



## Healthcare Intermediaries: Competition and Healthcare Policy at Loggerheads?

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### I. Introduction

Competitive concerns in the U.S. healthcare industry have focused largely to date on providers, such as large hospital and managed care organizations. Recent attention has been drawn, however, to potential competitive concerns in other important parts of the supply chain, namely intermediaries or “middlemen.” Of particular interest are Pharmacy Benefit Managers (PBMs) and buying groups such as Group Purchasing Organizations (GPOs) and Physician Buying Groups (PBGs).<sup>2</sup> Healthcare intermediaries can enhance economic efficiency by achieving scale and scope economies through access to larger product portfolios and multiple distribution networks. Buying group intermediaries can also reduce transactions costs by negotiating prices on behalf of multiple buyers, thus aggregating demand and leveraging buying power to obtain more favorable pricing for health plans, hospitals, and physician practices. In doing so, buying groups can potentially counteract the exercise of seller market power elsewhere in the supply chain. Intermediaries thus offer, at least in principle, benefits to competition and consumers.

Intermediary markets, however, have undergone fundamental changes, and those changes may provide a powerful motivation for re-examining the conventional wisdom. For example, mergers of intermediaries drive higher levels of market concentration and create dominant firms. Vertical integration also extends the influence of some intermediaries to other levels in the supply chain. Some intermediary markets may therefore be conducive to anticompetitive outcomes that are not outweighed by claimed efficiencies. Yet federal antitrust authorities generally have not challenged intermediary conduct or consolidation, much like the merger

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<sup>1</sup> Vice President and Director, American Antitrust Institute. This version of the White Paper reflects slight revisions to the original version issued on May 4, 2012. 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. Many thanks to Nigel Barrella, AAI Research Fellow, for the analysis of legal standards for bundling and exclusive contracts. The AAI is funded by contributions from a wide variety of sources, among which is a pharmaceutical company with an interest in the vaccine market. A list of contributors is available on request. AAI is managed by its Board of Directors, which alone has approved this White Paper. For more information, see [www.antitrustinstitute.org](http://www.antitrustinstitute.org).

<sup>2</sup> Insurers are also intermediaries but raise a different class of competitive issues and are not discussed in this White Paper.

approved by the Federal Trade Commission (FTC) in April 2012 between the two largest PBMs, Express Scripts and Medco.

The foregoing developments in intermediary markets lay the groundwork for growing competitive concerns, including exclusionary practices and anticompetitive agreements. Anticompetitive practices impair beneficial vertical and horizontal competition while unduly influencing outcomes in markets upstream and downstream of intermediaries, many of which are highly concentrated. A complex overlay of legislated safe harbors, antitrust exemptions, and tailored antitrust policies governing the evaluation of healthcare intermediaries exacerbate competitive concerns.

Intermediary conduct that is potentially designed to constrain competition affects a number of participants in the healthcare supply chain. Smaller manufacturers of pharmaceuticals, medical devices, and medical supplies, smaller distributors, and independent pharmacies are particularly exposed. Intermediate consumers of medical products (e.g., hospitals and physician practices) bear the adverse effects of anticompetitive practices, which are passed on to insurers and, in turn, to the ultimate consumer or patient. The potential harm that flows from exclusionary practices is reflected in the traditional antitrust metrics of higher prices, restricted output, lower quality, less choice, barriers to entry, and slower innovation. But it is also apparent in more indirect ways that threaten to impair the achievement of healthcare policy goals such as affordable healthcare, choice in medical products, a stable supply chain, and diversity of supply.

This American Antitrust Institute (AAI) White Paper examines the competitive role of healthcare intermediaries. These entities have become increasingly powerful and entrenched in the supply chain, a fact that has not escaped the attention of Congress, regulators, and state antitrust enforcers. The White Paper does not conclude that intermediary practices are anticompetitive – only thorough antitrust investigations can do that. However, it does articulate, using examples, the reasons that the conduct of certain healthcare intermediaries may be potentially detrimental to competition and consumers. Section II examines major features of intermediaries that are relevant to the analysis. Section III examines the intersection between public policy concerns and competition issues in healthcare. Section IV gives a brief overview of antitrust enforcement issues and the state of the law involving bundled discounts and exclusive contracts. To illustrate potential competitive and public policy concerns, Section V presents three case studies of healthcare intermediaries: (1) pediatric vaccines and PBGs, (2) drug shortages and GPOs, and (3) pharmacy choice and PBMs. Section VI concludes with policy recommendations and suggestions for further study.

## **II. Major Features of Healthcare Intermediaries**

Intermediaries reside in the midstream segment of the healthcare supply chain – downstream from manufacturers of drugs, medical devices, and medical supplies and upstream from

healthcare providers such as hospitals, pharmacies, and physician practices. The three types of intermediaries analyzed in this White Paper are PBGs, GPOs, and PBMs.

A GPO purchases drugs, medical devices, and supplies on behalf of member hospitals. Some GPOs also offer non-pricing services related to supply chain management and even clinical evaluation and assessments of new technologies.<sup>3</sup> The three largest GPOs are Premier, Novation, and Med Assets. A PBG deals primarily with groups of physician practices in procuring pediatric vaccines, usually in bundled offerings. PBMs manage insurance benefits associated with prescription drug coverage for health plan sponsors or directly for employers. PBMs maintain a formulary and negotiate discounts and rebates with drug manufacturers. The two largest PBMs are Express Scripts-Medco and CVS Caremark.

There are a number of important features of intermediaries that are relevant for the analysis in this White Paper. First, intermediaries are deeply entrenched in the healthcare supply chain. For example, PBMs manage drug benefits for 95 percent of Americans with prescription drug coverage.<sup>4</sup> Ninety-eight percent of U.S. hospitals use GPO contracts to purchase products and about 72 percent of purchases that hospitals make are done through GPO contracts.<sup>5</sup> The ubiquity of intermediaries casts some doubt on claims that they are merely an “option” for healthcare providers and plans to procure needed drugs, devices, and supplies. Membership in a buying group such as a GPO or PBG, for example, can require exclusivity, which limits choices available for the purchase of drugs, devices, and medical supplies.

Second, healthcare intermediaries can influence market outcomes not only at the level at which they compete, but in complementary markets. Perhaps the best analogy is the role of the meat packer or poultry processor in the agricultural supply chain. Concentration at the processing level facilitates the exercise of monopsony power to depress prices paid to ranchers and growers for cattle and poultry. This same concentration can promote the exercise of market power in sales to grocery retailers. In healthcare, the structure of markets in the supply chain is particularly impaired, with significant market power in some medical products markets, and in some intermediary and provider markets. When multilateral monopoly or oligopoly characterizes relationships between an intermediary and an upstream or downstream market, bargaining largely displaces competitive market forces. Under these circumstances, smaller rivals in markets along the supply chain are particularly exposed to potentially exclusionary conduct.

Third, the method of compensating some types of intermediaries for their services has

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<sup>3</sup> William Kolasky, *Group Purchasing Organizations (GPOs) Contracting Practices and Antitrust Law*, prepared for the Health Industry Group Purchasing Association (HIGPA) 4 (November 2009), available at [http://higpa.site-ym.com/resource/resmgr/research/kolasky\\_gpo\\_practices.pdf](http://higpa.site-ym.com/resource/resmgr/research/kolasky_gpo_practices.pdf).

<sup>4</sup> Emily Maltby, *The Death of the Corner Pharmacy*, CNN Money, June 16, 2009, [http://money.cnn.com/2009/06/16/smallbusiness/small\\_pharmacies\\_fight\\_for\\_survival.smb/index.htm](http://money.cnn.com/2009/06/16/smallbusiness/small_pharmacies_fight_for_survival.smb/index.htm).

