COMPETITION IN THE HEALTHCARE MARKETPLACE

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT SAFETY, AND INSURANCE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JULY 16, 2009

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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COMPETITION IN THE HEALTHCARE MARKETPLACE

THURSDAY, JULY 16, 2009

U.S. SENATE, SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT SAFETY, AND INSURANCE, COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION, Washington, DC.

The Subcommittee met, pursuant to notice, at 10:05 a.m. in room SR-253, Russell Senate Office Building, Hon. Mark L. Pryor, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. MARK L. PRYOR, U.S. SENATOR FROM ARKANSAS

Senator PRYOR. I'll go ahead and call this Subcommittee to order. This is the Subcommittee on Consumer Affairs, Insurance, and Automotive Safety.

I want to thank my colleagues for coming. We're going to have some coming-and-going today, given the events on the Hill relating to healthcare, and Supreme Court nominee, et cetera. We're going to have a little bit of in-and-out with our Senators today.

I want to thank all of you for attending today's hearing on healthcare competition. Anticompetitive practices healthcare industry players are an overlooked component of skyrocketing healthcare costs. When these players manipulate the market through price-fixing, collusion, anticompetitive mergers, and tactics that block new entrants to the market, prices artificially increase for consumers and patients, businesses, and governments that pay America's rising healthcare bills. In fact, a more competitive market for healthcare services would significantly reduce costs, and that would mean that, if we do healthcare reform this year, and we're able to accomplish that, it'd be a lot less we'd have to pay for over time. I think it's one of those issues that you can't just throw money at and solve the problem; you also have to change the system, and that's what we're talking about today.

There are several problems with the healthcare market. It lacks transparency; consumers have limited choice; there is unequal bargaining power among healthcare industry sectors; and conflicts of interest abound. Because the healthcare market is so much more complicated than selling something like television sets, we need to have strong government regulators watching for anticompetitive conduct and market manipulation. I believe that having a more vibrant, transparent healthcare system will help Americans make better-informed, more cost-conscious decisions.

Today's witnesses are uniquely qualified to discuss a wide array of issues relating to competition in healthcare, ranging from what options of health plans are available to consumers, to how doctors and hospitals should compete to deliver quality, cost-efficient care, to transparency for patients and payers of healthcare costs related to prescription medications. I also look forward to hearing insights from all the participants concerning what we can do to make the healthcare marketplace work better for patients.

We look forward to hearing today from the Federal Trade Commission about the manipulative behavior they see within the healthcare market. We also want to hear what actions the FTC has taken to date, and where they may be focused in their new areas

of concern.

I look forward to hearing from our healthcare policy analysts about the problems they see with competition in the healthcare market, and what ideas they may have to make the healthcare

marketplace work better for consumers.

And I especially look forward to hearing the local perspective from Mark Riley, a pharmacist from Arkansas who was kind enough to join us today. Mark is in the trenches of this every day, and he's going to tell a common story that, probably, any pharmacist in the country could tell today, but Mark was kind enough to travel to Washington to be before the Subcommittee, and we appreciate it very much.

Everyone wants fair competition in healthcare. They want a market that reduces costs. They want to provide better patient care. But, from what I've learned, the healthcare market is permeated with the opportunity for collusion, price-fixing, and conflicts of interest that inherently create an unfair market. And that unfair market is bleeding scarce resources for patient care from businesses, governments, and patients. We need to find out today how we can fix, and how we can address, these problems.

With that, I'd like to call on my distinguished colleague, Senator Wicker of Mississippi, the Ranking Member of this Subcommittee,

and ask him for his opening statement.

STATEMENT OF HON. ROGER F. WICKER, U.S. SENATOR FROM MISSISSIPPI

Senator WICKER. I thank my friend.

Of all the complex issues the United States will deal with in this Congress, none will be more important than healthcare reform. If we get it right, we could devise a program that makes healthcare more accessible and affordable; provides health coverage to millions of Americans who are currently without health insurance; relieves Americans from worry about the effect changing jobs will have on their healthcare; saves lives through an increased focus on prevention and wellness; saves money by curbing the out-of-control growth in government healthcare programs; keeps patients and families in control of their healthcare choices; and makes doctors the decisionmakers on treatment options.

We have a great opportunity before us to improve the American healthcare system, but we run a perilous risk if we do not act wisely and carefully. We can fix our broken healthcare system by making it more accessible and affordable for Americans, and we can do so without jeopardizing quality, individual choice, and personalized care.

There is common ground to be found that would continue the opportunity for the United States to be the world leader in quality. Congress and the American people need to pay close attention as we proceed, this summer and this fall, on one of the most important debates of our time. Above all, we must remember that healthcare in America is not just an economic issue, it is a personal issue. Working together, we can fix our broken healthcare system by making it more accessible and affordable for every person in our country, without jeopardizing quality, individual choice, or personalized care.

The healthcare marketplace is extremely complex. Until I became an elected official dealing with healthcare issues, I did not realize how arcane and complex the system is. I hope our witnesses today will help us understand better the intricacies of the marketplace; where free market principles and competition are working, and what steps need to be taken as we move forward to achieve a market-based approach on reform.

So I look forward to today's testimony, and I thank the Chairman

for holding this hearing.

Senator PRYOR. Thank you. Thank you very much.

Senator Nelson?

STATEMENT OF HON. BILL NELSON, U.S. SENATOR FROM FLORIDA

Senator NELSON. Thank you, Mr. Chairman, and thank you for having this hearing.

I just want to say, since we're dealing with the question of competition in the healthcare marketplace, that's one of the most important things that we can be discussing right now, because there's

a lot of anticompetition in the healthcare marketplace.

There's something known as "adverse selection." And that is that, when insurance companies just go and cherry-pick the desirable health-insured population so that they don't have to pay claims, that's, in effect, some of the worst anticompetition that you've ever seen. Or, where groups are not subject to regulation, such as—since regulation is normally done at the State level, by the State Department of Insurance—and their so-called out-of-State groups, not subject to that regulation, and they go in and get a group of people to insure by enticing them with very low rates, and then, over time, as that group gets older and older, and therefore it gets sicker and sicker, and they don't have any other place to turn to, and that insurer is unregulated—what do they do? They jack the rates up, and it puts the consumer in the position of not being able to afford the health insurance, and, now that they're older and sicker, they don't have any other place to turn to.

Now, what are—the practices going on in America today among health insurance are the most anticompetitive that we have—that you can imagine, that you could conjure up. And this is supposed to be—we embrace the free-market-competition model, and yet it

doesn't work.

So, thank you for calling this hearing.

Senator PRYOR. Thank you.

I want to introduce our panel today, and I want—again, I want to thank everyone for being here, making special arrangements to be here today.

And, what we're asking the panel to do is, if possible, limit their opening statements to 5 minutes. Then we will probably do a cou-

ple of rounds of questions.

And I want to thank you all for being here, but before I introduce the panel, I'd like to ask the Chairman of the full committee, Senator Rockefeller, if he'd like to make an opening statement.

STATEMENT OF HON. JOHN D. ROCKEFELLER IV, U.S. SENATOR FROM WEST VIRGINIA

The CHAIRMAN. Mindreader.

[Laughter.]

Senator PRYOR. Senator Rockefeller.

The CHAIRMAN. You sure it's OK? Has everybody made them? Am I interrupting protocol here?

Senator PRYOR. No. No, no, you're timing is good.

The CHAIRMAN. It's only—it's very short. It's only 4 pages.

OK. Good morning everyone. And I do apologize for messing

things up.

Healthcare is just so dominant these days, and some days we seem to surge ahead and some days we seem to surge backward. But, I do think there is going to be a healthcare bill, and actually, you all are very much a part of it, but not very much discussed as a part of it.

I think we've got to start with the soaring costs. The average American family pays twice as much for healthcare as they did 10 years ago. Just the mathematics of that are stunning. Healthcare is one of the top two reasons that people go into bankruptcy. They can't pay their healthcare premiums, bills, whatever, and can't pay off the insurance companies, and so, they go into bankruptcy. It's

true in Florida, West Virginia, Arkansas, and Mississippi.

I've heard stories from countless constituents forced into impossible circumstances by rising prices. My mind goes to a family in Fairmont whose 9-year-old son has leukemia and needs a bone marrow transplant, but they've reached their insurance policy premium—or limit—of what they can be paid, of \$1 million. And yes, that's a lot of money. But, insurance companies, whose profits have gone from something like \$2 billion to \$12 or \$14 billion in the last 6 years—health insurance—they won't budge, so the kid can't get any assistance, the parents have to live with this, the kid has to live with this, and it's just—it's heartbreaking and it's infuriating. One million is a lot, but leukemia is a lot, too.

Now, many factors contribute to these rising prices, and we all know that. The horrible reality is that a big reason behind rising healthcare costs is the coercive practices that manipulate the market, mask the true cost, burden healthcare consumers with even greater risks, while others reap the profits.

I have to let the record show that I'm very, very angry at insurance companies—health insurance companies. They're always the shark, swimming under the water, which can pull people down,

and do.

Last month, as our distinguished Chairman Pryor here knows, we had a series of Commerce hearings about a particular type of consumer, and that is consumers who go outside the plan. And people say, "Well, that must be 15- or 20,000." No, it's 100 million people. It's 100 million people. And without going into it a whole lot, it was all kinds of monopolistic and fraudulent, from my point of view, practices. Andrew Cuomo, the Attorney General of New York, caught that and allowed them to settle for \$350 million rather than what you perfectly well know would have happened; they would have been taken to court and charged with fraud and would have had to pay probably a lot more.

So, I'm not neutral on insurance companies. And it's clear that, for a decade or more, many of the largest insurance companies have plotted to fix those prices, skew their rates downward, significantly shortchange patients and doctors so that they could make

more money.

And I'm very proud, Mr. Chairman, of what the Committee did on that. We put out a wonderful report, which Bill Nelson can quote, from beginning to end. And this question of eliminating market manipulation, eliminating competition, is profoundly disturbing to me. It's one part of my unrelenting motivation to make insurance market reforms a fundamental piece of comprehensive healthcare reform, which it is not yet. It is not yet. For all the talk we've had in the Finance Committee and elsewhere, as Bill Nelson well knows—Senator Nelson well knows—there's been very little talk about insurance regulation and what we're going to do about it.

So, just to conclude, the FTC, which has already taken significant action, needs to be, in my judgment, much more aggressive with doctors and hospitals and pharmaceutical manufacturers and medical suppliers who manipulate the market, as well as insurance companies. The Commission needs resources and tools to maintain this downward pressure, and I want to question you on that. The Justice Department has been utterly lax over the last 8 years. I think of 400 merger cases that came before them, they turned down only three. It's just, "Let good times roll. Whoever can make the money, fine."

So, for too long, too many healthcare decisions have been made behind closed doors, with industry profits—not the patient's best interests—in mind. And if you come from any of the States we come from—and you have some very, you know, poor parts in your State—you have some wealthy parts, but you have some poor parts—people are poor, and it can—this cannot sustain itself. Government is here for a reason. And if you let insurance companies self-regulate. God belows all

self-regulate, God help us all. End of my statement.

Thank you Mr. Chairman.

Senator PRYOR. Thank you, Mr. Chairman. I'm glad you're here today, and I'm glad you're going to ask good questions. I appreciate your attendance here.

I would now like to introduce the panel. We have five very distinguished participants on the panel today. First is Mr. Richard Feinstein, Director of the Bureau of Competition, Federal Trade Commission. Then we have Dr. Len Nichols—and it's good to see you

again. He's Director of the Health Policy Program, New America Foundation. Then we have Mr. David Balto, Senior Fellow, Center for American Progress. And then we have Mark Riley, Executive Vice President of the Arkansas Pharmacists Association. And last, and certainly not least, we have Ms. Grace-Marie Turner, President of the Galen Institute.

Again, I want to welcome you all, and I'd like to recognize you for your 5-minute opening.

Mr. Feinstein?

STATEMENT OF RICHARD A. FEINSTEIN, DIRECTOR, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION

Mr. Feinstein. Thank you very much.

Chairman Rockefeller, Chairman Pryor, Ranking Member Wicker, and Members of the Subcommittee, I'm Richard Feinstein, Director of the Bureau of Competition at the FTC. I appreciate the opportunity to testify today on behalf of the Commission about the relationship between competition and antitrust enforcement, on the one hand, and lower healthcare costs and higher healthcare quality, on the other hand.

I should note for the record that the prepared written statement, which has been submitted for this hearing, represents the views of the Federal Trade Commission. My oral statement and my answers to questions today would represent my own views, but not necessarily those of the Commission, or any individual Commissioner.

I want to start by assuring you that, at the FTC, we share your deep concerns about the healthcare sector in the United States, and we have, frankly, no higher priority than protecting and promoting competition in that sector.

Antitrust enforcement contributes to the goal of delivering highquality, cost-effective healthcare in at least two ways. First, it prevents, or stops, anticompetitive agreements to raise prices, thus saving money that consumers, employers, and governments otherwise would spend on healthcare. Second, competition spurs innova-

tion that improves care and expands access.

The FTC has a long history of enforcing the antitrust laws in the healthcare sector and working to promote competition and efficient procompetitive arrangements. Today, I would like to briefly describe some of the Commission's recent efforts to promote competition in the healthcare sector, and, in particular, I want to address clinical integration among healthcare providers, healthcare mergers, and pharmacy benefit-management services, beginning with

price-fixing agreements and clinical integration.

The FTC recognizes that certain forms of collaboration among healthcare providers, such as clinical integration, have the potential to foster proconsumer innovations in healthcare organization. The FTC also works, however, to prevent anticompetitive agreements to fix the prices that healthcare providers charge. Such arrangements typically involve competing providers agreeing to charge the same high prices, and collectively refusing to serve a health plan's patients unless the health plan meets their fee demands. These agreements are likely to raise prices for the provider services without improving care. Such conduct was upheld as illegal by the U.S. Supreme Court in its 1982 Maricopa decision and

just last year, the Fifth Circuit, citing Maricopa, affirmed the FTC's conclusion that similar activities of a physician group in Texas were unlawful.

Now, appropriate enforcement of the antitrust laws should not impede new and potentially more efficient ways of delivering and financing healthcare services that can arise and compete effectively in the marketplace. Properly applied, antitrust standards distinguish between price-fixing by healthcare providers, which is likely to increase costs, and effective clinical integration among providers that has the potential to achieve cost savings and improve outcomes.

When analyzing these types of collaborations, we ask two basic questions. First, does the proposed collaboration offer the potential for proconsumer cost savings or qualitative improvements in the provision of the services? And second, are any price agreements—or other agreements among the participants regarding the terms on which they will deal with health plans—reasonably necessary to achieve those benefits? If the answer to both of those questions is "yes," then we consider any likely procompetitive or anticompetitive effects from the collaboration.

As long as the collaboration cannot exercise market power, which is typically what we have found, it is unlikely to raise significant antitrust concerns, because it has the potential to benefit consumers rather than harm them. Such collaborations often use electronic health records, and administrative and clinical support for care management and quality improvement, as means to achieve efficiencies and improve quality—to achieve efficiencies and improve quality. These are the same types of measures proposed by advocates of healthcare reform as ways to reduce costs and improve quality.

To aid providers considering these types of collaborations, the FTC and the Department of Justice Antitrust Division has issued statements of enforcement policy in healthcare to provide guidance. And we have also issued detailed advisory opinions on specific programs, when requested.

Let me turn now to healthcare mergers. The Commission has also worked vigorously to preserve competition in healthcare markets by challenging a number of proposed mergers and acquisitions involving hospitals, kidney dialysis clinics, drug manufacturers, pharmaceutical companies, and medical device manufacturers. A couple of recent examples: In 2007, the Commission found that a consummated merger in the Evanston, Illinois, area was anticompetitive because it resulted in substantially higher prices and a substantial lessening of competition in that market. More recently, a joint enforcement action by the FTC and the Virginia attorney general stopped a merger of two hospitals in Northern Virginia that, according to the complaint, would have resulted in control of 73 percent of the licensed beds in the area.

I realize I've hit 5 minutes. If I might just have another minute or two. Thank you.

And most recently, in May of this year, the Commission successfully challenged the proposed \$3.1-billion merger of two firms that supply plasma-derivative protein therapies.

Now let me turn to pharmacy benefit-management services or PBMs. Pharmacy services represent an important area of competitive concern, just like other parts of the chain of pharmaceutical marketing—manufacturing, marketing, and distribution. Thus, the FTC has engaged in law enforcement and competition advocacy to protect competition in the PBM sector, and to ensure that this competition benefits consumers. As described in more detail in the Commission's written testimony, there are circumstances where PBMs can help healthcare plans manage the cost and quality of the prescription drug benefits they provide to their enrollees. In the U.S., the PBM industry has evolved from one of numerous, smallclaims processing firms, to a more mature industry with comprehensive service offerings. Roughly 95 percent of patients in the United States with a drug benefit receive their benefits through a PBM. The FTC is mindful of the potential harm from aggregations of market power by purchasers in the healthcare sector, and actively monitors mergers in this industry.

Additionally, in 2005 the FTC conducted a conflict-of-interest study, at the request of Congress, regarding PBM practices. Among other things, the study examined whether PBM ownership of mailorder pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its report, the Commission found, among other things, that competition affords health plans substantial tools with which to safeguard their interests in lower prescription drug prices. The FTC staff has also analyzed and commented on proposed PBM legislation in several states.

Finally, the Commission's oversight of PBM industry participants is not confined to antitrust matters, but also includes vigorous enforcement of the FTC Act to protect consumer privacy. For example, CVS Caremark recently settled FTC charges that it had failed to take reasonable and appropriate security measures to protect the sensitive financial and medical information of its customers and employees, in violation of the FTC Act.

I appreciate this opportunity to share our views on these vitally important issues. We look forward to working with you, and I look forward to answering your questions.

Thank you very much, and thank you for your indulgence on the extra time.

[The prepared statement of Mr. Feinstein follows:]

PREPARED STATEMENT OF RICHARD A. FEINSTEIN, DIRECTOR, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION

I. Introduction

Chairman Pryor, Ranking Member Wicker, and members of the Subcommittee. I am Richard A. Feinstein, Director of the Bureau of Competition at the Federal Trade Commission (FTC). I appreciate the opportunity to testify on behalf of the Commission about the relationship between competition and antitrust enforcement, on the one hand, and lower health care costs and higher health care quality, on the other.¹ The magnitude of health care costs and the importance of health care quality demand our urgent attention. On a daily basis, millions of Americans require health care goods and services to maintain their basic quality of life. We have all seen the

¹This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

stories about the 46 million uninsured,2 and the fact that the U.S. health care system spends more per person, yet generates lower health care quality than health care services in many other developed countries.³ Health care costs burden both employees and employers, large and small, as well as Federal, state, and local govern-

ments that pay for care under various government programs.

Antitrust enforcement improves health care in two ways. First, by preventing or stopping anticompetitive agreements to raise prices, antitrust enforcement saves money that consumers, employers, and governments otherwise would spend on health care. Second, competition spurs innovation that improves care and expands access. Congress has charged the FTC with preventing unfair methods of competitions. tion and unfair or deceptive acts or practices in or affecting commerce,4 and the FTC

has been a cop on the beat in this area for the past 30 years.

The touchstone of the Commission's enforcement in this industry has been to stop practices that are likely either to increase costs or to limit competition that could improve the quality of health care. For example, the FTC has prevented anticompetitive agreements among health care providers to fix the prices they charge to a health insurance plan, conduct likely to raise prices without improving care.⁵ The Commission's enforcement efforts also have helped assure that new and potentially more efficient ways of delivering and financing health care services can arise and compete in the marketplace.⁶ The FTC has challenged hospital mergers that the Commission believed were likely to increase costs to consumers, such as the recently proposed merger of Inova-Fairfax and Prince William County Hospitals. After the Commission sued to enjoin that proposed merger in Federal district court, the parties decided to drop the deal.⁷ The FTC and its staff also have issued studies and reports regarding various aspects of the health care industry.⁸ and have analyzed competition issues raised by proposed state and Federal regulation of health care markets.9

Not surprisingly, some health care providers have long sought antitrust exemptions that would protect them against competitive pressures to lower costs and improve quality. The Commission consistently has opposed legislative proposals to exempt certain types of conduct, such as price fixing, from antitrust scrutiny, because such conduct will increase health care costs without benefiting consumers. 11

the Supreme Court has recognized the importance of competition and the application of anti-trust principles to health care.

11 See, e.g., FTC Statement Concerning H.R. 971, supra note 9 (criticizing proposal to exempt non-publicly traded pharmacies from antitrust scrutiny); Testimony of Robert Pitofsky, Chair-man, Federal Trade Commission, on H.R. 1304, the "Quality Health-Care Coalition Act of 1999" (June 22, 1999), available at http://www.ftc.gov/os/1999/06/healthcaretestimony.htm (regard-

² See U.S. Dep't of Commerce, U.S. Census Bureau, Income, Poverty, and Health Insurance Coverage in the United States: 2007, 19–20 (2008), available at http://www.census.gov/prod/2008pubs/p60-235.pdf (noting slight decrease from 2006-07, but a general increase in uninsured from 1987-2007).

sured from 1987–2007).

3 See, e.g., The Business Roundtable, The Business Roundtable Health Care Value Comparability Study, Executive Summary at 2 (2009), available at http://businessroundtable.org/sites/default/files/BRT%20exec%20sum%20FINAL%20FOR%20PRINT.pdf (observing 23 percent "value gap" relative to five leading economic competitors—Canada, Japan, Germany, the United Kingdom and France).

4 Federal Trade Commission Act, 15 U.S.C. § 45.

5 See Federal Trade Commission, FTC Antitrust Actions in Health Care Services and Products, available at http://www.ftc.gov/bc/hcupdate031024.pdf.

6 See infra note 30 and accompany.

⁷See infra note 30 and accompanying text.

⁷See infra note 30 and accompanying text.

⁸See, e.g., Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-order Pharmacies (Aug. 2005), available at http://www.ftc.gov/reports/pharmbenefit05/050906
pharmbenefitrpt.pdf [hereinafter PBM Study]; Federal Trade Commission, the Strength of Competition in the Sale of Contact Lenses: an FTC Study (2005), available at http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf; Federal Trade Commission and Department of Justice, Improving Health Care: a Dose of Competition (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf [Improving Health Care].

⁹See Prepared Statement of the Federal Trade Commission Before the Antitrust Task Force of the H. Comm. the Judiciary, Concerning H.R. 971, "the Community Pharmacy Fairness Act of 2007," 110th Cong. (Oct. 18, 2007), available at http://www.ftc.gov/os/testimony/P859910pharm.pdf [hereinafter FTC Statement Concerning H.R. 971] (criticizing proposal to exempt non-publicly traded pharmacies from antitrust scrutiny)

empt non-publicly traded pharmacies from antitrust scrutiny).

10 Some have argued that health care is "different," and that competition principles do not apply to the provision of health care services. Similar arguments that competition fundamentally does not work and is harmful to public policy goals have been uniformly rejected by the Supreme Court. See, e.g., F.T.C. v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990); National Society of Professional Engineers v. U.S., 435 U.S. 679 (1978). Beginning with the seminal 1943 decision in American Medical Association v. United States, 317 U.S. 519, 528, 536 (1943), the Supreme Court has recognized the importance of competition and the application of anti-

At the same time, as detailed below, the Commission has provided extensive guidance on how health care providers can collaborate in ways consistent with the antitrust laws, precisely because such collaborations have the potential to reduce costs

and improve quality.

The Commission recognizes that competition alone is not a panacea for all of the problems in health care markets. Although FTC antitrust enforcement has prevented anticompetitive conduct that would further increase health care costs, maintaining competition cannot alone achieve the health care reform goals on which Congress may agree. The Commission's purpose here is to explain that the FTC is a partner in efforts to reduce costs and improve quality in the delivery of health care. The testimony will describe how our activities in three important areas—(1) health care provider clinical integration, (2) proposed health care mergers involving hospitals, pharmaceutical manufacturers, and medical device manufacturers, and (3) pharmacy benefit management services (PBMs)—further those goals.¹²

II. Physician Services: Price Fixing vs. Clinical Integration

Some have suggested that the antitrust laws act as barriers to health care provider collaborations that could lower costs and improve quality. ¹³ That is simply wrong. Properly applied, antitrust standards distinguish between price fixing by health care providers, which is likely to increase health care costs, and effective clinical integration among health care providers that has the potential to achieve cost savings and improve health outcomes.

A. Price Fixing and Group Boycotts Are Likely to Raise Prices and Harm Consumers.

For more than 25 years, the Commission has challenged price-fixing and boycott agreements through which health care providers jointly seek to increase the fees that they receive from health care plans. 14 Such arrangements typically involve competing health care providers agreeing to charge the same high prices and collectively refusing to serve a health plan's patients unless the health plan meets their fee demands. Such conduct is considered to be *per se* unlawful because it is so likely to harm competition and consumers by raising prices for health care services and health care insurance coverage. Hence, in its 1982 *Maricopa* decision, the U.S. Supreme Court held that agreements among competing physicians regarding the fees they would charge health insurers for their services constituted per se unlawful horizontal price fixing. 15 Just last year, the Fifth Circuit, citing Maricopa, affirmed the Commission's conclusion that the activities of the North Texas Specialty Physicians, an organization of independent physicians and physician groups, amounted to horizontal price fixing that was unrelated to achieving any efficiencies such as cost savings or increased health care quality. 16

The Commission explained the clear consumer harms of health care price fixing agreements in 2007 testimony before Congress regarding a proposed antitrust ex-

emption for this type of conduct by certain health care providers: 1

The Commission's experience indicates that the conduct that the proposed exemption would allow could impose significant costs on consumers, private and

ing Federal legislation that would have exempted all health care workers from antitrust scrutiny); Letter from Federal Trade Commission Staff to the Hon. Dennis Stapleton, Ohio House of Representatives (Oct. 16, 2002) (criticizing proposed antitrust exemption for home health care providers), available at http://www.ftc.gov/os/2002/10/ohb325.htm.

12 On multiple occasions, the Commission has provided Congress testimony on the dangers of pay-for-delay patent settlements between brand and generic companies and the costs they impose on consumers, employers, and the government. To day, the Commission is providing testimony on other important areas of health care competition.

13 See, e.g., Letter from Michael D. Maves, MD, Exec . Vice President, CEO, American Medical Ass'n, to the Hon. William E. Kovacic, Chairman, Federal Trade Commission, regarding Physician Network Integration and Joint Contracting (June 20, 2008), available at http://www.ftc.gov/bc/healthcare/checkup/pdf/AMAComments.pdf ("We are extremely concerned with what we see as the significant regulatory barriers that restrict physicians' ability to collaborate in ways crucial to improving quality and containing costs"); cf. Timothy Stolzfus Jost and Ezekiel J. Emmanuel, Commentary: Legal Reforms Necessary to Promote Delivery System Innovation, 299 JAMA 2561, 2562 (2008) (suggesting that uncertainty about forms of clinical integration permitted under the antitrust laws "could deter attempts to create accountable health systems.")

14 See FTC Pursey of Commenting Overview of FTC Antitwet Actions in Health Core Services.

tion permitted under the anatoms and state thems.")

14 See FTC Bureau of Competition, Overview of FTC Antitrust Actions in Health Care Services and Products, available at http://www.ftc.gov/bc/0608hcupdate.pdf.

15 Arizona v. Maricopa County Medical Soc'y, 457 U.S. 332, 356-57 (1982).

16 In the Matter of North Texas Specialty Physicians, FTC Dkt. No. 9312 (Nov. 2005) (Opinion of the Commission), available at http://www.ftc.gov/os/adjpro/d9312/051201opinion.pdf, affd sub nom. NTSP v. F.T.C., 528 F.3d 346 (5th Cir. 2008), cert. denied, 129 S. Ct. 1313 (U.S., Feb. 23, 2009) (No. 08-515).

17 See FTC Statement Concerning H.R. 971, supra note 9.

governmental purchasers, and taxpayers, who ultimately foot the bill for government-sponsored health care pro grams. Past antitrust challenges to collective negotiations by health care professionals show that groups have often sought fee increases of 20 percent or more. For example, in 1998, an association of approximately 125 pharmacies in northern Puerto Rico settled FTC charges that the association fixed prices and other terms of dealing with third-party payers, and threatened to withhold services from Puerto Rico's program to provide health care services for indigent patients. According to the complaint, the association demanded a 22 percent increase in fees, threatened that its members would collectively refuse to participate in the indigent care program unless its demands were met, and thereby succeeded in securing the higher prices it sought.18

As this excerpt shows, antitrust enforcement against agreements that have no purpose except to increase the fees received by the health care providers involved are not only consistent with, but also reinforce, the cost-reducing goals of any health care reform.

B. The Antitrust Laws Promote Health Care Collaborations that Can Reduce Costs and Improve Quality.

The antitrust laws treat collaborations among health care providers that are bona fide efforts to create legitimate, efficiency-enhancing joint ventures differently. The Commission asks two basic questions with respect to such collaborations. First, does the proposed collaboration offer the potential for pro-consumer cost savings or qualitative improvements in the provision of health care services? Second, are any price or other agreements among participants regarding the terms on which they will deal with health care insurers reasonably necessary to achieve those benefits? If the answer to both of those questions is "yes," then the collaboration is evaluated under an antitrust standard that takes into account any likely procompetitive or anticompetitive effects from the collaboration. 19 As long as such collaborations cannot exercise market power, they are unlikely to raise significant antitrust concerns, precisely because they have the potential to benefit, not harm, consumers.

The FTC and the Department of Justice Antitrust Division is sued Health Care Statements in 1993, and supplemented them in 1994 and 1996,20 to provide guidance about the antitrust analysis the agencies will apply to various types of health care arrangements. As noted in the 1996 Health Care Statements, "[n]ew arrangements and variations on existing arrangements involving joint activity by health care providers continue to emerge to meet consumers', purchasers', and payers' desire for more efficient delivery of high quality health care services." ²¹ Statement 8 explains that bona fide clinical integration by health care providers with the potential for significant cost savings and quality improvements may be demonstrated by:

the network [of health care providers] implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.25

In recent years, FTC staff have issued detailed advisory opinions on such programs to help inform the industry and demonstrate that the antitrust laws are not a barrier to bona fide arrangements to improve quality and control costs through

¹⁸ See FTC Statement Concerning H.R. 971, supra note 9 (internal citations omitted).

19 This standard is known as the "rule of reason." See Maricopa County Medical Soc., supra note 15, at 343 ("since Standard Oil Co. of New Jersey v. United States, 221 U.S. 1 (1911), we have analyzed most restraints under the so-called 'rule of reason.' As its name suggests, the rule of reason requires the factfinder to decide whether under all the circumstances of the case the

or reason requires the facthinger to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.") 20 U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy In Health Care (1996), available at http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm [hereinafter Health Care Statements]. 21 Id. at 2.

²² Health Care Statements at Statement 8, § B.1.

clinical integration.²³ In evaluating health care collaborations that claim likely efficiencies from clinical integration, FTC staff have focused on the programs' structure. tural capabilities, systems, and processes for achieving such efficiencies, and the motivations and incentives for the participants to embrace the programs' goals. 24 Such collaborations often use programs such as electronic health records 25 and administrative and clinical support for care management and quality improvement, as means to achieve efficiencies and improved quality through, for example, collaboration among clinicians to create guidelines, measure their performance in relation to those guidelines, and agree on remedial measures and consequences for failures to achieve certain performance goals. These are the same types of measures proposed by advocates of health care reform as ways to reduce costs and improve quality.26 As shown here, antitrust standards for evaluating health care collaborations also are consistent with and supportive of the goals of health care reform to reduce costs and improve quality.

III. Increased Merger Scrutiny

The Commission has worked vigorously to preserve competition in health care markets via merger scrutiny as well. The FTC has challenged a number of proposed mergers and acquisitions involving, for example, hospitals, drug manufacturers, and medical device manufacturers.

Several recent hospital merger enforcement actions highlight the Commission's ongoing focus on competition among hospitals. If a hospital acquisition deprives patients of choices for health care, it can increase the health care costs to both patients and employers that purchase health insurance. For example, in 2007, the Commission ruled that Evanston Northwestern Healthcare Corporation's consummated acquisition of its competitor, Highland Park Hospital, was anticompetitionally and the competition of the competition o tive ²⁷ because the acquisition resulted in substantially higher prices and a substantial lessening of competition for acute care inpatient hospital services in parts of Chicago's northern suburbs. ²⁸ This challenge was based, in part, on information gathered during an empirical review of various consummated hospital mergers to examine their impact on markets; that review has found compelling evidence of adverse effects from mergers in certain instances.²⁹ More recently, a joint enforcement action by the FTC and the Virginia Attorney General stopped a merger of two hospitals in northern Virginia that, according to the complaint, would have resulted in control of 73 percent of the licensed hospital beds in the area.³⁰

²³ See, e.g., Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal (Sept. 17, 2007) [hereinafter GRIPA letter], available at http://www.ftc.gov/bc/adops/gripa.pdf. 24 See note 25 supra.

²⁵Clinical integration programs frequently use sophisticated health information technology (HIT) systems to help them implement their programs. However, the use of HIT systems or electronic health records alone is not sufficient to establish that a group has clinically integrated.

tronic health records alone is not sufficient to establish that a group has clinically integrated. It is how the collaboration uses those tools that counts for the antitrust analysis.

26 Elliot S. Fisher et al., Achieving Health Care Reform—How Physicians Can Help, 360 New Eng. J. Med. 2495, 2496 (2009); see also, e.g., TriState Letter, supra note 23 (discussing webbased HIT system, software, and clinical guidelines and review proposal); GRIPA Letter supra note 23 (regarding GRIPA's tablet computer, HIT system, and data sharing proposal).

27 In the Matter of Evanston Northwestern Healthcare Corp., FTC Docket No. 9315 (Aug. 6, 2007) (Opinion of the Commission), available at http://www.ftc.gov/os/adjpro/d9315/070806opinion.pdf (upholding with some modifications an October 2005 Initial Decision by an FTC Administrative Law Judge).

28 In the Matter of Evanston Northwestern Healthcare Corp., FTC Docket No. 9315 (Oct. 20, 2005) (initial decision), available at http://www.ftc.gov/os/adjpro/d9315/051021id textversion.pdf.

^{2005) (}initial decision), available at http://www.ftc.gov/os/adjpro/d9315/051021id textversion.pdf.

29 See, e.g., Farrell, J., Pautler, P., and Vita, M, Economics at the FTC: Retrospective Merger Analysis With a Focus on Hospitals, Rev. of Indus. Org. (2009), forthcoming) (reviewing project and related FTC working papers); Steven Tenn, The Price Effects of Hospital Mergers: A Case Study of the Sutter-Summit Transaction, Federal Trade Commission Bureau of Economics Working Paper No. 293 (2008), available at http://www.ftc.gov/be/workpapers/wp293.pdf; Deborah Haas-Wilson and Christopher Garmon, Two Hospital Mergers on Chicago's North Shore: A Retrospective Study, Federal Trade Commission, Bureau of Economics Working Paper No. 294 (2009), available at http://www.ftc.gov/be/workpapers/wp294.pdf; Alleen Thompson, The Effect of Hospital Mergers on Inpatient Prices: A Case Study of the New Hanover-Cape Fear Transaction, Federal Trade Commission Bureau of Economics Working Paper No. 295 (2009), available at http://www.ftc.gov/be/workpapers/wp295.pdf.

30 See In the matter of Inova Health System Foundation and Prince William Health Systems, Inc., FTC Docket No. 9326 (Jun. 17, 2008) (Order dismissing complaint), available at http://www.ftc.gov/os/adjpro/d9326/080617orderdismisscmpt.pdf.

The Commission also has acted to protect competition among kidney dialysis clinics to provide services to dialysis patients. In September 2007, the Commission challenged an agreement between two major dialysis clinics with facilities in the northeastern United States, American Renal Associates, Inc. (ARA) and Fresenius Medical Care Holdings, Inc. (Fresenius). Pursuant to that agreement, ARA would have paid Fresenius to close certain clinics nearby to competing ARA clinics, and ARA would have acquired other competitive Fresenius clinics. The Commission alleged that this agreement would have eliminated direct competition between ARA and Fresenius and resulted in ARA operating the only dialysis clinics in certain local markets in Rhode Island and Massachusetts. The parties terminated their agreement after Commission staff objected, and a Commission order prevents the parties from entering into similar agreements in the future.³¹

The Commission's merger scrutiny extends to other health care markets as well, including pharmaceuticals and medical device manufacturing. For example, in 2006, the Commission settled charges that Barr's proposed acquisition of Pliva would have eliminated current or future competition between Barr and Pliva in certain markets for generic pharmaceuticals treating depression, high blood pressure and ruptured blood vessels, and in the market for organ preservation solutions by requiring that Barr divest itself of certain key products.³² In the medical device arena, the Commission charged that the merger of Boston Scientific and Guidant would have harmed competition and consumers in several coronary medical device markets.33 In that matter, a consent agreement was achieved under which Guidant divested itself of intellectual property, plants, manufacturing technology, and other assets that had raised competitive concerns.³⁴

IV. Pharmacy Benefit Management (PBM) Services

PBM services are another health care industry area in which the Commission has engaged in law enforcement, competition advocacy, and policy development, to ensure that competition benefits consumers. PBMs can help health care plans manage the cost and quality of the prescription drug benefits they provide to their enrollees. To varying degrees PBMs:

- negotiate rebates from pharmaceutical manufacturers;
- provide access to mail order pharmacies for health plan enrollees on maintenance medications;
- develop drug formularies 35 and help plan sponsors determine which drugs should be on the plan's formulary and whether and how to provide co-payment incentives to the plan's enrollees to use those drugs;
- · provide drug utilization reviews that include analyses of physician prescribing patterns to identify physicians prescribing high-cost drugs when lower cost, therapeutically equivalent alternatives are available; and
- · provide disease management services by offering treatment information to and monitoring of patients with certain chronic diseases.

In the U.S., the PBM industry has evolved from one of numerous, small claims processing firms to a more mature industry with comprehensive service offerings. Roughly 95 percent of patients in the United States with a drug benefit receive their benefits through a PBM. There are approximately 40 to 50 PBMs operating in the United States, with three large, full-service PBMs of national scope: Medco, Express Scripts, and Caremark.³⁶ In addition to these three PBMs, several large insurers

³¹ In the Matter of American Renal Associates, Inc., FTC Dkt. No. C-4202 (Oct. 17, 2007) (decision and order), available at http://www.ftc.gov/os/caselist/0510234/071023decision.pdf.

³² In the Matter of Barr Pharmaceuticals, Inc., FTC Dkt. No. C-4171 (decision and order) (Nov. 22, 2006), available at http://www.ftc.gov/os/caselist/0610217/0610217barrdo

⁽Nov. 22, 2006), available at http://www.ftc.gov/os/caselist/0610217/061021/barrao_final.pdf.

33 In the Matter of Boston Scientific Corp. and Guidant Corp., FTC Dkt. No. C-4164 (complaint) (Apr. 20, 2006), available at http://www.ftc.gov/os/caselist/0610046/0610046cmp

¹⁰⁴²c.pq 34In the Matter of Boston Scientific Corp. and Guidant Corp., FTC Dkt. No. C-4164 (decision ad order) (Jul. 21, 2006), available at http://www.ftc.gov/os/caselist/0610046/060725 do0610046.pdf.

