ANTITRUST SAFE HARBORS FOR RURAL HEALTH CARE PROVIDERS

AMENDMENT

- **This amendment would instruct the DOJ and FTC to clarify existing and subsequent antitrust safe harbors specifically for rural providers by providing more illustrative examples in their policy guidelines.**

- **The DOJ and FTC would also be instructed to work with HHS' Office of Rural Health to develop methods to disseminate this information to providers.**

CURRENT LAW

- Providers can seek guidance from the agencies for activities they fear could be challenged under federal antitrust laws.

- In September 1993, the DOJ and FTC jointly issued antitrust guidance to health care providers in the form of The Health Care Antitrust Enforcement Policy Statements.

- The statements cover six areas -- (1) hospital mergers, (2) hospital joint ventures involving high technology or other expensive medical equipment, (3) physician's provision of information to purchasers of health care services, (4) hospital participation in exchange of price and cost information, (5) joint purchasing arrangements among health care providers and (6) physician network joint ventures.

- The DOJ and FTC expect to release additional and revised statements within the next few months. Critics allege that the policy statements do not address many of the issues that will be increasingly common in a managed competition framework.

- The policy statements contain antitrust safety zones for each category. For example, agencies will not challenge joint ventures among hospitals to purchase, operate and market the services of high technology equipment if the venture includes only the number of hospitals necessary to support the equipment.

- The statements also summarize the rule of reason analyses the agencies will use to review activities that fall outside the safety zones.

- If these statements do not offer enough guidance, providers can request a **business review and advisory opinion** from the DOJ and FTC to review the antitrust implications of a proposed activity. The agencies have established an expedited review process; reviews are completed within 90 days if the arrangement falls within a safety zone and 120 days otherwise.

RATIONALE FOR AMENDMENT

- Despite the issuance of the DOJ's Health Care Antitrust Enforcement Policy Statements, rural providers still require additional guidance and clarification on antitrust matters.

- It also appears that many rural providers are unfamiliar with the DOJ's guidelines and business review and advisory opinion processes. Hospital associations have made some efforts to distribute guidelines to their members in the states. **But the guidelines still need to be more widely distributed to all types of rural providers. Rural providers should also aware of the DOJ's business review and advisory opinion process.**

- Although the DOJ is already planning to issue more illustrative guidelines for rural health providers. this amendment would be a positive symbol to rural providers.

TALKING POINTS

- Rural health care providers cite an increased need to collaborate with colleagues and other facilities to share sparse equipment and decrease the fragmentation of care. Rural providers in South Dakota discuss efforts to merge hospitals, clinics, and physician practices to form "integrated health delivery systems." Unfortunately, they believe many of these activities are stymied because providers worry that they will be deemed collusive.

- **The mere threat of lawsuits, especially among isolated rural providers who often do not have access to sophisticated legal advice, may be inhibiting provider collaboration.** The threat of lawsuits by competitors and DOJ and/or FTC, the potential for treble damages and criminal prosecution, and the expense associated with antitrust challenges may create a chilling effect on provider collaboration.

- The DOJ's safe harbor guidelines were an important first step in delineating safe harbors from antitrust prosecution. **However, additional clarifications from the DOJ and FTC are still needed.**

- Rural health providers would be more likely to pursue more collaborative ventures and establish networks with additional guidance from the DOJ and FTC.

- In addition, it also appears that many rural providers are unfamiliar with the DOJ's guidelines and business review and advisory opinion processes. This amendment would instruct the DOJ and FTC would also be instructed to work with HHS' Office of Rural Health to develop methods to disseminate the policy guidelines and information on DOJ's business review and advisory opinions procedures to rural providers.

- This amendment does NOT establish broad antitrust exemptions for rural providers. The amendment simply clarifies existing and subsequent guidelines for rural providers and ensures adequate dissemination of this information. This amendment responsibly addresses the concerns of rural health care providers.

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OBJECTIONS TO HATCH ANTITRUST AMENDMENT

1. An important goal of health care reform is to increase competition in the health care industry in order to lower costs. It is self-defeating to seek to increase competition and at the same time constrain appropriate antitrust enforcement that preserves and protects competition.

2. The fundamental problem with the amendment--widely opposed by consumer groups--is that it replaces targeted, measured, limited antitrust enforcement with regulation of virtually the entire health care industry by the DOJ. The antitrust laws encourage, not prohibit, procompetitive, efficiency-enhancing, cost-cutting mergers and joint ventures among health care providers.

3. The "safe harbors" that DOJ must issue under the amendment would exempt a wide range of conduct from the antitrust laws. Inflexible government regulation would be substituted for the antitrust laws.

4. The broad, regulatory certificate-of-review program that would be established by the amendment would involve initial government approval of applications for antitrust immunity and continuing government oversight of certificated activities. The scope of such a program makes it totally impractical, liable to error that could harm competition, and virtually certain to impose great regulatory costs on the industry and the government. If only a tiny fraction of health care providers (less than 1%) sought a certificate of review, the costs to the government could amount to several hundreds of millions of dollars.

5. The amendment's broad notification scheme would affect substantive antitrust rules and substantially diminish the practical ability of consumers, health plans, and other health care providers that may be harmed by antitrust violations to recover their losses. Anticompetitive conduct could be given legal protection that it does not deserve and appropriate antitrust deterrence of harmful behavior could be diminished.

6. The amendment's mandate of DOJ guidelines regarding collaborative activities in several areas is unnecessary and potentially harmful. The DOJ and FTC have already issued several health care antitrust enforcement policy statements and are in the process of improving these and issuing more. A statutory mandate to issue guidelines is therefore unnecessary.

OBJECTIONS TO HATCH ANTITRUST AMENDMENT (REVISED S. 1658)

THE PROPOSED ANTITRUST AMENDMENT, A REVISED VERSION OF S. 1658, SHOULD BE REJECTED. ANTITRUST EXEMPTIONS AND GOVERNMENT REGULATION OF COMPETITION IN HEALTH CARE MARKETS ARE UNNECESSARY AND WOULD HARM COMPETITION AND CONSUMERS.

1. The amendment would replace measured, limited antitrust enforcement with broad antitrust exemptions and extensive government regulation of the competitive aspects of the health care industry. Regulation of one-seventh of the economy in this way is unnecessary and potentially harmful, and would be extremely costly.

2. The amendment would defeat a principal goal of health care reform--bringing increased competition to bear in the health care industry--by constraining appropriate antitrust enforcement and deterrence that safeguard competition. For this reason, antitrust exemptions are widely opposed by consumer groups.

3. The "safe harbors" that would be issued by the Department of Justice under the amendment would exempt a wide range of conduct from the antitrust laws. This is essentially government regulation as a substitute for the antitrust laws. The Justice Department and the FTC have issued enforcement policy statements that contain "safety zones" to provide guidance to the health care community, but safe harbors that provided complete antitrust exemptions and that could only be corrected or refined through a formal administrative rulemaking are far more inflexible and regulatory.

The amendment's revisions to the original safe harbor provisions in S. 1658 do not resolve their fundamental problems:

- **The safe harbors will still effectively be antitrust exemptions, notwithstanding revisions that give the government the ability to seek injunctions against safe-harbored conduct in extraordinary circumstances.**

- **While the revisions eliminate statutory safe harbors, they preserve the basic safe harbor regulatory scheme by delegating the responsibility to issue such exemptions to the Justice Department. Regulation through generally applicable safe harbors presents many of the same problems as regulation through individual certificates of review.**

- **The amendment continues to mandate safe harbors in a wide variety of areas, some of which may not be amenable to safe harbor treatment at the current time. The Department of Justice and the FTC currently can decide on the basis of their experience and the evolution of health care markets whether or what types of safe harbors are safe to establish in their enforcement policy statements.**

4. The broad, regulatory certificate-of-review program that would be established by the amendment would involve initial government approval of applications for antitrust immunity and continuing government oversight of certificated activities. The scope of such a program makes it totally impractical, liable to error that could harm competition, and virtually certain to impose great regulatory costs on the industry and the government.

The amendment's revisions to the certificate-of-review program originally proposed in S. 1658 do not address its fundamental problems:

- **Permitting injunctive actions notwithstanding certification does not diminish the scope or basic nature of the certificate-of-review program. Certificate protection against antitrust damages would still be significant and result in a program with much the same risks and costs.**

- **Possible extension of the time for action on a proposed certificate and revisions regarding the details of judicial review do not eliminate the basic regulatory burden of the certificate-of-review program. The vast majority of the costs of the program would still be incurred. User fees would allocate these costs to the industry and in turn to consumers—they would not eliminate them.**

5. The amendment's broad notification scheme would affect substantive antitrust rules and substantially diminish the practical ability of consumers, health plans, and other health care providers that may be harmed by antitrust violations to recover their losses. Anticompetitive conduct could be given legal protection that it does not deserve and appropriate antitrust deterrence of harmful behavior could be diminished.

The amendment's revisions to the notification scheme originally proposed in S. 1658 do not eliminate its possible adverse effects:

- **Eliminating the provision that "deemed" notifications to have been filed on behalf of certain types of conduct even if they were not notified to the government addresses only one of the original scheme's most blatant flaws.**

- **Restricting the notification scheme to joint ventures and disqualifying patent antitrust violations such as price fixing does not assure that the amendment will not result in anticompetitive changes in substantive antitrust rules. Distinguishing legitimate, integrative joint ventures from simple collective decisions on price by independent competitors is an important issue that could be wrongly preempted by the amendment.**

6. The amendment's mandate of Justice Department guidelines regarding collaborative activities in several areas is unnecessary and potentially harmful. The Department and the FTC have already issued several health care antitrust enforcement policy statements and are in the process of improving these and issuing more. A statutory mandate to issue guidelines is therefore unnecessary. Moreover, such a mandate could be harmful if it forced the Department to issue guidelines covering matters with which it was not sufficiently familiar. Such guidelines could be overly cautious, thereby deterring cnduct that was not in fact anticompetitive, or even overly permissive, thereby causing competitive harm.

to be on either one of them. I must say, I have had the misfortune, if you will, of being on both of them.

