Group Purchasing Organizations:
An Evaluation of Their Effectiveness in Providing Services to Hospitals and Their Patients

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1. EXECUTIVE SUMMARY

GPOs and the Healthcare Industry

A large majority of U.S. hospitals procure their supplies through Group Purchasing Organizations (GPOs). These organizations negotiate vendor contracts that are supposed to save money for hospitals and health-care providers by using the combined purchasing power of member hospitals to negotiate significant discounts from manufacturers and distributors of medical supplies.

The proliferation of the GPO industry in the early nineties had a humble beginning. They were established by groups of small hospitals to combine their purchasing power to gain buying leverage on their suppliers.

The modern-day GPOs could not be more different than their early predecessors. Rather than mere servants of their hospital masters, the new GPOs are giant behemoths in a very large industry.

By any measure, the GPO industry exercises tremendous influence on the financial health and operational policies of the hospitals and other healthcare providers. GPO-contracted purchases are estimated to be over $200 billion dollars in 2005. Almost 90% of the hospitals, nursing homes and other healthcare organizations procure a large part of their supplies through GPOs.

The activities of the GPOs, and the manner in which they are performed, have significant implications not only for the healthcare industry but also for the well-being of the US healthcare system, which is in a precarious financial condition. In the United States, healthcare spending as a percentage of GDP has grown from 13.2% in 2000 to 16% in 2005. While the healthcare spending from all sources has continued to increase at the rate faster than the GDP, the two groups that should be its principal beneficiaries have benefited the least from this largesse. These groups are hospitals and their patients. At the same time, the middlemen, e.g., group purchasing organizations (GPOs) - whose role should be to create efficiencies and economies in the delivery of services - have grown at the expense of the hospitals and their patients.

By any measure, the GPOs operate in a growth industry where they have benefited handsomely through a combination of highly protected markets, a government guaranteed and predictable source of revenue, operating practices that give these GPOs significant control over both the suppliers and the buyers, and, finally little or no oversight on the part of the regulatory agencies or the GPOs' beneficiary clients. This combination of market control and resulting economic power, when combined with lack of oversight and accountability requirements, has led to the inevitable consequences, where GPOs have found ample opportunities for abuse of market power for their own benefit and at the expense of their principal clients, hospitals, nursing homes and other healthcare organizations.

Scope of the GPO Report

This report examines the proper role of GPOs and the extent to which they have performed this role in a responsible, objectively measurable, and demonstrably accountable manner. Among the issues covered are:

a) the oligopolistic structure that allows major players a large measure of freedom from competition and thereby enables them to maximize their revenue and profits;

b) a discussion of the anti-kickback safe harbor and antitrust safety zone protections created by the federal government for the GPO industry; and,

c) a detailed analysis of the GPO activities, which have subverted the intent of these protections and thus undermined their very purpose.

In the second part of the report, we discuss the Healthcare Group Purchasing Industry's Initiative. The Initiative is a set of principles that were created by the GPO industry at the instigation of the U.S. Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights as a means of improving industry performance and to eliminate the many unethical and anti-competitive practices of GPOs revealed in the Senate Subcommittee's hearings.

The Initiative is subjected to extensive analysis as to its principles, the manner in which they are intended to be implemented, and the prospect of improved ethical industry conduct that is supposed to emanate from the implementation of the Initiative's principles.

The final section of this report presents our conclusions and recommendations. The report analyzes three reform proposals currently under review by the Senate Subcommittee and points out their strengths and weaknesses. It also offers a set of recommendations designed to make the GPO industry more competitive and responsive to the needs and interests of hospitals, nursing homes, and other healthcare organizations in a manner that would save these institutions billions of dollars in supply costs and improved operating efficiencies.

Industry Concentration and Market Power

The GPO industry is a classic example of a highly concentrated oligopolistic structure, where a handful of companies control over 80% of the hospital supplies purchased through GPOs. This oligopolistic market structure has allowed these privately owned and controlled entities to extract excessive rates of return for their own benefit and to the detriment of their member hospitals. In an economic situation that has been characterized by drastic increases in health-care costs and inefficiency, the GPO oligopoly is a major factor of heretofore unrecognized significance.

GPOs as middlemen present a set of unique opportunities, which makes their role as agents to be highly lucrative. The system favors agency at the expense of stewardship. The GPOs' primary role is that of providing a service to their healthcare clients, for which they assess a service charge. They are also, for the most part, privately-owned independent organizations, which seek to maximize profits for their shareholders.

The justification for their service must rest on efficiency, i.e., low unit transaction costs arising from economies of scale, which would yield greater benefits to their clients, i.e., hospitals, nursing homes and other healthcare organizations. However, these efficiencies and cost savings are unlikely to occur if the agency costs, i.e., opportunities and incentives toward self-enrichment are poorly controlled.

The report strongly indicates that a lack of oversight and regulatory indifference has culminated in a variety of unethical and anticompetitive practices among GPOs and their top managers, including conflict of interest and instances of self-enrichment. Furthermore, any meaningful improvement in the situation is highly unlikely without addressing the fatal structural flaws that are embedded in the current system of government mandated protections that create "virtually risk free" opportunities for abuse of market power and self-enrichment on the part of the GPOs and their management.

Impact of Anti-Kickback Safe Harbor and Antitrust Safety Zone

The principal culprit for this situation can be found in the regulatory protections created by the federal government in the form of the GPO anti-kickback safe harbor and the joint purchasing antitrust safety zone. Notwithstanding their initial intent, the anti-kickback safe harbor and the antitrust safety zone have had serious unintended negative consequences. Rather than helping the hospitals in securing supplies at the least cost, they have created incentives for the GPOs to maximize their revenues without necessarily providing the hospitals with the most cost effective and least expensive products. Furthermore, by sheltering them from market competition, they have led to a massive consolidation of the GPO industry, a further weakening of the bargaining power of both their customers and suppliers, and, exploitation of the market power for the benefit of the GPOs.

The consequences of this abuse of market power can only be estimated indirectly. As privately-owned, for-profit entities, most GPOs have strongly resisted disclosure of objective, verifiable information with regard to their sources of revenue, appropriateness of various categories of expenses, reasonableness of the top management compensation, and dividend returns to their shareholders. Instead, GPOs have made unsupportable assertions about the benefits of their operations to their member hospitals. They have also made specific but unsubstantiated claims that they save member hospitals billions of dollars through lower prices of goods purchased and improved efficiencies in the supply chain management.

Nevertheless, considerable information that refutes GPOs' claims has come to light by virtue of formal inquiries conducted by various federal agencies, private lawsuits, and investigations by the news media.

Financial Burden of GPO Activities on the Healthcare System

The full measure of the GPOs' financial activities can only be determined indirectly since GPOs have consistently resisted most attempts at voluntary disclosure. However, based on information generated in various governmental inquiries, and the sources of GPO revenue, some reasonable estimates are possible.

In theory, GPOs can earn 3% of the value of supplies purchased by the hospitals through contracts negotiated by the GPOs. This is an "administrative fee" levied on the suppliers. However, in practice, GPOs' earnings have generally ranged well above the 3% threshold envisioned by Congress. A fixed fee structure based on the total revenue produced creates a strong disincentive for the GPOs to create cost efficiencies, which would reduce their income. Furthermore, the total fee, currently generated by the GPOs, far exceeds the GPO expenses and provides inducements for the GPOs to find ways to inflate their expenses and thus keep a larger part of the excess revenue for themselves. Finally, the supplier paid fee gives the false impression that it is a "free good" provided by the suppliers. For the seller, it is just another cost of doing business, which must be reflected either directly or indirectly in the price of the product and paid by the customer.

Based on our analysis of the total revenue generated by the GPOs, their operating margins, and a careful assessment of their expenses, it is estimated that GPOs generate excess annual revenue in the range of $5 billion to $6 billion, which legitimately belongs to their member hospitals since they are the ones who actually paid for it through higher costs of their supplies purchased under the GPO-negotiated contracts. To these estimates, we must also add further savings that would result from a more competitive environment of GPO operations. GPOs may wish to challenge these estimates with full disclosure and transparency with regard to their revenue and expenses. However, in the absence of such disclosure, our projections – based on sound economic principles are reasonable and defensible.

Healthcare Group Purchasing Industry Initiative (HGPII)

On April 7, 2005, nine leading healthcare industry group purchasing organizations, namely Amerinet, Broadlane, Childhealth Corporation of America, Consorta, GNYHA Ventures, Inc., Healthtrust Purchasing Group, MedAssets, Novation and Premier, announced the launch of a new initiative that promotes best business practices in the industry – Healthcare Group Purchasing Industry Initiative. This was the industry's response to the Senate Subcommittee's hearings and also to thwart further pressure for increased regulatory oversight of the industry.

The Healthcare Group Purchasing Industry Initiative consists of six principles outlining commitments, responsibilities, and means of implementation. Our analysis of the six principles suggests that in its current form the GPO Initiative is encumbered with a lack of specificity, non-existent performance standards, an internally-controlled and self-serving governance structure, and, an absence of genuine independent external monitoring. The principles are nothing more than a statement of intent. All measures of substance are left entirely to the member companies. Industry members also set their own criteria with regard to compliance, performance evaluation, implementation assurance and public disclosure. In summary, this Initiative would not solve any of the problems raised by the industry's current structure and operating practices. Instead, it would provide the industry a mechanism with which to shield its operations from public scrutiny under the guise of "voluntary" compliance toward a superficial and ineffective code of conduct.

Overview of the Reform Proposals

At the hearing on March 15, 2006, the Subcommittee on Antitrust, Competition Policy and Consumer Rights, the U.S. Senate Committee On The Judiciary United States Senate, proposed three measures for consideration toward reforming the conduct of the Healthcare Group Purchasing Industry. These are: "the Proposal for Enacting the Hospital Group Purchasing Organization Reform Act," "S.2880 – Medical Device Competition Act 2004 (Introduced in Senate) 108th Congress, 2nd Session," and, "Ensuring Competition in Hospital Purchasing Act."

The first two proposals are aimed at improving regulatory oversight of the GPOs. While these proposals contain some good recommendations, they are unlikely to achieve their desired purpose. The regulatory oversight does not have enough specifics as to mandated performance, and does not provide targeted funds to implement the program. As such, they leave their future implementation to the changing priorities of the government agencies. They also make them vulnerable to lobbying pressures of the GPO industry. And finally, the two proposals fail to address the structural flaws in the current GPO operations under regulatory protections.

In our opinion, the best and the only viable resolution to reforming the GPO industry is contained in the third proposal, i.e., Ensuring Competition in Hospital Purchasing Act," which calls for the repeal of the anti-kickback safe harbor and thereby subjecting the industry to the discipline of the marketplace. The built-in incentives of the safe harbor provide the GPO industry with extremely powerful incentives to employ all possible means to maintain their lucrative and risk-free financial franchise.

Repeal of the safe harbor and its vendor driven administrative fee structure would necessarily involve some disruption in the established business practices and current contractual relationships between the suppliers, the GPOs and their member hospitals. Therefore, a transition period of 18-24 months and other short-terms facilitating arrangements should be created to ensure a smooth transition. Additional details of these proposals are provided in the full report.

2. OBJECTIVE OF THIS STUDY

Our focus in this inquiry is on the activities of group purchasing organizations (GPOs) and their financial and operational impact on the healthcare industry. GPOs were initially created as cooperatives of small hospitals that would combine their purchasing power to gain leverage on their suppliers and thus negotiate for lower prices and other discounts for related services. From these humble beginnings, GPOs have achieved enormous growth. In the process, they have transformed themselves into large, privately-owned, for-profit financial organizations.[1]

Currently, GPOs play a dominant role in the financial health and operational wellbeing of the healthcare industry, notably the hospitals, nursing homes, and other healthcare providers. They negotiate supplier contracts that total billions of dollars[2] and control hospital purchases covering a large majority of hospitals, nursing homes and other entities in the healthcare industry in the United States.[3]

A major source of the GPO growth and profitability can be found in two protective measures created by the U.S. government. In 1987 Congress created a GPO safe harbor from the Medicare anti-kickback statute. In 1996 the Department of Justice (DOJ) along with the Federal Trade Commission (FTC) created an antitrust "safety zone" for joint purchasing arrangements in healthcare, which included GPOs.[4]

Notwithstanding their enormous size, profitability, and protective provisions of the anti-kickback safe harbor and the antitrust safety zone, GPOs have, until recently, escaped serious public scrutiny. Furthermore, the complex and obscure nature of their operations, and lack of publicly available and reliable financial and operational data, have made public inquiries quite difficult.

This situation, however, has changed somewhat in the last six-plus years with a number of hearings initiated by the U.S. Senate Judiciary Subcommittee on Antitrust, Compensation Policy and Consumer Rights,[5] and investigations by the Government

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[1] For details, see section "3.1. GPOs and Their Economic Impact on the Healthcare Industry" of this report, p. 17.

[2] Submission for the record of Thomas J. Shaw, president and CEO of Retractable Technologies Inc. to the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002. See also Holding, R. and Carisen, W. "Watchdogs Fail Health Workers: How Safer Needles Were Kept out of Hospitals," *San Francisco Chronicle*, April 15, 1998, p. A1; Lastra, P., op. cit., supra note 2.

[3] BusIntell Report. (2005, May). "Group Purchasing Organizations", *Knowledge Source, Inc*., pp. 1-224 (the report is based on data solely provided by GPOs); Becker, C. (2005, August 15). "Of Two Minds," *Modern Health Care*, Vol 35, No. 33, pp. S1-S5 (the report is based on data solely provided by GPOs).

[4] Section 1128B(b) of the Social Security Act [42 U.S.C. 1320a-7b(b)] ["the anti-kickback statute"] provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the federal or state health care programs. See also Brock, T. H. (2003). "Hospitals, Group Purchasing Organizations, and the Antitrust Laws," *Healthcare Financial Management*, Vol. 53, Iss. 3, pp. 38-42.

[5] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002; Hearing before the Subcommittee on Antitrust, Business Rights, and

Accountability Office (GAO)[6] and other federal and state agencies.[7] There have also been reported incidents of abuse of the safe harbor and antitrust laws leading to private lawsuits and investigations by the news media.[8]

GPOs claim that their activities create tremendous benefits for the healthcare industry through efficient contract negotiations with suppliers resulting in cost savings, which they pass on to their members, i.e., hospitals, nursing homes and other healthcare providers. However, most of these claims are not fully substantiated.[9]

GPO activities involve substantial amounts of money, which is earned in the form of administrative fees and other levies imposed on the suppliers, and other activities. GPO revenues run into billions of dollars and far exceed their net operating expenses.[10] A part of these funds go to some member hospitals after GPOs deduct their cost of operations. The determination of appropriateness of operating expenses – including top management compensation - and the rationale and size of disbursement of surplus funds is left almost entirely to the discretion of the GPOs.

Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Has the Market Become More Open to Competition?" July 16, 2003; Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004; Hearing before the Antitrust, Competition Policy, and Consumer Rights Subcommittee of the Senate Judiciary Committee, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition? " March 15, 2006.

[6] Government Accountability Office. (2003, July 16). "Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products," GAO-03-998T; Government Accountability Office. (2002, April 30). "Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices," GAO-02-690T.

[7] See submission for the record of Mr. Said Hilal, President and CEO of Applied Medical Resources Corporation, to the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Has the Market Become More Open to Competition?" July 16, 2003; Testimony of Attorney General Richard Blumenthal to the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition?" March 15, 2006.

[8] Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4). "Medicine's Middlemen; Questions Raised of Conflicts at 2 Hospital Buying Groups." *The New York Times*, p. A1; Becker, C. (2002, October 28). "Say what?" *Modern Healthcare*, Vol. 32, No. 43, pp. 8-10.

[9] See submission for the record of Mr. Said Hilal, op. cit., supra note 7; Submission for the record of Thomas Brown, Executive Vice President of Biotronik Inc. to the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Has the Market Become More Open to Competition? "July 16, 2003; Submission for the record of Thomas J. Shaw, op. cit., supra 2. See also Dula, M.A. (2004, June). "Testing the GPO Waters," *Healthcare Financial Management*, 58-6, pp. 70-76.

[10] Everard, L. J. (2005, February 2). "Defining and Measuring Product-Based Cost Savings in the Health Care Supply Chain", pp. 1-20; Singer, H. J. (2006, June). "The Budgetary Impact of Eliminating the GPO's Safe Harbor Exemption from the Anti-Kickback Statue of the Social Security Act", Criterion Economics, LLC, pp. 1-29 (financial support for this report was provided by the Medical Device Manufacturers Association), available at http://www.medicaldevices.org/public/documents/Singer.GPO.CBO.FINAL.pdf; Levinston, D. R., Acting Inspector General. (2005, January 19). "Review of Revenue From Vendors at Three Group Purchasing Organizations and Their Members," Department of Health and Human Services, Office of Inspector General, A-05-03-00074; Vengrin, J. E., Deputy Inspector General for Audit Services. (2005, May 19) "Review of Revenue From Vendors at Three Additional Group Purchasing Organizations and Their Members," Department of Health and Human Services, Office of Inspector General, A-05-04-00073.

GPOs have now enjoyed the protection from anti-kickback statute for nearly twenty years and antitrust safety zone for over ten years. During this time, GPOs have made strong claims regarding the savings generated by them in terms of lower prices and also by way of sharing their surplus with member hospitals.[11] They have also made dire predictions of financial hardships for the hospitals in the event of any constraints or oversight of their conduct.[12] However, to date GPOs have not provided any objective data to verify these claims. The information provided by GPOs to date consists almost entirely of opinion surveys,[13] which cannot be a substitute for factual information. The only meaningful information about GPOs' financial operations to date was generated by the Government Accountability Office (GAO) reports in 2002 and 2003 as well as two Health and Human Services (HHS) Office of Inspector General (OIG) audits that were published in 2005.[14] Although, there have been other investigative stories on other aspects of GPOs' operations that have been reported in the news media.[15] The GAO report found that GPOs' prices were not always lower and were often higher than those paid by hospitals negotiating with vendors directly.[16] The HHS OIG audits found that six GPOs collected $2.3 billion in fees from vendors over a three to five year period. This exceeded their operating expenses by $1.6 billion.[17]

It should be noted here that as privately-owned for-profit organizations, GPOs are not obligated to make public their financial data and they have chosen to exercise their prerogative by not disclosing this information. Yet, this lack of information is contrary to the best interest of the hospitals, whose welfare is the *raison d'etre* for creating GPOs in the first place. This information should also be a mandatory requirement from the perspective of public interest because GPOs benefit from the government provided protection from antitrust laws and anti-kickback provisions. The GPOs' reluctance to provide factual information about their operations also raises questions about the credibility of their claimed contributions to the improved financial and operational performance of their principal clients, i.e., hospitals, nursing homes, and other parts of the healthcare industry.

It is, therefore, imperative that GPOs' activities be subjected to scrutiny to ensure that both their revenue generation and disposition functions are transparent and directly related to the interests of their clients, notably the hospitals and their patients. The situation in this context is best described by an industry analyst, Mr. L.J. Everard:

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[11] Becker, C. (2005, August 15). op. cit., supra note 3; "Questions and Answers Regarding the Healthcare Group Purchasing Industry Initiative," Healthcare Group Purchasing Industry Initiative, available at www.healthcaregpoii.com; Charter of the Healthcare Group Purchasing Industry Initiative, May 2005.

[12] Testimony of Mr. Richard Bednar, before the Subcommittee On Antitrust, Competition Policy And Consumer Rights, Committee On The Judiciary United States Senate, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition?" March 15, 2006.

[13] Becker, C. (2005, August 15), op. cit., supra note 3; BusIntell Report, op. cit., supra note 3.