³⁵A formulary is a list of plan sponsor-approved drugs for treating various diseases and conditions. This list will often be broken down into "tiers," which correspond to different co-payment levels for enrollees. For instance, a three-tier formulary may consist of a generic tier, a preferred brand tier, and a non-preferred brand tier. Whether a brand is preferred may depend on whether a generic alternative is available and also upon the financial terms available to the PBM on the care of the care the properties along.

drugs in the same therapeutic class.

³⁶ See PBM Study, supra note 8, at 2–3.

manage pharmacy benefits internally. Large retail supermarket/pharmacy chains also own PBMs, and several local and regional PBMs can compete with national PBMs for contracts with smaller employers or health plans that are geographically limited.³⁷ The three large national PBMs are the major players in many regional markets, but typically one-third to one-half of each market is serviced by other, smaller PBMs. The FTC found, in its most recent antitrust investigation of the PBM. industry, that competition among PBMs for contracts with plan sponsors is "vigorous.'

Pharmacy services—like other parts of the chain of pharmaceutical manufacturing, marketing, and distribution—represent an important area of competitive concern, given the large and increasing share of health care spending devoted to pharmaceuticals. Ongoing Commission scrutiny of competitive issues in the PBM area—including those posed by both private conduct and public intervention—is es-

sential to maintaining the benefits of competition for consumers.

Of particular relevance is the Commission's "Conflict of Interest Study" regarding PBM practices. In response to a request from Congress, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study (PBM Study), the FTC found, among other things, that constitute of such south that the constitution of the study is the state of the study of the study in the study is the state of the study of the study in the study is the state of the study of the study is the state of the study of the study of the study is the state of the study of t that competition affords health plans substantial tools with which to safeguard their interests in lower prescription drug prices.39

The FTC is mindful of the potential harm from aggregations of market power by purchasers in the health care sector. In 2004, the FTC conducted a thorough investigation of Caremark Rx's acquisition of Advance PCS, two large national PBM firms. As part of its analysis, the agency carefully considered whether the proposed acquisition would be likely to create monopsony power with regard to PBM negotiations with retail pharmacies and ultimately determined it would not. The Commission closed the investigation because it concluded that the transaction was unlikely to reduce competition.⁴⁰ In addition, FTC staff have analyzed and commented on

proposed PBM legislation in several states.⁴¹

The Commission's oversight of PBM industry participants is not confined to anti-trust matters, but also includes vigorous enforcement of the FTC Act to protect con-sumer privacy. For example, CVS Caremark recently settled FTC charges that it had failed to take reasonable and appropriate security measures to protect the sensitive financial and medical information of its customers and employees in violation of the FTC Act. 42 The Commission will remain vigilant not only in policing competitive markets, but also in engaging in strong consumer protection enforcement.

IV. Conclusion

Thank you for this opportunity to share the Commission's views on these vitally important issues. The Commission looks forward to working with the Subcommittee to ensure that competitive health care markets deliver on the promise of competitively priced health care goods and services and increased innovation and quality.

Senator PRYOR. Thank you.

³⁷See Improving Health Care: a Dose of Competition, supra note 8, at 14–15 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf; Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, at 16 (Mar. 2005), at http://www.healthstrategies.net/research/docs/Follow_the_Pill.pdf.

³⁸In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 0310239 n. 6 (Feb. 11, 2004) (statement of the Commission), available at http://www.ftc.gov/os/caselist/0310239/040211 ftcstatement0310239.pdf. The Commission closed the investigation because it concluded that the transaction was unlikely to reduce competition.

³⁹PBM Study. supra note 8, at 58 (noting diverse audit rights and reporting under PBM con-

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³⁹ PBM Study, supra note 8, at 58 (noting diverse audit rights and reporting under PBM contracts).

40 In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 0310239 n. 6 (Feb. 11, 2004) (statement of the Commission), available at http://www.ftc.gov/os/caselist/0310239/040211 ftcstatement0310239.pdf.

41 See, e.g., Letter from FTC staff to Hon. Nellie Pou, New Jersey Assembly (Apr. 17, 2007), available at http://www.ftc.gov/be/V060019.pdf; Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), available at http://www.ftc.gov/be/V060018.pdf.

42 In the Matter of CVS Caremark Corp., FTC Dkt. No. C-4259 (Feb. 18, 2009) (decision and order), available at http://www.ftc.gov/os/caselist/0723119/090623cvsdo.pdf (respondent allegedly "discarded materials containing personal information in clear readable text (such as prescriptions, prescription bottles, pharmacy labels, computer printouts, prescription purchase refunds, credit card receipts, and employee records) in unsecured, publicly-accessible trash dumpsters on numerous occasions.") Respondent independently agreed to pay \$2.25 million to resolve HHS allegations that it violated HIPAA.

Dr. Nichols?

STATEMENT OF LEN M. NICHOLS, Ph.D., DIRECTOR, HEALTH POLICY PROGRAM, NEW AMERICA FOUNDATION

Dr. Nichols. Chairman Pryor, Chairman Rockefeller, Ranking Member Wicker, indeed an honor to be here today to be talking about competition in the healthcare marketplace. It's a particular honor to be before you, Chairman Pryor, because we share roots. I met your father in my father's store when I was 8 years old, so we go way back.

[Laughter.]

Dr. NICHOLS. When you think about the healthcare marketplace, you know, you think we do have some of the very best clinicians and hospitals, nurses, in the world. The Saudi princes still do come here. But, we don't get anywhere near the market performance we should be getting. Fundamentally, we have prices way above costs, we are not delivering the right quality at the right time, we're probably doing too much of a lot of stuff and not enough of other stuff. And our cost structures are not efficient. The most amazing thing, though, to an economist is, there's no natural self-correcting mechanism. In most markets, when those prices are out of line, entry occurs, something changes, and we move price to cost, and indeed, often, technology lowers cost over time. In healthcare, we're stuck.

And when prices are stuck, policymakers basically have three options. You can use antitrust and some kind of competitive innovation, like a public plan; you could use the buying power of the Federal Government, if you can—and in our case, we can, because of the Medicare program; and you could use direct regulation of prices.

Now, I know everyone on this panel—I know Grace-Marie very well—we work very hard to avoid direct price regulations. That's why we're here. We're trying to figure out ways to change the rules so we don't have to use price controls, because there are better ways. But, it's all about you being able to change the rules to channel self-interest to serve the public interest in a way we all share—the goals.

So, let me spend the rest of my time talking about the three markets where I think we have the biggest problems, and then I'll be

glad to answer questions later.

The first market is the one where we spend the most money, and that is in hospitals. Now, let me hasten to add, all the people who work in hospitals are doing the best they can under the circumstances they operate under. They don't have time to think about the economist's criteria for optimal pricing. But, what we know is—and it's stunning to a simple country health economist like myself, to learn this—the variance in efficiency across our Nation's hospitals is stunningly large. The Medicare Pricing Advisory Commission, MedPAC, just put out some data that I think all of you should just go home and absorb. And it shows that two-thirds of our hospitals today lose money on Medicare. Yet they conclude—and I certainly agree—that does not mean Medicare underpays. It means that two-thirds of our hospitals are actually not very efficient at all, because one-third of our hospitals do make money on

Medicare. But, here's the amazing thing. Of those hospitals who lose money on Medicare, they end up making the largest net margin, because they charge private payers so much more, because they can.

Let me say that one more time. Our least efficient hospitals in our Nation have the largest average margins, in total, because they make up for what, for them, is the Medicare, and often Medicaid, underpayment with higher prices in the private sector, which is why healthcare costs so much and why so many people are becoming uninsured all the time. So, that's a clear, fundamental problem.

Now, in—what the MedPAC did was analyze these margins by competitive market. So, what they discovered was, the least competitive markets are the markets where the Medicare margins are the lowest—in some cases, minus—20 percent. But, they make it up by charging more than 20 percent higher than cost to the private sector, and therefore they end up with the largest margins. What—that's only possible when those hospitals have incredible local market power. Hence, the cry for antitrust relief.

The problem is—and I will just say, for the record, these guys tried, and they failed, because a lot of judges couldn't quite get around the prospect that nonprofit hospitals can do this. And so, they just basically lost the cases, even though the evidence was overwhelming. And now, I understand they're doing retrospective

studies, which I highly support.

And my point is, antitrust can't really help us solve the problem of local market power if there's just one hospital system that domi-

nates. We have got to think about other tools.

Simply put, we have no choice but to do Medicare payment reform. And Medicare payment reform is not about whacking prices, because we already know these hospitals are losing money off Medicare. They'll just charge private payers more. What you've got to do—and this is what I urge you to do in this Committee—think hard about incentives. We've got to change the way we pay—not so much the level, but the way we pay—to change incentives. And that's the general theme I'll apply across all these markets.

In the physician marketplace, I think it's fair to say, we all would agree very quickly, we underpay primary care. And there's lots of ways to think about how to fix that, so I'm not going to belabor that point, because we all agree. The place that I think that we've had not enough attention is—when you think about payment reform and prices that are distorted, we want to think beyond just the doctor's office. We've got to think the incentives that have been created to invest in certain kinds of capital equipment, which lead to too much utilization, which lead to too much spending.

You know, I grew up in the Delta. I know a lot about that Mississippi/Arkansas/Louisiana corridor. You look at the data on

where we spend a lot more per capita than other places in the country, and it pretty much follows the river. Now, why is that? Well, it's because a lot of people down there have invested in machines that are—you know, they think they're doing the right thing and all that, but they're doing too much of an awful lot, and we're beginning to figure that out, and we've got to figure out how to deal

with that.

The final market I'll talk about is insurance, because I think Senator Rockefeller and Senator Nelson, in their opening statements, absolutely hit the ball out of the park, here. If we don't fix the insurance market, none of the rest of this is going to work. And we clearly need to change regulation. And I won't belabor the point, because we probably agree about that. They've got to sell to all

comers and they can't discriminate based on health.

But, a more, I would say, difficult problem to solve is the problem where they have effective monopoly power and there's no competition where they are. And I'll give you a prime example right there in Arkansas, where we're from. BlueCross of Arkansas—fine company—has a 75-percent market share in the small-group market. United, today, has a 6-percent market share. That's the single closest competitor. Five years ago, when I studied that market professionally, it had a 12-percent market share, so BlueCross is gain-

ing.

Now, what is the deal? Why isn't there entry to try to bring more competition? Because in Arkansas, BlueCross BlueShield of Arkansas pays physicians—I'll just put it this way—very, very well, far above what Medicare pays. So, the competitor companies can't entice physicians to join a new network, so their dominance continues. Well, they're not doing anything illegal, and they're fine people, they buy full-color ads in every high school yearbook, you know; they're good people. But we're stuck with this very high price. People of Arkansas are uninsured. Twenty-nine percent of small businesses in Arkansas offer, compared to 43 percent nation-

wide, because prices are so high relative to income.

So, what do you do? Well, in my view, you—that's where the public plan is in, sort of, the perfect intervention, because what the public plan can do—let's just imagine, when you change market rules, who's going to not like that? It's going to be the companies that are doing very well right now. So, we change market rules. They're going to say, "Hmm. I'm still a big, dominant seller. I'm going to bid high, and blame government regulation on this high premium." And you know, it would work, if we had no counterargument. But, if you had the possibility of having an actuarially fair premium bid by a company competing on a level playing field—got to be created by you, but it can then be on a level playing field—that actuarially fair bid threat will prevent BlueCross from having total power to charge what they want. And therefore, it'll make BlueCross bid the right amount. In a sense, the threat of the public plan means you don't really need it, but if you don't have the threat, you will not have an outcome that you like.

So, I submit to you, there are lots of things you can do to make markets work better, and that's what we want to do and avoid

price regulation.

Thanks for the indulgence. Thank you very much. [The prepared statement of Dr. Nichols follows:]

PREPARED STATEMENT OF LEN M. NICHOLS, PH.D., DIRECTOR, HEALTH POLICY PROGRAM, NEW AMERICA FOUNDATION

Introduction

Chairman Pryor, Ranking Member Wicker and other distinguished Members of this Committee and Subcommittee, thank you for inviting me to offer my thoughts

today about how to improve the performance of health service markets. My name is Len M. Nichols. I am a health economist and I direct the Health Policy Program at the New America Foundation, a non-profit, non-partisan public policy research institute based in Washington, D.C., with offices in Sacramento, California. Our program seeks to nurture, advance, and protect an evidence-based conversation about comprehensive health care reform. We remain open minded about the means, but not the goals: all Americans should have access to high-quality, affordable health insurance and health care that is delivered within a politically and economically sustainable system. The best way, though not the only way, to accomplish these goals is to ensure reform legislation earns bipartisan support. I am happy to share ideas for your consideration today and hereafter with you, other members of the Committee, and staff.

The United States has some of the best clinicians and facilities in the world. We are the source of much of the world's innovations in health care products and services. Yet, despite the fact that more than 16 percent of our population is uninsured,1 we spend almost twice as much per person as our competitors. In addition, the United States has considerably shorter life expectancy and performs poorly on other population health summary measures. The World Health Organization ranks us number 32 (between Slovenia and Costa Rica) in terms of overall system performance, countries with 64 percent and 23 percent of our per capita GDP respectively.2

In economic terms, we pay more on average than the cost of efficient production. In fact, much of our production is amazingly inefficient. As a consequence of both problems, many patients receive care that is of sub-optimal quality. In short, we get very poor value for our health care dollars.

U.S. Health Care Markets

Why do U.S. health care markets underperform?

Asymmetric information among insurers, clinicians, and patients, third-party payment incentives, and local provider market power are known to be the root causes of poor health service market performance.³ These causes are very complicated to explain. Indeed, since "one person's excess cost is someone else's income." 4 our cultural reluctance to intervene in markets allows this poor performance to perpetuate itself.

In addition, our health care markets lack a natural self-correcting mechanism to help drive prices to the efficient cost level and quantities to optimal quality quantities over time. In most markets, deviations from optimal price and quality levels are reduced or erased by new competitors, changes in market share, or technical innovations that lower the cost of production over time. In the U.S. health care system, however, poor market performance is perpetuated decade after decade after decade.

To what extent do U.S. health care markets underperform?

Algebra can help us estimate the order of magnitude of our sub-par performance. Let P be the average price level of health services, and P* be the level we want. Let Q be the quantity of services, and Q^* the optimal quantity of appropriate quality services. Let C be the average cost of a unit of Q, and C^* the efficient cost of producing Q. In textbook equilibrium, $P^* = C^*$.

Table 1. Health Care Spending Variables

Variable	Definition
P	The average price level of health services. This tells us what a given procedure is likely to cost.
P*	The optimal price level of health services. This is the price level that would maximize the efficiency of our health care markets—where prices would be equal to costs. The goal is to move from price level P to level P^* .

¹The uninsured also receive roughly half as much as care as the insured.
²International Monetary Fund, "World Economic Outlook Data base—April 2009," Accessed on July 12, 2009. Data refer to the year 2008.
³Martin Gaynor, "What Do We Know About Competition and Quality in Health Care Markets?" National Bureau for Economic Research, April 5, 2006; Paul B. Ginsburg, "Cut Medicare with a Scalpel," New York Times, July 12, 2009; Len M. Nichols, Paul B. Ginsburg, Robert A. Berenson, Jon Christianson, and Robert E. Hurley, "Are Market Forces Strong Enough To Deliver Efficient Health Care Systems? Confidence Is Waning," Health Affairs 23, no. 2 (March/April 2004): 8–21.

April 2004): 8-21.

⁴ A wonderfully apt phrase first coined by Prof. Uwe Reinhardt of Princeton University.

Table 1. Health Care Spending Variables—Continued

Variable	Definition
Q	The quantity of health care services currently provided. Q measures how much health care is provided within a marketplace.
Q*	The optimal quantity of appropriate quality health services. This quantity of services would be the most efficient level where we are still receiving high-quality care.
С	The average cost of a unit of Q. In effect, this measures the cost to provide a unit of health care, which is distinct from the price we pay for a unit of health care.
C*	The efficient cost of producing a unit of Q. This would be the cost at which we are providing enough, high-quality care at the most efficient cost.
PQ	Actual health spending (price times the quantity of health care provided).
P*Q*	The optimal level of health spending (optimal price times the optimal quantity of care provided).

In a perfectly competitive market that is performing optimally, prices would be driven to the efficient cost level.⁵ Spending would be $P^*Q^* = C^*Q^*$. By contrast, actual health spending is PQ. Therefore, the ratio of actual health spending to optimal health spending is

$$PQ/C*Q* = (P/C)(Q/Q*)(C/C*)$$

This is a symbolic way of illustrating that our excess spending can be split into three distinct parts:

- *Non-competitive pricing:* the ratio of price to cost (P/C)
- Poor quality: the degree to which quantity or the wrong quantity does not make patients healthier (Q/Q*)
- Inefficiency: the ratio of actual average cost to efficient average cost (C/C*)

Specific research quantifies each of the three areas:

- Non-competitive pricing: the McKinsey Global institute estimates that our health service and product prices are 50 percent higher than those of other countries $(P/C = 1.5)^6$
- Poor quality: researchers at Dartmouth, the National Academy of Engineering, and the Institute of Medicine agree that about 30 percent of our services do not improve health $(Q/Q* = 1.3)^7$
- Inefficiency: the Medicare Pricing Advisory Commission (MedPAC) estimates that efficiency in our hospital sector, which represents the single largest share of our health dollars, varies by at least 25 percent (C/C* = 1.25)

It is not unreasonable to argue that we pay roughly 2.4 times more than we should for health care when you combine these estimates by using the equation developed above.

$$\mathrm{PQ/C*Q*} = (\mathrm{P/C})(\mathrm{Q/Q*})(\mathrm{C/C*})$$

2.4 = (1.5)(1.3)(1.25)

Tools for Reform

This decomposition—non-competitive pricing, poor quality, and inefficiency—helps illustrate that it will be necessary for specific policies to be aimed at each element of our excess spending problem. It also shows how cost, quality, and prices are linked.

⁵ Where cost includes a normal profit to cover the cost of capital.

⁵Where cost includes a normal profit to cover the cost of capital.
⁶Note: I assume other countries are not efficient producers either * > C* there, too); McKinsey Global Institute, "Accounting for the Cost of U.S. Health Care: A New Look at Why American Spend More," November 2008.

⁷Elliott S. Fisher et al, "The Implications of Regional Variations in Medicare Spending, Part I: The Content, Quality, and Accessibility of Care," Annals of Internal Medicine 138 (2003): 273–287; Elliott S. Fisher et al, "The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care," Annals of Internal Medicine 138 (2003): 288–298; National Academy of Engineering and Institute of Medicine, Building a Better Delivery System, (Washington D.C.: National Academies Press, 2005).

⁸Medicare Pricing Advisory Committee, "Report to the Congress: Medicare Payment Policy," March 2009.

When prices are stuck far from the efficient cost level, policymakers have three basic tools at their disposal:

- 1. Change rules related to market entry and structure to engender more market competition (e.g., antitrust)
- 2. Use countervailing market buying power (monopsony) to counter local provider market power and resistance to change
- 3. Impose direct regulation of prices or specific behaviors of competitors

In the remainder of my testimony, I will argue that all three are necessary to address specific market problems and achieve the salient goals of health system reform: cover all Americans and make our delivery system sustainable. Specifically, I will explore hospital, physician, and insurance markets to illustrate how each policy approach can be useful in improving health care markets.

Hospital Markets

Impact of Competition on Medicare Efficiency

Let me be clear: most hospitals and the people who work in them do not have time to worry about the economic optimality of market-wide performance. In many ways, they are doing the best they can by their patients given our inefficient system and its perverse incentives. Some leaders and organizations do amazingly well. By and large, however, we are getting the results we should expect from the rules and incentives our policies have created.

Hospital markets are heterogeneous. In general, they illustrate both the promise and problems in health service markets. The March 2009 MedPAC report to Congress helps illustrate how price, efficiency, quality, and competition are linked. The report finds that 72 percent of hospitals lose money on Medicare. Some infer from this that Medicare underpays hospitals. Thus, the solution must be for Medicare to adjust its prices upward. This is not, however, how MedPAC interprets the full set of data at their disposal.

Instead, MedPAC characterizes hospitals by the competitiveness of the market-place in which they operate. ¹⁰ According to MedPAC, a hospital is in a "high-pres-sure" market if their non-Medicare operating margin ¹¹ is 1 percent or less and if their net worth would grow by 1 percent or less if their Medicare margin were zero. These hospitals depend on Medicare for growth and financial success. By contrast, a market is "low pressure" if hospitals have non-Medicare margins of at least 5 percent and if their net worth would grow by more than 1 percent if their Medicare margin were zero. These hospitals lose money on Medicare and depend on private payers for financial strength. "Medium pressure" hospitals are those whose margins and net worth paths fall in between.

Table 2. Median Hospital Operating Margins In Markets Arraved By Competitive Pressure

	High pressure	Medium pressure	Low pressure
Medicare margin	4.2%	-3.8%	-11.7%
Non-Medicare margin	-2.4%	4.5%	13.5%
Share of all hospitals	28%	14%	58%
Share of large teaching hospitals	53%	18%	29%
Share of all discharges	27%	37%	36%

Source: MedPAC March 2009 Report to Congress, table 2A-7, p. 61.

Hospitals with negative Medicare margins compensate for Medicare shortfalls by charging other payers more to achieve very large non-Medicare margins. This is possible because of their local market power vis-à-vis private payers, commercial insurers, and self-insured employers alike.

In the most competitive markets, however, non-Medicare margins are negative. As a result of competition in these markets, hospitals cannot compensate for negative Medicare margins with large, positive non-Medicare margins. Therefore, their posi-

⁹To be perfectly optimal, the market must have distributed all goods and services in a way 10 be perietry optimal, the market must have distributed all goods and services in a way that maximize everyone's happiness. In a non-optimal situation, even just one person's happiness could be increased by a different distribution of goods.

10 They do not judge competitiveness like antitrust authorities (e.g., using Herfindahl-Hirshman index scores), but rather they adopt a more performance-based standard.

11 The non-Medicare margin includes private, Medicaid, and uninsured patients.

tive operating margins are solely a result of their relative efficiency in serving Medicare patients. Thus, they are highly motivated to become efficient enough to make

money off Medicare payments.

These data show that competitive pressure leads hospitals to be more efficient. The 28 percent of hospitals in high pressure markets find that Medicare payments are more than enough to cover the costs of delivering care to Medicare beneficiaries. This is proof, to MedPAC and to me, that Medicare payments are adequate. We need new tools, however, to engender inefficient hospitals in non-competitive markets to improve.

Range of Efficiency in Medicare

The range of efficiency (or inefficiency) in Medicare is considerable. In March 2009, MedPAC also examined median Medicare margins for those hospitals with Medicare margins less than -10 percent and those hospitals with positive Medicare margins. The median Medicare margin among those hospitals with a Medicare margin less than -10 percent was -20 percent. For those hospitals with a positive Medicare margin, the median Medicare margin was +7.6 percent.

Table 3. Medicare Margins By Hospital Category

Category of Hospital	Median Medicare Margin of Category	Average Overall Margin of Category
Medicare margins less than -10%	-20%	4.6%
Positive Medicare margins	7.6%	3.4%

Source: MedPAC March 2009 Report to Congress

Thus, the *median* efficiency differential for the same ¹² patients is 27.6 percent. The complete range of the efficiency distribution across hospitals must be much

In general, the stunning fact is total margins (including all patients) are highest for the least efficient hospital group. For those hospitals with Medicare margins below -10 percent, the average overall margin is 4.6 percent. Hospitals with positive Medicare margins have overall margins of 3.4 percent. Private market pricing power of inefficient hospitals must be considerable. This pricing power has a larger effect on their bottom line than efforts at cost cutting by hospitals in more competitive markets.

Solutions

Before I discuss specific solutions below, it is important to identify three potential approaches that will fall short of comprehensively addressing the underlying problems driving inefficient hospital markets:

• Increased anti-trust regulation alone is not enough. Some local payers have lamented the relative absence of antitrust enforcement in hospital mergers. 13 Since the FTC and Thomas Greaney are also testifying today, I will merely note that in many cases the underlying source of local market power for hospitals (and sometimes for single specialty or large multi-specialty physician groups) cannot be remedied effectively with traditional antitrust tools such as stopping a merger or a divestiture order. This is because the hospital (or physician group) is likely to either be a *de facto* monopoly (natural or not) or have an outsized quality reputation, a form of product differentiation that is impossible or difficult to calibrate and divest.

Quality reputation and actual quality are not necessarily the same. The last step in MedPac's analysis of these different hospitals examined and compared performance quality by efficiency class. Predictably, they found that the most efficient hospitals also consistently produced higher quality patient outcomes. ¹⁴ Patient satisfaction, however, was statistically indistinguishable between efficiency groups. Therefore, people on average do not know (or care) about true

¹² The "same" patients means that they are case-mix adjusted Medicare patients.

13 Antitrust authorities tried and largely failed to win for the wrong reasons in the 1990s; Len M. Nichols, Paul B. Ginsburg, Robert A. Berenson, Jon Christianson, and Robert E. Hurley, "Are Market Forces Strong Enough To Deliver Efficient Health Care Systems? Confidence Is Waning," Health Affairs 23, no. 2 (March/April 2004): 8–21.

14 The patient outcomes were measured by risk adjusted mortality for a variety of conditions.

15 This is one more bit of evidence supporting the conclusion that we can lower costs while

¹⁵ This is one more bit of evidence supporting the conclusion that we can lower costs while improving quality nationwide.

quality differentials. This is what makes quality reputation so difficult to change by antitrust or any other traditional means.

- Simply paying providers less will not solve the inefficiencies driving health care cost growth. The solution is not just about paying hospitals and providers less. It is about changing the incentives of health service delivery so that we move from a volume-based to a value-based system. If we did nothing but just pay hospitals less, hospitals in low and medium pressure markets would raise private payer rates even more. We must have a system-wide solution to the three problems of prices higher than cost, sub-optimal quality, and inefficient cost structures, or we will have no solution at all.
- Market forces alone cannot solve the problem. In much of the country, there are insufficient market forces to drive prices to the efficient cost level without policy intervention. 16 This does not mean there is no role for market forces, but we must be realistic about their potential and limits. Smarter Medicare payment policy, coupled with information and teaching tools, more transparency, and evidence-based regulatory changes can actually make latent market forces far more effective than they have been heretofore.

The only buyer with enough market clout to challenge hospitals or physician groups with considerable local market power is Medicare. *Therefore, Medicare payment reform is the key to optimizing hospital market competition.* A growing chorus is calling for significant restructuring of the Medicare payment structure.¹⁷

The overall strategy of fundamental payment reform in Medicare is complex. I will summarize key elements here since Medicare payment reform is not under the direct jurisdiction of this committee. Payment reform is, however, highly relevant to discussions of competitive performance in health care markets.¹⁸

A few observations at the outset:

¹⁶This was the conclusion of a team of researchers from the Center for Studying Health System Change 5 years ago. Len M. Nichols, Paul B. Ginsburg, Robert A. Berenson, Jon Christianson, and Robert E. Hurley, "Are Market Forces Strong Enough To Deliver Efficient Health Care Systems? Confidence Is Waning," *Health Affairs* 23, no. 2 (March/April 2004): 8–21

21.

17 Health CEOs for Health Reform, the Bi-Partisan Policy Center, noted scholars like Robert Berenson and Larry Casalino, David Cutler and Judy Feder, Elliott Fisher, Mark McClellan, and John Bertko, MEDPAC itself (more gently), the Center for Payment Reform, and very recently the New York Times Editorial Page all support it. The Obama White House and OMB Director Peter Orzag are also generally supportive, judging by their proposals in the President's Budget and beyond and by continuing policy statements linking health reform with economic sustainability and fiscal balance which will clearly require Medicare cost trajectories to be brought under control. Early health reform legislation and proposals in the Congress also include some elements that would move toward serious payment reform in the Medicare program, but many commentators are hoping you will all be emboldened by our arguments and logic, and in particular by the credibility of the health system stakeholders who are willing to embrace this approach, so that you will go even further in the final legislation that is sent to the President's desk to sign this fall.

See for examples: Health CEOs for Health Reform, "Realigning U.S. Health Care Incentives to Better Serve Patients and Taxpayers," New America Foundation, June 12, 2009. For more information, visit: http://www.newamerica.net/hc4hr; Howard Baker, Tom Dashcle, and Bob Dole, "Crossing Our Lines: Working Together to Transform the U.S. Health System," Bipartisan Policy Center, June 17, 2009; Len M. Nichols and Robert Berenson, eds., Making Medicare Sustainable, (Washington, D.C.: New America Foundation, 2009); Melinda Beeuwkes Buntin and David M. Cutler, "The Two Trillion Dollar Solution: Saving Money by Modernizing the Health Care System," Center for American Progress, June 24, 2009; Ellen-Marie Whelan and Judy Feder, "Payment Reform to Improve Health Care: Ways to Move Forward," Center for American Progress, June 24, 2009; Ellen-Marie Whelan and Judy Feder, "Payment Reform to Improve Health Care: Ways to Move Forward," Center for American Progress, June 24, 2009; Ellent S. Fisher, Mark B. McClellan, John Bertko, Steven M. Lieberman, Julie J. Lee, Julie L. Lewis, and Jonathan S. Skinner, "Fostering Accountable Health Care: Moving Forward In Medicare," Health Affairs 28, no.2 (March/April 2009): w219-w231;Medicare Payment Advisory Committee, "Report to the Congress: Reforming the Delivery System," June 2008; Center for Payment Reform, "Principles," http://www.centerforpayment reform.org/Principles.html, Accessed July 2009; "Financing Health Care Reform," New York Times, July 6, 2009; Senate Finance Committee, "Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs," Description of Policy Options, April 29, 2009; House Committees on Ways and Means, Energy and Commerce, and Education and Labor, "Key Features of the Tri-Committee Health Reform Draft Proposal in the U.S. House of Representatives," June 9, 2009.

U.S. House of Representatives," June 9, 2009.

18 For more elaboration, read: Health CEOs for Health Reform, "Realigning U.S. Health Care Incentives to Better Serve Patients and Taxpayers," New America Foundation, June 12, 2009; Len M. Nichols and Robert Berenson, eds., Making Medicare Sustainable, (Washington, D.C.: New America Foundation, 2009).

- Getting prices to efficient cost levels quickly will be difficult. Therefore, we should focus first on achieving optimal levels of quantity and quality, while we try to bring costs down to their efficient levels over time.
- The current Medicare payment structure drives inefficiency. Separate payment for 8,000 Current Procedural Terminology (CPT) codes and 745 diagnosis related groups (DRGs) is not likely to facilitate optimal quantity or quality.
- Some organizations and communities actually do provide something close to optimal quantities and optimal cost levels today. Examples include well-integrated systems like the Billings Clinic, Geisinger Health System, Denver Health, Intermountain Health Care, Kaiser Permanente in Northern California and Colorado, Mayo, Marshfield Clinic, Virginia Mason Medical Center and Group Health Cooperative (both in Seattle), and collaborative communities without integrated systems, like Grand Junction, Colorado.

Combining these observations leads me to the following conclusions.

- Fee-for-service payment methods are unsustainable. Medicare should announce that it will lead the transition away from fee-for-service payment within a specified timeframe. Medicare payment should move toward more bundled payment structures that are adjusted for patient acuity and tied to efficient quantities and cost structures. 19 This announcement will also be catalytic in moving the broader health system toward more value-based payment incentives.
- We must give providers the tools they need to succeed. Moving away from fee-for-service payment will be welcomed by many if it includes a commitment to coordinate the production and dissemination of best practice knowledge across private and public sectors through a program similar in scope to the Cooperative Extension Service in agriculture. In addition, this will require public investments in electronic medical records, decision support tools, best practice research, and interoperability standards.
- We must reduce the barriers to high quality and efficient practice styles wherever they exist. Evidence based regulation is just as essential to our health system's future as evidence based medicine. We must consolidate and streamline the monitoring and oversight of providers into distinct but complete quality, financial, and educational dimensions. Malpractice reform will protect clinicians who utilize agreed upon best practice protocols.
- Clinicians must be able to share in the savings from high-quality, efficient care. Existing antitrust laws, anti-kickback statutes, anti-bribing laws, and other laws and regulations often make it difficult for clinicians and hospitals to share in the savings realized when costs and utilization are reduced—sometimes known as "gainsharing." In order to move toward more bundled payment models, we must develop statutory and "safe harbor" solutions so that clinicians and hospitals can negotiate and share in resource savings when quality and patient care standards are met. Antitrust and regulatory authorities may feel these rules are clear and optimal already. Many clinicians and hospitals, in my experience, do not agree.
- Medicare Advantage plans should bid competitively. We must stop overpaying Medicare Advantage plans by formula. The Medicare Advantage plan should move toward a competitive bidding payment structure that also rewards highquality care and patient satisfaction.
- Medicaid must also be held to quality and efficiency standards. Once Medicaid payment rates are increased (as they must be), providers and managed care plans should be expected and required to meet the same quality standards as they do for private and Medicare enrollees. Our goal should be nothing less than complete parity and equity across insured and ethnic groups.

Innovations in Medicare payment structures should spread to the private sector. Yet, provider market power outweighs payer power in most markets today. As a result, even if Medicare moves to value-based payment rules there is a real danger

that hospitals could simply "charge" their way out of efforts to drive efficiency.

All payer rate setting does come to mind. Savvy analysts have recently recommended this tool be added back into the policy arsenal.²⁰ It is a logical solution

¹⁹ Bundled payment means combining the payments to hospitals and physicians—and a sufficient amount to purchase appropriate drugs, devices, and ancillary tests along the way—into one patient acuity-adjusted amount that will then be shared.

²⁰ Stuart H. Altman, "Financing Comprehensive Health Care Reform," *Testimony Before the U.S. Senate Committee on Finance*, May 12, 2009.

to the problem of local provider market power. However, it would require a far more elaborate regulatory apparatus than we have today. It would also tilt the playing field against providers and toward private insurers at a time when we really need providers to help usher in a value-based not volume-based health system. We might also benefit from innovation in private payer incentive contracts. These innovations could be foreclosed by a rapid push to all payer rate setting. It is hard to know which problem to tackle first, but perhaps a good rule of thumb is to not adopt the experiment that could end all experimentation.

Another potential solution to poor private market performance because of local market power is making Medicare bundling software, incentive forms, data reporting, shared savings contracts (with providers), and bundled price levels completely transparent and available to all. This would allow private insurers to quickly adopt them, piggybacking on Medicare's processes. Medicare could provide a bonus payment to providers who agreed to use similar bundling and incentive contracts with all or a critical mass of private insurers. This would likely improve the quality and efficiency of care delivery throughout the health care system including for Medicare efficiency of care delivery throughout the health care system, including for Medicare beneficiaries themselves.

Physicians

The top two problems with physician market performance at the current time are:

- 1. Too little payment for care coordination, evaluation, and management services. This results in the undersupply of these services and presents a serious threat to the long-term viability of primary care physician practices.²¹
- 2. Distorted prices from physician-owned capital equipment and facilities, which lead to too much diagnostic testing, technical procedures, and excess system

Flaws in Relative Physician Payment

As a result of flaws in the way Medicare and private payers pay physicians, we pay too much for some things and not enough for others. These distorted prices are

stuck," and do not adjust.

The Medicare physician pricing rule, resource based relative value scale (RBRVS), determines the time cost of each procedure in the 8000 CPT code manual and "values" a physician's time in proportion to the length of their training. By definition, this favors specialists over primary care. This technique is essentially an application of the labor theory of value. As such, it tries to build a market value by valuing only supply side inputs, without taking into account the value to patients and pay-

Adjustments to the RBRVS have been made repeatedly over the years. Yet, the all-physician committee that recommends updates is heavily dominated by specialists. All changes to the fee schedule must be budget neutral for the program. Payments to specialists would need to be cut in order to raise the fees of primary care providers. The Center for Payment Reform is leading an effort to get this RBRVS update committee (RUC) process changed to be more representative of all physicians and of payer interests.²² More importantly, this effort is seeking to reassess the RBRVS to account for the value of services from the perspective of patients and pay-

Most private payers effectively use the RBRVS as the basis for their fee schedule's relative payments to physicians, as the Medicare program's analytic work is like a public good which others can use for free. Private payers do use a different multiplier or "conversion factor" to translate the RVS per CPT code into dollar prices. Most often they pay more than Medicare, but not always.²³ This wholesale adoption of RBRVS by private payers has had the unintended effect of making the powerful

force of inertia oppose making adjustments to pay primary care physicians more. Why more private insurers do not deviate from the RBRVS on their own is unclear. This could be a result of simple economics. Because most payers effectively follow RBRVS, insurers do not have to pay more and go to the trouble of adjusting the RBRVS schedule because they can attract the primary care physicians they need by paying the lower rates. Yet, we face single digit percentages of new doctors going

²¹Thomas Bodenheimer, "Primary Care—Will it Survive?" New England Journal of Medicine 355, no. 1 (August 31, 2006): 861–864.

²²Peter V. Lee, "Health Care Reform: Creating a Sustainable Path to High Quality Health Care for All Americans," Testimony before the U.S. House of Representatives Committee on Ways and Means, June 24, 2009; Peter V. Lee, "Payment Reform: Getting the Payments Right Means Getting the Process Fixed," Pacific Business Group on Health, June 12, 2009.

²³Paul Ginsburg, "Comparing the Traditional Medicare Program to Private Insurance," Testimony before the U.S. Senate Committee on Finance, May 12, 1999.

into primary care. This is a truly unsatisfactory result and one we must change to build the 21st Century health system we want and need.

No single private insurer has a large enough market share to reverse the underpayment of primary care physicians caused by the RBRVS. One insurer paying more than "market" rates cannot deliver enough market share to enable primary care physicians to raise their reservation price (i.e., refuse to accept patients from all insurers that have not raised payment rates). Therefore, the first payer would end up just increasing its costs relative to its competitors with no salient effect. That just will not happen. Once again, fundamental payment reform within Medicare must be part of the solution. Medical home models ²⁴ are promising. But perhaps the most promising development are bundled payments that span the ambulatory,25 acute, post-acute, drug, and ancillary costs of treating specific patients combined with shared savings models to encourage collaboration, coordination, efficiency, and qual-

For shared savings, bundled payment, and some pay-for-performance payment models to work in settings outside a completely integrated delivery system, guidance and exemptions from some antitrust enforcement impulses may be necessary. I expect Thomas Greaney or the Federal Trade Commission (FTC) to have more insight. But I do want to make clear that revisiting antitrust prohibitions on collaborative 26 price incentive negotiations is warranted. I would recommend a task force jointly chaired by the Attorney General, the Chairman of the FTC, and the Secretary of HHS be formed as soon as possible. This should not wait for comprehensive health reform legislation to pass. We must pursue this type of payment reform regardless of potential coverage reforms.

Physician-owned Capital Equipment and Facilities

The second big physician market problem is one wherein some physicians' entrepreneurial impulses, combined with incentives partially created by past attempts to prevent self-referral, leads to growth in use and total cost that is not improving patient outcomes. This phenomenon has been masterfully described by Atul Gawande in his recent *New Yorker* article.²⁷ Currently, physicians can maximize income by investing in equipment and even facilities like specialty hospitals or labs rather than focus on delivering high quality evidence based care as efficiently as possible. This illustrates that payment reform must be considered broadly. Facility fee distortions to returns on investment, assumptions about percent time used, and proper depreciation schedules of physician-owned diagnostic equipment must all be on the table.

