Testimony

United States Senate Committee on the Judiciary

Hospital Group Purchasing: How to Maintain Innovation and Cost Savings September 14, 2004

Mr. David Balto

Esquire, Robins, Kaplan, Miller & Ciresi LLP

Testimony of David A. Balto before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Business Rights and Competition September 14, 2004

Chairman DeWine, Ranking Member Kohl and other distinguished members of the Subcommittee, thank you for this opportunity to appear before you today regarding a matter of great importance concerning the cost and quality of health care in America. The issue of how Group Purchasing Organizations, or "GPOs," negotiate contracts with vendors of medical supplies and devices on behalf of its members deserves the close and careful scrutiny which this Subcommittee, the General Accounting Office, the Federal Trade Commission and the Department of Justice have devoted to the matter over the past two years.

I have practiced antitrust law for over 20 years both in the government and in private practice. Prior to entering private practice, I was the Assistant Director of the Office of Policy and Evaluation for the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky. In these positions, I was a senior advisor in the FTC's merger and non-merger enforcement program. I was involved in the drafting and issuance of the FTC and DOJ Statements of Antitrust Enforcement Policy in Healthcare. I also assisted in the litigation of numerous monopolization cases as well as challenges to anticompetitive and exclusionary conduct by several health care companies.

My purpose before you today is to address three issues which have clearly arisen out of the extensive review of GPOs by this Subcommittee, the GAO, the FTC and the Department of Justice. First, is there a need for regulation of GPOs? Second, is self-regulation of the market sufficient to cure the problems identified by your prior hearings? Third, would the proposed legislation before us today be a sound approach to the problem?

Before I discuss each issue in more detail, allow me to offer a summary conclusion: There have been significant competitive problems in the GPO market. While I applaud this Subcommittee's success in working with GPOs to create and implement codes of conduct which attempt to address these anticompetitive concerns, these codes of conduct are inadequate for three main reasons: (1) they are not consistent industry wide and they are ambiguous; (2) there are no enforcement mechanisms for noncompliance; and, (3) there is no enforcement entity. Thus, enacting legislation to give the Department of Health and Human Services the power to regulate GPOs is appropriate.

Competitive Concerns

The past hearings on this issue document that competitive problems have existed and still exist with regard to GPO practices. The original purpose for GPOs was to allow them to act as collective bargaining purchasing agents on behalf of member hospitals. By pooling their purchases, member hospitals would be able to negotiate lower prices from medical supply and device vendors. This Subcommittee's prior hearings into the activities of GPOs raise serious questions as to whether GPOs continue to truly operate in this fashion, or whether they have used the safe harbor provisions of the anti-kickback statute to evolve into far more powerful entities with monopoly and monopsony powers which reduce competition, create barriers to market entry, and impede the functioning of a free market.

As the Subcommittee is aware there are a variety of contracting practices that have raised competitive concerns, including sole source contracting, bundling, market share discounts, and tying. As the GAO reports suggest GPOs have evolved from neutral buying units to "gateways" which permit manufacturers to enter into arrangements that may raise entry barriers, ultimately leading to higher prices and less innovation. The relationships between medical device manufacturers and GPOs have also created incentives for the manufacturers to share profits with a GPO. As a GAO report noted GPOs acknowledged that "a manufacturer dominant in a product line may contract with a GPO, or agree to a favorable contract, to preserve its market share and exclude competition."

Sole-source contracts, exclusive -dealing relationships and bundling or rebate programs are not necessary for hospitals to obtain costs savings and can cause market inefficiencies. In fact, the GAO found in its 2002 pilot study that in a number of instances "GPOs' prices were not always lower and were often higher than prices paid by hospitals negotiating with vendors directly." The GAO's follow-up report in 2003 concluded that "when used by GPOs with a large market share, these contracting strategies have the potential to reduce competition [and] discourage other manufacturers from entering the market."

Anti-Kickback Statute

Various aspects of GPOs' operations are regulated by federal statute and regulations. While anti-kickback provisions do exist under the Social Security Act, the Act also contains an exception for amounts paid by vendors of goods or services to a GPO. 42 U.S.C. Section 1320a-7b(b) states in part that provisions regarding illegal remunerations shall not apply to: "any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if," there is a written contract with the GPO disclosing the amount to be paid, and the GPO discloses in writing to the member hospital, medical facility or agency at least annually the amount received from each vendor supplier with respect to purchases made by or on behalf of the member.