[14] GAO-02-690T, op. cit., supra note 6; GAO-03-998T, op. cit., supra note 6; Levinston, D. R., op. cit., supra 10; Vengrin, J. E., op. cit., supra note 10.

[15] Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4), op. cit., supra note 8; Holding, R. and Carisen, W. op. cit., supra note 2; Lastra, P., op. cit., supra note 2.

[16] Government Accountability Office. (2002, April 30), op. cit., supra note 14.

[17] Levinston, D. R., op. cit., supra 10; Vengrin, J. E., op. cit., supra note 10.

> "The time has come to substantiate or refute GPO cost saving claims. If GPOs do produce valid and verifiable cost savings beyond what hospitals could do on their own…., then they should be given the full support of the government and the health care community. If, on the other hand, GPOs do not produce such cost savings or did once but not longer do so… then their future role in the health care supply chain must be questioned and the government protections afforded to them must be re-evaluated."[18]

This issue lies at the heart of the controversy as to the proper role of GPOs and the extent to which they have performed this role in a responsible, objectively measurable, and demonstrably accountable manner. This is the primary focus of this report.

In the first part of this report, we briefly describe the healthcare industry in the United States in the context of overall healthcare expenditures, their growth both in absolute numbers and as a proportion of GDP. We compare US healthcare expenditures with those of other industrially advanced countries.

Next we examine the role of GPOs in the healthcare industry. We trace their development from modest beginnings to their current giant financial power. Detailed attention is given to the role of safe harbor protections. These have had a profound influence on the operational structure of GPOs and have given them unprecedented influence and control over a large part of the supply-chain in the healthcare industry.

We undertake a systematic examination of the impact of the extremely high concentration in the GPO industry in terms of industry structure, intra-industry competition, high entry barriers that prevent new competitors from outside from entering the industry, and the relative lack of leverage on the part of both the suppliers and customers, i.e., hospitals, to exercise significant control and oversight on the activities of dominant GPOs and thus reduce their capacity for exploitation of their oligopolistic market power.

Next we examine publicly available evidence of the abuse of market power and agency control on the part of GPOs. These have culminated in a variety of unethical and anticompetitive practices, conflicts of interest, and instances of self-enrichment on the part of certain GPOs and their top managers. These activities have led to investigations by Congressional committees, federal and state agencies, as well as private lawsuits.[19]

In Part II of the report, we discuss the Healthcare Group Purchasing Industry's Initiative and its antecedents. This initiative was created by the GPO industry at the behest of the Senate Subcommittee.[20] It was the industry's response to forestall calls

[18] Everard, L. J., op. cit., supra note 10.

[19] Submission for the record of Mr. Said Hilal, op. cit., supra note 7; Testimony of Attorney General Richard Blumenthal op. cit., supra note 7.

[20] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002.

for further government oversight and changes in the industry's anti-kickback safe harbor and antitrust safety zone protections in the wake of numerous investigations and public disclosure indicating that a number of GPO activities and practices may have been contrary to the best interest of the industry's principal clients, i.e., hospitals, nursing homes and other healthcare providers. This Initiative consists of six principles to which the GPO industry has committed itself with the assertion that their implementation would improve the operations and thereby remove the necessity of repealing the industry's safe harbor and/or safety zone protections or additional regulatory oversight.

We subject the Initiative to extensive analysis as to its principles, the manner in which they are intended to be implemented, and the prospect of improved ethical industry conduct that is supposed to emanate from the implementation of the Initiative's principles. We then proceed to conduct another, more in-depth, analysis of the Initiative on the basis of the eight pre-conditions that are considered essential to the successful implementation of an industry-based voluntary code of conduct.

In the final section, we examine three proposals for the reform of the GPO Industry that are currently under discussion by the U.S. Congress. The focus of this analysis is to evaluate the feasibility and viability of these proposals to make sure that group purchasing activities of the healthcare industry are managed in a manner that is transparent, competitive, and passes the resultant benefits of competitive markets and supply-chain efficiencies to their principal beneficiaries, i.e., hospitals, nursing homes, and other healthcare providers. We recognize that a transformation of this magnitude would require a transitional period and a mechanism to prevent major disruption in the supply-chain management. We recommend a number of steps that should facilitate this smooth transition.

3. HEALTHCARE INDUSTRY OVERVIEW

In the United States, the financial health of the healthcare industry is in a precarious condition. Healthcare spending as a percentage of GDP has grown from 13.2% in 2000 to 16% in 2005.[21] Spending on healthcare in 2005 was projected to be 3.6 times higher than defense and 2.0 times higher than education.[22] National healthcare expenditures have been rising at an average rate of 6.5% per year and are expected to grow at the rate of 7.1% per year between 2003 and 2014.[23] U.S. healthcare spending exceeds that of the most developed countries in the world. The United States is estimated to have spent $1.92 trillion on healthcare in 2005. This amounts to $6,477 per person,[24] which on average is twice as much as in Canada, France and Germany.[25] Notwithstanding, it is clear that the U.S. does not receive comparable benefits from such a high level of expenditure. [Appendix A]

A large part of healthcare spending is paid by the U.S. government and taxpayers. Another major category of payer is the private companies that cover all or part of their employees' healthcare costs. We must also include the enormous amounts of philanthropic contributions by individuals and charitable foundations in support of hospitals and research organizations without which the large non-profit infrastructure of the healthcare industry could not exist. And last, but not least, are individual citizens who must shoulder this ever increasing burden of healthcare costs that outpace their income.

Increased healthcare spending in the United States should have benefited the two groups most in need for such help, i.e., hospitals and their patients,[26] but this is not the case. Most hospitals are facing financial crises and some are struggling to survive.

A large segment of the U.S. population is without healthcare insurance[27]. Latest estimates show that around 46 million people in the United States do not have any type of healthcare insurance.[28] Approximately 40 million elderly and disabled Americans are

[21] Sager, A. and Socolar, D., (2005, February 9). "Health Costs Absorb One-Quarter of Economic Growth, 2000 – 2005," *Health Reform Program, Boston University School of Public Health*, Data Brief No. 8; "Gross Domestic Product by Industry," U.S. Bureau of Economic Analysis, April 27, 2006.
[22] ibid.
[23] "U.S. Treasury Secretary John W. Snow and CMS Administrator Mark McClellan to Detail Medicare's Deepening Financial Crisis, Private-Sector Solutions, and the Competing Demands of Cost and Access to Medical Innovations at the 3rd Annual World Health Care Congress, April 17-19, 2006," *PRNewswire*, February 16, 2006. For details see also U.S. Bureau of Labor Statistics.
[24] "Enterprise Scheduling in the Healthcare Industry," BMC Software, 2004; "Gross Domestic Product by Industry," U.S. Bureau of Economic Analysis, April 27, 2006.
[25] op. cit., supra note 21.
[26] Anders, G., (2006, April 18). "Health-Care Gold Mines: Middlemen Strike It Rich; Rewarding Career: As Patients, Doctors Feel Pinch, Insurer's CEO Makes a Billion," *The Wall Street Journal*, pg. A1.
[27] "Desperate Measures," *The Economist*, January 26, 2006
[28] ibid.

currently on Medicare, and the number of people over 60 years old is expected to quadruple in the next decade due to the aging of the baby-boomers.[29]

Conversely, the two groups that appear to have benefited the most are the middlemen, i.e., healthcare insurers[30] and group purchasing organizations (GPOs) whose primary role is to create economies and efficiencies in the purchase of hospital supplies – the second largest category of expenditure for the hospitals, nursing homes and other healthcare providers.

3.1. GPOs and Their Economic Impact on the Healthcare Industry

The genesis of GPOs can be found in the common and quite essential activity where a number of small organizations combine their purchasing power to gain buying leverage on their suppliers to negotiate for lower prices and other discounts for related services. Buying cooperatives, or collective buying initiatives, of this type can be found in a number of industries especially when they are in the early stages of their growth.

As companies in an industry grow they become more complex and managing their supply-chain function may take different paths along a continuum. At one end, companies may create their own purchasing departments, which manage all aspects of purchasing and other elements of the supply-chain. At the other end, highly specialized middlemen may emerge to provide one or more of these services with greater efficiency in terms of product groups or concentrated geographical areas. Some hospital groups have chosen to locate these services within their own organizations or more recently through Integrated-Delivery Networks (IDNs).[31] However, a great many others have opted to work with independent middlemen, i.e., group purchasing organizations (GPOs). A large majority of the hospitals procure their supplies through GPO-negotiated vendor contracts.[32]

Emergence and Growth of GPOs

The first known hospital group purchasing organization was the Hospital Bureau of New York, founded in 1910.[33] Over the next half century, the GPO concept grew slowly. By the early 1970s, with the establishment of Medicaid and Medicare, there were 40 hospital GPOs in the United States.[34]

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[29] "Desperate Measures," op. cit., supra note 27. See also "Addressing the Healthcare Needs of Our Aging Population With Technology USA," *Medical News Today*, May 27, 2004.

[30] Anders, G., op. cit., supra note 26; Galloro, V. (2006, February 27). "Tenet settles outlier lawsuit," *Modern Healthcare*, Vol.36, Iss. 9, pp. 8-9; Fuhrmans, V. (2003). "Medco Gets Subpoena Tied to Criminal Probe; Florida Officials Seek Data On Records Tied to Business With Managed-Care Firms," *Wall Street Journal (Eastern edition)*, Iss. 23, pg. A.21.

[31] BusIntell Report, op. cit., supra note 3.

[32] Becker, C. (2005, August 15), op. cit., supra note 3; BusIntell Report, op. cit., supra note 3.

[33] For details, please visit HIGPA website at https://www.higpa.org/about/about_faqs.asp

[34] Bloch, R., partner of Mayer, Brown, Rowe & Maw, (2003, September 26) "Statement at the Joint Federal Trade Commission/DOJ Hearings on Health Care & Competition Law and Policy," pp. 1-40. Mr. Bloch attributed this information to SMG report, page 5-6. www.ftc.gov/ogc/healthcarehearings/index.htm.

The overall size of the GPO market has continued to grow in lock-step with the rise in healthcare expenditures. Estimates provided by GPO-financed studies indicate that GPO contract-covered purchases accounted for between $148 to $165 billion in 1999 and were expected to rise to $257 to $287 billion in 2009 (assuming a growth rate of 5.7% per year which is well above the growth rate of the overall economy). Although more recent data are not available, projecting past trends would indicate that by 2005, GPO contract-covered purchases by the healthcare industry would be in the neighborhood of $218 billion.[35] We believe this to be a conservative estimate since it does not take into account the higher growth rate of healthcare expenditures over the last five years, a trend that is likely to continue in the future.[36]

The late 1980s and the 1990s marked the highest growth rate in the number of GPOs. The impetus for this consolidation was provided by the enactment of the Medicare anti-kickback safe harbor.[37] This allowed the GPOs to charge an administrative fee of 3% from the suppliers on all purchases made by their member hospitals. However, various government investigations, private lawsuits, and reports in the news media indicated that in a significant number of instances, GPOs administrative fee had significantly exceeded the 3% level envisioned by Congress and ranged from 5% to as high as 18%.[38] During this time of consolidation, GPOs were able to create other contracting practices, which would further add to the fees and revenue-generating tactics. These included, among others, the landmark sole- and dual-source committed-volume deals.[39] GPOs had succeeded in broadening their "value added" services beyond of what they were intended to earn under the safe harbor provisions.

The GPO safe harbor and safety zone established by the federal government were followed by a massive consolidation of the GPO marketplace in the late 1990s and early 2000s. In 2003, a report by the GAO found that the seven largest GPOs controlled 85% of all hospital purchases nationwide that were purchased through GPOs.[40] In another, industry-reported study, GPOs indicated that the nine companies-signatories of the HGPII represent 80% of the total GPO market.[41] By this time, GPO consolidation was also complete. As we shall show in our analysis of intra-industry competition in the latter part of this report, any further consolidation would not be financially justifiable. Additionally, consolidation would surely invite the unwanted attention of the antirust division of the federal Justice Department.

The impact of the anti-kickback safe harbor and the manner of its execution is the single most important factor affecting the operation of GPOs. The safe harbor must also bear a large part of the blame for the structural flaws in the system, contributing to

[35] BusIntell Report, op. cit., supra note 3. It must be pointed out that information regarding GPO industry differ widely within the sources, check for example Muse and Associates' report "The Role of Group Purchasing Organizations in the U.S. Healthcare System", March 2000.

[36] Sager, A. and Socolar, D., op. cit., supra note 21; "Gross Domestic Product by Industry," U.S. Bureau of Economic Analysis, April 27, 2006; "Gross Domestic Product by Industry," U.S. Bureau of Economic Analysis, April 27, 2006

[37] Brock, T. H., op. cit., supra note 4.

[38] GAO-03-998T, op. cit., supra note 6.

[39] Barlow, R.D. (2005). "Healthcare Group Purchasing Milestones in History." *Healthcare Purchasing News*, p. 8.

[40] GAO-03-998T, op. cit., supra note 6.

[41] BusIntell Report, op. cit., supra note 3.

many anti-competitive practices, conflict of interest, and self-enrichment practices on the part of GPOs.

For reasons that will become apparent in the following discussion, accurate data are hard to find about virtually every aspect of the GPO industry. Whatever data are available, are voluntarily provided by GPOs to the industry's own association or GPO industry-supported data gathering organizations.[42] These data are not independently evaluated and their consistency and accuracy is subject to significant variability both across companies and over time.

Ownership Structure of GPOs

GPOs can be divided in three different categories based on ownership structure. In the first category, GPOs are owned and operated by private entities as for-profit business institutions. These GPOs are solely responsible to their owners for financial results. Hospitals served by these GPOs have no input into the GPOs management. The second category consists of membership-based GPOs. These are also owned by private third parties and operate as private, for-profit entities. Member hospitals have contractual relations with the GPOs and may have some input into the GPO decision-making. However, the real impact of hospital members on GPO decision-making is questionable given the very large of number of hospital members and the difficulty in coordinating and developing a cohesive position on GPO strategy and decision-making process. In this category, GPOs may voluntarily distribute a portion of their surplus revenue, i.e., revenue earned through administrative fee net of GPO expenses. However, they are not obliged to do so. Similarly, GPOs have no accountability to the member hospitals beyond the membership agreement. The third category consists of hybrid GPOs. These GPOs are also privately-owned, for-profit organizations and have participation from both the member hospitals and private owners as shareholders. Although member hospitals share in the surplus revenue, private owners have a determining role as to its distribution and receive a larger share. These organizations can be very large. For a majority of the hospital members there is little or no real participation in decision-making.

The Safe Harbor and Safety Zone Exemptions

Historically, the purpose of GPOs was to use the combined purchasing power of their member hospitals in order to negotiate significant discounts from manufacturers and distributors of medical supplies. By using the system of bulk purchasing through GPO contracts, member hospitals are to save money by eliminating duplicative transaction costs.

GPOs operate under the benefit of multiple government-sanctioned exemptions, which were intended to promote the growth of GPOs and assist hospitals in better

[42] BusIntell Report, op. cit., supra note 3; Muse and Associates "The Role of Group Purchasing Organizations in the U.S. Healthcare System", March 2000; Becker, C. (2005, August 15), op. cit., supra note 3; Verispan, L.L.C. (2003) "Multi-Hospital Systems and Group Purchasing Organization Market Report"; Hovenkamp, H., (2002, April) "Competitive Effects of Group Purchasing Organizations' (GPO) Purchasing and Product Selection Practices in the Health Care Industry" (prepared for the Healthcare Industry Group Purchasing Association).

negotiating with suppliers. The available evidence, however, suggests that these well-intended also created unintended negative consequences with regard to competition, innovation and the cost and quality of healthcare.[43]

The GPOs' safe harbor from the Medicare anti-kickback statute allows them to collect an administrative fee of 3% from the suppliers on the value of the products sold to the GPOs' member hospitals. In negotiating these contracts, GPOs and suppliers must meet certain broad eligibility conditions as prescribed in the law.[44] The antitrust safety zone describes joint purchasing arrangements among healthcare providers that "will not be challenged, absent extraordinary circumstances, by the Agencies under the antitrust laws."[45] *Health Care Statement 7* and its antitrust safety zone aim to address monopsony and oligopoly concerns with the formation of a GPO.[46] The details of legal provisions covering these two elements of the GPO safe harbor are provided in Appendix B.

The enormous size of the industry, and the fact that it controls buying power of such magnitude, would raise anti-competitive concerns under the best of circumstances, i.e., freely operating competitive markets. In the case of GPOs, the potential for abuse is even greater. As middlemen, they carry little risk or incur additional costs arising from normal business operations. The justification for their services - and the cost of these services, i.e., GPO revenues - must rest on the criterion of efficiency, i.e., low unit transaction costs arising from economies of scale, which would yield greater benefits to their clients and masters, i.e., hospitals, nursing homes and other healthcare organizations. However, these efficiencies and cost savings are unlikely to occur, if the agencies' costs - namely, opportunities and incentives toward self-enrichment on the part of GPOs - are not controlled.

3.2. Analysis of Industry Competitive Structure

Companies in an industry are subject to two types of competitors: current competitors within an industry and potential entrants into the industry. One factor bearing on this competitive situation is the entry barriers that protect the current industry members from outside competition. The second factor pertains to the ease with which a company might exit the industry without serious negative financial impact when the competition becomes too intense. These are called the exit barriers. Other things being equal, higher entry barriers protect incumbent companies from increased competition and thus create opportunities for above-normal profits. Similarly, low exit

[43] Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4), op. cit., supra note 8; Transcript of the hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002.

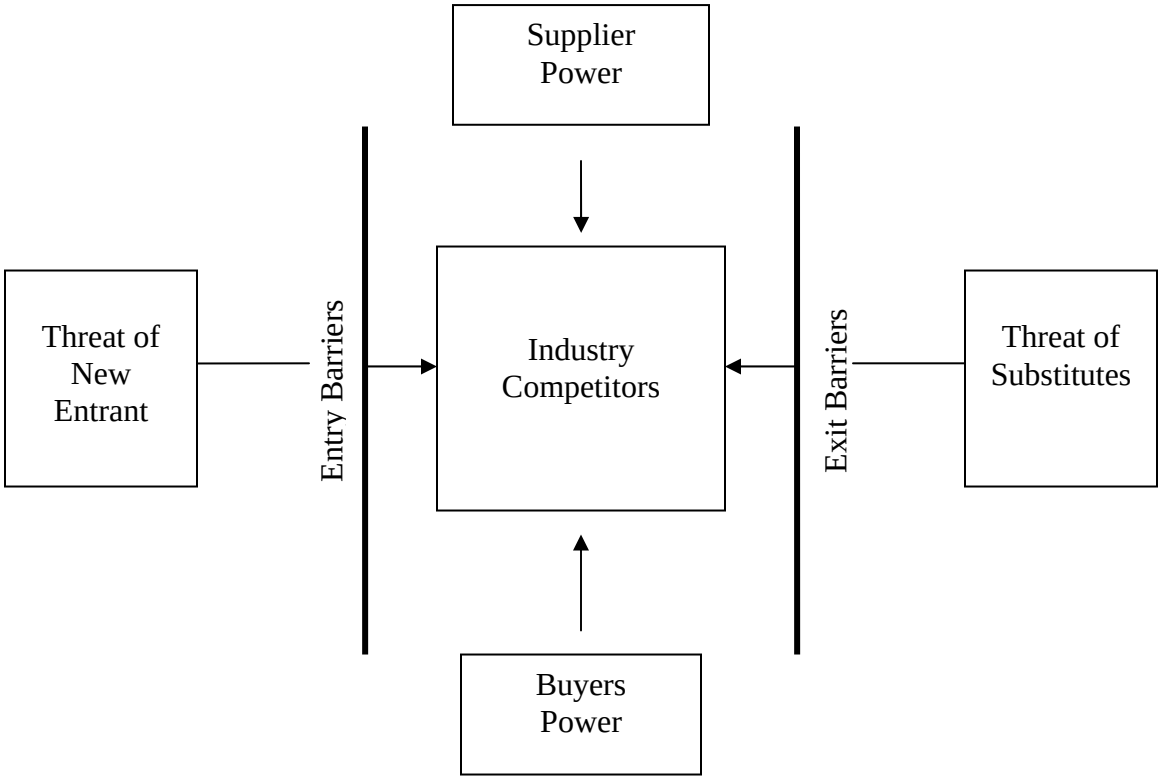
[44] Section 1128B(b) of the Social Security Act [42 U.S.C. 1320a-7b(b)] ["the anti-kickback statute"] provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the federal or state health care programs.