One option could be to consider allowing physicians who have overinvested in imaging equipment to have a one time immediate complete depreciation allowance and then find other uses for the machines elsewhere. These currently overused machines are kind of like toxic assets. We must get rid of them-or move them to more productive locations—before we can achieve the efficiencies we need.

Insurance Markets

Another witness is focusing on insurers so I will address two problems I think are most important about insurance market competition very briefly.

Exclusion of sick from risk pools. This must be solved through insurance market reforms, specifically requiring all insurers to sell to everyone (guaranteed issue) and prohibiting health status rating (guaranteed renewal, modified or pure community rating). To make insurance markets both more efficient and fairer, everyone must be required to purchase or obtain coverage.²⁸ This set of reforms will force insurers to compete based on price, value, and customer satisfaction rather than marketing and underwriting.

²⁴ American College of Physicians, "Patient-Centered Medical Home," Accessed July 2009: http://www.acponline.org/running_practice/pcmh/; American Academy of Family Physicians, "Patient-Centered Medical Home," Accessed July 2009: http://www.acfp.org/online/en/home/membership/initiatives/pcmh.html; Patient-Centered Primary Care Collaborative, "Joint Principles of the Patient-Centered Medical Home," February 2007.

²⁵ Primary and specialist ²⁶ multi-insurer and multi-provider

 ²⁷ Atul Gawande, "Annals of Medicine: The Cost Conundrum," New Yorker, June 1, 2009.
 ²⁸ Len M. Nichols, Reforming the Health Care Delivery System," U.S. Senate Committee on Finance, April 21, 2009; Len M. Nichols, "Addressing Insurance Market Reform in National Health Reform," U.S. Senate Committee on Health, Education, Labor, and Pension, March 24,

Many insurance markets lack adequate competition, especially in the small group market. The consolidation of the insurance industry is well-documented.²⁹ Therefore, I will focus on Arkansas. I grew up in Arkansas and had the opportunity to study the Little Rock market professionally while Vice President of the Center for Studying Health System Change from 2001–2004. The most recent data available show that Blue Cross Blue Shield of Arkansas has a market share of 75 percent in total. Its closest competitor, United, has a market share of 6 percent.³⁰ United's position has deteriorated since 2003 when I studied the Little Rock market 31

Competition in the Arkansas Small Group Market

How does Blue Cross Blue Shield of Arkansas maintain their dominance? During the Center for Studying Health System Change study in 2003, we were told by many respondents in Little Rock that Blue Cross Blue Shield of Arkansas reimbursed physicians at very high levels, substantially more than Medicare rates. This level of payment made physicians reluctant to contract with other plans such as United, Cigna, or Aetna who reimburse at lower rates. If physicians insist on "market" or "Blue Cross Blue Shield" payment levels, it makes it very difficult for other insurers to enter or grow in the market.

There is nothing illegal about this. In fact, at first glance premiums in Arkansas do not look unreasonably high. Premiums in Arkansas are about 21 percent lower than the national average.³² Of course, this reflects the fact that median household income in Arkansas is 21 percent below the national average as well.³³

Yet, the average deductible in Arkansas in the small group market—the market where competition is lacking in so many states—is 23 percent of the premium.³⁴ This compares with 17 percent nationwide. In other words, Arkansans are buying less-generous-than-average policies.

Another indicator of poor insurance market performance in Arkansas is the fact that only 29 percent of small employers with fewer than 50 workers offer health insurance in Arkansas. This is compared to 43 percent nationwide. Finally, Blue Cross Blue Shield of Arkansas reports that their overall "loss ratio" is about 85 percent, which means they charge an average load of 15 percent across all their business. In other words, 15 percent of premiums collected by Blue Cross Blue Shield of Arkansas are not used to pay for patient care.

Firms with fewer than 50 workers represent just 14 percent of the insurance market. Sixty percent of the market is made up of firms with more than 1,000 workers 36 who pay administrative loads between roughly 7 and 10 percent. Therefore, we must infer the average load in the small group market in Arkansas, as it is in most states, is considerably higher than 20 percent. In short, workers and small firms in Arkansas are paying very high loads for policies that are less generous than the already parsimonious national averages for small firms.

This is not to condemn Blue Cross Blue Shield of Arkansas—they are doing what our laws and incentives allow and encourage them to do. They are earning a healthy surplus (high load) off most sales, but why would they not, given their opportuni-

Public Health Insurance Plan

This scenario explains why so many people support the introduction of a competing public health insurance plan in addition to the insurance market reforms dis-

²⁹ John E. Dicken, "Private Health Insurance: 2008 Survey Results on Number and Market Share of Carriers in the Small Group Health Insurance Market," Government Accountability Of-

Flore, February 27, 2009.

The Shah Group Retail Institute American Competition: Insurance Market Domination Leads to Fewer Choices," Center for American Progress, June 2009; American Medical Association, "2007 Update: Competition in Health Insurance, A Comprehensive Study of U.S. Markets: 2007 Update," http://www.ama-assn.org/ama1/pub/upload/mm/368/

Carmen DeNavas-Walt, Bernadette D. Proctor, and Jessica C. Smith, Income, Poverty, and ³⁵Carmen DeNavas-Walt, Bernadette D. Proctor, and Jessica C. Smith, *Income, Poverty, and Health Insurance Coverage in the United States: 2007*, U.S. Census Bureau, Current Population Reports, P60–235, (U.S. Government Printing Office: Washington, D.C., 2008).

³⁴Agency for Healthcare Research and Quality, "Medical Expenditure Panel Survey: Insurance Component," 2006.

³⁵Quick Health Insurance Group, Inc., "Blue Cross Blue Shield of Arkansas," http://quickhealthinsurance.com/bluecrossblueshieldarkansas.htm, accessed July 14, 2009.

³⁶Agency for Healthcare Research and Quality, "Medical Expenditure Panel Survey: Insurance Component," 2006.

cussed earlier.³⁷ Insurance markets like Arkansas' are the indisputable reason competition will be well-served by a public health insurance plan competing on a level playing field with private plans.

Imagine year one of a new health insurance market (or exchange) without a public health insurance plan. Currently, dominant insurers do not want competition or the insurance reforms that will reduce their "loads" or margins. In the absence of a credible competitor that will compete on a level playing field and bid actuarially fairly, I worry that an unhappy but unchallenged dominant insurer will bid very high and blame the high bid on "excessive regulation."

However, if the dominant insurer knows that an actuarially fair bid is forthcoming from a public health insurance plan with the network capacity necessary to actually take substantial market share away from the dominant insurer, then I predict the insurer will be much more likely to bid competitively and low. In effect, the existence of a public health insurance plan could "keep insurers honest" in the ab-

sence of another way to engender competition in particular marketplaces.

Administrative Costs

The McKinsey Global Institute estimated that in 2006, the United States spent \$650 billion more on health care than we should have, given our demographics and wealth. Of this \$650 billion, \$91 billion or almost 15 percent is excess spending on administrative activities.³⁸ There are more than 1,100 insurers in the United States. The complexity of so many insurers requiring slightly different forms and information is considerable and results in very large costs for providers and patients.

Some commentators report that non-clinical personnel are the fastest growing category of hospital employees. Credible aggregate estimates approximate that 21 percent of hospital costs and 27 percent of physician office costs are spent on administration, half of that on billing and insurance related costs alone.³⁹ So as we work to change payment rules and incentives to engender better performance in health service markets, we should remember there is a lot of money to be saved in administration as well. Addressing these administrative burdens would boost clinician morale instantaneously.

A task force convened by the Secretary of Health and Human Services that includes payer and provider representatives should be given a deadline of 6 months to report on concrete ways to streamline administration, save money, and improve the efficiency and quality of data transmission. United Health Group recently released a working paper which concluded that known administrative processes could save as much as \$332 billion over 10 years, half of which would accrue to providers, another 20 percent of which would accrue to Federal and state governments. Some regulations and standards may be necessary to capture these savings, but the United paper would suggest the solutions are known.

Conclusion

I hope the ideas and opinions in this testimony are useful to you as you consider how to make health markets perform better. I do recommend relying primarily on Medicare payment (and insurance market) reform as the lynchpin of any comprehensive effort. However, in each case the intent and designed effect is to use information and realigned incentives to improve the chances all Americans will soon be getting high-quality care consistently, and paying prices closer to the efficient cost level. I would be glad to answer any questions you or your staff may have at any time.

Senator PRYOR. Thank You. Mr. Balto?

³⁷Len M. Nichols and John M. Bertko, "A Modest Proposal for a Competing Public Health Plan," New America Foundation, March 2009; Linda Blumberg and John Holahan, "Can a Public Insurance Plan Increase Competition and Lower the Costs of Health Reform," Urban Institute, 2008; Jacob Hacker, "The Case for Public Plan Choice in National Health Reform: Key to Cost Control and Quality Coverage," Institute for America's Future, December 2008.

³⁸ McKinsey Global Institute, "Accounting for the Cost of U.S. Health Care: A New Look at Why American Spend More," November 2008.

39 J.G. Kahn, et al., "The Cost of Health Insurance Administration in California: Estimates for Insurers, Physicians, and Hospitals," Health Affairs 24, no. 6 (2005): 1629–1639.

STATEMENT OF DAVID BALTO, SENIOR FELLOW, CENTER FOR AMERICAN PROGRESS ACTION FUND

Mr. Balto. Chairman Rockefeller, Chairman Pryor, Ranking Member Wicker, thank you for the privilege of testifying before you today.

I'm a Senior Fellow at the Center for American Progress, and I spent over 15 years in the antitrust enforcement agencies. In the Clinton Administration I was the Policy Director of the FTC. When I was there, I learned that there are three essential elements for a market to work: choice—alternatives; transparency; and a lack of conflicts of interest. In each of these respects, the health insurance market is clearly broken. This Committee deserves a lot of credit for the spotlight it has put on Ingenix and the relationship between Ingenix and United HealthCare, and how that has harmed patients and doctors.

I have a simple message for you today. The Ingenix example is only the tip of the iceberg. Few markets are as concentrated, opaque complex, and subject to rampant anticompetitive and deceptive conduct as the insurance market. As the healthcare debate progresses, you'll hear people call for some limited reform of the health insurance system. Their belief is that this is fundamentally a sound market, and you just need a little more regulation. They could not be more mistaken. Trying to correct the market with some slight regulatory reform is like trying to cure cancer with a bushel of Band-Aids.

Unfortunately, this is also a story of regulatory neglect, where the Federal enforcers have dropped the ball. During the Bush Administration, there were no enforcement actions by health insurers against anticompetitive, deceptive, or fraudulent activity. No challenges to mergers in the health insurance industry. And the same thing is true for pharmacy benefit managers and GPOs.

What is the result? The health insurance markets are tremendously concentrated. The PBM market has three firms with effectively an 80-percent market share. And what—how has that impacted consumers? Insurance premiums have increased by 87 percent over the last 6 years. The number of uninsured has skyrocketed.

How has that affected these market participants, who are supposed to squeeze every penny and represent the interests of the plans and consumers? Well, the profits for insurance companies have skyrocketed by over 400 percent over the past 6 years, to over \$13 billion. The same is true for PBMs. Those profits have increased almost \$3 billion, an increase of over 300 percent. As a former antitrust enforcer, when I see profits increasing like that, that tells me those markets aren't working, that tells me those people have market power, that tells me antitrust enforcement is necessary. But, we haven't gotten that.

Let me mention one thing about where the Federal enforcers, not—rather than even supporting efforts to make these market work, have inhibited that. And that's in the area of pharmacy benefit managers. State enforcers have stepped into the breach of no Federal enforcement, and a coalition of over 30 States have brought actions against each of the three major PBMs, securing over \$370

million of damages. Can you imagine what a large sum of money that is?

State legislators, in response to that, have proposed legislation to do two things—eliminate conflicts of interest and provide transparency—the two things that were problematic in Ingenix. And when they proposed that legislation, unions and plan sponsors and consumers lined up in support. And you know who's on the other side, opposing that legislation? The Federal Trade Commission. Whereas the sponsors of that legislation have actual real-world facts to support the need for that legislation, the FTC is there, weighing in on behalf of PBMs, using theoretical arguments to support these egregious anticonsumer practices. That simply makes no sense.

This record of regulatory neglect must be reversed. There needs to be greater enforcement actions against health insurers, PBMs, and GPOs. If you think the Ingenix case is a problem, PBMs are Ingenix on steroids. They are a vastly more significant problem.

I have a set of recommendations to the end. Let me just highlight four of them:

First, the Federal antitrust agencies need to readjust their enforcement priorities. They spend their time prosecuting negotiations by doctor groups. There is no evidence in the literature that suggests that collective negotiations by doctors are a significant, or any, source of higher prices that consumers have to pay. What they're doing is handcuffing the doctors, who are the best advocate for the patients. Those doctors do have a fiduciary duty, those doctors do represent the patients' interests. Those resources need to be spent in a more balanced fashion, as they were in the Clinton Administration, attacking both clearly egregious conduct by providers, and by also going after insurance companies.

Second, this Committee should build on its important study of Ingenix, and look at pharmacy benefit managers and how conflicts of interest and a lack of transparency cause similar types of problems in the PBM market.

Third, to the extent that the FTC believes it does not have jurisdiction over health insurance, this Committee must act immediately to make sure the FTC has that jurisdiction. There are no FTC health insurance enforcement actions whatsoever on the consumer protection side. You can't find the words "health insurance" on the FTC Consumer Protection website. That has to change. If there's a jurisdictional bar, let's get rid of it.

And then, finally, for the problems involving group purchasing organizations, Congress should act to eliminate the anti-kickback safe harbor for group purchasing organizations.

Thank you for your time, and I look forward to working with this Committee on addressing these important issues.

[The prepared statement of Mr. Balto follows:]

PREPARED STATEMENT OF DAVID BALTO, SENIOR FELLOW, CENTER FOR AMERICAN PROGRESS ACTION FUND 1

Chairman Pryor, Ranking Member Wicker and other Members of the Committee, I appreciate the opportunity to come before you today and testify about health care competition and consumer protection enforcement. As a former antitrust enforcement official I strongly believe the mission of the Federal Trade Commission and Antitrust Division of the Department of Justice is vital to protecting consumers and competition. However in the past administration the priorities of those enforcement agencies were not effectively aligned with the critical priorities in the health care market, with the result that there is substantial anticompetitive and fraudulent activity that raises prices and costs for consumers and the American taxpayer, especially conduct by certain health care intermediaries—Health Insurers, Pharmacy Benefit Managers ("PBMs") and Group Purchasing Organizations ("GPOs").

This Committee, like the rest of Congress has been devoting considerable resources to health care reform. This Committee, under the leadership of Chairman Rockefeller, has led the way in making the public aware of the deceptive and fraudulent conduct of health insurers, particularly by shining a spotlight on the egregious activity of Ingenix, the United HealthCare subsidiary which has harmed thousands of patients and doctors by distorting the usual and customary rates of those health care providers. Thanks to the efforts of New York Attorney General Cuomo this fraudulent scheme activity is being reformed.

The Problem of Regulatory Neglect

I have a simple and vital message for this Committee: the Ingenix example is only the tip of the iceberg. The fundamental elements for a competitive market are transparency and choice and in both respects, health insurance markets are clearly broken. Few markets are as concentrated, opaque and complex, and subject to rampant anticompetitive and deceptive conduct. As the health care debate progresses, many advocate for limited reform of the health insurance system. Their belief is that it is a fundamentally sound market and with a little dose of additional regulatory oversight, all the ills of the market will be cured. They could not be more mistaken.

The Ingenix example is important for other efforts at managing health care costs—PBMs and GPOs. Some suggest these entities serve an important function in controlling health care costs. But like the Ingenix example, they often are subject to deceptive conduct and conflicts of interest and can be used to forestall competition, rather than promote it. Again because of a lack of choice and transparency and the existence of conflicts of interest, these intermediaries have failed to fulfill their mission and foster competition and choice.

The FTC has accomplished tremendous things with its enforcement actions in the health care sector over the past 50 years, from opening up the practice of medicine to innovative forms of practice, to challenging conduct that has impeded entry of generic drugs. In a recent paper for the Center for American Progress, I detailed the positive results of the efforts of the FTC in expanding access to affordable generic drugs. By taking action against the deceptive strategies which allow drug companies to artificially extend the life of their patent-protected drugs, the FTC has given consumers wider choice in the drugs available to them. Consumers save billions of dol-

lars annually because of these efforts.

Unfortunately, the same attention has not been given to health insurers, PBMs, and GPOs. As I describe in my testimony much of the reason for the lack of competition and transparency, and the existence of conflicts of interest, is the failure of Federal antitrust and consumer protection enforcement in the health insurance industry. During the Bush Administration, there were no enforcement actions against health insurers' anticompetitive, deceptive or fraudulent conduct. None. There was tremendous consolidation in the market, and the Justice Department simply required minor restructuring of two mergers. There were no cases against anticompetitive conduct by health insurers. There were no Federal consumer protection enforcement actions. A similar record of regulatory neglect exists for PBMs and

State enforcement officials have frequently tried to fill the void created by this regulatory neglect. State legislators have tried to reform these markets through legislation. When they have they often face the FTC as an adversary, repeating the theory that the best regulation is no regulation. In the PBM market, the only seg-

¹I was a public servant in the Antitrust Division and the Federal Trade Commission for over 15 years. In the Clinton Administration, I was the Assistant Director for Policy in the FTC's Bureau of Competition. I represent consumers, consumer groups, and a wide variety of entities, including health care providers, in the health care antitrust matters.

ment of the health care industry that is unregulated, a coalition of over 30 states brought 5 enforcement actions against the three major PBMs attacking deceptive conduct and securing over \$370 million in penalties and damages. When legislators have tried to enact legislation to address these problems identified in these cases in a comprehensive fashion, the FTC files letters opposing the legislation—opposing the efforts of consumer groups, unions, and other supporters of the legislation and taking the side of these firms that have engaged in these egregious anticonsumer practices. That makes no sense.

This record of regulatory neglect must be reversed. Health insurers, PBMs, and GPOs can play a vital role in controlling health care costs and facilitating health care reform. Their size affords them strong purchasing power, and these savings can, in turn, be passed on to consumers and plan enrollees, where there is adequate choice and transparency and protections against conflicts of interest. But these are for-profit entities whose first obligation is to the bottom line. Where the regulators are asleep at the switch, or there is a lack of adequate regulation, these firms will exploit that opportunity. Frequently, these firms engage in deceptive and fraudulent conduct, the purpose of which is to build profits rather than control costs. A lack of competition and consumer protection regulation and enforcement means that the rigor of the competitive market is absent.

Why is there an imbalance in enforcement and a lax position on the conduct of health care intermediaries such as insurers and PBMs? Perhaps that is because the agencies treat the insurer or PBM as if it is the consumer. If they do, that is a mistake. Insurers and PBMs do attempt to control costs for employers and other purchasers of health plans. While these entities may attempt to control cost they are also for profit entities with an overriding incentive to maximize profits. When there are battles between healthcare providers and insurers, the FTC always weighs in on the side of the insurers. But insurers are not the consumers. When there are battles between pharmacies and PBMs, the FTC always weighs in on the side of the PBM. But PBMs are not the consumers. Increasingly unions and consumer groups are raising the most serious concerns over the conduct of insurers and PBMs. When organizations like Change to Win, which represents over 10 million union members who have to pay the cost of health care, speak up against the egregious conduct of CVS/Caremark in a landmark study, it is time for the FTC to take notice. When consumer groups and public interest advocates speak up against the egregious conduct of insurers, or seek legislation to regulate PBMs, the FTC should recognize the legitimate representatives of the consumer interest.2

Are health insurers and PBMs an appropriate proxy for the consumer interest? Obviously the ability to manage health care costs is critical for plans, and the insurance companies and PBMs have the potential for aiding that process significantly. However, any objective perception of the results of health insurer and PBM activity over the past several years would severely question whether these entities truly do act in the interest of the ultimate consumers. As documented in the hearings this Committee has held in the past several months there are rampant anticompetitive and fraudulent activities by health insurers. The primary goal of these for profit insurers and PBMs is to serve their shareholders and their profit margins, and not

consumers. They are not the representative of the consumer interest.

My testimony proceeds as follows. I first describe how the competition and consumer protection missions of the FTC have failed to adequately address the problems of health care intermediaries, including health insurers, PBMs and GPOs. For each, I describe how a lack of competition enforcement has led to highly concentrated markets across the country and high costs for consumers. I identify significant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by insurers, PBMs, and GPOs that have gone unificant anticompetitive practices by the practice of the pr challenged. In addition, I describe how a lack of consumer protection enforcement has created an environment in which deceptive conduct has flourished. To a certain extent, state enforcers and private litigants have filled the void from the lack of enforcement on the Federal level, but this is not an adequate substitute for Federal enforcement. Finally, I provide several recommendations for reversing the regulatory neglect of these important markets. Enforcement priorities must be realigned to build a sound structure from which the FTC can pursue its health care competition and consumer protection missions.

My recommendations include:

²In the Bush Administration there was a mixed record, at best, in securing the input of consumer groups in important policy issues. In the FTC/DOJ hearings on dominant firm conduct there was no testimony from consumer groups. In the FTC hearings on collaboration by healthcare providers, the FTC declined participation by consumer groups.

- Enforcement priorities should be readjusted with a greater focus on bringing enforcement actions against health insurers, PBMs and GPOs.
- The FTC should significantly increase health insurance consumer protection enforcement and create a separate division for health insurance consumer protection enforcement.
- The FTC should reinvigorate enforcement against anticompetitive conduct by health insurers, PBMs and GPOs, focusing on those which lead to higher costs and increase entry barriers. The FTC should conduct a retrospective study of health insurer mergers to identify those that have harmed consumers.
- The FTC should take a more fully informed and balanced position on PBM advocacy, recognizing substantial enforcement actions brought by states against PBMs for fraud and deceptive conduct.
- The enforcement agencies need to recognize that insurers and PBMs often do not reflect the interests of consumers, and are not proxies of the public interest.
- Congress should clarify the jurisdiction of the FTC to be able to bring enforcement against health insurers.

Rampant Competitive and Consumer Protection Problems in Health Insurance

Let me return to my earlier observation—the importance of choice and transparency to assure a competitive marketplace. Why are choice and transparency important? It should seem obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering lower prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire. Only where these two elements are present can we expect free market forces to lead to the best products, with the greatest services at the lowest cost. Where these factors are absent, consumers suffer from higher prices, less service, and less choice. As the Health Care for America Now report observed "Without competition among insurers, insurers have no reason to drive down costs, and without additional choices in the marketplace, consumers have no choice but to pay inflated prices." ³

As I describe below there has been no meaningful Federal antitrust or consumer protection enforcement against health insurers. The result of the lack of health insurance enforcement is profound. The number of uninsured has skyrocketed: more than 47 million Americans are uninsured, and according to Consumer Reports, as many as 70 million more have insurance that doesn't really protect them. In the past 6 years alone, health insurance premiums have increased by more than 87 percent, rising four times faster than the average American's wages. Health care costs are a substantial cause of three of five personal bankruptcies. At the same time from 2000 to 2007, the 10 largest publicly-traded health insurance companies increased their annual profits 428 percent, from \$2.4 billion to \$12.9 billion.

Minimal antitrust enforcement. Any reasonable assessment would conclude that adequate choice and transparency are clearly lacking from today's health insurance markets. Study after study has found that health insurance markets are overly consolidated: in a recent report by Health Care for America Now, in 39 states two firms control at least 50 percent of the market, and in nine states a single firm that controls at least 75 percent of the market, and in nine states a single firm that controls at least 75 percent of the market. A 2007 AMA study found almost 95 percent of all markets are highly concentrated. Industry advocates claim that many markets have several competitors. But the reality is these small players are not a competitive constraint on the dominant firms, but just follow the lead of the price increases of the larger firms.

During the past Administration there was massive consolidation of health insurance markets. As then Presidential candidate Obama observed,

There have been over 400 health care mergers in the last 10 years. The American Medical Association reports that 95 percent of insurance markets in the United States are now highly concentrated and the number of insurers has fallen by just under 20 percent since 2000. These changes were supposed to make

³ Health Care for America Now, "Premiums Soaring in Consolidated Health Insurance Market: Lack of Competition Hurts Rural States, Small Businesses." May 2009. Available at http://hcfan.3cdn.net/dadd15782e627e5b75_g9m6isltl.pdf.

⁴ Ibid.

⁵American Medical Association, "Competition in Health Insurance: A Comprehensive Study of U.S. Markets, 2007 Update."

the industry more efficient, but instead premiums have skyrocketed, increasing over 87 percent over the past 6 years.6

There is little evidence that this wave of consolidation led to significant efficiencies, or lower costs, or other benefits. In fact, the fact that insurance premiums continued to rapidly increase suggests that any efficiencies were simply pocketed by the companies, rather than resulting in lower premiums or other consumer benefits.

As Vermont Senator Patrick Leahy observed in hearings before the Senate Judiciary Committee in 2006 on health insurance consolidation:

A concentrated market does reduce competition and puts control in the hands of only a few powerful players. Consumers—in this case patients—are ultimately the ones who suffer from this concentration. As consumers of health care services, we suffer in the form of higher prices and fewer choices.⁷

Competition matters: A recent study noted that insurance premiums are 12 percent lower in those markets in which there is comparatively a lower level of concentration than in more concentrated markets.8

The Bush Administration reviewed numerous mergers, but approved all of them, requiring some modest restructuring in only two mergers. In one caseproposed acquisition of Independence Blue Cross-it chose not even to engage in an extensive investigation, despite the fact that, if the two insurers merged, the new insurer would have held over 70 percent of the Pennsylvania market and formed the sixth-largest insurer in the country. Allowing such a large firm to dominate a single market would make the barriers to entry nearly insurmountable, and consumers would be faced with few options. Ultimately, the Pennsylvania Insurance Commissioner was poised to challenge the merger and found such severe competitive problems that the parties were forced to abandon the acquisition.¹⁰ It is not unusual for the states to step in where the Federal enforcers fail to effectively challenge these mergers. As shown in appendix A, there have been several cases where state insurance commissioners have secured remedies even where the Federal enforcers have failed to act.

Similarly, the Bush Administration did not bring a single case challenging anticompetitive conduct by insurance companies. Certainly there are various types of conduct by dominant insurers that deserve very careful scrutiny because they rein-

force dominance and prevent rivals from entering and expanding.

Practices such as most favored nations provisions, all products clauses, and silent networks, which limit the ability of providers to enter into arrangements with rival insurers, increase the power of the insurer at the expense of the health care provider and limit the ability of rival insurers to enter and expand in the market. For example, a most favored nations provision prevents providers from entering into more attractive arrangements with new entrants into the insurance market. Other provisions may prevent physicians from making consumers aware of more attractive insurance products which may provide better coverage. Some of these practices were challenged in the Clinton Administration, but the Bush Administration, which took a mistakenly permissive view to conduct by dominant firms throughout the economy did not mount a single challenge.

Moreover, dominant insurers rarely invade each other's territories. This is disturbing since these firms certainly have the resources, incentives, and ability to enter new markets. The fact they choose not to raises serious concerns of market allocations. Take, for example, the fact that Blue Cross and Blue Shield plans hide behind a complicated system of licensed-based territorial allocations to claim that they don't compete with one another, even when there are multiple plans in the

mittee. Public Hearing on Proposed Merger between Independence Blue Cross and Highmark. August 25, 2008.

August 25, 2008.

⁹ Ario, Joel. "Statement of Pennsylvania Insurance Commissioner Joel Ario on Highmark and IBC Consolidation." January 22, 2009.; Balto, David. Testimony before the Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy and Consumer Rights. "Consolidation in The Pennsylvania Health Insurance Industry: The Right Prescription?" July 31, 2008. ¹⁰ Von Bergen, Jane M. and Angela Couloumbis, "Insurers IBC, Highmark withdraw merger plan." The Philadelphia Inquirer, January 15, 1990, accessed at http://www.philly.com/philly/news/homepage/38128494.html.

same state. This territorial allocation claim may have been what prompted the Bush Administration to take a pass on challenging the proposed Highmark/Independence Blue Cross merger in Pennsylvania. These allocations eliminate important sources of potential competition. The FTC should investigate and challenge these practices. It seems doubtful that a court looking at the Pennsylvania situation would have viewed such territorial allocations as procompetitive.

Overall, the total lack of antitrust enforcement results in rapidly increasing premiums, increasing profits, greater numbers of uninsured and noncompetitive market structures in all but a handful of markets.

Mistaken enforcement priorities. The lack of enforcement was not due to a lack of resources, but a serious misjudgment in enforcement priorities. During the Bush administration the FTC spent a hugely disproportionate amount of time, money and effort prosecuting relatively small groups of doctors who impermissibly attempted to collectively bargain with insurers. It brought 31 enforcement cases against health care providers, frequently small groups of doctors. The disproportionate focus on physician groups seems somewhat puzzling. There was no evidence that higher physician costs were a significant force in increasing health care expenditures. In fact, one can scan the entire literature on rising health care costs and see little mention of efforts by physicians to collectively negotiate as being a substantial contributing factor to higher health care costs. All of these cases were settled, probably because of the high cost of being subject to a government investigation for these modestsized groups of physicians. There was little evidence in the complaints filed by the government that these groups actually secured higher prices or that consumers were harmed. In fact, in none of the cases did insurers or consumers file any antitrust suits seeking damages for the alleged illegal conduct.

Over 40 percent of the enforcement actions were in rural areas which often face significant problems of securing adequate providers. These enforcement actions only increased the problems of providing adequate access and service in these markets.

These comments are not intended to condone illegal conduct. But the missions of the enforcement agencies should be focused on those areas which have the greatest impact on the economy and consumers. And it seems relatively clear that the anticompetitive and deceptive conduct by health insurers has a far more profound im-

No Federal consumer protection enforcement. The consumer protection story is also distressing. There were no FTC enforcement actions against deceptive or fraudulent conduct by health insurers. Enforcement is an absolute necessity in this market. The hearings held by this Committee have demonstrated that consumers also face an astounding lack of transparency in the marketplace. Health insurance products are complex and terms are not uniform, making it near impossible for consumers to meaningfully compare their options. Insurers make special efforts to prevent transparency and information. As Wendell Potter, a former insurance executive, testified before the full Committee, "Insurers make promises they have no intention of keeping, they flout regulations designed to protect consumers, and they make it near-

ly impossible to understand—or even to obtain—information we need." 11

In a June letter to several key Congressional leaders, Consumer Watchdog called for Congress to enact a "Patient Bill of Rights" and detailed a number of ways in which health insurers deliberately mislead and underpay patients, including: issuing excessive fine print that allows them to deny coverage for common procedures, failing to define "medical necessity" and "experimental treatment," creating junk policies that are "not worth the paper they're printed on," and manipulating risk to refuse coverage for ailments while charging higher rates. ¹² Health insurers allege that they have largely abandoned the practice of forcing "gag clauses" on physician that we have always a sure of the sicians that prohibit them from discussing insurance alternatives or reimbursement procedures; however, many physicians report having their hands similarly tied by "business clauses" that require many of the same concessions. 13 Consumers cannot

¹¹ Wendell Potter. Statement before the U.S. Senate Committee on Commerce, Science & Transportation Hearing: "Consumer Choices and Transparency In the Health Insurance Industry." June 24, 2009. Accessed at http://commerce.senate.gov/public/_files/PotterTestimony

try." June 24, 2009. Accessed at http://commerce.senate.gov/puoiic/_jues/fouerlesimiony ConsumerHealthInsurance.pdf.

12 Letter from Jamie Court and Jerry Flanagan, Consumer Watchdog, to House Members Nancy Pelosi, Henry Waxman, George Miller, Pete Stark and Charles Rangel and Senators Max Baucus, Ted Kennedy, and Chris Dodd (June 4, 2009). Accessed at http://www.consumerwatchdog.org/resources/PatientsBillofRightsHouseSenate.pdf.

13 Fogoros, Richard N. "Why Gag Clauses are Obsolete." The Covert Rationing Blog, June 20, 2007. Accessed at http://covertrationingblog.com/gekkonian-rationing/why-gag-clauses-are-ob-articlesis-senate.pdf.

access certain information about their benefits and insurers adjudicate claims based on inscrutable and even fraudulent formulas.

Consider, for example, the Ingenix matter—the recent scandal over abuse of an industry price-setting database that health insurers used to artificially depress reimbursements to consumers. For several years, United Health Care used its wholly owned subsidiary, Ingenix Corp., to calculate reimbursement rates for out-of-network coverage. These rates were artificially deflated, allowing United to lowball payments to customers. Consumers were systematically underpaid by millions of dollars. The New York State Attorney General's Office sued United over Ingenix and has secured over \$94.6 million so far, and a class action suit by the American Medical Association settled for \$400 million. 14 Numerous private suits continue. 15 As New York Attorney General Andrew Cuomo stated in testimony before the Senate Commerce Committee in March, Ingenix was "a huge scam that affected hundreds of millions of Americans [who were] ripped off by their insurance companies." 16

Instead of a vibrant, competitive marketplace, the lack of a sound regulatory and enforcement regime has allowed the development of a highly concentrated system in which deceptive and abusive practices flourish with inadequate checks from rivalry or regulation. With insufficient choice and severely limited transparency in the market, how do consumers fare? Let's examine Montana, where the single largest insurer, Blue Cross and Blue Shield of Montana, holds a 75 percent market share. According to a report by Health Care for America Now, the average annual combined premium for employers and employees in Montana rose from \$6,220 in 2000 to \$11,743 in 2007—over half of that year's average annual salary in the state, \$22,170.17 Montana is a leader in health insurer consolidation, but it is far from an outlier—similar markets exist in almost every state nationwide. 18

Why aren't health insurance markets working for American families? The answer, at least initially is regulatory failure. Health insurers are governed by a hodge-podge of local, state and Federal regulations. Moreover, these companies have fought tooth and nail over the last decade against any regulators' attempts to insti-tute even basic consumer protection measures—including, crucially, killing the origi-

nal patients' bill of rights legislation in 2001.

The Federal consumer protection enforcement record is as bleak as the competition record. The FTC has not brought a single case against deceptive or fraudulent conduct by health insurers. All of the FTC's health care consumer protection enforcement actions were brought against advertising of sham products, such as miracle diet pills, that capitalize on consumers' willingness to be deceived.

This lack of Federal oversight and the insurers' successful battle against regulation gave insurers great latitude to invent deceptive and fraudulent schemes to harm consumers. Insurers engage in a veritable laundry list of deceptive and abusive conduct such as egregious preapproval provisions, deception about scope of coverage, unjustifiably denying or reducing payments to patients and physicians, and

other coercive and deceptive conduct.

In addition to the aforementioned Ingenix case, insurers have been found liable or settled charges for a wide variety of fraudulent and deceptive conduct including: utilizing falsified data to calculate reimbursements, refusing to pay for visits to providers erroneously listed as in-network; wrongfully denying claims for sick patients; failing to pay reimbursements in a timely manner; overcharging customers for premiums; refusing to cover emergency treatment; failing to provide notice of rate increases; ignoring customer complaints; and various other similar methods of denying needed care while maximizing profit. There are countless complaints by hospitals and physicians that preapproval provisions prevent them from providing adequate and safe care. In testimony before the Senate Commerce Committee, Consumers'

¹⁴Cook, Bob. "Final health plan reaches settlement over Ingenix data base." American Medical News. July 6, 2009. Accessed at http://www.ama-assn.org/amednews/2009/06/29/

^{31, 2009).} Accessed at http://commerce.senate.gov/public/index.cfm?FuseAction=Hearings.
Statement&Statement ID=8704a1ba-d058-dad6-b6ff-3031bd2f0aef.

17 Health Care for America Now, "Premiums Soaring in Consolidated Health Insurance Market: Lack of Competition Hurts Rural States, Small Businesses." May 2009. Available at http://hefan.3cdn.net/dadd15782e627e5b75 g9m6istlt.pdf.

18 Center for American Progress Action Fund. "Every State Needs Health Care Reform: 50 State Fact Sheets." July 7, 2009. Accessed at http://www.americanprogressaction.org/issues/2009/07/health_factsheets.html.

Union characterized the insurance payer system as plagued by "a swamp of financial shenanigans"-including a lack of transparency, conflicts of interest, and deceptive practices—and called on regulators and enforcers to step up actions to "prevent

egregious consumer ripoffs." 19

To combat this conduct, State Attorneys Generals, Insurance Commissioners, and private parties have brought over 50 cases securing potentially over \$1 billion in damages and fines since 2000. Although these state actions are laudable, state enforcement is episodic and can only repair a problem involving a single company in a single state. Trying to fix these endemic problems with lawsuits is like treating

cancer with a bushel of Band-Aids.

These numerous enforcement actions do not suggest however that state enforcement is an adequate substitute for Federal enforcement. Indeed the contrary is true. As this Committee has heard, the level of enforcement resources that insurance commissioners possess varies significantly from state to state. Most states have relatively limited resources at best to police the insurance industry.²⁰ In addition, state laws serve at best as a patchwork quilt to address consumer protection issues. In addition, self-insured health care plans, which account for over 40 percent of the private health insurance market, are not subject to state regulation. Thus state regulation is far from an adequate substitute for Federal regulation of health insurance.

The Federal enforcers have not restricted the drive for consolidation nor limited the extent to which insurers could abuse the resulting market power. The result was the tsunami of health insurer consolidation and the accompanying wave of abusive business practices that have stuck small businesses and consumers with unreasonably high premiums and inadequate coverage. Indeed, a report by the Medicare Payment Advisory Commission, an expert panel appointed by Congress, found that insurers "have been able to pass costs on to the purchasers of insurance and maintain their profit margins." Moreover, as health insurers have used their market clout to reduce reimbursement for smaller health care providers, those providers disproportionately concentrated in rural or urban underserved areas—have been forced into offering assembly-line health care.

Anticompetitive and Deceptive Practices by Pharmacy Benefit Managers

PBMs can play an important function in health care markets by setting up pharmaceutical benefit networks and adjudicating pharmaceutical claims. But the same story of regulatory neglect is true for PBMs. The FTC has not challenged any PBM mergers, or anticompetitive or fraudulent conduct by PBMs. This is a particularly serious concern since PBMs are the only segment of the health insurance market that is unregulated.

First, like the insurance market, there has been tremendous consolidation among PBMs. In the Bush Administration, there were several large PBM mergers, so the three major PBMs (CVS/Caremark, Express Scripts and Medco) now have over 80 percent of the national PBM market. The FTC has not undertaken any enforcement activity in the face of this market consolidation. In fact, the past two substantial PBM mergers—Caremark's acquisition of AdvancePCS and CVS's acquisition of Caremark—were approved without a significant investigation, despite leading to a significant increase in market power.²² While consumers have faced rapidly increasing costs and inadequate access to pharmaceuticals, from 2003 to 2007, the three

¹⁹ Bell, Charles, Program Director, Consumers Union. "Testimony Before the Committee on Commerce, Science and Transportation, U.S. Senate, Hearing on Consumer Reimbursement for Health Care Services." March 26, 2009.

Health Care Services." March 26, 2009.