This statutory language is the result of Section 14 of Public Law 100-93, which

required the promulgation of regulations specifying the types of practices which would not be subject to criminal prosecution under Section 1128B of the Social Security Act and which would not serve as the basis for an exclusion under Section 1128(b)(7) of the Act. In implementing this legislation, Congress acknowledged that the anti-kickback statutory language was broad, had created uncertainty among health care providers, and needed to remain relevant in light of changes in the health care industry. The purpose in directing the Secretary of the Department of Health and Human Services was the recognition that such regulations were necessary to limit confusion among health care providers as to which commercial arrangements were legitimate and which were proscribed.

As a result, in 1991 the Department of Health and Human Services established a series of regulations setting forth various proposed business and payment practices, or "safe harbors" that would not be treated as criminal offenses under the Act.

FTC/DOJ Guidelines

Shortly thereafter, in 1993, the Department of Justice and FTC issued their joint Statements of Antitrust Enforcement Policy in Health Care. These policy statements were designed to advise the health care community in a time of tremendous change and attempted to address any uncertainty concerning the Agencies' enforcement policy. These statements were revised and expanded in 1994 and 1996.

Statement 7 sets forth 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." It sets forth the following specific guidelines:

Joint purchasing arrangements are unlikely to raise antitrust concerns unless (1) 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 (2) 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.

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."

Statement 7 was focused on the simple question of when a GPO may be too large or posed the threat of exercising monopsony power or facilitating collusion. It did not address the issues of exclusion that are the center of today's competitive concerns. As one of the collaborators in drafting these statements, we did not foresee the potential for GPOs to act to diminish competition and innovation in medical device market.

I am aware that certain members of this Subcommittee requested that the DOJ and the FTC revise Statement 7. In their joint healthcare report of July 2004, the FTC and DOJ declined to do so. While I agree with their comment that "no statement is likely to cover every issue that could arise," I disagree with their assertion that amending the statement "to address some issues but not all potential issues, is likely to be counterproductive." Even some additional guidance would be helpful. There are numerous examples of where the Agencies have provided specific guidance on marketing and contracting practices through Guidelines in the past.

It would appear that since the FTC and DOJ are not currently prepared to revise any guidelines, or that since the Secretary of HHS has not indicated any intention to formally re-evaluate the anti-kickback regulations, that it is time for Congress to step in and give these Agencies some direction. Not only should Statement 7 be revised to address many of the concerns raised by this Subcommittee, but legislation should be enacted to further regulate GPOs.

Evolution and Growth of GPOs

Allow me to briefly address the growth of GPOs and the current debate over their proper role in the medical supply/purchasing market sector. It is clear that the hospital and health care supply industries are greatly different today than they were when the safe harbor provisions were created in 1986. There have been significant changes. GPOs are no longer regional entities or small buying groups. In the 1990s, there was tremendous consolidation which created the large groups that dominate the hospital supply buying market today. I believe that GPOs have become much larger and more powerful than the industry, and Congress, contemplated when the exceptions to the anti-kickback laws were implemented.

As recent GAO reports and the July 2004 DOJ/FTC report indicate, this growth has been tremendous. As the GAO previously testified just seven of these GPOs collectively accounted for more than 85 percent of all hospital purchases nationwide mad through GPO contracts. More importantly, the two largest GPOs account for approximately 66 percent of total GPO purchasing.

This growth and the increasing allegations of abuses rightfully lead this Subcommittee to initiate this ongoing investigation. GPOs have evolved from their intended purpose of acting as a collective bargaining agent on behalf of hospitals in order to lower prices and reduce costs into an unhealthy hybrid which increasingly answers to the suppliers of medical supplies and devices which pay the administrative fees rather than their member hospitals. If left unchecked and unregulated, competition will continue to be harmed to the detriment of the cost and quality of patient health and medical innovation.

The Subcommittee's previous hearings on this topic have provided evidence of abuses which were never intended or contemplated at the time the anti-kickback exceptions were implemented. Testimony has been presented regarding clear conflicts of interest by employees of GPOs, the bundling of products and high contract commitment levels mandated in order to obtain discounts and higher administrative fees, the issuance of sole-source contracts which reduce choice,

restrict entry into the market and inhibit innovation, and the payment of administrative fees by in order to capture market share and dissuade the GPOs from doing business with competitors. There are serious questions raised about the extent to which GPOs act as the agents of their hospital members or as the agents of the sellers that pay the GPOs' administrative fees.

