The American Antitrust Institute

November 22, 2011

Jonathan Leibowitz, Chairman
J. Thomas Rosch, Commissioner
Edith Ramirez, Commissioner
Julie Brill, Commissioner
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Via Electronic Delivery

Re: Potentially Exclusionary Bundled Discounts for Pediatric Vaccines

Dear Chairman Leibowitz and Commissioners Rosch, Ramirez, and Brill:

The American Antitrust Institute (AAI) has been active in supporting a strong response to threats to competition in healthcare, particularly exclusionary practices in the pharmaceutical industry that harm competition and consumers.[1] Yet another potential impediment to competition may be emerging. In this letter, we set forth the basis for the concern that certain bundled discounting practices in the market for important pediatric and teenage (henceforth "pediatric") vaccines may be anticompetitive. A number of recent cases (e.g., *LePage's Inc., v. 3M* and *FTC v. Intel*) have given antitrust authorities the opportunity to reflect on the correct analytical frameworks for evaluating the competitive effects of bundled discounts and market-share or volume discounts. Because vaccination has positive spillover effects on those that are not immunized, the harms resulting from exclusionary bundled discounts also extend to the general population. This highlights the integral role that competition policy plays in achieving broader public policy goals in healthcare.[2] As the lead antitrust agency in this area, the FTC is ideally positioned to probe bundled discounts involving vaccines to determine if further action is necessary.

[1] The AAI is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. AAI is managed by its Board of Directors, which alone has approved of this letter. For more information, see www.antitrustinstitute.org. Thanks to Graciela Miralles Murciego for helpful research

[2] Vaccine shortages also illustrate the relationship between competition and public policy in healthcare. *See, e.g.,* F. M. Scherer, *An Industrial Organization Perspective on the Influenza Vaccine Shortage*, 28 MANAGERIAL AND DECISION ECONOMICS 393 (2007).

The Importance of Pediatric Physician Practices and Vaccine Programs

Pediatric physicians provide vital medical services such as vaccination programs to children. Pediatricians' ability to access vaccines in the private sector at competitive prices and to adopt high quality and innovative products based on performance or clinical data is critically important. However, vaccines are the second largest cost component for pediatric practices and are not particularly profitable. Pro-competitive price discounts from vaccine manufacturers are important in reducing procurement costs, therefore making vaccination programs more economically viable and available on an ongoing basis.

It is unclear, however, whether the bundled discounting practiced by some of the large incumbent vaccine manufacturers achieves pro-competitive goals, or whether such conduct distorts vaccine prices, limits choice by stifling access to new and better vaccines, and ultimately slows innovation. Because there is no pathway for generic vaccines at this time, physician practices do not benefit from the pricing discipline that generics impose on branded manufacturers.[3] Moreover, because physicians typically use the same vaccines for public and private patients, pricing policies employed in the private sector also affect outcomes in the public sector, where more than 50 percent of vaccines are administered.

The Pediatric Vaccine Market is Highly Concentrated with High Entry Barriers

In 2010, the pediatric vaccine market accounted for $10.4 billion, about 43 percent of which was privately funded under reimbursements by private insurers.[4] Significant industry consolidation in the 1980s and 1990s reduced the number of pharmaceutical rivals producing vaccines from 25 to five. Today, there are four incumbents in the market – Merck, Sanofi, GSK, and Pfizer. There have been only two instances of entry into the pediatric vaccines market in the last 15 years. One attempt was unsuccessful (i.e., North American Vaccines), and Novartis entered in 2010.[5]

Fifteen pediatric vaccines are recommended by the Center for Disease Control (CDC).[6] Three firms – Merck, Sanofi, and GSK – produce almost 90 percent of these vaccines.[7]

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[3] Vaccines are excluded from the Abbreviated New Drug Application process in the Drug Patent Term Restoration and Price Competition Act (Hatch-Waxman Act).