²⁰ Karen Pollitz. Statement before the U.S. Senate Committee on Commerce, Science & Transportation Hearing: "Consumer Choices and Transparency In the Health Insurance Industry." June 24, 2009. Accessed at Wendell Potter. Statement before the U.S. Senate Committee on Commerce, Science & Transportation Hearing: "Consumer Choices and Transparency In the Health Insurance Industry." June 24, 2009. Accessed at <a href="http://commerce.senate.gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-state-gov/public/figures-face-gov/public/figures-gov/public/figures-gov/public/figures-gov/public/figures-gov/public/figures-gov/public/figures-gov/public/figures-gov/public/figures-go

Health Insurance Industry." June 24, 2009. Accessed at http://commerce.senate.gov/public/files/PotterTestimonyConsumerHealthInsurance.pdf.

21 Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy," March 2009. Accessed at http://www.medpac.gov/documents/Mar09_EntireReport.pdf.

22 The American Antitrust Institute provided a white paper assessing the structural issues posed by the proposed Express Scripts/Caremark merger. See American Antitrust Institute, (2007), available at https://www.antitrustinstitute.org/archives/files/AAI_Express%20scripts_Caremark_2-14_021520071110.pdf. The law firm that represented one of the parties in the Caremark/AdvancePCS merger observed that the investigation was closed on a "quick look" review. See Jonesday.com, Experience Details: Caremark, http://www.jonesday.com/experience/experience_detail.aspx?exID=S9298 (last visited July 1, 2008). The CVS/Caremark merger was resolved without the FTC's issuing a second request.

largest PBMs-Medco, Caremark and Express Scripts-nearly tripled their annual

profits from \$966 million to over \$2.7 billion.

Today the Committee will hear testimony of the problematic conduct CVS has engaged in after acquiring Caremark. This combination of the largest pharmacy chain with the largest PBM poses significant competitive concerns. The pharmacist testifying today is not alone in expressing these concerns. Consumer groups including the Consumer Federation of American and U.S. PIRG, Change to Win (a coalition of unions), and the National Legislative Alliance on Prescription Drugs (a bipartisan group of state legislators) have called on the FTC to investigate allegations of anticompetitive and deceptive conduct that have increased prices and reduced choices for consumers.

The concerns raised about the CVS/Caremark alliance bear a striking and disturbing resemblance to the Ingenix situation. In order for the health insurance system to function effectively, there needed to be an honest, independent broker to determine usual and customary rates. That was the purpose of Ingenix. United's ownership of Ingenix, however, distorted that relationship and created a conflict of interest. That is why the New York Attorney General required the divestiture of Ingenix and the creation of a non-profit entity to perform its function. Similarly, CVS' ownership of Caremark distorts Caremark's incentive and ability to be an honest broker. There is a clear conflict of interest and an ability to manipulate the relationship to harm CVS' rivals and consumers. Moreover, controlling health care costs and health care reform is dependent on PBMs being honest brokers. Caremark, because it is a CVS subsidiary, is unlikely to function as an honest broker.

More generally, PBM consumer protection issues have an important impact on the potential for the government to control health care costs, and for many of the issues that the government will struggle with in health care reform. As described in other testimony presented to this Committee, today there is a significant lack of transparency in PBM markets. Because of this lack of transparency, PBMs are able to "play the spread" between pharmaceutical manufacturers, pharmacies and the health care plans. As the union coalition Change to Win noted, "A lack of transparency is one of the key problems in the pharmacy benefit management industry. For example, PBMs often charge the health plans they serve significantly more for the drugs than they pay the pharmacies that distribute the drugs to patients. PBMs also may switch patients to a drug other than the one their doctor prescribed sometimes a drug more expensive for the health plan and patient to take advantage of rebates the PBM receives from drug manufacturers, which are often hidden from the PBM's customers." ²³ By playing the spread, PBMs can artificially decrease the level of reimbursement to pharmacies. This conduct is clearly similar to the types of fraudulent and deceptive conduct that United Healthcare engaged in with its Ingenix subsidiary

The lack of PBM transparency harms the government's efforts at controlling health care costs. The House Committee on Oversight in Government Affairs recently held hearings on the lack of PBM transparency and its impact on Federal Governmental programs. Change to Win and numerous other witnesses testified that the lack of oversight and transparency have led to higher drug costs for the Federal Government. Change to Win in particular noted how the CVS/Caremark re-

lationship deterred the ability to effectively control costs.

There are numerous other competitive concerns raised by PBMs. Some PBMs secure rebates and kickbacks in exchange for exclusivity arrangements that may keep lower priced drugs off the market. This is similar to the concerns raised over kickbacks in the GPO context. More recently there have been a series of acquisitions by PBMs to acquire specialty pharmaceutical companies. These specialty pharmaceuticals are higher-priced drugs that need special handling. After these acquisitions, many of these PBMs rapidly increased the price of these specialty pharmaceuticals.24

Yet there have been no FTC enforcement actions against anticompetitive or deceptive conduct by PBMs. As in the health insurance market, both private parties and states have attempted to fill the void. In the past four years alone, cases brought by a coalition of over 30 state attorneys general have brought several cases attacking unfair, fraudulent and deceptive conduct. Between 2004 and 2008, the three major PBMs have been the subject of six major Federal or multidistrict cases over

²³Change to Win. Letter to Chairman Lynch and the members of the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform. June 24, 2009. Available at http://Federalworkforce.oversight.house.gov/documents/20090625153554.pdf.

24 Freudenheim, Milt. "The Middleman's Markup." The New York Times. April 19, 2008. (At-

allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases listed below, resulted in over \$371.9 million in damages to states, plans, and patients so far.

- United States v. Merck & Co., Inc., et. al.—\$184.1 million in damages for government fraud, secret rebates, drug switching, and failure to meet state quality of care standards.
- United States v. AdvancePCS (now part of CVS/Caremark)—\$137.5 million in damages for kickbacks, submission of false claims, and other rebate issues.
- United States v. Caremark, Inc.—pending suit alleging submission of reverse false claims to government-funded programs.
- State Attorneys General v. Caremark, Inc.—\$41 million in damages for deceptive trade practices, drug switching, and repacking.
- State Attorneys General v. Express Scripts-\$9.5 million for drug switching and illegally retaining rebates and spread profits and discounts from plans.

A group of state attorneys general and the DOJ are continuing to conduct several investigations of the three major PBMs, and several private actions challenging their conduct have been brought by unions and other customers. The current concentration of the national full-service PBM market only exacerbates these problems, increasing the need for government enforcement and potential regulation of the in-

PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud. As a bipartisan group of state legislators noted:

We know of no other market in which there have been such a significant number of prominent enforcement actions and investigations, especially in a market with such a significant impact on taxpayers. Simply put, throughout the United States, numerous states are devoting considerable enforcement resources to combating fraudulent and anticompetitive conduct by PBMs. This is because those activities are taking millions of taxpayer dollars and denying government buyers the opportunity to drive the best bargain for the state.25

In an important decision upholding state regulation of PBMs, one Federal court observed "[w]hether and how a PBM actually saves an individual benefits provider money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider." The court elaborated:

This lack of transparency also has a tendency to undermine a benefits prorider's ability to determine which is the best among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal offering the highest rebate for each prescription filled could actually be the worst proposal of the propos as far as net savings are concerned, because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary, to the most expensive drugs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.2

Some of the problematic practices challenged in these cases include:

- secretly retaining most manufacturer payments, e.g., rebates, discounts and other fees, instead of passing through such payments to clients;
- switching plan members from low- to high-cost drugs;
- · favoring higher-cost drugs on their formularies;
- manipulating generic (maximum allowable cost) pricing;
- entering into exclusivity arrangements with specialty pharmaceutical manufacturers that raise the prices of those drugs;

²⁵Letter from Mass. State Senator Mark Montigny to FTC Chairman Deborah Platt Majoras.

May 11, 2005. (Attachment D).

26 Pharm. Care Mgmt. Ass'n v. Rowe, 2005 U.S. Dist. LEXIS 2339, at *7–8 (D. Me. Feb. 2, 2005), aff'd, 429 F.3d 294 (1st Cir. 2005).

- · conspiring with manufacturers to violate Omnibus Budget Reconciliation Act and "best pricing" regulations; and
- committing other contract or fiduciary breaches.

One chronic problem with PBMs is that of self-dealing. Plan sponsors purchase PBM services with the assumption they are an "honest broker" that will select the lowest cost, best product on an objective basis. These concerns of self-dealing were part of the reason the FTC challenged the acquisition of PBMs by pharmaceutical manufacturers in the mid-1990s—Merck's acquisition of Medco and Lilly's acquisition of PCS. The concern was that the pharmaceutical manufacturers would favor their own drugs on the PBM formulary. These cases were resolved with orders that

protected plan sponsors from the risks of self-dealing.

Unfortunately, these problems of self-dealing have continued to exist for PBMs. Almost all PBMs have their own mail order operations. Often, PBMs may favor drugs in which they receive a greater margin because they are dispensed by mail order, even though the plan sponsor or consumer may pay more. PBMs often seek to drive consumers to more highly profitable mail order distribution and away from independent pharmacies that offer the level of quality, advice and personal service consumers prefer. Consumers often suffer from the conversion to mail order: they are given little choice, there is a greater chance of adverse medical reactions, and there is little if any consumer service. Any consumer who has spent hours on the phone waiting for an answer on a mail order prescription sees little "efficiency" from these efforts to drive independent pharmacies from the market. Although an FTC study appeared to find little evidence of these problems of self-dealing, recent state enforcement actions have demonstrated that these problems are ongoing.

Unfortunately, the FTC has failed to investigate or take any enforcement action against this anticompetitive, fraudulent, and deceptive conduct. Even more troubling, in response to the substantial deceptive and fraudulent conduct uncovered in these state enforcement actions, several state legislatures have considered legislation to regulate PBMs. Many of the proposed statutes: (1) require transparency so the health plans can secure adequate information so they can receive the full benefits of any rebates paid to the PBM and (2) establish a fiduciary duty between the PBM and a plan to address the problems of conflicts of interest and self-dealing. When states have attempted to regulate PBMs to address the lack of enforcement, increase transparency or address forms of this deceptive conduct, the FTC has advocated on the side of the PBM industry in opposition to the proposed legislation. This is a mistake. As the American Antitrust Institute report to the Obama transition team observed: "[c]onsidering the substantial number of enforcement actions and the severity of the PBM conduct, we believe these efforts at regulating PBMs are well founded and that the FTC's advocacy has been ill-advised." ²⁷

In many cases the FTC has placed itself in opposition both to consumer groups and union plan sponsors that support the legislation. Opposing efforts to reign in conflicts of interest and improve transparency seem questionable. If there is anything the Ingenix example must teach us, it is that there is a significant potential for fraud and deception by health care intermediaries. Efforts to either clarify the duties of those intermediaries by establishing legal provisions making it clear they have a fiduciary duty to the plans, and providing adequate transparency so that plans can effectively monitor the PBMs' activities, would seem to be crucial ele-

ments for managing and controlling health care costs

Anticompetitive Conduct by Group Purchasing Organizations

GPOs negotiate contracts on behalf of their member hospitals with numerous entities, including medical device manufacturers. The original purpose of GPOs was to obtain better pricing on products than hospitals could obtain individually, and to provide value-added services. Although GPOs have the potential to reduce purchase costs by giving hospitals greater bargaining power, growing GPO consolidation and market power has increased the exclusionary potential of some of the GPO contracting practices.²⁸ Moreover, the payment of kickbacks is pervasive and undermines the product selection system.

Many small medical device manufacturing start-ups have demonstrated that contracting practices by GPOs have effectively foreclosed them from entering the market. Examples of alleged exclusionary practices include kickbacks, sole-source con-

²⁷The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President (Albert A. Foer ed., 2008).

²⁸See Hospital Group Purchasing: Has the Market Become More Open to Competition?: Hearing Before the S. Comm. on the Judiciary, 107th Cong. 3-4 (2003) (statement of Lynn James

tracts, market share discounts, auto-substition and bundling of products so hospitals must purchase the bulk of their supplies from a single vendor to qualify for a discount on any one product. Small manufacturers argue that incumbent suppliers, together with GPOs, use these practices to eliminate competition and preserve their market share.²⁹

Particularly problematic are kickbacks paid by manufacturers to the GPOs. These kickbacks deceive buyers and third parties (including government entities) that are responsible for payment for the products of the real costs of the products. They may distort demand and provide the opportunity to artificially increase prices. Although there are regulations that prohibit kickbacks in many health care markets, the GPO payments fall into a safe harbor. In the past 7 years, the Senate Judiciary Committee has held four hearings concerning kickbacks and other exclusionary conduct by GPOs. The FTC also addressed the issue in its 2003 health care competition hearings.³⁰ Over a dozen private suits have been brought, some successfully, by small innovative medical device manufacturers against exclusionary practices by GPOs and device manufacturers.³¹ Yet the FTC has failed to bring any enforcement actions in this area.

That is particularly unfortunate because of the FTC's unique statutory powers. The FTC brings competition enforcement actions under Section 5 of the FTC Act which prohibits "unfair or deceptive acts or practices." Section 5 is broader than the more traditional antitrust laws and enables the FTC to attack practices or conduct

that are not necessarily a violation of the Sherman or Clayton Act.

Section 5 may provide a useful tool in two respects to cure the harmful practices in the medical device market. First, to the extent that potential enforcement actions against market share discounts, or other forms of de facto exclusivity seem deficient against market share discounts, or other torms of de facto exclusivity seem deficient for some element necessary for a Sherman Act challenge, Section 5 may enable the FTC to overcome that deficiency. Second, the practices of kickbacks can be addressed under Section 5 as an unfair method of competition. A gap in enforcement currently exists because of the difficulty in proving that a kickback scheme constitutes a violation of the Sherman Act. The Ninth Circuit, after acknowledging the existence of a kickback scheme by an alleged health insurance monopolist caused higher co-payments and premium payments, found no antitrust violation because of a lack of evidence of harm to the relevant market.³² Carried to its logical extreme that decision would mean that the antitrust laws would not prevent every insurance company from engaging in kickbacks that raised costs to consumers. However, under Section 5 a kickback scheme could be an unfair method of competition, particularly where there is evidence of consumer harm. The FTC should use Section 5 to challenge these kickbacks.

More generally, Congress needs to address the GPO kickback issue. Congress created a "safe harbor" from the Medicare anti-kickback statute in 1987, permitting dominant suppliers to pay billions of dollars to GPOs. These payments are often used to exclude competitors resulting in increased cost and decreased quality of medical devices over the past two decades. In order to restore competition in the procurement of medical supplies, this safe harbor must be repealed and suppliers must no longer be permitted to fund the GPOs.

As a 2002 GAO reports suggests, GPOs have evolved from neutral buying units to "gateways" which permit manufacturers to enter into arrangements that may port noted that "a manufacturer dominant in a product line may contract with a GPO, or agree to a favorable contract, to preserve its market share and exclude competition."

32 See Forsyth v. Humana, Inc., 114 F.3d 1467, 1477-79 (9th Cir. 1997) (rejecting a claim that an insurance company's alleged kickback scheme caused antitrust injury to group health insurance customers where the evidence showed the scheme caused higher co-payments and premium payments, but did "not explain how the scheme reduced competition in the relevant market"), aff d on other grounds, 525 U.S. 299 (1999).

²⁹ See, e.g., Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?: Hearing Before the S. Comm. on the Judiciary, 107th Cong. (2002) (statement of Joe E. Kiani, President and CEO, Masimo Corp.).

³⁰ Fed. Trade Comm'n, Health Care and Competition Law and Policy Public Comments (2003), available at http://www.ftc.gov/os/comments/healthcarecomments2/index.shtm.

³¹ See Masimo Corp. v. Tyco Healthcare Group, LP, Case No. 02-CV-4770 (C.D. Cal. 2002). See also Genico, Inc. v. Ethicon, Inc., No. 04-CV-00229 (E.D. Texas 2004); Rochester Medical Corp. v. C.R. Bard Inc., Case No. 5:04-CV-060 (E.D. Tex. 2004); Applied Med. Res. Corp. v. Johnson & Johnson, Inc., No. 03-CV-1329 (C.D. Cal. 2003); ConMed Corp. v. Johnson & Johnson, Inc., No. 03-CV-8800 (S.D.N.Y. 2003); Medtronic AVE Inc. v. Cordis Corp., Case No. 03-CV-212 (E.D. Tex. 2003); Retractable Techs., Inc. v. Becton Dickinson & Co., Case No. 5:95CV00755 (W.D. Tex. 1995).

³² See Forsyth v. Humana, Inc., 114 F.3d 1467, 1477-79 (9th Cir. 1997) (rejecting a claim that

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

Besides greater antitrust enforcement, Congress should repeal the kickback safe harbor that permits GPOs to engage in this conduct that harms consumers and competition.

Recommendations for Revitalizing Competition and Consumer Protection Enforcement

- 1. The FTC should change the enforcement priorities to focus on the segments of the market with the greatest potential for harm: health insurance, PBMs and GPOs. The areas of the market that seem to pose the greatest competitive problems are health care payment intermediaries, such as insurers and PBMs. These are the entities that operate in the most concentrated markets, and the complexity and opaque nature of their practices make these markets a fertile medium for anticompetitive and deceptive conduct.
- 2. The FTC should create a vigorous health insurance consumer protection enforcement program. The FTC's health care consumer protection enforcement currently focuses on marketers of clearly sham and deceptive products. This is unfortunate. In many other areas, such as financial services, the FTC uses a broad range of powers, including studies, workshops, policy hearings, legislative testimony, and industry conferences to better inform marketplace participants of how to properly abide by the law. The FTC should adjust its healthcare consumer protection enforcement to focus on health insurers and PBMs. These efforts should focus both on enforcement to prevent egregious and fraudulent practices and to assure that there is a sufficient amount of information and choice so that consumers can make fully informed decisions. Because of the importance of these issues, especially in controlling health care costs, the FTC should establish a new division for health insurance consumer protection.
- 3. Reinvigorated enforcement against anticompetitive conduct. The FTC also needs to reinvigorate enforcement against anticompetitive conduct by health insurers, PBMs, and GPOs. The FTC should scrutinize anticompetitive conduct and use its powers under Section 5 of the FTC Act. As this Committee knows, Section 5 of the FTC Act can attack practices that are not technical violations of the traditional antitrust laws, the Sherman and Clayton Acts. Thus the FTC can use that power under Section 5 to address practices that may not be technical violations of the Federal antitrust laws, but still may be harmful to consumers. As I have testified elsewhere, the FTC should begin to use that power under Section 5 to attack a wide range of anticompetitive and egregious practices by health insurers, PBMs, and GPOs. 33
- 4. Stronger health insurance and PBM merger enforcement. During the Bush administration there was significant consolidation in both of these markets, and now these markets are incredibly concentrated. If the FTC and/or Justice Department lacks sufficient resources to effectively challenge anticompetitive mergers, they should be given those resources. If the current merger standards do not appropriate to effectively challenge these mergers, those standards should be reevaluated. Simply, the public cannot afford any greater consolidation in either health insurance or PBM markets.
- 5. Conduct a retrospective study of health insurer mergers. I have suggested elsewhere that one approach to this issue would be for the FTC or the DOJ to conduct a study of consummated health insurer mergers. One of the significant accomplishments of the Bush administration was a retrospective study of consummated health insurance mergers by the Federal Trade Commission. This study led to an important enforcement action in Evanston, Illinois, which helped to clarify the legal standards and economic analytical tools for addressing health insurance mergers. A similar study of consummated health insurance

mergers would help to clarify the appropriate legal standards for health insurance mergers and identify mergers that have harmed competition.

- 6. Greater studies of competitive problems in health insurance. The FTC performs an important function in providing studies on key public policy issues. The FTC should provide studies on health insurance and begin its efforts with a long-overdue examination of the McCarran-Ferguson exemption, the elimination of which would increase the potential for competition between insurance companies in health insurance and in other areas.
- 7. A more fully informed and balanced position in advocacy. In many cases the FTC has placed itself in opposition both to consumer groups and in union plan sponsors in proposed legislation to regulate PBM markets by improving transparency and giving plan sponsors tools to prevent conflicts of interest. As a general matter, I question the FTC's approach about criticizing proposed legislation seeking greater transparency and preventing conflicts of interest. If there is anything the Ingenix example must teach us, it is that there is a significant potential for fraud and deception by health care intermediaries. Efforts to either clarify the duties of those intermediaries by establishing legal provisions making it clear they have a fiduciary duty to the plans, and providing adequate transparency so that plans can effectively monitor the PBMs' activities, would seem to be crucial elements for managing and controlling health care costs.
- 8. Recognizing that the insurer and the PBM do not represent the consumer. Although insurers and PBMs do help to control cost, they are not the consumer. The consumer is the individual who ultimately receives benefits from the plan. It is becoming increasingly clear that insurers and PBMs do not act in the interest of the ultimate beneficiary. They are not the proxy for the consumer interest, but rather exploit the lack of competition, transparency, and the opportunity for deception to maximize profits.
- 9. Clarify the jurisdiction of the FTC to bring enforcement actions against health insurers. Some may suggest that the FTC lacks jurisdiction over health insurance. I urge this Committee to ask the FTC to clarify their position on this issue. Is the claim of no jurisdiction the law or simply an urban legend? As I understand it, there is a limitation in Section 6 of the FTC Act that prevents the FTC from performing studies of the insurance industry without seeking prior Congressional approval. This provision does not prevent the FTC from bringing either competition or consumer protection enforcement actions. There may be arguments that the McCarran-Ferguson Act limits jurisdiction, but that exemption is limited to rate making activity. In addition, some people might argue that the FTC's ability to attack anticompetitive conduct by nonprofit insurance companies might be limited under the FTC Act. The solution to this problem is simple, straightforward and critical. If the FTC lacks jurisdiction in any respect to bring meaningful competition and consumer protection enforcement actions against health insurers, Congress must act immediately to provide that jurisdiction. There is no reason why health insurance should be immunized from the Federal Trade Commission Act. Nor is there any reason why the agencies' recent failure to deploy enforcement resources should create a de facto exemption from antitrust or consumer protection enforcement for insurers or PBMs.

Conclusion

Ultimately, the current health insurance and PBM markets suffer from anticompetitive and fraudulent activity practically unknown in any other market. The current market structure and the control of health care payment systems by forprofit entities raise serious questions if meaningful reform can ever be accomplished. At least we should start by assuring that the full resources of Federal antitrust and consumer protection enforcement are utilized to begin to reform these markets.

Before it is too late.

 $^{^{34}\}mbox{In}$ a forthcoming paper I argue that the public plan is necessary for meaningful reform of health insurance markets.

Comparison of State Insurance Mergers

Requirement	United-Sierra	Blue Cross of CA	PacifiCare of CO	PacifiCare Life and Health of CA	PacifiCare of CA
Continued role in marketplace	HPN must continue serving the same Nevada marketplace using the 20. 20. arket place approach. P. 20.	BCC will continue its historic role in serving the California marketplace, serving the California marketplace, with regard to Med-Cal, Health with regard to Med-Cal, Health Families Program, Access for In- fants and Nuthers, and California Major Risk Medical insurance Pro- gram, individual and small group markets (PP, Z-6).	N/A	Practices and methodologies for in- demityPD, elefferected health plans, and Medicare Supplement products will not vary post-merger products will not vary post-merger and methodologies. (P. 2).	PCC will continue its historic role in serving the California marketplace, and will continue its same market- place approach (F. 12).
Compliance reports	HPN must file an Annual Compliance ander Report, destabling compliance with the requirements set forth in the Commitment Letter (HPN must prove it has not changed practices and methodologies, post acquisition). (F. 27)	For a period of 3 years following the merged edosing, BCC shall fite annual reports demonstrating compiliance with the Undertakings and what it believes to be the benefits of the Merger. (P. 12).	United must file an annual report certifying, among other things, that no debt financing factors or merger costs have been included as part of any premium rates. (F. 1).	PLHC shall file annually a report demonstrating compliance with each of the Undertakings. (F. 14).	PCC shall file a report annually with the DMHC demonstrating compliance with the Undertakings. (F.10).
Premium stability	Premiums paid by HPN individual or groups shall not increase (fee sta- bility). (P. 29).	N/A	Merger costs will not be passed onto Colorado consumers in the form of higher premiums (P. 1).	UnitedHealth and PLHIC undertake that premiums payable by PLHIC policyholders will not increase as a result of the Merger. (P.1).	Represents and warrant that premiums payable by PCC enrollees will not increase as a result of Merger costs. (P. 6)
Underserved narbets/small and individual markets	Must participate in the "Reinsur- ance Program" to attract and enable competition and product choice in the Newal market (PP. 29-50). HPN must maintain its efforts to provide services to underserved com- munities including Medicare and Medicaid markets, and to offer and remew individual and small group	N/A	N/A	PLHIC will maintain its current level of efforts in offering and re- newing individual and small group medical products. (PF. 8–9).	
PCC will maintain support for commercial HMO product de- velopment with emphasis on products appealing to small groups and individuals (P.15).	products: (r. 21).				
Claims platforms	Practices and methodologies with respect to adjudicating and paying commercial and Medicare claims after the acquisition shall not vary from pre-Acquisition practices. (P. 30-31).	N/A	N/A	N/A	N/A
Medicare business	Must offer substantially the same Medicare products and benefit designs during the Acquisition period. (P. 31).	N/A	N/A	N/A	N/A
Payments related to change in control	All payments relating to the change in control (severance payment, retention bonus payment, shall be the sole responsibility of Applicant, (P. 31).	All of the change in control severace pane paners and reterition bonus payments payable by reason of the merger will be the sole payment responsibility of Anthem. (P. 1).	N/A	UnitedHealth has paid for all executive change in control severance payments and retention bonus payments you reason of the Merger, and is solely the responsibility of United. (PP. 1, 6).	All of the executive compensation by reason of the Merger, including change in control payments will be the sole responsibility of UnitedHealth. (P. 2).

PCC will maintain its organizational and administrative apacticy, and unless the Department otherwise grants prov approval, this administrative apact with mis administrative apact by includes clinical decision-making and medical policy development, prov authorization, enrolles grivenes es sistem, independent medical review. (P. 8). PCC will not take any of the following educine consult and the following and portion of any current or future loans by United. or permit any portion of loans obtained by United the fall of the United the passes of its affiliates to be assumed by PCC. (P. 5). If there are any changes to an administrative service agreement to which PCC is a party with any PCC affiliate, PCC will file notice of the dehanges, and must obtain prior approval from the DMHC. (P. 9). PCC will renew and not terminate any group or individual commercial health care benefit plan contract. (P. 11-12). PCC agrees that it shall not remove, require, permit, or cause the removal of PCC's books and records. (P. 9). PCC will not declare or pay dividends, make other distributions of each or property, or in any way upstream any funds or property to UnitedHealth (P. 2). PacifiCare of CA PLHIC will not take any of the following actions: considerate consideration of any current or fitting loans entered into by United or its affiliates, permit a portion of loans obtained by United to be assumed by PLHIC, (P. 7). PLHIC will not declare or pay dividends, make other distributions of east or property, or in any other way upstream any funds or property to its corporate parents. (P. 6). If PLHIC decides to amend, change, terminate or replace its administratery services agreement(s) with PacifiCare, CDI must first approve. (P. 9). PLHIC will maintain its current level of efforts in offering and re-newing individual and small group Medical Products. (P. 8). PacifiCare Life and Health of CA PLHIC agrees that it shall not remove, or require, permit, or cause the removal of PLHIC's books and records. (P. 9). N/A United has no current plans to reduce in any material respect or incention to change the executive and operational presence of Pedicare in Co. for the foreseeable future. (P. 8). Comparison of State Insurance Mergers—Continued PacifiCare of CO N/A N/A N/A N/A BCC will not declare or pay divided and many of the cash or property, or in any other way upstream any finds or property to Anthem or any of its affiliates. (P. 2). Any proposed changes to the reimbursement rates or method for reimbursement under BCCs administrative services agreements with WellPoint, Anthem or any of their affiliates is changed, BCC must obtain prior approval from DMHC. (P. 7). BCC will maintain its organization and administrative uppercity, and will maintain a number of adminis-trative processes, e.g. prior author-ization, enrollee grievance, Inde-pendent Medical Review, provider dispute resolution, (PP, 6-7). BCC will not take any of the following actions without the Departments prior approval: co-sign or assume any current or fiture loans entered into by Anthem or its Affiliates. (P. 4). BCC shall renew, and shall not terminate, any group or individual health care service plan contract prior to the expiration of its term unless otherwise permitted under the Knox-Keene Act. (Pr. 5, 11). BCC agrees that it shall not remove, require the removal, permit, or cause the removal of BCC's books and records. (P. 7). Blue Cross of CA During the Acquisition period, HPN Eshall not cosgn or guarantee any Ichans, permit any portion of loans obtained by Applicant to be assumed siy HPN, borrow any funds for the epurpose of making a Persent Company Distribution, IP, 333. During the Acquisition Period, Applicant shall ensure that such affilia at an entire and are maintain, at a minimum, then will offlowing organizational and administrative functions in Nevada for its rative functions in Nevada for its rative functions in Nevada for its rative function in Nevada for its rative function in Nevada for its rative function prior authorized decision—making, prior authorized function independent raneital review processes; enrollee grievance; provident dispute resolution. (T. 34). During the Acquisition Period, nei-ther HPN nor Pacificate of Newda, shall declare or pay dividends, or similar distributions of cash or prop-ery in respect to its capital stock. (P. 32). If HPN decides to materially amend, A demone, A demone, terminate, or replace any administrative services agreement(s) but may of the parties involved, the MPN must file the changes with the V commissioner. (P. 34–38). During the Acquisition Period, HPN shall renew and not terminate any health benefit plan for any commer-cial insured and shall not terminate any health benefit plan before the end of its contract term, (P. 35-34). During the Acquisition period, all parties shall not remove, or require, permit, or cause the removal of HPNs books and records. (P. 34). United-Sierra s agree-under stability Indebtedness or obligations Dividends/distributions Administrative services ments/reimbursement of ASAs Requirement Local record retention offering Retention of local Health plan

Comparison of State Insurance Mergers

PacifiCare of CA	If PCC desires to amend, change, terminate or replace its tax sharing agreements, as previously filed, PCC can only do so upon prior DMHC approval. (PP. 9–10).	PCC's administrative expense ratio shall me exceed 10 percent, measured on an annual basis, which reflects the average of the annual percentage over the years 2002–2004. (P. 10).				United will contribute \$50 to benefit California health eare consumers (Charitable Commitment), P. 18). UnitedHealth, PCC and their affliisted are gree to invest \$500 million in CA's health care infrastructure (Investment Commitment), (P. 15–16).	
PacifiCare Life and Health of CA	If PLHIC decides to amend, change, If PCC deminate or repending agreements, PLHIC will file any agreements, PLHIC will file any changes to those tax sharing and can on must have prior approval by CDi. proval (P. 9).	PLHIC represents that it will main- it is 'Administrative Expense shall it shall it shall it greats. (PP. 9-10). greats. (PP. 9-10).	N/A N/A	N/A N/A	N/A N/A	See next column United Chalifor (Chalifor Chalifor Chalif	N/A N/A
PacifiCare of CO	N/A III	N/A street by Street st	The present executive officers and directors of Pacificare will not change as a result of the merger. (P. 8).	United has no current plans to reduce the number of Penficare employees, and compensation will ployees, and compensation will to the merger or to what similarly. To the merger or to what similarly. (P. 8).	N/A N/A	United Healthcare has agreed to contribute 7.5.5 million to improve access to care to rural and underserved Coloradans.	N/A
Blue Cross of CA	If BCC decides to change its tax sharing greenents, as previously filed with, and approved by, the Department. BCC will file any changes to those tax-sharing agreements with the Department. (7. 7).	The percentage of BCC's administra- tive cosis to premium revene will not exceed 13.3 percent that re- flects that average of the annual per- centage that BCC's administrative costs bear to its premium revenues for the years 2001–2003. IP. 7).	BCC and Authem will promptly provide the Department with copies of the written agreements of the executive officers of WellPoint and BCC. (P. 12).	N/A	N/A	BCC and Anthem undertake to implement the Investment in a plement the Investment in a 1. Healthy California Program. (P. 10). The WellPoint Foundation has agreed to commit \$5 million in each of 3 years (for a total of \$15 million) to its Insuring Healthy Futures initiative. (F. 10).	N/A
United-Sierra	After the closing date, if HPN decides to amend, change, terminate, or replace any tax sharing agreements. HPN shall file tax-sharing agreements with the Commissioner. (F. 36).)	Medical Expense Ratio assumptions for commercial rate fillings (e.g., the schedule of changes) shall not change during the Aquistion Period from those used previously. (P. 190). HPVs, Administrative Expense Ratio for its commercial products will not materially exceed HPVs average Administrative Expense will not materially exceed HPVs average Administrative Expense Rate for exage Administrative Expense Rate of the season of the commercial products of the season of the seaso	Certain current executives with Sierra who will join the combined business shall continue to be located in Nevada. (PP. 36-37).	Applicant shall maintain at least seventy-the percent (75 percent) of HPNs current number of employees in the State of Nevada during the Acquisition Period. (P. 37).	Applicant and HPN each work extensively with agents, brokers, and other distribution channels in Nevada. (PP. 37–38).	Applicant is expected to maintain, and build on, its and Sterra's community presence, including charitable giving and philanthropic and community endeavors, in Nevada. (P. 38).	During the Acquisition Period, Applicant shall not implement the \$50 sanction laboratory protocol, or any similar monetary out-of-retwork laboratory referral sanctions. (PP. 38–39).
Requirement	Tax sharing agreements	Administrative medical expense ratio	Management continuity/execu- tive agreements	Retention of employees	Distribution channels	Social responsibility	Laboratory protocol

In the event there are reductions in the level of provider remburse-ments, such reductions shall not be artiputable to Mergero costs. (P. 6). PCC is also required to maintain currently acquisted PCC contracts with wiling and capable physician groups, subject to mutual agreement on contract terms, including upon renewal. (P. 13). United agrees to implement and/or maintain vertain quilty programs or reporting methanisms, e.g., reporting quality of ear results, importing quality of ear results, importing Paulf Care is performance on all CARIN sores. United will structure the Paulf Care Pup program so that e lighle programs will receive an additional \$13.76 million, and will promote HIT infrastructure. (P. 13). PCC shall promptly pay for the costs arising from activities of the Department in determining the PCC's compliance with the Undertakings. (P. 11). PCC's practices and methodologies for determining products and bene-fits designs and premium prices must remain unchanged. (P. 6). PacifiCare of CA 4 years N/A PLHIC shall maintain compliance with specific nerties, and shall report quarterly its performance against metrics relating to complaint resolution, appeals resolution, claims processing within 30 days, and a auto-adjudication (PP 14-15). PLHIC will pay for the costs of all reviews the CDI determines are necessary to confirm compliance with the Undertakings. (P. 9). PL/HIC's methodologies for determining premium rates and benefit designs must remain unchanged. (P. 2.) PacifiCare Life and Health of CA See next column 4 years N/A United and PacifiCare will convene a Colorado Physician Advisory w Council which will meet regularly to discuss physician concerns. (P.2.) and United and PacifiCare will appoint an ombufaman for the Colorado Advisory (P. 2.). For the duration of the Underscheening of the United and Pacific Propries and PacifiCare of CO 3 years N/A N/A N/A BCC undertakes to implement the Patient Advocate Improvement Program (PAI Program). C. a tom-prehensive effort by BCC to bring demonstrable improvements to the members. (PP. 8–10). BCC undertakes to promptly pay for the costs arising from activities of the Department in connection with the Undertakings. (P. 12). There is not to be a change in the structure, composition and reimbursement payable to the health care providers supporting BCC's provision of products. (P. 6). Until terminated by agreement of BCC, Anthem, and the DMHC. (P. 13). Blue Cross of CA N/A HPN's practices and methodologies for determining commercial products and benefit designs and premiums cannot vary materially from pre-Ac-quisition status. (P. 28). There is not to be a change in the structure, composition, and reimbursements payable to the health care providers supporting HPN's provision of products and services. (P. 27). United-Sierra 2 years N/A N/A ΝΆ Assumption of regulatory costs Benefit design/premium cal-culation Specific physician-protection provisions Provider reimbursements Requirement Quality initiatives Duration

Comparison of State Insurance Mergers—Continued

FEDERAL AND STATE LITIGATION REGARDING PHARMACY BENEFIT MANAGERS

David A. Balto

From 2004—2008, the three major PBMs (Medco, CVS Caremark, and Express Scripts) faced six major Federal or multidistrict cases over allegations of fraud; misrepresentation to plans, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases resulted in over \$371.9 million in damages to states, plans, and patients so far. Below is a summary of these six cases. Note that the regulatory provisions of many of these settlements will expire within 2–10 years.

1. United States v. Merck & Co., Inc., et al., (also cited as United States of America v. Merck-Medco Managed Care L.L.C., et al.) (E.D. Pa.)

Settled: October 23, 2006 Damages: \$184.1 million

States participating: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

Claims.

Whistleblower lawsuits, filed under the Federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc., alleged that Medco:

- systematically defrauded government-funded health insurance by accepting kickbacks from manufacturers in exchange for steering patients to certain products:
- · secretly accepted rebates from drug manufacturers;
- secretly increased long term drug costs by switching patients away from cheaper drugs; and
- failed to comply with state-mandated quality of care standards.

Settlement:

- A preliminary settlement in April of 2004:
 - Required Medco to pay \$29.1 million to participating states and affected patients:
 - o Placed restrictions on the company's ability to switch drugs;
 - o Imposed measures to increase transparency; and
 - $^{\circ}$ Required Medco to adopt the American Pharmacists Association code of ethics for employees.
- The final settlement, brokered in October 2006 required Medco to:
 - o Pay an additional \$155 million;
 - Enter into a consent degree regulating drugs switching and mandating greater transparency; and
 - Enter into a Corporate Integrity Agreement (CIA) as a condition of Medco's continued participation in government health programs.

The Corporate Integrity Agreement will expire in 2011.

 United States of America, et al., v. AdvancePCS, Inc. (Case No. 02-cv-09236)(E.D. Pa.)

Filed: 2002

Settled: September 8, 2005 Damages: \$137.5 million

Claims

Whistleblower lawsuit, filed under the Federal False Claims Act, alleging that Advance PCS (now part of CVS Caremark):

- Knowingly solicited and received kickbacks from drug manufacturers in exchange for favorable treatment of those companies' products;
- Paid improper kickbacks to existing and potential customers to induce them to sign contracts with the PBM;
- Submitted false claims in connection with excess fees paid for fee-for-service agreements; and

• Received flat fee rebates for inclusion of certain heavily utilized drugs.

Settlement:

A settlement in September, 2005 required Advance PCS, Inc., to:

- Pay a \$137.5 million settlement and face a five-year injunction;
- Submit to regulations designed to promote transparency and restrict drug interchange programs;
- · Enter into a five-year Corporate Integrity Agreement; and
- Develop procedures to ensure that any payments between them and pharmaceutical manufacturers, clients, and others do not violate the Anti-Kickback Statute of Stark Law.
- United States of America, et al. v. Caremark, Inc. (Case No. 99-cv-00914)(W.D. Tex.)

Filed: 1999

Pending as of January 2009

States participating: Arkansas, California, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, North Carolina, Tennessee, Texas, Utah and Virginia.