Self-Regulation Is Not Working

While it is laudable that the GPOs have created and implemented voluntary codes of conduct which attempt to address these anticompetitive concerns, these codes are inadequate. While the Health Industry Group Purchasing Association ("HIGPA") and some GPOs have adopted codes of conduct for GPO business practices, as the GAO has reported, the codes established by the individual GPOs are not uniform and they include diverse qualifying language and exceptions. There are no requirements for external accountability, and none of the codes of conduct I reviewed contained any enforcement mechanisms or dispute resolution procedures. Moreover, while this Subcommittee probably expected these codes to "evolve" and become more expansive they have not changed since the last hearing of this Subcommittee.

Let me provide several examples. Among the top four GPOs, their policies on sole-source contracting are inconsistent – with one making no statement at all on this topic, and another making only the generic statement that all contracts "should" be multi-source. No code of conduct entirely precludes sole source contracts. In spite of promises on sole source contracts, the GAO has found that for Premier and Novation, "the shares of dollar purchasing volume accounted for by sole-source contracts were 19 percent and 42 percent."

Many GPOs have also created de facto exclusive -dealing relationships with medical manufacturers via long-term contracts, commitment level requirements and rebate programs based on the volume purchased made from a manufacturer. The codes of conduct do not prevent such activity which can have the same effect as the restrictions of a sole-source contract. Another manner in which GPOs restrict competition comes in the form of bundling of products which also can be anticompetitive. As the GAO reported, "All but one of the GPOs in our study reported using some form of bundling, including the bundling of complementary products, bundling several unrelated products from one manufacturer, and bundling several products for which there are commitment-level requirements."

Self-regulation may work in several environments. However, there are several critical elements which must be present for self-regulation to work. First, there must be clear and unambiguous rules. Second, there must be an enforcement entity. Third, the entity must be able to impose significant penalties. Finally, there must be a system of due process with transparent decisions. Although the GPOs efforts to self regulate may be laudable, they are clearly insufficient to cure the competitive problems in the market. Their efforts at self-regulation lack each of these critical elements. Simply put, these voluntary codes of conduct have no teeth.

The anti-kickback exceptions and safe harbor provisions, as implemented, have failed to provide for any oversight or enforceable compliance measures. Now, efforts

at self-regulation have also failed to provide for these measures. Current news reports regarding a broad criminal investigation into the medical supply industry and its apparent relationship with various GPOs only heighten the need for this Subcommittee to seriously consider legislation to address this problem.

Finally, I want to raise a concern of whether private self-regulation is appropriate for the types of problems faced in this industry. Self-regulation may be appropriate where what is being regulated is not an important dimension of competition between competitors. For example, self-regulation of deceptive conduct raises few competitive concerns. But what is being regulated by the GPOs is contractual arrangements that are critical to competition. he antitrust laws are replete with cases where firms have agreed to diminish competition, collude or raise entry barriers under the guise of "self-regulation." As former Assistant Attorney General of the Antitrust Division Donald Baker once observed "self-regulators often combine – and sometimes confuse – self-regulation with self-service." Private self-regulation in this market may be readily captured by industry pressure and give inadequate attention to the interests of smaller firms, new entrants, or the needs of the public. Moreover, because the number of competitors are small there is the threat that collective self-regulation could lead to collusion. Simply, one cannot expect this market to police itself.

Selective Enforcement Will Not Work

It has been suggested that individual private litigation or government enforcement action challenging anticompetitive conduct on a case-by-case basis is the solution. I disagree. The problems with GPOs are too widespread.

It appears that private litigation is proliferating with regard to the conduct of GPOs. Applied Medical Resources Corporation, a manufacturer of medical devices used in minimally invasive surgery, in 2003 sued Johnson & Johnson and Novation for allegedly employing anticompetitive business practices. The lawsuit alleges that Johnson & Johnson harmed Applied's sales of two medical products through exclusionary practices "designed to obtain and maintain (J&J's) monopoly power" in the market.

In addition, ConMed Corporation has also sued Johnson & Johnson alleging that it engaged in anticompetitive conduct with respect to sales of products used in endoscopic surgery, resulting in higher prices to consumers and the exclusion of competition. The lawsuit alleges that ConMed's ability to sell its surgical products has been stifled by J&J's practices, which include entering into exclusive contracts with hospitals, tying and bundling the price of products to a hospital's agreement to buy a very high percentage of their specific J&J products, and imposing financial penalties on hospitals if they purchased competitive products such as those provided by ConMed. Rochester Medical Corporation, in March of this year, also filed suit against a number of medical device companies and GPOs charging the companies with anticompetitive practices to keep it out of the urological products and hospital markets.