<sup>5</sup> U.S. Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices (GAO-10-738)* 4 (August 2010), available at <http://www.gao.gov/assets/310/308830.pdf>. See also Healthcare Supply Chain Association, *Frequently Asked Questions*, <http://www.supplychainassociation.org/?page=FAQ>.

generated significant controversy. For example, rather than being paid for services by member hospitals, GPOs are compensated by drug or device vendors through administrative “fees.” This approach was originally justified on the grounds that smaller member hospitals could not afford to pay GPO fees, thus shifting the burden of funding GPOs to vendors. In response to pressure from GPOs, Congress amended the Social Security Act in 1987 to exempt GPOs from the general statutory ban on kickbacks where the government covers health care costs.<sup>6</sup> Five years later, In 1991, the Department of Health and Human Services (HHS) established safe harbors under the anti-kickback provision, including the requirement that GPOs have written agreements with customers stating that fees are to be either three percent or less of the purchase price, or if a higher specified amount, to be reported to the GPO member and potentially subject to review by HHS.<sup>7</sup>

Fourth, intermediaries generally do not take title to or handle drugs or medical devices. Instead, intermediaries such as GPOs work through large distributors that procure and deliver supplies. This has important implications for small and medium size distributors with whom intermediaries traditionally do not work. Instead, smaller distributors or wholesalers deal directly with healthcare providers, procuring hard-to-get drugs or meeting excess demand for certain products. Because they are excluded by intermediaries and manufacturers from the administrative fee system, smaller distributors charge hospitals higher prices than those under intermediary contracts. This has generated allegations that smaller distributors are engaged in price gouging when in fact the prices they charge hospitals are higher because they are not distorted by the contracting process that generates administrative fees.

Fifth, intermediaries negotiate discounts or rebates with drug and medical supplies manufacturers, often for large bundles of products. Bundling strategies can be complex and involve different types of discounts based on market shares or volumes. Intermediaries also employ a variety of contractual mechanisms with manufacturers, including exclusive agreements. While drug, device, and supplies manufacturers offer bundled discounts, it is clear that some group buyers add further conditions designed to extend and enforce exclusivity arrangements. For example, in their contracts with pediatric physician practices, some PBGs add exclusivity requirements whereby physicians can only purchase vaccine bundles from one manufacturer in order to qualify for discounts. Similarly, some GPO contracts with member hospitals also require exclusivity – the member cannot use a competing GPO and must agree to use one of the GPO’s authorized distributors.

Finally, there are some questions regarding whether intermediaries achieve better pricing for hospitals and other healthcare providers. A number of studies estimate that providers pay higher prices under GPO contracts than what hospitals can get on their own. For example, a U.S. General Accounting Office study performed in 2002 concluded that hospitals that purchased through GPOs paid between 26 percent less to up to 39 percent more for some

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<sup>6</sup> See 42 C.F.R. 1001.952(j). 4.

<sup>7</sup> See 56 Fed. Reg. 35952, 35982. See also GAO, *supra* note 5 at 11. See also U.S. General Accounting Office, *Group Purchasing Organizations Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products* (GAO-03-998T) 2 (July 16, 2003), available at <http://www.gao.gov/assets/90/82028.pdf>. See also, U.S. Governmental Accountability Office, *Group Purchasing Organizations: Federal Oversight and Self-Regulation* (GAO-12-399R) 6 (March 30, 2012), available at <http://www.gao.gov/assets/590/589778.pdf>.

models of pacemakers than those that negotiated prices on their own.<sup>8</sup> A more recent analysis based on after-market transactions (whereby hospitals sought bids once prices were set by the GPO auction) found that hospitals could have saved 15 percent on average by bidding outside the GPO contract.<sup>9</sup> If this is broadly correct, it is a devastating critique of GPOs (and potentially other intermediaries), since their *raison d'être* is to reduce prices.

### III. The Intersection of Competition and Public Policy Concerns in Healthcare

In some industries, traditional antitrust concerns surrounding price, output, quality, choice, and innovation intersect more visibly with broader public policy objectives such as human health and safety, quality, and supply chain stability. This is particularly true in healthcare, energy, and agriculture. In these industries, it is critical that the nexus between antitrust and public policy be properly “managed,” since the goals of competition do not always cleanly align with those of other public policies. The Obama administration’s response to the recent shortages of prescription drugs, particularly sterile injectables, illustrates the phenomenon. In late 2011, the administration called on the U.S. Food and Drug Administration (FDA) to take certain steps to prevent drug shortages, including working with the U.S. Department of Justice (DOJ) to determine whether “potential shortages have led to illegal price gouging or stockpiling of life-saving medications.”<sup>10</sup> While this is a worthy objective, it arguably puts the cart before the horse. The more important question is whether high levels of consolidation in intermediary markets and potentially exclusionary conduct have caused or exacerbated shortages. Such an approach requires a level of coordination between antitrust agencies and regulators that does not presently exist.<sup>11</sup>

Potential adverse competitive effects associated with some healthcare intermediary practices can work against achieving important public policy goals in healthcare. The three case studies examined later in this White Paper are good examples. It is widely recognized that the larger the percentage of the population that is immunized against potentially debilitating or fatal childhood diseases, the greater will be the positive spillover effects, or benefit to the unimmunized population. Public policy thus places significant emphasis on the accessibility and affordability of vaccines, which is a determinant of the vaccination rate. The major purpose of innovation in vaccines is to create superior vaccines at lower prices.

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<sup>8</sup> U.S. General Accounting Office, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices: statement for the record by William J. Scanlon* (GAO-02-690T) 3 (April 30, 2002), available at <http://www.gao.gov/assets/90/81813.pdf>.

<sup>9</sup> Robert E. Litan and Hal J. Singer, *Do Group Purchasing Organizations Achieve the Best Prices for Member Hospitals? An Empirical Analysis of Aftermarket Transactions?* 42, available at <http://www.puncturemovie.com/wp-content/themes/Romix/pdfs/gpo-pricing-litan-singer-distribution-oct-2010-title.pdf>. The study considers transactions pertaining to medical equipment.

<sup>10</sup> White House Office of the Press Secretary, *We Can't Wait: Obama Administration Takes Action to Reduce Prescription Drug Shortages, Fight Price Gouging* (October 31, 2011), available at <http://www.whitehouse.gov/the-press-office/2011/10/31/we-can-t-wait-obama-administration-takes-action-reduce-prescription-drug>.

<sup>11</sup> For a journalistic perspective, see e.g., Patricia Earl and Phillip L. Zweig, *Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-Dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U.S. Drug Shortage* (January 4, 2012), available at <http://www.puncturemovie.com/wp-content/themes/Romix/pdfs/earlzweigfinalgposdrugshortage010412.pdf>.

Bundled discounts that have the effect of excluding rivals can increase the price of vaccines, reduce choice, and discourage entry and innovation, thus making vaccines less accessible and affordable. Antitrust enforcement typically considers the adverse effects of exclusionary conduct on innovation. However, enforcement may not place sufficient weight on the effects of reduced competition and innovation on the accessibility of vaccines and associated spillover effects on the broader population. To this extent, therefore, antitrust enforcement alone is likely to constitute an inadequate tool for government to set the optimal policy.

The effect of drug shortages can be catastrophic. One major protection against shortages is a stable supply chain, which is largely determined by the number and diversity of suppliers. The concept of supply chain “fragility” is increasingly relevant in operations research, marketing, economics, and even sociology. Supply chains featuring only a few competitors and high entry barriers at critical junctures are excessively exposed to the risk of disruption and collapse following an exogenous shock. Shocks can range from input market disruptions to political events, weather, and quality control problems. Under the influence of Chicago School economics, antitrust has focused primarily on attaining efficiency, which entails the relentless reduction of redundancy. But a fragile supply chain can also be inefficient when it “fails” because of excessive consolidation that leaves few suppliers.<sup>12</sup> In determining whether a merger is likely to substantially lessen competition, antitrust enforcers may not consider its effect on supply chain stability and diversity of suppliers, both of which are important deterrents to drug shortages.

Consumer choice is particularly important in healthcare. This is largely because products and services can vary significantly on the basis of performance, clinical data, or physician and patient preferences. For example, an oncology drug that is effective in one patient may not be so in another, just as the services offered by a local independent pharmacist might not be available through a mail order pharmacy operation. In healthcare, these differences uniquely impact patient care and quality of life. Overly limited choices in drugs, medical devices, and pharmacies can result from exclusionary practices by intermediaries. With limited choice, consumers fail to receive the benefits of innovation and a diversity of products and services, ultimately suffering the consequences of poorer health and well-being. In assessing the adverse effects of mergers or anticompetitive conduct, antitrust enforcers may not give as much weight to the importance of maintaining “choice” as would be optimal under a broader public policy standard.

