GPOs). Indeed, many PBGs explicitly identify themselves as GPOs.⁵¹ Groups of medical practitioners that purchase chemotherapy agents and cancer care drugs are known as “oncology GPOs.”⁵² In the early 1990s, four companies—Oncology Therapeutics Network (OTN), Oncology Supply of Alabama, Florida Infusion, and PRN—became the first brokers of oncology products for practitioners. For example, OTN became the sole drug distributor to oncology practices in North Carolina. Drug manufacturers negotiated drug contracts directly with these GPOs and paid them an administrative fee for choosing their drug.⁵³ In the mid 1990s, some of these oncology GPOs were acquired by drug wholesalers; for example, Cardinal acquired PRN and Amerisource Bergen acquired Oncology Supply. In contrast, OTN was acquired by Bristol Myers Squibb, raising exclusionary concerns by other drug manufacturers.⁵⁴

Arrangements between drug makers and pharmaceutical GPOs have been the subject of recent litigation. Along with state attorneys general, former Amgen employee Kassie Westmoreland sued Amgen on behalf of the U.S. government, alleging that Amgen created a nephrology GPO, International Nephrology Network, that trained doctors how to overbill Medicare on Amgen’s anemia drug, Aranesp. In March 2010, five former Amgen employees and the office manager of one of their customers asserted their Fifth Amendment rights against self-incrimination.⁵⁵

51. For example, Main Street Vaccines describes itself as a “nationwide physician group purchasing organization with over 7000 members.” See <http://www.mainstreetvacs.com/>

52. Bryan Cote, *Evolution of the Oncology GPO*, ONCOLOGY BUSINESS REVIEW, Oct. 2007, available at www.oncbiz.com.

53. *Id.*

54. *Id.* (“Manufacturers questioned how they could distribute their oncology products to community physicians through a business that was owned by BMS— a primary competitor. This conflict opened the door for an alternative to the BMS/OTN model.”).

55. Jim Edwards, *Amgen Execs Plead the Fifth on Alleged Kickbacks Described in Spreadsheet*, CBS INTERACTIVE, Mar. 2, 2011, available at <http://www.bnet.com/blog/drug-business/5-amgen-exec-plead-the-fifth-on-alleged-kickbacks-described-in-spreadsheet/7582>.

According to the complaint, the scheme was designed to shift demand from Johnson & Johnson's Procrit, a rival anemia drug, to Amgen's Aranesp.

Like GPOs, PBGs aggregate member purchases of healthcare products in exchange for promised discounts, relative to what individual buyers could negotiate on their own. And like GPOs, PBGs earn their fees based on a percentage of members' aggregate purchase volumes. Both GPOs and PBGs are contractually required by manufacturers to meet specified sales targets, and both risk sacrificing crucial revenue streams if these benchmarks are not met due to member non-compliance. GPOs and PBGs both take measures to incentivize compliance among their membership, with varying degrees of aggressiveness.⁵⁶ Although GPO member hospitals can buy outside of the GPO's contract with a particular manufacturer, the hospital often sacrifices discounts not only on the product in question but on all other products purchased through the GPO. The primary difference is that a GPO (as the term is commonly understood) typically represents a group of hospitals, rather than a coalition of independent medical practices. Regardless of this distinction, a PGB is, at least in theory, subject to the same conflicts of interest as any other GPO.⁵⁷ As discussed below, these include compensation arrangements that implicate the Anti-Kickback Statute.

56. See, e.g., Main Street Vaccines, "Frequently Asked Questions," available at <http://www.mainstreetvacs.com/faq.html>, at FAQ #1 ("Q: What are the basic features of your vaccine contracts? A: We get rock bottom prices on Sanofi Pasteur and Merck Vaccines by agreeing to their exclusive use. Main Street Vaccines and its member practices may not use competing vaccines except for explicit reasons of medical necessity or product unavailability.") See also FAQ #10 ("Q: Can you really tell if I am buying vaccines outside the contract? A: Yes, we can. When that happens you may receive a warning or a notice terminating your membership with the loss of all accrued benefits. Periodically, competing manufacturers "advise" members of ways to skirt our agreements and use their products. This is almost always detected and results in removal from our contract(s).")

57. See John Jones, Jr., "Physician-owned group purchasing organizations," *Physician's News Digest* (October 2005).

The anti-kickback statute of the Social Security Act makes it illegal to receive any compensation to induce referrals of items or services reimbursable by federal health care programs.⁵⁸ Convinced by GPOs that administrative fees in conjunction with membership fees could reduce federal health care expenditures, Congress amended the Act in 1986 by exempting GPOs from the general statutory ban on such kickbacks where the government covers health care costs.⁵⁹ In 1991, the Department of Health and Human Services (HHS) established “safe harbors,” which provide that GPOs are to have written agreements with their customers either stating that fees are to be three percent or less of the purchase price, or specifying the amount or maximum amount that each vendor will pay.⁶⁰ Because PBGs are compensated in the same way as GPOs, PBGs face the same conflicts of interests as recognized by HHS when it imposed the three percent cap—anything more would potentially cause the intermediary to act as a shield for incumbent suppliers.

Although this safe harbor was intended to shift the burden of administrative costs,⁶¹ some have questioned whether the GPO compensation system, even when limited to three percent of revenues, creates significant competition issues. In his book on health care policy and competition, Professor Michael E. Porter of Harvard Business School explains that “buying groups may serve the interests of the suppliers that provide their funding, not providers, thereby

58. 42 U.S.C. §1320a-7b(b).

59. 42 C.F.R. 1001.952(j).

60. 56 Fed. Reg. 35952, 35982. Note that GPOs were asked to “self-regulate” and report fees greater than three percent.

61. Daniel DeLay, *Watch Out For GPOs*, FORBES, Nov. 12, 2009, available at <http://www.forbes.com/2009/11/12/gpo-medicare-hospitals-medical-health-opinions-contributors-daniel-delay.html>.

undermining value-based competition.... There is no valid reason for buying groups to accept financing or any payments from suppliers....”⁶²

Indeed, some wonder if “safe harbors” actually raise prices for GPO members and stifle competition relative to a world with a different GPO compensation system.⁶³ Naturally, if a GPO is receiving a kickback equal to a percentage of brokered sales, the GPO lacks a strong incentive to seek out the lowest prices.⁶⁴ Moreover, in the presence of a kickback, medical suppliers are induced to compete less aggressively on price, as some of their resources are shifted towards competing for the largest side payment. Even worse, because negotiating with GPOs is costly, some suppliers might simply forgo altogether the opportunity to participate in markets where kickbacks are permitted. The resulting lack of competition might raise net costs, despite the purported savings in transaction costs and consolidation of purchasing power made possible by GPOs.

The complex and veiled nature of these transactions has helped GPOs evade public scrutiny until recently. Over the past decade, the government and the media have begun to take notice of GPO practices, particularly in the midst of the economic turmoil and heightened attention to healthcare costs in recent years. Following a 2002 *New York Times* investigation that highlighted GPOs’

62. MICHAEL E. PORTER & ELIZABETH OLMSTEAD TEISBERG, REDEFINING HEALTH CARE: CREATING VALUE-BASED COMPETITION ON RESULTS 361-362 (Harvard Business School Press, 2006).

63. Einer Elhauge, The Exclusion of Competition for Hospital Sales Through Group Purchasing Organizations, Report to U.S. Senate, June 25, 2002, at 21, *available at* <http://www.law.harvard.edu/faculty/elhauge>.

64. Another potential incentive problem is that soliciting sales quotes from suppliers and reviewing product specifications likely requires effort on the part of the GPO, and given their compensation scheme, the GPOs internalize all of those costs. This aspect of the principal-agent problem is similar to the one faced by real estate agents, who are compensated with a percentage of the sale price. See Steven D. Levitt & Chad Syverson, *Market Distortions when Agents are Better Informed: The Value of Information in Real Estate Transactions*, NBER Working Paper No. W11053, Jan. 2005 (finding that that homes owned by real estate agents sold for about 3.7 percent more than other houses and stay on the market about 9.5 days longer, even after controlling for a wide range of housing characteristics).

conflicts of interest and violations of the three-percent-fee cap,⁶⁵ Congress initiated a series of hearings to determine whether further legislation on GPOs were needed.⁶⁶

A 2002 GAO study asked whether hospitals paid lower prices on their own or through a GPO when buying the same model of safety syringe.⁶⁷ The GAO found that median prices were higher by one to five percent through GPOs than outside them for all safety syringe models and for most pacemaker models.⁶⁸ According to an investigation by the *Los Angeles Times*, the prices that the largest GPO, Novation, charges the University of California on its drug purchasing contract have been undercut by hundreds of thousands of dollars by a group of oncologists at UCLA who decided to contract with suppliers themselves.⁶⁹ Similarly, a medical business magazine recently reported that, by eschewing GPOs in favor of in-house contracting, the pharmacy department at Duke University was able to negotiate “as good as or better pricing than the GPOs.”⁷⁰

Singer (2006) found that if the GPO safe-harbor provision were removed, GPO member hospitals would keep an additional 21 to 32 percent of administrative fees (net of operating expenses) currently paid to GPOs but not passed through to member hospitals less a competitive return on GPO expenses (as an alternative form of GPO compensation), representing a savings to hospitals of roughly half a billion dollars per year.⁷¹ He also estimated the overcharges to the

65. Walt Bogdanich, *Medicine’s Middlemen; Questions Raised of Conflicts at 2 Hospital Buying Groups*, NEW YORK TIMES, Mar. 4, 2002, at A1.