I would also note the recent case of Kinetic Concepts, Inc., et al. v. Hillenbrand Industries, Inc. While this antitrust case did not directly involve a GPO, it certainly

serves as another example of the impact various exclusionary practices can have in the medical supply market. Kinetic Concepts, Inc. ("KCI") sued Hillenbrand Industries and several of its subsidiaries for antitrust violations involving the manufacture and rental of specialty hospital beds and surfaces designed for patients suffering from burns, spinal injuries, pneumonia and other medical conditions. KCI alleged that Hillenbrand was bundling its specialty beds with its standard hospital beds, conditioning additional discounts on the standard beds to exclusive dealing commitments on rental of its specialty beds. Much of the evidence revolved around GPOs, their contracting policies, their relationships with hospitals, and the harm to competition. Ultimately, the jury returned a verdict in favor of the plaintiff in the amount of over \$170 million.

Private litigation, however, is not the answer for the competitive problems in this market because it is too time-consuming and too cost-prohibitive. In addition, any individual antitrust case only serves only to address the conduct of specific companies with regard to market practices for a specific product which have adversely affected a specific plaintiff. Such litigation does not, and cannot, address problems on an industry-wide basis as could legislation and regulation.

Antitrust challenges and/or enforcement actions by either the FTC or DOJ might rein in certain egregious behavior. However, the antitrust Agencies have taken no enforcement actions in this area in spite of these complaints. The failure of these Agencies to take enforcement action or revise Statement 7 and the failure of the Department of Health and Human Services to regularly review and revise its safe harbor regulations have set an extremely lax standard. In any event, agency enforcement actions are not the answer as such individual actions, just as with private litigation, will not lead to industry-wide changes.

As this Subcommittee knows, the Justice Department has initiated a broad criminal investigation of the medical-supply industry, apparently to determine whether hospitals and other medical care providers are fraudulently overcharging Medicare and other federal and state health programs. Based on the federal codes cited in the subpoenas, it appears that investigators are seeking evidence of health care fraud, conspiracy to defraud the United States, theft or bribery involving programs receiving federal funds, obstruction of investigations, and other possible violations. Given the very early stages of this investigation, we do not know whether any antitrust or consumer protection issues will arise. Nevertheless, this new criminal investigation, along with this Subcommittee's investigation, provides a clear indication that the GPO industry is in need of some form of oversight and regulation. GPOs and their hospital members should welcome this ove rsight and the accompanying regulations as a means to clarify what could be considered as anticompetitive behavior.

Effective Oversight and Enforcement is Necessary

In 1986, when the safe harbor provisions were created the healthcare supply industry was much different from what it is today. Today, GPOs need some form of oversight and regulation for anticompetitive concerns; and, consumers as well as medical device and supply manufacturers need a forum in which their interests can

be represented. While the FTC has recognized that self-regulation can serve an important role, the current voluntary GPOs' codes of conduct are not sufficient.

As I have stressed today, it is regulatory oversight and ability to undertake enforcement action which is missing from the GPOs' current self-regulatory efforts via their codes of conduct. Self-regulation can be successful when there are consistent and uniform standards industry-wide; when there is an enforcement mechanism in place; and, when the relevant federal agency and, if necessary, the courts have a role in any necessary enforcement. Let me provide several examples:

The National Association of Securities Dealers ("NASD") registers member firms, writes rules to govern their behavior, examines them for compliance and disciplines those that fail to comply. It has uniform policy guidelines and rules established for its members and takes disciplinary actions against firms and individuals for violations of those rules and federal securities laws and regulations. It has also established the National Adjudicatory Council ("NAC"), a national Subcommittee that reviews initial decisions rendered in NASD disciplinary proceedings. NAC decisions may be appealed to the Security and Exchange Commission which may affirm, modify, or set aside any of the findings made by the NAC, or remand the matter for further proceedings; and may also affirm, reduce, or set aside the sanctions imposed by the NAC. In addition to the SEC's role, a matter may be further appealed to a U.S. Court of Appeals for review.

