

NOTE

PAY-TO-PLAY: THE IMPACT OF GROUP PURCHASING ORGANIZATIONS ON DRUG SHORTAGES

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The United States prescription drug shortage crisis is a serious and preventable problem. Numerous reasons have been suggested as potential causes of the crisis; however, none are wholly satisfactory. This Note attempts to address the drug shortage crisis by arguing that the contracting practices of Group Purchasing Organizations (GPOs) create decreased pharmaceutical manufacturer diversity and a fragile supply chain. GPOs were formed with the purpose of consolidating buyer power for hospitals to secure the best possible prices for medical supplies, including prescription drugs, and the lowest possible cost for hospital patients. However, GPOs have strayed from this purpose, engaging in contracting practices that increase their profits at the expense of hospital patients and generic drug manufacturers. The contracting practices used by GPOs would be illegal under usual antitrust and fraud law, but GPOs enjoy several unique safe harbors that immunize them from prosecution. Eliminating the anticompetitive effect of GPOs will require significant reforms by both the executive and legislative branches. Repealing the safe harbors protecting GPOs from antitrust scrutiny will increase manufacturer diversity and lower manufacturer entry barriers. This will create a more robust healthcare supply chain capable of rapidly shifting production to meet demand in the face of potential shortages.

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INTRODUCTION

The United States is undergoing a critical shortage of certain prescription drugs. Although the impact of the shortage is undeniable, the cause of the

shortage remains an issue of considerable debate.¹ Commentators often point to manufacturing and production problems as the cause of the shortage.² This Note, however, argues that insufficient production capacity is a symptom, not the cause, of the problem. Policy positions taken by antitrust enforcement agencies and legislation legalizing certain types of kickbacks as “administrative fees” have exacerbated the problem. Group Purchasing Organizations (“GPOs”) have been granted free reign to legally engage in anticompetitive practices that depress pharmaceutical production capacity for certain drugs, creating shortages.

Part II of this Note provides background information explaining how GPOs contribute to the drug shortage crisis. Part II examines the drug shortage crisis generally, the role of GPOs in health care, the federal antitrust agencies governing GPOs, and the application of the Federal Anti-Kickback Statute to GPOs. Part III analyzes how federal policies and practices have allowed for, and in some cases, even encouraged, anticompetitive behaviors by GPOs. Part III begins by applying a traditional antitrust analysis to GPO practices. Part III then examines the safe-harbor provision of the Federal Anti-Kickback statute³ (“Safe-Harbor Provision”), as it relates to GPOs.

Part III argues that without the special protections afforded by the Safe-Harbor Provision, the “administrative fee” system under which GPOs operate would constitute fraud. Part III concludes by arguing that current practices lead to anticompetitive behaviors that raise entry barriers for drug and medical device manufacturers and increases certain generic drug costs. Part IV recommends that the executive and legislative branches of the

1. See *The Causes of Drug Shortages and Proposals for Repairing These Markets: Testimony Before the H. Comm. on Oversight and Gov't Reform* (Nov. 29, 2011) (testimony of Scott Gottlieb), available at <http://www.aei.org/speech/health/health-care-reform/the-causes-of-drug-shortages-and-proposals-for-repairing-these-markets/> (arguing that the drug shortage crisis is due to various regulatory factors). *But see* Roxanne Nelson, *GPOs to Blame For Drug Shortages, Says Physicians Group*, MEDSCAPE TODAY (Jan. 24, 2013), <http://www.medscape.com/viewarticle/778146> (discussing allegations before Congress that GPOs are a major factor in promoting the drug shortage crisis); Akiv Roy, *How Margaret Hamburg's FDA Causes Cancer Drug Shortages*, FORBES (June 15, 2012, 12:27 PM), <http://www.forbes.com/sites/aroy/2012/06/15/how-margaret-hamburgs-fda-causes-cancer-drug-shortages/> (arguing that the drug shortage crisis is a result of FDA enforcement policies undertaken by Commissioner Margaret Hamburg).

2. See Doug Schoen, *The Drug Shortages Crisis in America*, FORBES (Feb. 13, 2012, 1:08 PM), <http://www.forbes.com/sites/dougschoen/2012/02/13/the-drug-shortage-crisis-in-america/> (noting that while the FDA considers the cause of shortages to be manufacturing problems, other arguments include small profit margins for manufacturers, generic manufacturer consolidation, and ingredient shortages).

3. *Id.*

federal government reassess their policies to provide for stricter enforcement against anticompetitive behaviors by GPOs.

I. THE DRUG SHORTAGE CRISIS AND THE ROLE GPO'S PLAY

The drug shortage crisis affects millions of Americans each day, whether in the form of substituted medications, delayed procedures, or higher costs. The role GPOs play in contributing to the shortage may not seem readily apparent, but the impact is fundamental—an underlying force which drives down manufacturing capacity and leads to shortages. Federal regulation via administrative agencies and congressional legislation has contributed to this problem by creating safe harbors that shelter anticompetitive practices by GPOs.

A. *Drug Shortages Occur Because Only a Few Key Manufacturers Produce Certain Drugs, Leading to a Fragile Supply Chain*

The first instance of serious drug shortages in the United States occurred in 1999, and the problem has grown substantially since that time.⁴ In 2011, the crisis peaked, with the United States suffering a record 251 drug shortages.⁵ Since 2011, the numbers have diminished slightly, but the problem remains serious. The Food and Drug Administration (“FDA”) reported over 100 ongoing drug shortages as of December 2013.⁶ Certain classes of drugs are more susceptible to shortages than others.⁷ The majority of serious drug shortages occur in the market for sterile injectable drugs, which account for approximately eighty percent of such shortages.⁸

4. U.S. FOOD & DRUG ADMIN., A REVIEW OF FDA’S APPROACH TO MEDICAL PRODUCT SHORTAGES 3 (Oct. 31, 2011) [hereinafter APPROACH TO MEDICAL PRODUCT SHORTAGES], available at www.fda.gov/DrugShortageReport (explaining that the number of drug shortages in the United States tripled from 61 in 2005 to 178 in 2010).

5. See Katie Thomas, *Drug Shortages Persist in U.S., Harming Care*, N.Y. TIMES (Nov. 16, 2012), <http://www.nytimes.com/2012/11/17/business/drug-shortages-are-becoming-persistent-in-us.html>.

6. See *Current Drug Shortages Index*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> (last updated Dec. 2, 2013).

7. See C. Lee Ventola, *The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies*, 36 PHARMACY & THERAPEUTICS 740, 749 (2011) (reporting that certain classes of drugs, especially sterile injectables, are at a high risk for shortages); see also APPROACH TO MEDICAL PRODUCT SHORTAGES, *supra* note 4 (stating that in 2010–11, oncology drugs made up 28% of shortages, antibiotics 13%, and nutrition/electrolyte drugs 11%).