#### **IV. Antitrust Enforcement and Healthcare Intermediaries**

##### **A. Federal Enforcement Issues**

Competitive concerns involving intermediaries have been building for some time. Notably, the WALL STREET JOURNAL reported in 2006 that:

[W]hile the Internet, deregulation and relentless corporate cost-cutting have

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<sup>12</sup> 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).

squeezed middlemen elsewhere, the health-care middlemen are prospering. The three largest pharmaceutical benefit managers, for instance, had net income of \$1.9 billion last year, a sum that exceeds the annual operating budget of New York's Sloan Kettering cancer center. In corners of the system such as Medicaid managed care and nursing-home drugs, little-known intermediaries rack up tens or hundreds of millions of dollars in profit.<sup>13</sup>

Significant consolidation in key intermediary markets has proceeded relatively unchecked by federal antitrust enforcement. The oligopolies that currently dominate those markets – coupled with legislated safe harbors and narrowly-crafted guidelines for antitrust enforcement – have paved the way for the competition and public policy concerns that are the subject of this White Paper. In a 2008 report, *THE NEXT ANTITRUST AGENDA*, for example, the AAI noted that a key problem involving healthcare intermediaries is the exercise of market power to foreclose competition through a wide variety of exclusionary practices.<sup>14</sup> Other legal-economic analyses ratify these concerns.<sup>15</sup> The AAI report also noted that during the Bush administration, there were no federal antitrust enforcement actions against intermediaries, leading to higher prices and decreased choice for consumers. At the same time, the states have taken a more active role in enforcement through attempts to regulate anticompetitive and deceptive conduct, particularly by PBMs.<sup>16</sup> But even under the current administration, there remains little federal enforcement against intermediaries.

Federal enforcement pertaining to joint purchasing arrangements in healthcare is guided by the DOJ/FTC *Statement 7: Enforcement Policy on Joint Purchasing Arrangements Among Health Care Providers (Statement 7)*. In the statement, the agencies conclude that most arrangements do not raise antitrust concerns and typically allow parties to the agreement to “achieve efficiencies that will benefit consumers.”<sup>17</sup> The guidelines also attempt to assuage competitive concerns over buying groups, noting that antitrust concerns are lessened if members are not required

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<sup>13</sup> *Id.*, citing Barbara Martinez et al., *Health-Care Goldmines: Middlemen Strike it Rich*, WALL ST. J. A1 (December 29, 2006).

<sup>14</sup> American Antitrust Institute, *Competition in the Unhealthy Healthcare Sector*, Chapter 9 in *THE NEXT ANTITRUST AGENDA* 321(2008), available at [http://www.antitrustinstitute.org/files/Health%20Chapter%20from%20%20AAI%20Transition%20Report\\_100520082050.pdf](http://www.antitrustinstitute.org/files/Health%20Chapter%20from%20%20AAI%20Transition%20Report_100520082050.pdf).

<sup>15</sup> See Thomas Greaney, *Competition Policy And Organizational Fragmentation In Health Care*, 71 U. PITT. L. REV. 222 (2009-2010). Greaney, notes: “...in several important areas, such as anticompetitive exclusion by group purchasing organizations and pharmaceutical benefit managers, in which conflicts of interest may cause serious impediments to market entry and innovation, governmental antitrust enforcers have been relatively quiescent.” (citation omitted). See also Julie C. Klish, *Serving Economic Efficiencies or Anticompetitive Purposes? The Future of Group Purchasing Organizations and the Antitrust Safety Zone*, 2 IND. HEALTH L. REV. 171 (2005).

<sup>16</sup> David A. Balto, *Reviving Competition in Healthcare Markets: The Use of Section 5 of the FTC Act*, Testimony Before the FTC Workshop: Section 5 of the FTC Act as a Competition Law 3, 11 (October 17, 2008), available at <http://www.ftc.gov/bc/workshops/section5/docs/dbalto.pdf>.

<sup>17</sup> Department of Justice and Federal Trade Commission, *Statement 7: Enforcement Policy on Joint Purchasing Arrangements Among Health Care Providers* 1 (revised August 1996), available at <http://www.ftc.gov/bc/healthcare/industryguide/policy/statement7.htm>.

to enter into exclusive arrangements and that “a large number and variety of purchasing groups in the health care field suggests that entry barriers to forming new groups currently are not great.”<sup>18</sup>

The weight given by the agencies to the efficiency-enhancing aspects of joint purchasing arrangements is reflected in a tailored set of guidelines for determining if they pose competitive concerns. One is a monopsony safe harbor, which is based on a market share threshold, below which it would be difficult for a buying group (via a contract with a health care provider) to depress prices paid for products or services. The other is a collusion safe harbor for contracts that do not raise concerns regarding price fixing among participants to an agreement.<sup>19</sup> Other exclusionary conduct resulting from bundled discounting or exclusive contracts – particularly foreclosure of rivals from the market – is not addressed under the *Statement 7* guidelines.

Arguably, healthcare intermediary markets today do not look as they did when the antitrust agencies issued *Statement 7* 15 years ago. Consolidation and the remaining tight oligopolies that dominate the markets suggest very high entry barriers. Large buying groups, for example, offer features that smaller organizations do not, including exclusive distribution contracts and a greater ability to secure discounts and rebates from drug suppliers. Moreover, with few large buying groups to choose from, healthcare providers are less able to switch while still achieving the bundled discounts that are a central feature of large buying group contracts.

## **B. Overview of the Law on Bundling and Exclusive Contracts**

### **1. Influence of Tying and Predatory Pricing**

Many of the competitive issues surrounding competition and intermediaries in healthcare markets revolve around the use of bundled discounts and exclusive contracts. Bundling is characterized by the sale of distinct products or services together, often discounted as a package relative to the sale of each product or service individually. The law regarding bundling and bundled discounts is currently in a state of flux, and there is much disagreement over the proper antitrust analysis of such arrangements. One line of thinking analyzes bundles similarly to the traditional antitrust analysis of tying arrangements. Another analyzes bundling arrangements similarly to predatory pricing.<sup>20</sup>

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<sup>18</sup> *Id.* at 2.

<sup>19</sup> *Statement 7* states that the agencies “...will not challenge, absent extraordinary circumstances, any joint purchasing arrangement among health care providers where two conditions are present: (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.” *Id.* at 2.

<sup>20</sup> For a tying case, *see, e.g.*, *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984). On predatory pricing, *see, e.g.*, *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993). In anticompetitive tying, a firm uses its market power in market A to undermine competition in market B. By forcing buyers of A to buy B from it as well, a monopolist may be able to protect market power in market A and attain market power in market B. Contrary to tying arrangements, bundling arrangements may not necessarily force a buyer



The standards for analyzing bundling are unsettled. The relevant history starts with the Third Circuit's seminal *en banc* decision in *LePage's Inc. v. 3M*, in which the court upheld a jury verdict on monopolization against 3M based on its bundled rebates for office products, notably tape.<sup>21</sup> The court endorsed an analysis of bundling as a tying arrangement.<sup>22</sup> In 2007, the Antitrust Modernization Commission (AMC), skeptical of the tying doctrine, suggested a rule for bundled discounts that derives from predatory pricing theory.<sup>23</sup> Specifically, a bundled discount program is anticompetitive if: (1) when the entire bundled discount is subtracted from the competitive product's price, that price is below incremental cost; (2) the bundler is likely to recoup the loss from these sales; and (3) the bundle "has had or is likely to have an adverse effect on competition."<sup>24</sup> The AMC criticized the *LePage's* standard for not requiring the plaintiff "to prove that it could make tape as efficiently as 3M and therefore that 3M's conduct had excluded an equally efficient rival."<sup>25</sup>

In 2008, the Ninth Circuit weighed in on the different outcomes of *LePage's* and the AMC alternative test. The court's opinion in *Cascade Health Solutions v. PeaceHealth*, which involved the bundling of different healthcare services, endorsed element (1) of the AMC recommendation but the court rejected elements (2) and (3).<sup>26</sup> Importantly, it found recoupment was not necessary in multiple product lines because the seller may not incur losses on the bundle as a whole. Several cases have followed *Cascade*, including notable healthcare cases.<sup>27</sup> *LePage's* remains good law, at least for the time, and there are compelling scholarly arguments for treating bundling like tying and not requiring evidence of below-cost

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of A to buy B as well; the bundling firm might merely provide a discount on A and B when the two products are purchased together. Predatory pricing, meanwhile, involves a dominant predator selling its product or service at a loss – forcing potentially equally efficient competitors to take losses and eventually exit the market – at which point it begins to recoup its losses by charging the monopoly price. A bundling arrangement can be predatory when the dominant firm in market A uses the bundle as a discount program to effectively price its sales in market B below cost. If a buyer requires both A and B, buying A from the monopolist but B from a competitor causes the buyer to lose a significant discount, which it will not rationally do unless the competitor agrees to match or beat the below-cost price.