It also demonstrated something else to me, and that is, we do not have a health committee, as such, in the U.S. Senate. So we are working at it from a variety of other sources which makes the job very, very difficult.

I want to thank my colleague from Montana for his commitment. We have been going to breakfast together on Thursdays for 4 straight years down the Hall. He has been part of the Republican health reform task force, medical malpractice reform program, and a variety of others. I am really very appreciative of his comments.

I am reminded also of what he said about the Mitchell bill; that it took those of us who think we know something about it 4 straight days to get through the first draft of that bill and found in our efforts to try to come up with amendments, it is almost impossible to amend.

So I appreciate very much his comments, and as one who sees a lot of Canadian license plates—Ontario, in particular—in parking lots and hospital parking lots in Grand Forks, ND, Duluth, MN—a whole variety of cities, I am sure glad he told us what happened during the Calgary stampede to the hospitals in Canada. That happens in Toronto and other areas as well. It is not just in Saskatchewan.

Mr. DASCHLE addressed the Chair.

The PRESIDING OFFICER. The Senator from South Dakota.

Mr. DASCHLE. Mr. President, I listened with great interest to our dear friend from Montana. I have a profound respect for him and admiration for his great sense of humor. But I must say, I must differ with him on a number of points. I have not seen license plates on either side of the border enough to count, but I know that there are plenty of U.S. license plates on the other side of the Canadian border because that is where they get primary care, good preventive care at times. I know there are those Canadians who tell us that it is cheaper for them to fly first class to the United States and use our high technology than it is for them to buy it.

So I know there are plenty of arguments on both sides. But I think the main point that I would make is the same point I made this morning, a point the majority leader has made so eloquently on so many occasions, most recently last Sunday. And that we talk about how concerned we are, or I should say some of our colleagues talk about the concern that they have with regard to Government health care. Yet I have not yet seen a bill or an amendment to abolish Medicare. I have not seen a bill or amendment to abolish the Federal Employees Health Benefits Plan. I have not seen a bill or amendment to abolish the Capitol physician, or our opportunity to use Walter Reed or Bethesda when we need health care.

The fact of the matter is every Member of Congress uses the health care that is so criticized on the other side of the aisle so frequently every time we get sick. The President uses it. Senators use it. Members of Congress use it. There are times, of course, when our families have to use the health care provided so well in the Federal Employees Health Benefits Plan.

We talk about how extraordinary a plan it is and how we really do want to give everybody else the same opportunity to have access to good quality care that we have through the Federal Employees Health Benefits Plan. That is a Government plan. I have not seen any effort to abolish the Veterans Administration or the defense hospital system that has done such a good job.

I think we need to be clear here. Every Member of Congress benefits substantially from a Government health program and has chosen not to offer any legislation that I am aware of to abolish it. So that is point No. 1.

Point No. 2 is that it is somewhat ironic, frankly, that we talk about a Government-controlled plan when Senator MITCHELL's bill does just the opposite in providing 30 million Americans who are now under Medicaid the opportunity to buy private insurance. So we shift away from Government insurance in that case to a private plan. We want to build as much as we can on the private system. Now, ought there be some regulation? I think every Member of the Senate would agree that as we regulate the air traffic control system, the banking system, our agricultural system, our highway system, there has to be some form of a regulatory framework within which the private sector works to assure us access and confidence and cost control and all of the things we say we want.

So I would hope that as we go through this debate, we can have an honest debate, recognize the differences that exist in philosophy and position. But I would hope that we also would acknowledge that there are Government systems that work pretty well or we would not avail ourselves of them so frequently, and that, indeed, while we understand how good Government systems can be, that is not the purpose of the Mitchell bill.

ANTITRUST AND THE HEALTH SECURITY ACT

Mr. HATCH. Mr. President, we have had a very informative exchange of information today, which has revealed a number of defects in both our current health care delivery system and in attempts by the majority to remedy those problems.

One area which our discussion has not touched upon in any great detail is antitrust.

I have been dismayed that, despite a clear need for antitrust reform, as evidenced by hearings in both the Judiciary and Finance Committees, neither the Mitchell, nor the Kennedy, nor the Moynihan bills contain any antitrust relief for the myriad of actors in the rapidly changing health care marketplace.

As my colleagues are aware, in an attempt to address the need for antitrust reform, last year Senator THURMOND and I introduced S. 1658, the Health Care Antitrust Improvements Act. Our colleague, Representative BILL ARCHER, introduced the companion House legislation, which served as a model for amendments adopted by the House Judiciary Committee.

Since Senator THURMOND and I introduced S. 1658, a number of provider groups have expressed concern about provisions in this legislation which they believe would afford greater protection to doctors than to other health care providers.

As we have made abundantly clear on a number of occasions, that was neither our intent nor, we believe, the effect of the legislation we drafted.

However, due to substantial and continuing apprehension about that provision, Senator THURMOND and I offered to make changes in the legislation to address those concerns.

I think it would be useful for my colleagues to be aware of those changes, and for the health care community to be aware that I continue to believe that antitrust relief is a necessary part of health care reform.

For those reasons, I am inserting in the RECORD at this point a summary of our revised legislation, which I commend to my colleagues for their serious consideration.

SUMMARY OF HATCH-THURMOND HEALTH CARE ANTITRUST IMPROVEMENTS LEGISLATION

Following is a summary of the Hatch-Thurmond Health Care Antitrust Improvements legislation, which has been revised to address concerns raised about the "Health Care Antitrust Improvements Act" as introduced last November by Senators Hatch and Thurmond (S. 1658), and by Representative Archer (H.R. 3486). The principal changes made are indicated in bullet points.

The Hatch-Thurmond legislation is intended to resolve some of the uncertainty that surrounds the application of the antitrust laws to health care activities. The purpose is to save money and improve quality in health care, not for the benefit of providers, but for the ultimate benefit of patients and those who pay the bills. Four methods of achieving greater clarity in the antitrust laws are employed:

1. SAFE HARBORS

To reduce the costs of antitrust regulation in the health care marketplace and decrease the burden of repetitive review under the certificate process, the Department of Justice is directed to develop "safe harbors." DOJ must solicit input on possible safe harbors through notice and comment procedures. The safe harbors will be defenses in all federal, state and private antitrust suits, except for injunctive relief by the DOJ or FTC in "extraordinary circumstances."

The safe harbors to be developed must cover at least the following areas:

A. Joint Purchasing of Health Care Services;

B. Small Hospital Mergers;

C. Network Formation and Operation;

D. Medical Self-Regulatory Entities;
E. Provision of Information by Providers;
F. Participation in Surveys;
G. High-Tech and Tertiary Joint Ventures;
H. Market Power Screens;
I. Joint Purchasing Arrangements; and
J. Good Faith Negotiations.

The major change is that the safe harbors are not created by statute. DOJ may add to safe harbors it establishes, and may modify or eliminate them. This allows flexibility in the safe harbors, while giving meaningful legal effect to the standards established by DOJ.

Activitiy within a safe harbor is subject to antitrust actions for injunctive relief by DOJ or FTC. This encourages providers to monitor their own conduct to ensure that it does not cause anticompetitive harm even if it is technically within a safe harbor. Additional categories for safe harbors have been added.

II. CERTIFICATES OF REVIEW

Health care providers who seek greater certainty under the antitrust laws may apply to DOJ for a certificate of review, which will be granted (if appropriate) based on a review of the facts of the case. DOJ must take into account health care concerns such as access to care in underserved areas, in addition to conducting a traditional antitrust competition analysis. Activity covered by a certificate later found to be anticompetitive is subject to injunctive relief.

Certificates of review are not automatically approved by the end of a 90 day period. Private, state and federal antitrust actions for injunctive relief are permitted to stop anticompetitive conduct covered by a certificate of review. Judicial review of DOJ decisions concerning certificates of review is limited to abuse of discretion and must be brought in the U.S. District Court for the District of Columbia. "User fees" of up to $6000 may be collected to cover costs, on a sliding scale based on size of transactions proposed.

III. NOTIFICATION

Health care providers which form joint ventures may file a notification of their activities with DOJ and in return will, if sued under the antitrust laws, receive Rule of Reason analysis (analyzing procompetitive and anticompetitive effects of conduct) and be subject to actual damages (rather than treble damages).

Notification is restricted to joint ventures, rather than any collaborative activity. Provisions "deeming" notification without written submission of required information have been eliminated. Excludes "naked" price-fixing, bid-rigging, and market allocation from notification provision, but permits showing that conduct has procompetitive aspects. Authorizes collection of user fees of up to $250 to cover costs.

IV. GUIDELINES

DOJ is directed to issue guidelines regarding legitimate collaborative activities of health care providers to further health care reform, including:

Product and geographic market definitions;

Special rules for underserved areas, such as rural or inner city markets;

Provider networks;

Community health centers;

The subject matter areas of the safe harbors listed above. Additional categories for guidelines have been added.

Mr. DASCHLE. Mr. President, my friend, the Senator from Minnesota, has kindly consented to allow us to complete our work on a couple of the housekeeping chores, and I will do that at this point.

Mr. DURENBERGER. Will my colleague yield to me just a minute?