[45] "Statement 7 - Joint Purchasing Arrangements Among Health Care Providers," *Statements of Antitrust Enforcement Policy in Health Care*; Federal Trade Commission and Department of Justice, August 1996, p.54.

[46] "Improving Health Care: A Dose of Competition," the Federal Trade Commission and the Department of Justice, July 2004, pp. 1-361.

barriers suggest that a firm may easily exit the market without serious financial risk. It implies that profit opportunities are greater for the incumbent companies to stay in the market. Such a competitive environment, i.e., high entry barriers and low exit barriers, is quite attractive for consolidation among current industry members in their drive to gain from economies of scale. It also enhances their pricing power by reducing the number of competitors in the industry. The dynamics of competition within an industry and the industry structure are also influenced by the relative bargaining power of the industry's suppliers and customers. Exhibit 1 is a simplified presentation of this framework.

Exhibit 1: Analysis of Industry Competitive Structure of Group Purchasing Organizations (GPOs)



Adapted from Michael E. Porter, *Competitive Strategy: Techniques for Analyzing Industries and Competitors* (New York: Free Press, 1980): Chapter 1, pp: 74.

Intra-Industry Competition

Reports of the number of current GPOs range all over the map. One GPO industry-financed study claims that there are between 600 and 900, of which approximately 200 have direct contracts with suppliers.[47] In a study funded by the GPO industry, the author asserts that the market share of the top two GPOs was about 27%, and the top five GPOs – less than 40% of the total GPO market. Apparently, this is an

[47] BusIntell Report, op. cit., supra note 3; Becker, C. (2005, August 15), op. cit., supra note 3; Verispan, L.L.C., op. cit., supra note 42.

attempt to suggest a heightened level of competition in the industry. In calculating lower market shares, the author inflated the size of the total market by including hospital purchases that are not normally covered by GPOs.[48] The GPO industry's own website, however, states that there are fewer than 30 GPOs that negotiate sizeable contracts for their members.[49] Information generated in various hearings of the Senate Judiciary Committee and other government-sponsored investigations also provide a consensus number in the range of 30 GPOs.[50]

Self-reported data for the GPOs suggest that top GPOs have continued to increase their sales and revenue at an accelerated rate compounded GDP growth rates. The 16 companies reporting purchasing volume in 2004 collectively brokered $83 billion in supplies and services, a 17% increase from the $71 billion in purchasing volume in 2003.[51] It is almost impossible to find independently collected or verified data on any aspect of GPO operations. All major GPOs are privately owned and are not obliged to make public any of their financial information. In its annual survey of GPOs, Cinda Becker of Modern Healthcare reported that judging from the responses to the survey, most GPOs are "disinclined to publicly disclose financial data as part of the voluntary ethics initiative."[52]

The only exception to this rule was Consorta (one of the six largest GPOs) which reported earnings of $40.5 million in operating income on $58 million in revenue. Consorta also reported an operating margin of 70% and projected this margin to increase to 75.3% in 2005. Consorta also asserts that it returns 100% of its net income to members in cash.[53]

Our estimates of market share and other related factors are based on the annual survey of GPOs conducted by Modern Healthcare. The survey report is based on un-audited information provided by the GPOs.[54] The survey was sent to 65 GPOs, of which only 16 responded to the survey.

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[48] Hovenkamp, H., op. cit., supra note 42.

[49] Healthcare Industry Group Purchasing Association "Frequently Asked Questions," available at http://www.higpa.org/about/about_faqs.asp. See also Lastra, P., op. cit., supra note 2.

[50] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002; Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Has the Market Become More Open to Competition?" July 16, 2003; Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004; Hearing before the Antitrust, Competition Policy, and Consumer Rights Subcommittee of the Senate Judiciary Committee, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition? " March 15, 2006. GAO-03-998T, op. cit., supra note 6; GAO-02-690T, op. cit., supra note 6.

[51] Becker, C. (2005, August 15), op. cit., supra note 3.

[52] ibid.

[53] ibid.

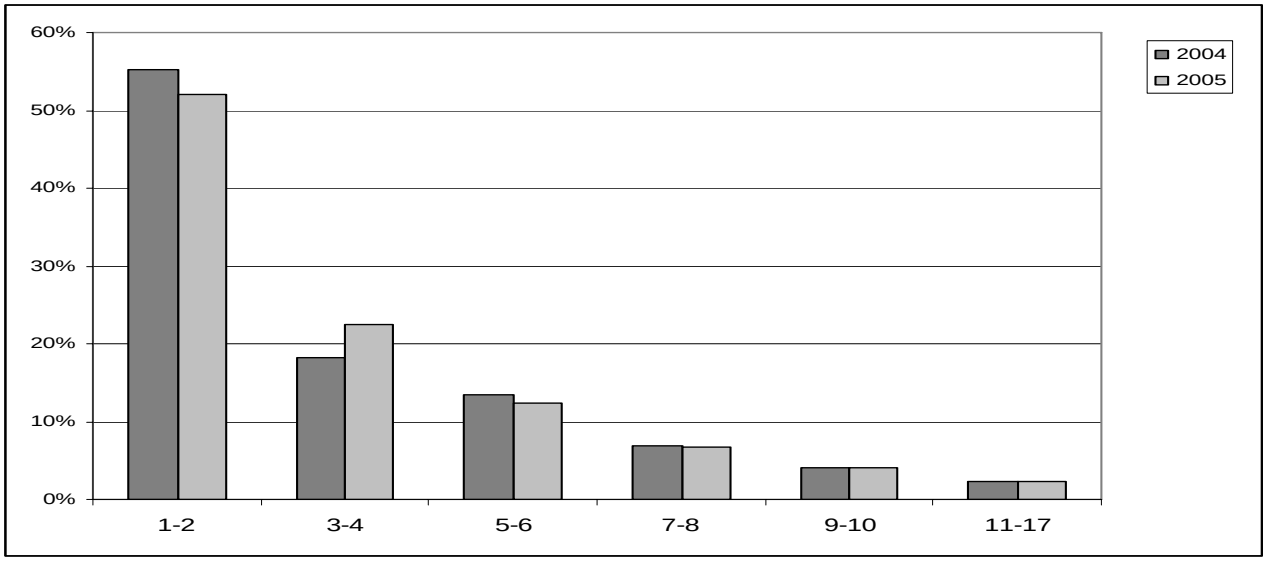
[54] Becker, C. (2005, August 15), op. cit., supra note 3; Becker, C., (2004, August 16). "Hanging tough; Modern Healthcare's Group Purchasing Survey reveals that the GPO Industry Continues to Grow Despite a Stagnant Customer Pool," *Modern Healthcare*,Vol. 34, Iss. 33, pp. S1-S5.

Oligopolistic Competition

As reported in an earlier part of this paper, the total volume of negotiated purchases reported for the entire industry are in a broad range of between $148 to $165 billion in 1999 and expected to rise to $257 to $287 billion in 2009. Hence, it is not possible to estimate reliable market shares of the GPOs as a percent of total volume. The second best approach would be to use the total volume reported by the top sixteen GPOs and calculate relative market shares within the group. This is not an unrealistic approach given the reported evidence from government investigations that top 7 GPOs control 85% of the market share.[55]

Notwithstanding the off-cited members of GPOs, all available evidence points to the GPO industry as a classic example of a highly concentrated oligopolistic structure, where a very small number of companies account for a very large part of the total market. (Exhibit 2)

Exhibit 2: Market Share of 17 GPOs including 9 companies-signatories of HGPII



1	Premier	9	GNYHA (Premier)
2	Novation	10	Innovatix
3	MedAssets	11	AllHealth
4	Broadlane	12	Hospital Purchasing Service
5	Amerinet	13	Yankee Alliance
6	Health Trust	14	Resource Optimization & Innovation
7	Consorta	15	Child Health Corporation of America
8	HealthCare Purchasing Partners International	16 17	National Capital Area Shared Services Shared Services Healthcare

* Companies-signatories of HGPII

Sources: Group Purchasing Organizations Report, Knowledge Source Inc. (May 2005); Cinda Becker, "Of Two Minds," Modern Health Care, August 15, 2005, pp. S1-S5.

[55] GAO-03-998T, op. cit., supra note 6.

Furthermore, the conduct of the industry members corresponds to behavior patterns that are characteristic of oligopolistic industries, e.g., mature industry, enhanced profitability through consolidation, stable rankings, high entry barriers, and non-price competition among the major competitors.

The GPOs face a finite universe of hospitals and nursing homes and, with few exceptions, a vast majority of these hospitals had already been signed up by a GPO. Although there is a tendency among certain hospitals to belong to more than one group,[56] this is generally based on differences in product offerings and service packages and does not involve price competition. The large GPOs can capture extra profits through buying out the smaller ones, which either compete or have the potential of competing with the larger GPOs. Given market saturation, consolidation allows the acquiring companies to grow by capturing revenue streams of the acquired companies. Consolidation also creates enhanced profit opportunities through reduced competition. Smaller companies find it attractive to sell because of the premium price offered by the larger players, which can easily pass on the extra costs to the customers through increases in their operating costs. The only GPOs left out from these combinations are likely to be the ones that provide specialized services or serve remote areas that cannot be served more effectively by the larger GPOs.

The current larger GPOs have no incentive to compete with each other. They provide essentially similar services and draw from the same pool of suppliers. Profits would, therefore, come not from greater efficiencies but through the abuse of their increased oligopolistic power. There is another equally important reason for the large GPOs not to compete with each other. Given the fact that their target competition is another equally large GPO, the potential competitor would offer strong resistance to losing market share. Survey findings by Modern Healthcare show that the composition of industry's top companies has remained relatively stable. When changes have occurred, they have resulted from consolidation from within the industry, which is also a typical characteristic of oligopolistic industries.[57] The end result of such competition would be increased costs for the two rivals. There is also the added risk of unintended disclosure of market practices of the GPOs, which may not be looked upon favorably by their customers, i.e., hospitals or the regulators seeking lower costs and greater efficiencies from the GPOs.

GPO Defense of Market Domination and Large Size

GPOs have argued that their size is necessary to generate additional economies of scale and increased bargaining power with the suppliers. Thus, they may argue that large size translates into greater savings for their member hospitals.[58] Large size does not always yield economies of scale as alleged by the GPOs. If this were the case, large organizations would almost always be more efficient than small and medium size organizations. Arguably, one GPO could serve the entire industry. Experience in the competitive marketplace provides substantial evidence to indicate that small and medium size organizations often can be more effective and flexible in their operations

[56] BusIntell Report, op. cit., supra note 3; Becker, C. (2005, August 15), op. cit., supra note 3.
[57] Becker, C. (2005, August 15), op. cit., supra note 3.
[58] Hovenkamp, H., op. cit., supra note 42.

and in their response to market conditions. Transaction cost economics theory suggests that all transactions have certain costs attached to them and that beyond a certain size these costs increase in larger organizations because of their increased complexity, bureaucratic controls, and multiple layers of management.

One way the GPOs can substantiate these claims would be to show that their operating expenses are declining with increase in the overall volume of contracting purchases. Total operating costs should also decline since a large number of suppliers, and a large volume of contracted purchases, remain the same over a number of years. Hence the cost of contract renewal negotiations and contract management should decline as percentage of operating costs. Unfortunately, GPOs have not made this type of information publicly available to permit such analysis.

Threat of Competition from New Entrants

For reasons described in the previous section, it should be clear that the current industry structure and concentrated market share by a small number of dominant players poses high barriers to entry by new companies from outside the industry. It is prohibitively expensive for a new entrant to gain significant market share because most current and potential customers are already locked in to existing GPOs through various contractual arrangements. Evidence of this situation can be found in the fact that over the last five-plus years, industry dominance by the top GPOs has remained unchanged. There have been no new entrants of meaningful size from outside into the GPO industry to challenge the hegemony of current top players.

Bargaining Power of Suppliers and Buyers

GPOs also face no threat from their current or future suppliers who might want to work directly with hospitals or promote competition among different GPOs. It is not financially attractive for the suppliers to compete because lower prices would become the prevailing prices. Instead, suppliers are happy to pay higher fee and other charges to GPOs because: (a) they benefit from larger production runs; (b) capital costs are amortized over larger volumes and thus reduce overall costs; (c) there is less pressure for product innovation which lowers their R&D expenses; and, (d) all such fees are eventually passed on to the buyers in the prices they charge for their product.

GPOs have strong contractual lock-ins with both the suppliers and the hospitals (Exhibit 3). The Modern Healthcare study of 16 GPOs shows that the number of contracted hospitals is increasing on average 5% per year, with the top three GPOs representing about 40% of the total number of hospitals covered by the 16 GPOs' contracts. These contractual arrangements generally carry strong penalties and other disincentives to discourage both the suppliers and the hospital customers to change their relationship from their current GPO to another one.

Exhibit 3: GPOs' Ranking by Contract Purchases and Membership

	Value of Contracts ($ millions)			Member Hospitals (# of hospitals)		Alternate Sites		Total Members	
GPO*	**2003**	**2004**	**2005 (Proj.)**	**2004**	**2005**	**2004**	**2005**	**2004**	**2005**
Premier	$24,157	$25,264	$27,031	1,433	1,478	30,731	33,952	32,164	35,430
Novation	$20,700	$23,700	$24,700	1,545	1,671	12,925	15,090	14,470	16,761
Med Assets	$7,000	$10,000	$15,000	2,200	2,400	18,000	21,028	20,200	23,428
Broadlane	$5,000	$6,100	$7,400	856	935	13,169	20,935	14,025	21,870
Amerinet	$6,000	$6,150	$6,350	1,856	1,890	18,703	22,227	20,559	24,117
Health Trust**	N/A	$5,700	$6,000	N/A	N/A	N/A	N/A	900	1,200
Consorta	$2,980	$3,700	$4,200	338	363	1,171	1,550	1,509	1,913
GNYHA (Premier)	$1,900	$2,000	$2,100	110	132	N/A	N/A	110	132
CHCA	$149	$191	$195	35	35	3,600	N/A	3,635	35
Total	**$67,886**	**$82,805**	**$92,976**	**8,373**	**8,904**	**98,299**	**114,782**	**107,572**	**124,886**
Total (17 GPOs)	**$71,249 *****	**$88,631**	**$99,433**	**13,161**	**13,886**	**127,450**	**156,228**	**141,511**	**171,314**

* Becker, C. (2005) "Of Two Minds," *Modern Helthcare*, Vol. 35, Issue 33, pp. S1-S5, 08/15/2005. .

** Information for Health Trust: "Group Purchasing Organizations," BusIntell Reports, May 2005. 2005 data is retrieved from the company's website.

*** Data for year 2003 is available for 16 GPOs only.

Principal Agency Dilemma, Moral Hazard and Unintended Consequences

GPOs as middlemen present a set of unique opportunities when operating under the anti-kickback safe harbor and antitrust safety zone. The system provides GPOs with a stable and predictable flow of revenue through administrative fees, protects them from certain antitrust laws, and does not subject them to any meaningful regulatory oversight. This makes their agency role highly lucrative. The system favors agency (GPOs' self-interest) at the expense of stewardship and the best interest of their primary clients. Although their primary role is that of providing a service to their healthcare clients, for which they collect a service charge, they are also, for the most part, independent privately owned organizations that seek to maximize profits for their shareholders.

Present day GPO organizations are radically different from their early predecessors. As a highly concentrated oligopoly, the industry members have the opportunity of earning large non-market rent, i.e., above-average profits from their operations. At the same time, the structure of the industry is protected through the government exemptions and has provided the GPO industry with virtually risk free

incentive to exploit these oligopolistic conditions for realizing profits. The agency problem is further compounded by a relative lack of oversight on the part of their clients and regulators. This condition has been widely studied in economics as "moral hazard," which is associated with uncertainty. Moral hazard arises whenever (1) a principal cannot perfectly monitor the actions of his agent and (2) the agent's success depends in part on some random process that is outside the control of the agent.[59]

GPOs currently control the customer and the supplier through tied contracts, sole source buying and customer use of bundled products and services. This makes it difficult for hospitals to exercise meaningful freedom of choice. Even where GPOs are member-owned, the very large number of member organizations makes effective governance all but impossible. The situation is quite well-known in economics where it is described as the "principal-agency" dilemma, where agents, i.e., GPOs, are able to control and thereby render ineffective, the principal's role to monitor and govern the activities of the agent. The agent in return, exploits the situation for self-enrichment and to the detriment of the principal.

The consequences of this structure should have been easily predicted and measures taken to minimize their occurrence. The negative consequences of this state of affairs have been revealed through various private lawsuits, investigations by regulatory agencies, and congressional hearings. The range of questionable activities is connected – in one way or another – with the unlikely abuse of government exemptions. These include, among others, anti-competitive practices, conflict of interest, the discouragement of innovation, and improper use of tax-exempt funds. Appendix C provides further details of specific cases highlighting these issues.

3.4. Financial Burden of GPO Activities on the Healthcare Industry

In the previous section, we discussed the current GPO industry structure, operational policies, and their impact on the GPOs' principal clients. In this section, our focus is on the financial impact of GPO operations on their principal clients, i.e., hospitals, nursing homes, and other healthcare providers. GPOs' financial operations have two important components. The first concerns the administrative fees collected by the GPOs from their contracted suppliers, and the extent to which the magnitude of these fees may have unintended and undesirable consequences. The second deals with the notion of appropriateness and reasonableness of various expense categories in which the GPOs apportion their fee-generated revenues. These include: operating expenses, top management compensation, return to shareholders, and the allocation of retained earnings for future projects.

Administrative Fees

[59] Laffont, J.J. (1995). "The Economics of Uncertainty and Information," (MIT Press) pp. 180-195, cited by Singer, H. J. op. cit., supra note 10, p. 9.

There are three problems with fixed fee arrangements which cause them to lose any direct and meaningful relationship to the cost of service that this fee is intended to cover:

1. Instead of creating incentives toward lower costs and better efficiencies, a constant fee rate creates incentives that do the opposite, i.e., while the actual costs may be going down, the prices paid remain constant so as to protect GPO earnings from declining.

2. The fee structure generates rewards that further retard the process of innovation and cost efficiencies.

3. It is important to recognize that the administrative fee is not a "free good" delivered by the suppliers. For the seller, it is just another cost of doing business which must be reflected either directly or indirectly in the price of the product.

It is well nigh impossible to find reliable financial data on any aspect of GPO operations. GPOs are privately-owned for-profit organizations. They have no legal obligation to make public this data. GPOs have repeatedly made claims as to the benefits their operations generate for the healthcare industry. These claims, however, have not been supported by any verifiable data.[60] Nevertheless, an effort must be made to generate a reasonable projection of GPO revenues. This is needed for no other reason than to at least challenge the GPO industry into providing reliable financial and thereby become more transparent if they wish to garner public trust and retain regulatory protection.