66. Mary Williams Walsh, *Senators Investigate Hospital Purchasing*, NEW YORK TIMES, Aug. 14, 2009, at *1.

67. See GAO, *Group Purchasing Organizations—Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices*, Apr. 30, 2002.

68. *Id.* at 11 (showing that GPOs’ median price is higher for all safety needle models and for 60 percent of pacemaker models) [hereinafter *2002 GAO GPO Study*].

69. Michael Hiltzik, *Supply Middlemen May Leave Hospitals Ailing*, L.A. TIMES, Apr. 14, 2005, at B1.

70. Brendon Nafziger, *What’s the verdict on GPO savings?*, DOTMEDBUSINESS NEWS, March 2011.

71. Hal J. Singer, *The Budgetary Impact of Eliminating the GPOs’ Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act* (2006).

federal government relating to Medicare reporting problems; relative to direct payment of rebates by manufacturers, hospitals tend not to credit indirect, lump-sum payments of rebates from GPOs to individual medical device purchases on their cost reports. That study made no attempt to quantify the anticompetitive impact on medical supply prices attributable to the GPO safe harbor. A subsequent study by Litan and Singer (2010) analyzed a database of approximately 8,100 aftermarket transactions, in which the winning GPO price was put up for bid by a broker (whose compensation was *not* tied to auction proceeds) after the initial GPO auction.⁷² They found that hospitals were able to achieve average savings of approximately 10 to 14 percent across the entire database (2001 through 2010) and a savings of 15 percent on average for 2010 data, suggesting that GPOs are not securing the best prices for their members.

In sum, economic theory and empirical evidence suggests that intermediaries who are compensated by suppliers lack the incentive to secure the best prices for hospitals (GPOs) or for physicians (PBGs). After all, lower prices mean lower fees. Most problematic are PBGs that broker exclusively on behalf of a single manufacturer. It is there that the incentive to subvert the interest of physicians to suppliers is most pronounced.

IV. THE LEGAL TEST TO ANALYZE BUNDLED REBATES

The legal framework governing the use of bundled discounting by dominant firms differs substantially from the antitrust laws on single-product predatory pricing. When only one product is involved, an incumbent firm can undercut an equally efficient rival only by setting prices below its own (variable) costs, implying that even a successful predatory strategy requires

72. Robert Litan & Hal J. Singer, Do Group Purchasing Organizations Achieve the Best Prices for Member Hospitals? An Empirical Analysis of Aftermarket Transactions, Working Paper, Oct. 2010.

immediate profit sacrifice in exchange for long-run recoupment. In the multi-product world of bundled discounts, however, a firm that is dominant in market *A* can potentially impair or exclude its rivals in another, more competitive market *B* without any profit sacrifice, by leveraging market power from *A* to achieve bundled offers that competitive rivals cannot match. Recognizing this distinction, courts have articulated cost-based tests designed to determine whether bundled rebates are anticompetitive. In this section, we describe the relationship between antitrust law and anticompetitive bundled discounts, and apply this framework to the pediatric vaccine market, specifically that for meningococcal vaccines.

A. Background

The issue of when the antitrust laws should regulate the use of bundled discounting by dominant firms has received an immense amount of attention. In *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, the Supreme Court ruled that in a single-product predatory pricing case, plaintiffs must prove that the defendant has priced the product at issue below an appropriate economic measure of cost and that the defendant has “a reasonable prospect, or under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices.”⁷³ Although some have argued that this test should be applied to bundled discounts—that is, for a bundle to be anticompetitive, the total price charged for all of the goods in the bundle is below the aggregate cost of producing all of the them (“total bundle predation standard”)—two significant appellate court decisions have rejected this approach.

In *Le Page’s Inc. v 3M*, the Third Circuit Court of Appeals concluded that the predatory pricing test articulated in *Brooke Group* did not necessarily apply to any conduct but single-product

73. *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222, 224 (1993).

predation.⁷⁴ Using a rule-of-reason approach, the Court found that the loyalty discounts in question were bereft of offsetting efficiencies, and were sufficient in magnitude to harm competition by forcing foreclosed rivals to sacrifice significant scale economies.⁷⁵

In *Cascade Health Solutions v. PeaceHealth*, the Ninth Circuit Court of Appeals rejected the argument that *Brooke Group*'s recoupment requirement applied in bundling cases, citing a substantial body of economic literature demonstrating that anticompetitive bundling can immediately increase a monopolist's profits and requires no profit sacrifice.⁷⁶ The Ninth Circuit went on to articulate the following cost-based test:

[A] plaintiff who challenges a package discount as anticompetitive must prove that, when the full amount of the discounts given by the defendant is allocated to the competitive product or products, the resulting price of the competitive product or products is below the defendant's incremental cost to produce them.⁷⁷

Under this standard, known as the *Cascade* test, a bundled discounting arrangement is anticompetitive when a firm who has monopoly power in one market, but faces competition in an adjacent market, sets the price of the bundle such that a hypothetical equally efficient rival in the competitive market would not be able to compensate consumers for breaking the bundle. In other words, rather than a total-bundle predation standard, the *Cascade* test turns on whether the bundle would foreclose a single product rival attempting to compete with the dominant firm in any single product market.

74. *LePage's Inc. v. 3M*, 324 F.3d 141, 151 (3d Cir. 2003) (en banc).

75. *Id.* at 159-64.

76. *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 910, n.21 (9th Cir. 2008) ("We do not believe that the recoupment requirement from single product cases translates to multi-product discounting cases. Single-product predatory pricing, unlike bundling, necessarily involves a loss for the defendant...By contrast, as discussed above, exclusionary bundling does not necessarily involve any loss of profits for the bundled discounter.").

77. *Id.* at 910.

The legal test for evaluating a bundle has been incorporated in part in the economics literature. For example, Professor Nalebuff defined exclusionary bundling as follows: “Under exclusionary bundling, a firm with market power in good *A* and facing actual or (potential) competition in good *B* prices an *A-B* bundle in a way that makes it impossible for equally-efficient one-good rivals selling *B* to compete.”⁷⁸

Despite these judicial trends, in a 2009 *Harvard Law Review* article Professor Elhauge asserted that cost-based tests such as *Cascade* are ultimately inconsistent with two Supreme Court cases that are the standing law on bundling.⁷⁹ Instead of these tests, Professor Elhauge advocates a two-pronged approach to the antitrust treatment of bundling arrangements. If the product over which the firm has market power is sold on a standalone basis at a price above its price but for the bundling arrangement (also known as the independent monopoly price, or the but-for price), then, absent offsetting efficiencies, the bundling arrangement should be deemed anticompetitive based on a rule-of-reason review as long as plaintiffs can prove that the defendant has market power over the product sold on a standalone basis.⁸⁰ If, however, the price of the standalone product does not exceed its but-for price, then the bundling arrangement “should be condemned

78. Barry Nalebuff, *Exclusionary Bundling*, 50 ANTITRUST BULL. 321 (2005) [hereinafter *Exclusionary Bundling*].

79. Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARVARD L. REV. 397, 465 (2009) [hereinafter *Elhauge Tying*] (“Any cost-based test also seems inconsistent with various other Supreme Court cases. In *United Shoe Machine Corp. v. United States*, the Court condemned bundled discounts that (along with other contractual clauses) had the “practical effect” of a tie, without requiring any evidence that they resulted in a bundled or effective price that was below cost. In *Loew’s*, the Court held that an injunction against a firm that engaged in illegal bundling should prohibit bundled discounts that either had the effect of imposing a tying condition or exceeded any efficiency gains created by the bundling, without requiring any evidence that the bundled discounts resulted in a bundled or effective price that was below cost. Although injunctive remedies can extend beyond illegal conduct, the Court would have designed its remedy to avoid interfering with any bundled discounts it deemed procompetitive. *Loew’s* thus implicitly holds that not all bundled discounts that result in bundled or effective prices above cost are procompetitive or merit safe harbor. This holding conflicts with the logic of the cost-based tests, which conclude precisely the opposite.”).

80. *Id.* at 403 (“Thus, when the unbundled price exceeds the but-for price, bundled discounts should be treated like ties, which means they should be condemned based on market power absent offsetting efficiencies.”)

only if a substantial foreclosure share or effect is proven.”⁸¹ Professor Elhauge also contends that because economic theory indicates that monopoly leveraging requires a profit sacrifice if the products in the bundle (a) are sold in a fixed ratio, and (b) lack separate utility; in this instance, the law should also require plaintiffs to prove substantial foreclosure share or effect.⁸²

Although the *Cascade* test is a cost-based test, its economic ramifications are quite different from the sort of single-product predatory-pricing test that the Supreme Court adopted in *Brooke Group LTD v. Brown & Williamson Tobacco Corporation*.⁸³ In the case of single-product price predation, the predator attempts to protect or expand its monopoly over the product in question by cutting the price of the product below the cost necessary for a rival to remain in business. The predator actually incurs losses until its rivals are driven out of business, at which point it attempts to make up for its losses through monopolistic price increases (called “recoupment”). In contrast, economic theory has demonstrated that bundled-pricing arrangements may be exclusionary *without any profit sacrifice*.⁸⁴ The critical difference between the two forms of predation is that under a bundled-pricing scheme, the predator can sell the individual elements of the bundle at arbitrarily high standalone prices. Thus, what appears to be a discount to the buyer for purchasing a product as part of a bundle (as opposed to paying the arbitrarily high standalone price) is, in reality, a penalty for purchasing the standalone product relative to the profit-maximizing price of the monopolist in the absence of the bundle or tie. Rivals are placed at a

81. *Id.* at 403.