Claims:

Filed by an ex-employee, this case was prosecuted under the Federal False Claims Act and numerous state False Claims Statutes. It alleges that Caremark (now part of CVS Caremark):

- Submitted reverse false claims to the Government in order to avoid, decrease
 or conceal their obligation to pay the government under several Federal health
 insurance programs including Medicaid, Indian Health Services, and Veterans
 Affairs/Military Treatment Facilities.
- 4. States Attorneys General v. Caremark, Inc.

Filed: February 14, 2008

Settled: February 14, 2008

Damages: \$41 million

States participating: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia and Washington.

Claims:

Complaint decrees and consent orders against Caremark issued by 29 Attorneys General on February 14, 2008 allege that Caremark:

- Engaged in deceptive trade practices by encouraging doctors to switch patients from originally prescribed brand drugs to different brand name drugs.
- Did not inform clients that Caremark retained all the profits reaped from these drug switches; and
- Restocked and re-shipped previously dispensed drugs that had been returned to Caremark's mail order pharmacies.

Settlement:

In conjunction with the complaints, states issued a consent decree/final judgment that required Caremark to:

- Pay a collective settlement of \$41 million;
- Significantly change its business practices by imposing restrictions on drug switches and creating greater transparency;
- · Apply a code of ethics and professional standards; and
- Refrain from restocking and re-shipping returned drugs unless permitted by law.

5. State Attorneys General v. Express Scripts

Settled: May 27, 2008

Damages: \$9.3 million to states, plus up to \$200,000 to affected patients

States participating: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington.

Claims:

State Attorneys general settled consumer protection claims alleging that Express Scripts:

- Engaged in deceptive business practices by illegally encouraging doctors to switch their patients to different brand name drugs; and
- Illegally increased their spreads and rebates from manufacturers without passing the savings on to the plans.

Settlement:

The settlement required Express Scripts to:

- \bullet pay \$9.3 million to the states, plus up to \$200,000 in reimbursements to affected patients.
- Accept restrictions on drug switching practices;
- · Increase transparency for plans, patients and providers; and
- Adopt a certain code of professional standards.
- Local 153 Health Fund v. Express Scripts (In re Express Scripts, Inc. Pharmacy Benefits Management Litigation) (Case No. 4:05-md-01672-SNL)

Case consolidated: April 29, 2005

Pending as of January 2009

Claims:

This case, filed in the Eastern District of Missouri, alleges that Express Scripts:

- Retained undisclosed rebates from manufacturers;
- · Enriched itself by creating a differential in fees;
- Failed to pass on or disclose discounted drug rates and dispensing fees;
- Gained kickbacks from drug manufacturers in exchange for favoring certain drugs on the formulary;
- · Circumvented "Best Pricing" rules to artificially inflate AWP; and
- Enriched itself with bulk purchase discounts that it failed to pass on to the plaintiffs.

The New York Times—April 19, 2008

THE MIDDLEMAN'S MARKUP

By Milt Freudenheim

Doctors treating children with a rare and severe form of epilepsy were stunned by the news. A crucial drug, H.P. Acthar Gel, that had been selling for \$1,600 a vial would now cost \$23,000.

The price increase, put in place over last Labor Day weekend, also jolted employers that provide health benefits to their workers and bear the brunt of drug costs. As it turned out, the exclusive distributor of H.P. Acthar Gel is Express Scripts,

a company whose core business is supposed to be helping employers manage their drug insurance programs and get medicines at the best available prices.

But in recent years, drug benefit managers like Express Scripts have built lucrative side businesses seemingly at odds with that best-price mission. A growing portion of their revenue comes from acting as exclusive or semi-exclusive distributors of expensive specialty drugs that can cost thousands of dollars. And the prices of such medicines are rising much faster than for the mainstream prescription drugs available through a wide variety of distributors.

Critics say that distributing specialty drugs with ever-higher prices runs counter to the best interests of the employers that hire companies like Express Scripts.

"We are headed right down into conflict alley with these exclusive arrangements," said Gerry Purcell, an Atlanta-based health benefits consultant to big employers. As exclusive or semi-exclusive distributors of specialty drugs, the benefit managers "can raise the prices at will," Mr. Purcell said, "and the employer will have little chance but to pay the bill."

Express Scripts' main competitors, CVSCaremark and Medco Health Solutions, have also built lucrative side businesses in specialty drugs. So have some of the biggest insurers that provide medical benefits to corporate America, including UnitedHealth Group, Wellpoint, Aetna and Cigna.

When asked about the potential conflicts, Express Scripts and the other companies—which are known as pharmacy benefit managers—tend to describe themselves as mere middlemen with little influence over what the drug makers choose to

Steve Miller, an Express Scripts executive vice president, said of the H.P. Acthar Gel episode: "The increase was a manufacturing decision. I can't comment on that."

The pharmacy benefit managers say that keeping a lid on employers' drug costs is still their top priority. And they defend their involvement with specialty drugs, saying it helps them keep better track of the medicines' use.

"I don't believe it is a conflict," said Dave Rickard, an Executive Vice President

of CVS Caremark. "We saved clients \$115 million last year that would have been

spent on specialty drugs that were not appropriate.

But CVS Caremark, meanwhile, sold nearly \$6 billion in specialty drugs last year through its pharmacy benefit management business—nearly 14 percent of the company's annual revenue.

The main drug benefit managers make as much as 10 to 15 percent on each sale of a specialty drug, whose prices can range from \$5,000 a year for certain anemia drugs to \$389,000 in the case of Soliris, a drug for a rare blood disorder, whose distributors include Express Scripts' specialty drug unit, CuraScript.

Spending on specialty drugs rose 16.5 percent in 2006, growing twice as fast as traditional drug spending, and totaled about \$62 billion—which was about 23 percent of overall drug sales in this country, according to Charles Boorady, a Citigroup health care analyst.

Big employers and organizations including General Motors, Caterpillar and Calpers, the large California public employees health and pension group, say their spending on specialty drugs is growing at double the rate of the rest of their drug benefits for employees.

In some cases, employers are starting to push back. A group of large- and medium-size companies like Kinder Morgan Energy, a Houston pipeline company, and Enodis, an international restaurant equipment maker with United States head-quarters in Florida, recently pushed CVS Caremark to agree to hand back \$15 to the employers on each prescription filled for all specialty drugs listed in a Caremark

The giveback is meant to let the employers share a portion of the rebates that the pharmacy benefit managers often collect from drug makers in addition to keeping a portion of sales. But the giveback is relatively minuscule, acknowledged David Dross, a drug benefits specialist at the Mercer benefits consulting group who helped organize the employer effort.

With specialty drugs, the pharmacy benefit managers are "getting a lot more than

Susan A. Hayes, a drug benefits consultant based in Lake Zurich, Ill., said she had seen rebate contract terms that give the pharmacy benefit managers rebates

of 3 percent to 10 percent of the selling price.

Specialty drugs are aimed at diseases that include cancer, multiple sclerosis and hepatitis C. Some, for rarer disorders, may have Federal "orphan drug" status that gives a manufacturer exclusive marketing rights for a certain period. Specialty drugs also include medications whose distribution is tightly regulated as federally controlled substances, like the narcolepsy treatment Xyrem, which is distributed through Express Scripts.

Makers of specialty drugs can command lofty prices mainly because patients have few alternatives, and there is typically little or no competition—whether because the medicine still has patent protection or the drug is difficult to make. Or it may be, as with H.P. Acthar Gel, that the patent has long since lapsed but there is a relatively small number of patients.

With specialty drugs representing about 60 percent of the new medicines submitted for approval by Federal regulators, their overall cost will probably keep pushing up drug expenses well into the future.

Express Scripts is smaller than Medco and CVS Caremark, but it gets a bigger share of its revenue from specialty medicines—19.8 percent of its 2007 revenue of

That compared with about 13 percent of Medco's \$44.5 billion total revenue last year. And it compared with about 13.9 percent of CVS Caremark's total of \$43.3 billion, not counting \$2 billion sales of specialty prescriptions filled at CVS retail drug-

Express Scripts also has a larger number of exclusive distribution deals, with sole rights to 7 specialty drugs, all of which have orphan drug designation, as well as 11 more that are available through only one or two other national distributors.

Medco's specialty unit, Accredo Health, lists 4 orphan drug exclusives and 21 more drugs it shares with one or two other distributors. CVS Caremark said it had one exclusive and 35 drugs available from a limited group of specialty pharmacies.

In the case of H.P. Acthar Gel, an injectable anti-seizure medication derived from long hormones, the fourteen-fold price increase came after the maker. Questor Phar-

hog hormones, the fourteen-fold price increase came after the maker, Questcor Pharmaceuticals, gave exclusive distribution rights to Express Scripts' CuraScript unit last summer.

"This sort of puts the spotlight on the greed angle of the business," said Dr. Robert R. Clancy, a pediatric neurologist at Children's Hospital of Philadelphia. He has been using H.P. Acthar Gel to treat a severely ill 3-year-old girl, Reegan Schwartz. Employer health plans bear most of the drug's steep cost, with individuals in many cases making only a standard co-payment. In the case of the two courses of Acthar treatments for Reegan, the cost to her father's health plan was about \$226,000. Her father, Mike Schwartz, who works for a large pharmaceutical company, Merck, that has no ties to Acthar or its manufacturer, said he ended up paying only \$60 out of pocket for the Acthar therapy.

Steve Cartt, a Questcor Executive Vice President, said the new price was chosen

by looking at the prices of other specialty drugs and estimating how much insurers

and employers would be willing to bear.

"We did some market research," Mr. Cartt said. Talking to pediatric neurologists and others about various pricing options "gave us some comfort that the strategy would work, and physicians would continue to use the drug, and payers would pay," he said. "The reality was better than we expected."

May 11, 2005

Hon. Deborah Platt Majoras, Chair, Federal Trade Commission, Washington, DC.

RE: FTC ADVOCACY ON PHARMACEUTICAL BENEFIT MANAGERS

Dear Chair Majoras:

I am writing to you as Chair of the National Legislative Association on Prescription Drug Prices ("the Association"), a nonpartisan alliance of state legislators from 10 states and the District of Columbia. The goal of the Association is to foster efforts by state legislators to effectively manage pharmaceutical costs. As you know pharmaceutical costs are a rapidly increasing amount of state budgets and control of these costs is vital to the fiscal well-being of the states.

On May 6, 2005, the members of the Association met and discussed the FTC's recent opposition to bipartisan legislation seeking to regulate Pharmaceutical Benefit Managers (PBMs). As you know, PBMs have the capability of enabling buyers to secure lower priced pharmaceuticals. However, there have been numerous state and Federal investigations and enforcement actions which have uncovered a variety of deceptive and fraudulent practices by PBMs. Our own experience as state legislators dealing with state agencies which must negotiate with PBMs has shown that PBMs often act contrary to the interests of the buyers they represent.

PBMs often direct individuals to drugs that provide the PBM with the highest rebates, and the greatest margins, while failing to pass those savings on to purchasers. These practices can be dangerous, especially when the PBM directs an individual to a drug that is less beneficial to that individual than the prescribed drug. The operations of PBMs are often not transparent, which enables them to engage

¹Current membership includes the following legislative bodies: Connecticut, District of Columbia, Hawaii, Maine, Massachusetts, New Hampshire, New York, Pennsylvania Senate, Rhode Island, West Virginia, Vermont. In addition, legislators from over 20 other states participate in the Association's meetings, in working groups, and subscribe to our newsletter.

in these practices without regulation from market forces. There have been numerous state and Federal investigations and enforcement actions that have uncovered a variety of deceptive and fraudulent practices by PBMs.

In several states, state legislators have sought to address the problem of this deceptive and fraudulent activity by introducing legislation to require PBMs to provide a certain level of transparency on the rebates and side payments they receive. The purpose of this legislation is to enable buyers, both governmental and private, to be fully informed and be able to effectively bargain for lower prices and better service.

At our meeting the Association voted to express our profound concern about the FTC's recent efforts to oppose this bipartisan legislation. As state legislators we appreciate the efforts of the FTC to inform the legislative debate, especially when based on solid empirical information. The FTC's advice is particularly useful when the FTC has taken enforcement actions in an area and through those actions has extensive experience in the market. Unfortunately, the FTC's recent efforts opposing state legislation concerning PBM practices fails to meet these standards and the past practice of the Commission. Indeed, the FTC's comments ignore the strong evidence of deceptive practices in the market, the need for state regulation, and the inability of buyers, including governmental entities, to secure information about these practices.² The comments appear to be based on economic theory, but theory not backed up by empirical evidence is not particularly helpful in this environment. Moreover, by failing to speak with the elected officials advocating this legislation the FTC creates the appearance of being one-sided and denies the advocates the ability to make their case for the legislation.

Deceptive, Fraudulent and Anticompetitive Activities by PBMs. As state legislators we are keenly aware of the types of deceptive and fraudulent practices engaged in by PBMs. We know that many of our state agencies which contract with PBMs have been victimized by fraudulent conduct by PBMs. In numerous states there are ongoing investigations on this type of activity and some cases have been brought. As you know, many of the major PBMs are under investigation by a multi-state coalition of state attorneys general. Some of these investigations have been joined by the U.S. Attorney's offices in Massachusetts and Pennsylvania.

Let me focus on the most significant enforcement action to date. On April 26, 2004, the United States, 20 state attorneys generals (including six states that are members of the Association), and the defendants Merck & Co., Inc., Merck-Medco Managed Care, L.L.C., and Medco Health Solutions, Inc. (together referred to as "Medco"), agreed to a settlement of claims for injunctive relief and violations of unfair trade practice laws. The complaint attacked a wide variety of fraudulent and deceptive conduct by Medco, documenting at length Medco's efforts to prefer higher priced drugs, engage in unwarranted and harmful "therapeutic interchange" (in other words, drug switches), and fail to pass on payments to the covered entities.

For this fraudulent and deceptive conduct the states secured \$20 million in damages, \$6.6 million in fees and costs, and about \$2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. As important is the injunctive relief. This settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in 2 years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;

² See Letter to Assembly Member Greg Aghazarian, Sept. 4, 2004; Letter to Senator Richard T. Brown, March 8, 2005.

³Consolidated Case No. 00–cv–737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches:
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

This case and its settlement was a significant step forward in holding PBMs accountable for their actions, making their activities more transparent, and ensuring that consumers are protected. The settlement resolved only some of the charges in the Medco complaint. Further enforcement actions are expected as investigations by two U.S. Attorney's Offices and over 20 attorneys general continue. For your review and consideration, I attach an index of recent Federal and state enforcement actions

The recent decision of the Federal District Court in *Pharmaceutical Care Management Association (PCMA)* v. *Rowe*, Civil No. 03–153–B–H (April 13, 2005), which upheld the Maine law that regulates PBM practices such as drug switching and requires greater transparency in transactions between PBMs and their clients affirmed the advantages of such regulation. The court noted that "(w]hether and how a PBM actually saves an individual benefits provider money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider." In fact, the court stated.

This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best proposal among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal as far as net savings are concerned, because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary, to the most expensive drugs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.⁴

We know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, especially a market with such a significant impact on taxpayers. Simply put, throughout the United States, numerous states are devoting considerable enforcement resources to combating fraudulent and anticompetitive conduct by PBMs. This is because those activities are taking millions of taxpayer dollars and denying state government buyers the opportunity to drive the best bargain for the state.

tunity to drive the best bargain for the state.

Despite this growing body of hard evidence of at worst fraudulent activity, and at best merely obfuscating behavior, the FTC has either remained on the sidelines or weighed in apparently in support of the PBM industry. We are unaware of any significant competition or consumer protection investigations of PBMs in recent years, nor has the FTC joined in any of the state or Federal investigations. We recognize that the FTC has limited resources. But we question the decision by the FTC to expend those limited resources actively opposing bipartisan PBM legislation pending in state legislatures around the country, while abstaining from involvement in these enforcement actions and investigations. Moreover, the FTC's comments have been used by the PBM industry's advocates in these legislative debates to suggest that the FTC has given the PBM market a "clean bill of health." That is belied by our actual experience in the marketplace.

The FTC Comments Lack an Empirical Basis for their Broad Conclusions. The FTC comments fundamentally argue that transparency would be harmful because it would limit the ability of PBMs to engage in selective contracting and offer limited formularies. The comments also suggest that transparency may lead to tacit col-

 $^{^4}Pharmaceutical\ Care\ Management\ Association\ (PCMA)\ v.\ Rowe,\ Civil\ No.\ 03-153-B-H\ (April\ 2005)(at\ 4-5).$

lusion and higher drug prices. As you have acknowledged, the FTC's advocacy comments are most effective when they are based on a sound empirical foundation.⁵ In this case, the comments are primarily based on general economic theory. As far as we know there was no effort by the FTC to analyze the market environment in either North Dakota or California, two of the states in which the FTC has intervened in the legislative debate. Nor was there any effort to analyze how transparency has affected the market in those states where it is required or in other health care environments (such as Federal regulation of group purchasing organizations) where transparency is mandated.

As far as we know, most of the FTC's "empirical basis" for its understanding of the PBM market was its investigation of the Caremark/Advance PCS merger. Of course, that was a merger investigation which focused on the likelihood of anticompetitive price increases and not fraudulent activity in the market.⁶ Although the PBM industry uses the approval of that merger to suggest there are no competitive problems in the market, as far as we know it did not address any of the consumer protection and deceptive conduct investigations being investigated by the states and the U.S. Attorney's offices. We presume the fact that a market is competitive does not suggest that there can not be deceptive and unfair conduct in the market.

The lack of real world analysis is most apparent in the FTC's comments on the supposed potential for transparency to facilitate collusion among pharmaceutical manufacturers. The FTC's speculation in this area rests on the assumption that prescribers will share rebate information with manufacturers. The FTC does not, however, provide any empirical basis for that assumption. It seems questionable that prescribers would have any incentive to share this information. Nor does the FTC identify that this type of information sharing has actually happened in the states where transparency is mandated.

The FTC comments fundamentally argue that transparency would be harmful because it would limit the ability of PBMs to engage in selective contracting and offer limited formularies. The comments also suggest that transparency may lead to tacit

collusion and higher drug prices.

The FTC's comments rest upon a misunderstanding of the dynamics of the pre-scription drug market. The FTC argues that competition among PBMs will bring about the efficient level of disclosure and transparency. We can not concur with the assessment of vigorous rivalry in the market. Health plans, both government and commercial, face high PBM-switching costs, which prevent them from reaping the benefits of this supposed competition. The market is highly concentrated in the hands of the three largest PBMs, which are insulated from potential competition by high barriers to entry. But even if the assessment of active rivalry was correct, the major PBMs have declined to provide a significant degree of transparency. Finally, as the FTC and the courts have noted in several instances, lack of transparency denies information to consumers, which in turn prevents markets from functioning efficiently. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 454-55 (1986). Even if a market is competitive, it may nonetheless contain deceptive or unfair conduct that would justify legislation by the states and the Federal Government.

We believe that there should be a fully informed debate about the effect of transparency on competition in the market. To the extent transparency may be harmful, by facilitating collusion, for example, those concerns could be addressed by protections against sharing the information. The FTC could provide a valuable role by explaining how transparency could be implemented with safeguards to prevent inadvertent collusion. Significantly, the only court decision to address the issue head on, based on an evidentiary record, found that a greater degree of transparency would benefit consumers by lifting the "layer of fog" PBMs introduce.

Finally, we believe it is important for the FTC to know the on-the-ground facts before commenting on proposed legislation. Information such as whether a state's market is dominated by a single PBM is relevant to the question of whether states, pharmacies and health plans have any bargaining power when negotiating with the dominant PBM. Other information such as allegations that PBMs have engaged in therapeutic substitution which ultimately lead to the use of higher priced drugs is also relevant to the legislative debate, and it would be helpful if the FTC would investigate these and other allegations prior to opining that regulation is unnecessary or even harmful to consumers.

⁵ See Remarks of Chairman Deborah Majoras, "A Dose of our Own Medicine: Applying a Cost/Benefit Analysis to the FTC's Advocacy Program." (Feb. 8, 2005).

⁶ We note that the lawyers for one of the parties in the merger claimed that the investigation was completed after only a "quick look" review. See http://www.jonesday.com/experience/experience_detail.aspx?exid=1718903.

The Process of Making Fully Informed Advocacy Comments. As duly elected state legislators, we strongly believe in the legislative process and the opportunity for a fully informed and balanced debate. We are therefore concerned about the fact that in its comments to the North Dakota and California legislatures, the FTC failed to speak to the advocates of the legislation. Such a discussion may have provided better information about the reasons for the legislation, the alternatives considered, the specific "on-the-ground" facts that led to the legislation, and the unique circumstances of the markets in those states. The discussion would have highlighted problems that state buyers have had in securing even a moderate level of transparency and concerns about inappropriate therapeutic substitutions. Such a dialogue may have better informed the FTC staff's perspective on the legislation in question. The FTC's failure to seek this input has created the impression that its comments are not balanced or fully informed.

We hope you find these comments helpful. We look forward to the opportunity to work together with the FTC to assist it in obtaining a balanced and fully informed

perspective on proposed state legislation.

Respectfully submitted,

SENATOR MARK MONTIGNY, Chair of the Board.

Attachment: Appendix of legal actions cc. FTC Commissioners

Senator PRYOR. Thank you. Mr. Riley?

STATEMENT OF MARK RILEY, NATIONAL TREASURER. NATIONAL COMMUNITY PHARMACISTS ASSOCIATION (NCPA)

Mr. RILEY. Good morning, Chairman Rockefeller, Chairman Pryor, and Ranking Member Wicker. Thank you for allowing me the opportunity to speak before you this morning on the critical issue of fair competition in the community pharmacy industry, par-

ticularly the independent community pharmacy industry. My name is Mark Riley and I've been an independent pharmacist

for over 30 years, and I currently serve as national treasurer of the National Community Pharmacy Association, or NCPA. In addition to my duties as a national officer for NCPA, I have owned East End pharmacy in a small town outside of Little Rock for-Little Rock, Arkansas—for the last 26 years. I currently serve as the Executive Vice President of the Arkansas Pharmacy Association, where I've been for the last 6 years.

I've spent my entire career serving patients in the independent community pharmacy marketplace, and advocating for a level playing field throughout the pharmacy industry. I've also worked as a pharmacy consultant for 10 years within the pharmacy benefit manager industry, the PBM industry. My background has afforded me the opportunity to work on a variety of challenges and problems that are anticompetitive—that have an anticompetitive nature within our healthcare industry, and I would like to take this opportunity to discuss just a few of those with you today, particularly concerning the PBM industry.

The first issue I'd like to address is the retail class of trade pricing. In the United States, pharmaceuticals are sold by the pharmaceutical manufacturers at different prices to different entities, such as retail pharmacies, hospital pharmacies, long-term care pharmacies, and mail-order pharmacies. Historically, the differences in pricing have not substantially affected retail pharmacies, because retail pharmacies are not competing for patients in hospitals or in

long-term care facilities.

However, mail-order pharmacies pose a different threat to retail pharmacies, because mail-order pharmacies are competing for the same patients as retail pharmacies. And the mail-order pharmacies are doing so using preferentially priced prescription medications. This results in mail-order pharmacies buying prescription medications at prices that retail pharmacies cannot access, and this is why we're so concerned with mail-order pricing being included in the calculation of average manufacture price, or AMP. This discrepancy in pricing is fundamentally unfair, and does not promote true competition.

This leads to my second issue today: mail-order pharmacies. Now, I'm going to reverse myself a little bit. Because of the preferential pricing afforded mail-order pharmacies, one might assume that mail-order prescriptions are cheaper. This seems to be the general consensus. However, in my experience, this is not the case. Mail-order is steeped in deceptive pricing schemes that are intended to dupe employers into believing that they are saving money.

If you would turn to Exhibit 1 in your handout, I will walk you through how pharmacy benefit managers, PBMs, and their mail-order pharmacies deceive their clients.

Retail vs. Mail Ord Lipitor 20mg #30	ler Pricing
At RetailPharmacy PaidAWP-15% + \$2.00	At Mail Order Pharmacy Paid AWP-22% + \$0.00
AWP* = \$4.58/tablet 30 x \$4.58 = \$137.40	AWP* = \$7.08/tablet 30 x \$7.08 = \$ 212.40
*2009 Red Book Pricing	\$212.40 - \$46.73 = \$165.67 lail Order vs. Retail

Prescription medications are currently priced on average wholesale prices, AWPs, which are determined by the drug manufacturer. The PBMs have devised ways to change their AWPs to their advantage.

If you will look at this sheet, in front of you, you see—that's about Lipitor. We took the number-one drug in the United States—Lipitor—and what you'll see on the left column is what—the price that the retail pharmacies typically pay for this drug. And we'll use

a typical retail pharmacy reimbursement that is 15 percent off of the AWP.

The AWP of this drug at retail pharmacies, the size they get, is \$4.58 a tablet. For 30 of those tablets, if you multiply, the sheet shows it's \$137.40. Does everybody have that? The \$137 minus the 15 percent, which comes to \$20.61—and the number you need to remember is \$116.79—would be paid to the retail pharmacy for the drug portion of that product. They would also get a \$2 dispensing fee, a meager \$2 dispensing fee. But the drug portion would be \$116.79.

In the next column, mail-order will offer a 22-percent discount—AWP minus 22 percent—and spout about having no fee. AWP of—we took a middle-of-the-road product that had been repackaged. The way this is done is, the drugs are bought in bulk, they're repackaged, given a new NDC number, and a—and given a whole new set of pricing—AWPs that are elevated. The range was from the \$4.58 up to about \$11 in the Red Book, which—it lists those.

We picked one in the middle. It's \$7.08. So you see the math. Thirty times \$7.08 is \$212.40. Take away the 22-percent discount

of \$46.73, and the final price to the payer is \$165.67.

So, we have a payer who thinks they're getting a better deal, they've gotten a 22-percent discount instead of a 15-percent discount, and yet they paid \$48.88 more, in final, for the drug. This happens in about 30 to 35 percent of the prescriptions, we believe, in mail-order prescriptions today, which actually runs the cost higher, not lower, while the employer thinks they got a better deal.

As you can see, PBMs sell their so-called savings in terms of percentages, not real dollars. This is only one of the games the PBMs

use to deceive purchasers of prescription drugs.

This leads to the third issue I want to address today, PBM spread pricing. Spread pricing is another game that the PBM's use, which thwarts competition by making local community pharmacy prices look inflated. Simply put, the PBMs pay the pharmacy one amount and charge the purchaser a larger amount, but lead the purchasers to believe that the larger amount was actually paid to

the pharmacy. In reality, the PBM pockets the difference.

If you'll look at Schedule 2—Exhibit 2, very quickly, this is an example of—we worked with an employer in Hot Springs who was—and to make this very simple, these are showing the spreads—and we'll go over this later, if you'd like to—but, the bottom line was that employer, small employer with 200 employees, about 500 lives, was paying \$22.25 a prescription more than they were paying the pharmacists on their generic prescriptions. It was extremely egregious, as to what was happening to that employer, and they had no idea. Essentially, the pharmacy was being paid about \$22-and-some-change, on average; they were adding \$22-and-some-change, for a total price of \$45 to the employer on their generics.

Arkansas E			
Drug	Pharmacy Paid	Employer Charged	Hidden PBM Spread
Meloxicam Tab 15mg #28	\$10.00	\$117.25	\$107.25
Gemfibrozil 600mg #31	\$15.28	\$35.50	\$20.22
Timolol Gel Solution 0.5%	\$22.93	\$29.32	\$6.39
AVERAGE CLAIM DATA	\$22.95	\$45.50	\$22.55
	1000		3 74 7

Let me move on and finish. One of the examples, we didn't even put on here, the most egregious example. Pharmacy was paid \$14.40 for a cholesterol-lowering drug, but the PBM charged the employer \$126.72 for a drug they paid the pharmacy \$14.

This leads to the final issue. So, how can a community pharmacy compete fairly, when the true amount paid to them is virtually ir-

relevant to the ultimate cost of the purchaser?

This leads to the final issue I want to address this morning, and it's the CVS Caremark merger. This ill-advised merger, approved by the FTC, takes the smoke-and-mirrors practices of the PBMs to a whole new level, and its effects are obviously anticompetitive.

In additions to the acts I have previously discussed, the merger now allows CVS Caremark to monitor and utilize every aspect of the community pharmacy transaction to their own advantage. Please, imagine a business that gets to determine which of its competitors can compete for the customers, how much the competitor will be paid, and then captures all of the data from the competitor's transaction, and uses this data to solicit the competitor's customers.

This scenario is exactly what CVS Caremark is doing. CVS Caremark, in its PBM capacity, controls the pharmacy network, controls the amount paid to its competing community pharmacies, and controls all the data from the transaction which is being supplied to its retail pharmacy division—to its own retail pharmacy division.

Mr. Chairman, these are just a few of the problematic anticompetitive issues that community pharmacies and their patients are facing due to the PBMs. I thank you for the opportunity to speak before the Committee today, and I welcome any questions you may have.

[The prepared statement of Mr. Riley follows:]

PREPARED STATEMENT OF MARK RILEY, NATIONAL TREASURER, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION (NCPA)

Chairman Pryor, Ranking Member Wicker, and Members of the Consumer Protection, Product Safety, and Insurance Subcommittee of the Senate Commerce, Science, and Transportation Committee. The National Community Pharmacists Association (NCPA) and I appreciate you conducting this hearing on "Competition in the Health Care Marketplace", and for giving me this opportunity to testify on behalf of independent community pharmacists. My name is Mark Riley. I have been an independent pharmacist for over thirty years, and I currently serve as national treasurer of NCPA. From my perspective, in order to increase the quality of care and the number of people receiving care, there must be transparency and the elimination of self-dealing, so that competition is fair and ensures that both private and public health care expenditures are used efficiently.

NCPA was founded in 1898 as the National Association of Retail Druggists

NCPA was founded in 1898 as the National Association of Retail Druggists (NARD) to promote pharmacy as a profession and the role of independent community pharmacy in delivering quality prescription and related health care to their patients. NCPA represents the 55,000 pharmacists, pharmacist owners, managers and 300,000 employees of more than 23,000 independent community pharmacies across the United States. Independent pharmacists provide prescription drug and related health care services to millions of patients, many of them in underserved areas.

In addition to my duties as a national officer for NCPA, I have owned East End

In addition to my duties as a national officer for NCPA, I have owned East End Pharmacy in a small town outside of Little Rock, Arkansas for the last 26 years. I currently serve as the executive vice president of the Arkansas Pharmacists Association, where I have been for the last 6 years.

I have spent my career serving patients in the independent community pharmacy marketplace and advocating for a level playing field throughout the pharmacy industry. I've also worked as a pharmacy consultant for 10 years within the Pharmacy Benefit Manager (PBM) industry. During that time as a PBM consultant, I saw the industry change from a claims processing industry, to an industry veiled in secrets that often deceives its own clients for the sake of corporate profits. In addition, they have created an environment of anti-competitiveness where self-dealing is the norm. Simply put, the unregulated, anticompetitive practices of the PBMs are costing our healthcare system so much money that I absolutely do not believe it is possible to control costs in the prescription drug sector without exposing their egregious business tactics.

Mr. Chairman, NCPA proposes reforms that will make their PBM operations transparent, thus ensuring that PBMs can no longer keep these excessive profits from patients and the government. Second, I will discuss the need for the correct "class of trade" pricing to ensure that the appropriate sectors of the pharmacy market are measured according to the same terms. These discussions naturally lead to a third issue, the FTC's unbalanced study of mail order pharmacy operations. I will present the drawbacks of the study and mail order. Finally, I will close with a discussion of the anti-competitive merger of CVS, the Nation's largest chain pharmacy, and Caremark, one of the Nation's three largest PBMs. The non-transparency and the self-dealing aspects of these areas skew the health care market and prevent the implementation of level competition, to the detriment of the health care system, patients and taxpayers.

Mr. Chairman, the result of the current system is that powerful competitors (chain pharmacies aligned with large PBMs) know the prices at which we buy pharmaceuticals, they know to whom we sell our prescription drugs, and they know the prices at which we sell them. I can think of no other industry—health care or otherwise—in which there is such a gross imbalance of power that skews the market, to the detriment of most of the stakeholders in it and those people and entities affected by it.

I. The Need for PBM Reforms

A. The Problems and Proposed Reforms

Through its purely administrative actions, a PBM plays a critical role in both gathering patient eligibility information from the payer and providing this information to the pharmacy to allow for online processing of prescriptions claims. As part of these transactions, the PBM often makes critical decisions about the patient's health care including determining the benefit plan design, and determining the amount the patient is responsible for paying, commonly referred to as the copay.

Besides these key functions, PBMs also fix pricing for the retail pharmacies who articipate in their networks. This creates a huge conflict of interest because the PBMs also own mail-order pharmacies that compete directly with the retail pharmacies with whom they are contracted. This leads to the PBM being able to collect not only pricing information from the retail pharmacy, but also to collect patient specific data. PBMs have become increasingly aggressive with the large amount of data that they have and they are using this data to steer patients away from the community-based pharmacy into a mail-order pharmacy that the PBM owns

This type of self-dealing is becoming more and more prevalent in the marketplace and is at its heart anticompetitive. In the Medicare Part A & B worlds, this type of physician self-dealing would be illegal. PBMs simply call it part of their everyday business plan. Due to the large volume of prescriptions that are managed by PBMs, transparency of these intermediaries is much needed to shed light on the many deceiving acts that add unneeded expense to our healthcare system. This transparency

will provide substantial savings to patients and plan sponsors.

There are two markets for prescription drug pricing. The first market is where the PBM and the plan sponsor negotiate regarding how much the plan sponsor will pay the PBM for prescriptions dispensed to patients covered under that plan. The second market is between the PBM and the pharmacy network, where the PBMs are able to set the rates at which community pharmacies will be reimbursed for dispension and interest that the patients are the patients and the patients. pensing medications to the patient under that health plan. Due to inadequate transparency regarding PBMs, they are able to engage in "spread pricing" where they charge the plan sponsor a rate substantially higher than what is paid to the pharmacy for services rendered. These spreads can vary dramatically on individual prescription drugs, and represent a substantial additional cost to plan sponsors, yet provide no added value to the health of patients. It has also been argued by many experts that PBMs use vague and inadequate language when defining what constitutes a "brand" and a "generic" prescription drug, allowing these intermediaries to maximize their revenue by charging the brand name while artificially increasing their reported generic utilization rate.

Lack of transparency and inadequate auditing also allows these PBM's to keep payments from pharmaceutical manufacturers, rather than passing these rebates on to plan sponsors. For example, an audit was performed for the Federal Employees Health benefits Program (FEHBP) Retail Pharmacy Drug Program, for the years 2000 through 2005. It found that the PBM administering that program had collected over \$13 million in administrative fees, which should have been considered drug rebates and hence subsequently returned the FEHBP Program.² Such audits are dif-

ficult to administer, due to a severe lack of transparency

I also want to bring to your attention an article published by the Creighton University Medical Center, titled "Spread Pricing in the Prescription Benefit." ⁴ This document provides examples from actual claims data for four different employers, detailing the spreads charged by PBMs for a sample of prescription drugs. As an example, looking at atenolol, a blood pressure drug, the PBM charged the plan sponsor \$80, but paid the pharmacy only \$7, creating a spread of \$73, equal to 91 percent of the entire cost that the PBM charged the plan sponsor. In another example, the PBM charged the plan sponsor \$104 for propoxyphene, a pain medicine, but only paid the pharmacy \$40, creating a spread of \$64, equal to 62 percent of the entire

It is important to note that the plan sponsor is not made aware of the spread and is charged an administrative fee by the PBM on top of that. One expert has argued that the spread retained by PBMs is responsible for as much as 5 percent of prescription drug spending, and is done with little knowledge of the plan sponsor due to inadequate transparency.⁵ These serve as but two examples of the wide variability of the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific plan in the specific plan is the specific plan in the specific bility that can exist when analyzing spread pricing. There are, however, multiple peer-reviewed studies and commentaries from many experts demonstrating this same wide range in spread prices, thus indicating the need for transparency.

¹Learner, N. "PBMs Allegedly Manipulate Definitions of 'Brand' and 'Generic' Rx at Payers' Expense. 2008; http://www.aishealth.com/DrugCosts/DBN_PBMs_Generic_Brand.html. 2*Testimony for Susan A. Hayes for the Committee on Oversight and Government Reform, Subcommittee on Federal Workforce. June 24, 2009.

³ Drug Benefit News. "PBM Auditing Increasing as Rx Costs Rise, But Critics Allege PBMs Are Foiling Audits." September 5, 2009.

⁴ Garis RI, Mohammad A. "Mail-order prescription pricing: a critical examination." Creighton University Medical Center School of Pharmacy and Health Professions. https://www.pbdsuite.com/documents/spread_brochure.pdf.

⁵ Testimony for Susan A. Hayes for the Committee on Oversight and Government Reform, Subcommittee on Federal Workforce. June 24, 2009.

To provide an example from my home state of Arkansas, the Arkansas Pharmacists Association had an opportunity to review 103 claims for a small self-insured business in central Arkansas. This company was paying a per claim administrative fee to the PBM for the PBM's "services." What we found was shocking. After comparing the employer's PBM invoice with the pharmacy's payments, we found that the employer was being charged, on average, \$45.50 per generic prescription. The pharmacies were only paid, on average, \$22.95 per generic prescription. In this example, the PBM was blindly charging this small, self-insured business, on average \$22.55 more than the prescription actually cost. In essence, the PBM added \$22.55 per prescription in worthless healthcare expenses. Attached is a two-page PowerPoint power that outlines these dramatic differences.

These expenses did not improve outcomes, they did not help manage chronic diseases, they did not help to provide additional medications to the patients. Instead these added expenses went solely to pad the corporate profits of the PBMs. The most egregious example from this employer was the drug Simvastatin, a medication commonly used to lower cholesterol. The pharmacy was paid \$14.40 for this drug, while the PBM charged the small, sell-insured employer \$126.72. That's an 880 percent overcharging of the employer. And remember, no added benefit was provided to the healthcare system in this example, just corporate profits run rampant at the expense of our healthcare system. And perhaps the single most disgusting aspect of this business practice is that the PBM leads the small, self-insured employer to believe that the local pharmacy was actually paid the full \$126.72.

To address this spread pricing issue and other key PBM issues, NCPA proposes

the following four reforms, the third of which would eliminate these inflated costs by mandating that the PBM cannot reimburse the pharmacy less than what they are billing the payor for covered medications. Each reform requires that a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, cannot enter into a contract with any pharmacy benefit manager (PBM) to manage the prescription drug coverage provided under such plan or insurance coverage, unless the PBM satisfies the following re-

- 1. The group health plan provides to the patient an explanation of benefits (EOB) statement:
- 2. The PBM uses equal payment bases and disclosure of reimbursement amounts for mail order and retail in order to avoid unfair steering to mail
- 3. The PBM can not engage in spread pricing, which occurs when a PBM charges the group health plan or health insurance issuer a higher price for a drug than the amount the PBM pays the pharmacy for the same drug.
- 4. The PBM must identify and pass along in the form of lower copays or premiums any cost savings it negotiates with a manufacturer.