<sup>21</sup> 324 F.3d 141 (3d Cir. 2003).

<sup>22</sup> 324 F.3d at 155 ("Rather than analogizing [bundled rebates] to predatory pricing, they are best compared with tying, whose foreclosure effects are similar.") (quoting Philip E. Areeda and Herbert Hovenkamp, ANTI-TRUST LAW).

<sup>23</sup> See Antitrust Modernization Commission, REPORT AND RECOMMENDATIONS 399 (2007) (describing the logic of the leading case on tying as "often non-economic.").

<sup>24</sup> *Id.* at 83.

<sup>25</sup> *Id.* at 97.

<sup>26</sup> *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008). The court cited variable cost as the proxy for incremental cost. 515 F.3d at 910.

<sup>27</sup> See, e.g. *Masimo Corp. v. Tyco Health Care Group*, 350 Fed. Appx. 95 (9th Cir. 2009) (adopting *Cascade* predatory pricing framework but noting the possibility of an exclusive dealing analysis, see next section); *Natchitoches Parish Hosp. Serv. Dist. v. Tyco Internat'l*, 05-cv-12024, 2009 U.S. Dist. LEXIS 108858 (D. Mass. 2009); *Peoria Day Surgery Ctr. v. OSF Healthcare Sys.*, 06-1236, 2009 U.S. Dist. LEXIS 121077 (C.D. Ill. 2009); *Safeway, Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874 (N.D. Cal. 2011).

pricing.<sup>28</sup> Avenues therefore exist for a potential successful challenge to bundling of healthcare services when either (1) the bundler has a monopoly over at least one product or service in the bundle; or (2) one product or service is priced below cost when the rebate is applied to its price.

## 2. Exclusive Dealing

Exclusive contracts can have both pro-competitive and anticompetitive effects. As a result, they are generally analyzed under the “rule of reason” by examining a number of factors in a fact-specific inquiry. These include: how much of the market is affected, what efficiency is gained through the exclusive dealing arrangement, and the specific terms of the agreement.<sup>29</sup> As a general matter, exclusive agreements that lock up large shares of the market for significant periods of time raise competitive concerns. By contrast, in unconcentrated markets where supply agreements are shorter, exclusive dealing is rarely (if ever) condemned.

There are multiple avenues for challenging an exclusive dealing contract. For example, such contracts can be characterized as unreasonable restraints of trade under Section 1 of the Sherman Act, and they are addressed specifically by Section 3 of the Clayton Act.<sup>30</sup> Exclusive dealing can also be challenged as monopolization or an attempt to monopolize, under Section 2 of the Sherman Act.<sup>31</sup> Yet another avenue for challenging exclusive dealing is Section 5 of the FTC Act, which broadly forbids unfair methods of competition.<sup>32</sup> The FTC has long challenged exclusive dealing arrangements,<sup>33</sup> the most recent and high-profile case being *Intel*.<sup>34</sup>

Contracts may sometimes be analyzed as exclusive dealing contracts even when they are not literally exclusive. Certain contracts may, as a practical matter, exclude rivals without containing an express prohibition against dealing with rivals. For example, a contract may require exclusivity for a very high percentage (e.g. 90 percent) of the purchaser’s requirements. These clauses regarding “market penetration targets” have been successfully

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<sup>28</sup> In addition to Areeda and Hovenkamp, *supra* note 22, cited by the *LePage’s* court, *see, e.g.*, Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397 (2009).

<sup>29</sup> *U.S. v. Microsoft Corp.*, 87 F. Supp. 2d 30, 52 (D.D.C. 2000) (citing cases).

<sup>30</sup> 15 U.S.C. § 14. Factors considered under a rule of reason analysis include: (1) the degree of exclusivity and the relevant line of commerce implicated by the agreement’s terms; (2) whether the percentage of the market foreclosed by the contract is substantial enough that rivals will be largely excluded from the market; (3) the agreements’ actual anticompetitive effect in the relevant line of commerce; (4) the existence of any legitimate, procompetitive business justifications; (5) the length and irrevocability of the agreement; and (6) the availability of any less restrictive means for achieving the same benefit.

<sup>31</sup> The analysis under Section 2 may sometimes find contracts anticompetitive where the Section 1 analysis does not. *See, e.g.* *U.S. v. Microsoft Corp.*, 253 F.3d 34, 70-71 (D.C. 2001) (affirming §2 liability where no §1 liability for exclusive dealing contracts.)

<sup>32</sup> 15 U.S.C. § 45(a)(1).

<sup>33</sup> *See, e.g.* *FTC v. Brown Shoe*, 370 U.S. 294 (1962).

<sup>34</sup> *In the Matter of Intel Corp.*, FTC Docket No. 9341.

challenged in recent cases.<sup>35</sup> Further, contracts that do not forbid dealing with a competitor, but instead give a large rebate or discount conditioned on not dealing with a competitor, can be fairly characterized as economically identical to an exclusive contract. The lost rebate or discount is, in effect, damages for a breach of contract, and in many cases may be substantially more than the damages for actual breach of an exclusive contract.<sup>36</sup> Certain rebate and discount structures have been challenged successfully for having an effect much the same as exclusive dealing.<sup>37</sup> This class of cases is noteworthy for its potential applicability to contracts involving healthcare intermediaries that often involve large rebates that can be lost if the provider deals with a competitor.<sup>38</sup>

## V. Three Case Studies of Intermediaries and Competition

### A. Pediatric Vaccines and Physician Buying Groups

#### 1. Vaccines and Innovation

In 2010, pediatric vaccines were a \$9.4 billion market, about 43 percent of which was funded under reimbursements by private insurers.<sup>39</sup> Vaccines are the second largest cost component, but one of the least profitable programs, for pediatric practices. Indeed, one recent study indicates that a significant proportion of physicians have delayed introducing new vaccines for financial reasons and experienced decreased profit margins from immunizations.<sup>40</sup> Because there is no pathway for generic vaccines at this time, physician practices do not benefit from the pricing discipline that they impose on branded manufacturers.<sup>41</sup> As a result,

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<sup>35</sup> See e.g. *id.*, Administrative Complaint at ¶51; *ZF Meritor LLC v. Eaton Corp.*, 800 F. Supp. 2d 633 (D. Del. 2011) (enjoining use of market penetration targets).

<sup>36</sup> Professor Elhauge argues that the rebate structure in the GPO industry is actually far worse than a mere exclusive dealing contract, due to the large amounts of the rebates at stake and the ease of enforcement. See Einer Elhauge, *Exclusion of Competition for Hospital Sales Through Group Purchasing Organizations* 7 (2002), available at [www.law.harvard.edu/faculty/elhauge/pdf/gpo\\_report\\_june\\_02.pdf](http://www.law.harvard.edu/faculty/elhauge/pdf/gpo_report_june_02.pdf).

<sup>37</sup> See, e.g. *Intel*, note 35, Administrative Complaint at ¶53; *Eaton*, *supra* note 35. But see *Allied Orthopedic Alliances Inc. v. Tyco Health Care Group*, 592 F.3d 991 (9th Cir. 2010) (rejecting such a theory in the context of a particular GPO's exclusive agreement).

<sup>38</sup> Contracts referencing rivals (CRRs) are currently a primary concern of the DOJ because of their potential "horizontal effects" in the form of softening price competition and leading to higher equilibrium prices. See e.g., Fiona Scott-Morton, *Contracts That Reference Rivals*, speech at the Georgetown University Law Center (April 5, 2012), available at <http://www.justice.gov/atr/public/speeches/281965.pdf>

<sup>39</sup> Kevin W. Caves and Hal J. Singer, *Bundling in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* 14 (August 11, 2011), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1908306](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1908306). The study was funded by Novartis.

<sup>40</sup> Gary L. Freed, Anne E. Cowan and Sarah J. Clark, *Primary Care Physician Perspectives on Reimbursement for Childhood Immunizations*, 124 PEDIATRICS S470 (2009).

<sup>41</sup> Vaccines are excluded from the Abbreviated New Drug Application process in the Drug Patent Term Restoration and Price Competition Act (Hatch-Waxman Act). Vaccines are complex biological drugs and generic "equivalence" is difficult to demonstrate by simple tests. Rather, full clinical safety and efficacy testing of a generic copy would be required.

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. Pro-competitive price discounts from vaccine manufacturers are the principal method for reducing procurement costs – making vaccination programs more economically viable and available.