8. See APPROACH TO MEDICAL PRODUCT SHORTAGES, *supra* note 4; KEVIN HANINGER, AMBER JESSUP, & KATHLEEN KOEHLER, U.S. DEP’T OF HEALTH & HUMAN SERVS., ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES (Oct. 2011) [hereinafter HHS ECONOMIC ANALYSIS], available at <http://aspe.hhs.gov/sp/reports/2011/drugshortages/ib.shtml> (declaring that, in 2010, 74% of shortages involved sterile

The most common major therapeutic classes of drugs in shortage are oncology drugs, antibiotics, and electrolyte/nutrition drugs.⁹ There have also been noticeable shortages in certain pain medications and anesthesia agents.¹⁰

There is no shortage of theories as to the cause of the drug shortage crisis.¹¹ Both the United States Department of Health and Human Services (“HHS”) and the FDA have suggested a variety of causes as factors leading to the drug shortage crises; however, their analyses have largely focused on issues relating to manufacturing and shipping.¹² Although manufacturing and shipping problems can harm drug supply, the shortages caused by manufacturing and shipping issues are the symptom of a greater underlying problem: an unstable supply chain for certain types of drugs and medical devices.¹³ A stable supply chain is a major protection against shortages, and stability is promoted by having a large and diverse group of suppliers.¹⁴ However, only a few manufacturers produce the bulk of generic drugs, making generics particularly susceptible to shortages.¹⁵

injectable drugs, and the majority of shortages for sterile injectables was concentrated in the generics industry).

9. See APPROACH TO MEDICAL PRODUCT SHORTAGES, *supra* note 4.

10. See Sharona Hoffman, *The Drugs Stop Here: A Public Health Framework to Address the Drug Shortage Crisis*, 67 FOOD & DRUG L.J. 1, 3 (2012) (noting that the drug shortage crisis has raised concerns from commentators of an “alarming dearth” of some chemotherapy drugs in recent years, as well as concerns regarding shortages in heart drugs, pain medications, attention deficit hyperactivity disorder therapies, and anesthesia agents).

11. See *id.* at 4–8 (discussing the various factors that commentators have pointed to as the cause of the drug shortage crisis).

12. See APPROACH TO MEDICAL PRODUCT SHORTAGES, *supra* note 4, at 15–16 (proposing various reasons for drug shortages, including causes such as manufacturing issues, labeling mistakes, increased demand, and poor business decisions); HHS ECONOMIC ANALYSIS, *supra* note 8, at 1 (indicating that interruptions to manufacturing are the primary culprit of drug shortages); see also *Frequently Asked Questions About Drug Shortages*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm> (last visited Oct. 13, 2013) (stating that the major reasons for drug shortages are quality/manufacturing issues).

13. See U.S. GEN. ACCOUNTING OFFICE, GAO-12-116, DRUG SHORTAGES: FDA’S ABILITY TO RESPOND SHOULD BE STRENGTHENED 7 (2011), available at <http://www.gao.gov/assets/590/587000.pdf>.

14. See DIANA L. MOSS, THE AM. ANTITRUST INST., HEALTHCARE INTERMEDIARIES: COMPETITION AND HEALTHCARE POLICY AT LOGGERHEADS? 6 (2012), available at <http://www.antitrustinstitute.org/~antitrust/sites/default/files/AAI%20White%20Paper%20Healthcare%20Intermediaries.pdf> (indicating that supply chains with only a few competitors are at high risk for collapse following any unexpected disruption).

15. See Ventola, *supra* note 7 (declaring that most drug shortages affect generic medications and that most generic drugs are produced by only a few manufacturers); see also HHS ECONOMIC ANALYSIS, *supra* note 8, at 6 (reporting that only seven

B. GPOs are Upstream Purchasing Agents that Engage in Conduct That Raises Antitrust Concerns

GPOs are economic intermediaries originally established by hospitals to pool their purchasing power for more favorable contracts with medical suppliers.¹⁶ Legislatively, a GPO is defined as “an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made under a federal healthcare program.”¹⁷ By purchasing as a group, hospitals can achieve greater discounts and lower prices than they could achieve by bargaining independently, while also minimizing transaction costs.¹⁸ Membership in a GPO is voluntary, however independent hospitals are subject to the added expense of directly contracting for drugs and supplies with individual manufacturers and distributors.¹⁹ However, due to the fiscal efficiencies that GPOs can offer, GPO use is widespread in the healthcare industry. The Government Accountability Office (“GAO”) has stated that ninety-eight percent of U.S. hospitals use GPO contracts to purchase products, and about seventy-three percent of purchases made by hospitals are done through GPO contracts.²⁰ The field for national GPOs is highly concentrated, with five GPOs commanding ninety percent of the market.²¹

Many of the agreements entered into between GPOs and pharmaceutical manufacturers amount to exclusionary agreements, either explicitly through contractual arrangements, or implicitly through arrangements between the

manufacturers produce the bulk of generic drugs and that, of those, it is rare for more than three to produce any given drug).

16. See S. PRAKASH SETHI, INT’L CTR. FOR CORPORATE ACCOUNTABILITY, ICCA-2006.G-01, GROUP PURCHASING ORGANIZATIONS: AN EVALUATION OF THEIR EFFECTIVENESS IN PROVIDING SERVICES TO HOSPITALS AND THEIR PATIENTS 6, 17 (2006), available at http://www.icca-corporateaccountability.org/PDFs/HGPIL_Report_07-20-06.pdf (stating that GPOs are a form of buying cooperative designed to combine purchasing power to form leverage to secure lower prices from sellers).

17. 42 U.S.C. § 1320a-7b(b)(3)(C) (2012); 42 C.F.R. § 1001.952(j) (2013).

18. See ROBERT E. LITAN & HAL J. SINGER, DO GROUP PURCHASING ORGANIZATIONS ACHIEVE THE BEST PRICES FOR MEMBER HOSPITALS? AN EMPIRICAL ANALYSIS OF AFTERMARKET TRANSACTIONS 2 (Oct. 2010), available at http://www.medicaldevices.org/sites/default/files/GPO_pricing_litan_singer_distributio_n_oct%202010.pdf.

19. See 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. 173, 175 (2005).

20. U.S. GEN. ACCOUNTING OFFICE, GAO-10-738, GROUP PURCHASING ORGANIZATIONS: SERVICES PROVIDED TO CUSTOMERS AND INITIATIVES REGARDING THEIR BUSINESS PRACTICES 4 (2010) [hereinafter GAO-10-738], available at <http://www.gao.gov/assets/310/308830.pdf>.