Similarly, the advertising industry has an effective self-regulatory program which, when necessary, refers matters to the FTC for investigation and possible enforcement action. The National Advertising Review Council ("NARC") was established to provide guidance and set standards of truth and accuracy for national advertisers. NARC sets the policies for the National Advertising Division ("NAD") which investigates complaints against advertisers brought by consumers and other advertisers. The review process by NAD is known to be quick, fair, and a less-costly form of dispute resolution. Compliance with NAD is voluntary, however, an advertiser who disagrees with a NAD recommendation may appeal it to the National Advertising Review Board ("NARB"). NARB is the second part of the advertising industry's self-regulatory process. When an advertiser or challenger disagrees with a NAD finding, the decision can be appealed to NARB for additional review. When an advertiser refuses to comply by a NAD decision, the matter can be referred to the FTC for further investigation and action.

These self-regulatory methods are effective not simply because they have uniform standards and enforcement mechanisms, but also because both the consumers and industry may participate and because the enforcement process is transparent (i.e., decisions and reports are made public). Such provisions are necessary in order to enhance the credibility of any self-regulatory program. None of this is present in the GPOs' efforts at self-regulation. Instead, they appear to have undertaken a haphazard and inadequate effort in a mad dash to avoid further scrutiny by this Subcommittee and the possibility of the implementation of additional regulations.

Additional Regulations are Necessary for GPOs in Order to Ensure Competition

The current situation is not what Congress envisioned or intended when it implemented safe harbors in Medicare's anti-kickback provisions for GPOs. Something is amiss in the hospital, GPO, medical device and supply market. The relationships and markets have evolved beyond the original purpose of allowing hospitals to form GPOs to aggregate their purchasing power to benefit consumers through lower prices.

The legislative history for Public Law 100-93 indicates that the House Committee on Ways and Means foresaw the need for periodic review and public input to ensure that the anti-kickback regulations remained relevant in light of industry changes. House Report 100-85 states: "Accordingly, the Subcommittee expects that the Secretary will formally re-evaluate the anti-kickback regulations on a periodic basis and, in so doing, will solicit public comment at the outset of the review process." Therefore, I would submit that the Department of Health and Human Services has the ability to effectively modify existing regulations, and to adopt and enforce new regulations. In any event, if legislation is necessary Congress clearly has the authority to move beyond self-regulation and require the federal government to implement and enforce regulations upon an industry.

There are several examples where Congress has decided to regulate after self-regulation has failed. Here are two examples:

The history of telemarketing gives an excellent example of how self-regulation failed to protect consumers and how Congress moved to implement and enforce regulations. In 1991, Congress passed the Telephone Consumer Protection Act requiring the Federal Communications Commission ("FCC") to prescribe regulations to implement methods and procedures for protecting the privacy rights of consumers. While setting forth specific offensive and prohibited practices, the legislation only stated that the FCC "may" require the establishment of a single national "do-not-call" database. The FCC decided against the idea of such a database, preferring company-specific do-not-call lists which required consumers to inform companies to put them on a do-not-call list.

In response to continued abuses and telemarketing fraud, Congress in 1994 enacted the Telemarketing and Consumer Fraud Abuse Prevention Act which empowered the FTC to issue the Telemarketing Sales Rule prohibiting deceptive and abusive acts or practices. The Act also authorized State attorneys general and private persons to bring civil actions in federal district court to enforce compliance with the FTC Rule.

There were significant efforts at self-regulation. Throughout the 1990s, the Direct Marketing Association ("DMA") advocated self-regulation. But, not until 1998 did DMA establish mandatory compliance programs requiring its members, as a condition of membership, to provide their customers with notice and the right to opt-out. However, the DMA applied sanctions only against its members, and there remained telemarketers who took advantage of consumer confusion and committed fraud. Despite these self-regulatory efforts, telemarketing complaints continued to rise.

Therefore, in 2003, the FTC implemented a national do-not-call list, and Congress enacted the "Do-Not-Call Implementation Act" which allowed the FTC to collect fees to implement and enforce the provisions of the Telemarketing Sales Rule. To date, the regulations and do-not-call registry have withstood legal challenges brought by telemarketers.

Another instance where Congress has gone beyond self-regulation is in protecting the privacy of children. During the 1990s there were significant concerns raised about the protection of children's privacy on the Internet. Self-regulatory efforts did not diminish these concerns. In response in 1998, Congress enacted the Children's Online Privacy Protection Act ("COPPA") and the FTC implemented rules (the Children's Online Privacy Protection Rule) enforcing the Act. The Act was passed in response to a growing awareness of Internet marketing techniques that targeted children and collected their personal information from web sites without any parental notification.