Pharmaceutical manufacturers coordinate broad vaccine offerings in bundles and offer multiproduct discounts on those bundles. PBGs offer these bundled vaccines to their pediatric physician members. While bundled discount programs may be valuable to physicians, an important question is whether they prevent physicians from using rival vaccines that they may prefer for reasons of cost, clinical data, or performance. Under these circumstances, a procompetitive mechanism becomes a potentially anticompetitive one, by foreclosing more innovative, lower cost vaccine manufacturers from the market. The broader consequences of this problem are potentially enormous. As one author notes: “Because pediatricians are caught between pharmaceutical manufacturers and health plan payers, strategies should address reducing the price of vaccines (and other vaccine-related practice costs) and increasing reimbursements.”<sup>42</sup> A number of public interest and competition advocacy organizations have raised competitive concerns regarding vaccine bundling in recent letters to the FTC.<sup>43</sup> At the time of this writing, there are a number of pending lawsuits regarding alleged exclusionary bundled discounts.<sup>44</sup>

## 2. Bundle-Based Competition

Fifteen pediatric vaccines are recommended by the Center for Disease Control (CDC).<sup>45</sup> Currently, there are five incumbents in the market for pediatric vaccines – Merck, Sanofi, GlaxoSmithKline (GSK), Pfizer, Novartis. This number, however, is somewhat misleading. There are only two instances of entry in the last 15 years: North American Vaccines' unsuccessful attempt in 1998, and Novartis' successful entry in 2010.<sup>46</sup> Moreover, Merck, Sanofi, and GSK produce almost 90 percent of pediatric vaccines on the market.<sup>47</sup> Novartis, which produces the meningitis vaccine *Menveo* in competition with Sanofi's *Menactra*, and

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<sup>42</sup> Stephen Berman, *Is Our Vaccine System at Risk for a Future Financial "Meltdown?"* 122 *PEDIATRICS* 1373 (2008).

<sup>43</sup> See, e.g., American Antitrust Institute, *Letter to the Federal Trade Commission, in "Re: Potentially Exclusionary Bundled Discounts for Pediatric Vaccines"* (November 22, 2011), available at [http://www.antitrustinstitute.org/~antitrust/sites/default/files/AAI\\_vaccines%20bundling%20ltr%20to%20FTC.pdf](http://www.antitrustinstitute.org/~antitrust/sites/default/files/AAI_vaccines%20bundling%20ltr%20to%20FTC.pdf). See also Citizens for Responsibility and Ethics in Washington, letter to the Federal Trade Commission (March 19, 2012), available at <http://www.citizensforethics.org/page/-/PDFs/Legal/Investigation/3-19-12%20FTC%20Vaccine%20Bundling.pdf>.

<sup>44</sup> See e.g., Cheryl Armstrong, *Doctor Alleges Monopoly on Vaccine*, Courthouse News Service, December 13, 2011, <http://www.courthousenews.com/2011/12/13/42191.htm>.

<sup>45</sup> 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.

<sup>46</sup> Caves and Singer, *supra* note 39 at 5.

<sup>47</sup> *Id.* at 10 (Table 1).

Pfizer, which produces a sole-source pneumococcal vaccine known as *Prennar 13*, account for the two remaining vaccines in the market. The market for pediatric vaccines is therefore highly concentrated, since few firms carry out R&D, production, sales and marketing, and distribution. Moreover, the production of vaccines is marked by high sunk and fixed costs, low marginal costs, and significant scale economies. These factors create barriers to entry, but others contribute as well, including long lead-times for regulatory approvals, and CDC recommendations that affect the rate of vaccine uptake.<sup>48</sup>

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 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 bundle level between Sanofi/Merck and 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 individual basis with the *Menactra* vaccine that is offered as part of the Sanofi bundle.<sup>49</sup> This mode of competition could extend to Novartis and GSK after the latter's new meningitis vaccine *MenHibrix* receives regulatory approval.<sup>50</sup> When competition is primarily at the bundle level, the foregoing scenario poses a significant challenge to firms that attempt to gain a foothold in the market with unbundled vaccines.

### 3. Competitive Implications

The competitive implications of bundled discounts are best understood by considering the consequences for physicians that attempt to substitute vaccines within the bundle (i.e., "break the bundle"). For example, a physician wishing to purchase a meningitis vaccine from a source other than Sanofi thus risks not only giving up the bundled discount on *Menactra* but the discounts on all Sanofi vaccines.<sup>51</sup> Empirical economic research 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

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<sup>48</sup> *Id.* at 17-18.

<sup>49</sup> *Id.* at 19.

<sup>50</sup> *MenHibrix Approval Status*, Drugs.com, September 26, 2011, <http://www.drugs.com/history/menhibrix.html>.

<sup>51</sup> Caves and Singer, *supra* note 39 at 37.

to switch.<sup>52</sup>

Under the Ninth Circuit's *Cascade* test for whether a bundled discount is exclusionary or predatory, the foregoing findings leave little doubt concerning the potentially adverse effects of bundling in the vaccine market. If competition is largely at the bundle level, and exclusionary bundled discounts are employed to restrict competition, then single-product entry is likely to be unprofitable. Expansion of market share by a competitor offering unbundled vaccines would also be difficult.<sup>53</sup>

Some PBGs can exacerbate or extend the potential exclusivity effects of bundled discounts offered by vaccine manufacturers by incorporating restrictive contract terms and conditions. For example, PBGs typically serve three classes of customers, those that primarily purchase Sanofi/Merck vaccines, GSK vaccines, or different manufacturers' vaccines to replenish their inventories.<sup>54</sup> PBGs that carry Sanofi/Merck vaccines may impose contractual conditions that restrict purchases from GSK, thus enforcing manufacturer exclusivity.

Aside from price discounts, it is therefore unclear whether the bundled discounting practices by some of the large incumbent vaccine manufacturers, and reinforced by some PBGs, generates any significant efficiencies that could outweigh their potential adverse competitive effects. Bundled discounts may be strategically designed to foreclose competition, with the effect of raising vaccine prices, stifling innovation, and reducing the accessibility of vaccinations. It is therefore important for antitrust enforcers to distinguish between bundled discounts administered through PBGs that are procompetitive and those that are designed to exclude rivals.

## **B. Drug Shortages and Group Purchasing Organizations**

### **1. Recent Drug Shortages**

The healthcare industry in the U.S. is in the midst of a highly publicized shortage of drugs, ranging from cancer treatments, to anesthetics, emergency medicine, and intravenous feeding. Two major government studies of drug shortages appeared in late 2011 – one by the FDA and a complementary study by HHS. Shortages increased by almost 200 percent from 2005 to 2010 and they increased 13 percent between 2009 and 2010 alone.<sup>55</sup> The FDA's study of 127 drugs in shortage during the 20-month period between January 2010 through August 2011 indicates that 80 percent, by method of administration, involve sterile

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<sup>52</sup> *Id.* at 41.

<sup>53</sup> See *Cascade*, *supra* note 26 (suggesting that 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).

<sup>54</sup> Caves and Singer, *supra* note 39, at 19.

<sup>55</sup> U.S. Food and Drug Administration, (FDA) *A Review of FDA's Approach to Medical Product Shortages* 10 (October 31, 2011), available at <http://www.fda.gov/DrugShortageReport>.

injectables. The largest shortage by class of drug is oncology, at 28 percent of the total.<sup>56</sup>

The FDA study acknowledges that an array of factors – economic, legal, regulatory, policy, and clinical – are likely responsible for shortages. The HHS study, which focuses on sterile injectables, notes that shortages appear to be the result of an increase in the scope and volume of products produced over a short time, without a corresponding expansion in manufacturing capacity.<sup>57</sup> Both the HHS and FDA studies propose a variety of specific causes of the drug shortages. The largest appears to be problems surrounding manufacturing and shipping. These problems account for 63 percent of drugs in shortage in the FDA sample.<sup>58</sup> In the HHS sample quality problems in manufacturing account for 54 percent of shortages of sterile injectables.<sup>59</sup> Other reasons for shortages include supply and demand problems, raw materials problems, and product discontinuations.<sup>60</sup>

Any number of reasons not explored in the FDA and HHS studies can potentially help explain drug shortages in general, or shortages of generics in particular. For example, economic theory lends some support to the notion that when calculating optimal manufacturing lot sizes, letting the drug run out of stock before remanufacturing is the profit-maximizing solution.<sup>61</sup> Lower profit margins for generics may be due, in part, to the loss of economies of scale in production or to increasingly vigorous generic competition as more branded drugs come off patent. Given uncertainty about the causes of recent drug shortages, the question therefore remains as to what factors can shed more light on the problem, particularly any connection between shortages, competition, and GPOs.