21. HHS ECONOMIC ANALYSIS, *supra* note 8, at 5.

GPO and member hospitals.²² These exclusionary contracting practices can be complicated, and often involve bundling arrangements, extended terms, and exclusivity provisions. Product bundling occurs when GPOs group together multiple drugs and/or medical devices and offer the package to member hospitals at a discount.²³ In addition to bundling, GPOs typically award long-term contracts to drug and medical device manufacturers.²⁴ These long-term agreements commit the GPO to purchasing the manufacturer's products and improve efficiency by reducing the need to renegotiate contracts.²⁵ Furthermore, GPOs frequently use exclusionary sole-source contracts. A sole-source contract requires that only one person or company provide the goods or services requested in the contract.²⁶ In general, member hospitals are not compelled by GPOs to purchase specific drugs or medical devices through GPO contracts; however, they must do so if they wish to obtain the discounts offered by their GPO.²⁷

C. Regulations by Federal Antitrust Authorities Concerning GPOs

In 1993, the United States Department of Justice ("DOJ") and Federal Trade Commission ("FTC") first issued a joint guidance document explaining the agencies' views regarding joint purchasing arrangements in healthcare, last revised in 1996.²⁸ The joint guidance document concluded

22. Cf. EINER ELHAUGE, THE EXCLUSION OF COMPETITION FOR HOSPITAL SALES THROUGH GROUP PURCHASING ORGANIZATIONS 2 (2002) [hereinafter EXCLUSION OF COMPETITION], available at http://www.law.harvard.edu/faculty/elhaug/pdf/gpo_report_june_02.pdf (arguing that many contracts GPOs enter into with medical device manufacturers amount to exclusionary agreements).

23. See U.S. GEN. ACCOUNTING OFFICE, GAO-03-998T, GROUP PURCHASING ORGANIZATIONS: USE OF CONTRACTING PROCESSES AND STRATEGIES TO AWARD CONTRACTS FOR MEDICAL-SURGICAL PRODUCTS 6 (2003) [hereinafter GAO-03-998T], available at <http://www.gao.gov/assets/90/82028.pdf> (explaining that bundling links price discounts to specified groups of products, and discussing several types of bundling arrangements GPOs frequently engage in).

24. See *id.* at 14 (declaring that a study found that the two largest GPOs typically award with longer terms than the next five largest GPOs).

25. See *id.* (discussing motivation for GPO contract term length).

26. See GAO-10-738, *supra* note 20, at 2 (in which a letter from Sen. Chuck Grassley defines sole sourcing as "contracting with only one vendor for a given product when multiple vendors of comparable products are available").

27. See EXCLUSION OF COMPETITION, *supra* note 22, at 3 (explaining that member hospitals are free to accept or reject exclusionary contracts on a contract-by-contract basis).

28. U.S. DEP'T OF JUSTICE & FED. TRADE COMM., STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTHCARE 1, 1-7 (1996) [hereinafter JOINT GUIDANCE DOCUMENT], available at <http://www.ftc.gov/reports/hlth3s.pdf> (providing a history of the Joint Guidance Document).

that most GPO arrangements do not raise antitrust concerns, and that any antitrust concerns raised by such arrangements are typically outweighed by efficiencies that will benefit consumers.²⁹

The joint guidance document primarily applies to the anticompetitive effects of GPOs on downstream market participants, such as hospitals and medical patients.³⁰ The joint guidance document suggests a low risk of downstream anticompetitive effects, finding few entry barriers to the formation of GPOs, and that hospitals are a low risk for collusive action due to the ease with which member hospitals may terminate their contract with GPOs.³¹ As a result of these presumed protections, the joint guidance document states that the FTC and DOJ will not challenge GPOs absent “extraordinary circumstances,” provided that GPO arrangements with health care providers meet a two-part test.³²

The first condition of the two-part test provides that “the purchases [of a particular drug by a GPO] account for less than thirty-five percent of the total sales of the purchased product or service in the relevant market.”³³ This effectively creates a monopsony safe harbor that is based on a market share threshold, with the idea that below the thirty-five percent threshold it is difficult for a GPO to depress prices below a competitive level.³⁴

The second condition of the two-part test requires that “the cost of all the products and services purchased jointly [under GPO contract] accounts for less than twenty percent of the total revenues from all products or services sold by each of the competing participants in the joint purchasing arrangement.”³⁵ This means that the total cost of all GPO purchases made by any member hospital cannot exceed twenty percent of that hospital’s total profits.³⁶ This condition applies only where some or all of the GPO’s member hospitals are direct competitors, and is intended solely to prevent collusive arrangements among GPO member hospitals.³⁷ As a result, the

29. *See id.* at 53 (“Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers.”).

30. *See id.* at 53–60.

31. *See id.* at 58 (stating that entry barriers for GPOs are not high).

32. *See id.* at 54 (“[the agencies] will not challenge, absent extraordinary circumstances, any joint purchasing arrangement among healthcare providers where two conditions are present . . .”).

33. *Id.* at 54–55.

34. *See* MOSS, *supra* note 14, at 8 (noting that the first test requirement of the joint guidance document effectively creates a monopsony safe harbor).

35. JOINT GUIDANCE DOCUMENT, *supra* note 28, at 55.

36. *See* Klish, *supra* note 19, at 178 (explaining that the aggregate purchases of GPO member hospitals cannot exceed 20% of the total profits made from all goods and services sold by each competing member).

37. *See* JOINT GUIDANCE DOCUMENT, *supra* note 28, at 55–56 (indicating that even

second condition creates a collusion safe harbor for contracts that do not raise concerns regarding price fixing among member hospitals.³⁸

Despite the good intentions of the joint guidance document, it is in many ways woefully inadequate. Most importantly, the joint guidance document does not provide any guidance on enforcing exclusionary agreements between GPOs and suppliers.³⁹ Although the joint guidance document provides a list of mitigating factors for arrangements that fall outside the safe harbor, if an arrangement falls inside the safe harbor, the federal agencies cease to consider any possible anticompetitive effects of the arrangement.⁴⁰ Therefore, the agency safe harbor shields GPOs engaged in anticompetitive practices, so long as they meet the minimal requirements of the two-part test.

The joint guidance document is also alarmingly dated. Conditions today are vastly different than they were in 1996.⁴¹ Market consolidation has led to an oligopoly market structure for national GPOs, suggesting that entry barriers are no longer low.⁴² Additionally, the prevalence of bundling and exclusivity contracts has placed disproportionate power in the hands of large GPOs, preventing smaller GPOs from offering comparable packages to hospitals.⁴³ This not only raises entry barriers, but also creates a market that naturally trends towards consolidation.

where member hospitals are direct competitors, common GPO membership is not likely to facilitate collusive price-setting so long as the goods and services purchased account for only a small percentage of the total hospital profits).

38. See MOSS, *supra* note 14, at 8 (arguing that the second requirement effectively creates a collusion safe harbor).

39. EINER ELHAUGE, ANTITRUST ANALYSIS OF GPO EXCLUSIONARY AGREEMENTS 1 (Sept. 26, 2003), available at <http://ftc.gov/os/comments/healthcarecomments2/elhaug.pdf>.

40. See Klish, *supra* note 19, at 178 (noting that any GPO arrangements that fall within the antitrust safety zone are exempt from antitrust enforcement except in extraordinary circumstances).