Mr. DASCHLE. I would be happy to yield to the Senator from Minnesota.

Mr. DURENBERGER. Before we leave the subject of Government-run programs, I think it is fair to make a distinction between the Federal Employees Health Benefit Plan, which is merely an OBM or human resource run process by which each of us can buy a private health plan, and access to a private system. The only role the Government plays in there is the role of the employer, and they pay 72 percent of the premiums.

On the other hand, Medicare and Medicaid are Government-run systems, where the Government pays a specific fee for a service much like they do in Canada. And I think it is appropriate to at least make that distinction. Where, in the private health plan that President Clinton promised to all Americans, that could not be taken away from them, the Mitchell bill does not give the elderly or the disabled the opportunity to get the same kind of health care through the same system that we can.

Mr. DASCHLE. I appreciate the Senator's clarification, but I would only say that I think it fits certainly my definition of Government program when it is limited to Government employees and their families. It is run by Government employees. It is designated to be a governmentwide system specifically designed for all agencies of Government and their employees, paid for by the Federal Government as the employer.

So from that perspective it would seem to me that it would meet the definition of Government. But that is, I suppose, a matter of interpretation, and I appreciate the Senator from Minnesota making his point.

MORNING BUSINESS

Mr. DASCHLE. Mr. President, I ask unanimous consent that there now be a period of morning business with Senators permitted to speak therein for up to 3 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

IS CONGRESS IRRESPONSIBLE? YOU BE THE JUDGE ABOUT THAT

Mr. HELMS. Mr. President, before we ponder today's bad news about the Federal debt, let us have a little pop quiz: How many million dollars would you say are in a trillion dollars? And when you answer that, just remember that Congress has run up a debt exceeding 4½ trillion dollars.

To be exact, as of the close of business this past Friday, August 12, the Federal debt stood—down to the penny—at $4,645,748,084,784.22, meaning that every man, woman, and child in America owes $17,819.53, computed on a per capita basis.

Mr. President, to answer the question—how many million in a trillion—there are a million million dollars in a trillion dollars. I remind you, the Federal Government, thanks to the U.S. Congress, owes more than 4½ trillion dollars.

CURIOUSER AND CURIOUSER

Mr. DECONCINI. Mr. President, I do not necessarily believe everything I read in the paper. And I certainly do not believe everything Mr. Greenspan has to say. But the overwhelming weight of what I hear is that Mr. Greenspan and the Federal Reserve are planning on raising interest rates again.

Do not do it, Mr. Greenspan. If you are bored down there at the Fed, if a rosy economic outlook makes you blue, get out of town, take a vacation, do anything, but just do not raise those interest rates.

There seems to be general agreement that we can expect another increase in interest rates at the Fed's August 16th meeting. This fact is seen as a done deal, in spite of economic indications that it is not necessary. The August 15 edition of Business Week notes that even the Fed's own August 3 survey of regional economies points to a slowing in the economy, but acknowledges that "it is unlikely to prevent another widely expected hike in short rates by the Federal Reserve in mid-August." Why not, Mr. President? Does Mr. Greenspan like bad news so much that he wants to create more?

The Commerce Department estimates that the first quarter growth rate was 3.3 percent and the second merely 3.7 percent—substantially below the 4½ percent to 5 percent that Business Week asserts was widely anticipated. But clearly this isn't gloomy enough for Mr. Greenspan. Following Mr. Greenspan's logic is a little like Alice in Wonderland—it gets curiouser and curiouser.

Do America a favor, Mr. Greenspan, defy conventional wisdom, do not raise interest rates. Economic growth is good. Americans working is good. Low interest rates are good.

Alan Greenspan reminds me a little of Shakespeare's Hamlet who said "Nothing is either good or bad but thinking makes it so." Hamlet was a tragedy, do not turn the American economy into a tragedy as well, Mr. Greenspan.

VERMONT LAWYERS HELP DEVELOP RULE OF LAW IN FORMER SOVIET UNION

Mr. LEAHY. Mr. President, Vermont lawyers have been volunteering their time and energies to help develop the rule of law in the emerging Democracies of the former Soviet Union.

They have been helping their counterparts in Russia and other democratic states learn the values of the American system of jurisprudence, iec-

Antitrust Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

APR 14 1994

The Honorable Howard W. Metzenbaum
Chairman
Subcommittee on Antitrust, Monopolies,
and Business Rights
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

Dear Mr. Chairman:

I am writing in response to your letter of March 22, 1994, also signed by Chairman Brooks, requesting the views of the Department of Justice on S. 1658 and its companion bill, H.R. 3486, the "Health Care Antitrust Improvements Act of 1993." These bills would create special new broad based statutory immunities from the antitrust laws for a wide range of health care activities.

The Department is committed to reasonable and responsible application of the antitrust laws in the health care area to promote new competition in evolving markets. We have established as a priority the issuance of antitrust enforcement policy statements in the health care area designed to bring down health care costs to consumers while providing effective quality health care services. Six such statements have already been issued and others will be considered. We are committed to ongoing review and supplementation of these statements.

Effective antitrust laws have for over a century been the principal guarantor of competition in the American system and have time and again proved far superior to pervasive government review, regulation, and oversight of collective activities that may have competitive consequences. Health reform should build on a commitment to competition in health care markets. Consequently, the Department of Justice opposes the broad new statutory antitrust immunities contained in these bills.

The antitrust laws are enforced so as to take fully into account increased efficiency, lower administrative and other costs, improvements in quality, and other factors that are important to the cost-effective delivery of health care services. Neither the Justice Department nor the Federal Trade Commission has ever challenged a joint venture among hospitals to purchase, operate and market high-technology or other expensive medical equipment. And of the more than 250 hospital mergers since 1987,

only 11 have been found by the Department or the FTC to have likely anticompetitive effects that warranted antitrust challenge. Only those combinations that will harm the American consumer by raising prices, decreasing quality or availability of services, or discouraging innovation face antitrust challenge.

The Department and the FTC have recognized that uncertainty over the application of the antitrust laws in the health care area should be addressed, and have issued specific antitrust guidance to the health care industry. In September 1993, the agencies issued several joint Statements of Antitrust Enforcement Policy in the Health Care Area. Moreover, recognizing that issues and circumstances may change over time, the agencies have committed to providing additional general guidance, and also developed an expedited process whereby health care providers can obtain the views of the Department or the FTC on specific proposed activities.

Private remedies have been an integral part of antitrust enforcement for over 100 years. Moreover, the "private" antitrust remedies are used by State attorneys general to protect consumers in their states from localized anticompetitive activity. Such actions are an important adjunct to federal enforcement: Our enforcement resources are limited, and cannot uncover or move against every anticompetitive practice that may be harming consumers. At the same time, however, there is no reason to expect that health care providers will face a multitude of baseless private antitrust suits. Private parties are unlikely to institute meritless lawsuits and even less likely to be successful in pursuing them. This is especially the case with regard to health care matters, where it can be expected that courts will take into account the views of the government, including those expressed in the DOJ-FTC Statements of Antitrust Enforcement Policy, in private antitrust actions. This will help ensure sound and reasoned decisions in private litigation.

S. 1658 and H.R. 3486

S. 1658 and H.R. 3486[1] provide several types of broad immunities from the operation of the antitrust laws to the health care industry. Briefly, Section 2 of each bill provides antitrust immunity for any health care activity that:

(1) falls within one of the "safe harbors" described in Section 3 of the bill;

(2) falls within an additional safe harbor established by the Attorney General, after seeking public suggestions for

[1]The two bills are nearly identical. The Department objects equally to both S. 1658 and H.R. 3486.

further safe harbors via Federal Register notice under Section 4 of the bill; or

(3) is covered by a "certificate of review" issued by the Attorney General with the concurrence of the Secretary of Health and Human Services ("the Secretary") under Section 5 of the bill.

Additionally, Section 6 of each bill provides special antitrust protections in the form of guaranteed rule-of-reason treatment and the "detrebling" of any antitrust damages for a health care cooperative venture, if notice of the venture is provided to the Attorney General.

The broad new statutory antitrust immunities accorded by S. 1658 and H.R. 3486 are unnecessary and potentially harmful. The certificate of review immunity scheme in the bills, covering any activity relating to the provision of health care services, would create pervasive and continuing Federal government regulation of the competitive and other dimensions of an unknown and potentially vast number of health care provider activities. This task could well overwhelm the Justice Department, seriously impeding its ability to focus on any activities that actually would have anticompetitive effects. It likely would result in a massive new bureaucracy within the Department of Justice to administer such a program. Moreover, regulatory attempts to guard against anticompetitive behavior have consistently proved to be no substitute for the standard operation of the antitrust laws. The notification-based antitrust protections in the bills, broadly covering any collective activity among health care providers, could undercut sound antitrust substantive standards and skew the balance of antitrust remedies that has served so well for over a century. And the "safe harbor" immunities in the bills, based as they would be on hard-to-amend statutory or regulatory language and legislative or regulatory history, could have unintended anticompetitive effects, whereas enforcement policy statements based on common sense, basic competitive principles, would not.

Having summarized the Department's views on S. 1658 and H.R. 3486, I will address below our concerns with each aspect of the bills in more detail.

CERTIFICATE OF REVIEW PROVISIONS OF S.1658 AND H.R. 3486

The most comprehensive and complex new antitrust immunity scheme provided by S. 1658 and H.R. 3486 is the certificate of review process set out in Section 5 of each bill. This section provides complete antitrust immunity to successful applicants for a certificate of review that may cover any activity relating to the provision of health care services. In deciding whether to issue a certificate, the Attorney General and the Secretary are to take into account the extent to which a particular activity will:

A) lead to an increase in access to health care services;

B) enhance the quality of health care services;

C) establish cost efficiencies that will be passed on to consumers, including economies of scale and reduced transaction and administrative costs;

D) increase the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations; and

E) improve the utilization of health care resources or reduce inefficient duplication of such resources.