Plan sponsors will also realize additional health care savings by mandating that PBMs keep a verifiable and transparent account of all rebates received from pharmaceutical manufacturers. Due to inadequate transparency, it is difficult to know the amount of revenue collected by PBMs from pharmaceutical manufacturers, making it difficult to ensure that these payments are passed on to the plan sponsor. As an example, according to Winkelman Management Consulting, in 2004 Medco collected over \$3 billion in revenue from pharmaceutical manufacturers through prescription drug rebates, but failed to pass along \$1.3 billion (44 percent) of this revenue to their plan sponsors.⁶ One expert has testified that as much as 50 percent of drug manufacturer rebate payments are kept by the PBM and never paid to the plan sponsor.⁷ Also, one-sided PBM/client contracts give PBMs undue influence on audits in many cases. PBMs generally restrict the number of rebate agreements that can be audited.

PBMs should therefore be required to meet the following fiduciary duties to health plans:

1. The PBM must annually provide to the group health plan or health insurance issuer all financial and utilization information requested by them, and must annually provide all financial terms and arrangements for remuneration between it and a drug manufacturer;

 $^{^6\,\}rm Winkelman$ Management Consulting. April 2005. $^7\,\rm Testimony$ for Susan A. Hayes for the Committee on Oversight and Government Reform, Subcommittee on Federal Workforce. June 24, 2009.

- 2. PBMs must also disclose, before signing an agreement with a prospective client plan, its methodology of soliciting and receiving payment from drug manufacturers; and
- 3. PBMs owned by a retail pharmacy are prohibited from sharing with that pharmacy any patient identifiable data that may be sent to the PBM by competing pharmacists to process prescription drug claims for enrollees.

NCPA is not alone in seeing the need to address these concerns. PBMs have been subject to a remarkable number of enforcement actions by state attorneys generals and the Justice Department. There are over 6 key pending and settled government enforcement actions brought against the three major PBMs. Many of these cases have been brought by a coalition of over 30 state attorneys generals securing monetary penalties of over \$370 million. As the National Legislative Association on Prescription Drug Prices (NLARx), a bipartisan alliance of state legislators, has observed "we know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, especially a market with such a significant impact on taxpayers." 8 The enforcement actions address:

- 1. conflicts of interest because PBMs both manage drug benefits and dispense drugs;
- 2. improper prescription drug switching to a higher priced drug without medical justification and without the authorization of the prescribing physician; and
- 3. failing to disclose and pass on the full extent of rebates and other incentives received from drug manufacturers, and failing to pass through such discounts to pharmacies and consumers.

The tremendous amount of litigation by employers, insurers, consumer groups and others demonstrate the chronic conflicts of interest and the lack of transparency. Regulation to create some sort of market transparency is crucial to the proper functioning of this market. The First Circuit Court of Appeals that upheld Maine's regulatory statute noted that PBMs "introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs." Over the past 4 years, more than twenty states either have passed or are considering regulation of PBMs to address these problems.

PBMs harm consumers by using their market power to reduce compensation to pharmacies. As noted below the PBM market is highly concentrated and that enables them to exercise "monopsony" or buyer power to reduce compensation to the pharmacies that provide dispensing services. Although a reduction in compensation may appear attractive from the perspective of a buyer of PBM services, that attraction is misleading. The savings from reducing compensation is not passed on to buyers in lower prices because of the market power of PBMs. Moreover, ultimately the consumer of drugs is harmed because there are fewer pharmacies available because of reduced reimbursement rates, or other forms of pharmacy services diminish. Leaving the PBM scheme unfettered and without oversight to ensure true open competition, along with leaving matters to litigation, is unworkable.

B. FTC Study

The FTC has spoken today about its report, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies" August 2005. (The Study). \(^{10}\) As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which became law in November, 2003, Congress requested that the Federal Trade Commission determine whether PBMs that own a mail-order pharmacy act in a manner that maximizes competition and results in lower prescription drug prices for its plan sponsor members. The FTC acknowledged that "in theory they (PBMs) could have incentives to increase costs and generate additional profits through mail-order pharmacies. However, the FTC concludes that, in 2002 and 2003, PBM's ownership of mail-order pharmacies generally did not disadvantage plan sponsors." (The Study, Executive Summary, p. ii).

The Study, however, contained many methodological structural flaws, including

The Study, however, contained many methodological structural flaws, including (but not limited to) its methods of assessing costs and Generic Dispensing Rates (GDRs) for owned-mail order, non-owned (independent) mail order and retail pharmacy and by therapeutic class between mail order and retail, in comparing Generic Substitution Rates (GSRs); in assessing brand-to-brand therapeutic interchange; in

 $^{^8} L {\rm etter}$ from Senator Mark Montigny, on behalf of NLARx, to Deborah Platt Majoras, FTC Chair, May 11, 2005.

⁹This monopsony power that PBMs enjoy is similar to that of health insurers, which have the ability to impose take-it-or-leave it contracts on physicians.

¹⁰http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

failing to fairly determine conflicts of interests and in simply mischaracterizing its analyses. (An Assessment of the Federal Trade Commission Conflict of Interest Study, John N. Demos and Stewart Stewart, April 2006, particularly pages ii—iv of the executive summary, found at: http://www.ncpanet.org/pdf/ftcassessment-exsum.pdf). (An Assessment).

More specifically, I would highlight that:

- 1. In assessing payments and their plans for drugs dispensed by mail order operations which are owned by PBMs, compared to mail-order operations not owned by PBMs and retail pharmacies, costs may be lower at retail pharmacies. In addition, mail order cannot accomplish the face-to-face counseling and medication management, which are especially important for elderly patients taking multiple drugs, which is featured at retail community pharmacies." ¹¹
- 2. In response to the question of whether plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees, PBMs suffer from a conflict of interest created, to a large extent, by retention of pharmaceutical manufacturer payments.¹²
- 3. Mail-order pharmacies that are owned by PBMs (or by entities that own PBMs) dispense "significantly fewer" generic drugs compared with mail-order pharmacies that are not owned by PBMs."The FTC's assessment of PBM spreads at mail-order is erroneous in that it looks at spreads on average rather than assessing specific transactions." ¹³
- 4. Therapeutic interchange is a prevalent practice at PBM mail-order pharmacies, which helps explain the lower generic dispensing rates at these facilities. ¹⁴
- 5. If PBMs pursue their interest in mail-order, "it will have a substantial impact on the national cost of drug benefits and the burden on the taxpayer." 15

II. The Need for Uniform Application of Class of Trade Pricing

A reoccurring issue for community pharmacy is that there are increasingly harmful, illogical inclusions of various pharmacy pricing structures where a well-defined retail pharmacy class of trade should be used. A "retail pharmacy class of trade" has traditionally been defined to mean any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, traditional chain pharmacy—including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

Unfortunately, government programs are increasingly expanding the class of trade to include areas such as low cost drug pricing under the 340B program. Congress created the program to provide low cost drugs to low income and uninsured individuals. Lack of a strong regulatory structure has created situations, however, where the low cost drugs are provided by 340B (health care) entities, such as 340B hospitals, to their own employees, many or perhaps all of whom are not the type of individuals for which the program was designed to assist. If different pricing structures, such as the 340B program, mail order drug operations, and various hospital price programs, are included in different drug programs, then market forces will not work correctly, as there will be differently priced products "competing" for purchase within the same program. Lumping together differently priced drugs runs counter to the purposes of each individual program/pricing structure, and inappropriately mixes the types of patients each is designed to reach.

In the United States, pharmaceuticals are sold by the pharmaceutical manufacturers at different prices to different entities, such as retail pharmacies, hospital pharmacies, long-term care pharmacies, and mail-order pharmacies. Historically, the differences in pricing have not substantially affected retail pharmacies because retail pharmacies are not competing for patients in hospitals or long term care facilities. However, mail order pharmacies pose a different threat to retail pharmacies because mail order pharmacies are competing for the same patients as retail pharmacies, and mail order pharmacies are doing so using preferentially priced prescription medications. This results in mail order pharmacies buying prescription medications at prices that retail pharmacies cannot access and this is why we are concerned with mail order pricing being included in the calculation of Average Manufacturer Price (AMP). This discrepancy in pricing in fundamentally unfair and does not promote true competition.

¹¹An Assessment at vii.

¹² Id. at vii, viii.

¹³ *Id.* at x, xi. ¹⁴ *Id.* at xiv.

¹⁵ *Id.* at xv–xvii.

In sum, Retail Class of Trade should focus on the class of patients being served, and not on who is sending the pharmaceutical product. Medicaid AMP is a situation where putting mail order in the same class of trade as retail pharmacy class of trade makes no sense, as there are differentials in the pricing structure of each cat-

The problem of mixing pricing structures is also highlighted by the self-dealing that is inherent in the merger of CVS and Caremark.

III. Problems of the CVS-Caremark Merger

The merger of CVS, the Nation's largest retail pharmacy, and Caremark, the Nation's largest pharmacy benefits manager (PBM), has produced a prescription services giant. The resulting company operates more than 6,800 pharmacies, affects 134 million consumers and fills or manages 1.2 billion prescriptions annually—controlling or influencing the prescription benefit of an estimated 1 out of 3 Americans. With \$9 billion in incremental earnings last year and a nearly \$50 billion market cap, CVS/Caremark has created a virtual monopoly limiting consumer options.

PBMs do have a role to play through their "pharmacy benefit administer" role.

When a giant PBM is owned by a pharmacy, however, there is the ability and incentive for the pharmacy to misuse this relationship to diminish competition among non-CVS pharmacies. With the substantial market share CVS possesses in numer-

ous markets, such conduct may raise significant competitive concerns.

On May 13, 2009, the Federal Trade Commission (FTC) met with more than 80 independent community pharmacists and several patients to discuss the negative impact of the March 2007 CVS/Caremark merger and to urge the FTC to re-examine it. At the meeting, NCPA members explained how their patients experienced higher costs, fewer choices and less privacy since the merger took effect. NCPA therefore urged the FTC to take a number of steps, including investigating allegations of anti-competitive and deceptive conduct by CVS/Caremark; requiring CVS/Caremark to treat all pharmacies in a nondiscriminatory fashion; and ensuring that the company creates an ironclad barrier between CVS and Caremark so that competitively sensitive Caremark information cannot be used by its retail operations.

Some of the recent conduct by CVS/Caremark that raises these concerns includes the following activities and examples which were discussed at the May 13 meeting. Due to the potential for retaliation by CVS/Caremark through excluding pharmacies from their network, the patient and pharmacy names have been withheld

- CVS/Caremark has significantly increased the copay for members when they seek to fill prescriptions at non-CVS pharmacies. This clearly raises the costs for members for using non-CVS pharmacies;
 - o In New England, Pharmacist D. was appalled when his patient's co-pay on a monthly refill suddenly increased from approximately \$5 to \$50. When D. asked her if she knew why, he learned she had been receiving letters that said she would have to either pay a "penalty co-pay" or transfer her prescriptions to CVS retail or Caremark mail order. CVS/Caremark was also requiring her to get a 3-month supply of a liquid drug which was much too heavy for the 94-year-old patient to lift. Instead, D. offered her the drug at cash price—less than half the price CVS/Caremark wanted her to pay.
- CVS/Caremark has adopted a program to attempt to steer consumers to CVS pharmacies. When a Caremark member fills a prescription at a CVS pharmacy, the CVS pharmacist is informed through the Caremark electronic system of whether the recipient uses another non-CVS pharmacy. In those situations, the CVS pharmacist is instructed to inform the consumer of the dangers of using multiple pharmacies. Obviously the only way the CVS pharmacists knows the consumer uses multiple pharmacies is through the misuse of consumer information possessed by Caremark; and
 - ° A longtime patient of Pharmacist R. in Louisiana was shocked when her monthly refill was denied and the system claimed the drugs had already been processed—at a CVS/pharmacy two towns over. When R. called to ask why the drugs had been filled at a different pharmacy without the patient's request, the CVS pharmacy refused to comment and only said, "We'll back them out [reverse the prescription claims]" out [reverse the prescription claims].
- CVS/Caremark co-brands its prescription drug card in such a fashion to confuse consumers that the benefit card can only be used at CVS.
- From Pharmacist K. in Wisconsin: "Today we attempted to fill a medication for a customer who needed it to coincide with her chemotherapy. Her plan does cover the medication but when we attempted to fill she was told it had to come

from their [CVS/Caremark] mail-order service. This delay will affect her chemo cycles and possibly her whole recovery.'

One North Carolina patient on a Medicare Part D plan operated by CVS Caremark switched his and his wife's prescriptions to CVS pharmacy in March 2009, expecting lower costs, as advertised. Instead, he had an extra \$302 billed to his plan in pharmacy reimbursements, in addition to \$12 in extra co-pay. At the local pharmacy, the plan paid a total of \$11.08 for seven of their drugs; at CVS, it paid \$313.17. These actions raised the government's payments by more than 2,800 percent, pushing seniors to the donut hole coverage gap sooner.

NCPA hopes that these examples and the previous discussion of the vital need for PBM transparency reforms will spur the Subcommittee, the Committee, and Congress to call on the FTC to carefully re-examine the CVS-Caremark merger. For your reference, we are attaching a copy of the May 12, 2009 letter of NCPA President Holly Henry to FTC Chairman Jon Liebowitz in which she outlines how the merger and recent CVS/Caremark actions might diminish pharmacy competition, and also asks for specific relief. 16 We believe that CVS/Caremark's actions may be violations of Section 5 of the FTC Act, and the original acquisition may be a violation of Section 7 of the Clayton Act.

It is not too late for the FTC to investigate the merger and challenge any anti-

competitive conduct. They have done so in the past on numerous occasions. In 1998, for example, the FTC investigated Merck's acquisition of the Medco PBM 5 years after its approval and found "the merger has made it possible for Medco to share with Merck sensitive pricing information it gets from Merck's competitors." The company signed a consent agreement to settle the FTC investigation, agreeing to refrain from sharing proprietary or other non public information that receive from refrain from sharing proprietary or other non-public information they receive from

one another's competitors.

NCPA knows about some of CVS/Caremark's practices which, for profit making motives, migrate customers from low value behaviors to higher value behaviors. NCPA does not, however, have full knowledge of CVS/Caremark's operations, yet CVS/Caremark has full knowledge of the operations of independent community pharmacies. CVS/Caremark knows the prices at which we buy pharmaceutical products, who we are selling the product to, and at what prices we are selling. I respectfully submit that the Subcommittee should be extremely concerned about this concentration of power and the impact it has upon fair competition in the pharmaceutical industry. As I have tried to highlight by stating some "real life" examples, the problem is not an obscure accounting practice—it is that profits are kept from those providing services in this health care industry and grossly overly rewarding the PBM sector for merely providing administrative services. Instead, the manager of the transaction takes large profits at the expense of patient care.

Finally, I wish to highlight that CVS/Caremark's actions include breaches of pri-

vacy rights:

- In October 2007, a Massachusetts judge condemned CVS for advising patients to switch drugs in a direct-to-consumer mailing that was secretly financed by manufacturers and by which CVS profited.17
- In June 2008, CVS/Caremark sent a letter to one doctor urging that physician to switch several patients-mentioned specifically by name, patient identification number, and date of birth-to Januvia, a Merck diabetes medication that costs between 5 and 11 times more than other comparable treatments.1

I thank you for the opportunity to speak before you today to provide this testimony and I want to submit to you one final statement. Independent retail pharmacists know how to save money and how to maximize healthcare expenses. We do it every day. We are quite literally the only providers in the entire healthcare system that understand both the therapeutics of the medications and their economics. When we have a chance to compete on a level playing field with all the huge companies, we save the healthcare system money

I would be pleased to answer any questions.

Senator PRYOR. Thank you. Ms. Turner?

¹⁶ http://www.ncpanet.org/pdf/needftcinvestigation.pdf.
17 Change to Win report, "CVS Caremark: An Alarming Prescription." Page 16.
18 Marley Seaman, "Unions Accuse CVS Caremark of Pushing Merck Drug," Forbes 11/14/08, http://www.forbes.com/feeds/ap/2008/11/14/ap5696569.html>.

STATEMENT OF GRACE-MARIE TURNER, PRESIDENT, GALEN INSTITUTE

Ms. Turner. Thank you, Chairman Pryor. Thank you, Chairman Rockefeller. Thank you, Ranking Member Wicker and Senator

Cantwell, for the opportunity to testify today.

I'm going to bring a slightly different perspective to the discussion today. I think there are, indeed, huge problems in our health sector that need to be addressed. But I think that it's important, also, to look at some of the things that are working so that we can build on those successes in making the changes that we will actually encourage more competition and give consumers greater control over their health care decisions.

In my written testimony, I highlight many examples of innovations in care delivery, creative benefit designs that lower the cost of care, and I would like to highlight a few of them here in my tes-

timony today.

There are so many changes happening in the medical profession, with patient-centered medicine, micro-targeting of treatments that are tailored to individual genetic codes. Advances in medical science, I think, demand that this progress continue without being blocked by regulatory obstacles that could have unintended consequences.

Ålso, Americans consistently tell public-opinion pollsters that they don't want a larger role for government in the health sector, but that they do want policies that build on private-sector initiatives. Looking at some of those initiatives and highlighting

strengths of our health sector could be very useful.

It's also important to recognize, as the panel has so well described today, the need for change, including the need for more consumer-friendly information, greater transparency, and more individual control over health care decisions and health coverage. For example, individuals and small businesses purchasing health insurance find their choices are limited by a lack of competition among insurers in their States—as in Arkansas, in particular, as Len mentioned. Further, most people with employment-based coverage have limited choices of plans offered by their employers. The lack of control over decisions and the lack of transparency limits consumers' choices and, rightly, this often angers them.

We do need to change—changes that would bring more discipline into our health sector, yet it's instructive to build on some of these

innovative ideas.

A few examples: Safeway's CEO, Steve Burd, has become an evangelist for wellness incentives in the company's health plans. In the first year after they were introduced, Safeway's health costs

went down by 11 percent.

Target offers its employees a range of health insurance choices. One health savings account option costs them as little as \$20 a month, and this company deposits \$800 a year into families' health spending accounts. It also offers decision guides to help employees compare price and quality and estimate their costs, access to wellness programs, a nurse hotline, and other support tools.

Whole Foods deposits up to \$1800 a year into spending accounts for each employees. Any unspent money in the account rolls over to the next year. Some employees have accumulated as much as \$8,000 in their accounts, and yet, Whole Foods still saves money on its health costs, while still covering 100 percent of its employees' health insurance premiums.

These companies have used incentives to engage consumers in their health spending decisions. The health costs of these consumer-directed plans increased by only 2.6 percent in 2006. That's

about a third of price increases for traditional insurance.

Private firms also have responded to consumer demands for more convenient access to more affordable medical care. TelaDoc, for example, offers its customers telephone consultations with physicians from anywhere in the country—really anywhere in the world—for \$35 for a call. Also, about 1,200 retail health clinics have opened up in big-box stores and retail pharmacies around the country, giving people 7-day-a-week access to nurse practitioners, primarily, to treat common illnesses. Prices are a fraction of emergency rooms' charges.

Competition among insurers is also leading to more choices for consumers. I know there is a lot of criticism of the health insurance industry, but it's important to look at some of the things they're doing right. For example, Aetna has launched a program to help patients find physicians, compare costs and quality, and get personalized information about their care. Four years of evidence shows sustained savings for their client companies, more patient engagement in managing health care costs, and greater utilization

of preventive services.

Competition, primarily from the use of generic drugs, also is helping to moderate prescription drug spending. We all know about Wal-Mart and its \$4 for a month's supply of prescription drugs that led to a lot of competition from other insurers, as well. Safeway and some other food stores now will fill a prescription for antibiotics for free. Largely as a result of greater use of generics, prescription drug spending increased by only 1.6 percent in 2007, the lowest rate since 1974.

There are many more options and descriptions of other innovative health plans in the private sector that I describe in my testimony. One in particular, I think, in the public sector that's worth mentioning is the way that the Medicare prescription drug benefit was structured. It gives people a choice of competing private plans and—for the first time—is lowering the cost of a new government entitlement program, coming in about 40 percent under the expected cost of the program. A lot of that is because consumers were smart shoppers and went to the plans that provided the best value for the dollar.

In conclusion, I commend you and the many other members of Congress who are working so hard to expand access to health coverage for the uninsured, to modernize our health care system, and provide relief for private and public payers to rising health care costs. I believe that it's important to focus on the innovation in our health sector—as Len mentioned—the quality of clinicians, hospitals. We must build on this system, look at what's working in our private sector, and then begin to think about how we can bring more discipline into our health sector so that these kinds of innovations can continue.

Thank you very much.

[The prepared statement of Ms. Turner follows:]

PREPARED STATEMENT OF GRACE-MARIE TURNER, PRESIDENT, GALEN INSTITUTE

Thank you Chairman Pryor, Ranking Member Wicker, and Members of the Committee for the opportunity to testify today on the issue of competition in the health care marketplace. My name is Grace-Marie Turner, and I am president and founder of the Galen Institute, a non-profit research organization devoted to advancing an

informed debate over market-based health reform ideas.

There are many problems in our health sector that require careful and deliberative change, including the issue you are exploring today involving the lack of competition in many parts of the health sector. I would argue that many of the problems the country is facing involving cost, quality, and access to health care could be addressed by encouraging more competition and empowering consumers to have greater control over decisions involving their care and coverage.

In my testimony, I will highlight some of the progress that is being made through innovations in care delivery, in creative benefit offerings, and even in lowering the cost of treatments to show that the competitive market can respond to the demands

of consumers for better quality care at more affordable prices.

While health care is different than other sectors of our economy and requires special consideration, there are many areas where consumers can and want to have more control over their health care choices. I believe the evidence shows that competition can work by engaging consumers as partners in getting better value for their health care dollars.

Change Is Indeed Needed

Congress is attempting to address in major health reform legislation the many problems in our health sector: Health insurance and health care still cost too much. As a result, tens of millions of Americans don't have health insurance, and many more are worried they are one pink slip away from losing their coverage. The lack of competition in health insurance in many states limits the options for coverage and over-regulation drives up costs. And the costs of Medicare and Medicaid are swallowing up a growing share of Federal and state revenues, compromising other functions of government and threatening huge tax increases just to pay for current entitlement commitments.

But because Americans consistently tell public opinion pollsters they do not want a larger role for government in the health sector, policies that build on the private sector are much more likely to gain public acceptance.

Consider, for example, the progress that has been made in moderating costs over the last several years:

- In 2007, U.S. health spending grew at its slowest rate since 1998, increasing just 6.1 percent, with year-over-year increases of 6.7 percent and 6.8 percent in 2006 and 2005. These increases are still higher than the general inflation rate, but not the double-digit spikes seen over the last several decades.
- Premiums for private health insurance also rose by only 6 percent in 2007, the same rate as in 2006, but much lower than the peak of nearly 11 percent in 2002.
- Premiums for new consumer-directed health insurance plans introduced in this decade increased by much smaller amounts—2.8 percent in 2005 and 2.6 percent in 2006—helping to moderate costs overall.³

A Climate Friendly to Innovation

The private sector is much more adept at innovation and evolutionary change than government-dominated programs. Continued innovation is vital to progress in health care. The medical profession is moving toward patient-centered medicine, with micro-targeting of treatments tailored to the individual genetic code of individual patients. Advances in medical science demand that progress continue without being blocked by regulatory obstacles and restrictive payment systems.

¹Micah Hartman, Anne Martin, Patricia McDonnell, Aaron Catlin, and the National Health Expenditure Accounts Team, "National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998," Health Affairs, January/February 2009, at http://content.healthaffairs.org/cgi/content/abstract/28/1/246.

at http://coment.neutrayjans.org/cgr/coment, society, 21bid.

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3"Reducing Corporate Health Care Costs: 2006 Survey," Human Capital Practice of Deloitte Consulting LLP and the Deloitte Center for Health Solutions, 2006, at http://www.deloitte.com/dtt/cda/doc/content/us_chs_red_cor_hea_costs_0106.pdf.

Two Segments of the Health Sector

The U.S. health economy has two distinct segments—the public and private sectors—and each operates under different sets of rules. About 46 percent of the U.S. health sector is largely financed with tax revenues through government-operated programs, such as Medicare, Medicaid, the State Children's Health Insurance Program, the Veterans Health Administration, community health centers, and others. The rest of health care is financed privately, largely through businesses' contributions to support employment-based health insurance but also through direct purchase of insurance and out-of-pocket payments by patients.

Many analysts refer to our public and private health sectors as a health care system, but we do not have anything approaching a health system in the U.S. Rather, it is made up of conjoined twins, with one run by various government agencies and the other more reliant upon market forces. As health policy analysts attempt to achieve consensus on reforms for our health sector, it is becoming increasingly clear

that this operational divide is one reason compromise is so difficult.

The government sector works primarily on a model that provides people eligible for public programs with an entitlement to a government-determined set of benefits within government-determined payment structures. Some patients receive care from physicians employed by the government in government-owned facilities, but most obtain care through private hospitals and physicians who are paid at government-determined rates.

Within the public sector, private health plans also are involved. For example, many states have contracted with private managed care companies to offer care through their Medicaid and SCHIP programs, and Medicare allows participation by private plans in Medicare Advantage and the Part D prescription drug benefit program. But the majority of publicly-financed health care is delivered through the feefor-service (FFS) model that the private sector largely left behind in the 1980s as unacceptably expensive and inefficient. The response of the public sector to these problems has been to place restrictions on benefits and payments to providers in an effort to restrain costs, which often result in patients having difficulty accessing services and providers.

The private health sector is much more diverse in its range of options and payment systems, representing an alphabet soup of program options from PPOs, POSs, MCOs, and HMOs to HSAs, HRAs, FSAs and even FFS.⁴ Private health plans, employers, and countless other companies in the health sector are continually innovating to provide more options for care and coverage. But the centralized control of health care even in these private sector plans limits and restricts consumer choices, giving them fewer options than they would have in a more competitive and open marketplace, as we have written in numerous papers, articles, and our book, *Empowering Health Care Consumers through Tax Reform*. (For more information see

www.galen.org.)

For example, most people with employment-based coverage have limited choices of plans offered by their employers. And many of these plans contract with a limited number of pharmacy benefit managers (PBM) who determine which drugs will be covered and what copayments will be. Patients can be given incentives to purchase one drug over another, not because it may be the one their doctor thinks is best for them, but because the PBM has a special deal with a particular drug company to push their product. This lack of transparency limits consumers' choices and rightly often angers them.

We do need changes that would make the private market for health care in the United States more open and transparent. Yet, it is instructive to look at the innovative ideas coming from the private sector for improvements in the delivery and financing of health care where competition, transparency, and consumer choice are working.

⁴PPO: Preferred Provider Organization

POS: Point of Service Organization

MCO: Managed Care Organization

HMO: Health Maintenance Organization HSA: Health Savings Account

HRA: Health Reimbursement Account

FSA: Flexible Spending Account FFS: Fee-For-Service

Benefits and Compensation Glossary, 11th Edition, Judith A. Sankey, Ed., International Foundation of Employee Benefit Plans, March 30, 2005, at http://www.ifebp.org/Resources/News/ResearchTools/Glossary/default.htm.

Private Sector Innovation

Entrepreneurs and private investors have been making significant investments in new health care solutions: MinuteClinics, TelaDoc, specialty hospitals, innovative medical practices, and employer plans that empower consumers to engage in their health care and spending decisions are just a few examples.

Here is a summary of some of the other countless private sector initiatives in

care, financing, and delivery:

Employer Innovations

Many leading employers are working to get better value for spending on health care and health insurance for their employees in order to shape their health insurance offerings to fit their resources and work forces. A few examples:

- · Safeway chief executive Steve Burd has become an evangelist for wellness incentives in the company's health insurance arrangements. In the first year after these plans were introduced, the company's health costs went down 11 percent. "If you design a health care plan that rewards good behavior, you will drive costs down," he said. The company shared its cost savings with employees, cutting their costs by 25 percent or more. Safeway introduced a program called Healthy Measures that encourages employees to get health assessments and provides support and incentives for responsible health behaviors. Safeway also covers the full cost of recommended preventive care.6
- Target offers its employees a range of health insurance choices. One Health Savings Account option costs them as little as \$20 a month, and Target contributes \$400 a year to health spending accounts for individuals and \$800 for families.⁷ "We've seen, and national research supports, that team members make more cost-conscious decisions when they participate in a consumer-based plan," according to John Mulligan, Target's vice president for pay and benefits. "These plans engage our team members in a decision-making process that gives them greater ownership and control of their health care dollars." The company offers its 360,000 employees Decision Guides to help them compare price and quality and estimate their costs, plus access to wellness programs, a nurse hotline, and other support tools.8
- Wal-Mart offers dozens of health plan options to its employees, one with premiums as low as \$5 a month. For this, employees receive a \$100 health care credit, more than 2,400 generic drugs available for \$4 a month, and major medical coverage with no lifetime maximum that starts at \$2,000—basically the moment they step into a hospital. Employees can choose to pay higher premiums for lower deductibles and more comprehensive coverage. For \$62 a month, employees can choose a \$500 deductible policy with a \$100 health care credit and no lifetime maximum on their insurance coverage.
- Whole Foods' CEO John Mackey toured the country talking to employees about health benefits options. Afterward, employees voted to switch to new account-based health plans with higher-deductible insurance coverage. Whole Foods deposits up to \$1,800 a year into a spending account for each employee, with Mackey pointing out that this is not charity but part of the employee's compensation package. If they don't spend the money on medical care, it rolls over and the company adds more the next year. Some workers have as much as \$8,000 in their accounts. 10 Whole Foods saves money and still covers 100 percent of its employees' health insurance premiums.
- "Whole Foods Market Benefits," Whole Foods Market, at http://www.whole foodsmarket.com/careers/benefits us.php.

⁵ Victoria Colliver, "Preventive health plan may prevent cost increases," San Francisco Chronde, February 11, 2007, at http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/02/11

Victoria Colliver, "Preventive health plan may prevent cost increases," San Francisco Chronicle, February 11, 2007, at http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/02/11/BUG02020R81.DTL&type=printable.
 Scott Shreeve, "Safeway uses incentives and transparency to improve employee health," The Health Care Blog, October 29, 2008, at http://www.thehealthcareblog.com/the_health_care_blog/2008/10/safeway-uses-in.html.
 61bid.
 7"Target Offers Employees Health Savings, Reimbursement Accounts, Plans to Eliminate Traditional Health Plans, USA," Medical News Today, May 18, 2006, at http://www.medical newstoday.com/articles/43453.php.
 8"Thought Leaders: John Mulligan, Vice President, Pay & Benefits, Target Corporation," hub.

newstoday.com/articles/43453.php.

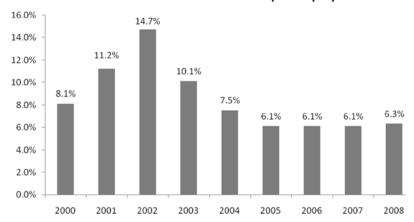
8 "Thought Leaders: John Mulligan, Vice President, Pay & Benefits, Target Corporation," hub Magazine, Summer 2008, at http://www.hubmagazine.net/printer.php?ID=180.

9 "Wal-Mart Announces Improvements to 2008 Health Benefits Package," Wal-Mart Stores, Inc., September 18, 2007, at http://walmartstores.com/PrintContent.aspx?id=6731.

10 John Stossel, "Control Your Own Health Care," RealClearPolitics, October 3, 2007, at http://www.realclearpolitics.com/articles/2007/10/control_your_own_health_care.html.

These companies and many others have worked extraordinarily hard to find the delicate balance between getting health benefit costs under control and continuing to provide coverage that satisfies their workers. There simply is no way that a benefit or cost structure dictated by Washington could achieve these same results. Maintaining ERISA protection is crucial to allowing companies to continue to inno-

Total health benefit cost increases per employee



Source: Mercer's National Survey of Employer-Sponsored Health Plans; Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April) 1988–2008; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey (April to April) 1988–2008.

New Health Care Financing Options

Several new private sector health coverage options are available to companies and individuals. For example, the Medicare Modernization Act authorized the creation of Health Savings Accounts (HSAs) 11 in 2004, with further enhancements enacted in 2006 and before that with creation of Health Reimbursement Arrangements

HSAs permit individuals to combine health insurance with a tax-free health spending and savings account. The account is used to pay for routine health care expenses, such as doctor's visits, for services not covered by insurance, and to create a cushion to pay premiums in lean economic times. The high-deductible insurance policy covers larger medical expenses such as hospitalization and surgeries. Federal law also allows the insurance contract to cover preventive care, such as cancer screenings

Eight million Americans had health insurance that qualifies holders to open HSAs as of January 2009.12

The older sisters of HSAs, Health Reimbursement Arrangements, were created via a regulatory interpretation in 2002 to give employers more flexibility in structuring health coverage for their workers. HRAs operate much like HSAs but can be offered only through the workplace. They are generally account-based plans accompanied by health insurance. While the money in HSAs is truly portable to the employee or individual holder, access to HRA funds is generally restricted after an employee leaves a company. But HRAs give employers more flexibility in shaping their benefit packages, including providing incentives for prevention and wellness activi-

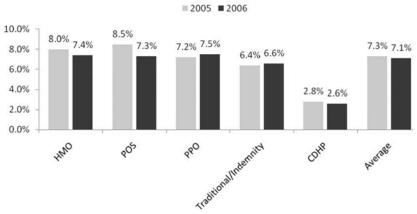
Both products are helping to make health insurance more affordable and are helping companies lower their health costs. Health insurance premiums generally are lower than average because deductibles are higher, and the savings on premiums can help fund the HSA or HRA.

¹¹ Introduced by Rep. Paul Ryan, R–WI.
¹² "January 2009 Census Shows 8 Million People Covered by HSA/High-Deductible Health lans," America's Health Insurance Plans, May 2009, at http://www.ahipresearch.org// pdfs/2009hsacensus.pdf.

Companies that have introduced health plans with new incentives for consumers to be engaged as partners in managing health costs generally have seen lower-thanaverage health cost increases. Annual premium increases for employment-based coverage averaged about 6 percent for the last 3 years, down from double digits earlier in the decade. 13 The most impressive results have come from consumer-directed plans such as HSAs and HRAs.

Deloitte's Center for Health Solutions found that cost of consumer-directed health plans (CDHPs) increased by only 2.6 percent in 2006 among the 152 major companies it surveyed. This is about a third the rate of increase for traditional plans. 14

Cost increases for employment-based health plans



Source: "Reducing Corporate Health Care Costs: 2006 Survey," Human Capital Practice of Deloitte Consulting LLP and the Deloitte Center for Health Solutions, 2006.

Lower Costs of Insurance Coverage

Consumer-directed health products have helped to moderate health cost increases overall.

- UnitedHealthcare found that employer health benefit costs were more than 15 percent lower in 2007 for its HRAs than for traditional PPO plans. Importantly, 85 percent of the cost savings were attributable to lower utilization costs, such as avoiding hospitalizations and greater use of generic drugs—and not from cost shifting to employees.15
- A Mercer study found that consumer-directed health plans delivered substantially lower cost per employee than either PPOs or HMOs in 2008. CDHP medical plans averaged \$6,207 per employee, compared to \$7,768 for HMOs and \$7,815 for PPOs. 16
- In addition, health insurance that people purchase in the individual market is often more affordable than employment-based coverage. eHealthInsurance, the largest online broker for individually-purchased and small-group health insurance, found that the average yearly health insurance premium in 2007 was \$1,896 for individuals and \$4,392 for a family.¹⁷

¹³Total U.S. health benefit cost rose by 6.1 percent in 2007. "Mercer National Survey of Employer-Sponsored Health Plans," Mercer LLC, November 19, 2007, at http://www.mercer.com/summary.jhtml?idContent=1287790.

summary, intm!:tatContent=1287/90.

14 "Reducing Corporate Health Care Costs: 2006 Survey," Human Capital Practice of Deloitte Consulting LLP and the Deloitte Center for Health Solutions, 2006, at http://www.deloitte.com/dt/cda/doc/content/us_chs_red_cor_hea_costs_0106.pdf.

15 Meredith Baratz and Todd Berkley, "Consumerism in Health: A Conversation with Galen Institute and the Consensus Group," UnitedHealthcare, January 7, 2009.

16 "Mercer National Survey of Employer-Sponsored Health Plans," Mercer LLC, November 19, 2008, at https://www.mercer.com/summary.htm?idContent=1328445.

17 "Content Reports of Reports of Individual and Employer Personseh." Formatter Personseh.

Costs and Benefits of Individual and Family Health Insurance Plans," Forrester Research and eHealth Insurance, November, 2008, at $http://www.ehealthinsurance.com/content/expert\ center$ New/eHealthCBreport2008FINAL.pdf.

Other Benefits

In addition to moderating cost increases, HSAs also are providing new options for the uninsured. Up to 43 percent of those enrolling in HSA-qualifying health insurance were previously uninsured, showing that uninsured Americans in particular have been looking for an affordable alternative to traditional health insurance, according to Assurant Health. 18 Assurant Health's most recent data show that they have broad appeal:

- · 66 percent of HSA purchasers are families with children
- 63 percent of HSA purchasers are over age 40
- 52 percent of all HSA purchasers have high school or technical school training as their highest level of education
- 30 percent of HSA purchasers have family incomes of less than \$50,000

UnitedHealthcare found, based upon a survey of 300,000 HSA owners, that the average account holder had household income of \$55,500, and 25 percent of those with an HSA had income of less than \$39,000.19 Changes in Federal law in 2006 allowing employers to make larger deposits for lower-income workers also are apparently succeeding, since UnitedHealthcare found that they were more likely to have employer contributions in their HSAs than higher-income HSA holders.

Other Private Insurance Options

Many other employers are offering innovative programs to help their employees get and stay healthier and spend health care dollars wisely. They are offering incentive programs to encourage employees to get health assessments to detect problems early and health coaching to help those with chronic illnesses better manage their care. These companies generally work in partnership with health plans to design the consumer-based products, manage the finances, educate employees about using them, and provide wellness programs and support for employees with chronic conditions.

For example, in 2005, Aetna launched a program that offers a range of consumersupport tools to help patients find physicians, compare costs and quality, and get personalized information about medical conditions and treatment. Its personalized search engine provides health information tailored to patients' individual needs.²⁰

The results show this patient engagement works. Aetna is following health care claims and utilization of 1.6 million members of its Aetna HealthFund consumerding the consumer of the consumer directed plans. Four years of evidence show sustained savings, more patient engagement in managing health, and greater utilization of preventive services. Employers who offered an Aetna HealthFund plan lowered their health care spending trend and saved money through all 4 years with the plan, across all Aetna products they offered.21

Aetna studied its members to identify the keys to successful implementation and found the keys were greater spending on preventive care, including wellness programs; focusing on employee communication and education; and carefully structuring benefits packages with appropriate levels of employee responsibility.2

Many companies are offering turnkey solutions to health plans and employers. U.S. Preventive Medicine, for example, offers employers packages of services they can tailor to fit the needs of their work forces for preventive care services.²³

In addition, a galaxy of websites has evolved to offer everything from treatment information to diet advice. EverydayHealth has just surpassed WebMD as the mostvisited site for medical information, and new sites appear every day to help patients find the best doctors, the lowest cost medicines, and the most cost-effective diagnostics.

^{18 &}quot;Quick Facts: Health Savings Accounts," Assurant Health, at http://www.assurant health.com/corp/ah/AboutAssurantHealth/HSAFactSheet.htm.

Maureen E. Sullivan, "Health Plan Initiatives, Trends and Research in Consumer-Driven Care," BlueCross BlueShield Association, October 20, 2008, at http://www.bcbs.com/news/bluetvradio/consumerdriven2008/.