41. See MOSS, *supra* note 14, at 8 (arguing that the healthcare intermediaries market currently has high entry barriers and operates as an oligopoly market, resulting in an environment in which it is more difficult for hospitals to compete without being a part of a major GPO).

42. See *id.* (declaring that GPO entry barriers have risen since 1996); HHS ECONOMIC ANALYSIS, *supra* note 8, at 5 (stating that five GPOs command 85–90% of the market).

43. Cf. EXCLUSION OF COMPETITION, *supra* note 22, at 4 (stating that exclusive dealing arrangements cause anticompetitive harm by denying rivals the economies of scale that they need to compete effectively).

D. GPOs are Protected from Prosecution Under the Federal Anti-Kickback Statute Through an Easily Attainable Safe Harbor

Purportedly, when a GPO seeks to carry a particular class of product, it attempts to secure the highest quality and lowest prices possible through a competitive bidding or auction process that allows vendors to bid for a contract to supply the GPO's entire network of member hospitals.⁴⁴ To cover operating expenses, GPOs are not paid a fee by hospitals; rather, they charge vendors "administrative" and other fees in exchange for providing contracting services to hospitals.⁴⁵ Under the Federal Anti-Kickback Statute of the Social Security Act ("Federal Anti-Kickback Statute"), it is illegal for anyone to receive payment from a party in exchange for contracting to order a good for the party if the good is in any way paid for through a federal healthcare program (e.g., Medicare).⁴⁶ However, in the late 1980s, GPO interest groups convinced Congress that by charging administrative fees to manufacturers rather than to medical providers, GPOs would achieve greater efficiencies, which would result in lower federal healthcare expenditures.⁴⁷ Congress, therefore, amended the Social Security Act in 1987, exempting GPOs from the statutory ban on kickbacks.⁴⁸

In 1991, HHS formally established a GPO anti-kickback provision "safe harbor," (hereinafter "GPO Safe Harbor") which promulgated the specific requirements that GPOs must meet to be exempted from prosecution for fraud under the Federal Anti-Kickback Statute.⁴⁹ To meet the GPO Safe

44. See LITAN & SINGER, *supra* note 18, at 2 (explaining that GPOs contract to supply the entirety of their member hospital networks through a bidding or auction process).

45. See *id.* (noting that GPOs cover operating expenses by charging vendors "administrative" fees based on a percentage of the proceeds generated by the auction, as well as through other fees); Daniel DeLay, *Watch out for GPOs*, FORBES (Nov. 12, 2009, 4:23 PM), <http://www.forbes.com/2009/11/12/gpo-medicare-hospitals-medical-health-opinions-contributors-daniel-delay.html> (explaining and critiquing the administrative fee system, which GPOs use instead of charging fees to hospitals).

46. 42 U.S.C. § 1320a-7b(b) (2012).

47. See Patricia Earl & Phillip L. Zweig, *Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Cause the U.S. Drug Shortage*, CARE AND COST (Feb. 14, 2012) [hereinafter *Connecting the Dots*], <http://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/> (stating that in 1987, GPO interest groups successfully lobbied Congress to allow them to charge administrative fees to vendors, arguing that this would be more cost efficient for consumers).

48. See 42 C.F.R. § 1001.952(j) (2013); S. REP. NO. 100-109, at 27 (1987).

49. 42 U.S.C. § 1320a-7(b) (providing a detailed overview of the specific

Harbor, GPOs must meet the following requirements: (1) they must have a written agreement with each entity to which they provide services, (2) the agreement must be signed by both parties, and (3) the agreement must state either that administrative fees from vendors are capped at three percent or less of the purchase price, or the agreement must specify a fixed amount or percentage of the value of purchases each vendor will pay.⁵⁰ In other words, administrative fees are capped at three percent of total purchase value unless the contract explicitly provides any other amount or percentage.⁵¹

In most cases, a GPO's member hospitals actually own the GPO.⁵² At the end of each fiscal year, GPOs redistribute a portion of their profits to their member hospitals in the form of patronage or corporate dividends.⁵³ In theory, this system encourages GPOs to secure the best possible deals for hospitals, since they are entering into those deals for themselves.⁵⁴ However, because administrative fees are a percentage of the price of total sales volume, it is not always in the best interest of GPOs to negotiate the lowest possible price with manufacturers.⁵⁵ This problem is compounded by the fact that member hospitals frequently do not have any incentive to pressure GPOs for lower negotiated prices, as a percentage of the supracompetitive profits are returned to hospitals in the form of dividends.⁵⁶ The end result is that, although hospitals and GPOs both

requirements set forth by the HHS necessary to meet the safe-harbor requirements, as well as their rationale).

50. See 42 C.F.R. § 1001.952(j).

51. See GAO-10-738, *supra* note 20, at 11 (observing that, as reported by the GPOs, the average contract administrative fees weighted by purchasing volume ranged from 1.22 percent of purchases to 2.25 percent of purchases). *But see* GAO-03-998T, *supra* note 23, at 2 (noting that the administrative fees can be much higher, in one case reaching nearly 18 percent).

52. DeLay, *supra* note 45 (stating that most member hospitals are owners of their respective GPOs, acting akin to shareholders); see also EXCLUSION OF COMPETITION, *supra* note 22, at 41 (explaining that a portion of GPO revenue gets redistributed to shareholder hospitals).

53. Cf. HERBERT HOVENKAMP, HEALTH INDUS. GRP. PURCHASING ASS'N, COMPETITIVE EFFECTS OF GROUP PURCHASING ORGANIZATIONS' (GPO) PURCHASING AND PRODUCT SELECTION PRACTICES IN THE HEALTH CARE INDUSTRY 4 (Apr. 2002) (discussing shareholder hospitals and GPO profit redistribution); see also DeLay, *supra* note 45 (declaring that GPOs return a portion of excess fees to shareholder hospitals in the form of dividends).

54. See *id.*

55. See LITAN & SINGER, *supra* note 18, at 4 (arguing that if a GPO is receiving kickbacks equal to a percentage of the auction proceeds, the GPO lacks a strong incentive to seek out the lowest price; furthermore, administrative fees impose a cost on medical product vendors, causing them to bid less aggressively on price so that they have excess resources to afford the large side payment).

56. See EXCLUSION OF COMPETITION, *supra* note 22, at 26 (discussing the

benefit from the administrative fee system, medical patients—the intended beneficiaries of the administrative fee system—do not receive any efficiencies.⁵⁷

II. GPOS AND ANTICOMPETITIVE BEHAVIOR: A FAILURE OF FEDERAL REGULATION

Antitrust law traditionally bans a number of arrangements and practices considered anticompetitive. This section examines how federal policies and practices have allowed GPOs to engage in behaviors, which would otherwise be deemed anticompetitive, and examines what specific anticompetitive behaviors GPOs engage in. Part III(A) is divided into three sections, which analyze: (i) GPO exclusionary contracting practices, (ii) GPO bundling and tying arrangements, and (iii) market concentration and pricing issues. Part III(B) argues that the safe-harbor provision of the Federal Anti-Kickback statute has been subverted from its original purpose, and now effectively permits otherwise fraudulent kickbacks.