They must also consider whether:

A) the activity will help health plans and other health care insurers, consumers of health care services, and health care providers to better negotiate payment and service arrangements that will reduce costs to consumers;

B) taking into consideration the characteristics of the particular purchasers and providers involved, competition will not be unduly restricted;

C) equally efficient and less restrictive alternatives do not exist to meet the criteria described above; and

D) the activity will not unreasonably foreclose competition by denying competitors a necessary element of competition.

Section 5 requires the Attorney General, in consultation with the Secretary and the Chair of the FTC, to establish procedures to be used in applying for and approving certificates. It also requires published notice of each application in the Federal Register within 10 days of receipt, and action by the Attorney General and the Secretary within 90 days. If an

application for a certificate has not been denied within 90 days, it is deemed approved. There is also provision for expedited action if an applicant "indicates a special need for prompt disposition."

Further provisions in Section 5 deal with denial of applications, requests for reconsideration, fraudulent procurement, amendment and revocation of certificates, requests for compliance information, investigative authority, review of certification determinations in federal court, the effect of rejected applications, publication of decisions, annual reports, restrictions on disclosure of information, and prohibition against use of information to support or answer claims under the antitrust laws. In short, section 5 replaces the normal operation of the antitrust laws with ongoing government review and regulation of certificated activities under the comprehensive standards set out above.

Objections to the Certificate of Review Provisions

Antitrust immunity for any and all activities relating to the provision of health care services pursuant to the complex certificate of review process contained in S. 1658 and H.R. 3486 is unnecessary and potentially harmful. There is no evidence that establishment of such a pervasive regulatory scheme or such a substantial departure from the antitrust standards and procedures applicable in virtually all other sectors of the economy is necessary to foster the innovative health care delivery systems envisioned by the Health Security Act and most of the other reform proposals currently before the Congress. Justice Department and FTC policy and practice have accorded favorable treatment to the vast majority of cooperative activities in the health care area. Nor does the ability of health care providers, consumers or third party payers to seek redress of antitrust grievances through private litigation warrant the substitution of continuing government oversight of health care activities for the discriminating application of sound antitrust law.

The dangers of a comprehensive certification/antitrust immunity scheme are manifest. First, such a scheme would place the entire responsibility of initially and prospectively detecting anticompetitive threats and continually monitoring approved health care activities on the Departments of Justice and HHS. In light of the breadth of the scheme, analyzing and processing certification applications could be overwhelming, impeding the Justice Department's ability to screen proposed activities for anticompetitive effects, and diverting its staff from their primary mission--the detection and prosecution of antitrust violations and the prevention of anticompetitive mergers and joint ventures. Competitive harm in such circumstances is entirely predictable.

The certification scheme provided by S. 1658 and H.R. 3486 also would require unwarranted and continuing government oversight of an unknown and potentially vast number of day-to-day activities of health care providers. Government agencies would have the ability to approve a wide range of individual or collaborative activities, perhaps on condition that they be altered in a particular way. In addition, the agencies would have the power, and indeed the obligation, after certification to intervene in a regulatory manner whenever they determined that the complex and judgmental criteria in the bill were no longer met. Constant monitoring of existing certificate holders would be required to determine whether a certificate should be amended or revoked. To effectively administer such a scheme would require a massive new bureaucracy within the Department of Justice. Finally, the certification scheme in the bills likely would impose increased costs on the health care industry as providers spent substantial sums preparing and filing requests for certificates for activities that typically raise no colorable antitrust issues.

NOTIFICATION PROVISIONS OF S. 1658 AND H.R. 3486

Section 6 of each bill would create a notification procedure whereby any "health care cooperative venture" would be guaranteed a "rule-of-reason" antitrust analysis if challenged under the antitrust laws, and any antitrust relief granted against such a venture would be limited to actual rather than treble damages. Parties could obtain such protection by affirmatively notifying the Attorney General of their activities, but in addition many types of ventures would be "deemed" to have submitted such a notification. These include any ventures that have applied for a certificate of review under Section 5, and any health care cooperative ventures of a certain size[2] among non-institutional providers who share risks.[3]

Objections to the Notification Provisions

As with certification schemes, rule-of-reason/single damage protection via notification for unknown and potentially broad

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[2]For a nonexclusive network, any group including 50 percent or fewer of the providers in a relevant market and 50 percent or fewer of the members of any one specialty within that group; for an exclusive network, any group including 35 percent or fewer of the providers or specialists in a relevant market.

[3]H.R. 3486 deems either ventures below the size limits in Note 2 supra or ventures wherein providers share risks to have been notified; S. 1658 imposes both size limits and risk sharing before ventures will be deemed to have been notified. H.R. 3486 also omits the "non-institutional" qualifier.

categories of collaborative health care activities is unnecessary and potentially harmful. There is no indication, in light of the sound enforcement policies applied to health care activities, that cost-saving or otherwise efficient joint ventures in the health care area are unusually vulnerable to antitrust attack. In fact, quite the opposite is clear from the record. There is no sound reason to extend antitrust protection to joint ventures that present no anticompetitive risks and that would not be in danger of challenge in the first place. Moreover, such a provision could actually increase costs in the health care industry as the costs of notifications were passed on to consumers.

A notification scheme such as that set out in S. 1658 and H.R. 3486 could be harmful to competition and consumers by providing unwarranted rule-of-reason or single damage protection to potentially anticompetitive activities. There is no indication that procompetitive joint activity in the health care area is being placed at unusual or undue antitrust risk. Moreover, there is no legitimate distinction between health care and other industries such that potential treble damages should not produce the same salutary compensatory and deterrent effects in the health care area that they do generally.

Absent clear and convincing evidence of aberrations or abuse, antitrust standards and remedies should not be abrogated by special industry-specific protection for broad ranges of activities. Blanket, automatic protection for any "health care cooperative venture," which is defined in the two bills as "any activities, including attempts to enter into or perform a contract or agreement, carried out by two or more persons for the purpose of providing health care services," and for broad categories of activities that without any notice at all would be "deemed" to have filed a notification, would significantly constrain appropriate antitrust enforcement and deterrence. The rationale behind notification schemes is to give the government an opportunity to step in and stop potentially harmful activities, and the trade-off is that parties who notify are given rule-of-reason and single damages protection if they come forward. In light of the thousands of ventures that could potentially be presented to the Department under a notification scheme, there is a very real danger that potentially harmful arrangements would be granted a degree of protection that they do not deserve, and that could result in substantial harm to consumers.

CODIFICATION OF SAFE HARBORS

Section 3 of each bill would create several categories of statutory health care antitrust immunities that are in part patterned on the safety zones described in the six Department of Justice/FTC Statements of Antitrust Enforcement Policy in the

Health Care Area issued in September 1993. The "safe harbor" immunities in S. 1658 and H.R. 3486, however, are broader, and there are seven categories of exemptions instead of six. Section 4 of each bill would create a process whereby the public could submit suggestions for additional safe harbors to be established by the Attorney General, in consultation with the Secretary and the Chair of the FTC.

Objections to Codification of Safe Harbors

Statutory "safe harbors" from antitrust scrutiny for health care providers would be both unnecessary and potentially harmful. Such protections are unnecessary because the Department and the FTC have already set out significant safety zones in their joint Statements of Antitrust Enforcement Policy in the Health Care Area that inform health care providers of activities that are clearly lawful. We have committed to continuing review and supplementation of these Statements, and have complemented them with an expedited process through which health care providers may obtain the views of the Department or FTC on specific proposed health care activities, whether or not they are covered by the existing policy statements.

The harm that the Department foresees from codification of health care antitrust safety zones is that it could have unforeseen consequences and needlessly encumber law enforcement and development in areas that may require fine tuning for some time to come. Consumers, health care providers and enforcement officials all need leeway to adjust to changes in relevant markets as health care systems evolve and competition and efficiencies in health care delivery become better understood. Statutory antitrust immunities are not easily amended, and their intended effects can be distorted by interpretations of both statutory language and legislative history. On the other hand, the articulation of safety zones in flexible, competition-oriented enforcement policy statements such as those set out by the agencies last September is a process much more geared to an optimal outcome for both providers and consumers. What looks like a perfectly reasonable activity today could have unforeseen anticompetitive ramifications in the future and, similarly, what appears to be a problematic activity today may be perfectly reasonable in the future. Although it is extraordinary for one particular industry to have a set of specific guidelines put forth for its benefit, the Department and the FTC have done so for the health care industry. It would be totally unprecedented for such guidelines to be codified.[4]

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[4]We would also note that some of the particular safe harbors defined in the two bills are substantially broader than the safety zones in the DOJ/FTC Statements of Enforcement Policy, and (continued...)

* * *

In sum, the Department of Justice opposes S. 1658 and H.R. 3486. I appreciate very much your interest in the importance of sound antitrust enforcement and the preservation of competitive health care markets. The Department is committed to reasonable and responsible application of the antitrust laws in the health care area and will continue to work to promote a fair and competitive health care marketplace; however the broad new statutory antitrust immunities in these bills could be detrimental to the goals of health care reform.

This Department has been advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

Anne K. Bingaman
Assistant Attorney General

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[4](...continued)
may protect anticompetitive conduct that significantly harms consumers.

U.S. Department of Justice

Antitrust Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

JUN 29 1994

The Honorable Daniel Patrick Moynihan
Chairman
Committee on Finance
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

We understand that a slightly revised version of S. 1658 may be offered as an amendment during Finance Committee discussions of health care reform legislation.