An extensive inquiry into available information sources yielded only one study conducted by Dr. Hal J. Singer, president of Criterion Economics, LLC. The study entitled "The Budgetary Impact of Eliminating the GPO's Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act," was published in June 2006.[61]

Dr. Singer's estimate assumes that 100 percent of the rebates (net of expenses) paid to GPOs by medical suppliers are passed on to member hospitals. He also provides GPOs with another amount in the form of "dividend" or return on investment to the GPOs' owners, i.e., shareholders. This is calculated at the rate of 13.5% of a GPO's self-reported net expenses. For this exercise, he also assumes that there is no distortion effect of the current regime on the incentive of these GPOs to secure the best prices possible for hospitals.

Dr. Singer's estimate of the resultant savings to member hospitals ranges between $1.3 billion and $4.96 billion. These estimates take into account that GPOs have created other ways to enhance their revenues from the suppliers that are in excess of the 3% administrative fee recognized under the safe harbor protection.

[60] Everard, L. J., op. cit., supra note 10; Dula, M.A., op. cit., supra note 9.

[61] Singer, H. J., op. cit., supra note 10. It should be noted here that financial support for this report was provided by the Medical Devise Manufacturers Association. Nonetheless, the quality of economic analysis and resulting conclusions are based on sound logic and defensible.

These have been reported in the GAO findings and discussed in an earlier section of this report.[62] For example, the GAO report (2003) revealed that two out of seven GPOs admitted that the maximum contract administrative fee received from manufacturers in 2002 exceeded the three-percent threshold.[63] The GAO report also found that fee levels for private label products, i.e., products sold under a GPO's brand name, were on average five percent.[64] For one of the GPOs in the GAO study, the administrative fee for private label products was nearly 18 percent.[65] GPOs are also known to have collected additional fees from suppliers.[66] These include marketing fees, licensing fees, stocking fees, switching fees, and growth fees. It should be noted that the original intent of the administrative fee was to cover the overhead of the GPO contracting functions. It was never intended for other business ventures or overages.[67] And as earlier stated, 2005 HHS OIG reported that six GPOs collected $1.6 billion in excess fees over a three to five year period.[68]

I have two observations with regard to Dr. Singer's projections, which have the effect of underestimating the financial impact of GPOs current business model. The first one deals with the operating expenses and the second one pertains to returns on shareholders' equity.

Deductibility of Operating Costs

Dr. Singer has accepted at face value the reasonableness of GPOs' claims of their operating costs. Since we do not have any comparable and verifiable data from various GPOs, there is no easy way to assess the reasonableness of these costs. Therefore, we have devised an alternative approach to measure these expenses.

Premier, the largest GPO in size and market share, has indicated on its website that in 2005 its operating expenses were 54.4% of its total revenue.[69] However, Premier did not provide any breakdown of these operating expenses. In our opinion, this amount is excessive and needs further justification when viewed in the context of GPOs' primary activities.

The main function for the GPOs is to negotiate and manage contracts with suppliers. GPOs do not undertake any activities that are normal for a business engaged in producing and delivering goods and services. They do not maintain inventories or engage in other aspects of supply chain management. Therefore, GPO's operating costs are akin to general and administrative expenses in large corporations, where this category generally ranges between 15% - 20%. Even if we were to give GPOs extra credit for ancillary services, such as new product evaluation, information management systems, etc. The total expenses should not exceed beyond 30%. One can only

[62] GAO-03-998T, op. cit., supra note 6; GAO-02-690T, op. cit., supra note 6. See also section "Emergence and Growth of GPOs" of this report, **p. 14**.
[63] GAO-03-998T, op. cit, supra note 6, cited by Singer, H. J., op. cit., supra note 10.
[64] ibid.
[65] ibid.
[66] Lawn, J. (2005, January). "The GPOs. Where Do They Go from Here?" *Food-Management*, pp. 24-34.
[67] Singer, H. J., op. cit., supra note 10.
[68] Levinston, D. R., op. cit., supra note 10..
[69] See Premier's website for details: www.premierinc.com.

speculate on the reasons for such a high level of operating expenses, which may include high level of top management compensation, overstaffing, lobbying. One should also examine the character of ancillary activities, which are used to justify additional GPO expenses, but with no direct bearing on GPOs activities that should be covered by the 3% administrative fee. We therefore conclude that the gap between the current expense level of 54.4% and our projection of 30% legitimately belongs to the GPOs' client hospitals and should be returned to them.

Return on Shareholder Equity

Dr. Singer allows GPO a rate of return of 13.5% of net operating costs. We have already argued these costs to be excessive. In the case of GPOs, the need for having shareholder equity is unnecessary and can only be explained as another way by the GPOs to keep a large portion of GPO income from its principal clients, i.e., hospitals, nursing homes and other healthcare providers, who are the true beneficiaries and entitled to these funds.

GPOs currently generate cash flows – through the levy of administrative fees and other charges on suppliers - that far exceed their operating costs. This fact has been recognized and admitted to by the GPOs and well documented in the two HHS OIG audits published in 2005.[70] Furthermore, this revenue stream is predictable, stable and totally risk free. The primary role of equity capital is to provide a company with "risk bearing" funds or operating funds when a company is unable to borrow short-term funds to cover operating expenses. The need for equity capital emanates from the nature of "risk" that is inherent to a business operation. It is the risk carrying capacity of the capital that determines shareholder expectations of commensurate return. Unlike other for-profit organizations, GPOs have no need to risk their capital and, therefore, do not need capital in the risk taking sense of the word. Given their strong financial position, the GPOs should have no problem in borrowing working capital from financial institutions at prime lending rates.

One possible explanation for GPOs seeking equity is that it allows private owners to earn above-market returns on their capital. The fact that GPOs managers may also be part of the "owner group," this private equity becomes another means for generating additional compensation for the GPO owner-managers.

For these reasons, we conclude that Dr. Singer's estimates are considerably below the level of reasonableness. We estimate that GPOs could generate excess revenues in the range of $5.0 to $6.0 billion. This would legitimately belong to their client hospitals and nursing homes. GPOs may challenge the basis of our calculations and magnitude of our estimates. However, in the absence of transparent and full disclosure of the financial records of GPOs' own estimates, our projections – based on sound economic principles – are reasonable and defensible.

[70] Levinston, D. R., op. cit., supra note 10; Vengrin, J. E., op. cit., supra note 10.

4. HEALTHCARE GROUP PURCHASING INDUSTRY INITIATIVE

We now turn our attention to an analysis of the Healthcare Group Purchasing Industry Initiative (hereinafter referred to as the Initiative or HGPII). This analysis includes an examination of the context and antecedents that led to the creation of the Initiative, and a brief discussion of the theoretical and empirical underpinnings for a successful implementation of industry-wide codes of conduct.

The next step in our analysis consists of a detailed, step-by-step, examination of the Initiative, including its six principles that are the foundation of the GPOs' reform efforts. We evaluate the implementation framework through which the GPOs are expected to deliver on their promised reforms. These include, among others, establishment of internal reporting and audit procedures, data gathering and public disclosure, governance structure, independent external monitoring, and verification of the GPO industry's claims as to compliance with the Initiative. Finally, we test the adequacy of the entire structure of the Initiative in the context of certain standards that have been shown in other industry-wide codes to be the necessary pre-conditions for effective implementation of such codes.

4.1. Antecedents to the HGPI Initiative

The creation of the HGPII was not inspired by the industry's self-realization of its obligations to the industry's principal beneficiaries, or to better align industry members' self-interest with those of their beneficial clients. Instead, the industry was responding to the rising media criticism and regulatory concerns, lawsuits, and federal and state investigations of certain practices that were found to be prevalent among GPOs and their managers. These practices were considered to be of questionable legality and probably violated ethical and professional norms of business conduct in the healthcare industry.[71]

Another important event was a series of four hearings by the U.S. Senate Judiciary Subcommittee on Antitrust, Competition, Business and Consumer Rights, with the latest one on March 15, 2006.[72] At the Committee's first hearing, on April 30, 2002, Senator Herb Kohl, the Chairman of the Subcommittee, outlined three major concerns

[71] Brock, T. H. op. cit., supra note 4; Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4), op. cit., supra note 8. See also submission for the record of Mr. Said Hilal, op. cit., supra note 7; Testimony of Attorney General Richard Blumenthal, op. cit., supra note 7.

[72] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002; Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Has the Market Become More Open to Competition?" July 16, 2003; Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004; Hearing before the Antitrust, Competition Policy, and Consumer Rights Subcommittee of the Senate Judiciary Committee, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition? " March 15, 2006.

that the Subcommittee had about the GPOs' business practices. These concerns included:

a) Conflicts of interest that raise the specter of critical healthcare decisions being influenced by financial ties to suppliers.

b) Contracting practices that may reduce competition and innovation in healthcare and narrow the ability of physicians to choose the best treatment for their patients.

c) The study by the Government Accountability Office (GAO) which found that buying groups, whose goal is to save money, do not always get the best deal.

Senator Kohl called for the entire GPO industry to work on the creation of a code of conduct that would address ethical problems and contracting issues. The code was scheduled to be presented to the Subcommittee by the end of July 2002.[73]

In this context, it is important to examine the antecedents that led to the creation of the Healthcare Group Purchasing Industry Initiative (HGPII) because they establish a base-line or threshold which the industry members must exceed with regard to code components, implementation procedures, independent compliance verification, and transparency in public disclosure. In general, an industry's credibility and public trust are likely to be lower where the antecedents to the code creation are negative. Therefore, for such a code to be credible, the industry leaders must provide convincing evidence of their good faith in order to earn public trust and regulatory dispensation in evaluating the "voluntary" and "self-regulatory" characteristics of their code's implementation and compliance verification.

Premier's Report "Best Ethical Practices For The Group Purchasing Industry"

In response to the pressure and demands of the Senate Subcommittee, the Board Audit Committee and CEO of Premier, Inc. decided to commission an independent study of the GPO industry and to recommend the best practices to be adopted by the company. In March 2002, Premier engaged Prof. Kirk O. Hanson, Executive Director of the Markkula Center for Applied Ethics at Santa Clara University, to carry out the necessary inquiries and prepare the final report.[74]

The Report, which was released in October 2002, outlined as its goals: (a) to examine the structure and business practices of the GPO industry; (b) to examine the current ethical practices of the industry; (c) to identify best ethical practices for the industry; and, (d) to compare these best practices to the current policies of Premier, Inc.

The publication of this report led to certain questions, and even criticism from within the industry, as to the thoroughness of the data gathering process, the

[73] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002.

[74] Hereinafter in this section referred to as the Report.

transparent nature and objectivity of its findings, and the substance of its assertions about the Initiative's viability.[75] The details of the process used by Prof. Hanson in preparing his report are presented in Appendix D.

4.2. HGPII – The Principles

The creation of the Healthcare Group Purchasing Industry Initiative (HGPII) was announced by the industry leaders on April 7, 2005. Its nine founding members are among the leading companies in the GPO industry with a combined market share of 85%.[76] The declared purpose of the Initiative was to engage and sustain "best ethical and business conduct practices in the GPO industry."[77]

In announcing the Initiative, industry representatives praised their groundbreaking document, which they claimed would be a role model for other industries. The Initiative, they asserted, would provide improved benefits to hospitals, nursing homes, and other healthcare providers. They claimed that these benefits could not be duplicated through any other means, including greater regulatory oversight. Industry representatives further asserted - without any substantiating logic or factual data - that any change in the existing operating structure of GPOs would be quite harmful to the principal beneficiaries of the current system, i.e., hospitals, nursing homes, and other healthcare providers.[78]

The Healthcare Group Purchasing Industry Initiative consists of six principles:

1. Each Signatory shall have and adhere to a written code of business conduct. The code establishes the high ethical values expected for all within the Signatory's organization.

2. Each Signatory shall train all within the organization as to their personal responsibilities under the code.

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[75] Becker, C. (2002, October 28), op. cit., supra note 8.

[76] BusIntell Report, op. cit., supra note 3. The nine founding members and initial signatories of HGPII are: Amerinet, Inc., Broadlane, CHCA, Consorta, Inc., GNYHA Ventures, Inc., HealthTrust Purchasing Group, MedAssets, Novation, and Premier, Inc. Of the nine GPOs covered by the HGPII, four GPOs, namely CHCA, Consorta, GNYHA, and Premier serve exclusively not-for-profit hospitals. Two others (HealthTrust and MedAssets) serve exclusively for-profit hospital alliances. The remaining three GPOs (Amerinet, Broadline, and Novation) serve both not-for-profit and for-profit hospital alliances. See for details "Questions and Answers Regarding the Healthcare Group Purchasing Industry Initiative," Healthcare Group Purchasing Industry Initiative, available at www.healthcaregpoii.com and "Key Senators and Largest Hospital Groups Express Support for New Initiative Promoting Greater GPO Transparency," Healthcare Group Purchasing Industry Initiative, press release, July 12, 2005.

[77] Becker, C. (2002, October 28), op. cit., supra note 8; "Speech by Yuspeh, A. R. Senior Vice President, Ethics, Compliance and Corporate Responsibility at HCA, Inc., delivered to the Sponsoring Partner Forum of the Ethics Office Association on April 8, 2005," (2005, April 15) *Vital Speeches of the Day*, Vol. 71, Iss. 13; pp. 390-397.

[78] Hanson, K.O. (2002). "Best Ethical Practices For the Group Purchasing Industry," A Report to the Audit Committee of the Board of Directors of Premier, Inc., pp. 1-23; Testimony of Mr. Richard Bednar, op. cit., supra note 12.

3. Each Signatory commits itself to work toward the twin goals of high quality healthcare and cost effectiveness.

4. Each Signatory commits itself to work toward an open and competitive purchasing process free of conflicts of interest and any undue influences.

5. Each Signatory shall have the responsibility to each other to share their best practices in implementing the Principles; each Signatory shall participate in an annual Best Practices Forum.

6. Each Signatory shall be accountable to the public.[79]

In describing their Initiative, the GPO groups made a number of claims. These covered both the benefits of the "voluntary" and "self-regulating" character of the Initiative, and also pointed to the harm that would be inflicted on the healthcare industry if any regulatory or mandatory changes were imposed on the industry.[80]

The Initiative is intended to encourage best ethical and business conduct practices by requiring each signatory company to pledge to follow six core ethical principles; to report annually on adherence to these principles using an Annual Accountability Questionnaire; and to participate in an Annual Best Practices Forum to discuss best ethical and business conduct practices with other GPO representatives and with representatives from government and other organizations.

There are two important considerations required of any analysis of an industry's code of conduct. The first has to do with the code principles and how they are to be implemented. The second pertains to the assertions made by the code's proponents concerning the anticipated changes in the industry members' ethical conduct and their business operations, and the enhanced benefits that would accrue to the industry's primary clients and public-at-large. These benefits must be significant, and the industry's claims of enhanced performance more credible, when a code of conduct has been created in response to allegations of prior improper conduct on the part of the industry members and when the industry is contesting the need for additional regulatory oversight as unnecessary and counter-productive.

In analyzing the potential effectiveness of the Initiative in delivery on its promises, we have used a two-pronged approach.

1. We provide a generalized framework that sets forth the situation with regard to competitive dynamics of the marketplace surrounding an industry and the industry structure that must be addressed for an industry-wide code to have a reasonable chance of meeting its performance standards.

2. We examine the extent to which the HGPII has been structured to anticipate and overcome the challenges and emanating for competitive market conditions and

[79] Charter of the Healthcare Group Purchasing Industry Initiative, May 2005

[80] Hanson, K.O., op. cit., supra note 78; "Questions and Answers Regarding the Healthcare Group Purchasing Industry Initiative," Healthcare Group Purchasing Industry Initiative, available at www.healthcaregpoii.com.

intra-industry competitive structure and thus ensure that the Initiative's performance expectations are likely to be fulfilled.

Industry or Group-Based Codes of Conduct Dealing with Issues of Corporate Social Responsibility (CSR) and Accountability

Industry-based codes of conduct seek to create and sustain a common position by industry members from challenges by non-industry stakeholders concerning their normal business practices, which have been viewed as adversely affecting other segments of society. These types of codes are a recent phenomenon, although they are fast expanding under the rubric of "social responsibility codes." These codes are invariably created as "voluntary initiatives" by the industry and are designed to deflect public pressure for further regulation and mandatory conduct on member companies in the industry. An industry-based CSR-related code of conduct consists of a set of activities that industry members voluntarily commit themselves to undertake in order to minimize, if not completely eliminate, sources of real or perceived conflict member companies' conduct and societal expectations. HGPII falls in this category of industry-codes. As such, it is subject to structural and operational constraints that are embedded in this form of voluntary code and the obstacles that these codes must overcome if they are to succeed in narrowing the credibility gap between societal expectations and industry performance. The economic logic underpinning the creation of such codes, and their socio-political implications are discussed and analyzed in Appendix E.

Impact of Competitive Markets and Industry Structure on Industry-wide Voluntary Codes of Conduct

An industry-based code of conduct is in the nature of a "private law" or a "promise voluntarily made" whereby an institution makes a public commitment to certain standards of conduct. While the "private law" character of voluntary codes of conduct gives the sponsoring organization a large measure of discretionary leeway, it also imposes a heavy burden on the organization to create independent systems of performance evaluation, monitoring and verification, and public disclosure. It must be emphasized that the "private law" character of the code does not reduce the obligations of the companies or industries. It increases their burden to ensure that its skeptical critics and the public-at-large believe in the industry's responses and performance claims.

Industry Structure

To be effective and credible, industry-based voluntary codes of conduct must contend with three issues that are embedded in the code structure. These are (a) the free rider problem; (b) the problem of adverse selection; and, (c) the notion of "best business practices." The magnitude and severity of these problems would adversely impact their collective operation.

Free rider problems arise when some type of pressure and coercion is necessary to ensure that member organizations, which benefit from the collective effort, also share

the cost of maintaining such effort in proportion to the benefits derived by them.[81] Adverse selection occurs when companies joining the industry group have a lower level of acceptable ethical conduct than is called for under the proposed voluntary code of conduct. In that case, they stand to gain immediate credibility by their association with the code. These companies are likely to exploit the benefits accruing from their participation in the industry's voluntary code while inflicting harm (through bad reputation) on other members of the group.[82]

An industry's effort to improve "best practices" invariably suffers when the group is dominated by free riders and companies with bad performance (adverse selection). These companies exert pressure on other members to keep a lid on the costs associated with improving compliance as the price of ensuring their participation in the industry's code of conduct.[83]

The notion of constantly improving "best practices" also suffers from the twin elements of the free rider problem and adverse selection. Innovative companies cannot benefit from improving their practices under the guise of standardization. Scholarly research in economics and management literature shows that industry practices are most likely to improve under conditions of highly competitive markets where insiders must continuously improve to gain competitive advantage. Improvement in the "best business practices" is unlikely where the "improvements" might increase costs through absorption of negative externalities, which the least efficient and most recalcitrant members are unlikely to accept.

Pre-Conditions for Creating an Effective Industry-wide CSR-related Voluntary Code of Conduct

Based on our research and field work in monitoring code compliance, we have identified eight conditions that must be met for an industry-based code to demonstrate measurable and credible compliance with the industry's voluntary initiative.

1. The code must be substantive in addressing broad areas of public concern pertaining to industry's conduct.

2. Code principles or standards must be specific in addressing issues embodied in those principles.

3. Code performance standards must be realistic in the context of industry's financial strength and competitive environment. The industry should not make exaggerated promises or claim implausible achievements.

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[81] Andreoni, J. and McGuire, M. C. (1993). "Identifying the Free Riders: A Simple Algorithm for determining who will contribute to a public good," *Journal of Public Economics, Amsterdam*, Vol. 51, Issue 3, pp. 447-455; Conlon, J. R. and Pecorino, P. (2002). "Policy Reform and the Free-Rider Problem," *Public Choice*, Vol. 120, Issue 1-2, pp. 123-142.