A. GPO Contracting Practices Led to Increased Market Consolidation

Current federal antitrust policies have allowed for, and in some cases promoted, GPO action that would constitute antitrust violations in different circumstances. This section analyzes the market structure and contracting practices of GPOs in relation to traditional federal antitrust regulations.

i. GPOs Utilize Sole-Source Contracts and Rebate Penalties to Restrict Member Hospitals From Purchasing From Independent Third Parties

Under Section 3 of the Clayton Act, it is an antitrust violation for a company to make a contract “where the effect of such . . . contract for sale . . . may be to substantially lessen competition or tend to create a monopoly in any line of commerce.”⁵⁸ Subsequent case law has interpreted this to mean that vertical non-price restraints, including exclusionary contracts, are subject to a rule of reason analysis.⁵⁹

incentives member hospitals have to gain through compliance with the side-payment system).

57. See *id.* at 41 (stating that member hospitals benefit from both side-payment schemes, such as dividends to shareholder hospitals, and special discounts; both of which align the interest of member hospitals with GPOs, but which pass down additional costs to nonmember hospitals, patients, insurers, and government payors).

58. 15 U.S.C. § 14 (2012).

59. See *Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 49–50 (1977) (declaring that the rule of reason applied to all vertical non-price restraints, and that per-se illegality was the exception). A “rule of reason” analysis, as first developed in *Standard Oil Co. v. United States*, 221 U.S. 1 (1911), provides that in certain situations

A contract may be legally analyzed as an exclusive dealing arrangement even if the agreement is not literally exclusive.⁶⁰ Few GPO contracts explicitly impose a restriction on their member hospitals that they may never deal with competitors.⁶¹ An example of the typical requirements imposed upon GPO members may be seen in Premier's 2008 group purchasing policy, which incorporates a "market penetration target" of fifty percent of total supply purchasing for member hospitals, with penalties imposed on those who fail to meet the target.⁶² While a requirements contract of ninety-five percent would likely be held to be anticompetitive, a requirement of only fifty percent is unlikely to raise any serious exclusionary concerns in court.⁶³ However, membership contracts are not the primary means by which GPOs engage in exclusive dealing.

The majority of exclusionary contracts entered into by GPOs are not mandatory arrangements.⁶⁴ Rather, the GPO member hospitals are given the option to opt into exclusionary agreements on a contract-by-contract basis.⁶⁵ These voluntary contracts offer significant incentives to hospitals, but at a high cost—they are frequently bundled to cover multiple products and manufacturers, they may impose retroactive fiscal penalties for deviation, and may even ban the purchase of specific rival products.⁶⁶

only business practices or contracts that unreasonably restrain trade shall be considered violations of Section 1 of the Sherman Act, 15 U.S.C. § 1 (2012), which allows for the circumstances of business practices to be considered in assessing their legality for antitrust purposes.

60. See *id.* (noting that certain contracts may, as a practical matter, exclude rivals without containing an express prohibition against dealing with rivals; and that such contracts may be analyzed as exclusive dealing contracts despite not being literally exclusive).

61. See EXCLUSION OF COMPETITION, *supra* note 22, at 4 (declaring that many agreements GPOs enter into between both vendors and member hospitals qualify as exclusive agreements, even though many do not expressly prohibit dealing with all competitors in all instances).

62. See PREMIER, PREMIER GROUP PURCHASING POLICY (Jan. 1, 2008), available at <http://www.alliant-has.com/sites/default/files/PremierPurchasingPolicy.pdf> ("If a member's participation falls below 50%, adjustments to the member's fiscal year Supply Chain Improvement Plan will be developed to move participation to 50% or above.").

63. See *ZF Meritor LLC v. Eaton Corp.*, 769 F. Supp. 2d 684 (D. Del. 2011) (enjoining use of market penetration ranges); MOSS, *supra* note 14, at 10–11 (observing that market penetration ranges have been successfully challenged in court).

64. See EXCLUSION OF COMPETITION, *supra* note 22, at 3 (explaining that, although GPOs offer numerous exclusionary contracting arrangements, the majority of these arrangements do not mandate member hospital participation).

65. See *id.* (remarking that member hospitals are typically free to accept or reject the vast majority of exclusionary contracts offered to them by GPOs).

66. See *id.* at 3–4 (explaining the trade-off between the positive incentives GPO exclusionary agreements provide to hospitals, and the high costs they often impose:

Hospitals enter voluntary exclusionary agreements with GPOs for a wide variety of compelling reasons. The most common reason that a member hospital enters into a voluntary commitment contract through its GPO is that the GPO is capable of offering the hospital a supracompetitive price on the product through its monopsony buying power.⁶⁷ However, the incentives GPOs offer to hospitals through discounted goods only sometimes take the form of an outright cut to sale price. In some cases, hospitals find that the standardization resulting from sole-source or dual-source contracts is an efficiency benefit in of itself.⁶⁸ One common tactic GPOs employ in exclusionary contracts is the use of loyalty discounts or rebate programs.⁶⁹ In contracts employing a loyalty rebate, a member hospital is eligible for a rebate upon purchasing a high percentage share of specified GPO products.⁷⁰ These loyalty rebates typically last five to seven years, and may include a retroactive enforcement clause.⁷¹

The penalties GPOs assign for breach of voluntary contracts may, in some cases, exceed the penalties assigned for breach of a mandatory contract.⁷² A failure to meet an explicit (mandatory) commitment contract can result in fines or penalties; however, these penalties are subject to antitrust scrutiny.⁷³ Under voluntary contracts, a GPO often does not issue fines—they instead withdraw rebate or discount offers. A GPO's withdrawal of a rebate offer has the same effect as an outright fine; however, by guising the penalty as loss of a rebate, the GPO can avoid scrutiny under antitrust law.⁷⁴ In many ways, loyalty rebates can be more

binding hospitals to the mandated product despite the possible availability of better and/or cheaper products elsewhere).

67. *See id.* at 39 (contending that GPOs have the capacity to exercise monopsony power to demand supracompetitive rates on many items, and that the ability to exert such power is itself anticompetitive).

68. *See id.* at 5 (observing that various interested parties exert pressure on hospitals to encourage the use of standardized devices, and that standardization internally within a hospital often leads to efficiency benefits).

69. *See id.* at 7 (arguing that loyalty rebates are utilized by GPOs to impose penalties on noncompliant hospitals).

70. *See id.* at 8 (explaining that rebates or discounts are conditioned on purchasing a high share of the buyer's purchases from the supplier, as opposed to a standard discount, which would be a per item price cut).

71. *See id.* at 8–9 (disclosing that a retroactive enforcement clause means that if the hospital deviates from its agreement and purchases a lower share than required to meet the rebate, it has to refund the GPO the total amount of all prior rebates received).