The Department previously has expressed serious concerns with S. 1658; those concerns, expressed in our comments, also are applicable to many of the provisions that we understand will be included in the amendment. I enclose herewith a copy of our previous comments. If you have questions in this regard, I will be very happy to discuss them with you.

Sincerely,

Anne K. Bingaman
Assistant Attorney General

U.S. Department of Justice

Antitrust Division

Washington, D.C. 20530

[4843b]

DATE 8/18/94

TO: Jennifer Klein
White House

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COMMENTS: Rural antitrust language

TOTAL PAGES TRANSMITTED: 1 (EXCLUDING TRANSMITTAL SHEET)

PANAFAX NO. 202-514-9082

At the end of subtitle E of title III, add the following new part:

PART 4—ANTITRUST SAFE HARBORS FOR RURAL HEALTH PROVIDERS

SEC. 3491. ANTITRUST SAFE HARBORS FOR RURAL HEALTH PROVIDERS.

(a) IN GENERAL.—The Attorney General, in consultation with the Commissioner of the Federal Trade Commission, shall clarify existing and future policy guidelines, with respect to safe harbors, by providing additional illustrative examples with respect to the conduct of activities relating to the provision of health care services in rural areas.

(b) DISSEMINATION OF INFORMATION.—The Attorney General, in consultation with the Commissioner of the Federal Trade Commission and the Assistant Secretary for Rural Health, shall develop methods for the dissemination of the guidelines established under subsection (a) to rural health care providers.

In section 3695(b), strike paragraph (8) and insert the following new paragraph:

"(8) with respect to the National Health Service Corps program referred to in section 3471, $381,000,000 for fiscal year 1996, $335,000,000 for

Section-by-Section of S. 1658, the Hatch-Thurmond Health Care Antitrust Improvements Act

Senators Hatch and Thurmond introduced the Health Care Antitrust Improvements Act, S. 1658, on November 10, 1993. A companion bill was introduced in the House of Representatives on November 10 by Representative Archer (H.R. 3486).[1] Subsequently, the 37-page antitrust bill was fully incorporated into the health care reform proposals of both Senator Chafee[2] and Senator Nickles.[3]

The Hatch-Thurmond bill establishes a framework for adjusting the antitrust laws to changing health care markets. In the absence of such legislation, much of the other substantive health care reforms could run into antitrust objections or challenges. This would result in desirable conduct by health

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[1] The Archer bill contains two notable differences from the Hatch-Thurmond bill: the market power threshold screen in the Archer bill is 25% rather than 20% in Section 3(1); and the Archer bill has a broader definition of cooperative ventures which are deemed to have filed a written notification under Section 6(a)(2).

[2] S. 1770, the Health Equity and Access Reform Today Act of 1993, was introduced on November 22, 1993 by Senator Chafee and 17 co-sponsors. The Hatch-Thurmond bill is incorporated as Title IV, Subtitle C.

[3] S. 1743, the Consumer Choice Health Security Act of 1993, was introduced on November 20, 1993 by Senator Nickles and 24 co-sponsors. The Hatch-Thurmond bill is incorporated as Title VI.

care providers being chilled due to actual or perceived levels of antitrust risk.

The Hatch-Thurmond bill provides three types of antitrust adjustments for evolving health care markets:

- Safe harbors for listed categories of conduct and a process for developing additional safe harbors.
- Case-by-case waivers by the Attorney General for specific conduct based on stated criteria.
- Actual (rather than treble) damages and Rule of Reason analysis (comparing pro-competitive and anti-competitive effects) for collaborative activities which are disclosed to the Attorney General, if they are later challenged.

The bill contains safeguards requiring the Attorney General periodically to review the safe harbors and waivers and report to Congress, to ensure that the act continues to serve its intended purpose. The bill also imposes annual reporting requirements on those granted waivers and permits termination of waivers.

Section 1. SHORT TITLE.

The bill's short title is the Health Care Antitrust Improvements Act of 1993.

Section 2. ANTITRUST EXEMPTIONS FOR CERTAIN HEALTH CARE ACTIVITIES.

Health care related activities are exempt from federal and state antitrust laws if they come within a safe harbor listed in Section 3 of the bill, come within an additional safe harbor designated pursuant to Section 4, or are covered by a specific

antitrust waiver, called a certificate of review, under Section 5.

Certificates of review will be granted on a case-by-case basis by the Attorney General. Certificates granted during the first two years after enactment of the bill will retroactively cover activities within the two year period prior to issuance of the certificate.

Section 2(b) provides that a court is to award the defending party its costs and attorneys' fees for any frivolous or unreasonable antitrust action which is brought against exempt activities. However, an award of costs and attorneys' fees may be offset if the prevailing party's conduct in litigation was frivolous or unreasonable.

Section 3. DESCRIPTION OF SAFE HARBORS COVERING SPECIFIC CATEGORIES OF CONDUCT.

Seven categories of conduct are defined as safe harbors which are exempt from federal and state antitrust laws. Several of these are based on the Statements of Antitrust Enforcement Policy in the Health Care Area jointly issued by the Department of Justice ("DOJ") and Federal Trade Commission ("FTC") in September 1993, which provide "safety zones" for certain categories of conduct that generally will not be challenged by the two agencies. The safe harbors of the Hatch-Thurmond bill are broader and provide more certainty than the safety zones in the DOJ/FTC Statements, which have no legal effect on courts, no effect on private antitrust challenges, no effect on state

antitrust enforcement, and even allow DOJ and FTC challenges of activities within a safety zone if there are "extraordinary circumstances."

The safe harbors are:

(1) 20% Market Power Screen. All health care related activities by combinations of providers comprising 20% or less of the relevant product and geographic markets are exempt.

(2) Medical Self-Regulatory Entities. Standard setting and enforcement activities by medical self-regulatory bodies (such as hospital boards and medical societies) to promote health care quality are exempt, unless done for financial gain.

(3) Participation in Surveys. Health care providers may lawfully participate in written surveys of prices of services, reimbursements received and employee compensation, as long as a third party (such as a trade association) conducts the survey, the data is more than three months old, and the survey results are adequately aggregated before dissemination.

This safe harbor expands the safety zone for hospital surveys in the DOJ/FTC Statements to all health care providers.

(4) High-tech Joint Ventures. Activities of joint ventures to purchase and use or provide high technology or costly equipment and services are exempt as long as the health care providers included in the venture are necessary to its financial viability. Other providers not needed for viability may be included in the venture if they are unable financially to support a separate competing venture.

This safe harbor expands the safety zone for high-tech equipment ventures in the DOJ/FTC Statements to include other costly equipment and services.

(5) Small Hospital Mergers. Two hospitals may lawfully merge under the antitrust laws as long as one of them had no more than 150 operational beds on average over the last three years and inpatient censuses of less than 50% of that number.

This broadens the safety zone in the DOJ/FTC Statements which permits mergers between general acute-care hospitals where one averaged less than 100 licensed beds and 40 inpatients over the last three years.

(6) Joint Purchasing Arrangements. Health care providers may purchase jointly as long as their purchases are less than 35% of the total amount of the product or service purchased in the relevant market, and the cost of the jointly purchased items is less than 20% of the revenues from all products and services sold by the joint purchasers involved.

The terms of this safe harbor are identical to a safety zone in the DOJ/FTC Statements.

(7) Good Faith Negotiations. Good faith negotiations to initiate or engage in activities defined as safe harbors, additional safe harbors, or which are the subject of an application for a certificate of review are exempt from the antitrust laws.

Section 4. DEVELOPMENT OF ADDITIONAL SAFE HARBORS.

Within 30 days of enactment of this bill, the Attorney General is to solicit proposals for additional safe harbors covering health care activities which should be exempt from the antitrust laws. Within 180 days of enactment, the Attorney General in consultation with the FTC Chairman and the Secretary of the Department of Health and Human Services ("HHS") is to review the proposals, report to Congress on which proposals have been accepted, and publish them in the Federal Register. Within 180 days after publication, the Attorney General is to issue final rules for the additional safe harbors (in the absence of action by Congress).

Section 4(b) provides that additional safe harbors are to be based on the following criteria: (i) the extent to which the activity increases access to health care, enhances quality, improves utilization, and provides cost efficiencies for the benefit of consumers, and (ii) whether health care providers and purchasers will be better able to negotiate arrangements to reduce costs to consumers, whether competition will be unduly restricted or foreclosed, and whether less restrictive alternatives exist.

Section 5. PROCEDURES FOR CASE-BY-CASE ANTITRUST WAIVERS.

The competitive impact of many arrangements cannot be determined without analysis of the specific facts involved, so the bill establishes a process in which certificates of review are given to health care providers for desirable conduct which

meets the criteria set forth in Section 4(b) of the bill. This improves upon DOJ's system of providing business review letters and the FTC's advisory opinions on the legality of proposed actions under the antitrust laws, by providing full protection from private antitrust challenges and state enforcement agencies, as well as the federal agencies (which legally are not bound by their own advisory opinions), so that health care providers can proceed in confidence with approved transactions.

Within 180 days of enactment, the Attorney General in consultation with the FTC and HHS is to begin issuing certificates of review and assisting in the application process.

Applicants for certificates must specify activities which satisfy the criteria in Section 4(b), set forth above. Federal Register notices are required for each application and each decision to issue, amend or revoke a certificate. Applicants may seek expedited action, but certificates may not be issued until 30 days after the Federal Register notice.