[4] Kevin W. Caves and Hal J. Singer, *Bundling in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* (August 11, 2011), at 14. *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1908306.

[5] *Id.* at 5.

[6] The vaccines are: hepatitis B, rotavirus; diphtheria, tetanus, and pertussis (collectively TDaP or DTaP); haemophilus influenza type b (Hib); pneumococcal; inactivate poliovirus; measles, mumps, rubella and varicella (collectively MMRV); hepatitis A; human papillomavirus (HPV); and meningococcal.

[7] Caves and Singer, *supra* note 4, at 10 (Table 1).

Novartis, which produces the meningitis vaccine *Menveo* in competition with Sanofi's *Menactra*, and Pfizer, which produces the only pneumococcal vaccine (*Prevnar 13*), account for the two remaining vaccines in the market. The market for pediatric vaccines is therefore highly concentrated, since relatively few firms engage in the R&D, production, sales and marketing, and distribution necessary to supply the market. Moreover, the production of vaccines is marked by high sunk and fixed costs, low marginal costs, and significant scale economies. This in itself creates barriers to entry. But other factors can contribute as well, including long lead-times for regulatory approvals, CDC recommendations that affect the rate of vaccine uptake, and as discussed next, some bundled discounts that potentially create an unlevel playing field for competitors.[8]

Bundled Versus Single Products – Competition in the Pediatric Vaccines Market

Some pharmaceutical manufacturers coordinate vaccines in bundles that cover broad vaccine offerings and offer multiproduct discounts to customers that purchase these bundles. For example, the Sanofi and Merck vaccine portfolios *together* cover all recommended vaccines except the pneumococcal vaccine supplied by Pfizer. In other words, the Sanofi and Merck portfolios are complementary in that they each fill gaps in each other's portfolio. Indeed, the only overlap between Sanofi and Merck is the haemophilus influenza type b (Hib) vaccine. Competition between Sanofi and Merck at the level of individual vaccines (i.e., "intra-portfolio" competition) is therefore limited, if not nonexistent. In contrast, with the exception of the pneumococcal and meningitis vaccines, GSK's vaccine portfolio has far more points of overlap with both Sanofi's and Merck's offerings. In light of the available offerings across vaccine suppliers, it is clear that the predominant mode of competition in the market is at the vaccine portfolio level ("inter-portfolio" competition) between the bundles of vaccines offered by Sanofi/Merck and that offered by GSK.

Pfizer's sole source pneumococcal vaccine fills a gap in both the Sanofi/Merck and GSK portfolios. Because the CDC's Advisory Committee on Immunization Practices recommends the vaccine, Pfizer is virtually guaranteed the market. In contrast, Novartis' *Menveo* meningitis vaccine must compete head-to-head on an intra-portfolio basis with the *Menactra* vaccine that is offered as part of the Sanofi bundle.[9] This mode of competition could extend to Novartis and GSK after the latter's new meningitis vaccine *MenHibrix* receives regulatory approval.[10] When competition is primarily at the inter-portfolio level, the foregoing scenario poses a significant challenge to firms offering single or unbundled vaccines and attempting to enter or gain a foothold in the market.

[8] *Id.* at 17-18.

[9] *Id*. at 19.

[10] *MenHibrix Approval Status*, Drugs.com, September 26, 2011, http://www.drugs.com/history/menhibrix.html.

A Closer Look at Bundled Discounts and Physician Buying Groups

A closer look at bundled discounts and the role of Physician Buying Groups (PBGs) reveals the potential for strategic competitive behavior in the pediatric vaccines market. Vaccines bundles are offered largely through PBGs[11] that serve three classes of customers, those that: (1) primarily purchase Sanofi/Merck vaccines, (2) primarily purchase GSK vaccines, and (3) attempt to switch suppliers, and replenish their vaccine inventories from various manufacturers.[12] The terms of bundling contracts offered through PBGs vary. PBGs can provide significant value to physician practices through volume aggregation and price discounting. However, some PBGs incorporate restrictive contract terms and conditions. Manufacturer exclusivity is one example, whereby to achieve aggregate volume targets, PBGs that carry Sanofi/Merck vaccines may impose contractual terms that restrict purchases from GSK. More important, physicians that attempt to substitute vaccines within the bundle (i.e., "break the bundle") may face significant financial penalties through the loss of discounts. For example, if a buyer wishing to purchase a meningitis vaccine from a source other than Sanofi risks not only giving up the bundled discount on *Menactra* but the discounts on *all* Sanofi vaccines.[13]