## 2. GPO Contracts

The perverse incentives that underlie the GPO business model may help clarify the role of group buyers in drug shortages. Under the current system of compensation, GPOs are paid by vendors, rather than by parties to the agreement. An arrangement whereby a manufacturer, rather than the principal (i.e., buying group member), pays the agent (i.e., buying group) raises the classic principal-agent problem. This is similar to the compensation structure for credit rating agencies, under which the agencies are paid by the firms they rate rather than by the users of their reports. In the GPO context, medical products manufacturers have little incentive to serve the interests of the principal. Rather, the

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<sup>56</sup> *Id.* at 13-15.

<sup>57</sup> FDA, *supra* note 55 at 3. *See also*, Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, U.S. Department of Health and Human Services (HHS), *Economic Analysis of the Causes of Drug Shortages 1* (October 2011), available at <http://aspe.hhs.gov/sp/reports/2011/drugshortages/ib.pdf>.HHS.

<sup>58</sup> *Id.* at 16.

<sup>59</sup> HHS, *supra* note 57, at 13.

<sup>60</sup> HHS also reports 47 percent of shortages due to unknown causes based on data from American Society of Health-System Pharmacists. *Id.* at 16.

<sup>61</sup> F. M. Scherer, *THE ECONOMICS OF MULTI-PLANT OPERATION* 49-62 (1975).

incentive is to maximize administrative fees, which is directly at odds with the objective of obtaining lower prices for member hospitals.<sup>62</sup>

GPOs can maximize administrative fees by increasing the volume of products purchased under a contract, such as when a vendor wins the rights to supply a range of products under a sole-source agreement. Single, large contracts often garner proportionately larger percentage administrative fees than multiple smaller contracts. One prominent example of sole-sourcing is Premier's \$1.8 billion, 7.5 year deal with Becton Dickinson in 1996, that included the requirement that member hospitals purchase 90 percent of syringes and blood collection tubes from the company.<sup>63</sup>

The GPO compensation structure also creates incentives for the GPO to maintain monopoly pricing on the part of the winning bidder(s) of the contract because total fees increase with prices charged under the contract.<sup>64</sup> Monopoly pricing for supplies under a GPO contract may be aided by complex bundled discounts for hospitals that meet certain buying quotas. Under such a price discrimination scheme, the incentives are to maintain higher prices for profitable drugs for which there is little price competition and lower those for drugs for which there is more competition.

There is little incentive under the current GPO administrative fee system for member hospitals to police pricing under their contracts with GPOs. For example, hospitals are often the beneficiaries of a portion of the revenue generated by administrative fees protected by the anti-kickback safe harbor. The lack of transparency in GPO contracts with hospitals, revenue-sharing, and complex bundled discount systems creates disincentives to police pricing. This increases the probability that the ultimate consumer (i.e., the patient) will not see the benefits of group purchasing. Similarly, because higher prices are absorbed by insurers and passed on through higher premiums, hospitals may have less incentive to monitor pricing.

A number of factors impede switching by buying group members that might be dissatisfied with prices, service, or quality under GPO contracts. As noted earlier, some GPO contracts with member hospitals require exclusivity or *de facto* exclusivity by imposing penalties for failing to meet buying quotas. For hospitals that do have the flexibility to switch, there are few alternatives available because the GPO market is concentrated. In 2011, for example, over 80 percent of the GPO industry revenue was earned by the three largest firms – MedAssets, Novation, and Premier.<sup>65</sup> Participation in multiple GPOs also may not be

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<sup>62</sup> GAO, *supra* note 5 at 12-13. Following a spate of concern over GPO practices in the early 2000s, the industry responded by developing a “code of conduct” that, among other things, imposed self-regulation as to the maximum administrative fees that could be charged to pharmaceutical and medical device vendors, with promises to limit sole-source contracting.

<sup>63</sup> Mariah Blake, *Dirty Medicine*, Washington Monthly, July/August 2010, <http://washingtonmonthly.com/features/2010/1007.blake.html>.

<sup>64</sup> Litan and Singer, *supra* note 9 at 1.

<sup>65</sup> See <http://www.hpnonline.com/resources/GPOs.html>.



evidence of easy switching, as it is sometimes postulated, since replacing a large GPO contract may be difficult and multiple smaller contracts are imperfect substitutes that raise transactions costs. Moreover, despite evidence that hospitals can do better outside GPOs, efforts to purchase outside GPO contracts are limited by the “golden handcuffs” effect of potentially losing bundled discounts.<sup>66</sup>

### 3. Competitive Implications

The skewed GPO compensation system creates incentives for exclusionary conduct that may exacerbate drug shortages. Smaller drug and device manufacturers that offer lower-cost or superior products, but cannot afford to pay high administrative fees associated with high volume contracts to GPOs, are potentially foreclosed from the market. As key analysts note, the system of compensation to GPOs creates entry barriers, and “the greater the compensation to the GPOs, the greater the exclusivity concession received by dominant firms, and a diminished market access for new market entrants.”<sup>67</sup>

Another result of GPO practices might be to force non-preferred manufacturers or those with smaller margins such as some generics to further reduce prices under bundled discounting schemes. This could lead to smaller inventories or discontinued production of some drugs. Indeed, HHS observes that generic manufacturers have shifted production from “shrinking lines of business to growing ones,” citing declining volumes and prices for generic drugs over the six-year period from 2006 to 2011.<sup>68</sup>

Foreclosure of manufacturers that do not have the ability to participate in GPO administrative fee schemes could have the effect of concentrating drug manufacturing among only a few firms. High concentration in the markets for drugs in short supply amplifies this concern. For example, sterile injectables account for 80 percent of the drugs in shortage. In 2010, 60 percent of sterile injectable “molecules” were sole-sourced.<sup>69</sup> Markets for specific drugs are likely to be even more concentrated because only one or two firms produce them. Markets for generic drugs – which accounted for 60 percent of sterile injectables and 50 percent of all shortages – are also concentrated.<sup>70</sup> In 2010, the top three firms accounted for about 70 percent of the generic sterile injectable market<sup>71</sup> and 90 percent

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<sup>66</sup> A number of studies in the early 2000s concluded that GPOs are largely pro-competitive. *See, e.g.*, Herbert Hovencamp, *Competitive Effects Of Group Purchasing Organizations’ (GPO) Purchasing And Product Selection Practices In The Health Care Industry*, report prepared for the Health Industry Group Purchasing Organization (April 2002). *See also* Kolasky, *supra* note 3.

<sup>67</sup> Litan and Singer, *supra* note 9 at 42.

<sup>68</sup> For drugs in shortage since 2008. HHS, *supra* note 57 at 12.

<sup>69</sup> FDA, *supra* note 55 at 31.

<sup>70</sup> Of the total shortages, 50 percent were generic and 43 percent were innovator drugs. FDA, *supra* note 55 at 14.

<sup>71</sup> FDA, *supra* note 55. at 30.

of the generic sterile injectable oncology segment of the market.<sup>72</sup>

While the economic reasons that might account for drug shortages are worth exploring, it remains that high levels of concentration in markets for drugs in short supply exacerbate an already fragile supply chain. The FDA notes that while demand in the generic and oncology segment of the market is robust, the supply system is “vulnerable to drug shortages because a large supply disruption is difficult to make up with alternative suppliers.”<sup>73</sup> This is compounded by low demand and supply elasticities for certain drugs, stringent product manufacturing quality controls, dedicated production lines, and “just-in-time” manufacturing and inventorying practices. The severity of the drug shortage problem, coupled with impaired market structures and perverse incentives created by GPO contracting practices and compensation, calls for a careful collaborative investigation by antitrust enforcers and regulators.

### **C. Independent Pharmacies and Pharmacy Benefit Managers**

#### **1. Consumer Choice and Independent Pharmacies**

PBMs vary by size and integration with other levels in the supply chain such as retail pharmacy chains and insurers. PBM involvement in managing prescription drug purchasing is pervasive. Not only do PBMs manage prescription benefits for the vast majority of Americans with prescription drug coverage, but an estimated 25 percent of companies require employees to refill ongoing prescriptions through mail order.<sup>74</sup> With the FTC’s recent closure of its investigation into the Express Scripts-Medco merger, independent pharmacies will likely face an increasingly tough battle with the duopoly of large PBMs that are vertically integrated with their own mail order pharmacy operations.<sup>75</sup>

Large PBMs that dominate an already concentrated market potentially have the ability and incentive to influence which drugs are dispensed and what sources they are dispensed from. This dynamic may account in part for the gradual loss of business from independent pharmacies to PBM mail order operations.<sup>76</sup> While small, independent pharmacies remain part of the pharmacy networks of the large PBMs they are, by virtue of their size and lack of bargaining power, susceptible to exclusionary conduct.