82. *Id.*

83. *Brooke Group LTD v. Brown & Williams Tobacco Corporation*, 509 U.S. 209 (2008).

84. See Patrick Greenlee, David Reitman & David S. Sibley, *An Antitrust Analysis of Bundled Loyalty Discounts*, 26 INT. J. IND. ORG. 1132, 1140 (2008) [hereinafter *Greenlee Bundling*] (“Our analysis [of bundling] also shows that the second prong either makes no sense or is vacuous—either there is no profit sacrifice or recoupment is instantaneous”); *Elhauge Tying, supra*, at 459 (2009) (“Thus, whether or not unbundled prices exceed but-for levels, bundled discounts need not require any short-term profit sacrifice or commitment by the bundler to achieve foreclosure share effects.”).

competitive disadvantage because the penalty price to buyers that break the bundle renders rival products relatively more expensive than the predator's. The predator is then able to increase the price of the bundled product above the competitive level *even though it still appears that there is a discount relative to the arbitrary penalty price*. In contrast, in the single-product situation, the predator cannot use monopoly power in one market to increase its power in an adjoining market. Thus, with single-product predation, the only way that the competitor can drive out equally efficient competitors is to set a price that is truly below its costs of production and continued sale.

In sum, the economic characteristics of bundled-pricing schemes differ markedly from single-product predatory pricing schemes. *First*, because there is no profit sacrifice with bundling, it is inappropriate to apply a recoupment requirement in the evaluation of a bundled-pricing case. *Second*, because the bundled-pricing schemes are immediately self-sustaining, they are much more likely to succeed than single-product predation, which involves sacrificing profits in the short run in the hope of making them back (and more) in the long run. *Third*, anticompetitive bundled pricing schemes are far more pernicious than single-product predation because supra-competitive prices persist in the competitive product for the entire duration of the bundling scheme. In single-product predatory pricing, consumers actually benefit during the predatory phase of the pricing scheme. No such benefits accrue to consumers in an anticompetitive bundled-pricing scheme, because, as discussed above, the relative prices of rivals' products increase immediately once the penalty price is established.

B. Applying the *Cascade* Framework to the Pediatric Vaccine Market

In this section, we apply the *Cascade* framework to the pediatric vaccine market by estimating the margin left over for an equally efficient standalone producer of a Meningitis vaccine that compensates a buyer for breaking the bundles imposed by Novartis's rivals. Stated differently, we estimate the forgone discount incurred by buyers who fail to comply with the contractual terms of Novartis's rivals, equal to the difference between the in-bundle price of competitors' vaccines and the out-of-bundle price. This amount is often referred to as the "imputed price" because it represents the maximum amount that a standalone producer of a Meningitis vaccine would be able to charge if it compensated buyers for the cost of purchasing the other components of rivals' bundles on a standalone basis. By increasing the stand-alone cost of the bundled products, incumbent vaccine producers such as Sanofi and GSK can reduce or eliminate the margin available to rival producers.

1. Existing Sanofi Bundles

Sanofi imposes contractual terms via PBGs that typically require at least 90 percent compliance on *all* products in the bundle to receive contractual discounts on *any* product. A PBG is required to maintain compliance at the contract level, and works with Sanofi to identify non-compliant buyers, who must demonstrate compliance based on the prior year's purchases of Sanofi's pediatric and adolescent vaccines. If buyers are non-compliant with respect to either Sanofi's pediatric vaccine purchases or its adolescent vaccine purchases, then they may forfeit discounts on all Sanofi vaccines contemplated by the contract and/or be removed from the contract.⁸⁵

85. As noted previously, Merck and Sanofi offerings have been coordinated to span the relevant line of pediatric vaccines through, e.g., PBG exclusivity arrangements. Thus, a buyer who defects from Sanofi is likely to

Although many of the details of PGB contracts are proprietary, more information is publicly available with respect to Sanofi’s “Tier 1” contracts, the terms of which form the primary basis of the detailed analysis below. Therefore, the analysis that follows combines general features of PGB contracts with specific details of Tier 1 contracts, providing a blended representation based on the available information for contractual terms faced by pediatric vaccine customers.

The analysis demonstrates that existing bundled pricing schedules for Sanofi vaccines impose substantial penalties relative to buyers electing to purchase vaccines without a contract. On a per-dosage basis, these penalties are particularly severe for buyers who are loyal to GSK. However, Sanofi’s pricing schedule also penalizes noncompliance even among buyers not fully committed to GSK *or* Sanofi. In this way, Sanofi is able to cultivate a degree of buyer loyalty even among nominally “Non-Loyalist” buyers, as documented in Section VI.

With respect to pediatric vaccines, 90 percent compliance is mandatory under both Sanofi’s Tier 1 contracts and under the PGB contracts that typically govern Sanofi vaccines. Sanofi’s Tier 1 contracts allow buyers to satisfy the compliance requirement by choosing between either (a) Sanofi’s pediatric combination vaccine, Pentacel, which combines Sanofi’s IPV, Dtap, and Hib vaccines into a single injection; or (b) specified combinations of the individual vaccine components of Pentacel. Compliance with Tier 1 also prohibits the purchase of GSK’s Dtap, HepB, and IPV vaccines.

For adolescent vaccines, PGB contracts governing Sanofi products focus primarily on vaccines for Tdap (Adacel) and Meningitis (Menactra). The compliance requirement for adolescent

forfeit discounts on Merck vaccines as well. However, to maintain conservative assumptions in the analysis below, we ignore any foregone discounts on Merck vaccines.

vaccines is straightforward, and requires a buyer to purchase at least 90 percent of its Tdap and Meningitis requirements from Sanofi.

The compliance requirement for infant vaccines is more complicated, and can be satisfied through one of two approaches. First, buyers may simply purchase Pentacel (which combines Sanofi's IPV, Dtap, and Hib vaccines). If the buyer chooses this route, then 100 percent of each infant vaccine regimen is procured from Sanofi.⁸⁶ Alternatively, buyers may purchase each component of the infant vaccine bundle on a stand-alone basis, maintaining a ratio of 1:1.25 between IPV and Dtap, and a ratio of 3:1 between Hib vaccines from Sanofi versus other manufacturers. In practice, compliance under the stand-alone approach requires purchasing 100 percent of stand-alone IPV and Dtap vaccines from Sanofi, and at least 75 percent of Hib vaccines from Sanofi, giving Sanofi at least a 92 percent overall share in component pediatric vaccines.⁸⁷ In this way, the 90 percent compliance threshold is maintained for Sanofi's pediatric vaccines, regardless of whether buyers choose to purchase the combination vaccine or stand-alone components.

Buyers who fail to adhere to these compliance requirements are subject to higher prices for Sanofi's vaccines. In particular, a buyer wishing to purchase Meningitis vaccines from a non-Sanofi source runs the risk of sacrificing not just the bundled discounts on Menactra, but also the discounts on all of Sanofi's pediatric and adolescent vaccines.

86. Given that Tier 1 buyers are contractually prohibited from purchasing GSK's Dtap and IPV vaccines, it would, in practice, be impossible for buyers to fulfill, say, 90 percent of their needs with Pentacel, and the other 10 percent with some Pentacel-equivalent product: With GSK's Dtap and IPV products off limits, there is no Pentacel-equivalent product on the market.

87. Purchasers of component vaccines require four IPV doses and five DtaP doses per patient. (IPV is administered on a four-dose schedule, at 2,4,6, and 12-18 months; Dtap is administered on a five-dose schedule, at 2,4,6,15-18, and 48-72 months). Monovalent Polio is available only from Sanofi, so sales of IPOL represent 100 percent of the inactivated polio component vaccine sold. Therefore, keeping the ratio of IPV:Dtap at 1:1.25 means that nine out of nine out of nine doses of IPV/DtaP are purchased from Sanofi. Given that three out of four Hib vaccines must also be purchased from Sanofi, its overall component share is equal to $(9 + 3)/(9 + 4) = 92$ percent.

To illustrate, in Table III we compute the forgone discounts associated with non-compliance for a hypothetical Sanofi customer, who is contemplating switching from Sanofi's Menactra to Novartis' Menveo for its Meningitis vaccine needs. The most straightforward analysis involves a comparison between Sanofi's contract prices and list prices, under the assumption that the buyer initially desires to purchase Pentacel, Adacel, and Menactra.⁸⁸ As seen in Table III, a buyer purchasing pursuant to Sanofi's Tier 1 contract may purchase Pentacel at a price of \$55.97 per dose, while the list price per dose of Pentacel is \$75.28.⁸⁹ Similarly, a Tier 1 buyer pays \$32.58 per dose of Adacel, compared with a list price of \$37.75. A non-compliant buyer purchasing at list prices therefore incurs a penalty of \$24.49 for each combined dose of Pentacel/Adacel. As seen in the Table, this represents an aggregate penalty equal to 27.7 percent of the compliant price of the Pentacel/Adacel bundle.