The Attorney General, with the concurrence of HHS, is to issue a certificate within 90 days of receiving an application if the activities to be covered satisfy the Section 4(b) criteria and the benefits from the proposed activities outweigh any disadvantages from reduced competition. The certificate must specify the health care activities covered, the person covered, and any other terms and conditions. Applications are deemed approved if they are not rejected by the Attorney General within 90 days. Certificates are void ab initio *if procured by fraud.*

The Attorney General must provide the reasons for any denial to the applicant. Requests for reconsideration may be made within 30 days of denial, and the Attorney General (with HHS concurrence) must act on such requests within 30 days.

An annual report is required from each certificate holder describing the activities within the scope of the certificate during the previous year. Holders must report changes relevant to the certificate and may submit an application to amend the certificate under the usual procedures.

The Attorney General may revoke certificates based on: failure within two years to accomplish the purposes for which the certificate was issued, failure to comply with any terms or conditions of the certificate, or the activities covered no longer satisfy the criteria in Section 4(b), set forth above. The Attorney General may request information from the certificate holder to determine whether grounds for revocation exist. Upon written notice, the Attorney General may revoke or modify a certificate to cover only activities which meet the requirements for issuance of certificates.

Denials of certificates and revocations are reviewable in federal court on a preponderance of the evidence standard. Denials or revocations and the reasons underlying the decisions are not admissible in other antitrust actions.

If an application is denied, supporting documentation must be returned upon request. Information relating to certificates of review are exempt from FOIA requirements and must not be

disclosed by the government except in limited circumstances, such as a request of Congress.

The certificate of review process is based broadly on the Export Trading Company Act of 1982 (15 U.S.C. §§ 4001-21).

Section 6. REDUCED DAMAGES FOR DISCLOSED COLLABORATIVE ACTIVITIES.

This section provides for actual, rather than treble, damages and application of the Rule of Reason standard (which compares the pro-competitive and anti-competitive effects of conduct) to all collaborative health care activities which are disclosed to the Attorney General, if they are later challenged under the antitrust laws. This approach has been used successfully for research & development joint ventures in the National Cooperative Research Act of 1984 ("NCRA," 15 U.S.C. § 4301, et seq.). NCRA was expanded to cover production joint ventures by the National Cooperative Production Amendments Act of 1993 (Pub. L. No. 103-42), but the 1993 legislative history states that the "bill's protections will not extend to joint ventures to provide what are simply services, such as health care or legal services, that are unconnected to any concrete technological innovations, or to joint ventures solely to purchase medical equipment." (Senate Report 103-51 at 9.)

The concept, which has been validated by NCRA over the last decade, is that those intending to unlawfully conspire will not notify the Attorney General because of the likelihood of prosecution, including possible criminal penalties and even

imprisonment for some antitrust offenses. On the other hand, those who seek to engage in lawful collaborative ventures will be able to obtain the benefits of this section by a simple filing, so that economically desirable conduct will not be deterred by the risk of treble damages.

A health care cooperative venture will be subject only to actual, rather than treble, damages and analysis under the Rule of Reason (rather than per se) standard in any subsequent antitrust challenge, if it submits a notification to the Attorney General disclosing the parties involved and the nature and objective of the venture. Notice about the venture must be published in the Federal Register.

A separate written notification is not necessary to obtain the benefits of this Section for (i) an applicant for a certificate of review under Section 4, or (ii) non-institutional health care providers in a nonexclusive network of less than 50% of the providers in the relevant market, or an exclusive network of less than 35%, as long as there is substantial financial risk-sharing within the venture.

The venture must submit information about changes in its membership. At any time the Attorney General may request additional information about the venture, which is exempt from disclosure under FOIA and must not be made publicly available by any agency except in judicial proceedings.

In litigation over activities which are covered by a notification, the court is to award costs and attorneys' fees to the successful claimant in all cases and to the successful

defendant only if the claim or the claimant's conduct was frivolous or unreasonable. The fact of notification and information submitted are admissible only to obtain the benefits of this section.

Section 7. ATTORNEY GENERAL'S REVIEW OF EXEMPTIONS AND RECOMMENDATIONS TO CONGRESS.

The Attorney General in consultation with the FTC and HHS is periodically to review and recommend appropriate changes in the safe harbors (Section 3) to Congress, issue appropriate proposed revisions to the additional safe harbors (Section 4), and submit a report to Congress on certificates of review and their effectiveness in increasing access to high quality health care at reduced costs, as well as provide recommendations for any legislation needed to improve the certificate of review process.

Section 8. PROMULGATION OF RULES, REGULATIONS AND GUIDELINES.

The Attorney General with the concurrence of HHS is to promulgate rules, regulations and guidelines to carry out the provisions of the bill. In addition, the Attorney General is to issue and periodically update guidelines to assist health care providers in analyzing what activities may be within a safe harbor or suitable for a certificate of review.

Section 9. CREATION OF HHS OFFICE OF HEALTH CARE COMPETITION POLICY.

An Office of Health Care Competition Policy is created within HHS to handle competitive issues in health care.

This section is based on Section 4003 of the Export Trading Company Act of 1982, which created an Office of Export Trade within the Department of Commerce.

Section 10. DEFINITIONS.

Among other definitions, the term "antitrust laws" includes unfair competition law in addition to traditional antitrust law, and all comparable state laws. "Provider" is defined broadly as any person or entity required to be licensed by a State to provide health care services. A "specialty" is also determined according to state licensing requirements.

K.L.S.
January 19, 1994

American Medical Association
February 24, 1994

THE CASE FOR ANTITRUST REFORM FOR PHYSICIAN GROUPS

The Transformation of the Health Care Industry

The market for health care insurance and the market for the delivery of health care services are in the process of being dramatically transformed. New methods are rapidly replacing the traditional methods for providing these products.

Traditionally, health care insurance and health care services were sold separately. Health care insurers took no responsibility for providing health care services, and providers took no responsibility for insuring health care risk. Patients had complete freedom to choose a provider, and the patient in consultation with the patient's physician had complete control over the health care services that the patient received. Providers were paid on a fee for service basis at usual, customary, and reasonable levels. Health care services were delivered in a "cottage industry" style, by numerous independent providers.

The new methods change the traditional mode in three ways. First, health care insurance is being integrated with the delivery of health care services, meaning that the same organizations are taking responsibility for both. These organizations, such as preferred provider organizations (PPOs) and health maintenance organizations, are generally referred to as "managed care organizations" (MCOs), because they "manage" the health care services received by their beneficiaries as well as paying for the care.

Second, MCOs are paying providers on a discounted fee for service basis, or with arrangements whereby a percentage of fees are withheld and paid if utilization goals are met, or on a capitation basis, or with some combination of these approaches. These payment methods are designed to give providers incentives to find the least costly way to treat a patient.

Third, independent providers are being organized into health care delivery networks that provide health care services for MCOs. They are designed to thrive under the new methods of payment by rendering health care services at a lower cost than the cottage industry style of practice. However, the cost savings techniques used result in restrictions on patient choice of providers, and in a shift in control over the health care services received by a patient from the patient and physician to the network or the MCO.

Phases of the Consolidation Process

The consolidation is occurring in phases along a continuum. Markets at one end of the continuum are organized in the

increase the number of primary care physicians to preserve referrals to their specialists. Hospitals and physicians start to become more active in organizing networks that engage in direct contracting with employers or that contract with MCOs. Physicians start to organize more group practices in a variety of formats. More horizontal coordination of patient care starts to occur in the various networks to achieve cost savings.

The final step along the continuum involves the emergence of staff and group model HMOs as the dominant health plans. These HMOs tend to be the lowest price plans in the market, and gain market share as a result. As their market share increases, they gain enough critical mass to expand the size of their capitated networks. The volume that these HMOs have attracts providers, and capitation or salaries starts to become more attractive to physicians, especially primary care physicians, that are struggling to maintain enough volume to maintain income levels.

Although these HMOs expand their networks, they do not become broadly inclusive. Quite the opposite, they operate the most exclusive networks, and only take on enough providers to handle their patient volume. They also move towards requiring that the providers in the network be exclusively dedicated to serving HMO patients. In addition, they engage in more coordination of patient care by the providers. To meet the savings generated by these networks, the PPOs and IPA-model HMO networks have to become more exclusive and more dedicated to their MCOs. Eventually competition in the market features intense competition between staff and group model HMOs and PPOs or IPA model HMOs that have tightly structured and exclusive networks capable of competing with the other HMOs.

Reasons Why the Consolidation Process is Occurring

The consolidation process is occurring due to market forces and government policy. The objective is to reduce costs -- private sector payers and government entitlement programs want greater control over their aggregate expenditures on health care and the rate at which those expenditures are increasing. They believe that the consolidation process will accomplish that. The theory is that expenditure savings and reductions in the rate of growth in expenditures increases as health care insurance and delivery markets move along the continuum from unstructured towards dominance by large staff or group model HMOs.

It is believed that the major breakthrough in the achievement of savings comes with the transition from markets dominated by PPOs and IPA-model HMOs that rely on discounted fee for service and fee withhold arrangements, to markets dominated by large staff and group model HMOs that rely on capitation or salaries. The previous steps towards consolidation achieve significant savings, but the savings achieved in this last step are several orders of magnitude higher. For example, studies have shown that the use of

techniques used by group and staff model HMOs become understood by the medical profession, other types of organizations may emerge that are able to achieve the same efficiencies.

Importance of the Partially Integrated Provider Network

Although fully consolidated markets featuring competition between large group and staff model HMOs are believed to result in the most savings in health care expenditures, partially integrated provider networks have an important role to play.