[82] Fabel, O. and Lehmann, E. E. (2000, February 21). "Adverse selection and the economic limits of market substitution: an application to commerce and traditional trade in used cars", *Diskussionbeiträge Series I*, No. 301, retrieved on March 4, 2005 from http://ssrn.com/abstract=213088; Wilson, C. (1980). "The Nature of Equilibrium in Markets with Adverse Selection," *Bell Journal of Economics*, Vol. 11, pp. 108-130.

[83] For further discussion and elaboration of these issues, please see Appendix E

4. Member companies must create an effective internal implementation system to ensure effective code compliance.

5. Code compliance must be an integral part of a management performance evaluation and reward system.

6. The industry must create an independent governance structure that is not controlled by the executives of the member companies.

7. There must be an independent external monitoring and compliance verification system to engender public trust and credibility in the industry's claims of performance.

8. There should be maximum transparency and verifiable disclosure of industry performance to the public. Standards of performance disclosure should be the sole province of the code's governing board.

In our analysis of the potential effectiveness of HGPI Initiative, we would apply these standards to test the viability of the Initiative's six principles, their operative mechanism and governance structure to deliver on the promises of enhanced ethical conduct made by the GPO industry.

GPO Industry's Assertions and Claims

In his testimony before the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, Mr. Richard Bednar, the new coordinator of HGPI Initiative, makes further claims about the benefits of the new Initiative. He asserts that the HGPI Initiative, which has been modeled after the Defense Industry Initiative (DII) holds a similar promise of enhanced industry performance.[84] He claims that this Initiative would be the best and most far-reaching industry-based code of conduct ever created. In order to lend further credence to the Initiative's promises, he alluded to recent developments in corporate governance, i.e., the Sarbanes-Oxley Act and U. S. Sentencing Commission Guidelines for Organizations,[85] both of which urge companies

[84] It should be noted here that Mr. Bednar is also the current coordinator of the Defense Industry Initiative. He asserts that "DII is widely held to be a success story…and that it continues to experience strong public and government confidence in its sincere commitment to the highest ethical and conduct standards. Testimony of Richard Bednar, op. cit., supra note 12.
Mr. Bednar's praise of DII notwithstanding it is doubtful that the defense industry's ethical conduct has markedly improved either because of DII or despite it. Recent scandals involving Boeing, Halliburton and other defense contractors would suggest otherwise.

[85] For a discussion of Sarbanes-Oxley and the Sentencing Guidelines see, Laufer, W. S. (2006). "*Corporate Bodies and Guilty Minds: The Failure of Corporate Criminal Liability"* (Chicago, Ill.: University of Chicago Press). See also, Cunningham, L. W. (2003). "The Sarbanes-Oxley Yawn: Heavy Rhetoric, Light Reform (and it might just work Connecticutt Law Review, Vol 35, pp. 915-947; Romano, R. "*The Sarbanes-Oxley Act and the Making of Quack Corporate Governance*," *Yale Law School, Center for Law, Economics and Public Policy, Research Paper No. 297* (discussing reforms as symbolic politics and window-dressing); Coglianese, C., Healey, T.J., Keating, E.K. and Michael, M.L. (2004) "The Role of Government in Corporate Governance," *Regulatory Policy Program Report RPP-08,* (Cambridge, MA: Center for Business and Government, John F. Kennedy School of Government, Harvard University).

to install in-house training and monitoring processes, whose effectiveness would be considered as mitigating factors when companies are found to be in non-compliance with required legal or regulatory standards of conduct.

There are two serious problems with Mr. Bednar's assertions. The six "principles" are nothing more than a set of exhortations which these companies would fulfill as they see fit. All measures of substance are left entirely to the member companies. Industry members also set their own criteria with regard to compliance, performance evaluation, implementation assurance and public disclosure.

In asserting the potential benefits of the voluntary Initiative, an industry document states: "Achieving exemplary ethics and business practices across an industry is something that will occur only if the leadership of the industry makes a significant commitment to achieve the articulated standards. With this Initiative, each CEO is pledging that his or her organization will achieve the ethics and business conduct standards that are addressed in the core principles and the questionnaire."[86]

The document also defends the inherent merits of a voluntary code when compared with the alternative of governmental regulation and alludes to the agile and dynamic nature of member companies' management in responding to the evolving needs of the health care marketplace. The document further argues that "an additional regulatory solution is much less likely to be successful. Faced with a complex regulatory scheme, companies inevitably turn primarily to lawyers to try to ensure that they are meeting the letter of the law. Any aspiration to best practices tends to be extinguished by regulatory complexity and burden."[87] Furthermore, any "attempt to regulate the industry would take several years, and would be unlikely to keep up with the structure of the industry. A voluntary system can require extensive ongoing transparency and respond most effectively to the changing structure of the industry."[88] Underlining these value-loaded assertions are such terms as complex regulatory schemes, where companies "inevitably" turn to lawyers, and where aspiration to best practices "tends to be extinguished by regulatory complexity and burden." Left unstated is the question as to what happens when industry members fail to meet their commitments.

The references to Sarbanes-Oxley and U.S. Sentencing Guidelines are also misplaced. Under the Sarbanes-Oxley, the top managers of a company are held responsible for any misstatements or omissions of material facts, which they have certified as accurate. Similarly, the Sentencing Guidelines consider a company's diligence in installing and monitoring control systems. The guidelines, however, do not absolve managers for their illegal conduct in any way. It should be apparent that no such provisions exist in the HGPI Initiative and hence any comparison between the two is inaccurate and unjustified. Mr. Bednar also states that insofar as the sanctions are concerned, "this Initiative is not designed to tee up penalties for misconduct. It is

[86] "Questions and Answers Regarding the Healthcare Group Purchasing Industry Initiative," Healthcare Group Purchasing Industry Initiative, available at www.healthcaregpoii.com.
[87] ibid.
[88] ibid.

designed to encourage ethical conduct."[89] Mr. Bednar goes on to state that "CEOs believe in ethical leadership as the best way to introduce ethical business conduct within their organizations. The CEOs do not believe in out-sourcing this responsibility." Mr. Bednar places his confidence in the integrity of the CEOs of the member companies and thus asks us to commend the Initiative's system of self-governance, one in which the same group of people whose performance is being evaluated are the people who are doing the evaluation.

Reduced to its bare essentials, the final product of this process is essentially a compilation of the reports provided by the member companies based on their own self-evaluation. Member companies are asked to be accountable and transparent. What is left unsaid, however, is the mention of specific standards for which they should be held accountable. What are the specific requirements of transparency that they are expected to meet? A review of the detailed questionnaires furnished by the first round of member companies further supports this observation. These questionnaires provide us with extensive details on individual GPO's polices and procedures, but there are no details on how these policies are being implemented, incidents of failure to comply, and the corrective actions, if any, taken by the management.

The governance structure of the GPO initiative does not provide any mechanism for independent external monitoring and verification of member companies' self-reported performance. Such an assertion would be untenable given the industry's current record.

Evaluation of HGPI Initiative against Independent External Criteria

In an earlier section of this report, we outline eight pre-conditions, which have been found to be indispensable in creating and implementing meaningful and effective industry-based codes of conduct. Our analysis of the HGPI Initiative in the previous section -- based on the content of the Initiative and the claims of its sponsors and supporters -- leads us to conclude that the Initiative fails to meet the standards of any of the eight conditions of creating an effective industry-based code of conduct.

Our discussion and analysis in the preceding sections effectively demonstrates that the HGPI Initiative is not structured to achieve its professed objectives. It has built-in structural characteristics that are designed to prevent it from attacking the problems, which initially gave rise to public controversy and pressure for additional regulatory oversight.

In summary, the GPO Initiative is weakened by a lack of specificity, non-existent performance standards, an internally-controlled and self-serving governance structure, and, an absence of genuine independent external monitoring. Given its current structure, it is difficult to see how it can or will make any meaningful improvement in the system of GPO operations and in delivering benefits to the hospitals, which must be their principal beneficiaries. Conversely, the realization of these benefits is entirely

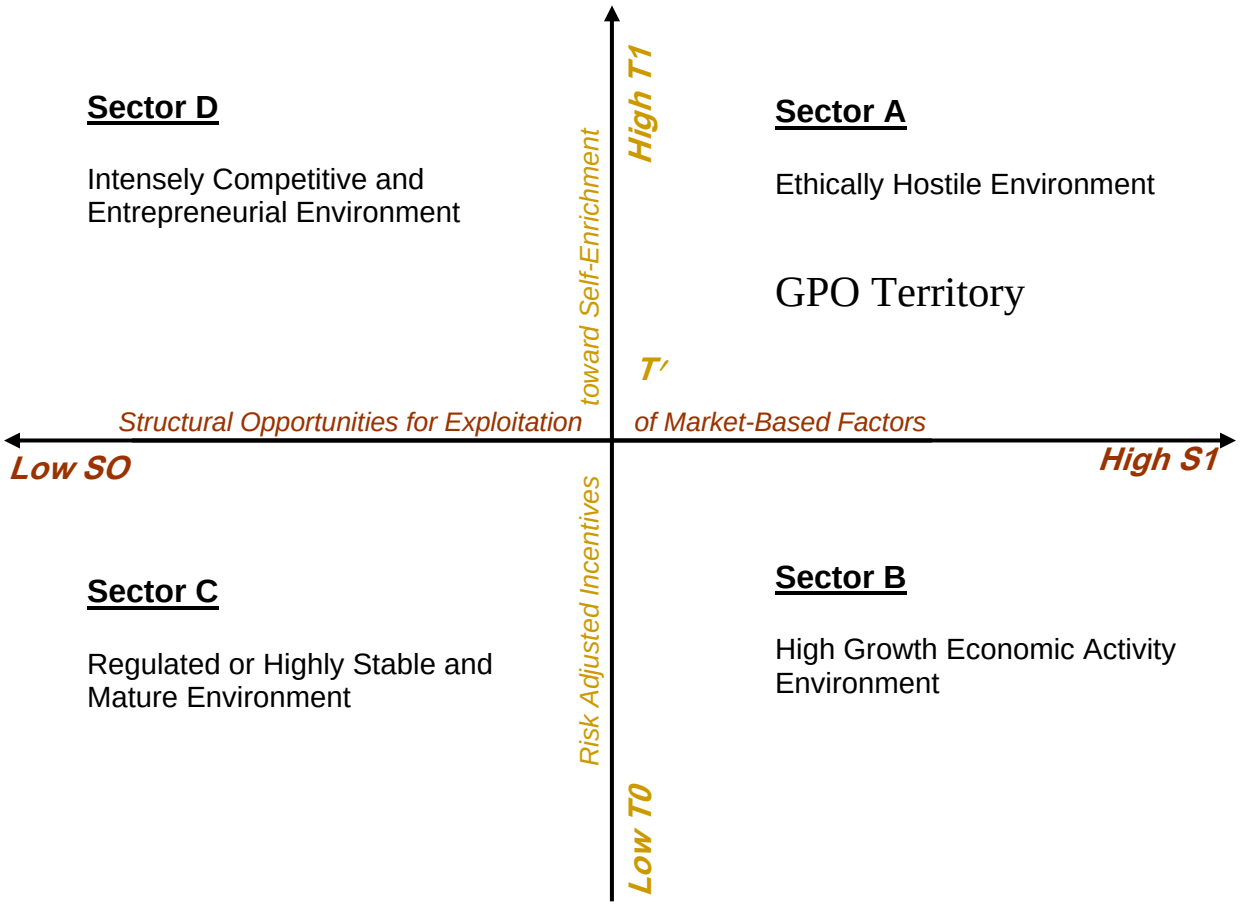
[89] Hearing before the Antitrust, Competition Policy, and Consumer Rights Subcommittee of the Senate Judiciary Committee, "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition? " March 15, 2006.

feasible, if and when GPO operations are independently monitored and GPOs are held accountable for their conduct.

Structural Flaws in the HGPI Initiative

The current conduct of GPOs can best be understood in the context of external environment which provides GPOs with the opportunities to maximize agency revenues without regard to communicate benefits to the agency's beneficiary clients, i.e., extract rewards that are far in excess of reasonable compensation. However, market-based opportunities for revenue generation are not sufficient by themselves. There is the attendant risk of being caught and punished for unethical or illegal conduct. Therefore, self-enrichment on the part of GPOs, funded directly by exorbitant agency costs, would be influenced by a confluence of the twin factors of external opportunities and risk-adjusted possibilities of self-enrichment. These are illustrated in Exhibit 5.

Exhibit 5: Influencing Ethical Conduct In Group Purchasing Organizations



The first dimension, S_0S_1, of the framework deals with GPOs' external, market-based environment and opportunities that it provides for the middlemen to maximize agency profits. The second dimension, T_0T_1, indicates the magnitude of incentives

available to GPOs, or the middlemen, and the extent to which these middlemen can exploit available opportunities for self-enrichment because of low risk of apprehension and punishment.[90]

An analysis of GPOs' operational environment clearly suggests that GPOs fall in the sector delineated by $T'T_1$ and $S'S_1$. As an industry, GPOs are a highly concentrated oligopoly where two top companies commanded nearly 60% of the market share in 2004.[91] The nine companies, which are signatories of the Healthcare Group Purchasing Industry Initiative, account for 80% of the total market share.[92] The industry's oligopolistic structure provides the suppliers with built-in incentives to work only through GPOs. It also makes it unnecessary and unproductive for the industry leaders to compete with each other. Instead, they maximize their market control and revenues through consolidation via mergers and acquisitions and thereby minimize intra-industry competition. This situation -- where opportunism is not legally or economically controlled -- leads to a disregard of ethical conduct even under conditions of normal business operations.

The second dimension of GPO sector $T'T_1$ should also be apparent. GPOs exercise strong control over the information with regard to sources and amount of revenues, supplier relationships and revenues beyond the 3% administrative fee; justification for their operating expenses and management compensation; and, determination of the size and distribution of the surplus revenue to the member hospitals.

The benefits of combined purchases would be greatly reduced under conditions where the middlemen, i.e., GPOs, control the entire process through restrictive arrangements with suppliers and customers. These arrangements would allow them to capture a large portion of the gains from group purchasing activities. These excessive agency costs, i.e., compensation for the GPOs and their managers, are further facilitated through GPOs' control of all relevant financial information; and, where the governance and accountability structure of these activities is largely, if not entirely, controlled by the GPO management.

To the extent that GPOs are profit-making organizations and largely self-governing, the current arrangement provides them with the most opportunity for self-enrichment, and maximum incentive to structure their operations in a manner that would maximize their income and management rewards. Under these circumstances, seeking lower prices from the suppliers would take a back seat to higher returns generated by products that would maximize revenue for GPOs through administrative fee and other forms of payments. Consequently the member hospital group is both large and highly

[90] The framework presented here is adapted from Sethi, S. P. and Sama, L. (1998, January). "Ethical Behavior as a Strategic Choice by Large Corporations: The Potential Impact of Industry Structure and Market Place Competition," *Business Ethics Quarterly,* Vol. 8 Iss. 1, pp. 85-104.

[91] Becker, C. (2005, August 15), op. cit., supra note 3. It must be mentioned here that out of 65 GPO only 19 organizations responded to survey and Modern Health Care does not audit the reported results. This survey is carried out by sending the questionnaire to the GPOs and the GPOs fill in the information and send it back. Survey figures and interpretation is based on this. But all this surveys are signed by their respective CEO or CFO's. Only 5 GPOs reported any financial data.

[92] BusIntell Report, op. cit., supra note 3.

diffused. Individual hospitals generally have neither the expertise nor the resources to exercise effective oversight and governance over GPO operations.

Administrative Fee and Safe Harbor

HGPI Initiative is conspicuously silent in its discussion of two important problems, i.e., administrative fees and anti-kickback safe harbor that lie at the core of practically all questionable practices attributed to GPOs. The questionnaires, which establish the accountability system and transparency in disclosure also do not deal directly with these issues. One of the most contentious items in this regard is the GPOs' collection from their suppliers of an administrative fee, rebates, and charges for various services.

The safe harbor protection give the GPOs almost total discretion in the use of this fee to cover their operating costs, and the distribution of any residual surplus to their member hospitals. This fee is intended to cover the cost of providing contract negotiations and management services by the GPOs. The administrative fee, however, has become a primary source of self-enrichment on the part of GPO management and to the detriment of their beneficiary clients.

Principal – Agency Conflict

There are three problems with the fixed fee arrangement, which causes them to lose any direct and meaningful relationship to the cost of service that it is intended to cover. First, instead of creating incentives to lower costs and better efficiencies, a constant fee rate creates incentives that do the opposite, the prices paid remain constant without regard to whether actual costs go down. A constant fee will eliminate the possibility of earning lower revenue from the administrative fee by the GPOs. Second, the fee structure generates rewards that further retard the process of innovation and cost efficiencies because the current system of administrative fee has no relation whatsoever to the cost of running GPO operations. Nor is the fee related to the efficiency and cost of products contracted by different suppliers. Instead, the fee has become a key part of a system of "pay to play" where the middlemen, i.e., GPOs, strive to maximize their revenues by increasing the total size of purchases. And, all other things being equal, a higher priced product – given the same volume and a percentage fee -- will yield a higher level of revenue to the middleman.

Third, the most important factor for the hospitals to understand and recognize is that the administrative fee is not some "free good" delivered by the suppliers out of the goodness of their hearts. For them, it is just another cost of doing business. Someone must pay this cost and it is reflected in the price, at which these goods are sold by the suppliers. It should be apparent to everyone that GPOs' current suppliers are not running a charity and that any fee that they have to pay, no matter what it is called, eventually would have to be added to their costs and reflected in the prices they charge for their products. When this fee is eliminated, the money saved does not evaporate into thin air. It would either be reflected in lower prices charged by the suppliers, or someone else would reap the profits. The inevitable result of a buyer's lack of control is that middlemen continue to earn enormous profits, and their manager's excessive

compensation, while hospitals struggle to make ends meet through excessive cost-cutting that often endangers the quality of service and patient care.

5. ALTERNATIVE PROPOSALS FOR THE REFORM OF THE GPO INDUSTRY

From our analysis of the HGPI Initiative – when viewed in the context of the dynamics of competition, oligopolistic industry structure, instances of questionable industry practices - it is almost certain that the GPO industry's current efforts would fail to deliver any meaningful reforms. Instead, given its current formulation, the Initiative is more likely to protect the GPOs current *status quo* and would not create an independent external oversight and transparent accountability. The Initiative allows the GPO industry to maintain complete control of its operations. Through a web of locked contractual arrangements with suppliers and end-users, GPOs deter new competitors from entering their markets. Above all, the system creates a bubble, which shields industry members' activities from independent external monitoring while providing it with the false patina of respectability as a socially responsible industry.

To be effective, any alternative reform proposals must address two sets of issues. The first one has to do with the current structure of the industry and the manner in which it creates and exploits market-based opportunities and garners above-normal profits for the benefit of the GPO owners. The second issue deals with the challenges posed by the agency problem through which GPOs engage in practices that enrich them at the expense of their beneficiary clients, i.e., hospitals, nursing homes and other healthcare providers.

5.1. Reform Proposals Suggested by the Senate Judiciary Committee

At its hearing on March 15, 2006 the Subcommittee on Antitrust, Competition Policy and Consumer Rights of the U.S. Senate Judiciary Committee proposed three measures for consideration toward reforming the conduct of Healthcare Group Purchasing Industry. These are: "the Proposal for Enacting the Hospital Group Purchasing Organization Reform Act," "S.2880 – Medical Device Competition Act 2004 (Introduced in Senate) 108th Congress, 2nd Session," and "Ensuring Competition in Hospital Purchasing Act." [93]

In the following section, we provide our analysis and evaluation of these three proposals pointing out their strengths and weaknesses. These are followed by a fourth proposal put forward by ICCA. This proposal is to be of a short-term duration, and is intended to cover a necessary transition period. It is based on the assumption that any substantial change from the current GPO *modus operandi* would require some action to ensure that the transformation process is smooth and minimizes any disruptions in the normal workings of the hospitals and other healthcare servicing organizations.