Under a Tier 1 contract, a buyer may purchase Menactra for \$96.37 per dose. A hypothetical equally efficient rival producer seeking to induce the buyer to break Sanofi's bundle and obtain the Meningitis vaccine from a competitor would need to compensate the buyer by at least the amount of the forgone discount. This could be accomplished by offering a discount on the Meningitis vaccine equal to the amount of the forgone discount on the bundled vaccine package. As seen in column (1) of Table III, the hypothetical rival could induce the buyer to "break the bundle" by charging a price per dose no greater than \$71.88 (a discount of 25 percent relative to Menactra's Tier 1 price). At any higher price, the buyer would lose more in forgone discounts than would be gained from switching.

88. Because they are reported on a uniform and consistent basis, and because they are available to any and all customers, list prices provide a useful baseline for the analysis here.

89. Vaccine prices reflect a one percent on-line order discount, a two percent prompt pay discount, and applicable federal tax.

TABLE III: NON-COMPLIANCE PENALTIES WITH SANOFI'S BUNDLED PRICING:
CONTRACT PRICES VS. LIST PRICES

	(1)	(2)	(3)
	Dollars Per Dose	Dollars Per Patient (Recommended Dosage)	Dollars Per Patient (Expected Dosage)
Pentacel Tier 1 Contract Price [1]	\$55.97	\$223.86	\$223.86
Pentacel List Price [2]	\$75.28	\$301.13	\$301.13
Adacel Tier 1 Contract Price [3]	\$32.58	\$32.58	\$23.47
Adacel List Price [4]	\$37.75	\$37.75	\$27.20
Penalty For Non-Compliance (Aggregate Tier 1 Discount) [5] = [2] - [1] + [4] - [3]	\$24.49	\$82.44	\$80.99
Aggregate Penalty % [6] = [5]/([1] + [3])	27.7%	32.1%	32.7%
Menactra Tier 1 Contract Price [7]	\$96.37	\$96.37	\$66.94
Maximum Rival MenACWY Price [8] = [7] - [5]	\$71.88	\$13.93	(\$14.05)

Source: Authors' calculations based on Sanofi contractual offers and list prices. Pricing effective as of January 2011.

Although the prices in column (1) of Table III are denominated in terms of dosages, in practice, the price per patient is likely more relevant to medical practitioners. This distinction would not affect the analysis if each patient required exactly one dose of each of the vaccines in the bundle. However, this is not the case: Pentacel is approved for administration as a 4 dose series (at 2, 4 and 6, and 15-18 months of age). In contrast, the adolescent vaccines contemplated above are administered only once per patient.⁹⁰ Furthermore, it is well established that adolescent immunization rates fall well short of infant immunization rates, which would tend to further skew demand in favor of Sanofi's tying products.

90. Note that any appearance of "fixed proportions" among vaccines would not implicate the "single monopoly profit theory," which has been used to argue that monopolists cannot increase profitability by leveraging market power from the tying market to the tied market. The classic example involves nuts and bolts: Because each product is useless without the other, having monopoly pricing power over both products should not yield incremental profits, relative to a monopoly over only one of the two. Antitrust scholars have shown that the single monopoly profit theory is valid only under restrictive assumptions that do not apply here. Pediatric and adolescent vaccines are conceptually distinct from nuts and bolts. For example, being vaccinated against polio creates value for an infant (and society), independent of whether the patient later receives a Meningitis vaccine in adolescence. See *Elhauge Tying* at 399-417.

Columns (2) and (3) of Table III take these additional factors into account. Specifically, column (2) computes the price per patient under the assumption that each patient receives the recommended dosages of the vaccines in question. Thus, the price of Pentacel is multiplied by four, while the adolescent vaccine prices remain unchanged. As seen in Table III, the per-patient penalty of non-compliance is \$82.44—significantly higher than in column (1). Thus, a hypothetical rival could induce the buyer to break the bundle only by charging a price per patient no greater than \$13.93 (a discount of 86 percent relative to Menactra’s list price).

The per-patient metrics in column (2) are based on the assumption that every patient adheres precisely to the officially recommended immunization schedules—or at least that adherence does not vary significantly across age groups. But this assumption is inconsistent with the fact that pediatric vaccine coverage rates are significantly higher than adolescent rates of vaccination. Column (3) accounts for this heterogeneity in compliance rates by constructing prices based on the expected value across patients.

Average coverage rates for the pediatric vaccines comprising Pentacel are estimated at approximately 77.2 percent.⁹¹ In contrast, coverage rates for the relevant adolescent vaccines are just over 50 percent.⁹² Using these observed coverage rates, the per-patient prices in column (3)

91. Based on average U.S. pediatric coverage rates for Dtap (≥ 4 doses), Polio (≥ 3 doses), and Hib (≥ 3 or ≥ 4 doses, depending on brand, including primary series plus booster dose). CDC, *National Immunization Survey, (Children 19-35 Months)* (Jan. – Dec. 2009), available at: <http://www.cdc.gov/vaccines/stats-surv/nis/default.htm#nis>

92. The estimated adolescent coverage rate for MenACWY (≥ 1 dose) is 53.6 percent; the estimated coverage rate for Tdap (≥ 1 dose since age ten) is 55.6 percent. Note also that adolescent coverage rates for Td or Tdap are significantly higher (76.2 percent nationwide), as many adolescents have received a dose of dose of tetanus toxoid-diphtheria vaccine (Td), but have not been vaccinated against pertussis, which remains relatively “poorly controlled” in the US. Since 2005, the ACIP recommendations have called for vaccination with tetanus toxoid, reduced diphtheria toxoid and acellular pertussis—that is, Tdap rather than Td—for both adolescents and adults to improve immunity against pertussis. See CDC, *National Immunization Survey (Adolescents/Teens 13-17 years)* (Jan. – Dec. 2009), available at: http://www.cdc.gov/vaccines/stats-surv/nisteen/data/tables_2009.htm#overall; see also CDC, *Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap)*

of Table III are adjusted to account for the frequency of pediatric vaccinations relative to adolescent vaccinations. As seen in Table III, the calculation in column (3) is normalized to the pediatric vaccines, such that the price of Pentacel remains unchanged relative to column (2). However, in the case of adolescent vaccines, the *expected* price per patient (column (3)) is substantially below the per-patient price based on the *recommended* dosage (column (2)).⁹³

As a consequence, the penalty for noncompliance now exceeds the expected price per patient of Menactra, and there is *no positive price* at which a hypothetical rival could induce the buyer to break the bundle: Even if a competitive entrant were to give away Meningitis vaccines for free, buyers defecting from Menactra would still lose \$14.05 per patient in expected value. Because Sanofi's avoidable cost of producing and distributing one unit of Menactra (including its variable costs plus some allocation of fixed costs that are not sunk, such as recurring R&D), is necessarily positive, such a bundle would be considered anticompetitive under the *Cascade* standard.

These findings are difficult to square with efficiency-based explanations for bundling. First, it is doubtful that bundles of this nature would lead to significant efficiencies in the production process, which should be invariant to whether or not vaccines are bundled together. Put differently, although it is quite likely that manufacturing efficiencies are derived from the *physical* combination of vaccines, as in Pentacel, it is unlikely that *contractual* bundles of, say, Pentacel, Adacel, and Menactra are any more efficient to manufacture than the individual components. Furthermore, given that vaccine production is characterized by high fixed costs and

Vaccine from the Advisory Committee on Immunization Practices, 2010 (January 14, 2011), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w (“Despite sustained high coverage for childhood pertussis vaccination, pertussis remains poorly controlled in the United States.”)

93. For example, the Menactra Tier 1 contract price is multiplied by the ratio of the MenACWY coverage rate (53.6 percent) to the estimated Pentacel coverage rate (77.2 percent). Thus, the Menactra Tier 1 contract price per representative patient, in column (3), is approximately 30 percent below the Menactra Tier 1 contract price based on recommended per-patient dosages, in column (2).

low marginal costs, it is unlikely that the penalties reflected in Table III could be justified based on purported bundle-driven cost savings, which would presumably apply only to marginal costs (such as potential supply chain efficiencies, or potential savings in selling and marketing expenditures).

Some buyers purchase pursuant to “VaxMax,” Sanofi’s online purchasing service. VaxMax allows some buyers purchasing sufficiently large quantities to avoid paying the full penalty price for the tying products. VaxMax pricing imposes compliance requirements at the level of the transaction, with discounts dependant on both the volume of doses per vaccine product and the breadth of vaccine products in the transactional bundle. The high volume requirements of the VaxMax offers would appeal primarily to large group practices and Integrated Health Networks. For example, a buyer would have to spend over \$38,000 on a single order of Pentacel and Adacel to qualify for the maximum volume-based incentives under VaxMax.

Importantly, although any buyer may purchase through the VaxMax system, in order to obtain the full degree of protection against paying the penalty price, buyers must purchase pursuant to an approved buying group, such as an approved PBG, which, as noted above, typically requires at least 90 percent compliance on a bundle of pediatric and adolescent products in order to qualify for membership. These compliant buyers are eligible for rebates that are calculated as a percentage of the aggregate dollar value of all vaccine purchases (and hence are not directly attributable to any single product). Failure to adhere to the compliance requirements of PBGs (or other buying groups) risks forfeiture of these discounts relative to the penalty price.