To begin with, partially integrated provider networks are important to the consolidation process. Many health care industry analysts consider partially integrated networks that serve PPOs and IPA-model HMOs to be transitional organizations that start to familiarize providers, payers, and patients with managed care. They feel that fully consolidated managed care organizations involve such dramatic changes from the choice, autonomy, and responsibilities that providers, patients, and payers are accustomed to that it is generally not feasible to implement those systems without a phasing in period. Partially integrated networks modify the UCR provider reimbursement system with discounted fee for service payments, and fee withhold arrangements. They familiarize providers and patients with limits on choice by giving patients financial incentives to use selected providers. Independent providers begin to coordinate their activities in order to make the new payment systems work.

In addition, PPOs and HMOs that use partially integrated provider networks may be the best type of managed care organization for the vast areas of the United States that do not have sufficient population density to sustain competition between large group and staff model HMOs. Competition among partially integrated managed care plans may be the end point of the consolidation process in these markets.

Further, even in some densely populated markets, partially integrated provider networks may have an important role. Physicians in these networks may find ways to make them perform as efficiently as the fully integrated networks that serve staff or group model HMOs. Much of the savings achieved by group and staff model HMOs is attributable to a style of practice as opposed to the inherent advantages of consolidation. The managerial style of group and staff model HMOs has made it easier to implement this style of practice by professionals that have been trained in a high cost style of practice since their first days in medical school. Once this style of practice becomes more predominant among physicians, the controls that fully integrated networks have may not be necessary to achieve a lower cost style of practice.

Under some market conditions, partially integrated networks may even achieve a cost advantage over fully integrated networks

To gain an understanding of the gravity of this shift of control, it is as if hospitals operated without a medical staff structure, and that the ultimate decisions about medical management were made by the non-physician administrators of the hospital. That is not how hospitals are organized. They are generally required by law to delegate medical management to an organized medical staff that sets up committees and departments to manage the provision of medical care in the hospital. This system has resulted in the highest quality medical care in the world.

Some fully consolidated managed care plans are owned and operated by physicians. Others contract with a large, fully integrated network of providers to render care to the health plan beneficiaries, and the network takes responsibility for medical management. However, many large HMOs are not operated by physicians, do not contract with a large network, and have no structure whereby member physicians participate in medical management decisions.

Government Health Care System Reform Plans

Certain government health care system reform plans would facilitate the consolidation process that is already taking place in the market. There are several versions of these plans, all of which are based on the "managed competition" theory of health care system reform.

The managed competition theory is designed to improve the performance of health care markets by increasing the leverage of purchasers and improving the information that can be used to guide purchasing decisions. It would accomplish that by amassing purchasing pools that would negotiate with health plans, and by requiring health plans to offer standardized plans and to report standardized information about the quality of care experienced by their beneficiaries. The information is meant to facilitate comparisons between plans based on cost and quality. The theory presumes the integration of insurance and health care delivery, because the plan is deemed responsible for and able to control the quality of care provided by its participating physicians.

The versions of the managed competition bills pending in Congress vary in the amount of regulation that they would impose on the consolidation process. Republican lawmakers in Congress have introduced managed competition reform bills that would implement a comparatively light amount of regulation. These bills would create purchasing pools composed of individuals that are currently uninsured, such as employees of small businesses. However, they would leave the rest of the market for health care insurance and services largely intact.

A bipartisan bill would implement a comparatively moderate

One would expect the antitrust laws to facilitate the consolidation process, because the goal is to create entities that reduce costs while maintaining a high level of quality. But, the antitrust laws as currently interpreted actually obstruct key steps in the consolidation process.

The problems caused by the antitrust laws do not affect all aspects of the consolidations that are occurring. For example, the antitrust laws do not obstruct vertical combinations involving persons at different levels of the health care industry, such as insurance company acquisitions of providers to develop a health care delivery network, or hospital acquisitions of physician practices to form an integrated provider network. Therefore, insurance companies and hospital holding companies have a relatively free hand to assemble physician networks.

Nor do the antitrust laws bar horizontal combinations of competitors where the participants fully integrate their activities in a merger, provided that the merger does not result in an unacceptably large concentration of market power. Most mergers of physician practices fall into this category. Therefore, physicians who are willing to fully merge their practices have a relatively free hand to assemble networks, except in rural areas where there is a small number of physicians. Hospitals, however, face more difficulties in merging because there is a small number of hospitals in most markets.

Where the antitrust laws cause problems in the consolidation process is in the formation of any horizontal combination of providers where the participants partially integrate their activities. Unless these partial integrations offer capitation or fee withhold arrangements, or follow certain awkward procedures in the development of discounted fee for service schedules, they are vulnerable to allegations of per se violations of the antitrust laws, such as price fixing and horizontal market divisions. Therefore, whenever physicians seek to form a health care delivery network, but do not fully merge their practices in the network and remain actual or potential competitors outside of the network, antitrust compliance is a major concern and a major constraint.

Horizontal combinations of providers where the participants do not integrate their activities also face difficult compliance problems. These combinations generally cannot interact with payers on economic issues without committing a per se violation, unless their activities fall within an exemption to the antitrust laws, such as the exemptions that allow lobbying of government administered health care programs by provider associations. For example, if the participating physicians in a health plan met to collectively develop positions on various issues to present to health plan management, the physicians would risk antitrust law violations.

numbers of physicians learn the managed care style of practice.

Under the antitrust laws, partially integrated horizontal networks of physicians are considered to be combinations of competitors. Therefore, if the network members engage in joint marketing of their services at agreed-on prices, that is considered to be a per se illegal price fixing agreement that could be subject to criminal sanctions. However, if the network members sufficiently integrate their activities so that a new product is created that generates substantial efficiencies that are passed on to consumers, then the network is regarded as a legitimate joint venture enterprise, and not an illegal conspiracy, even if the network members agree on the prices to be charged by the network. But, legitimate joint venture networks of providers may yet be found illegal if too many providers in the market participate in the joint venture, or if the members of the joint venture account for too large a share of sales of provider services in the market.

As a result, partially integrated plans face a pair of major antitrust questions as they are formed. One is whether they meet the test for being a legitimate joint venture. If they do not, then the second major question is whether their planned activities constitute price fixing or another antitrust violation.

Enforcement policy statements issued by the United States Department of Justice (DOJ) and the Federal Trade Commission (FTC) provide some guidance on what those agencies consider to be a legitimate joint venture. A partially integrated physician network that accounts for 20% or less of the physicians in a market, in aggregate and by specialty, and whose members engage in substantial risk sharing, is deemed by the DOJ and FTC to be legitimate. Substantial risk sharing is defined as the acceptance of capitation or fee withhold arrangements where payment of the portion withheld is contingent on meeting utilization goals. Networks that have more than 20% of the physicians in a market and whose members engage in substantial risk sharing may ultimately be considered to be legal by the DOJ and FTC, but they are not deemed to be legal and are subject to scrutiny under the antitrust laws.

These criteria are overly restrictive for partially integrated networks in two ways. First, the 20% limit may be manageable for a group or staff model HMO, but partially integrated networks are typically more inclusive. One of their selling points is the ability of patients to select a physician from a large panel of physicians that represents all of the specialties and has wide geographic coverage. They typically have panels with a minimum of 40% of the physicians in a market, and often have well over 50%. These networks are almost always nonexclusive, meaning they do not bar their members from joining other networks or contracting individually with other health plans, so the large size of the panels does not inhibit the formation of competing networks and new health plans. Most physicians in these markets belong to several

physicians. Each physician then makes a unilateral decision about whether to accept the offer. The messenger then informs the payers about which physicians accepted which offers. Another structure is the "power of attorney model", under which each physician in the network informs an agent about the range of fees that the physician is willing to accept, and grants the agent a limited power of attorney to accept payer offers that fall within the range. The agent keeps each physician's fee range confidential from the other physicians in the network. The agent then negotiates with payers and can bind physicians that have authorized the agent to accept offers that fall within a range that is offered by a payer.

These convoluted structures not only add costs and inefficiencies to the operation of a partially integrated network, they also place physicians at a disadvantage in the development and control of health care delivery networks in comparison to insurers, hospital holding companies, and other institutions. These organizations can create a discounted fee for service provider network of literally any size, provided that they do not require exclusivity from network members, without antitrust barriers since those are considered to be vertical arrangements instead of horizontal combinations. They further possess the advantages of organizational simplicity, access to massive capital, and access to managerial personnel. Physicians, on the other hand, face difficult barriers in all of these areas, and that hinders their ability to form their own partially integrated networks. This makes it difficult for physicians to begin the process of developing networks that can evolve into tightly structured health plans, as discounted fee for service is usually one of the first steps in the process.

There are no compelling reasons why physicians should be restricted to such inefficient and cumbersome structures when organizing partially integrated discounted fee for service networks. Enforcement agencies are concerned that such networks would fall within the technical definition of price fixing if their members were allowed to agree upon a fee structure that would be offered by the network. They are also concerned that such agreements might form the basis for agreeing upon minimum prices as opposed to fees designed to be competitive. Falling within the technical definition does not seem to be a rational reason to require awkward and inefficient organizational structures. Further, it would not benefit a network to agree upon minimum prices because physicians who participated in such a conspiracy would not be competitive and would lose volume. If the conspiracy crossed networks and became market wide, it would surely be detectible by payers.

There are compelling reasons why physicians should be allowed to organize partially integrated networks that rely upon discounted fee for service arrangements. The importance of these networks has already been discussed, and it defeats the purpose of the antitrust

risk sharing is not recognized by the enforcement policies of the DOJ and FTC. If it was, then partially integrated networks that relied upon discounted fee for service arrangements could fall within the criteria of a legitimate joint venture. The requirement would be that physicians in the network make a substantial investment in it to become members. As a further assurance of legitimacy, the network could be required to have comprehensive utilization control and quality assurance programs in place.