19 Moredith Rends and Tadd Bayklay, "Consumering in Health: A Conversation with Colon

bluetvradio/consumerdriven2008/.

¹⁹ Meredith Baratz and Todd Berkley, "Consumerism in Health: A Conversation with Galen Institute and the Consensus Group," UnitedHealthcare, January 7, 2009.

²⁰ "Aetna and Healthline Networks Announce First Ever Personalized Health and Health Benefits Search Engine—Aetna SmartSource," Aetna Inc., March 12, 2008, at http://www.aetna.com/news/news/Releases/2008/0312.html.

²¹ "Aetna Research Identifies Four Keys to Success for Consumer-Directed Health Plans," Actna Inc. Increases 21, 2008, at http://www.aetna.com/news/news/news/2008/0121.htm.

Aetna Inc., January 31, 2008, at http://www.aetna.com/news/2008/0131.htm.

²³ U.S. Preventive Medicine, http://www.uspreventivemedicine.com/.

Lower drug costs

Competition, primarily from greater use of generic drugs, helped to moderate prescription drug spending. Prescription drug spending increased only 1.6 percent in 2007, the slowest rate since 1974.24 Part of the reason is increased use of lowercost generic drugs, but private competition over drug pricing in the Medicare Part D program also contributed. And retail establishments also have engaged in private price wars. In 2006, Wal-Mart began offering 30-day supplies of several hundred generic drugs for just \$4. Competitors quickly followed suit, with some even offering to fill prescriptions for antibiotics for free. It's impossible to imagine this happening in a price-controlled, government-regulated environment.

There also has been active engagement by pharmaceutical companies in creating programs for low-income and uninsured people to obtain their products at little or no cost. Pharmaceutical companies have made significant investments to develop, expand, and promote patient assistance programs like Together Rx Access, Pfizer Helpful Answers, Partnership for Prescription Assistance, and many others. New private partnerships, like the Asheville Project and the Ten Cities Challenge, also have been created to help patients with chronic illnesses, including diabetes, get the medicines and counseling they need to manage their diseases.²⁵

The private sector also has demonstrated its responsiveness to crisis. After Hurricane Katrina, more than a million people were displaced. They not only lost their homes, but also their support communities, including their physicians whose offices were literally washed away in the storm. Many were on important medications but the records of their prescriptions were lost.

Pharmacy chains, pharmaceutical companies, pharmacy benefit managers, physicians, technical experts, and philanthropic groups came together to create KatrinaHealth.org, a website that compiled pharmacy records and allowed physicians anywhere to access through a secure website the medical records of displaced patients who came to them for help. It was a remarkable achievement that showed the power of private enterprise to respond quickly in a crisis.

Innovation in Medical Treatment

The lists of innovations in medical treatment could consume a library. From pharmaceuticals to biologics and new medical devices, diagnostics, and surgeries, the list is endless.

For example, proton beam therapy can vaporize tumors with no damage to nearby tissue, and DNA mapping already is allowing doctors to determine before chemotherapy is begun which cancer patients will respond to which treatments. Telemedicine is extending the reach of medical skills to rural areas, into people's homes, and even to other countries.

Modern pharmaceuticals are dramatically expanding life expectancy and quality of life. Pharmaceutical research continues to be one of the most costly-and riskyinvestments in the health sector. In 2007, the pharmaceutical industry spent nearly \$59 billion on research and development. Yet only 24 new drugs were approved last year. 26 For every 5,000 to 10,000 compounds tested, just five will make it to clinical trials. And only one of those will receive FDA approval. And then, only two out of every 10 drugs that reach the market will recoup the costs invested in creating and developing the drug.

²⁴ Murray Aitken, Ernst R. Berndt, and David M. Cutler, "Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point," *Health Affairs Web Exclusive*, December 16, 2008, at http://content.healthaffairs.org/cgi/content/abstract/hlthaff.28.1.w151.

²⁵ Grace-Marie Turner, "Gold Standard," Health Policy Matters Newsletter, Galen Institute, March 14, 2008, at https://www.galen.org/component,8/action,show_content/id,14/blog

id,1030/category_id,0/type,33/.

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Carole W. Cranor, Barry A. Bunting, and Dale B. Christensen, "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program," Journal of the American Pharmaceutical Association, Vol. 43, No. 2, March/April 2003, at http://www.aphafoundation.org/searchable_files/filemanager/JAPhA_Long%20term.pdf.
Toni Fera, Benjamin M. Bluml, William M. Ellis, Cynthia W. Schaller, and Daniel G. Garrett, "The Diabetes Ten City Challenge: Interim Clinical and Humanistic Outcomes of a Multisite Community Pharmacy Diabetes Care Program," Journal of the American Pharmaceutical Association, Vol. 28, No. 2, March/April 2008, at http://www.diabetestencitychallenge.com/pdf/DTCCInterimReport.pdf.

26 Jared A. Favole and Jennifer Corbett Dooren, "FDA Approved More Drugs in 2008," The Wall Street Journal, January 2, 2009, at http://online.wsj.com/article/SB123084693842347299 html

^{42347229.}html.

Yet innovation in this sector is particularly important to overall cost savings as every additional dollar spent on newer drugs in the United States saves \$7 in other costs. 27

The U.S. continues to lead the world in medical research. In 2007, more than 2,700 compounds were in development in the United States, compared to 1,700 in the rest of the world, 1,400 of which were under development in Europe. ²⁸ The U.S. is indeed the medicine chest for the world.

The most important role for government is to support this innovation in life-saving and life-enhancing medicines. Policies that would tax away the money that pharmaceutical companies spend on research would lower the quality of care for this generation and future generations.

Care Delivery

Private health care firms have responded to consumer demand for more convenient, accessible medical care. For example:

- TelaDoc offers its customers telephone consultations with physicians from wherever they are, anytime of day, 365 days a year. The average patient gets a call returned by a doctor in less than 40 minutes, and the cost per call is just \$35. TelaDoc physicians also use electronic prescribing to minimize errors and keep a record of patients' medications.29
- There also has been an increase in the number of low-cost walk-in medical clinics like RediClinic, Take Care, and MinuteClinic. There are now more than 1,175 retail clinics nationwide, a net increase of 274 new clinics opening in 2008.³⁰ They are usually located in malls or chain stores and are typically staffed by nurse practitioners working in conjunction with local doctors and hospitals to diagnose and treat common illnesses. They are open 7 days a week, before and after work, and prices are a fraction of emergency room charges.
 - These clinics use Mayo Clinic and Cleveland Clinic protocols to diagnose and treat a range of routine health problems, from allergies and bronchitis to poison ivy, ear and bladder infections, and strep throat, usually for a fraction of the cost of hospital emergency rooms. Wal-Mart found that about half of the people visiting its in-store clinics were uninsured and did not have other sources of care. Wal-Mart partners with local hospitals and doctors' groups to create the clinics in many areas, but it insists that all of them create electronic health records for every patient that are accessible at any other clinic in the chain.
- Specialty hospitals owned by physicians are showing the value of focused care in delivering high-quality, efficient care with greater patient satisfaction and better health outcomes.
- Physician practices also are innovating to become more consumer-friendly. Some are opening an hour or more a day for same-day appointments. Others are working with employers to staff on-site clinics so employees can see a doctor without taking time off work.
- Hospitals are experimenting with new ways to ease crowding in their emergency rooms, visited by an estimated 119 million patients in 2006. There are more than 8,000 walk-in urgent care facilities nationwide staffed by practicing physicians. Inova Health System and Shady Grove Adventist in the Washington, D.C., area and dozens of other hospitals nationwide are opening freestanding emergency facilities to treat everything from lacerations to heart attacks and gunshot wounds. Patients are seen faster, and if they need to be admitted, they are transported by ambulance to nearby hospitals.³¹
- A growing number of physicians are experimenting with innovative medical practice design, ³² including direct medical practices. Physicians, generally internists or family practitioners, contract directly with their patients to offer a medical home, providing medical care, consultation, and coordination with specialists for a fixed fee. The fees range from \$60 to \$15,000 in some practices, but

²⁷ Frank Lichtenberg, "Benefits and costs of newer drugs: An update," National Bureau of Economic Research Working Paper #8996, June 2002, at http://papers.nber.org/papers/w8996.pdf. 28 Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2008. Washington, D.C.: PhRMA, March 2008, at http://www.phrma.org/files/2008% ²⁸ Pharmaceutical Research and American 2008. Washington, D.C.: PhRMA, March 2008, at http://www.phrma.org/fues/2006/2009rofile.pdf. ²⁹ TelaDoc, http://www.teladoc.com. ³⁰ "Merchant Medicine News: U.S. Retail Clinic Market Report," Merchant Medicine, Volume 2, Number 1, January 1, 2009, at http://www.merchantmedicine.com/home.cfm. ³¹ "ER Care, Stat!," Sandra G. Boodman, The Washington Post, September 16, 2008. ³² Society for Innovative Medical Practice Design at http://www.simpd.org/.

generally cost about \$1,500 a year.33 Other physicians are bypassing insurance and simply posting prices for medical services. They find they can charge patients much less because they save on the administrative overhead of insurance

Health Advocate, a Pennsylvania-based company, helps consumers find the right doctor for their ailments, work with insurance companies on coverage, and manage other administrative headaches. This service helps consumers, via call centers, who are being given more responsibility to navigate the world of health care and health coverage.34

Innovation in Public Programs

Medicare Modernization Act

The structure of the drug benefit created by the Medicare Modernization Act of 2003 (MMA) has been an unusual success, with costs coming in significantly under estimates and with strong approval among Medicare beneficiaries.³⁵

The MMA created a market-based delivery system for the drug benefit. Many opponents wanted the drug benefit to be delivered like other Medicare benefits, with government deciding what products would be available and how much suppliers and providers would be paid.

Instead, Congress created a new, private sector model for delivery of this largely publicly-funded benefit. Private drug plans compete for the business of seniors, vying to offer the most generous benefit packages for the lowest costs. The result has surprised even the most optimistic observers: Average premium costs are \$28 a month this year, down from the \$44 expected this year when the legislation was originally passed.³⁶

The competitive model is saving taxpayers hundreds of billions of dollars. The 10year cost of the prescription drug program, originally estimated at \$634 billion, has been revised to about \$395 billion. The Centers for Medicare and Medicaid Services (CMS) credits competition among plan providers and consumers selecting lower-priced drugs. Health and Human Services Secretary Michael Leavitt also credits the slowing of drug cost trends and higher rebates from drug manufacturers.

In addition, more seniors are benefiting from the program. CMS estimates that

the total number of Medicare beneficiaries with drug coverage now is approximately 39.5 million.³⁷

This experience shows that the forces that work in the private sector to drive down costs and increase choice also can be integrated into public programs.

Satisfaction

News reports were highly critical after the launch of the drug benefit in January of 2006, particularly in switching those dually-eligible for Medicare and Medicaid to MMA drug plans. But much of the confusion was attributable to the difficulties in synchronizing Medicare and Medicaid data bases to track each of the seniors.

Today, the highest satisfaction rates with Part D are among dual-eligible patients. These beneficiaries previously received their drug coverage through Medicaid and who therefore have the most experience with traditional government-run drug coverage. More than 9 out of 10 dual-eligible enrollees say they are satisfied with their

³³ David Albenberg, MD, "Concierge Medicine: The Pitfalls and the Pendulum," Fall 2008, at http://pri-med.com/DigitalAssets/Shared%20Files/Syllabus%20Files/Fall08/C&E/Mid-Atlantic/Practice%20solutions/Session11-Concierge%20Medicine%20Part%20IFNL.pdf.
34 Mike Stobbe, "Booming Business Helps Patients Navigate Medicine," Associated Press, July

<sup>25, 2008.

35</sup> The President also had the wisdom to appoint Mark McClellan, M.D., Ph.D., as administrator of the Centers for Medicare and Medicaid Services to implement the MMA. His leadership that the Mark of the Success of the Suc and belief in the value of market-based policies were a transformative force in the success of the MMA. Dr. McClellan convinced private plans to participate and one of the only criticisms is that he was too successful because seniors had so many choices of plans.

is that he was too successful because seniors had so many choices of plans.

36 "Lower Medicare Part D Costs Than Expected in 2009," Centers for Medicare and Medicaid Services, August 14, 2008, at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3240&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

37 "Medicare Prescription Drug Benefit's Projected Costs Continue to Drop," Centers for Medicare and Medicaid Services, January 31, 2008, at http://www.cms.hhs.gov/pf/printpage.asp?ref=http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2868&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&intNumPerPage=10&srchOpt=0&checkDate=&checkKey=2&pYear=&srchType=2&numDays=0&showAll=1&srchData=part+d&kevwordType= checkKey=2&pYear=&srchType=2&numDays=0&showAll=1&srchData=part+d&keywordType= All&year=0&cboOrder=date&desc=.

new and less-restrictive Part D coverage, and 95 percent say the coverage is working well for them, according to a study by KRC Research.³⁸

Nonetheless, there are still calls for the government to "negotiate" drug prices with the plans. Yet independent experts at both the Office of the Actuary at HHS 39 and the Congressional Budget Office 40 have said that government involvement in price negotiation would *not* lead to lower costs for taxpayers. In fact, it could lead to significant restrictions in access to drugs for seniors. Further, the private plans offering Medicare drug coverage are companies with decades of experience in negotiating prices—experience the government does not have.41

Private Plan Competition in Medicare Advantage

Another success of the MMA was keeping private plans in Medicare through the Medicare Advantage Program.

Medicare Advantage gives seniors the option of receiving their health coverage through private plans, including health maintenance organizations (HMOs), preferred provider organizations (PPOs), Medicare medical savings accounts (MSAs), and private fee-for-service (PFFS) plans. In addition, private special needs plans (SNPs) provide comprehensive coordinated care for beneficiaries with severe and chronic illnesses.

Because Medicare Advantage plans offer more comprehensive benefits, most MA enrollees pay less for full medical coverage than they would under traditional Medicare supplemented with individual Medigap coverage. MA plans are particularly attractive to those who do not have other sources of supplemental coverage and are more sensitive to price. 42 As a result, seniors with the most limited resources have been most attracted to the broader coverage and more predictable costs of MA plans.

In 2008, Medicare Advantage enrollees received basic prescription drug coverage at a lower cost than stand-alone Part D plans. For basic coverage, MA plan drug premiums were, on average, about \$6 less than average prescription drug plan premiums for basic coverage. 43 Many Medicare beneficiaries have the option of enrolling in MA plans that provide a drug benefit at no extra cost.

While MMA boosted payments for MA plans, it also provides more than \$1,000 a year in added health services to the average beneficiary enrolled, or an average of \$96 a month over standard Medicare coverage.44

The MMA also offers new incentives for private plans to provide health care to Medicare beneficiaries with serious and chronic illnesses through Special Needs Plans. Special Needs Plans provide specialized care for patients with severe and chronic illnesses, including diabetes, mental disorders, congestive heart failure, and HIV/AIDS.⁴⁵ Many SNP patients are eligible for both Medicare and Medicaid, and some are institutionalized. Similar to other types of plans, SNPs receive risk-adjusted payments to ensure that the greater health needs of these patients are met.

Enrollment in all private Medicare health plans has now reached an all-time high of more than 10 million beneficiaries, up from 5.3 million in 2003,46 and the per-

^{38 &}quot;Seniors' Opinions About Medicare Rx: Third Year Update," KRC Research and Medicare Today, October 2008, at http://www.Medicaretoday.org/pdfs/2008Survey.pdf.
39 Memo from Richard S. Foster, Chief Actuary, Centers for Medicare & Medicaid Services, to Mark B. McClellan, Administrator, Centers for Medicare & Medicaid Services, February 11,

⁴⁰Letter from CBO Director Douglas Holtz-Eakin to Senate Majority Leader William H. Frist,

January 23, 2004. http://www.cbo.gov/showdoc.cfm?index=4986&sequence=0

41"The Facts: Medicare Part D and Prescription Drug Prices," This fact sheet was jointly prepared by health policy experts from the American Enterprise Institute, the Center for Medicine in the Public Interest, the Galen Institute, The Heritage Foundation, the Institute for Policy Innovation, the Institute for Research on the Economics of Taxation, the National Center for Policy Analysis, and the Pacific Research Institute, January 9, 2007, at http://www.galen.org/fileuploads/PartDandPrices.pdf.

fileuploads/PartDandPrices.pdf.

42 Marsha Gold, Sc.D., Maria Crupples Hudson, and Sarah Davis, "2006 Medicare Advantage Benefits and Premiums," Mathematica Policy Research, Inc., November 2006, at
http://assets.aarp.org/rgcenter/health/2006_23_Medicare.pdf.

43 The Hon. Kerry Weems, Acting Administrator, Centers for Medicare and Medicaid Services,
testimony before the House Ways and Means Subcommittee on Health, February 28, 2008, at
http://waysandmeans.house.gov/media/pdf/110/Weems.pdf

44 Ibid.

⁴⁵ Dtd.
⁴⁵ Centers for Medicare and Medicaid Services, "Special Needs Plans: Fact Sheet and Data Summary," at http://www.cms.hhs.gov/SpecialNeedsPlans/Downloads/finalSNPfactsheetsum2-14-06.pdf.

⁴⁶ "Medicare: A Primer 2009," The Henry J. Kaiser Family Foundation, January 2009, at http://www.kff.org/Medicare/upload/7615-02.pdf.

centage of beneficiaries who have chosen Medicare Advantage has grown from 12.1 percent of all Medicare beneficiaries in 2004 to 20 percent in 2008.⁴⁷

Now, seniors who rely on these plans once again risk losing their source of more

comprehensive medical and drug coverage as Congress threatens to cut payments to Medicare Advantage. $^{\rm 48}$

Medicaid and SCHIP

Many patients on Medicaid and SCHIP find they have an extremely difficult time finding a private physician who will see them because reimbursement rates are so low in many states. As a result, Medicaid recipients often are forced to get care in crowded hospital emergency rooms, depriving them of continuity of care. Giving Medicaid patients more choices of care and coverage would allow them to have the dignity of private coverage.

The Deficit Reduction Act, enacted in early 2006, provided new flexibility to the states in designing their Medicaid program. As a result, Governors have been policy entrepreneurs. For example, in Indiana, Gov. Mitch Daniels has created a new program that allows the uninsured to obtain coverage in a model that looks like an HSA.⁴⁹ In Oklahoma, Gov. Brad Henry has helped the uninsured and low-income

workers purchase private health coverage with Medicaid dollars.

The Medicaid Commission on which I served provided a number of recommendations about modernizing this program so it can be more responsive to patients and more financially sustainable for the future. 50

Unfinished Agendas

I commend you and the many other Members of Congress who are working to expand access to health coverage for the uninsured, modernize our health care delivery system, and provide relief for private and public payers to rising health costs.

The challenges are enormous. Health costs are expected to double by 2017.⁵¹ The costs of public programs threat to squeeze out other public services provided by Ended and the costs of public programs that Milliam f. Poly. Poly Federal and state governments. Millions of Baby Boomers are aging into Medicare, putting new pressures on the system. Millions of people continue to lose their health insurance when they lose or change jobs. There is a growing need for electronic medical records and better chronic care management, and more incentives are needed for people to purchase long-term care coverage. These are all huge challenges to tackle.

The Path Forward

Addressing the health care needs of 300 million Americans for better quality at more affordable prices requires modernizing our health sector to become more efficient and innovative. It is not possible to expect that one piece of legislation could be written carefully enough to accommodate these needs and also continue to provide a platform for future innovation to enhance the quality of medical care in the

While we face major problems with cost and access to coverage, the evidence shows that careful reform that respects the diverse needs of our population is cru-

⁴⁷The Hon. Kerry Weems, Acting Administrator, Centers for Medicare and Medicaid Services, testimony before the House Ways and Means Subcommittee on Health, February 28, 2008, at

http://waysandmeans.house.gov/media/pdf/110/Weems.pdf.
Robert E. Moffit, Ph.D., "Medicare Advantage: The Case for Protecting Patient Choice," Web Memo #1836, The Heritage Foundation, March 6, 2008, at http://www.heritage.org/Research/

Memo #1836, The Heritage Foundation, March 6, 2008, at http://wwm1836.cfm. "Medicare Advantage: Increased Spending Relative to Medicare Fee-for-Service May Not Always Reduce Beneficiary Out-of-Pocket Costs," Government Accountability Office, February 2008, at https://www.gao.gov/new.items/d08359.pdf. "The Facts: Medicare Advantage," This fact sheet was jointly prepared by health policy experts from the American Enterprise Institute, the Center for Medicine in the Public Interest, the Galen Institute, The Heritage Foundation, the Institute for Policy Innovation, the Institute for Research on the Economics of Taxation, the National Center for Policy Analysis, the Pacific Research Institute, and Project HOPE, March 21, 2007, at http://www.galen.org/fileuploads/MAFactSheet.ndf.

Research Institute, and Project HOPE, March 21, 2007, at http://www.galen.org/fileuploads/MAFactSheet.pdf.

49 Grace-Marie Turner, "Indiana's Free-Market Idea to Help the Uninsured Get Coverage," Galen Institute, December 31, 2008, at http://www.galen.org/component,8/action,show_content/id,13/category_id,8/blog_id,1139/type,33/.

50 Medicaid Commission, "Final Report and Recommendations," December 29, 2006, at http://aspe.hhs.gov/Medicaid/122906rpt.pdf.

51 Sean Keehan, Andrea Sisko, Christopher Truffer, Sheila Smith, Cathy Cowan, John Poisal, M. Kent Clemens the National Health Expenditure Accounts Projections Team, "Health Spending Projections Through 2017: The Baby-Boom Generation Is Coming to Medicare," Health Affairs, Vol. 27, No. 2, March/April 2008, at http://content.healthaffairs.org/cgi/content/abstract/hlthaff.27.2.w145.

cial. As the examples I have offered here show, competition can work in public and private programs and force the system to be more responsive to consumers. By properly structuring incentives and creating a climate friendly to this innovation, Congress could put us on a path to uniquely American health care solutions. As I believe the evidence shows, competition works, even in health care.

Senator PRYOR. Thank you. I'll go ahead and start, here.

Dr. Nichols, let me start with you, if I may. In a recent *New York Times* column, the economist Paul Krugman wrote that the health insurance marketplace, quote, "is currently a collection of local monopolies and cartels," end quote. And, you're pretty familiar with healthcare, health insurance options around the country in various markets. Do agree or disagree with Mr. Krugman's characterization?

Dr. NICHOLS. In general, Mr. Chairman, I agree that the fundamental problem that has been least—not noticed, is local monopoly power. It's not necessarily that they have a 100-percent market share, but it is that they have a large enough market share that they're dominant. And there are just so many examples that we don't have time to go through them all. I definitely agree.

Senator PRYOR. Why has that happened? I mean, what is it in our system that promotes this kind of market power in the health

insurance industry?

Dr. NICHOLS. Well, there are a number of sources, you know, as you know quite well—this is a big old country and there's lots of reasons, but the two that I think are probably most important are—there are good reasons to have collaboration, and cooperation, and growth. I mean, sometimes the growth is absolutely natural. You want to have a hospital that can treat all diseases and all illnesses, because you don't know what people have when they come in. So, that community-hospital concept means it's got to be of a certain size, and in some places there are just not enough patients to have more than one big community hospital. And so, fundamentally, you end up with kind of a—what we call in the profession a "natural monopoly" situation. And that's the case in a lot of places. There might be one big one and some little ones that don't really compete in an effective way.

Another reason we got into this place is that, frankly, Senator, we've done a very bad job of measuring quality. And as Grace-Marie points out, we don't really do a great job of disseminating information about that quality, and that's what some of those innovations she's talking about are doing very, very well. We need to do more of that. Because what happens is that a place might get a reputation for quality. It doesn't actually have the data and the outcomes to back it up, but no one knows it. And so, we end up with a de facto—everybody's got to have that hospital, everybody's got to have that physician group, but they may not be performing as well as we would like. I believe in Ronald Reagan's phrase, "Trust, but verify."

Senator PRYOR. Let me ask Dr. Nichols and Mr. Balto sort of a legal question, and that is—the McCarran-Ferguson Act largely exempts insurance companies from Federal antitrust laws. And I think the practical effect of that is, the Federal Trade Commission currently has very little jurisdiction over the insurance industry.

How important a factor is that in the way the health insurance marketplace is today?

Dr. Nichols?

Dr. NICHOLS. Boy, that's a great question, and I'm sure my colleague is going to have more to say on this than I am. But, I will tell you, I know a little bit about McCarran-Ferguson's origins. Because you go back to the—it came out of an antitrust case, actually—right?—U.S. versus Southeast Underwriters—where the deal was, they were using a rating bureau to fix prices. And in 1944, that decision came down on the Supreme Court, and Congress was a little busy with World War II, and said, "Maybe we should put the regulation of insurance in the State level."

What they said was, "We're going to leave it with the States, as long as what the States do is consistent with Federal purpose." 1944, Federal purpose was, prevent price fixing. I think it's fair to say we've done that. What we haven't done is promoted effective competition. And there are lots of reasons why we don't have that competition, but I would say, in today's world, antitrust may have a role to play. It's not what I would call the first option, because, more importantly, it seems to me, is, we haven't really tried what I would call "open competition," where individuals have a lot of choice, and that's really what, in some ways, these insurance reforms that we're talking about are doing.

But, think about how FEHBP works, versus the way the small-group market works. In FEHBP, you've got 9 million people picking among, in every market in the United States, at least eight choices. And that's because the market's so big, everybody wants to compete in there. Well, that Arkansas small-group market's not big enough,

and we already talked about the pricing problem.

So, it really is not so much antitrust, as it is the way we've structured how the markets are organized.

Senator PRYOR. Mr. Balto?

Mr. Balto. I think it's important to distinguish between urban legend and what the law really is. And I think there's an urban legend that the FTC doesn't have jurisdiction over insurance, but I'm not sure that the law really prevents them from having jurisdiction over insurance. If there is an obstacle, the Committee should act promptly to eliminate that. The McCarran-Ferguson act creates obstacles to effective insurance competition, and that's unfortunate. But I'm not convinced that the Federal Trade Commission could not have gone after Ingenix.

And we—you should recognize, there's this huge regulatory gap here. You know, if there's no Federal enforcement here, we're left to a patchwork quilt of State insurance commissioners, who you've heard have limited resources—Karen Pollitz, in testimony a month ago—how limited their resources are. That's why we need a strong Federal enforcement agency against insurance companies.

Senator PRYOR. I've gone over my time, but I would like to hear from Mr. Feinstein and Ms. Turner on the McCarran-Ferguson and

the FTC. Can you comment on that?

Mr. FEINSTEIN. Certainly. And I agree, in part, but not completely, with my old friend David Balto. There is no question that the McCarran-Ferguson Act does limit the ability of both the FTC and the Justice Department, or, for that matter, private plaintiffs,

to bring antitrust actions involving what's called "the business of insurance" that is regulated at the State level.

There are—it's also the case that the Federal antitrust enforcement agencies would have jurisdiction over aspects of the health insurance marketplace that do not fit into the "business of insurance" definition. So, for example, mergers among health insurers are not in any way immunized by McCarran-Ferguson. Historically, as a result of the, sort of, informal arrangement between the Justice Department and the FTC to avoid duplicating effort and to promote developing expertise, the Justice Department has had primary responsibility for antitrust enforcement in the health insurance industry. Conversely, the FTC has had primary responsibility, for example, in pharmaceuticals, where we've also been extremely aggressive, and, we also think, successful in many instances.

It is—there's no question that there's been enormous consolidation in the health insurance industry. You know, I think it's likely that the—I guess I began my remarks by saying I don't speak for the Commission. I certainly don't speak for the Justice Department. But, I do think it's likely that the new administration, at the Justice Department, is going to, you know, take a very careful look at additional consolidation in the health insurance industry.

Now, I've departed a bit from your question. The short answer is, there are aspects of the insurance industry that the FTC does have jurisdiction over, notwithstanding McCarran-Ferguson. However, there are limitations, entirely apart from McCarran-Ferguson, on the FTC's ability to operate in that sphere. For example, section 6 of the FTC Act authorizes the FTC, generally, to conduct reports and issue compulsory—issue subpoenas and compulsory process to get information, even if it's not in the context of a law enforcement—of a case, or an investigation. We can conduct industry studies. There is an exemption, relating specifically to the insurance industry, which provides that only when specifically requested by one of the committees with oversight of the FTC can it conduct such a study in the insurance industry. That's an example.

So it is certainly the case that the FTC's jurisdiction over the insurance industry is limited.

Senator PRYOR. Ms. Turner, did you have any comments on——Ms. Turner. Just——

Senator PRYOR.—McCarran-Ferguson?

Ms. Turner.—very briefly. I think that the consolidation and centralization of the health sector is really determined by the way we finance healthcare. We have large public programs—primarily Medicare, Medicaid—that purchase coverage, basically through price-control led and tightly structured benefit package design but also employer-based health insurance, where so many people don't have a choice in the individual market and don't have a choice of policies on their own in an FEHBP-like environment, because the policies are purchased for them by large employers and by—through health plans negotiating prices. So, the lack of transparency—the lack of individual choice—has really led to greater centralization, greater consolidation, and greater centralized control. Change in the financing mechanism would give people more power to begin to change this to be more responsive to consumers.

Senator PRYOR. Senator Wicker?

Senator WICKER. Dr. Nichols and Ms. Turner, you start on this. What if we just let people in Arkansas, for example, purchase insurance across State lines? Wouldn't that be an amendment to Federal law that this Congress could do that would open up States to

a lot more competition choices?

Dr. NICHOLS. You know, Ranking Member Wicker, it's a good idea to think that way, in terms of "Let's get more—let's take a crowbar and open up this market and get more competitors in there." The difficulty we have goes back to McCarran-Ferguson, goes back to State regulation. If you said, "We're going to allow competition across State lines," and in Arkansas they might have a rule that says, "Well, you have to cover X, for sure, then a company can locate"—

Senator WICKER. Mandates. Dr. NICHOLS. A mandate.

Senator Wicker. Yes.

Dr. NICHOLS. They might locate in another place, where they don't have that rule, and they'll come in and offer a lower price to those who aren't worried about that service. So, what you'll have is a kind of a "tail wagging the dog," until eventually you get down to no regulation of any kind. And the thing about "no regulation of any kind," in an insurance market that's voluntary, is that they're not going to sell to the sick, they don't want to sell to those who have any kind of health condition that's a big risk, and you end up having that kind of market work very well for the healthy—it would work very well for the healthy—but, it won't work for the unhealthy. And the thing is, as you know, over time we all become in that unhealthy state. So, it would lower prices for the healthy in the short run, and I'm afraid, in the long run, it would be even more unsatisfactory than what we've got now.

So, that's my view of across State lines.

Senator WICKER. Ms. Turner?

Ms. Turner. To take a somewhat contrary view, actually, Dr. Ken Thorpe of Emory University has done some important studies about the hypothesis of adverse selection in the Federal Employee Health Benefit Program, which he says does not actually turn out, in reality—I think it is possible for Congress to carefully structure the rules so that you can avoid the kind of adverse selection that Len is talking about. But if you were to allow health insurance to be purchased across State lines, you would have a mechanism for breaking down State monopolies to give people more options in purchasing coverage. We have interstate commerce in virtually every other sector of the economy. I think one of the reasons that we have so much centralized power at the State level is because of the lack of ability, if somebody lives in the highly regulated State of New Jersey, for example, to be able to purchase health insurance across the State line, in Pennsylvania, or in West Virginia, to find a more affordable policy. This would begin to bring discipline to the market by giving people more choices.

And I also think the adverse-selection issue could be mitigated significantly by giving people resources to purchase health insurance, so people who are young and healthy have just as much of an incentive to purchase health insurance as anyone else does, to

begin to get them into the pool.

I think purchasing health insurance across State lines could be a very beneficial part of health reform.

Senator Wicker. So, it would be purchasing across State lines, plus some added provisions—

Ms. TURNER. I don't think-

Senator Wicker.—to address the—

Ms. Turner.—that in isolation—

Senator Wicker.—problems that Dr. Nichols—

Ms. TURNER.—I think that it needs to be done in a more disciplined market, with better regulation, and with subsidies to get everybody into the system in a fairer way.

Senator Wicker. Mr. Balto?

Mr. Balto. Let me just add one thing. I wouldn't bank on that idea. In part, the dominant health insurance companies don't invade each other's territories now. In fact, the Blue plans, which are very dominant in many States, have a system of territorial allocations, licensing arrangements, which, prevent them from entering each other's markets. That is a subject that the enforcement agencies should look at to see whether or not it's an antitrust violation.

Senator WICKER. Ms. Turner, you mentioned the great steps that Safeway is taking, Whole Foods, innovations at Target and Wal-Mart. What does Congress need to do to encourage this type of success story, which I think we can all agree is a success story?

Ms. TURNER. I think that the most crucial thing is allowing employers, who really are invested in trying to get better value for health dollars, to help make sure that their employees stay healthy and get healthy, and to allow these innovations to continue. Employers have channels of communication with their—

Senator Wicker. We allow it now.

Ms. Turner.—employees—We allow it now through ERISA protection. I'm worried that if ERISA were opened up, it would significantly compromise the ability and the incentive of companies to be able to continue these kinds of innovations. I also am concerned about some of the proposals that would have a government-mandated benefits package that would severely restrict the kind of innovation that these companies have demonstrated can save them money and keep their work forces healthier. In many cases, trusting the employers to continue to do what they have done, and using the resources and the tools they have, is tremendously important. New Federal regulation that drives them into a more centralized, highly regulated market, I think, would backfire in losing many of these innovations that are benefiting both companies and their employees.

Senator WICKER. What do you get for \$20 a month at Target?

Ms. Turner. The benefits package is basically real insurance. So, if you show up in the hospital—if you have to go to the hospital—then you're going to be able to get the care that you need. It's returning to the concept of real insurance. But Target has put \$800 into a spending account so that employees do have money to access routine care. Many Target stores also have retail health clinics on site, so employees can go on their break, and they don't even have to take a half-day off of work to go see a physician. So, there are a lot of these concepts. Obviously that's an employee's choice to use that kind of mechanism. The important thing is that they have a

broad range of options so that employees can pick the kind of system and the kind of services that work best. It's very likely going to be people who are the young and healthy who you really want in that pool—who will say, "OK, for \$20 a month, I'll be able to afford that policy, to make sure that I have hospital care and hospital coverage if I need it."

Senator WICKER. Thank you.

Senator PRYOR. Senator Kockefeller?

The CHAIRMAN. Thank you, Mr. Chairman.

There's a lot of misconception going around. This is sort of a statement in general, you can react to it as you will—about the public option. And people hear the word "public" and they think, "Oh, my heavens, here comes the slippery slope, here comes the beginning of socialized medicine, here comes the"—you know. And what they fail to recognize is, the public option is exactly that; it's an option, it's simply an option. If you like the healthcare that you have, you keep it. If you're paying more for the healthcare that you have than you would under the public option, because you're simply comfortable with your healthcare insurer, you keep it. I mean, there's just nothing mandatory. You can opt in, you can opt out.

But, I want to ask a question, and to you, Mr. Feinstein—well, to anybody, but—one of the problems about the public option, which is easy to fix, but I'd like to get your advice on it, is that if you do a public option, people are going to say, "Well, everybody is just going to—you know, employers are going to dump their people, because they're just going to figure that the public option is going to totally undersell, and there's no way they can catch up." And a couple of you have made reference to that. I mean, it was—I can remember, with the Chairman's father, when we made a "public plan," so to speak, out of the Veterans Administration, and the prescription drugs went down 50 percent, you know, when it took effect. Medicare, as far as I know, is a "public plan," which people kind of like. Medicaid is a "public plan," which most people who, you know, care about people who are vulnerable, like. And they're not leading to anything bad. They're good. People love them. In fact, Medicare is—other than Social Security, is the most popular program in the government.

So, my question to you is, If we were to do a public option—and I think that will happen—I think the wisdom today is that it won't happen, but I think it will happen, because it has to happen, and because it's the only way that you really are able to begin to control some costs—that means you're offering competition. Now, if you offer competition too quickly, then people don't have a chance to respond, and they either panic and just write it off forever, or they jump in before knowing what they're doing. So, my instinct on a public option would be to phase it in over a period of years so

that people had a chance to find out what it was.

Because one of our problems is that the American people suffer horrendously, often, in healthcare, but aren't aware of how they're being had, or how much better they could do, or how they, you know, could measure the outcomes, Dr. Nichols, that you were talking about.

So, would you recommend it—regardless of what you think of a public option—that taking 4 or 5 years to let it come in, so that

the rest of the healthcare market had a chance to adjust to its fact, and people had a chance to learn more about it, would be a good idea, rather than just having it take effect, and not being sure exactly, you know, how people would react?

Mr. FEINSTEIN. Let me take the first cut at that one. I mean, I think, to some degree, that's a health policy question, but I'm going to answer it in terms of competition, which is sort of where I'm

coming from.

I view the public option as a form of competition and an additional choice in the marketplace, which I view as a good thing. And in this sense, I think the goals of competition policy, and antitrust enforcement, are entirely harmonious with the goals of health reform, including the public option, because so much of it turns on having meaningful choices. And for those choices to be meaningful, there has to be competition among them. So, that's sort of where I start.

In terms of whether it would be more advisable to phase it in, as opposed to doing it immediately, again, from—you know, from my perspective, I think the—I think that that judgment ought to be informed by what the impact on competition would be by doing it one way or the other. If we—if, for example, we were to conclude that, in the long run, the promotion of choice and competition would be more robust if it were phased in, then I would—yes, I would think that would be the way to go. If, on the other hand there were a conclusion that, starting at the—you know, all at once, would have, potentially, anticompetitive effect—and it's not clear to me what that would be, but it could, I suppose—then I think that should be given some weight.

The CHAIRMAN. So, knowledgeable competition is a virtue, in

your view.

Mr. Feinstein. Yes, well, competition is a virtue. Knowledgeable competition is even more virtuous, I would say.

[Laughter.]

The CHAIRMAN. OK.

Mr. FEINSTEIN. I mean—and because that's—you know, for competition to work best, the participants in the marketplace, on both sides—consumers and providers of goods and services—should be

informed by knowledge.

The CHAIRMAN. It is stunning to me—and I'm over my time already—but, people in healthcare policy look for what to be afraid of—or, what it is they don't know, they assume is going to come back to hurt them. There's never the view that—I mean, people really don't realize that the VA—that we were able to do that very simply, back in 1993, with the Chairman's father leading the way, that—you know, we did that with—we simply had all veterans hospitals all across the country, and clinics, and everybody else who purchased pharmaceuticals—they all joined together as a single buyer, which created a rather large—rather a large leverage for them, and they got these huge competitions. Now, there's nothing wrong with that; it was very good. It was very good for veterans.

wrong with that; it was very good. It was very good for veterans. Medicare, Medicaid work very well. To the extent that States have problems with Medicaid sometimes, they don't work so well. But, the instinct to try and find out what's wrong, as opposed to the instinct to say, "Could this, maybe, help? Could this, maybe, be

a good thing?" is just a reflection, on my part, of the concern that the American people have about change in any aspect of their life which is really fundamental to them. I mean, 71 percent of the people are saying, "We favor public options,"—61 percent, 71 percent—under the Clinton plan, it was always 72 percent, no matter who took the poll. Problem was, they didn't mean it, when it came down to actually confronting the possibility of a fundamental change in their lives.