Because a VaxMax buyer can reduce per-dosage penalties only by opting to place orders for higher volumes of Sanofi brands, a broader package of Sanofi vaccines, or both, Sanofi’s pricing

schedule effectively penalizes “Non-Loyalist” buyers attempting to avoid paying the full penalty price for tying products by frequently switching from one buying group to another and/or maintaining memberships in multiple buying groups. Such cost-cutting strategies are likely to impose costs of their own, such as the administrative hassle and switching costs of juggling a relatively large number of PBG contractual arrangements over a relatively short period of time, as well as the risk that premature cancellation of a PBG contract, or violation of PBG exclusivity terms, may be grounds for discount forfeiture. By requiring large volume commitments to maximize discounts relative to penalty prices, the VaxMax pricing schedule (and the associated compliance rebates) impose additional costs on such “frequent switching” strategies.

In this way, Sanofi is able to cultivate buyer loyalty even among nominally “Non-Loyalist” buyers: As documented in Section VI, these buyers are significantly more likely to purchase from Sanofi.

2. Hypothetical GSK Bundles

Although GSK does not currently offer a Meningitis vaccine, the company has been developing a Meningococcal and Hib Combination Vaccine, MenHibrix, for years, and has been working to receive FDA approval for the candidate vaccine. If approved, MenHibrix might be administered in conjunction with the CDC’s standard Hib vaccination schedule, requiring no additional injections during first two years of life.⁹⁴ As such, GSK and Novartis are potential competitors in

94. See, e.g., “GlaxoSmithKline Receives Complete Response from FDA for Candidate Meningococcal and Hib Combination Vaccine,” GSK Press Release (June 2010) [hereinafter *GSK MenCY Press Release*], available at http://us.gsk.com/html/media-news/pressreleases/2010/2010_pressrelease_10054.htm

the future market for infant Meningitis vaccines.⁹⁵ Given GSK's existing suite of vaccine products, the introduction of MenHibrix would also open up new opportunities for GSK to impose penalties on buyers electing to purchase Meningococcal vaccines from competing suppliers in this market.

An example of the type of hypothetical compliance penalties that GSK could impose, based on GSK's current pricing schedule, is given in Table IV below. Consider a hypothetical buyer purchasing Pediarix (Dtap + HepB + IPV), and MenHibrix (Hib + MenCY) from GSK.⁹⁶ As seen below, GSK currently charges a price of \$47.59 per dose for Pediarix if buyers purchase at least five GSK brands.⁹⁷ The price that GSK would charge for compliant purchasers of MenHibrix is, of course, not known. However, the hypothetical price of the Hib component of MenHibrix can be estimated at \$15.75, based on GSK's in-bundle price for Hiberix. The hypothetical price of the MenCY component of MenHibrix is also unknown, as GSK does not currently offer a Meningococcal vaccine. Therefore, Table IV presents different hypothetical prices, as explained below. Under compliance, the buyer's hypothetical expenditures for the five-vaccine bundle (IPV + Dtap + HepB + Hib + MenCY) is equal to $(\$47.59 + \$15.75 + P_{hm})$, where P_{hm} is the hypothetical price of the MenCY component of the bundle.

Buyers electing to break the bundle and purchase Meningitis vaccines from another manufacturer would pay the non-compliant prices for Pediarix and Hiberix, GSK's stand-alone Hib vaccine. Of course, if the penalty prices are set too high—say, above the stand-alone prices that a rival

95. See, e.g., "Phase III Data Show That Novartis Meningococcal Vaccine Menveo Demonstrated Robust Immunogenicity in Infants," Novartis Press Release (October 2010), available at <http://www.novartis.com/newsroom/media-releases/en/2010/1454719.shtml>.

96. As noted above, MenHibrix contains the Men C and Y serotypes only.

97. Prices reflect Federal tax and a two percent prompt pay discount. Given that the hypothetical compliant buyer here purchases five vaccines from GSK (Dtab+HepB+IPV+Hib+MenCY), we apply GSK's five-brand discount in this example.

charges for the same vaccines—then buyers might abandon GSK altogether. Therefore, the Pediarix price per dose under non-compliance is estimated at \$70.47, equal to the sum of Sanofi’s list price per dose for IPV (\$24.68), Sanofi’s list price per dose for Dtap (\$23.03), and the list price for Recombivax, Merck’s HepB vaccine (\$22.75). Similarly, the non-compliant Hiberix price is set equal to Sanofi’s list price for Hib (\$23.60). Thus, the non-compliant buyer faces a total price for the four-vaccine bundle (IPV + Dtap + HepB + Hib) of $\$70.47 + \$23.60 = \$94.07$ per dose.

The maximum price that a rival Meningitis vaccine producer could charge is equal to the difference between (a) the price of the five-vaccine bundle (IPV + Dtap + Hib + HepB + MenCY) under compliance; and (b) the penalty price of the four-vaccine bundle (IPV + Dtap + HepB + Hib) that would be purchased from GSK under non-compliance. As illustrated in Table IV, this depends critically on the hypothetical price of the MenCY component of the MenHibrix bundle, P_{hm} : The lower is P_{hm} , the lower the price that the rival Meningitis vaccine producer could charge. For instance, if GSK set $P_{hm} = \$96.37$ —equal to Sanofi’s Tier 1 contract price of Menactra—the maximum price that a rival could charge would be \$65.63 per dose. But in theory, there would be nothing to prevent GSK from lowering P_{hm} much further. In particular, if the MenCY component price per dose is lowered to \$30.73, there is no margin whatsoever left over. As a consequence, an otherwise indifferent buyer could not be induced to switch to a competitive provider of Meningococcal vaccines at *any* price.

TABLE IV: HYPOTHETICAL NON-COMPLIANCE PENALTIES WITH GSK'S MENHIBRIX

	Dollars Per Dose	
	$P_{hm=High}$	$P_{hm=Low}$
Pediarix (Dtap+HepB+IPV) Compliant Price [1]	\$47.59	\$47.59
Hypothetical MenHibrix Compliant Price (Hib Component) [2]	\$15.75	\$15.75
Hypothetical MenHibrix Compliant Price (MenCY component)= P_{hm} [3]	\$96.37	\$30.73
Hypothetical Bundle Expenditure (Dtap+HepB+IPV+Hib+MenCY) Under Compliance [4] = [1] + [2] + [3]	\$159.70	\$94.07
Hypothetical Non-Compliant Price (Dtap+HepB+IPV) [5]	\$70.47	\$70.47
Hypothetical Non-Compliant Price (Hib) [6]	\$23.60	\$23.60
Hypothetical (Dtap+HepB+IPV+Hib) Expenditure Under Non-Compliance [7] = [5] + [6]	\$94.07	\$94.07
Hypothetical Max Rival MenACWY Price [8] = [4] - [7]	\$65.63	\$0.00
	Dollars Per Patient (Recommended Dosage)	
	$P_{hm=High}$	$P_{hm=Low}$
Pediarix (Dtap+HepB+IPV) Compliant Price [1]	\$142.76	\$142.76
Hypothetical MenHibrix Compliant Price (Hib Component) [2]	\$62.98	\$62.98
Hypothetical MenHibrix Compliant Price (MenCY component)= P_{hm} [3]	\$385.48	\$100.06
Hypothetical Bundle Expenditure (Dtap+HepB+IPV+Hib+MenCY) Under Compliance [4] = [1] + [2] + [3]	\$591.22	\$305.80
Hypothetical Non-Compliant Price (Dtap+HepB+IPV) [5]	\$211.40	\$211.40
Hypothetical Non-Compliant Price (Hib) [6]	\$94.39	\$94.39
Hypothetical (Dtap+HepB+IPV+Hib) Expenditure Under Non-Compliance [7] = [5] + [6]	\$305.80	\$305.80
Hypothetical Max Rival MenACWY Price [8] = [4] - [7]	\$285.42	\$0.00

Source: Authors' calculations based on GSK and Sanofi contractual offers and list prices. Pricing effective as of January 2011.

As before, it is also important to perform the calculation in terms of dollars per patient (based on recommended dosages). Pediarix is approved as a three-dose series,⁹⁸ while the proposed indication for MenHibrix is a four-dose series.⁹⁹ Therefore, in the second set of calculations, the Pediarix per-dosage prices are multiplied by three, to arrive at the recommended price per patient: The compliant price for Pediarix is $\$47.59 \times 3 = \142.76 ; the non-compliant price is $\$70.47 \times 3 = \211.40 . Correspondingly each of the relevant MenCY and Hib prices are multiplied by four. For example, the price per patient of the Hib component becomes (approximately) \$63, equal to the cost of four individual Hib doses priced at \$15.75 each.¹⁰⁰

As seen in Table IV, if the MenCY component is priced at priced at \$100.06 per patient, or about \$25 per dose, then, as before, an otherwise indifferent buyer could not be induced to switch to a competitive provider of Meningococcal vaccines at *any* price. Notably, GSK has already signaled that it may be considering a pricing strategy of this nature for MenHibrix, in the form of a price of \$20 or less per dose for the MenCY component.¹⁰¹

Thus, GSK, through adjustments to the price of MenHibrix, could make it difficult or impossible for a rival producer of a Meningitis vaccines to induce substitution, regardless of any competitive price cuts by the entrant. Because the avoidable cost of producing and distributing one unit of

98. See, e.g., <http://www.cdc.gov/vaccines/vpd-vac/combo-vaccines/pediarix/faqs-hcp-pediarix.htm>.

99. GSK MenCY Press Release, *supra*. (“The proposed indication for this combination vaccine is immunization of infants and toddlers against meningococcal serogroups C & Y, and Haemophilus influenzae type b (Hib) diseases at two, four, six and 12-15 months of age.”)