72. *See id.* at 7–9 (noting that conditioned rebates have the potential to impose much harsher penalties for noncompliance than a traditional contract).

73. *See id.* at 7 (stating that GPOs may assign contractual penalties to purchasing arrangements for breach by a buyer, but that any such penalties may not unreasonably restrain trade).

74. *See id.* at 7 (stating that the termination penalty imposed on buyers that do not

exclusionary than an explicit sole-source contract.⁷⁵ This is primarily due to retroactive enforcement clauses, which can result in a higher financial penalty for a hospital breach of the agreement than would be otherwise allowed under the law for breach of contract.⁷⁶

Both sole-source contracts and loyalty rebate contracts are designed to exclude rivals from the relevant market. Each form of contract is designed to secure the GPO the highest possible market share for the product in question, leaving rivals with a share that is not large enough to support economies of scale.⁷⁷ This raises entry barriers for manufacturers and concentrates the supply chain.

Although exclusive arrangements between hospitals and GPOs can have notable anticompetitive effects, the most significant antitrust concern regarding exclusive dealing arrangements arises from contracts with sellers, particularly generic manufacturers who sell to GPOs.⁷⁸ These companies operate on razor-thin margins, and, due to economies of scale, acquiring a GPO contract is integral in determining whether the manufacturer can make a profit.⁷⁹ Upriver exclusive dealing arrangements significantly raise entry barriers for small manufacturers attempting to enter the generic drug market, and create a risk that large manufacturers and GPOs will enter into collusive arrangements designed to keep small generic manufacturers out of the market.⁸⁰

comply with rebate programs is serious enough to make exclusive dealing agreements raise antitrust concerns); *see also* Moss, *supra* note 14, at 11 (stating that “a lost rebate or discount is, in effect, damages for breach of contract,” and in many cases may far exceed the damages for an actual breach of contract).

75. *See* EXCLUSION OF COMPETITION, *supra* note 22, at 11 (arguing that the fact that payments given for loyalty commitments are often not proportional to volume actually worsens the anti-competitive effect of such agreements by creating a more effective means of dividing monopoly profits created by seller-buyer collusion designed to enhance seller market power).

76. *See id.*

77. *See id.* at 14, 17 (declaring that, even in cases where a new entrant can enter the market, if the innovators who succeed cannot access a large share of the product market and gain economies of scale, then capital markets will provide less funding for innovation than they otherwise would).

78. *See Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?: Hearing Before Subcomm. on Antitrust, Bus. Rights, & Competition of S. Comm. of the Judiciary*, 107th Cong. 68 (2002) (statement of Sen. Orrin Hatch), available at <http://www.gpo.gov/fdsys/pkg/CHRG-107shrg85986/pdf/CHRG-107shrg85986.pdf> (“‘[S]ole source’ contracts . . . create strong disincentives for hospitals to purchase competing products, effectively shutting smaller competitors out of the market.”).

79. *See id.* (statement of Sen. Herbert Kohl, Subcomm. Chairman) (“Gaining a GPO contract is essential for any [pharmaceutical or] medical equipment supplier.”).

80. *See* EXCLUSION OF COMPETITION, *supra* note 22, at 4, 30 (stating that exclusive dealing arrangements raise rivals’ costs by denying those competitors economies of

ii. *GPOs Utilize Bundling Arrangements to Expand Market Share and Exclude Potential Competition*

GPOs often offer discounts that are conditioned on a hospital buying multiple products together.⁸¹ Federal antitrust enforcement authorities have adopted policies that allow GPOs to engage in both upriver and downriver bundling and tying agreements.⁸²

“Tying” and “bundling” are not always easily defined. In theory, tying simply describes an arrangement where a supplier conditions the sale of one product on the purchaser’s agreement to purchase another (often complementary) product.⁸³ Bundling is like tying, with the caveat that the customer is not actually required to buy a second product, but must do so to qualify for a discount on the first product.⁸⁴ Despite this difference, in practice, bundled discounts can produce many of the same anticompetitive effects as tying.⁸⁵

To secure a contract with a GPO, many large manufacturers are encouraged to bundle various product lines together, with one product acting as a loss leader.⁸⁶ Most GPOs use some form of bundling, and the two top national GPOs do a majority of their business through bundled buying and selling.⁸⁷ The prevalence of manufacturer bundling deals provides a significant advantage to incumbent suppliers and raises entry barriers for smaller manufacturers with fewer products.⁸⁸ Smaller

scale, and that powerful buyers have incentives to agree to terms that enhance seller market power in instances where the seller can share supracompetitive profits).

81. See LITAN & SINGER, *supra* note 18, at 35 (noting that GPOs frequently offer discounts that are conditioned on bundling).

82. For the purpose of economic analysis, “upriver” means companies upstream in the supply chain, and “downriver” means companies downstream in the supply chain.

83. See Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397, 399–400 (2009) (defining and discussing tying in light of the Chicago school of economics).

84. See *id.* (“Bundled discounts can produce the same anticompetitive effects as tying without substantial tied foreclosure, but only when the unbundled price exceeds the but-for price.”).

85. See *id.* (“[W]hen the unbundled price exceeds the but-for price, bundled discounts should be condemned based on market power absent offsetting efficiencies, with the same exception for products with a fixed ratio that lack separate utility. When the unbundled price does not exceed the but-for price or this exception applies, bundled discounts should be condemned only when a substantial foreclosure share or effect exists.”).

86. See *Connecting the Dots*, *supra* note 47, at 9 (“To win a contract, a manufacturer would often use a drug as a loss leader, bundling it with other generics in its product line.”).

87. See GAO-03-998T, *supra* note 23, at 11 (noting that the two largest national GPOs used bundling agreements to conduct a majority of their business).

88. See MOSS, *supra* note 14, at 13–14 (stating that the effect of losing bundled

manufacturers, if they produce more than one product, may lack the variety of product line to create a compelling bundle and compete for GPO contracts. Additionally, smaller manufacturers who are able to offer a bundled deal may lack the resources to compete with one of their products sold as a loss leader.⁸⁹ The lack of any antitrust protection against bundling poses real problems for medical supply chains in particular, as bundling arrangements that exclude rivals can increase the cost of medication, reduce choice, and discourage entry and innovation—all factors that contribute to the drug shortage crisis.⁹⁰

iii. GPOs are Currently Operating as Oligopolies Which Leads to Many of the Same Anticompetitive Concerns as Monopolization

Currently, six GPOs dominate the national market for acute care medical supplies, controlling over ninety percent of sales.⁹¹ Within the GPO industry, the three largest firms—MedAssets, Novation, and Premier—dominate industry earnings, controlling approximately seventy-five percent of total industry revenue in 2012.⁹²

GPO sole-source contracts and near-mandatory bundling packages have resulted in upstream market consolidation by raising entry barriers and concentrating market share in the hands of large manufacturers who are able to secure GPO contracts.⁹³ Monopolies or oligopolies on multiple tiers of a single supply chain have the potential to be particularly anticompetitive.⁹⁴ When both an intermediary and its supplier have

discounts is so significant that smaller competitors attempting to enter the market would, in some instances, have to actually pay the buyer to purchase their product(s) to fully compensate the buyer for the loss of the bundled discount).