[93] "The Proposal for Enacting the Hospital Group Purchasing Organization Reform Act," Discussion Draft, 108th Congress, 2nd Session, pp. 1-8; "S.2880 – Medical Device Competition Act 2004," Discussion Draft, 108th Congress, 2nd Session, pp. 1-3; "Ensuring Competition in Hospital Purchasing Act," Discussion Draft, 109th Congress 1st Session, pp.1-3.

I. S.2880 – Medical Device Competition Act

The intent of this bill is to create a regulatory mechanism through the Secretary of Health and Human Services, in consultation with the Attorney General and Federal Trade Commission, which would restrain GPOs from engaging in practices – business or otherwise – that are contrary to "the anti-trust law and competitive principles, to ethical standards, or to the goal of ensuring that products necessary for proper patient care or worker safety are readily available to physicians, health care workers, and patients."[94]

There are a number of practical issues in this bill that would seriously undermine its effectiveness in achieving its intended goals, i.e., to improve the competitive environment in which GPOs operate. It is unlikely that it would have the necessary "reform" effect on GPOs' current business practices.

The regulatory enforcement of this bill would be highly adversarial. The organizations to be regulated, i.e., GPOs, would have a strong financial incentive to prolong and even scuttle all enforcement efforts because every delay and dilution translates into substantial financial gains.

An adversarial regulatory environment would require substantial commitment of financial and professional resources on the part of the regulatory authorities. S.2880 does not provide any additional resources to the Department of Health and Human Services (DHHS). Nor does it make any specific regulatory demands to be implemented by the DHHS. Therefore, implementation of these regulations would be highly vulnerable to DHHS's own changing priorities and to the changing political climate in Washington. Thus while the GPOs current practices will continue, their effective regulation would be ensured even with the passage of this S.2880.

The current effort at regulating GPOs is vulnerable to unequal financial, political, and organizational leverage. GPOs, who are the primary beneficiaries of the *status quo*, are a highly focused, amply financed, and well-organized industry. It could and certainly would mobilize significant financial resources to dilute and delay effective enforcement of S.2880. If this bill is enacted into law in 2006, GPOs would have two years to continue business as usual and also devise other ways, which would allow them to maintain their stranglehold on the purchasing process, without violating this law. Moreover these groups have the will and the means to persist in their efforts over a long period of time.

Conversely, the groups that stand to gain from a strong and effective regulatory oversight are widely dispersed and not as well organized. They include, among others, smaller hospitals, nursing homes, other healthcare providers, the vast patient population and ultimately the American public. In their current mode, they lack adequate financial and informational resources, effective organizational mechanisms, and political muscle with which to counterbalance the potential power and influence of GPOs.

[94] "S.2880 – Medical Device Competition Act 2004," op. cit., supra note 93, p.1.

Another problem with S.2880 is that it is non-specific as to what constitutes "reasonable costs." This issue is left to future rule-making by the Department of Health and Human Services. The regulatory history of the Federal Trade Commission, Consumer Safety Commission and other similar bodies, is replete with instances where larger companies would dump truckloads of documents asserting that this information supported the companies' position while fully knowing that FTC did not have the resources to evaluate and analyze those documents. This situation invariably leads to a settlement in terms that are at best face-saving on the part of the regulators without necessarily bringing about significant changes in the conduct of the companies' conduct.[95]

Adequate enforcement requires sufficient staff and financial resources, which are not always available given our history of budget tightening in the arena of health and human services. There would always be pressure to cut back in one area in order to meet other "more important" priorities.[96] It should be apparent that GPOs would have every incentive in the world to overplay the so-called "unnecessary cost" of this regulation.[97]

II. Proposal for Enacting the Hospital Group Purchasing Organization Reform Act

This proposal has two components. The first one pertains to the establishment of a Hospital Group Purchasing Organizations Ethics and Business Practices Compliance Office (hereinafter called the Office) in the Department of Health and Human Services. This Office would monitor and ensure compliance-related activities of hospital group purchasing organizations that meet certain minimum criteria as to their size and scope, and would be covered under the proposed Act.

The second component, which would be the main activity of the Office, pertains to the certification by the Office to the effect that the covered GPOs have complied with the industry's code of conduct. The Act and the Office also stipulate as to the major components of such a code of conduct and the manner in which the covered organizations (GPOs) would comport themselves in their compliance with the industry's code of conduct.

The Office would provide an important forum for highlighting the problems associated with the current *modus operandi* of the GPOs and their new Initiative. It would also provide a forum where GPO activities and performance can be presented with some external assurance as to their accuracy and transparency. This would allow

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[95] See Ayres, I. and Braithwaite, J. (1992). "*Responsive Regulation: Transcending the Deregulation Debate"* (New York: Oxford University Press); Braithwaite, J. (1990). "Convergence in Models of Regulatory Strategy," *Current Issue Criminal Justice*, Vol. 2, Iss. 59; Braithwaite, J. (1984) "*To Punish Or Persuade: Enforcement Of Coal Mine Safety*" (New York; SUNY) (extending theories of self-regulation to the coal industry); Braithwaite, J. (1982). "Enforced Self-Regulation: A New Strategy for Corporate Crime Control," *Michigan Law Review*, Vol. 80, 1466 (proposing a new concept of regulatory cooperation).

[96] See Braithwaite, J. (1998). "Institutionalizing Distrust, Enculturating Trust," in V. Braithwaite and M. Levi (Eds.) *Trust and Governance* (New York: Russell Sage), p. 356.

[97] Laufer, W. S. op. cit., supra note 85.

those groups and individuals - who are adversely affected by the activities of GPOs - to have a venue for airing their complaints and seek redress. As such, it should serve as a first line of "preventive" deterrence.

As noted previously, the quality of regulation is greatly influenced by: (a) the willingness to cooperate on the part of those who are to be regulated; (b) the quality and accuracy of the information provided to the regulators by the organizations that are to be regulated, and their willingness to do so; and (c) the resources – financial and professional – available to the regulators to perform their duties under the proposed Act.

This proposed Act provides only a broad framework for creating a code of conduct for the GPO industry. However, it leaves the entire process of code creation, implementation, monitoring, and compliance assurance, to "self-regulation" on the part of the GPOs. This is an unrealistic assumption given the fact that GPOs are adamantly opposed to any code of conduct that goes beyond generalities as to standards of performance and does not have meaningful assurance of compliance with code standards no matter how ambiguous and vague they might be. In the absence of compliance standards that are outcome-oriented and not merely process-oriented, and a compliance verification system that is independently monitored and certified, the proposed Act would fail to achieve any of its intended objectives. Instead, it would result in negating any potential benefits that might come from the establishment of the Office and its certification of GPOs.

The conditions outlined in the Act for the GPOs' code of conduct do not mention any requirements for creating standards that would specify minimum levels of compliance. The Act also does not specify activities that would be strictly proscribed. There are no provisions in the Act requiring that a GPO would be legally liable, and subject to civil and even criminal penalties, for making false and inaccurate claims as to its performance under the code.

To be effective, an industry code of conduct must also have a governance process that is independent of the GPOs whose activities it is supposed to monitor and verify. It would also be beneficial to separate the primary activities of GPOs, i.e., manage negotiations of group purchasing contracts with suppliers, from the role of collecting and disbursing the proceeds of administrative fee received from the suppliers.

An industry code of conduct must have significant representation in its governance and oversight structure from the beneficiaries of the group purchasing system, in whose sole interest the GPOs are supposed to operate. Otherwise, the code content and its implementation would be reduced to the self-serving claims by the GPOs.

An effective measure to overcome this situation would be to treat the official reports by the GPOs as "implied contract"[98] and thus any false claims made in these reports would be subject to legal proceedings and penalties. The new Act should

[98] Compare to civil false claim act cases, see: Boese, J.T. (2006). "*Civil False Claims and Qui Tam Actions*" (Aspen Law & Business, 3rd ed.).

specifically allow private action by injured parties against GPOs where their reports based on the self-evaluation of compliance with the industry's code of conduct would be considered factual statements of the GPOs activities.[99]

III. Ensuring Competition in Hospital Purchasing Act

The objective of this bill is "to repeal a safe harbor with respect to vendors in order to ensure full and free competition in the medical device and hospital supply industries."[100] In our view, this is perhaps the most significant and effective action that the Congress can take to bring greater efficiency, reduced costs, and increased transparency in an opaque area of costs-benefits related to the operations of GPOs, hospitals, nursing homes, and other healthcare providers.

For obvious reasons, GPOs are adamantly opposed to the elimination of safe harbor provision. Because of the enormous amount of money involved even a small reduction in GPO costs can yield substantial benefits to the healthcare providers that are covered by GPO-contracted and managed purchasing programs. In defending their role and justifying their modus operandi, GPOs make a variety of unsubstantiated and unverifiable assertions concerning the savings they achieve and pass on to hospitals, nursing homes and other healthcare providers.[101] They also make claims for their economic efficiencies in negotiating lower prices from their suppliers, which are then passed on to the GPOs' beneficial owners. They further raise the specter of hospitals being deprived of savings and surpluses distributed by the GPOs in the event that the safe harbor is repealed and the administrative fee is phased out.[102] The impression invariably created but never supported with data and facts from the GPOs is that the repeal of safe harbor would amount to financial catastrophe for a large number of hospitals, nursing homes, and other healthcare providers.

It is worth repeating that there are good reasons for the hospitals, nursing homes and other healthcare providers to combine their purchases and thereby leverage their buying power to negotiate lower prices and volume discounts. However, the benefits of combined purchasing power are considerably reduced because of the middleman, i.e., GPOs, control the entire process through restrictive arrangements with suppliers and customers. These arrangements allow the GPOs to capture a large portion of the gains from the group purchasing activities. These excessive agency costs, i.e., compensation for the GPOs, are further facilitated through GPOs' control of all relevant financial information; and, where the governance and accountability structure of these activities is largely, if not entirely, controlled by the GPO management.

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[99] For the importance of verification, see, e.g., Braithwaite, J. (1982), op. cit., supra note 95; Fisse, B. and Braithwaite, J. (1993) *Corporations, Crime and Accountability*, p. 159.

[100] "Ensuring Competition in Hospital Purchasing Act," op. cit., supra note 93, p.1.

[101] Hovenkamp, H., op. cit., supra note 42; Schneller, E. S. "The Value of Group Purchasing in the Health Care Supply Chain," *School of Health Administration and Policy, Arizona State University College of Business*, pp. 1-20; DeJohn, P. (2005, August)."HIGPA Enters New Phase with Year-end Betz Exit," *Hospital Material Management*, Vol. 30, Iss. 8, p. 9; Bloch, R., op. cit., supra note 34.

[102] ibid; GAO-03-998T, op. cit., supra note 6; Singer, H. J., op. cit., supra note 10.

The current business model provides the GPOs with the most opportunity and also the maximum incentive to structure their operations in a manner that would maximize their income and management rewards. Under these circumstances, seeking lower prices from the suppliers take a back seat to higher returns generated by products that maximize revenue for GPOs through administrative fee and other direct and indirect payments.

The current system of administrative fee has no relation to the cost of running GPO operations. Nor is it related to the efficiency and cost of products contracted by different suppliers. Instead, it has become a system of "pay to play" where the middlemen, GPOs, attempt to maximize their revenue by increasing the total size of purchases. And, all other things being equal, a higher priced product would yield a higher level of revenue to the middleman.

IV. Alternative Proposal for Reform of the GPO Industry

A review of the three Senate sponsored proposals indicates that there are significant problems in creating and implementing any reform measure where the GPOs current business model, including the safe harbor provision, remains intact. This report has provided strong evidence that structural flaws embedded in the GPOs business practices would be extremely difficult, if not impossible, to correct, given the GPOs' vested interest in maintaining the lucrative financial franchise and their oligopolistic control of the marketplace. In the long term, competitive markets would create various alternatives for covering the administrative costs associated with group buying programs in a manner that would balance the interests of both the suppliers and their customers. A market-based system would clearly be superior to the current arrangement. It would also obviate the necessity of cumbersome regulatory mechanisms, which are susceptible to manipulation through "technicalities," excessive delays, and political influence on the part of GPOs and other parties who stand to benefit from a protected business environment.

Repeal of the Medicare anti-kickback safe harbor and the administrative fee structure would necessarily involve disruption in established business practices and current contractual relationships between the suppliers, GPOs and their beneficial owners. Therefore, a transition period and some short-term facilitating arrangements would be necessary.

We believe that a transition period of between 18 to 24 months should be sufficient to implement the necessary changes. The transition period should help create a business environment which ensures that:

(a) the agent's financial incentives are closely aligned with the economic interests of the master, i.e., hospitals, nursing homes, and other healthcare providers;

(b) the agent's rewards are closely tied to clearly defined and measurable performance targets;

(c) there are effective measures of oversight and governance to monitor the agent's activities and to hold the agent accountable for pre-defined performance targets; and,

(d) the agent's performance orientation must be shifted away from self-enrichment of the GPOs and their management, toward the notion of stewardship of resources for the benefit of the GPOs' principal clients, i.e., hospitals, nursing homes and other healthcare providers.

Separation of GPO Services from Revenue Collection

An important first step would be to separate the GPOs from the control and management of funds generated from the administrative fees. It would require a separation of the activities of contract negotiation, vendor selection, and contract management, from the function of fee collection and its disbursement. This is an absolute must in bringing a "ray of sunshine" into the activities of GPOs.

Financial Disclosure

During the transition phase, GPOs must be required to make full and complete disclosure of their finances. Moreover, the financial disclosure would be certified and independently verified by an outside auditing firm. The information to be provided would include:

1. All sources of income and their connection with GPO operations.

2. Disclosure of operating expenditures in meaningful categories.

3. Details of compensation packages for top executives.

4. Distribution of surplus revenue to member hospitals and the criteria used to determine allocations.

5. Disclosure of ownership interests in GPOs by their managers and also by the managers of member hospitals.

APPENDIXES

Appendix A

Table 1: Health Indicators by Country

	United States	United Kingdom	Germany	Canada
Life Expectancy at birth (2003)	77.0	79.0	79.0	80.0
Child mortality, probability of dying under 5 years (per 1000) (2003)	8.0	6.0	4.5	5.5
Adult mortality, probability of dying between 15 and 59 (per 1000) (2003)	110.5	83.5	87.0	75.0
Percentage of total life expectancy lost due to poor health (%) (2002)	10.3	9.6	8.5	9.6
Total expenditure on health as % of GDP (2002)	14.6	7.7	10.9	9.6
Per capita expenditure on health in international dollars (2002)	5,274	2,160	2,817	2,931

Source: World Health Organization, Country Health Indicators.

Appendix B

Safe Harbor in the GPO Industry

On August 17, 1987 the Social Security Act was amended by the Medicare and Medicaid Patient Program Protection Act. This Act specifically mandated the U.S. Department lf Health and Human Services (HHS) to promulgate regulations specifying various payment and business practices which, although potentially capable of inducing referrals of business under federal and state healthcare programs, would not be treated as criminal offenses under the federal anti-kickback statute.[103] [Pub.L. 100-93, section 14]. One of the so-called safe harbor provisions protects healthcare GPOs from the anti-kickback statute by excluding:

> "any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met -
>
> (1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following:
>
> (i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.
>
> (ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO). [42 C.F.R. 1001.952(j)]"

On July 29, 1991, HHS and the Office of Inspector General (OIG) issued the final rule implementing section 14 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, by specifying various payment practices which, although potentially capable of inducing referrals of business under Medicare or a state health care program, would be protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

[103] Section 1128B(b) of the Social Security Act [42 U.S.C. 1320a-7b(b)] ["the anti-kickback statute"] provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the federal or state health care programs.

Specifically the Final Rule stated that the following payment practices would not be treated as a criminal offense under section 1128B of the Act and would not serve as the basis for exclusion:

> (j) Group purchasing organizations. As used in section 1128B of the Act, "remuneration" does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met -
>
> (1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the Following:
>
> > (i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.
> >
> > (ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).
>
> (2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term group purchasing organization (GPO) means 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 in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

In addition to concerns with Medicare violations, the GPO system also raises antitrust concerns. In 1993 the Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued joint "Statements of Antitrust Enforcement Policy in Health Care."[104] In 1996 the Statements were revised and included Statement 7, dealing with

[104] "Statements of Antitrust Enforcement Policy in Health Care," Federal Trade Commission and Department of Justice, 1993, cited in Testimony of David A. Balto before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Business Rights and Competition, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004.

joint purchasing arrangements. Statement 7 specifies the Agencies' enforcement policy on joint purchasing arrangements among health care providers, including the formation of GPOs. It states that "[m]ost joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns. Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers."[105] It outlines the following specific guidelines:

> Joint purchasing arrangements are unlikely to raise antitrust concerns unless (i) the arrangement accounts for so large a portion of the purchases of a product or service that it can effectively exercise market power in the purchase of the product or service, or (ii) the products or services being purchased jointly account for so large a proportion of the total cost of the services being sold by the participants that the joint purchasing arrangement may facilitate price fixing or otherwise reduce competition. If neither factor is present, the joint purchasing arrangement will not present competitive concerns.[106]

This statement sets forth an "antitrust safety zone" that describes joint purchasing arrangements among health care providers that "will not be challenged, absent extraordinary circumstances, by the Agencies under the antitrust laws."[107]

The joint purchasing antitrust safety zone limits antitrust exposure for GPOs if two conditions are met: (i) membership purchases through the GPO must account for less than 35 percent of the total sales of the product or service; and (ii) the aggregate costs of the products and services each hospital purchases through a GPO must account for less than 20 percent of the hospital's total revenue.[108] In 2004, the FTC and DOJ released a report on healthcare competition and stated that Statement 7 is not a safe harbor for anticompetitive contracting practices and that such behavior is subject to antitrust scrutiny.[109]

[105] "Statement 7 - Joint Purchasing Arrangements Among Health Care Providers," op. cit., supra note 45.
[106] ibid.
[107] ibid.
[108] Brock, T. H., op. cit., supra note 4.
[109] The FTC and DOJ report states: "Health Care Statement 7 and its safety zone aim to address monopsony and oligopoly concerns with the formation of a GPO. This statement does not address all potential issues that GPOs may raise. The Agencies believe amending the statement to address some, but not all potential issues, is likely to be counterproductive. Health Care Statement 7 does not preclude Agency action challenging anticompetitive contracting practices that may occur in connection with GPOs. The Agencies will examine, on a case-by-case basis, the facts of any alleged anticompetitive contracting practice to determine whether it violates the antitrust laws." For details see "Improving Health Care: A Dose of Competition," the Federal Trade Commission and the Department of Justice, July 2004, pp. 1-361.

Appendix C

Cases Involving GPOs Practices

Most of the problems that arise from the functioning of the GPO current business model fall into three categories. These are:

(i) Contracting practices that seriously reduce innovation and competition.

(ii) Conflicts of interest that allow for critical health decisions to be made based on financial ties to suppliers which utterly harm patients and healthcare workers.

(iii) Inability to systematically realize savings for hospitals, which ultimately constitutes a fundamental flaw of the GPO business model.

Limits to Competition and Innovation

A variety of questionable contracting practices that raise competitive concerns include: exclusionary agreements, bundling of companies, bundling of unrelated products, inviting bundled bids, sole- and dual-source committed-volume deals, market share discounts, and tying.