100. Totals may differ slightly due to rounding issues arising from the two percent prompt pay discount (noted previously).

101. CDC, *Advisory Committee on Immunization Practices: Summary Report* (February 2010), available at <http://www.cdc.gov/vaccines/recs/acip/downloads/min-feb10.pdf>, at 126-133. Although an ACIP gathering obviously does not constitute a forum for binding commitments with respect to the price of future vaccine offerings, according to the minutes of the meeting, GSK’s representative appeared to acknowledge “health outcomes data” suggesting that “[t]he incremental cost of HibMenCY over monovalent Hib vaccine would have to be under \$20,” and stated that the vaccine “will be priced at an appropriate value.”

GSK's Meningitis vaccine would necessarily be positive, a bundle that foreclosed competitive rivals at any positive price would be considered anticompetitive under the *Cascade* standard.

V. THE ECONOMIC TEST TO ANALYZE BUNDLED REBATES

Even when the discount-allocation test from *Cascade* is not triggered, bundled discounts can be an effective anticompetitive mechanism for leveraging market power. For this reason, the economic test to determine when a bundle is anticompetitive differs from the legal test. In this section, we describe this economic test, and demonstrate empirically that pricing behavior by incumbents in the pediatric vaccine market is consistent with the anticompetitive hypothesis, using benchmarks derived from cross-sectional data.

Recent scholarship demonstrates that cost-based tests such as the discount attribution standard may fail to properly classify a given bundled pricing scheme as anticompetitive.¹⁰² Specifically, if the incumbent sets an unbundled penalty price that exceeds the independent monopoly price (IMP)—defined as the stand-alone profit-maximizing price of the tying product—then bundled discounts can produce anticompetitive effects, and consumer welfare is reduced. In contrast, if the incumbent selects a penalty price that does not exceed the IMP, then the bundle may actually

102. See *Elhauge Tying*, *supra*, at 402-403. Elhauge compares this standard with other standards based on (1) cost-based tests (such as *Cascade*); (2) tests based on the proportion of buyers accepting the bundle; and (3) tests based on comparisons between the penalty price and the price charged by the defendant in the tying market before the bundled pricing scheme. With respect to (1), cost-based tests do not account for the anticompetitive harm that results when the defendant successfully prevents rivals from realizing economies of scale; moreover, an equally-efficient competitor standard, such as *Cascade*, ignores the fact that even less efficient rivals can still discipline the pricing of a more-efficient incumbent. With respect to (2), the fact that some fraction of buyers may choose to purchase outside the bundle does not demonstrate the absence of harm, because successful anticompetitive bundled pricing schemes raise market-wide prices to all buyers. With respect to (3), such comparisons assume that cost and demand conditions remain constant before and after the bundle is implemented; moreover, such a test would create an obvious loophole wherein a defendant could artificially elevate its price level shortly before implementing the bundled pricing regime.

be welfare-enhancing for consumers, although it is unlikely to be profit-maximizing for firms.¹⁰³ In either case, prices in both the tying and tied markets will generally exceed marginal costs.¹⁰⁴ Thus, a finding of consumer harm turns not on the outcome of a cost-based test, but rather on whether the incumbent sets a penalty price in the tying market that would be inconsistent with profit-maximization in that market alone.

Anticompetitive bundled discounts stifle competition in the tied market by curtailing competing firms' ability to impose price discipline. Under competitive conditions, the incumbent would be obligated to compete more vigorously on price in the tied market, because a competitive supplier of the tied product can induce substitution away from the incumbent by dropping its own prices. In contrast, an incumbent that engages in anticompetitive bundled discounting can nullify any rival price cuts simply by raising the penalty price of the tying product, thus discouraging consumers from switching suppliers. In this scenario, it makes little sense for the competitive provider to attempt to lure customers away by dropping its price, as any attempt to do so would be self-defeating.¹⁰⁵ Indeed, this is consistent with the fact that Meningitis vaccine prices have actually risen since Menveo was introduced.

Although the penalty price is typically known to all market participants, the IMP is not directly observable. For example, we cannot observe the amount that Sanofi would charge for its vaccines in the tying market if it did not bundle its products. Instead, at any given point in time, we can observe the amount that Sanofi charges to compliant buyers, as well as the (higher) price

103. For this reason, firms are more likely to choose a penalty price that exceeds the IMP, particularly if prices are set in an unconstrained environment. However, the prospect of antitrust scrutiny might conceivably induce a firm to choose a penalty price at or below the IMP, despite the fact that doing so would generally not be profit maximizing. *Greenlee Bundling, supra*, 1136-38.

104. *Id.*

105. See *Elhauge Tying, supra*.

charged to those who refuse to purchase Menactra. Thus, to determine whether the economic test for an anticompetitive bundling is satisfied, an empirical estimate of the IMP is required. The benchmarks we examine are based on cross-sectional comparisons of pricing behavior across different incumbent manufacturers.¹⁰⁶

Specifically, we observe the amount that GSK charges for vaccines in the tying market, and compare that to Sanofi's prices for an equivalent set of vaccines. Because GSK does not currently produce any vaccines in the tied market, GSK lacks an incentive to charge anything other than the IMP in the tying market. Of course, GSK does offer bundled discounts in the tying market (by offering lower prices to buyers opting to purchase multiple brands). However, because GSK's current offerings do not span the tied market, it is reasonable to assume that GSK's pricing schedule is designed to maximize profits in the tying market alone.¹⁰⁷ Stated differently, if Sanofi did not produce Menactra, it would presumably maximize profits in the tying markets by charging more or less the same prices as GSK for equivalent vaccines. Therefore, GSK's prices in the tying market yield a plausible benchmark for the IMP.

Because economic theory predicts that bundling will generally be harmful to consumers unless Sanofi sets a penalty price that does not exceed the IMP, the economic test for anticompetitive bundled discounts in the market for meningitis vaccines can be applied simply by comparing the IMP implied by GSK's existing pricing structure to Sanofi's penalty price structure. If the former

106. One alternative approach would be to obtain an econometric estimate of the IMP. *See Elhauge Tying, supra*, at 469 (“regression analysis or economic models may yield good results on the but-for price.”) Unfortunately, data limitations in this market preclude this approach. For example, although the CDC publishes separate public and private sector prices, there is no comparable data available on public versus private sector quantities. This makes it infeasible to econometrically estimate the elasticity of the private quantity demanded with respect to the private sector price for a given vaccine in the tying market.

107. GSK does, of course, offer bundled discounts to buyers who purchase a broader set of vaccines—as evidenced by the fact that GSK charges both compliant prices and penalty prices. In any case, what matters is that, because GSK does not supply the tied product, its incentives should be to maximize profits on its vaccine portfolio in the tying markets by charging profit-maximizing prices to its customers for the vaccines that it offers.

is less than the latter, this implies that buyers refusing to comply with the terms of Sanofi's contracts are charged a penalty price in excess of the IMP.

Table V summarizes Sanofi and GSK's vaccine prices for compliant and non-compliant buyers. In Table V, for any given vaccine, and for any given level of compliance, GSK's prices are extremely close to Sanofi's prices. If GSK chooses prices to maximize profits in the tying market, then the IMP for each vaccine should lie somewhere between the compliant price and the non-compliant price. Moreover, because the majority of purchases are made by compliant buyers, the IMP should lie closer to the compliant price than to the list price. Thus, according to this benchmark, Sanofi's penalty price exceeds the IMP for each of the vaccine combinations listed.¹⁰⁸

TABLE V: GSK VS. SANOFI PRICES IN THE TYING MARKET

	GSK Compliant Price	Sanofi Compliant Price	GSK Penalty Price	Sanofi Penalty Price
IPV + Dtap + Hib	\$49.74	\$55.97	\$68.83	\$75.28
IPV + Dtap	\$34.00	\$35.65	\$46.66	\$47.72
Hib + Dtap	\$30.88	\$31.60	\$42.57	\$45.05
Hib	\$15.75	\$16.28	\$22.17	\$23.60

Source: GSK and Sanofi contractual offers and list prices. Pricing effective as of January 2011.

108. For example, the IMP for (IPV + Dtap + Hib) should be closer to \$49.74 than to \$68.83. But Sanofi's penalty price is \$75.28, which implies that the penalty price exceeds the IMP.

VI. EMPIRICAL EVIDENCE OF FORECLOSURE

If successful, anticompetitive bundled discounts foreclose rivals from significant segments of the marketplace, by impairing their ability to compete effectively for customers bound by exclusionary contracting and bundling practices. In this section, we analyze data on rival penetration rates, and show that they are consistent with the hypothesis that incumbent manufacturers have induced significant foreclosure of rivals from the relevant segments of the MenACWY vaccine market. In addition, the data imply that the share of the private market foreclosed by Sanofi's bundling practices is substantial (at least 70 percent), and therefore significantly exceeds the threshold foreclosure share that antitrust scholars associate with anticompetitive effects (20 percent).