These reforms would facilitate the formation of partially integrated physician networks, and would be more likely to enhance competition than restrain trade.

Facilitation of Input into Health Plans by Unintegrated Physicians. As discussed earlier, control over medical decision making is shifting away from the individual physician and becoming centralized in the health plan. Further, physicians who participate in non-physician directed health plans generally have no organized vehicles for providing input to the health plan about medical policy. As a result, the administrative management of these health plans, who usually lack medical training, have extraordinary power over medical decision making, and this power is likely to grow in the future. In stark contrast, other institutions responsible for medical care, such as hospitals, offer the participating physicians organized vehicles for providing input into the medical management of the institution, such as the hospital medical staff.

Some observers may believe that influence over medical management should be removed from physicians if our society is to succeed in the implementation of a new practice style that is lower cost than current practice styles. There is some rationale behind the belief that the existing medical establishment needs to be motivated into shifting into a low cost style of practice, and that forcing them to take direction is one way of accomplishing that. However, that method may yield results in the short run, but is likely to be destructive on a long term basis. Better long term results are much more likely if physicians continue to control medical decision making, but have the incentive to shift away from a high cost style of practice to a low cost style of practice. Given their knowledge and position as the caretaker, motivated and enthusiastic physicians are likely to be the best at finding ways to reduce costs while maintaining a high level of quality. Highly centralized control is likely to have the same poor results that it has had in every other endeavor.

Reforms to Facilitate Physician Input into Health Plans. Therefore, health plans should have formal structures, such as committees of participating physicians, which gives them a vehicle for input into the plan, and physicians should be allowed to organize and operate these vehicles. These structures should not be barred by the antitrust laws, and physicians who participate in

> agents for large groups of consumers; they use the clout of their consumer base to drive down health care service fees. Uniform fee schedules--anathema in a normal, competitive market--are standard operating procedure when medical plans are involved. In light of these departures from a normal competitive market, individual health care providers are entitled to take some joint action (short of price fixing or a group boycott) to level the bargaining imbalance created by the plans and provide meaningful input into the setting of the fee schedules. Thus, health care providers might pool cost data in justifying a request for an increased fee level..... Providers might also band together to negotiate various other aspects of their relationship with the plans such as payment procedures, the type of documentation they must provide, the method of referring patients and the mechanism for adjusting disputes. Such concerted actions, which would not implicate the per se rule, must be carefully distinguished from efforts to dictate terms by explicit or implicit threats of mass withdrawals from plans.

The Alston case is not the only federal decision to recognize the legitimacy of these activities. Similar results were arrived at in Barry v. Blue Cross of California, 1986-2 Trade Cases ¶ 67,367 (9th Cir. 1986), and U.S. v. American Society of Anesthesiologists, Inc., 473 F. Supp. 147 (S.D.N.Y, 1979).

Although the federal courts have clearly spoken on this issue, the DOJ and FTC enforcement policies explicitly state that physicians who collectively present fee information to payers run a serious risk of violating the antitrust laws. As a result, physicians have been advised by antitrust lawyers not to engage in the activities involved. Antitrust reforms should recognize what the courts clearly allow physicians to do. Unintegrated physicians participating in a health plan should be authorized to collectively develop and present information and positions on economic matters provided that they do not attempt to negotiate agreements with the health plan that binds the plan and purports to bind each of the physicians, or explicitly or implicitly threaten to boycott the plan or actually boycott the plan. Finally, in developing positions and information, physicians should not be allowed to share fee information, except in aggregate form that does not reveal the specific fees charged by any individual physician.

Negotiations With the Government and Other Entities in a Highly Regulated Health Care System. If President Clinton's Health Security Act were passed, many functions of a market would be replaced by regulation or other anticompetitive structures. Health alliances would have monopsony power in their jurisdictions over health plans and providers. The alliances would be subject to global budgets and price controls, and they would have the ability to impose price controls. Health plans and providers would be required to meet performance standards, and would be provided with

practice parameters designed to assist them in meeting the standards. One of the purposes of the global budgets is to motivate health plans and providers to find ways to reduce costs through managed care, but another purpose is to control increases in expenditures by controlling the rate at which new medical technology is brought into use. This aspect of global budgets limits the ability of providers to compete with innovative technology.

The overregulated nature of the Health Security Act makes it resemble the health care systems of other industrialized nations, in particular Germany. In those countries, physician associations negotiate with government agencies and, in some cases, with health funds that are roughly equivalent to the health alliances in the Health Security Act. The negotiations are important to that kind of system because it allows physicians to provide their perspective and knowledge about the functioning of the system, and about their own economic interests. A system that is highly regulatory and does not allow for substantial input from affected interest groups is autocratic. An autocratic system ultimately performs poorly because it does not obtain the benefit of knowledge, information, and creativity from the groups it regulates, and it destroys the morale of the regulated groups.

Further, allowing the negotiations does not result in physicians or other interest groups dominating the health care system. In fact, the countries where negotiations occur between physician associations and the government and health funds have a better record of cost control than does the United States. Therefore, allowing these negotiations is not likely to lead to any disasters. In fact, the negotiations process is likely to improve the performance of a highly regulated system.

Reforms to Facilitate Negotiations in a Highly Regulated Health Care System. The Health Security Act does allow a limited amount of negotiations by physician associations, and it provides antitrust exemptions for those negotiations processes. Physician groups will be allowed to negotiate with health alliances or states, at the option of the states, to set a fee schedule for the fee for service plan called for by the Act. However, this is a very narrow area for allowable negotiations. There are no formal mechanisms for physicians to be involved in negotiations over the national and regional per capita premium targets, for example. The ability to negotiate over the setting of national quality performance standards, the development of practice parameters, or the content of the standard benefits package is not included.

If a health care system envisioned under the Health Security Act is legislated, it must provide for negotiations between the government, entities that serve as the proxy of the government such as health alliances, and interest groups like physician associations. Different negotiation processes can be designed for

different issues. For example, several interest groups would want to be included in negotiations over issues like global budgets or national and regional per capita premium targets. Other issues, such as fees or capitation rates for physicians, would be more restricted to physicians and governments or alliances.

Some of the ground rules for the negotiations process could be drawn from the Negotiated Rulemaking Act of 1990, 5 U.S.C. §561, et. seq. That Act allows federal agencies to use negotiated rulemaking as an alternative to public notice and comment rulemaking provided for in the federal Administrative Procedure Act, 5 U.S.C. § 551, et seq. Under negotiated rulemaking, the agency involved convenes the interest groups that would be affected by a proposed area for regulation, and the interest groups and the agency negotiate an initial draft regulation. That regulation is then submitted for public notice and comment. The agency retains ultimate authority over the content of the regulation.

These principles could be used, but modified to fit the particular area of regulation, especially when it is an issue that will be regularly negotiated, such as per capita premium targets or fee schedules. A dimension that would be particularly important is a dispute resolution mechanism that could be used in the event that an impasse is reached in negotiations.

It might be possible to conduct the kind of negotiations process discussed here under existing antitrust exemptions, such as the Noerr-Pennington doctrine and the state action exemption, provided that the negotiations are with federal or state government entities. However, to the extent that negotiations would take place with alliances, or other quasi-governmental agencies, it is uncertain whether they would be considered government entities, and antitrust reforms would be needed to assure that physician participants would not be exposed to antitrust liability.

Conclusion

In conclusion, current antitrust laws are based on the traditional organization of the health care system where physicians and other providers operated independent and autonomous businesses. That is no longer the case -- physicians and other providers are rapidly organizing into networks designed to produce medical care more efficiently. Antitrust reforms would improve the performance of the health care system of the future. Further, this paper has only touched on some of the issues that make it difficult for networks to be formed and operate. Antitrust theory and enforcement in the antitrust area must undergo a thorough review and reform in order to facilitate high performance in health care, rather than impede it.

H.R. 3486/S. 1658
HEALTH CARE ANTITRUST IMPROVEMENTS ACT OF 1993

The Health Care Antitrust Improvements Act of 1993, introduced as H.R. 3486 by Representative Bill Archer (R-TX) and as S. 1658 by Senators Orrin Hatch (R-UT) and Strom Thurmond (R-SC), represents a critical first step toward ensuring physician involvement in the changing medical delivery system.

Improvements are needed because:

- Today's health care marketplace is increasingly characterized by corporate, and often for-profit, organizations and large managed care plans that are taking aggressive action to control the delivery of health care services and reduce their cost.

- Efforts to save costs are appropriate and desirable, but excessive concern for costs can interfere with the availability and delivery of health services to patients and diminish the quality of those services.

- If physicians are going to be successful advocates for their patients in ensuring access to high quality, affordable health care, they must have a strong voice on issues relating to the delivery, quality and financing of health care services.

The American Medical Association urges you to cosponsor H.R. 3486 or S. 1658. This important legislation would exempt certain activities from the antitrust laws if the conduct falls within one of seven safe harbors defined in the legislation OR within any additional safe harbors designated by the Attorney General OR within the terms of a "certificate of review" issued by the Attorney General. The seven safe harbors are:

(1) collective activities related to the provision of health care services in which the number of each type of provider or specialty does not exceed 20% of the market (note: 25% in the Archer bill);

(2) activities of medical self-regulatory entities;

(3) joint participation in cost or price surveys to be used with third party payers;

(4) joint ventures for high-tech, high-cost equipment and services;

(5) hospital mergers;

(6) joint purchasing arrangements representing less than 35% of sales in the relevant market; and

(7) negotiations to carry out any activity protected as a safe harbor.