89. *Cf. id.* at 14 (observing that competition in a market that primarily deals in bundles inherently disadvantages the smaller competitor and single-product new entrants, who are unable to offer comparable discounts).

90. *See id.* at 6 (noting that the exclusionary effects of bundled discounts lead to fewer market entrants and a more fragile supply chain, resulting in limited choices in drugs and medical devices, depriving consumers of innovation and product diversity).

91. *See The Effect of Regulatory Neglect on Health Care Consumers: Hearing on Competition in the Health Care Marketplace Before the Subcomm. on Consumer Prot., Prod. Safety and Ins. of the S. Comm. on Commerce, Sci. and Transp.*, 111th Cong. 2 (2009) (statement of David Balto, Senior Fellow, Center for American Progress Action Fund), available at <http://www.pbmwatch.com/uploads/8/2/7/8/8278205/balto.senatecommerce09.testimony.pdf>.

92. *See GPO Facts and Figures*, HEALTHCARE PURCHASING NEWS (Oct. 2012), <http://www.hpnonline.com/resources/GPOs.html>.

93. *See LITAN & SINGER, supra* note 18, at 39 (arguing that there is significant economic literature supporting the proposition that bundling and exclusive contracting agreements result in anticompetitive harm by raising entry barriers).

94. *See MOSS, supra* note 14, at 3 (stating that healthcare intermediaries can influence market outcomes not only at the level in which they compete, but also in

monopoly power, traditional competition is replaced by bargaining.⁹⁵ These arrangements are not only at high risk for vertical collusion, they also raise entry barriers by promoting exclusion of smaller rivals in the supply chain.⁹⁶

B. A Rose by any Other Name: Administrative Fees and the Side-Payments as Kickbacks

The most problematic anticompetitive behaviors leading to decreased market competition and drug shortages are kickbacks paid by manufacturers to GPOs in exchange for exclusive contracts. At first glance it may seem odd for GPOs to engage in practices like sole-sourcing, which increase manufacturer market power (by consolidating the manufacturing market), as this can result in manufacturers being able to charge higher prices; however, GPOs are actually rewarded for such practices because manufacturers share their supracompetitive profits through side-payments.⁹⁷ GPOs benefit when the manufacturer pays a higher administrative fee, and the increased price for the monopolized good is simply passed on to the buyer's customers in the form of increased marginal cost.⁹⁸ Since hospitals also receive a cut of the side-payments through dividends, the only loser in this scenario is the consumer of the good—the medical patient. The following section examines these side-payments, or “kickbacks,” in greater detail.

i. The Administrative Fee System is Not Only a Kickback, It Actually Raises Drug and Medical Device Costs

The Federal Anti-Kickback statute was originally enacted in 1972, and provides both civil and criminal penalties for offering or paying any remuneration to induce someone to purchase, lease, or order any item or service for which payment may be made under a federal healthcare

complimentary markets, and arguing that GPOs have significant influence).

95. *See id.* (declaring that when multilateral monopoly or oligopoly characterizes the relationship between an intermediary and upstream seller, bargaining displaces traditional market forces).

96. *See id.* (claiming that small upstream vendors are particularly at risk from GPO control over complimentary markets).

97. *See* EXCLUSION OF COMPETITION, *supra* note 22, at 29 (providing an analysis of why buyers might agree to an arrangement that enhances seller market power, suggesting that one such method is for intermediaries to pass along the increased profits to the buyers through various mechanisms).

98. *See id.* (stating that because such cost increases are passed onto consumers, the participating buyer's only actual losses are from reduced sales, the cost of which is effectively offset by side-payments from the seller's monopoly overcharge).

program.⁹⁹ Initially, the administrative fee system under which GPOs currently operate violated the Federal Anti-Kickback statute.¹⁰⁰ However, in 1987, the GPO Safe Harbor was passed under the belief that GPOs could operate more efficiently if they were able to charge administrative fees to manufacturers rather than rely solely on the participation fees of hospitals.¹⁰¹ The GPO Safe Harbor has permitted GPOs to require significant payments from manufacturers in exchange for awarding contracts. Because GPO contracts are often exclusionary, administrative fees effectively act as payments by manufacturers to exclude competitors.¹⁰²

Under the Safe Harbor provision, administrative fees theoretically have a soft cap at three percent of sales.¹⁰³ Anything above this limit requires that the GPO annually disclose the percentage of administrative fees to the Secretary of HHS.¹⁰⁴ However, GPOs have managed to avoid the reporting requirements by inventing new fees or accepting payments which together frequently may amount to twenty percent or more of the total sales price.¹⁰⁵ In one instance, the fees reportedly reached ninety-four percent of total sales volume.¹⁰⁶ The sheer scale of the kickbacks required from many GPOs is problematic, as smaller manufacturers may not have the capital or manufacturing capacity necessary to meet GPO demands.¹⁰⁷

99. 42 U.S.C. § 1320a-7b(b) (2012).

100. See CYNTHIA Y. REISZ & CATHERINE J.B. SLOAN, 2006 HEALTH L. HANDBOOK § 12:3 (Alice G. Gosfield ed., 2006) (arguing that prior to 1987, the administrative fees system under which GPOs currently operate would have constituted fraud).

101. See *Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?: Hearing Before Subcomm. on Antitrust, Bus. Rights, & Competition of S. Comm. of the Judiciary*, 107th Cong. 4 (2002) (statement of Sen. Mike DeWine), available at <http://www.gpo.gov/fdsys/pkg/CHRG-107shrg85986/pdf/CHRG-107shrg85986.pdf> (“GPOs in some cases have strayed from their original purpose of allowing hospitals to work together to limit costs.”); REISZ & SLOAN, *supra* note 100, § 12:3.

102. See *generally Connecting the Dots*, *supra* note 47 (providing a critique of the administrative fees system, with a particular focus on the exclusionary effect on innovative manufacturers).

103. 42 C.F.R. § 1001.952(j) (2013).

104. *Id.*

105. See *Connecting the Dots*, *supra* note 47, at 5 (noting that GPOs frequently accept additional payments such as up-front payments, signing bonuses, prebates, and rebates in addition to the contracted administrative fees).

106. See Mariah Blake, *Dirty Medicine*, Washington Monthly (July/Aug. 2010), available at <http://www.washingtonmonthly.com/features/2010/1007.blake.html> (stating that the total annual fees one manufacturer paid to a major GPO amounted to ninety-four percent of the total sales volume).

107. *Cf.* United States *ex rel.* Fitzgerald v. Novation, L.L.C., No. 3:03-CV-1589-N, 2008 WL 9334966, at *2–3 (N.D. Tex. Sept. 17, 2008) (asserting that GPOs engaged in anticompetitive practices which purposefully excluded smaller competition).