A. Analysis of Rival Penetration Rates

As noted above, Sanofi's bundled contracts impose concrete penalties on buyers electing to purchase MenACWY vaccines from rivals. In contrast, GSK's ability to engage in similar practices is currently only hypothetical, given that regulatory approval of MenHibrix is still pending.

Under the hypothesis that bundled contracts are in fact exclusionary, one would expect to observe lower levels of rival MenACWY penetration among Sanofi-loyal customers than among GSK-loyal customers, because Sanofi-loyal customers incur higher costs when switching to a rival supplier. In addition, as noted above, Sanofi's pricing schedule effectively penalizes Non-Loyalist buyers that attempt to switch back and forth between incumbent suppliers. Therefore, the foreclosure hypothesis also predicts that rival penetration among Non-Loyalist buyers should

be less than that of GSK-loyal buyers, yet still greater than penetration among Sanofi-loyal customers.

More formally, let R_G denote rival penetration among GSK-loyal buyers, and let R_S denote rival penetration among Sanofi-loyal buyers. Finally, let R_N represent rival penetration among Non-Loyalist buyers. The foreclosure hypothesis yields the following prediction: $R_G > R_N > R_S$.

To formally test the foreclosure hypothesis, we analyzed penetration patterns using publicly available data from standard industry sources (IMS) spanning a large sample of 18,661 accounts. The accounts in the sample represent actual and potential purchasers of Menveo, such as hospitals, clinics, and (most frequently) pediatric practices. All accounts in our sample were targets of Novartis' sales and marketing efforts in the private market for Menveo during the year 2010. Thus, the dataset consists of a large subset of private vaccine buyers viewed by Novartis as most likely to purchase Menveo.

Unlike other vaccine manufacturers, Sanofi has not traditionally disclosed its direct purchase data to IMS. Therefore, a multi-step classification algorithm was used to determine whether a given account was likely a Sanofi-Loyalist, defined as a buyer relying primarily on Sanofi/Merck vaccines, and subject to the terms of Sanofi's compliance contracts. To be conservative, the classification algorithm requires that the account satisfies certain purchase-based screens (based on IMS data) before it can be classified as a Sanofi-Loyalist. As explained below, the screens are designed in a conservative fashion: First, the default is to err on the side of over-classifying accounts as GSK loyalists. This decreases the likelihood of accepting the hypothesis that $R_G > R_N > R_S$, because, if the foreclosure hypothesis is correct, then any over-classification would artificially deflate R_G , relative to its true value. Second, the algorithm also errs on the side

of classifying Non-Loyal accounts as Sanofi-Loyal, and Sanofi-Loyal accounts as Non-Loyal. This over-classification would tend to inflate R_S relative to R_N , again making it less likely that the foreclosure hypothesis would be accepted if it is true. On the other hand, if the null hypothesis ($R_G = R_N = R_S$) is true, then the likelihood of accepting the null hypothesis should not be affected by reshuffling accounts from one classification to another.¹⁰⁹

The first screen in the classification algorithm determines whether the account in question should be classified as a GSK-Loyalist, defined as a buyer relying primarily on GSK for its private sector pediatric vaccine purchases. As a GSK-Loyalist, the buyer would not be expected to receive significant discounts on Sanofi products (including Menactra) relative to the full list price. Thus, in theory, this segment of the market should be the easiest for Menveo to penetrate (at least until MenHibrix is approved in the United States). Buyers are classified as GSK-Loyal if they are observed to purchase even a single dose of Pediarix (one of GSK's core franchise products). Buyers are also classified as GSK-Loyal if they purchase Boostrix, Kinrix, and Rotarix in conjunction (at least one dose of each), or if they purchase at least one dose of any two out of the three. Even if buyers are observed to purchase only one of these three GSK vaccines, buyers are still classified as GSK loyal as long as they purchase a sufficient quantity of Varicella vaccine.¹¹⁰ This classification is clearly conservative: First, it is likely to include some buyers who do not rely primarily on GSK vaccines. Second, it is very unlikely to exclude true GSK-

109. Of course, one could conceivably hypothesize that the true relationship involves a different set of inequalities, such as $R_G < R_N < R_S$ (although there is no apparent basis in theory for doing so). But note that any reshuffling between groups will tend to steer inequalities in the direction of equalities, generating bias towards accepting our null hypothesis: If $R_i > R_j$, but we accidentally classify some j as i , and vice-versa, this increases the likelihood of concluding that $R_i = R_j$ (unless the reshuffling is so extensive that it reverses the inequality, which is unlikely here).

110. To eliminate trivial, one-off transactions, for this analysis buyers are screened to a minimum of 40 doses of Varivax, Merck's Varicella vaccine. Varivax is universal, in the sense of being recommended for all children and manufactured by a single company, and therefore provides a proxy for the size/scale of a given account.

Loyalists. Thus, it increases the likelihood of accepting the null hypothesis that $R_G = R_N = R_S$, even if the foreclosure hypothesis is correct.

The second screen in the classification algorithm determines whether the account in question should be classified as Non-Loyalist, defined as a buyer that does not rely primarily on GSK or Sanofi for its private sector vaccine purchases. As a Non-Loyalist, the buyer would be expected to incur potentially smaller penalties on Sanofi products (including Menactra) relative to the full list price than a GSK-Loyalist, although penalties would still exceed those of Sanofi Loyalists. This is due to the fact, discussed above, that Sanofi's pricing is structured to cultivate a degree of loyalty even among nominally non-loyal buyers that attempt to toggle intermittently between different buying groups and incumbent suppliers.

To implement the second screen, IMS data were used to determine, on an account-by-account basis, the share of business accounted for by the public sector. Accounts with a sufficiently high proportion of public-sector purchases were classified as Non-Loyalist accounts, because these purchasers have relatively little to lose by switching between incumbents to fill their (relatively modest) private sector vaccine inventories. The proportion of public sector purchases was determined using IMS purchase volume data. Specifically, a buyer's purchases of Varivax were used to estimate its total demand across both the public and private sector.¹¹¹ IMS data on private sector purchases of another universal vaccine (Merck's MMR) were then used to estimate private sector demand for each account. One minus the ratio of MMR purchases to Varicella purchases

¹¹¹ The varicella vaccine is unique in that it must remain frozen during transportation, and is therefore drop-shipped directly to the purchaser, rather than first passing through a physical intermediary. As a consequence, IMS reports total varicella purchases by account, rather than private sector purchases only.

yields an estimate of the proportion of each account's vaccine needs accounted for by the public sector.

Accounts were classified as Non-Loyalist if more than 80 percent of their vaccine needs were estimated to be fulfilled through the public market. Finally, any accounts passing both the first and second screens were classified as Sanofi Loyalists.

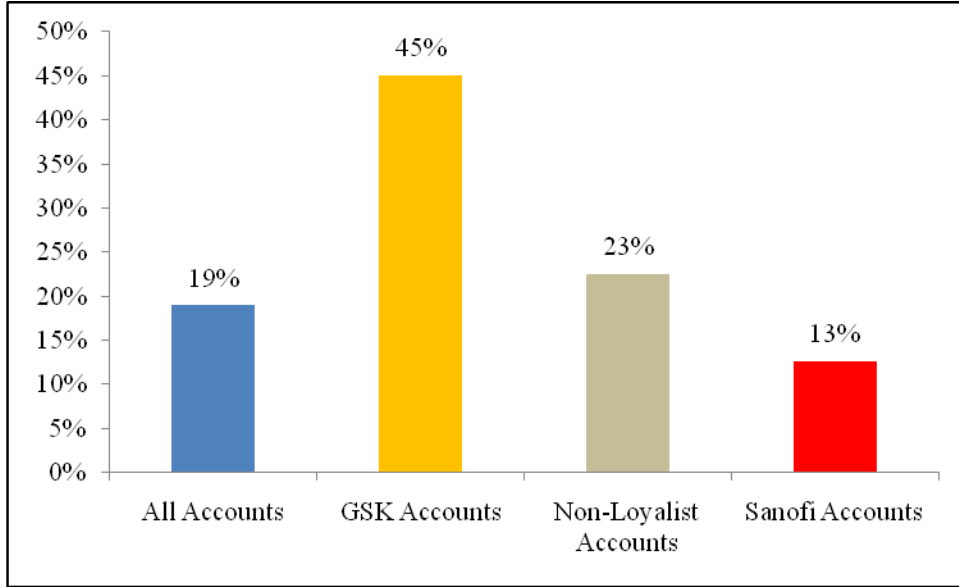
The second screen, like the first, is conservative. First, note that the second screen is likely to classify some Non-Loyal accounts as Sanofi-Loyal, because Non-Loyal buyers purchasing less than 80 percent of their vaccines in the public sector will be classified as such. The algorithm is also likely to classify some Sanofi-Loyal accounts as Non-Loyal, because Sanofi Loyalists purchasing more than 80 percent of their vaccines in the public sector will be classified as such. As noted above, this reshuffling of loyalists decreases the likelihood of accepting the foreclosure hypothesis that $R_G > R_N > R_S$, and increases the likelihood of accepting the null hypothesis that $R_G = R_N = R_S$.