(a) Masimo Corporation

This case was brought to public attention in 2002 by *The New York Times* investigation of GPOs.[110] It dealt with an experimental monitor called "oximeter" that saved a 2-week-old baby's life. Seven years later, and after being recommended by many U.S. hospitals as a promising device for premature infants, the manufacturing company (Masimo Corporation) was unable to sell this device to hospitals because the GPOs had contracts with a competitor for an allegedly similar type of product.[111] The case uncovered a series of practices which discouraged competition. Two of the largest GPOs, Premier and Novation, were involved. Mr. Joe E. Kiani, Masimo Corporation's CEO, stated before the U.S. Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights[112] that his product had been locked out of the market because his main competitor, Nellcor, paid fees to the two national GPOs.[113] Furthermore, both Premier and Novation had awarded sole source contracts to Nellcor. It also appeared that Nellcor was paying fees to the GPOs disguising them as

[110] Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4), op. cit., supra note 8; Masimo Corp. v. Tyco Healthcare Group, L.P., No. 02-CV-4770 (C.D. Cal.), available online: http://www.rkmc.com/Recent-Medical-Device-Antitrust-Cases-March-2006.htm.

[111] ibid.

[112] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004.

[113] op. cit., supra note 112

investments in venture capital partnerships or donations for health institutes or foundations.

The evaluation process for Masimo's oximeter by Premier was also riddled with irregularities. After issuing a promising evaluation of the product, Premier declared that the improvements weren't good enough to justify a contract. It also indicated that more study was needed. This study took more than two years and led to a final rejection of the product by Premier. By then Nellcor had come out with its own improved model. Premier also blamed high staff turnover and Masimo's slow response to inquiries from its panel.[114] After pressure from the Senate Judiciary Committee's hearing on April 30, 2002, Richard Norling, Premier's CEO, promised to personally expedite the process of evaluation of Masimo's product under Premier's breakthrough technology program.[115] In less than six months after the hearing, Masimo was awarded a contract from Premier. However, within two years, circumstances again turned against Masimo, as Mr. Kiani revealed in the September 14, 2004 congressional hearing. Although he was content with Premier's actions, he was disappointed by Premier's decision to go back to sole-source contracting seriously limiting Masimo's ability to sell their products in a competitive environment.

With Novation, the story was somewhat different. There was no contract up until the eve of the 2004 Congressional hearing when Novation opened up its sole-source contract and awarded a contract to Masimo. Problems followed because Novation sent letters to their member hospitals requiring them to continue to purchase between 75% and 95% of their requirements from Nellcor and thus leaving very little opportunity for Masimo to sell its device to the hospitals contracted by Novation.[116] Masimo Corporation has sued two Tyco affiliates, Tyco Health Care Group, L.P. (manufacturer and distributor of Nellcor brand among others) and Mallinckrodt Inc., for violating antitrust laws. The case was tried in February 2005; a month later the jury found that four of five of the practices were certainly anticompetitive and awarded Masimo $140 million in damages which were then tripled to $420 million under a federal antitrust statute. However, almost a year later, on March 2006, Federal District Court Judge Mariana Pfaelzer in district court in Los Angeles, threw out the entire award and ordered a new trial.[117] A date for a trial is still pending.[118]

(b) Retractable Technologies, Inc.

Another case of questionable practices threatening competition involved Retractable Technologies, Inc. (RTI) and its pursuit of a contract with Premier and

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[114] op. cit., supra note 112.

[115] Transcript of the hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation? " April 30, 2002.

[116] Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings," September 14, 2004.

[117] "Big Suits." (2006). *American Lawyer*, Vol. 28, Is. 6.; Masimo Corp. v. Tyco Healthcare Group, L.P., No. 02-CV-4770 (C.D. Cal.), available online: http://www.rkmc.com/Recent-Medical-Device-Antitrust-Cases-March-2006.htm.

[118] Big Suits," op. cit., supra note 117.

Novation in competition against Becton Dickinson & Company (BD), which is one of the largest suppliers to Premier and Novation. In December 1996, BD signed a 7.5 year multi-billion dollar exclusive contract with Premier to supply Premier's member hospitals with needle devices.[119] A month later and after agreeing otherwise, Mr. Douglas Hawthorne, CEO of Presbyterian Hospitals (Dallas), said that there was no way he could buy VanishPoint devices (brand name of automated retraction syringes from RTI). RTI alleged that even its sales people weren't allowed to make sales calls and demonstrate their products in hospitals affiliated to GPOs, i.e., Premier and Novation.[120] Furthermore, doctors and nurses, who requested RTI products, were pressured to withdraw such requests.[121] Mr. Thomas J. Shaw, president and CEO of RTI, stated in his testimony that in a visit to Mt. Sinai Hospital in NY (Premier member), an official advised him to sell Premier a stake in the company in order to get a contract. In 1998, in a meeting with Novation, a Novation representative proposed to RTI that the company put a private label on RTI's blood collection tube holder, increase the per unit price of 27 cents to $1.00, and split the difference. As it turned out, this was a common practice in the industry.[122] Novation first needed permission from BD, which never happened. The exclusive contracts that Premier and Novation had signed with BD called for tying and bundling products. Furthermore, in 1997, Premier suggested that RTI should have its devices evaluated at a Premier-BD testing facility. Later it was clear that a payment of $1,000,000 to "Premier Innovation Institute" would be necessary to be considered for a contract.[123] In 1998, a number of news media started to look at the issue and several U.S. senators requested an inquiry into GPO practices. The same year, RTI filed a civil antitrust suit against BD, Sherwood (later acquired by Tyco), VHA (Novation), and Premier challenging the contracting practices.[124] RTI settled with Tyco, VHA (Novation) and Premier in 2003 for $55.5 million[125] and with BD in 2004 for $100 million.[126]

(c) Biotronik

Biotronik is a privately-held US company based in Oregon. It manufactures cardiac pacemakers and implantable cardiac defibrillators. Mr. Thomas Brown, Biotronik's Executive Vice President, indicated in his written statement submitted to the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights that one of its areas of concern was the fact that GPO's contracting decisions continued to be influenced by large suppliers and the amount of money a supplier contract will

[119] Submission for the record of Thomas J. Shaw, op. cit., supra note 2. See also Holding, R. and Carisen, W. op. cit., supra note 2; Lastra, P., op. cit., supra note 2; Retractable Technologies v. Becton Dickinson & Co. Inc., No. 01-CV-036 (E.D. Tex.), available online: http://www.rkmc.com/Recent-Medical-Device-Antitrust-Cases-March-2006.htm.

[120] ibid.

[121] ibid.

[122] ibid.

[123] ibid.

[124] Submission for the record of Thomas J. Shaw, op. cit., supra note 2.

[125] Data provided by the Spokesman of Retractable Technologies, Inc. on July 18, 2006.

[126] Gray, P. B. (2005, March). "Stick it to 'em." *Fortune Small Business*, Vol. 15, Is. 2, pp. 82-88, 5p, 5c.; "Retractable Technologies, Inc. Settles Antitrust Suit against Becton Dickinson for $100 Million in Cash" *Business Wire*, July 2, 2004; Retractable Technologies v. Becton Dickinson & Co. Inc., op. cit., supra note 119.

generate for the GPO.[127] Biotronik had been excluded from several contracts to supply its products because of its inability to pay extra-fees to the GPOs.[128]

(d) St. Jude Medical

St. Jude Medical is a maker of pacemakers. The company wanted to sell its product to Premier. However, its two main competitors, Medtronic and Guidant, already had contracts with Premier. To help evaluate St. Jude's claims that its technology represented a "breakthrough", Premier formed an expert panel of six cardiologists, including Dr. Anne Curtis of the University of Florida. St. Jude claimed its pacemaker could operate using less electricity, which would mean that the implanted battery would last longer. According to the New York Times investigation, on September 19, 2000, the panel concluded: "In light of the increased device longevity and ease of use, the expert panel agreed unanimously that St. Jude's breakthrough claim is substantiated." However, Premier reported to its contracting committee that the experts had found only a "theoretical breakthrough potential" and never mentioned the unanimous expert conclusion. In March 2001, Premier's contracting committee rejected St. Jude's request after concluding that the product's battery did not last significantly longer than the battery of its rivals.[129]

(e) Applied Medical

Applied Medical was founded in 1987 in Orange County, California. The company designs, develops, manufactures, licenses, markets, and sells specialized devices for cardiovascular, vascular, laparoscopy, urology and general surgery. In 2000, Applied was invited to bid on a Novation contract for sutures, trocars, and other devices. Applied offered a price of $150 against $250 offered by Johnson & Johnson. Applied's bid was rejected even though it had the best price. It took months to get an audience with Novation to be informed that Applied didn't have the rest of the products that Johnson & Johnson and Tyco bundled with the trocars.[130]

Conflict of Interest

(a) Neoforma

Novation charges its vendors for the required use of Neoforma, an e-commerce company whose largest shareholders are Novation's parent companies, VHA and UHC. Neoforma has lost hundreds of millions of dollars since its inception while adding little of

[127] Submission for the record of Thomas Brown, op. cit., supra note 9.
[128] ibid.
[129] Bogdanich, W.; Meier, W. & Williams Walsh, M. (2002, March 4), op. cit., supra note 8.
[130] Submission for the record of Mr. Said Hilal, op. cit., supra note 7; Applied Medical Res. Corp. v. Johnson & Johnson, Inc., No. 03-CV-1329 (C.D. Cal.), available online: http://www.rkmc.com/Recent-Medical-Device-Antitrust-Cases-March-2006.htm.

value to the member hospitals. It represents yet another layer of administrative costs imposed by GPOs.[131]

(b) VHA Health Foundation

VHA Health Foundation is a wholly owned Section 501(c)(3) tax-exempt not-for-profit subsidiary of Novation's parent, VHA Inc. (nationwide network of community-owned healthcare systems).[132] It receives nearly all of its support in the form of donations from the same manufacturers that have benefited from sole-source or bundled contracts with Novation. These manufacturers include among others, Abbott Laboratories, Baxter Health, Cardinal Health, Eastman Kodak, Johnson & Johnson, and Standard Textile.

According to IRS filings, VHAHF spends a small portion of its annual donations on activities that are appropriate or acceptable under 501(c)(3).[133] Substantial portions of VHAHF's annual contributions are paid back to its owner VHA Inc, in management fees, rent and other miscellaneous and sometimes questionable payments. On September 14, 2004, the Service Employees International Union (SEIU) submitted testimony before the U.S. Senate Judiciary Committee, Subcommittee on Antitrust, Business Rights, and Competition on the impact of hospital group purchasing organizations (GPOs). SEIU specifically cited research involving the VHA Health Foundation linking it with allegedly questionable donations from manufacturers affiliated to Novation including two million-dollar donations from unnamed companies.[134]

In an article published on September 27, 2004 in *Modern Healthcare* and titled "Lucrative Liaison? Critics Question VHA Foundation – Novation Connection", Cinda Becker investigated the charge made by the SEIU in the hearing.[135] Critics of the VHA Health Foundation contended that the foundation and its grant program was a way to solicit extra cash from vendors that do business with the hospitals' GPO, Novation.[136]

Money for the VHAHF's "Creating Better Health through Innovation" grants came from Novation suppliers. The SEIU had questioned the appropriateness of vendor donations to the foundation. The SEIU was looking into the donations that were redistributed to VHA executives as compensation.[137] In a June 28, 2004 article in Modern Healthcare, VHA's CFO explained that "we looked at the issue very carefully

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[131] Comments by the Service Employees International Union on Hospital Group Purchasing Organizations before The United States Senate Judiciary Committee, Subcommittee on Antitrust, Business Rights and Competition on September 14, 2004; Lastra, P., op. cit., supra note 2.

[132] Rudikoff, N., Research Memorandum on VHAHF, available at www.seiu.org.

[133] ibid.

[134] VHA Health Foundation IRS Form 990, 2002, 2001; cited in Comments by the Service Employees International Union on Hospital Group Purchasing Organizations before The United States Senate Judiciary Committee, Subcommittee on Antitrust, Business Rights and Competition on September 14, 2004.

[135] Becker, C. (2004, September 27). "Lucrative liaison? Critics question VHA foundation-Novation connection," *Modern Healthcare*, Vol. 34, No. 39, pp. 8- 12.

[136] ibid.

[137] op. cit., supra note 132.

and the consensus was that there was not a lot to be gained from disclosing salaries."[138]

(c) The Healthcare Research and Development Institute (HRDI)

The Healthcare Research and Development Institute (HRDI) is an arcane for-profit company which serves as a network of healthcare corporate executives as well as manufacturers and suppliers of medical and healthcare related products.[139] As stated by Connecticut's Attorney General Richard Blumenthal in his testimony before the Senate Subcommittee on March 15, 2005,[140] HRDI dealings are not transparent leading him to believe that the purpose of this organization was to conceal questionable business practices from the public. HRDI ownership structure is another issue of concern. CEOs of major hospitals and healthcare systems, many of who sit on boards which control the nation's largest GPOs, own the institute, and 45 or so corporate members apply for membership to HRDI. When accepted, these corporate members pay significant annual dues and extra fees. HRDI asserts that its goal is to get together healthcare executives, manufacturers and suppliers of healthcare related goods and services. This networking and idea exchanges would help them in improving the quality of hospitals and healthcare systems.[141]

HRDI plays an important role in facilitating access for the suppliers and vendors to hospitals and healthcare system CEOs. The money collected through annual dues is used to pay "honorarium" for their services in the context of HRDI. All HRDI sponsored activities, including meetings and educational events are conducted in secrecy. HRDI website is inaccessible to the public.

Connecticut's Attorney General, Mr. Richard Blumenthal, has initiated an investigation of HRDI as part of a broader investigation of GPOs' practices.[142] Another issue uncovered by this investigation involved Medicaid. Some Connecticut Medicaid providers that purchase health care supplies through contracts negotiated by their GPO have not properly accounted for rebates received in connection with these purchases.[143]

[138] Becker, C. (2004, June 28). "Going on the record; VHA offers financial information but withholds executive compensation," Modern Healthcare, Vol. 34, No. 26, pp. 26-27.
[139] Testimony of Attorney General Richard Blumenthal, op. cit., supra note 7.
[140] ibid.
[141] ibid.
[142] ibid.
[143] ibid.

Appendix D

Professor Kirk Hanson's Investigation and Recommendations Leading to the Creation of Healthcare Group Purchasing Industry Initiative

The initiative for the report came from Premier, one of the largest GPOs in the industry. The Premier's CEO engaged Prof. Kirk O. Hanson, Executive Director of the Markkula Center for Applied Ethics at Santa Clara University, to carry out the necessary inquiries and prepare the final report.[144]

Prof. Hanson began his work in late March 2002 and presented his final report to the Audit Committee and Board of Directors on October 18, 2002.[145] Prof. Hanson's report was a significant effort involving a consultative process that included Premier's board members, conferences with a cross-section of Premier's employees, CEOs and other top officers of member hospitals in the Premier family, and four academic experts in the area of applied ethics, who are affiliated with major universities in the United States.

The Report contained 50 recommendations for the best practices in the GPO industry. These recommendations along with "Additional Commitments" set forth by Premier's executives laid the foundation for the company's code of conduct, announced in early August 2002.

The final Report was released in October 2002. Prof. Hanson indicated that in the preparation of this report, he was given full freedom to access any company documents; to communicate with anyone inside or outside the company; and to consult with other experts deemed necessary. The Report's author also had the final determination as to the Report's content and its release to the public.

The findings of the Report are important because what they cover provides a framework which has been emulated in the GPO Industry Initiative. But the Report is even more important for what it does not cover, which in our opinion, seriously undermines its potential with regard to the effectiveness and credibility of the HGPI Initiative.

In his final report, Prof. Hanson states that the study does not examine the past practices of Premier or other GPOs. Nor does it seek to examine the charges that "compromises" have been made. The Report does not indicate where it draws the line between past practices that it has excluded and current practices (which it has included

[144] Hereinafter in this Appendix referred to as the Report

[145] Hanson, K.O. (2002). "Best Ethical Practices For the Group Purchasing Industry," A Report to the Audit Committee of the Board of Directors of Premier, Inc., pp. 1-23. Professor Hanson started with a clean slate. At the initiation of the study, Prof. Hanson indicated that "he knew next to nothing" about hospital group purchasing organizations. See, Becker, C. (2002, October 28), op. cit., supra note 8. Furthermore, while Markkula Center for Applied Ethics is recognized for its work pertaining to ethical context of corporate and industry practices, neither the Center nor Prof. Hanson had substantial exposure to industry-based voluntary codes of conduct. The entire process of the study preparation took approximately seven months of work. Premier paid Markkula Center and Prof. Hanson a total fee of $223,000 or approximately $32,000 per month.

in the "Terms of References" for the inquiry). The Report does not specify any current activities that it considers objectionable or commendable, and the extent to which these practices are at variance with past practices. One cannot help but wonder at Prof. Hanson's decision not to examine or analyze past activities and accusations of misconduct against Premier and other GPOs. It is hard to conceive of a situation where a new set of ethical practices is being suggested while ignoring all prior circumstances and incidents of unethical and even possibly illegal conduct on the part of the company involved and whether these activities were unique to the company or were a common pattern in the industry. This situation is comparable to a physician's prescribing medication to a patient while deliberately ignoring the patient's past history of diseases and symptoms of current ailments. If this decision was based on sound logic, the public is entitled to an explanation. If not, it may raise questions about lack of independence on the part of the report's author.

The Report's discussion of the current industry practices does not provide any specifics. Instead, it includes a list of "unavoidable and ever-present tensions" that shape [GPO industry and Premier's] ethical practices.[146] The Report also does not identify which other GPOs, in addition to Premier, were consulted in the preparation of the report. The goals of the study were to examine the GPO industry and its current ethical practices and then identify best ethical practices for the industry. The final Report does include a short overview of the industry and current practices of group purchasing organizations. However, the Report does not list what companies, other than Premier, participated in the study and which executives were interviewed, or the extent to which the report represents industry-wide report. As Curt Nonomaque, executive vice president, chief financial officer and treasurer of VHA (one of the co-owners of Novation), said in an interview with *Modern Healthcare*: "I am surprised [the study] was couched as an industry report. Nobody from our organization was contacted about it."[147]

Professor Hanson indicated that he interviewed in person and by telephone almost 100 individuals including company executives and employees, directors and advisors. He also interviewed member hospital CEOs and staff of Premier member hospitals, vendor representatives, venture capitalists, trade associations' executives, journalists who have written about the industry, and Congressional staff."[148]

Although the study was meant to create a set of "best practices" that would be applicable to all industry members, the author himself admits that "no matter how detailed a list of ethical principles and practices might be, there will still be work

[146] These are extracts from the report's section on "Inherent Tensions in the GPO Industry": "The tension between good medical outcomes and cost control. These two primary goals of GPOs are at times in conflict … The tension between the unit cost of goods and services and their total cost in use after assessing their effectiveness in use, technological capabilities and data on medical outcomes … The tension between the cost and other advantages of working with 'familiar vendors' … The tension between being a private for-profit organization which must sustain its own financial strength and being owned by nonprofit organizations." It should be apparent that these so-called tensions encompass most of the charges of unethical and illegal practices by GPOs. To call them "tensions" appears to be an attempt to ignore the obvious and thus move away from a recognition of the very practices for which the GPOs have been accused.

[147] Becker, C. (2002, October 28*),* op. cit., supra note 8.