COPPA and the FTC Rule provide that industry groups or others can create self-regulatory guidelines to govern participants' compliance with the FTC's Rule. These guidelines must include independent monitoring and disciplinary procedures and must be submitted to the FTC for approval. The FTC then publishes the guidelines and seeks public comment in considering whether to approve the guidelines. An operator's compliance with FTC-approved self-regulatory guidelines will generally serve as a safe harbor in any enforcement action for violations of the COPPA. To be entitled for a safe harbor treatment, the operator's guidelines must contain requirements that are substantially similar to COPPA, a mechanism for evaluation of the operators' compliance with the FTC Rule, and incentives for compliance.

I use these examples to highlight the fact that Congress has the authority to step in and regulate an industry when self-regulation is failing to protect the interests of consumers. I believe the proposed GPO legislation is a sound step in the right direction. The Inspector General's Office of HHS has a proven record of effectively enforcing the anti-kickback provisions of the Act. As for any regulations on the activities of GPOs, any new regulations should provide minimal standards to address the abuses and conflicts of interest which have been uncovered by this Subcommittee. I would suggest efforts towards additional regulations concentrate on more clearly defining abusive acts or practices, and the implementation of some form of clear and fair procedures to give parties affected by the regulations an opportunity bring complaints and/or defend against comp laints of anticompetitive behavior. And, the statute should be amended so that GPOs do not automatically enjoy the special status of a government safe harbor. The safe harbor should be earned and granted only after sufficient oversight and approval by the Department of Health and Human Services.

Conclusion

Let me close with an important thought. There may be entities, especially hospitals, that may fear that the enforcement of the safe harbor provisions will lead to higher prices. But my experience of over a decade as an antitrust enforcer involved in dozens of enforcement actions has shown that the elimination of impediments to

competition will bring the greatest long-term benefits. Ultimately, restricting these anticompetitive practices will lead to more competition, lower prices and greater innovation. Everyone will benefit.

The GPO industry's efforts at establishing voluntary codes of conduct fall far short of any effective self-regulatory program. The current system, including the voluntary codes of conduct, is insufficient to ensure that anticompetitive activity is prohibited and that consumers are protected. The time for effective self-regulation has passed and Congress should act to regulate anticompetitive activity to protect the consumers' right to a competitive marketplace.

Thank you for allowing me to testify before the Subcommittee today.

Appendix A -- Past Antitrust Cases Involving Anticompetitive Self-Regulation In Fashion Originators' Guild v. Federal Trade Commission, 312 U.S. 457 (1941), the Supreme Court struck down a self-regulatory scheme -- implemented by a group of high-priced dress designers designed to exclude those who would copy the dress designs of the high-price firms. The Defendant organized a boycott scheme whereby each "originator" agreed not to deal with the outlets to which the "pirates" sold their goods. The Supreme Court condemned the boycott observing that, "the combination is in reality an extra-governmental agency, which prescribes rules for the regulation and restraint of interstate commerce, and provides extra-judicial tribunals for determination and punishment of violations, and thus, 'trenches upon the power of the national legislature.'" (citation omitted).

In Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975), the Supreme Court struck down a local county bar associations rules prescribing the minimum prices that lawyers could charge for real estate services.

In National Society of Professional Engineers v. United States, 435 U.S. 679 (1979), the Supreme Court struck down an association's ethical rules that prevented the negotiation over fees for engineering service until after the engineer had been selected for the job. The defendants attempted to justify the restraint on the grounds that ruinous price competition would lead to unsafe structures. The Court rejected the defense explaining that "the [analysis of restraints under the Sherman Act] does not support a defense based on the assumption that competition itself is unreasonable."

In U.S. v. National Association of Broadcasters, 1982-83 Trade Cas. (CCH) 65,049 (D.D.C. 1982) (consent decree), the Department of Justice successfully challenged a self-regulatory scheme limiting the number of minutes of advertising that a TV broadcaster could run in any particular hour. The Department asserted that this arrangement was simply an output limitation that would be likely to result in higher prices for TV advertising.

Board of Regents of the Univ. of Okla. v. NCAA, 468 U.S. 85 (1984), involved the NCAA's efforts to maintain a "level playing field" among football-playing colleges by restricting the number of college football broadcasts to one a week. The rule prevented each individual member from going out and selling its own TV rights. The

Supreme Court found this an unreasonable restraint of trade, rejecting the defense that TV broadcasts would diminish attendance for less popular teams.

In FTC v. Indiana Federation of Dentists, 476 U.S. 447 (1986), the FTC challenged an effort by an association of dentists to prevent members from providing X-rays to insurance companies on the ground that it was inconsistent with professional standards. The Court found this self-regulatory effort interfered with the workings of a free market.