Independent pharmacies play an important role in providing consumers with choice in pharmacy services. Consumers rely on community pharmacists for advice related to their medication and general health. Independent pharmacies offer a wide range of patient

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<sup>72</sup> Based on the HHS sample. See HHS, *supra* note 57 at 6.

<sup>73</sup> FDA, *supra* note 55, at 31.

<sup>74</sup> *Id.* See also Maltby, *supra* note 4, based on a 2008 survey.

<sup>75</sup> The Express Scripts-Medco merger was opposed by numerous industry participants, public interest groups, trade associations, and members of Congress.

<sup>76</sup> Other factors may also account for the decline of the independent pharmacy, including scale economies and other economic conditions.

services, from immunizations to diabetes training and blood pressure monitoring.<sup>77</sup> This is particularly important for seniors under Medicare Part D. Mail order pharmacies do not provide the services offered by independent pharmacies that are a crucial component of consumer choice. In forced conversions to mail order, consumers are given little choice and customer service, and stand a higher chance of adverse medical reactions.<sup>78</sup> As one observer states: “The growth in mail order has little to do with consumer preferences. Numerous surveys have found that consumers strongly prefer retail pharmacies, which offer face-to-face consultations, medical information, and a range of healthcare services.”<sup>79</sup>

The loss of services offered by independent pharmacies implies real costs for ultimate consumers. These can take the form of medication misuse and loss of monitoring services relating to chronic conditions. Indeed, the services provided by community pharmacies in monitoring patients for diabetes have been shown to reduce direct medical costs.<sup>80</sup> Because choice is an important competitive variable, it is important that the potential loss of independent pharmacy services be accounted for in evaluating any adverse competitive effects associated with PBM consolidation and market conduct.

## 2. Concentration in PBM Markets

A steady increase in market concentration due to successive mergers in PBM markets has sparked competitive concern. The 2007 merger of CVS and Caremark reduced the number of large PBMs from four to three. With the three-to-two merger of Express Scripts and Medco, the large PBM duopoly will control drug plans for over 40 of Fortune 50 companies, and between 80 and 90 percent of the large commercial employer market.<sup>81</sup> A combined Express Scripts-Medco will also control approximately 50 percent of the specialty market, 60 percent of the mail order prescription market, and over one-third of all prescriptions.<sup>82</sup> Even

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<sup>77</sup> National Community Pharmacists Association, *National Pharmacy Today* (undated), <http://www.ncpanet.org/index.php/independent-pharmacy-today>

<sup>78</sup> Balto, *supra* note 16 at 10.

<sup>79</sup> New Rules Project, *Pharmacy Equity Laws*, Newrules.org, March 20, 2008, <http://www.ilsr.org/rule/pharmacy-equity-laws/>. A number of states, including Arkansas, Illinois, Mississippi, Missouri, and Tennessee, have enacted legislation designed to level the playing field for consumers, regardless of what type of pharmacy they purchase from.

<sup>80</sup> The National Community Pharmacists Association estimates such costs associated to be \$290 billion per year. See National Community Pharmacists Association, *Mail Order is Not for Everyone* (undated), [http://www.ncpanet.org/pdf/leg/jan12/mail\\_order\\_is\\_not\\_for\\_everyone.pdf](http://www.ncpanet.org/pdf/leg/jan12/mail_order_is_not_for_everyone.pdf). See also, Carole W. Cranor, Barry A. Bunting, and Dale B. Christensen, *The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program*, 43 JOURNAL OF AMERICAN PHARMACEUTICAL ASSOCIATION 183-84 (March/April 2003).

<sup>81</sup> See, e.g., American Antitrust Institute, *Letter to Chairman Jon Leibowitz re: Proposed Merger of Express Scripts, Inc. and Medco Health Solutions* (November 30, 2011), available at <http://www.antitrustinstitute.org/~antitrust/sites/default/files/FTC%20Letter%20ExpressScriptsMedco.11.3.0.11.pdf>. See also *Dissenting Statement of Commission Julie Brill concerning the Proposed Acquisition of Medco Health Solutions Inc. by Express Scripts, Inc.* 2 (April 2, 2012), available at <http://www.ftc.gov/speeches/brill/120402medcobrillstatement.pdf>.

<sup>82</sup> AAI, *id.* at 4.

under a broader definition of the relevant market, to include the provision of full-service PBM services to health care plan sponsors (i.e., the all employer market), Express Scripts-Medco has a 45 percent market share. As defined by the FTC, while this market contains at least 10 significant competitors, it is still highly concentrated post-merger.<sup>83</sup>

Concerns surrounding high concentration and dominant firms in the PBM market have not escaped the scrutiny of state antitrust enforcers and regulators. A number of states have proposed to regulate the non-price aspects of PBM activity, including New York and Mississippi, calling for regulatory oversight of conflicts of interest, contractual relationships between PBMs and health plans, and disclosures on PBM contracts with drug manufacturers. The FTC, however, has opposed state efforts to reign in their conduct, generally finding that PBMs behave in pro-competitive ways. In opposing efforts by states to regulate PBMs in 2009 and 2011, the FTC noted that such requirements limit the ability of health plans and PBMs to establish cost-effective relationship. Resulting higher costs are likely to raise the cost of prescription drug coverage.<sup>84</sup>

Moreover, a 2005 FTC study concluded that PBM ownership of mail order pharmacies generally did not “disadvantage plan sponsors” and that competition affords plan sponsors “sufficient tools to safeguard their interests.”<sup>85</sup> While the FTC study pre-dates significant changes in the structure of the PBM industry, including the mergers of Express Scripts-Medco and CVS and Caremark, its basic conclusions appear to hold sway. Notwithstanding the FTC’s reasoning in Express Scripts-Medco, it stands to reason that the dominance of large PBMs increases the probability that the intermediaries may be able to affect competitive outcomes in PBM and complementary markets.

### 3. Competitive Implications

Dominant PBMs may have the ability and incentive to engage in a number of exclusionary practices. These include foreclosing the market for lower-priced or clinically superior drugs and engaging in monopsonistic practices that potentially force independent pharmacies from the market. Both concerns have occupied much of the PBM debate. Foreclosure of lower-priced or superior drugs is, in part, a of function of the lack of transparency in how PBMs share drug manufacturer rebates and discounts across parties to their contracts. As opposed

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<sup>83</sup> Federal Trade Commission, *Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.* 2 FTC File No. 111-0210 (April 2, 2012), available at <http://www.ftc.gov/os/2012/04/120402expressmedcostatement.pdf>. Post-merger concentration is almost 3,000 HHI, with change in HHI of almost 1,000 HHI. Brill, *supra* note 81 at 2.

<sup>84</sup> Federal Trade Commission, *FTC Staff Comment Says New York Bill to Regulate Pharmacy Benefit Managers May Increase Pharmaceutical Prices for New York Consumers*; (April 3, 2009), available at <http://www.ftc.gov/opa/2009/04/nyrohmmaas.shtm>. See also Federal Trade Commission, *FTC Staff: Mississippi Bill That Would Give State Pharmacy Board Authority Over PBMs Likely to Increase Prescription Drug Costs and Reduce Competition* (March 20, 2011), available at <http://www.ftc.gov/opa/2011/03/pbm.shtm>.

<sup>85</sup> Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* ii (August 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>. The study notes that the data considered were highly aggregated, and the study does not draw any conclusions regarding individual PBMs and plan sponsors.

to minimizing costs for health plans, PBM incentives may be instead to maximize revenues. This can be accomplished in a number of ways. For example, PBMs can strike exclusive contracts with drug manufacturers and large distributors, switch patients to more expensive drugs (“interchange”) to take advantage of vendor rebates, favor higher-margin drugs dispensed by mail order operations over generics, and drive consumers to more profitable mail order operations and away from independent pharmacies. PBMs can pass on higher costs to health plans and employers, which make their way into higher premiums for consumers.