[148] Hanson, K.O. op. cit., supra note 145., p.7.

adapting and applying the principles to a specific organization." He also states that he has "drafted these ethical practices with Premier in mind."[149] This is puzzling. Clearly, reported unethical practices that gave rise to the Senate hearings and other governmental investigations were not limited to one or two GPOs but were endemic to most of the major companies in the GPO industry. Otherwise, there would be no point in creating an industry-wide code of conduct. Instead, the Report focuses on the future design of best ethical practices that "will enable Premier and other GPOs to maximize their contribution to these twin goals of health care, and to avoid conflicts of interest."[150] The above-quoted description of the research process fails to indicate the participation of any public interest groups, advocates of healthcare consumers, and other interested parties, such as healthcare insurance companies, with a vital interest in the conduct of GPOs. The committee, which was set up to review the first draft of the report, consisted of four independent academic scholars and four top managers of Premier. No other representatives of other GPOs, vendors, hospitals or public interest groups were asked to provide their views on the preliminary findings of the study.[151]

The Report lists 18 general underlying principles, which "seek to resolve or at least balance these inherent tensions and other dilemmas of operating efficiently and profitably in the GPO industry."[152] The issue, unfortunately, is not to balance these "inherent tensions" but to prevent GPOs from abusing their market power and information control for their benefit and at the expense of their primary clients. If all we can hope for is to seek a "balance" then the "voluntary principles" cannot be the solution when the scope, implementation and performance evaluation of these principles are controlled entirely by the GPOs. In this context, it should be noted that the 50 ethical measures recommended in the report are in the form of exhortations of "what thou shalt not do" and have no mention of any outcome-oriented standards against which GPOs' conduct could be measured.

Another issue which we consider potentially damaging is the Report's complete omission of the structural issues that lie at the core of the industry's past questionable activities and potential future misconduct. These structural issues comprise the system of revenue generation, i.e., the so-called administrative fee, which is the source of a substantial number of GPO abuses. The problem is further compounded by the opaque accounting systems used by GPOs to justify their operational expenses and the criteria they use to distribute the so-called revenue surplus to the member hospitals. In conclusion, and in the absence of an objective and forthright analysis of these two factors, any recommendations based on this Report would be of dubious validity and questionable effectiveness.[153]

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[149] Ibid., p.13.

[150] Ibid., pp. 1-23.

[151] It is disappointing to note that the report's analysis of the GPO industry was not based on an independent, objective analysis by its author. Instead, it bears a remarkable similarity to the industry's modus operandi and accomplishments, which can be found in the publicly available statements by Premier and other GPOs.

[152] Op. cit., supra note 152.

[153] The final irony of the report, which raises another question regarding its objectivity, is found in Prof. Hanson's "General Observations Regarding Premier, Inc." which is suffused with laudatory comments about Premier's management and their commitments to exemplary ethical conduct. These observations are the opinions of the author, but are presented as if they were objective statements of fact.

Prof. Hanson has since relinquished his position as the Initiative's coordinator. The new coordinator of the Initiative is Mr. Richard Bednar of the law firm Crowell & Moring in Washington, D.C. Mr. Bednar also holds a similar position with the Defense Industry Initiative. Mr. Bednar echoes similar sentiments in defending the Initiative during his recent testimony, before the U.S. Senate Committee on the Judiciary, on March 15, 2006: "I am very pleased to report that this GPO Initiative is off and running on a path destined for success."[154]

[154] Testimony of Mr. Richard Bednar, op. cit., supra note 12.

Appendix E

A Generalized Theoretical Framework for Analyzing Industry-Based Codes of Conduct

Industry-based codes of conduct are neither a recent phenomenon nor a radical innovation. Business organizations develop voluntary arrangements to standardize technical and quality standards for products, contracts, and other arrangements that create economies of scale and reduce transaction costs.[155] The economic case for voluntary cooperation among business enterprises in this area is clear and compelling. Such voluntary arrangements often involve the adoption of industry-codes that are designed to advance and protect the interests of member companies from market–based competition by companies in other industries.

This form of industry cooperation has been most successful in creating a pro-business and pro-industry regulatory and financial environment in the United States. In its extreme form, regulatory regimes that are created to protect consumers and other groups that may be adversely affected by industry action often end up protecting the industry, a phenomenon that has been described as the "capture" theory of regulation and widely discussed and analyzed in economics, political science and other pertinent fields of social inquiry.[156] Experience in the United States with regard to the power and influence of lobbying by industry groups can be easily gauged from the number of trade associations and their registered lobbyists in the nation's capitol and in those of the fifty states in the Union. Notwithstanding their vociferous support of competitive markets and free enterprise, these trade associations are single-minded in their pursuit of regulations, subsidies and tax incentives that protect their market position from competition and create a playing field that is tilted in their favor.[157]

Another dimension of the benefits of industry coalitions is the protection of companies from the cost of negative externalities by transferring them to other segments of society, reducing operational costs and improving returns on investment.[158] Examples of such externalities include air pollution, untreated waste water, etc.

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[155] Sethi, S. P. (2005)."The Effectiveness of Industry-Based Codes in Serving Public Interest: the Case of International Council on Mining and Metals," published in a special issue of *Transnational Corporations* (United Nations Conference on Trade and Development, Geneva, Switzerland), vol. 14, No. 3, pp 55-99.

[156] Roberts, R.W. and Kurtenbach, J.M. (1998)."State Regulation and Professional Accounting Education Reforms: An Emperical Test of Regulatory Capture Theory," *Journal of Accounting and Public Policy*, Vol. 17, Iss. 3, pp. 209-217; Wiley, J. S. Jr. (1986). "A Capture Theory of Antitrust Federalism," *Harvard Law Review*, Vol. 99, Iss. 4, pp. 713-790; Stigler, G. (1971). "The Theory of Economic Regulation," *Bell Journal of Economics and Management Science*, Vol. 2, pp. 3-21; Peltzman, S. (1976). "Toward a More General Theory of Regulation," *The Journal of Law and Economics*, Vol. 5, pp. 335-358.

[157] Cioffi, E.C. (2004). "A Friend of the Court," *Risk Management*, Vol. 51, Iss. 8, pp. 44; Mullins, B. (2006, February 16) "Politics & Economics: U.S. Lobbying Tab Hits A Record; Bush's Social Security Plan, Tort-Reform Issues Drive Washington Spending Spree," *The Wall Street Journal* (Eastern Edition), pg. A6.

[158] Murty, S. and Russell, R. R. (2005, February). "Externality Policy Reform: A General Equilibrium Analysis," *Journal of Public Economic Theory*, Vol. 7, Iss. 1, p. 117-150; Herve, M. (1990, December). "Uniform externalities: two axioms for fair allocation", *Journal of Public Economics*, Vol. 423, No. 3, pp. 305-327; Dybvig, P. H. and Spatt, C. S. (1983). "Adoption Exernalities as Public Goods," *Journal of Public Economics*, Vol. 20, Issue 2, pp. 231-347.

Individual companies and industries mobilize their combined efforts to minimize their cost burden for such externalities by pushing them on to other segments of the community.

The business case or the economic justification for corporate social responsibility (CSR) related principles or codes of conduct, is infinitely more complex compared to the conventional codes of conducts for business groups. In direct contrast to the conventional principles or codes, CSR-related codes of conduct call for the industry or group members to voluntarily assume some of the costs associated with the industry's negative externalities.

The past two decades have witnessed an enormous growth on the part of industry groups to create various types of statements of principles or codes of conduct that would establish the sponsoring organization's *bona fides* as a socially responsible organization. Available data, although not comprehensive, suggests that these codes have become *de rigueur* among corporations and industry groups all over the world.[159] Unfortunately, the widespread creation of such codes by corporations and industry groups has not gone beyond the rhetorical stage. Sponsoring organizations, in general, have failed to take adequate steps to implement their codes of conduct and to make more transparent their efforts toward compliance and improved performance. Nor do business organizations as yet view them as a means of building public trust. The inevitable result of this state of affairs has been that these principles or codes of conduct are treated with disdain and largely dismissed by knowledgeable and influential opinion leaders among various stakeholder groups, the news media and even the public-at-large. Instead of gaining public trust and credibility for their efforts, the sponsoring organizations suffer from the backfire effect of poor public relations and potential damage to their institutional reputation.[160]

CSR-related codes of conduct or voluntary ethical principles have become a staple of large industry groups, large corporations, and especially multinational corporations.[161] Generally categorized under the rubric of principles or codes of

[159] Sethi, S. P. and Emelianova, O. (2006, June). "A Failed Strategy of Using Voluntary Codes of Conduct by the Global Mining Industry," accepted for publication: *Corporate Governance: the International Journal of Business and Society*, Vol. 6, Iss. 3; Melrose, R. (2004, March 22). "Big Business is Usually Seen as Being Interested Only in Making Money. But More and More Companies are Realizing that it Pays to put Something Back into the Community," *The Guardian* (London), p.2; Kolk, A. (2003). "Trends in Sustainability Reporting by the Fortune Global 250," *Business Strategy and the Environment*, Vol. 12, Iss. 5, pp. 279-291.

[160] Sethi, S. P. (2003). "Globalization and the Good Corporation: A Need for Proactive Co-existence," *Journal of Business Ethics*, Vol. 43, Nos. 1-2, pp. 21-31; Sethi, S. P. (2003). "*Setting Global Standards: Guidelines for Creating Codes of Conduct in Multinational Corporations*," (New York: John Wiley & Sons, Inc.); Sethi, S. P. (2002). "Corporate Codes of Conduct and the Success of Globalization," *Ethics & International Affairs*, Vol. 16, No. 1, pp. 89-106; Laufer, W. S., op. cit., supra note 85; *Tapper*, R. (1997). "Voluntary Agreements for Environmental Performance Improvement: Perspectives on the Chemical Industry's Responsible Care Programme," *Business Strategy and the Environment*, Vol. 6, Iss. 1, pp. 287-292*;* Jenkins, R. (2004). "Globalization, Production, Employment and Poverty: Debates and Evidence*,*" *Journal of International Development*, Vol. 16, pp. 1-12.

[161] Sethi, S. P. (2005), op. cit., supra note 155; Kolk, A. and van Tulder, R. (2005). "Setting New Global Rules? TNCs and codes of conduct," *Transnational Corporations* (United Nations Conference on Trade and Development, Geneva, Switzerland), vol. 14, No. 3, pp. 1-28; Herrmann, K. K. (2004, Summer). "Corporate

corporate social responsibility (CSR), they are established by industry or group-based organizations that protect and advance the groups' shared interests. They allow an industry the flexibility to create responses that are cost-effective, maintain member companies' discretion to conduct their business without outside intervention and oversight, and project the industry's performance in the most positive manner. Another sub-set of this category includes codes whose primary focus is to burnish the industry's image as a socially responsible and member companies as good corporate citizens.

Structural Problems Associated with Industry-Based Voluntary Codes of Conduct

In the final analysis, a code of conduct is only as good as the results it produces. The code planners must also create a process that would ensure proper implementation, internal monitoring and control, and accountability for achieving pre-established performance standards. Otherwise, the code would produce the opposite of its intended purpose. It would also create unintended consequences, which would worsen the situation. One of the most difficult, and potentially costly, situations from society's perspective is to allow those who benefit from a weak or ineffective code to take control of the process of code creation and implementation.

There are certain fundamental differences between the conventional form of industry-based organizations and their principles or codes of conduct, and the CSR related principles or codes of conduct. These distinctions have the potential to limit the scope of cooperation among companies and exacerbate the problems associated with industry-based groups. In the case of conventional industry-wide codes, industry members feel that, to be successful, an industry-wide or group-based code must include the largest possible number of companies in the collective effort. The consensus approach is intended to create solutions that are amenable to most members and thus facilitate industry-wide effort in bringing about desired changes.

Overcoming the Problems of Adverse Selection, Free Rider and Diminution of Best Business Practices

CSR-related industry codes of conduct must contend with the vexatious problems of free rider, adverse selection and a diminution of best business practices. Adverse selection occurs when the companies with poor performance records join the industry-group thereby tainting the industry's reputation and public distrust of the industry's code of conduct. It also discourages high performing companies from joining the group for fear of adversely impacting their current reputation.

The industry's desire to enroll the largest number of companies in the code effort gives rise to the free rider problem because of the reluctance of the poor performing companies to improve their performance. There is no need to do so, because they enjoy higher reputation by riding on the coat-trails of high performing companies. Similarly, a desire to include the largest possible number of company in the industry-

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social responsibility and sustainable development: the European Union initiative as a case study", *Indiana Journal of Global Legal Studies*, Vol. 11, No. 2, pp. 204-216.

wide code gives the recalcitrant and poor performing companies an effective veto toward any changes in best business practices, which may add to their operational costs. The net result is that poor performing companies drag down the so-called best business practices to the lowest common denominator. The free rider situation discourages high performance companies from going beyond the minimum level of performance standard.

Adverse selection results in discouraging good companies from joining the group and thereby undermine the industry-based code's potential effectiveness in creating improved industry conduct that would narrow the gap between societal expectations and industry performance.

Private Law Character of CSR-Related Voluntary Codes of Conduct

The nature of "voluntariness," and by implication, the flexibility afforded to companies, depends on the basic premise that the sponsoring organizations and their critics share a common interest in improving the underlying conditions of the affected groups and that it is in the interest of all parties to resolve these issues within the realistic constraints of available financial resources, competitive market conditions, and the adverse societal impact of current business practices.[162] This is a proactive stance and perhaps the best practice in the best of all possible worlds. It provides scope for experimentation and building consensus, and where necessary and desirable, facilitates the enactment of public law.

Another potentially volatile, highly unpredictable, and often miscalculated, factor has to do with the nature of adverse public reaction and regulatory response if the industry's code fails to meet societal expectations of the industry's reform efforts. Their participation would also result in undermining the credibility and reputation of the companies that have better track records and stronger commitment to compliance with the code of conduct.

It may seem counter-intuitive, but this approach yields exactly the opposite result from the one publicly claimed by the codes' sponsors when it is examined in the context of CSR-related codes of conduct. Industry-wide CSR-related codes that depend on voluntary compliance and rarely incorporate enforcement measures are most vulnerable to the problems of free rider and adverse selection. The need to keep the largest number of companies in the group pushes performance standards to the lowest common denominator. Companies with the weakest records can force standards down to what they are willing to live with. This situation suits the poorly performing and recalcitrant companies, i.e., adverse selection, which stand to gain from enhanced public approval – at no or little cost to themselves – as a result of the time and resources expended by the best-performing companies. At the same time, the best-performing companies suffer from the taint caused by the actions of recalcitrant companies.

[162] Sethi, S. P. (2003). "*Setting Global Standards: Guidelines for Creating Codes of Conduct in Multinational Corporations*," (New York: John Wiley and Sons, Inc.); Melrose, R., op. cit., supra note 159.

This situation is further exacerbated under conditions where the most recalcitrant members are also industry leaders. The fact that a voluntary code lacks any independent external monitoring and compliance verification also contributes to this tendency because the industry members can conceal their motives against making any changes in their business practices from public and regulatory scrutiny. The combined effect of the three structural flaws, i.e., the free rider problem, adverse selection, and inherent disincentives in improving the current business practices in the operations of the voluntary industry codes, are further exacerbated when the control of the code of governance structure is held exclusively or primarily by the industry members, and where there is no system of independent outside monitoring and compliance verification. Such a code, when stripped of its self-serving verbiage, is reduced to a hapless piece of public relations exercise, which no one takes seriously either inside the industry or outside among the industry's critics.

Creating Internal Cohesiveness and a Commonly Shared Vision

Industry-wide voluntary codes of conduct that deal with societal concerns also face major challenges in transforming this need "to do something" into active strategies. Their difficulties, including those described below, arise from conflicts among member companies within the industry and a lack of trust by external constituencies in the industry's external socio-political environment.

a) Many companies are philosophically opposed to creating voluntary codes which they view as giving-in to the industry's critics.

b) There is the inherent difficulty of finding common ground among member companies that otherwise compete vigorously against each other.

c) Another set of difficulties emanates from individual companies' operational constraints, financial concerns, and above all, corporate culture and management orientation toward responding to social and environmental challenges.[163]

d) The long-term benefits of industry-wide cooperative effort, nevertheless, carry short-term costs, which must be compensated through improved productivity. This takes time and requires structural and organizational changes that are not always easy to accomplish.

A more serious, albeit negative, outcome of this approach lies in its lack of credibility with the industry's external stakeholders. Most current industry-based codes, which fall in the category of "principles," suffer from a low level of community trust. Most industry groups offering codes make similar claims regarding their effectiveness and yet are unable and unwilling to satisfy industry critics with credible performance measures.

[163] Sethi, S. P. (2005), op. cit., supra note 155; Sethi, S. P. (1994). "*Multinational Corporations and the Impact of Public Advocacy on Corporate Strategy: Nestle and the Infant Formula Controversy,*" (Kluwer Academic Publishers, Boston, MA); Herrmann, K.K., op. cit., supra note 161.

This phenomenon is generally described in the economic literature as a problem of asymmetric information and is best illustrated by the example of selling used cars, as discussed by the Nobel laureate economist George Akerlof.[164] Just as in the case of used cars (pejoratively called "lemons"), industry-groups find it difficult to persuade their external stakeholders that they are telling the truth about their code elements and performance standards. As in the case of used cars, each seller knows the quality of his or her offerings. Since the products are not similar, the customer must have sufficient and believable information about the claims made by each seller. Each seller immediately matches the claims of every other seller, while these sellers however, are unwilling or unable to provide verifiable or trustworthy information. Since the buyer has no means to compare the truthfulness of competing claims, he/she treats each seller's information as equally false and thereby debases the quality claims of all sellers.

The situation discourages the companies willing to offer greater compliance toward a code's broader principles because they cannot improve their credibility with the public. At the same time, the enhanced effect on their reputation arising from the efforts of the forward-looking companies is shared equally by the recalcitrant companies in the group who benefit at the former's expense. Conversely, any public reprobation of the recalcitrant companies taints the reputation of the forward-looking companies because they belong to the same group.

Positive Aspects of Industry-wide Voluntary Codes of Conduct Dealing with Societal Issues

Industry-based CSR codes of conduct, nevertheless, can serve an important business and social purpose. From the business viewpoint, these codes provide industry members with the opportunity to develop solutions that are focused, economically feasible, and cognizant of the industry's special needs. They engender public trust through "reputation effect" and avoid being tainted by the actions of other companies.[165] From the public's perspective, voluntary codes also serve an important purpose. They obviate the need for further governmental regulation. They also allow the moderate elements among the affected groups to seek reasonable solutions to the issues involved.[166]

Unfortunately, most industry groups, advancing CSR-related codes, have not gone beyond the rhetoric stage with the result that well-informed segments of population and industry critics treats business assertions with disbelief. The success of this system depends largely on the industry's ability to create and sustain a high level of public credibility. Public trust, under these circumstances, is highly fragile and transitory.

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[164] Akerlof, G. A. (1970). "The Market for 'Lemons': Quality Uncertainty and the Market Mechanism," *Quarterly Journal of Economics*, Vol. 84, pp. 488-500; Johnson, J. P. and Waldman, M. (2003, Summer). "Leasing, lemons, and buybacks", *The Rand Journal of Economics*, Vol. 34, No. 2, pp. 247-263; Kim, J.-C. (1985). "The Market for 'Lemons' Reconsidered: A Model of the Used Car Market with Asymmetric Information," *The American Economic Review*, Vol. 75, No. 4, pp. 836-843.

[165] Sethi, S. P. (2002)., op. cit., supra note 160; Kapstein, E. B. (2001). "The Corporate Ethics Crusade," *Foreign Affairs*, Vol. 80, Iss. 5, pp. 105-120.

[166] O'Rourke, D. (2003). "Outsourcing Regulation: Analyzing Nongovernmental Systems of Labor Standards and Monitoring," *Policy Studies Journal*, Vol. 31 Issue 1, pp. 1-30; Paton, B. (2000). "Voluntary Environmental Initiatives and Sustainable Industry," *Business Strategy and the Environment*, Vol. 9, Iss. 5, pp. 328-338.

It must be continuously and consistently nurtured to build a reservoir of goodwill. This would be a kind of invested social capital, which yields a regular flow of social dividends in the form of public trust.

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