Offering a large side-payment is one way that dominant manufacturers may secure a sole-source contract from a GPO, thereby excluding rivals that may offer a better quality product or more competitive price.¹⁰⁸ The incentive GPOs have to acquire large kickbacks and the incentive manufacturers have to acquire market power have led to instances of GPOs auctioning off exclusive contracts to manufacturers in exchange for large kickbacks.¹⁰⁹

In addition to having exclusionary effects, side-payments may raise the costs of drugs and medical supplies. Because GPO revenue is derived from kickbacks, and is largely based on a percentage of vendor sales volume, higher product prices mean more money for GPOs.¹¹⁰ The additional cost is then passed on to buyers downstream.¹¹¹ One may expect that hospitals would not agree to a side-payment system that creates upstream market consolidation and raises prices, however, because most member hospitals are GPO shareholders and receive dividends, the hospitals also benefit from the side-payment system.¹¹²

There is considerable evidence that GPOs do not actually lower drug and medical device prices when compared to a market able to operate freely.¹¹³ A 2002 GAO report found that in some instances, hospitals may pay up to thirty-nine percent more for goods purchased through GPOs than if they had negotiated the purchase of those same goods directly with the manufacturer.¹¹⁴ A 2010 independent analysis of the subject found that hospitals could save an average of fifteen percent on the cost of drugs and medical supplies by bidding outside of GPO contracts.¹¹⁵ These studies are

108. See EXCLUSION OF COMPETITION, *supra* note 22, at 39–31 (declaring that GPO exclusionary agreements are likely to be particularly attractive to incumbent device manufacturers who face or fear entry by innovative new products).

109. Cf. *Novation, L.L.C.*, 2008 WL 9334966, at *2–3 (in which Novation was sued for allegedly auctioning off exclusive contracts in exchange for kickbacks).

110. See EXCLUSION OF COMPETITION, *supra* note 22, at 30 (noting that GPOs are not incentivized to drive down prices for consumers).

111. See *id.* (explaining how the side-payment system ultimately raises costs for consumers).

112. See *id.* (discussing hospital participation in the side-payment system).

113. See generally *Pilot Study Suggests Buying Groups Do Not Always Offer Hospitals Lower Prices: Hearing Before the Subcomm. on Antitrust, Competition, and Bus. and Consumer Rights of the S. Comm. on the Judiciary*, 107th Cong. (2002) (statement of William J. Scanlon, Director, Health Care Issues) (stating that by eliminating competition and extracting fees of indeterminable amounts from manufacturers, GPOs inflate the cost of drugs beyond what it would be if the market were able to operate freely).

114. See *id.* at 3 (declaring that, for some product models, hospitals using GPO contracts got prices up to 39 percent higher than hospitals not using GPO contracts).

115. See LITAN & SINGER, *supra* note 18 (noting that an independent study determined that GPOs charge in excess of 15% compared to a free market); *Connecting*

a major critique of the administrative fee system, as they show that the effect of GPOs directly contradicts their intended purpose.

III. THE NECESSARY PARADIGM SHIFT: HOW THE FEDERAL GOVERNMENT SHOULD REGULATE GPOS

Anticompetitive effects associated with GPO contracting practices can work against achieving important public policy goals in healthcare, such as ensuring drug availability and affordable healthcare costs. Eliminating GPOs entirely is unnecessary—GPOs have the potential to act as efficient intermediaries to lower costs without causing any anticompetitive effects. Rather, the solution is to eliminate the anticompetitive business practices of GPOs. Achieving this goal will require both the executive and legislative branches to take action.

A. Executives Agencies Should Impose Traditional Antitrust Scrutiny on GPOs

Federal antitrust engagement authorities need to reassess their position regarding GPOs, and more vigorously enforce antitrust laws in the healthcare market. This can be achieved through several steps. First, the 1996 joint guidance statement issued by the FTC and DOJ should be revised so that antitrust concerns in healthcare are treated more consistently with general antitrust analysis. There should not be an automatic assumption of procompetitive effects for GPOs. Second, the FTC and DOJ should perform a new analysis of market concentration and barriers to entry on all levels of the medical supply chain. The areas of the market that pose the greatest competitive problems, such as GPOs, should face heightened scrutiny and lower barriers for antitrust enforcement actions. Given the need for significant reform in the market, the FTC and DOJ should set up a temporary new division to protect competition in the healthcare supply chain, which should exist for a period of approximately ten years, long enough to establish a new corporate culture for GPOs.

B. Congress Should Revoke the GPO Safe Harbor from the Federal Anti-Kickback Statute

Perhaps the most important reform necessary for halting GPO anticompetitive practices is for Congress to take steps to eliminate the supplier-funded business model for GPOs. To achieve this, Congress should ban GPOs from having any investment interest or option in

the Dots, *supra* note 47, at 19 (stating that based upon a study by Navigant Economics, in a truly free market a vial of propofol (sold in GPO for \$.048 per vial, and out of GPO for \$7.60 per vial) would cost hospitals only \$0.36).

pharmaceutical or medical device manufacturers. Preventing GPOs from investing directly in any specific drug or medical device will ensure that decisions to supply a particular drug or medical device are based on the merits of that product, not whether the GPO has a fiscal interest in the success of the product. Further, Congress should provide a general ban on GPOs taking any payments from manufacturers with whom they contract, regardless of whether these payments are tied to purchasing volumes. Although it seems like these policies might be difficult to legislate, the solution is actually quite simple. The only step necessary to provide a total ban on GPO side-payments is for Congress to repeal the GPO anti-kickback safe harbor provision.¹¹⁶ Without the safe-harbor provision, side-payments would be considered fraud, and subject to civil and criminal penalties.

To the extent that any side-payments are permitted, GPOs engaging in such practices should be required to disclose the full terms and conditions of any such agreement, as well as the terms and conditions of any alternate bids to appropriate government agencies, most likely HHS and FTC. Such agreements should be subject to heightened scrutiny for anticompetitive effect.

CONCLUSION

GPOs engage in anticompetitive behaviors that damage the pharmaceutical supply chain and lead to drug shortages. The contracting practices of GPOs have led to significant market consolidation, not only for healthcare intermediaries, but also for upstream suppliers. Current GPO contracting practices would violate antitrust law if not for the safe harbors granted to GPOs by both federal antitrust enforcement authorities and Congress. Those safe-harbors have been abused by the GPO industry.

To eliminate anticompetitive action by GPOs, both the executive and legislative branches must take action and revise their treatment of GPOs. Federal antitrust agencies should apply traditional antitrust law scrutiny for GPOs, and Congress should repeal the GPO Safe Harbor. Applying these recommendations would lead to a stronger and more robust drug and medical device supply chain, and lower the potential for serious drug shortages.

116. See *Connecting the Dots*, *supra* note 47, at 21 (arguing that the GPO safe harbor of the Anti-Kickback Statute should be repealed).