Equally concerning is the effect that increasing PBM market concentration is having on independent pharmacies. The atomistic nature of the independent pharmacy market, coupled with the duopoly of large PBMs, means that independents possess little bargaining power in negotiations with PBM networks.<sup>86</sup> Vertical integration of PBMs and large health plans into mail order operations enhance their ability and incentive to exercise monopsony power vis-à-vis independent pharmacies. The tools for unleveling this playing field range from driving down dispensing fees and delayed reimbursement for independent pharmacies, cherry-picking the most profitable prescriptions from independents, and complex, “take-it-or-leave-it” contracts between PBMs and independents.<sup>87</sup>

Buyer power concerns involving PBMs have arisen in a number of venues. For example, in *Alameda Drug Co. Medco Health Solutions*, plaintiff pharmacies alleged that Medco unfairly increased market share and market power, and restricted price competition by reducing the amount of reimbursement to plaintiffs for dispensing drugs under Medco Health Plans.<sup>88</sup> In *Express Scripts-Medco*, however, the FTC’s concerns over monopsony were assuaged by a number of factors. For example, the merged firm would have a 29 percent share of retail pharmacies’ sales, lower than the threshold generally considered the minimum necessary to exercise monopsony power. The FTC also found little correlation between PBM size and reimbursement rates paid to retail pharmacies and little evidence that reduced reimbursement rates would reduce output or curtail pharmacy services.<sup>89</sup>

Many of the FTC’s rationales regarding the potential for competitive harm from monopsonistic PBM practices, while compelling in general, should be scrutinized in light of the idiosyncratic features of the PBM business model. These include anticompetitive incentives created by PBM integration into their own mail order operations and drug manufacturer rebate systems. Finally, while reduced output of pharmacy services is a central feature of monopsony, it is also true that other adverse effects should be considered. These

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<sup>86</sup> Independent pharmacy cooperatives currently do not have immunity from the antitrust laws.

<sup>87</sup> Karen E. Klein, *End of Days for Independent Pharmacies?* Bloomberg Business Week, March 8, 2012, <http://www.businessweek.com/articles/2012-03-08/end-of-days-for-independent-pharmacies>.

<sup>88</sup> David A. Balto, *Federal and State Litigation Involving Pharmacy Benefit Managers* 22 (updated January 2011), available at [http://www.ncpanet.org/pdf/leg/aug11/fed\\_state\\_litigation\\_pbms.pdf](http://www.ncpanet.org/pdf/leg/aug11/fed_state_litigation_pbms.pdf), citing *Alameda Drug Co., Inc., et al., v. Medco Health Solutions, Inc., et al.*, No. CGC-04-428109 (Cal. Super. Ct. Jan. 20, 2004). See also Balto, *id.* at 47, citing *Bellevue Drug Co., et al. v. Advance PCS*, No. 2:03-cv-04731; and *Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al.*, No. 2:03-cv-04730 (E.D. Pa. Aug. 15, 2003).

<sup>89</sup> FTC, *supra* note 83, at 7-8.

include lower quality, in the form of fewer independent pharmacies and the unique services they offer, and loss of consumer choice.

Given the market dominance of the two large PBMs, it is questionable whether smaller PBMs or health plan PBMs can constrain potentially anticompetitive conduct by the large PBMs. A number of factors solidify the large PBM's hold on the market and maintain significant barriers to entry. These include their greater ability to offer exclusive distribution contracts and secure discounts and rebates from drug suppliers that smaller PBMs may not. In light of the foregoing, the potential adverse effects of anticompetitive conduct by large PBMs should be carefully scrutinized, particularly those that jeopardize important sources of consumer choice in pharmacy services.

## **VI. Conclusions and Policy Recommendations**

This White Paper examines three types of intermediaries in the healthcare arena. Each type is idiosyncratic to a specific sector, but the three have much in common. Each negotiates important aspects of contracts with suppliers on behalf of ultimate purchasers of drugs and medical devices and supplies, with the purpose of imparting efficiencies into the healthcare system. However, each intermediary examined raises competitive issues ranging from high market concentration to the potential for exclusionary conduct. These problems support the notion that intermediaries are producing less efficient outcomes and are instead generating substantial benefits for themselves and fewer to intermediate and ultimate consumers.

Moreover, the presence of legislation and policies that fundamentally distort or obscure the competitive process – coupled with the absence of transparency and public data – make it difficult for industry observers to evaluate where the problems exist, their magnitude, and how they may best be resolved. Nevertheless, available information suggests that there are problems, most particularly in the creation of closed “systems” centered on intermediaries that are increasingly impervious to smaller, newer, or more innovative entrants at the supply level. Such developments are likely to reduce innovation, price competition, and choice. These factors make it important for antitrust enforcers to give a higher priority to investigating healthcare intermediaries in areas of high concentration.

The answers to many of the questions raised in this White Paper regarding competition in intermediary markets can be effectively addressed by a refocusing of regulatory and antitrust enforcement approaches. This refocusing would consider both competition and public policy objectives to create a mutually reinforcing system that will ensure competition, choice, and a stable, robust, and secure healthcare supply chain. Ensuring that intermediaries deliver promised benefits will also require more vigorous antitrust enforcement. Based on the foregoing analysis, we suggest a number of policy considerations and priorities.

1. Regulatory initiatives designed to address disruptions to the supply chain (e.g., drug shortages) should focus less on reporting requirements and more on the analysis of competition in intermediary markets and upstream markets for drugs, and medical devices and supplies. This analysis should focus on the diversity and number of suppliers necessary to promote stability.
2. In balancing the procompetitive effects of intermediaries against the potential

anticompetitive effects of exclusionary conduct, antitrust analysis should consider both direct and indirect effects. Indirect effects include structural changes in markets and firm conduct that impair supply chain stability, diversity of suppliers, and negative spillovers relating to public health. While these factors may not fit squarely within the traditional antitrust metrics for assessing competitive harm, considering them recognizes the idiosyncratic features of competition in healthcare and aligns antitrust and broader healthcare policy objectives.

3. The *Statement 7* guidelines regarding how joint purchasing arrangements will be analyzed should be revised to be neutral with respect to the procompetitive effects of group purchasing arrangements and more consistent with general antitrust analysis of monopolization and coordinated interaction.
4. Consumer choice should be given more weight as a critical parameter of competition in issues involving intermediaries. Interviews with healthcare providers, including hospitals, physicians, and patients themselves are essential for establishing better parameters surrounding the substitutability of products (e.g., oncology drugs) and services (e.g., pharmacies). This analysis should include a focus on hard-to-quantify factors such as clinical performance and physician preference.<sup>90</sup>
5. Congress should repeal the anti-kickback safe harbor that has created the principal-agent problem surrounding GPO compensation. Because GPOs are compensated by vendors, rather than their member hospitals, small pharmaceutical and medical device and supplies manufacturers, who do not benefit from this legislated advantage, but that may produce superior, lower-price products, are potentially foreclosed from the market.
6. Industry codes of conduct, much like those created in the early 2000s, amount to self-regulation. In this case, the incentives facing group buyers are such that self-regulation is an ineffective form of policing the underlying features (e.g., administrative fee levels) that promote potentially exclusionary practices that can harm competition and consumers.
7. Many of the competitive issues regarding intermediary practices would be illuminated by information on the structure and terms of contracts between intermediaries and suppliers, distributors, and healthcare providers. This is particularly true for bundled discount agreements and sole-source contracts. These agreements are not in the public domain, lack transparency, and are critical for establishing whether certain practices are exclusionary and harmful to competition and consumers. Exclusionary conduct may foreclose lower cost, more innovative vendors of drugs and devices, unduly influence the structure of upstream drug, devices, and supplies manufacturers, and potentially contribute to drug shortages.
8. The terms of agreements between group buyers (e.g., PBGs) and vendors deserve particular attention. Numerous factors are present that could facilitate

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<sup>90</sup> For further discussion, see, e.g., Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?* 89 OREGON L. REV. 813 (2011).

anticompetitive coordination between group buyers and drug and medical device manufacturers. Moreover, certain agreements involving PBGs may create incentives (e.g., via commission structures paid to PBGs) for PBG representatives to enforce or extend potentially exclusionary practices by vaccines manufacturers.

9. Antitrust enforcement should investigate whether the bundled discounts offered by major vaccines manufacturers potentially target suppliers of single vaccines attempting to compete against bundled offerings in order to frustrate entry or growth. The effect of such conduct is apparently to raise prices, limit choice, and stifle innovation.
10. PBM conduct vis-à-vis – and contracts with – independent pharmacies should be investigated for their effect on depressing prices paid for prescription drugs. Monopsonistic conduct potentially forces the exit of an important source of healthcare choice to the consumer.