Figure IV shows the relative penetration rates according to the three definitions of buyer loyalty discussed above. Here, an account is defined as penetrated if the buyer purchased Menveo during the year 2010. In Figure IV, the data are consistent with the hypothesis that Sanofi's contractual terms successfully impair rivals by significantly decreasing the probability of converting a buyer to rival Meningitis vaccines. Specifically, only 13 percent of targeted Sanofi accounts purchased Menveo even once, compared with approximately 45 percent of GSK-loyal accounts targeted, 23 percent of Non-Loyalist accounts, and 19 percent of accounts overall.¹¹² Thus, the data

112. Note that this pattern is unlikely to be explained by buyer preferences for dealing with fewer manufacturers and sales representatives. In particular, this would not explain why Non-Loyalist penetration is lower than GSK

suggest that buyers unencumbered by the Sanofi’s loyalty contracts are over three times as likely to purchase Menveo, relative to encumbered buyers—despite the fact that the Sanofi Loyalist accounts were selected into the sample based on perceived penetrability.

FIGURE IV: MENVEO PENETRATION BY ACCOUNT TYPE



Source: Account-level purchase data from IMS. All accounts in sample were targets of sales and marketing efforts for Menveo during the year 2010.

Using standard statistical techniques, we can formally test the hypothesis that $R_G > R_N > R_S$, starting from the null hypothesis that $R_G = R_N = R_S$ (which is consistent with zero foreclosure effects). The test statistic for the difference in two proportions is

$$z = \frac{p_1 - p_2}{\sqrt{\bar{p}(1 - \bar{p}) \left[\frac{1}{n_1} + \frac{1}{n_2} \right]}} \quad (1.1)$$

penetration, given that Non-Loyalists are likely to do business with multiple incumbent suppliers. Furthermore, if Menveo’s low penetration rates among Sanofi accounts were really driven by preferences for dealing with only one supplier, then there would be no need to impose stiff pricing penalties on buyers choosing to defect from Menactra, as they would continue to purchase Menactra even if there were no noncompliance penalty at all.

Above, p_1 and p_2 give the observed probabilities at the two comparison points, and \bar{p} gives the weighted average probability across the two comparison points. Finally n_1 and n_2 denote the sample size used to compute p_1 and p_2 .¹¹³

The results of the hypothesis tests are displayed in Table VI. In each case, the null hypothesis of equal underlying penetration rates is easily rejected at the one percent level of significance, and the alternative hypothesis is accepted. Thus, the account-level data are consistent with the foreclosure hypothesis, which posits that rival penetration at Sanofi accounts is significantly lower relative to rival penetration at GSK both accounts and non-loyalist accounts, and that rival penetration at GSK accounts is lower at non-loyalist accounts than at GSK accounts.

TABLE VI: TEST RESULTS FOR FORECLOSURE

H_0	H_a	p_1	p_2	z	$p > z $	Result
$R_G = R_S$	$R_G > R_S$	45%	13%	40.41	0.000	Accept H_a
$R_N = R_S$	$R_N > R_S$	23%	13%	13.11	0.000	Accept H_a
$R_G = R_N$	$R_G > R_N$	45%	23%	17.48	0.000	Accept H_a

B. Estimating Foreclosure Shares

From the perspective of competition analysis, the foreclosure share is an important statistic. In particular, antitrust scholars have concluded that foreclosure of 20 percent (or more) of the market constitutes a significant, presumptively anticompetitive foreclosure share because, in the

113. See RICHARD LARSEN & MORRIS MARX, AN INTRODUCTION TO MATHEMATICAL STATISTICS AND ITS APPLICATIONS 380 (Prentice-Hall 1986).

presence of economies of scale, the inability to effectively penetrate such a large portion of the market can inflate a rival's average costs.¹¹⁴

In this Section, we use the available data to estimate the extent to which incumbents have succeeded in foreclosing rivals in the private meningitis vaccine market. Foreclosure from private markets is likely to be especially significant in this industry, for at least three reasons. First, given the public/private pricing differentials discussed previously, foreclosure from the private market would have a disproportionate impact on an entrants' profitability even in the absence of economies of scale. Second, this effect is compounded because the vaccine industry is in fact characterized by substantial scale economies, which implies that entrants are disproportionately reliant on their ability to sell a sufficient quantity of vaccines at private sector prices to defray the high costs of production incurred on their inframarginal units. Thus, even if an entrant is able to achieve some scale economies in the public market, to extent it is reliant on relatively high-margin sales in the private sector to recoup its fixed costs and/or earn an economic rate of return, it would be unable to do so. Third, as noted previously, pediatric practices face strong incentives to stock the same vaccine brands for both their public and private sector patients. As a consequence, foreclosure from the private sector likely translates into effective foreclosure from the public sector as well.

The share of the private market that is foreclosed can be estimated simply as the share of the market comprised of Sanofi-Loyalists. The same account-level IMS data underlying Figure III

114. See PHILLIP AREEDA, IX ANTITRUST LAW 375, 377, 387 (Aspen 1991) (indicating that 20 percent foreclosure is presumptively anticompetitive); See also HERBERT HOVENKAMP, XI ANTITRUST LAW 152, 160 (indicating that 20 percent foreclosure and an HHI of 1800 is presumptively anticompetitive).

can be used to produce such an estimate. As shown in Table VII, these data indicate that Sanofi-loyalists represent approximately 71 percent of the private market, when measured by the number of accounts in the sample, and 80 percent when measured by purchase volumes (with private sector MMR vaccine purchases used to estimate private sector demand, as before). Both figures are, of course, well in excess of the presumptively anticompetitive threshold of 20 percent.

TABLE VII: PRIVATE SECTOR MENINGITIS VACCINE MARKET FORECLOSURE ESTIMATES

Market Segment	Account Type(s)	Freq. Share	Purchase Vol. Share
Foreclosed Segment	Sanofi-Loyalist	70.9%	79.7%
Non-Foreclosed Segment	(GSK-Loyalist + Non-Loyalist)	29.1%	20.3%
TOTAL	All Accounts	100.0%	100.0%

Source: Account-level private sector vaccine purchase data from IMS.

Finally, it bears emphasis that the data analyzed here consists of a selected sample of accounts that were targeted based on their perceived penetrability in the private market. Because Sanofi-loyalist accounts are likely to be perceived as less promising targets, the true proportion of Sanofi-Loyalist buyers—and the true share of the meningitis vaccine market that is foreclosed—could be even higher than what these data would suggest.

VII. CONCLUSION

We have evaluated bundled pediatric vaccine offerings in the United States under both a legal and an economic standard. With respect to the former, an analysis of actual contractual terms imposed by incumbent vaccine manufacturers indicates that single-product entrants attempting to penetrate the Meningitis vaccine market are placed at a significant competitive disadvantage by

incumbents' bundled-pricing schemes. Specifically, under existing contractual terms, even if a competitive entrant were to give away Meningitis vaccines for free, a buyer opting to defect would still incur losses, owing to the penalties associated with foregone discounts on the tying products.

With respect to the latter, analysis of pricing benchmarks derived from cross-sectional data suggests that standalone prices of the vaccines over which incumbents have significant market power could exceed the independent monopoly price, indicating potential harm to consumers. Furthermore, observed rival penetration rates suggest that incumbent manufacturers have induced significant foreclosure of rivals from the relevant market segments, and that foreclosure of the Meningitis vaccine market significantly exceeds the presumptively anticompetitive threshold.

In an industry served almost exclusively by large, multi-product incumbents, with no prospects for generic competition and extremely limited entry by competitive rivals of any kind, these findings have significant implications for public policy and antitrust enforcement. Given the high barriers to entry and expansion in pediatric vaccine markets, along with the compensation arrangements for physician buying groups, anticompetitive conduct may reduce consumer welfare substantially. First, such conduct may elevate prices, leading to reduced vaccination rates both in the private sector, which is directly affected by the conduct noted above, and in the public sector, whose prices are subject to spillover effects. Second, consumers would incur additional harm to the extent that anticompetitive conduct stifles investment and/or innovation in the industry, ultimately resulting in diminished manufacturing capacity, an increased likelihood of vaccine shortages, and a degradation in the quality, reliability, and availability of existing and future pediatric vaccines, relative to what would otherwise prevail.

APPENDIX I:
RECOMMENDED IMMUNIZATION SCHEDULE FOR PERSONS AGED ZERO THROUGH SIX YEARS

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years	
Hepatitis B ¹	HepB		HepB		<i>see footnote 1</i>	HepB							
Rotavirus ²				RV	RV	RV ²							
Diphtheria, Tetanus, Pertussis ³				DTaP	DTaP	DTaP	<i>see footnote 3</i>	DTaP				DTaP	
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	Hib ⁴		Hib					
Pneumococcal ⁵				PCV	PCV	PCV		PCV				PPSV	
Inactivated Poliovirus				IPV	IPV			IPV				IPV	
Influenza ⁶								Influenza (Yearly)					
Measles, Mumps, Rubella ⁷								MMR		<i>see footnote 7</i>		MMR	
Varicella ⁸								Varicella		<i>see footnote 8</i>		Varicella	
Hepatitis A ⁹								HepA (2 doses)				HepA Series	
Meningococcal ¹⁰												MCV	

 Range of recommended ages
 Certain high-risk groups

Source: CDC.