Empirical economic research by Caves and Singer (2011) shows that in order to induce Sanofi purchasers to switch to Novartis' *Menveo* vaccine, the latter would have to pay a negative price (i.e., compensate the physician practice) for losing the bundled discount. Moreover, even if Novartis gave away *Menveo*, physician practices would not find it optimal to switch.[14] Under the Ninth Circuit's test for whether a bundled discount is exclusionary or predatory in *Cascade Health Solutions v. PeaceHealth*, these findings leave little doubt concerning the potentially adverse effects of bundling in the vaccine market, since no single-product entry would ever turn out to be profitable.[15]

The dynamics of restrictive vaccine bundling can potentially limit physicians' ability to select vaccines on the basis of clinical data or how they perform. Aside from price discounts, it is not clear that restrictive contractual bundling generates any significant efficiencies that could outweigh its potential adverse competitive effects, including PBG practices that appear designed to lock out competition. Such conduct raises prices to physician practices, limits choice, hampers entry, and stymies innovation.

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[11] Physicians can also purchase vaccines at a discount directly from the pharmaceutical company through a Vaccine Savings Program (VSP). Our information from industry experts indicates, however, that VSP programs are less well-known than PBGs and pharmaceutical company representatives steer practices toward the latter because of more advantageous internal commission structures.

[12] Caves and Singer, *supra* note 4, at 19.

[13] *Id*. at 37.

[14] *Id.* at 41.

[15] *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 910, n.21 (9th Cir. 2008). Per this case, a bundled discount is anticompetitive when a firm with monopoly power in one market that faces competition in an adjacent market prices the bundle so that an equally efficient (hypothetical) rival in the adjacent market would not be able to pay the consumer for breaking the bundle.

Suggestions and Recommendations

The importance of vaccination and the critical role of pediatric physician practices in administering vaccine programs highlight the importance of promoting competition in vaccines. As such, an important distinction should be made between bundled discounts administered through PBGs that are pro-competitive and those that are designed to exclude rivals. In light of the analysis above, there are a number of questions that would be useful for the FTC to explore:

- Certain bundling practices administered by PBGs dealing in the complementary Sanofi and Merck vaccine portfolios deserve particular attention, as numerous factors are present that could facilitate anticompetitive coordination.

- Examining bundled discounting programs administered by pharmaceutical companies for vaccines through PBGs would be useful. Such programs may be designed to create incentives (e.g., via commission structures paid to PBGs) for PBG representatives to enforce or extend potentially exclusionary practices.

- Sanofi's vaccine bundles should be evaluated for the purpose of determining if they are potentially exclusionary, per the *Cascade* standard. This includes conduct that targets suppliers of a single vaccine attempting to compete against bundled offerings – the effect of which is to raise prices, limit choice, and stifle innovation.

- Interviews with physician practices would be useful in establishing that while discount programs may be valuable to them, there are rival vaccines on the market that they may prefer but cannot use because of some bundled discounting practices. This preference may be based on price but also on performance. The importance of ensuring that physician practices are able to exercise choice in selecting vaccines cannot be understated.

We appreciate your attention to this matter. If the AAI can be of further assistance, please feel free to call on us.

Sincerely,

Diana L. Moss

Diana Moss
Vice-President, American Antitrust Institute

Albert Foer
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cc: Richard Feinstein, Director, Bureau of Competition