How do we get people to understand that change can be a good thing? Either of you. You're both excellent. This is a terrific panel, incidentally.

Dr. NICHOLS. Well, Mr. Chairman, I would say that you hit something really, really important here, and I would describe it as-all bad behavior is based on fear. And so, what we've got to do is reassure the fearful. And I like your idea, I just would like to say, of having this public plan come in gently, maybe even, not in year one, but to have it there in reserve, if it turns out we don't get the competition we want. The point would be to reassure the people who do worry about that this might be some kind of Trojan horse or stalking horse, for all the stuff you have alluded to. But, in fact, I know that's not your intent. In fact, I know that can't be your intent. And I know, in fact, that's not the intent of the vast majority of Senators and people in Congress. They want competition to keep insurers honest, because we have all these examples where insurance markets don't work. Yet, there's legitimate concern that this could be some kind of backdoor stalking horse for a government takeover.

So, how do you deal with that, Senator? I would agree with you, you have to prove it to them. But, you can't prove it to them if you don't get it started.

So, create it. Walk it gently. Maybe have a trigger, something like that and go for—and keep those rules such that you've got a level playing field. That's extremely important.

The CHAIRMAN. Yup. You had a comment.

Mr. Balto. Yes, Mr. Chairman. I frequently represent consumer groups. And if I was here on behalf of consumer groups, I would say the problem right now is reaching crisis proportions and—you know, with thousands of people becoming uninsured every day. So, you know, there's really a need for some type of urgent action.

I want to deal with one of the reasons why people say, "Go slow." Sometimes people say "Go slow" because the public plan is going to go there and it's going to drive the—all these insurance companies out of the market.

Let's be realistic, here. These insurance companies, just the largest for-profit ones, have over \$13 billion in profits. The nonprofit ones are very well funded. I do advocacy against mergers when there's a merger investigation. I get to go and actually investigate these markets. These insurance firms have a stranglehold. A public plan is necessary to get some other entity in there—in a market like Arkansas, where there's failed entity entry—to get some other entity in there to provide some new form of competition.

The CHAIRMAN. I thank you.

And I thank you, Mr. Chairman, for allowing me to go on at such length.

Senator PRYOR. Thank you.

Senator Cantwell?

STATEMENT OF HON. MARIA CANTWELL, U.S. SENATOR FROM WASHINGTON

Senator Cantwell. Thank you, Mr. Chairman, and thank you for holding this important hearing. And obviously, Senator Rockefeller, thank you for the Committee's interest in something that I think is critically important to the American consumers.

And as the Chairman discussed, moving forward on healthcare legislation, I think it's critically important that we have transparency in drug pricing, so I certainly will be offering a previous legislation that I have sponsored, requiring PBM disclosure infor-

mation, to make sure that we are getting the best price.

But, it seems to me that we're talking about this gap that exists with the FTC, certainly just applying antitrust issues, and we have this merger happening. I mean, to me, PBMs are the great negotiator of a discount. And the issue is, Who are they passing the discount on to? And how much of it are they pocketing? And the previous States going after the fact that pharmaceutical manufacturers owned PBMs—and as someone was saying, you know, passing these laws about evergreening of—stopping evergreening of patents and stopping the purchasing—the—basically, the fact that there was this tight relationship between manufacturers and producers. But, now we're replicating that with, basically, PBMs; and CVS being, like, one in three on prescription drugs. And who is passing—and how much of the discount is being passed on to the consumer?

So, to me, I think that's a very fair question in a merger, and I think that we ought to have transparency on that, and at least from the perspective of the FTC investigating whether those benefits are being passed on to the consumer or not, whether that information is public.

So, Mr. Balto, could you comment on how you think that we get transparency, here, and still protect, you know, what is private market functions, but clearly a need by government to make sure that the structure here isn't being abused on the benefit of just gouging consumers?

Mr. BALTO. Thank you, Senator.

First, what this Committee's work in Ingenix has shown that is, for these middlemen markets to work, we need three things: transparency, choice, and something to prevent conflicts of interest. That's what Ingenix was about. All of those things are problems in the PBM market. And because those are problems in the PBM market, the PBMs are doing fabulous. Their profits have skyrocketed over 300 percent, to almost \$3 billion. That tells you where the money is going. That money shouldn't be going to the PBMs' bottom line, it should be going to the health plan so that they can help lower their drug costs.

By the way, this isn't just a private issue. This is a public issue. The Federal Health Benefits Program has the same problems, as highlighted in recent hearings of the House Government Oversight

Committee. We need transparency so plan sponsors—as Mr. Riley has documented in his testimony—plan sponsors have the necessary information to derive the best bargain and make sure that those benefits really go to them so that they can reduce their costs of healthcare.

Senator Cantwell. Well, we certainly want to make sure that, in the new healthcare reform bill, that that transparency is there. We've tried to sponsor this before, but I think now we have a dif-

ferent opportunity.

But why can't it also be a discussion of mergers? To be asked, in a merger, OK, "What percentage of discount are you passing on to the consumer? And how much are you pocketing?" I mean, we do this when we look at telecom mergers. We look at the structure and whether the consumer's best interest is going to be met or not, and whether we're going to allow the merger to happen. Why can't we look at this way, as well, and ask, What kind of benefits are the consumers really going to get?

Mr. Balto. I think that's absolutely the right question. The agencies have not challenged any insurance mergers or PBM mergers. There is little evidence that any of those mergers have benefited consumers in lower premiums or lower pharmaceutical costs, in terms of PBMs. I don't know why they haven't been able to bring those challenges, but clearly the evidence isn't that consumers are

better off because of them.

Senator Cantwell. Mr. Riley, I don't know if you have any comments, but I think, from these cases that were brought by States when pharmacy manufacturers could own PBMs, they were finding instances where you were negotiating a discount, but 65 or 70 percent of the negotiated discount went to the PBM and back to the parent company, and only, you know, a very small percent got passed on to the consumer.

Mr. RILEY. Thank you. If I may speak to this.

This goes back to the Hauser family's testimony before FTC committees recently, where the family was—had been going to their local community pharmacy, and the pharmacy was paid \$9 for the prescription, approximately, and the patient had a \$5 copay. CVS Caremark then informed them, under their plan, they had to go to a CVS or get it mail-order. The CVS store was reimbursed \$67 for the prescription, instead of the \$9, a local pharmacy, \$5 copay for the patient made them not notice it, they thought. But, the bottom line is—and it was in the Medicare Part-D plan, so their TrOOP amount, their total amount, they were driven toward the doughnut hole by another \$62. And when they got to the doughnut hole, they would have to pay \$67, not \$9. And so, it's those kinds of things that concerns us.

I think the real important part, Senator Cantwell, is that 30 years ago—25 or 30 years ago, we looked at a prescription, and we said, there's the amount the drug costs, there's the amount the pharmacy is paid for the dispensing services, and that's the total cost. For 15 or 20 years, we've been in a situation where it's the amount the drug costs, the amount the middleman makes, plus what little bit the pharmacy gets is the total, and we have not adjusted to that. And within this marketplace, everyone in the prescription drug chain is highly regulated except the PBM. And while

we, none of us, like regulations—and fair trade practice rules certainly are in order here to stop some of the things that's going on.

I would like just to add, real quickly, that in Arkansas we just passed a law. It applies only to public dollars, but—right now—but, that law says, very simply—it puts some simple regulation that says, when a PBM gives an invoice to an employer or a payer of what the prescription costs, they have to tell them how much of it went to the pharmacy. It's just one piece of information that they have, and that alone creates some transparency.

Senator Cantwell. Well, I thank you, and I thank the Chair.

I certainly believe there's price-gouging going on, and we shouldn't have Federal agencies be the last to figure it out. And so, I hope that our committee can figure out how to get better protections for consumers.

Mr. Balto. Can I just add one thing, just—the practical thing, here. The pharmacist, here, who deals with a patient, who's opening his store any time of the day the patient needs help, the pharmacist, here, may be getting \$5 a prescription. The PBM may be getting \$30 or \$40 a prescription. Who's really providing the value when a prescription drug is dispensed? Why should the PBM be getting that much more than the pharmacist, who really does help the consumer and represents the consumer's interest?

Senator PRYOR. Thank you.

Senator Thune?

STATEMENT OF HON. JOHN THUNE, U.S. SENATOR FROM SOUTH DAKOTA

Senator Thune. Thank you Mr. Chairman. And I appreciate our Committee engaging in the debate about healthcare. I think it's the issue that everybody seems to be talking about around here, and lots of action in other committees, in terms of legislation that we

may be, at some time, voting on in the Senate.

I guess I don't argue, for a minute, the importance of taking this issue on, and trying to reform our healthcare system in a way that lowers costs. I think that's the main issue for most Americans. Obviously, if you're one of the people who doesn't currently have insurance, that's a big issue, too, and one that we need to address to make sure that we provide access for all Americans. But, for most Americans, it is the issue of cost and affordability, and seeing these continual increases in the overall cost of healthcare. I think that that's where they want to see some action. And, of course, there are lots of different ideas out there about how best to tackle the problem.

My State of South Dakota is a fairly low-cost and, I would argue, high-quality healthcare region, but we have some big challenges delivering healthcare in rural areas of the country. For example, access to insurance for small businesses or self-employed farmers, adequate reimbursements for hospitals and doctors, are all signifi-

cant challenges.

I would argue that creating a government program is not the correct way to address these challenges. But, I do think that we have to—we do have to make some changes.

I would be curious in knowing—and maybe I'd direct this to Ms. Turner—your thoughts about steps that Congress might be able to

take that would improve the overall access to healthcare in this country, and provide more opportunities for small businesses to cover their employees that would be based in the market, in the private-sector delivery system, if you will, as opposed to coming up with a government plan.

Ms. TURNER. Thank you, Senator.

The market is so stacked against individuals and small businesses right now. And it's primarily, as I mentioned earlier, because of the way that we finance and reward the purchase of

health coverage in this country.

The logo of the Galen Institute is actually a chart that describes, I think, the real problem we have. People who are at the lowest end of the income scale generally have access to Medicaid and SCHIP. This is true in every state, of course, but generally, as people move up the income scale, they fall out of public programs, but don't yet have the better, higher-paying jobs that come with health insurance, or that give them the resources to purchase coverage themselves.

I think one of the most important things—and I know it's not in this Committee's jurisdiction, but it's part of the larger package of reform—is to equalize these subsidies so that people that are most likely to be in lower-income categories have the opportunity to purchase coverage and to create new markets so that they don't just have to rely only on their employer to provide coverage. That could mean allowing the purchase of health insurance across State lines. It could mean new kinds of groups, such as church groups, or professional associations, labor unions, affinity groups that give people a sense of security with their association.

And I think a lot needs to be done to deal with helping people with preexisting conditions to be able to get coverage. Some states have very innovative programs to help people purchase health insurance. It's a kind of a guaranteed issue program, but run pri-

vately by the states.

I think the most important thing is looking at the innovation in the States. What are people doing well? Where is centralization and the lack of competition not helping? How could states help to

give everybody an equal chance of getting into the system?

Senator Thune. And I appreciate your thoughts in that regard. Those are many things that we've been trying to do here, for some time, and reforms that I think would help lower costs, and provide greater access to people in the country. And so, those are all things that I think ought to be part of any kind of a reform proposal that we move through here, that don't include a government takeover or a government plan, if you will, that, in my view, is going to create more government interference, intervention, and impose government making a lot of decisions that I think rightfully ought to be made by patients and their physicians.

I appreciate the focus, too, on pharmaceutical issues, and how pharmacies would be impacted. We've got a lot of small-town retail pharmacies in my State. And I guess the question I'd direct to anybody on the panel, is given some of the challenges that some of your members face with Medicare Part D, and with inadequate reimbursements from Medicaid, Medicare D, M, and E accreditation, and the list goes on—do you have reservations with having all of

your consumers on government insurance if we were to create a new government-run plan? And maybe you've already been asked some of those questions. If you have, I apologize, but I'd be curious to get some reaction.

Mr. Riley?

Mr. RILEY. Thank you, Senator Thune.

I think our pharmacists want two things. I think they want a level playing field, and I think they want fair reimbursement. And I think—we believe that, in prescription drugs now, the most important aspect of what we need to do is to have transparency, so we see where all the money's going, money that—for instance, employers pay \$40 a prescription, and pharmacies pay \$20; they don't know that. They think they paid the pharmacy \$40, but the middleman, the PBMs pocketed the half of the money, or whatever, in that case. And so, I don't think pharmacists are as concerned about fairness in government, as long as there's transparency, so that we can see where the money really went and who got that money. I think that's the concern we have right now.

Senator Thune. Mr. Chairman, I am out of time. Thank you. Senator PRYOR. Thank you. Senator Thune. Thank you all very much for your testimony.

Senator PRYOR. Thank you.

Let me, if I may, talk about something, Mr. Riley, that you mentioned in your statement, and that is the Caremark/CVS merger. And you alluded to this in your statement, but I just want to be clear. Tell the Subcommittee, here, how you believe the merger has

harmed patients and consumers.

Mr. RILEY. Well, I gave you the example, Senator Pryor, that was—the testimony before FTC recently, but we have—the NCPA has several examples from pharmacies where prescriptions were filled at their pharmacies and, within hours, there was contact by CVS about how the consumer could supposedly save money if they bought it from their mail-order, or went to their stores. In reality, in the case the Hausers showed, the PBM—CVS Caremark is very careful to keep the copays the same, so maybe the patient doesn't see it, but the—but increases the price, which is—increases the cost of the overall system significantly, and differentiates between what they will pay their pharmacy, but what—and what they will pay—pay their pharmacy much more than they'll pay any other pharmacy.

So, we think, one of the things that Medicare Part D has brought to the system is, finally the consumer needs to changes their thinking to understand the total cost of the program, because of TrOOP and all, ultimately, is what's driving healthcare costs, not just what they pay. And so, many cases in the mail-order situations, which are very close to CVS Caremark, the PBM sells the employer on a lower copay for mail-order. Well, essentially, that makes the consumer—you know, they do—they are getting a better deal if you do that. It doesn't lower costs to the program. Those other copays are just paid by the employer, or whoever the payer is, and the costs

of the program really go up.

And so, I think what we're facing, is about 20 years of where we've tended to remove the consumer from the cash register, if you will, with steady copays, while the costs of prescription drugs have gone from about 6 percent of the healthcare dollar, in 1985, to almost 18 percent, by the turn of the century. And all that's not the PBMs' fault. But the model that the PBMs have set up to line their own pockets have created those kind of costs.

I believe we've got—I think this fits into the equation, that we've really, essentially, got a situation where the PBMs and the drug manufacturers, in some sense, are playing "I scratch your back, you

scratch mine.'

"I don't care what the drugs cost," the PBMs are saying, "as long as I get my piece of it when it flows through." And so, I think that

particular thing cost—overall costs to run through the roof.

I would like to say one other thing, and that is, I commend CMS for making the changes in their program, that January 1, 2010, there will be no more spreads in prescription drug pricing for the Medicare Part D plan. I think that will have a major effect. Basically, they said to the plans, "You can pay the PBMs all the money you want to pay them, but you're not going to wrap those hidden costs into the prescription drug costs that run the consumers' cost up. You can only charge against the consumers' Troop what was paid to the pharmacy." And I think that's the kind of regulation, and—that's helpful so the consumer doesn't get charged higher for prescription, without knowing it.

Senator PRYOR. Mr. Feinstein, let me follow up, if a may, on the CVS/Caremark merger. And I know there's probably limits to what you can say about that, but let me just ask if the Federal Trade Commission analyzed that merger before it was consummated.

Mr. Feinstein. There are limits to what I can say about that, for two reasons. Number one, I've been at the FTC for 10 weeks, so I wasn't actually there. But, I will say that it's certainly my understanding that the—that merger was submitted, in the premerger notification filings in the ordinary course, to the Commission, and was analyzed by the staff.

If I could elaborate a bit—

Senator PRYOR. Sure.

Mr. FEINSTEIN. And I know you have a second question of me.

I don't know whether this will anticipate it or not.

At the time that a merger is being presented for review, by either the Justice Department or the FTC, essentially the analysis is making—trying to make a prediction. You know, what is this—how is this merger—and our focus is on competition—how is this merger going to impact competition? And if it's going to reduce competition, you know, our primary focus is on consumers. It's not our only focus, but that's our primary focus.

It is also the case, sometimes, that, after mergers are not challenged and are completed, that they may have anticompetitive effects. I'm speaking generally, now. And we receive—when we receive complaints, whether it's before, during, or after the consider-

ation of the merger, we take them seriously.

I can't comment on, you know, any ongoing—the presence or absence of any ongoing investigations, except to say that a month or two ago, Mr. Balto and a number of his clients had a meeting at the FTC—which is a matter of public record, that's why I can comment on that—and they made a number of complaints, and—you know, with, again, the focus on what's—the primary focus on, How

is this impacting competition and consumers? As well as once—I suppose there could also be, at least in theory, a consumer-protection aspect to the analysis, which goes beyond the competition analysis. In other words, you could have a circumstance where the conduct is problematic in ways that wouldn't necessarily violate the antitrust laws, but might raise some other consumer protection issues. Again, I'm speaking in the abstract—

Senator PRYOR. Right.

Mr. FEINSTEIN.—now. But, that's my preliminary response. Now, I don't know whether I've already answered your second question, or not.

Senator PRYOR. Well, you did. And let me ask my final question, with the Committee's indulgence, here, to Mr. Riley, and that is—I recently toured the prescription drug program in Arkansas, the evidence-based prescription drug program that we've done—and, just for the Subcommittee's background, as I understand it—I think the numbers they told me were—3 years ago, the State legislature decided to spend \$1 million a year on this evidence-based prescription drug program, and it goes to look at Medicaid and the State employee system, which includes more than just your pure State employees, like maybe university people, et cetera. But, none-theless, they've spent \$3 million, and they calculate now that they've saved \$70 million, just by going for pure, evidence-based recommendations.

And just—Mr. Riley, is that consistent with what you know about the program? And how is that program working for the average pharmacist out there?

Mr. RILEY. Thank you, Senator Pryor.

And, yes, it is working that way, and I appreciate the opportunity to comment on this, because I think it's the type of model

that we need to adopt nationwide, because it works.

When I came in the—first of all, the Medicaid program works a little bit differently, and it's saved them a ton of money just on the drug costs. But I'd like to focus on the State employees' program more, because it was more like a private sector—what most of the other businesses are. The State employees in Arkansas, in 2003 when I came to my job, I began to meet with Sharon Dickerson, who was then the director of that program—they had had—their program had essentially tripled in cost in 4 years. They had 4 years of the big PBMs—2 with one PBM and 2 with another, that were the big three—and their costs were out of control, and the legislature, that you once served in, had served them notice that, "If you don't do something, we're going to cut this program off." So—but, they were doing everything that the PBMs recommended, and their costs continued to rise.

So, I began to meet with her. And over about a 6-month period, we educated them to understand what was really happening to them, and what was being—that they didn't know, that was going on.

On March 1, 2004, they made the first recommendation that the pharmacy community recommended. The savings were so great from that, that, within a year, they kicked out their consultants they were paying \$600,000 a year to, they got rid of their PBM, they—we helped them write a completely transparent contract.

And the bottom line is what you want to know. The 4 years previous, from 1999 to 2004, their cost increases had been over \$62 million, just the increases. The 4 years since then, we have the data, and the cost increases have been \$12 million to \$13 million. We helped them reduce their rate of increase by 80 percent, just by two things: getting rid of the big PBMs; second—and getting them good, sound information so they could make good, evidence-based decisions. And they used—because that consultant became the College of Pharmacy, which just gave them good information about what were the drugs.

The other thing about evidence-based medicine, I think is important, is that the patient is considered first. You make sure you're using the right drug, then you talk about competition between the costs of those drugs. And so, the patient's never disadvantaged in that principle; as opposed to the PBM model, where the biggest rebate, that they keep most of is, is what drug gets chosen, whether

it's the best drug or not.

So, thank you for your question. I think it's a glowing example of what you can do once you get the information that we think we need in the—in this market.

Senator PRYOR. Thank you.

Senator Wicker?

Senator WICKER. Thank you.

Ms. Turner and Dr. Nichols, I'd like for you to discuss the idea of a public plan a little more. And it may not be fear on my part, but it's alarm, I think, based on the fact there are slippery slopes out there, and anything that might lead to a Canadian-style, or British-style, or Western European-style healthcare system, I want to try to avoid. And it's not just folks from the center-right, like me, it's the *Washington Post*—last Friday in their lead editorial, that urged the Democrats to abandon, or not insist on, the public plan, and mentioned that it is risky, and it doesn't need to be done on a partisan basis.

Now, Ms. Turner, you talked about Part D, with approval, as an entitlement program where we actually cut costs, and stated that it's 40 percent under the expected cost. There is plenty of private competition in Medicare Part D. Is there an alternative public plan in the law that never kicked in? And if so, why is that? And why, then—if it never kicked in, why should we be concerned about the

public plan proposal that is before us now in the Congress?

Ms. TURNER. An excellent question.

When the Medicare Prescription Drug Benefit was being debated in 2003, there was a proposal to allow private, competing drug plans to offer this benefit. There really wasn't anything in the market like that at the time. In private health insurance, health benefits are generally part of the overall health benefit plan. Congress decided to have the public plan be a backstop in case no other plans came forward to offer this freestanding drug benefit.

Well, as we all know, so many of them came forward that it really caused a confusion of its own, giving seniors many choices of

these competing plans.

This, I think, is very different than in talking about a new government health insurance plan because we do have private insurance out there already. We don't need to create something new.

And all of the evidence, from the Congressional Budget Office to the Lewin Group, shows that if you introduce this new, government, public plan into the marketplace, it absolutely will crowd out private insurance. Even if the rules initially are set to create a level playing field, there will be such an incentive to change the rules as it goes along, that it will be like having the referee say, "I'm going to set the rules and I'm going to go on the playing field, and I can change them as the game goes on." The pubic plans will have Federal price-control authority, they will use Federal subsidies, and will have Federal money to create the public plan, which doesn't have to be raised in the open market, like a private insurance company would.

Senator Wicker. How can we structure a Part-D-like backstop? And I think Dr. Nichols said it'd be OK with him if it never kicked

Ms. Turner. Well, you know-

Senator WICKER. Can we put you two in a room and get-

Ms. Turner. We actually-

Dr. NICHOLS. Sir, I've written that-

Ms. Turner.—have much less-

Senator Wicker.—and get-

Ms. TURNER. Can I offer an idea to Senator Rockefeller's point, earlier, about why people are so afraid of change? Well, maybe we don't need the new government public plan. Maybe what we need is to allow State employee health plans, that already exist, to be the backstop. If the private marketplace does not come forward after subsidies are offered and new insurance regulations are put into place, then State employee health plans, which already are out there, could be the backstop. This doesn't require putting all the infrastructure of the Federal Government into play to give people a backstop. Len and I actually had lunch last week and explored this

Dr. NICHOLS. We talk all the time. And we'd be glad to go in any room you want. But, I-

[Laughter.]

Dr. NICHOLS. Here's what I honestly believe. Fundamentally, what we're talking about here is, let's change the rules of the way the individual and small-group markets work now, because I think we all agree those markets don't work very well for the consumer. A large-group market does work. And the whole point in—at least in my interpretation, sir-the whole point of an exchange and a new marketplace, all that stuff, is about giving individuals in small groups access to same economies of scale, and the same ability to pool risk, and buy lots of choices, that the big people have now. Senator WICKER. I think every member of the House and Senate

wants that.

Dr. NICHOLS. There you go. So, what we—I'm more than happy to say, let's set that up, see how it goes, and have the public plan kick in later. The difficulty you're going to have is, if you—if some people want to constrain that other new marketplace to be so small, and to not let it really be robust—it's got to be big enough it's got to have enough people there to entice the entry. We all agree we've got to get more competition. The question is, How do you get the entry? You were here when I described Arkansas, you

know it quite well; Mississippi's probably not all that different. So, at the end of the day, we've got to figure out how to get more com-

petition on the ground.

And I—my recent proposal, sir, for the public-plan option was to think about the way States do it now for their State employees. What they typically do is, they have a number of competing plans, and then they have one self-insured plan for which the State bears the insurance risk, the State picks the managers, so that it reassures those people—and there are some, I'm sure you know—who do worry about private insurance managers having an incentive to deny care and all that. You remove that fear, but then that competes on a level playing field, because those people are paying market rates, there's no compulsion to join, there's no compulsion for providers to participate. It really is, in my opinion, a level playing field.

We could do that, and you could have it as a backup, if people didn't like what the options were. I think you can open that door.

Senator WICKER. Do you agree that, in Part D, dozens of profitoriented insurance companies have competed, have provided coverage, and have come in 40 percent below the estimated cost?

Dr. NICHOLS. Yes, sir. I think Part D worked in that way. And all I'm trying to say is, let's think about reproducing the conditions of the competition that engendered that entry—that engendered that competition. And what I'm trying to say to you is, in a lot of markets today, right now, we don't have enough competition on the ground. So, the enticement of the public plan is to get more competition on the ground as soon as possible.

But I would agree, if you change the way the markets are structured, which I think we're all talking about, make the exchange big enough and have enough lives there, you could run it like FEHBP, like State employee plans, like very, very large employers do. And then you probably wouldn't need a public plan. But, if you had it as a backup, it would reassure people. And again, you could use the existing creatures, if you will, as the fallback, if you wanted to.

So, I think there's a lot more common ground, sir, than sometimes the headlines might imply.

Senator WICKER. Thank you, Mr. Chairman.

Senator PRYOR. Thank you.

And I want to thank the panel, again, for being here. It's very informative, very helpful. I had several of my colleagues, on the way out, just tell me they really appreciated the panel for your

thoughts and insights.

What we're going to do is, we're going to keep the record open for 2 weeks, and—because of various things going on here in the Senate today, not all of our members could be here, but it's very possible that we will be sending you some more questions in writing, and we'd appreciate those back within 2 weeks. And the Committee staff will be working with you on that as they come. I actually may have a few to submit in writing myself.

Senator PRYOR. But, again, thank you all for doing this. This is

very helpful, very important topic.

And with that, we'll adjourn the hearing. Thank you. [Whereupon, at 12 p.m., the hearing was adjourned.]

APPENDIX

PREPARED STATEMENT OF THE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP). PCMA appreciates the opportunity to submit written testimony to the U.S. Senate Commerce Subcommittee on Consumer Protection, Product Safety, and Insurance.

Health reform faces four major challenges: reducing costs, improving care, expanding access and ensuring, if nothing else, to "do no harm." These are things America's PBMs do every day for a diverse client base. In health reform, the key is to avoid policies that make it harder or more expensive to deliver benefits while

pursuing policies that actually improve health care.

PBMs typically reduce drug benefit costs by 30 percent 1 for public and private payers by encouraging the use of generic drug alternatives, negotiating discounts payers by encouraging the use of generic drug alternatives, negotiating discounts from manufacturers and drug stores, saving money with home delivery, and using health information technology like e-prescribing to reduce waste and improve patient safety. Prior to the advent of these tools, there was no system wide approach to fully address the real dangers and costs of misuse, overuse, or under-use of prescription drugs. In the Medicare Part D program, PBMs have used these tools to help keep overall program costs 30 percent below original projections.²

PBMs achieve savings for the Federal Government as well as thousands of different employer and health plan clients who have different needs and different resources available to finance health benefits. However, all PBM clients—private and

sources available to finance health benefits. However, all PBM clients—private and public sector alike—share the goal of wanting benefits that provide great access, are affordable and, in the case of the private sector, help retain and recruit top-notch

The Federal Trade Commission (FTC) has extensively evaluated the PBM industry and confirmed that it is both highly competitive and provides savings. It should be noted that the FTC found in its most recent antitrust analysis of the PBM industry that competition among PBMs for contracts with plan sponsors is "vigorous." 3

According to the FTC, there are 40 to 50 PBMs operating in the United States including those owned by supermarkets, large pharmacy chains, and large insurers. In addition, the commission states that one-third to one-half of each regional market is serviced by smaller PBMs. 5

In evaluating mail-order pharmacy, the FTC also determined that PBM-owned mail-order pharmacies save payers money and that allegations of PBMs' conflict of interest were "without merit." Specifically, FTC found that PBM-owned mail-order pharmacies:

· Offer lower prices on prescription drugs than retail pharmacies and non-PBM owned mail pharmacies;

Pharmacies," August 2 050906pharmbenefitrpt.pdf

¹PricewaterhouseCoopers, "Medicare Part D: An Assessment of Plan Performance and Potential Savings," analysis prepared for the Pharmaceutical Care Management Association, January

<sup>2007.

&</sup>lt;sup>2</sup> Centers for Medicare and Medicaid Services press release, "Medicare Part D Plan Premiums for 2008 Show Continued Impact of Strong Competition," August 13, 2007.

³ U.S. Federal Trade Commission, In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 0310239 n. 6, February 11, 2004, statement of the Commission, available at http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf

⁴ U.S. Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005, available at http://www.ftc.gov/reports/pharmbenefit05/050066/harmbenefitmt.pdf

⁵U.S. Federal Trade Commission, "The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care," Statement before the Subcommittee on Consumer protection, Products Safety, and Insurance Committee on Commerce, Science, and Transportation, U.S. Senate, July 16, 2009.

- Are very effective at capitalizing on opportunities to dispense generic medications; and
- · Have incentives closely aligned with their customers: the third-party payers who fund prescription drug care.

Policymakers need to be wary of other policies that could undermine the incentives and tools PBMs use to lower costs and enhance quality. It would be a mistake, for example, to force PBMs to publicize the discounts they negotiate with drug manufacturers and drug stores. If sensitive pricing information is made public, the greatest benefactors are not consumers or taxpayers, but drug manufacturers, drug retailers and others who learn their competitors' negotiating strategies and raise

prices accordingly.

The Federal Trade Commission and others have explored this issue and found that the wrong kind of transparency increases, rather than decreases, costs. The Congressional Budget Office concluded that such a policy would have increased Medicare Part D's costs by 10 percent if it had been included in the program. ⁷

In addition, we caution against any policy which would grant special antitrust exemptions to independent pharmacies. During testimony before the U.S. House Judiciary Committee Antitrust Task Force on this issue, the FTC stated: "Giving heath care providers . . . a license to engage in price fixing and boycotts in order to extract higher payments from third -party payers would be a costly step backward, not forward, on the path to a better health care system."8

As policymakers seek specific ways to improve competition and reduce costs, there are several common-sense policies that can accomplish this without restricting access to medications or shifting costs from one part of the health care system to another. These include:

- Real Biogenerics Reform: Real biogenerics legislation is strongly supported by AARP, AFL–CIO, the Ford Motor Company, PCMA, and dozens of other consumer, labor, and employer organizations concerned about runaway health care costs in both the private and public sectors. This proposal—which allows generics to compete with expensive biotech medicines the way they already do with conventional brand-name drugs—is one of the few proposals that actually delivers score-able savings and is a good bellwether for health reform prospects overall.
- Reduce waste by making formularies in Medicare Part D more closely resemble those in FEHBP. This could include eliminating so-called "protected drug classes" in Medicare. These Part D provisions eliminate price competition among manufacturers without providing seniors greater access to those drugs. This reform alone would save Medicare \$4.2 billion over 10 years, according to CMS.9
- Increase efficiency and save billions by allowing greater use in Medicare of home delivery for refills of long-term, chronic medications. Seniors appreciate the convenience and are more likely to stay on their drug regimens if their longterm maintenance medications are delivered right to their homes.

Ensuring and improving competition will continue to be critical aspects in any revised health care system. These recommendations, coupled with PBMs' proven track record of improving quality, reducing costs, and expanding access to affordable prescription drugs, are true steps toward enhancing competition in health care reform.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DAVID VITTER TO GRACE-MARIE TURNER

Question 1. I have long advocated for opening the health care market to allow Americans to shop across state lines for their health care. Do you believe allowing Americans to shop across state lines for health care would lower costs, and has the Galen Institute conducted any studies or analysis to show any cost-lowering bene-

⁶U.S. Federal Trade Commission and U.S. Department of Justice Antitrust Division, "Improv-

ing Health Care: A Dose of Competition," July 2004.

⁷ Congressional Budget Office, "Cost Estimate: S. 1, Prescription Drug and Medicare Improvement Act of 2003," page 15. July 22, 2003.

⁸ U.S. Federal Trade Commission, Concerning the "Community Pharmacy Fairness Act of 2007," Statement before the Antitrust Task Force of the Committee on the Judiciary, U.S. House of Prepresentatives, October 18, 2007.

of Representatives, October 18, 2007.

⁹ CMS interim final rule "Medicare Program; Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies," January 2009.

Answer. As many as 18 million people purchase health insurance in the individual market. They are trapped by the rules and regulations set by their state legislatures. The markets for individual and small group insurance are highly regulated in many states and lack genuine competition that would allow consumers more choices of more affordable coverage.

According to an August 19, 2009, article in *The New York Times*, "there are nine states where a single insurer covers 70 percent or more of the people. In Hawaii, one insurer covers 78 percent. In Alabama, it's 83 percent. And in at least 17 other

states one insurer covers at least half the population.

This lack of competition means that companies that dominate the market can charge higher prices for coverage. There also is less incentive for state legislators to curtail regulations such as community rating and guaranteed issue or coverage mandates that dry up competition and drive up the cost of health insurance. A policy purchased in a lightly-regulated state like Iowa can cost a fraction of the price of a similar policy purchased in a highly-regulated, non-competitive state like New York or New Jersey. Our health insurance system is Balkanized, much to the detriment of consumers who most need help in purchasing affordable health insurance. A study by Stephen Parente and Roger Feldman, both health economists with the University of Minnesota, found that 12 million previously uninsured people would

be able to get insurance if there were competition between and among states. The study was presented in August of 2008 during an American Enterprise Institute conference on ways to increase access to the uninsured through interstate competition for individual insurance.

I commend Senator Vitter for seeing the value of allowing people to purchase health insurance across state lines. This would significantly increase the choices available to consumers and would force insurance companies to provide more affordable options or to consumers by increasing competition among health insurers. This policy change, which clearly is allowed by the Commerce Clause of the Constitution, would be an important change that could significantly increase access to health insurance without any new costs to the Federal Government.

Question 2. What has been the impact of the Stark law on healthcare competition

and structural innovation?

Answer. An entire industry has developed to help providers and health care institutions comply with the quagmire of Stark law. This forces doctors and hospitals to spend tens of millions of dollars trying to figure out how to comply with increasingly complex laws. This in turn dries up innovation and forces doctors and hospitals to focus on navigating the regulatory maze rather than figuring out how to provide better, more efficient care to patients.

A recent report by Kathleen Boozang, Associate Dean and Professor of Law at Seton Hall University, provides important insights. She writes about a recent Whitepaper entitled: "A Public Policy Discussion: Taking Measure of the Stark Law" analyzing the "Ethics in Patient Referrals Act" (and its progeny), more commonly known collectively as the "Stark Law," after its primary sponsor, Congressman Pete Stark. The whitepaper was released by "The American Health Lawyers Association's Palls."

Public Interest Committee. Boozang writes:

Stark was enacted in response to empirical studies showing that physicians who hold an equity interest in an entity that provides ancillary health care services, such as a clinical laboratory or MRI, more frequently order those services for their patients, referring them, unsurprisingly, to the entity they own (the Whitepaper notes that no studies indicated that this higher use equated to over-utilization). The implication, then, is that the opportunity for additional profit causes excessive referrals, whether consciously or unconsciously. Thus, Stark sought to establish a bright line test regarding the propriety of physician referrals. Stark prohibits a physician from referring patients to entities in which the physician (or a family member) holds an equity interest. Congress seeks to ensure that patients are referred only for tests and other health care services that are medically necessary and appropriate. The law also prohibits the entity actually providing the services to the patient (the recipient of the referral) from billing Medicare if the patient care resulted from an impermissible referral (even if the patient needed the service).

"But a basic prohibition proved too broad to be practicable. For example, how should the law treat rural areas where the only potential investors in an MRI for the community are all of the local physicians? While many of situations crying for exceptions have been legitimate, virtually every single business relationship that seems justified requires the adoption of a new exception—which, the Whitepaper

points out, stymies innovation in a dynamic health care market."

It is imperative that Congress assess and correct the damage the Stark law is doing to innovation, cost, and quality patient care in any health reform measure it Question 3. What are the effects on hospital competition and patients of the pro-

posed ban on physician-owned hospitals?

Answer. In 2003, Congress imposed an 18-month ban on development of new physician-owned specialty hospitals, the majority of which provide cardiac or orthopedic care. The moratorium expired on June 8 of 2005, but now there are efforts to reinstitute and expand the ban in a way that would eventually strangle any physician-owned hospitals.

A ban on physician-owned hospitals would have serious detrimental effects on the quality of care delivered in communities across the country. They set a higher standard for care-producing better outcomes because physicians are able to create environments where they can provide higher quality, more efficient care to their patients. Rather than emulate them, many large community hospitals are working to shut down physician-owned hospitals, not because they don't provide superior care,

but because they don't want the competition.

Senator Tom Coburn of Oklahoma, wearing his hats both as a legislator and physician, spoke at an event the Galen Institute hosted on Capitol Hill in 2005 to explore the issue of specialty hospitals. Dr. Coburn said that quality patient care must come first, and many doctors prefer to practice in specialty hospitals because they believe they can provide better care. "Competition helps to lower costs and improve quality, in health care as in the rest of the economy," he said. Harvard Professor Reggie Herzlinger also spoke and stressed that specialization is key to productivity growth and that ownership by experts is key to innovation. Other speakers used analogies from telecommunications, retailing, and automobiles to stress the value of competition and specialization. She said that extending the ban on specialty hospitals would "strangle an innovation that holds great promise for productivity gains in health care.

Current legislation would reinstate the moratorium as well as revoke the entire hospital exemption to the Stark laws under which physician hospitals operate. This would mean there could never be another physician-owned hospital that could receive Medicare certification. Competition and access to quality care would be nega-

tively affected.

Hospitals already in existence could not grow—they could not add new beds, operating rooms, emergency departments, and would not be able to add new procedures or respond appropriately to technological advances. Existing physician-owned hospitals would eventually become obsolete.

In addition, there are currently more than 100 physician hospitals under development. If proposed legislation passes, communities and patients would suffer direct

economic hardship.

As Congress attempts major changes to our health sector, improvements in care delivery and access are high on the list of priorities. It only makes sense to look at the hospitals that are providing high quality care with lower infection and readmission rates, as physician-owned hospitals do, to learn from them, not shut them down.

Question 4. How have physician-owned hospitals affected the communities they

Answer. Physician-owned hospitals provide communities with options for top-qual-

ity care and inject much-needed competition into the health care market.

A study this summer by Consumer Reports rates physician-owned hospitals as among the best in the country. The Consumer Reports study was based on responses from more than one million patients. In the report, physician-owned hospitals were ranked as the top hospital by consumers in 19 states (20 states do not have physician-owned hospitals).

Physician-owned hospitals received the top ranking, according to the report, in:

- Arkansas (the top two and four of the top seven are physician-owned);
- Arizona (four of the top five hospitals)
- California (the top two hospitals)
- Idaho (the top two and three of the top four hospitals)
- Indiana (the top two and four of the top five hospitals)
- Kansas (the top five and 10 of the top 13 hospitals)
- Louisiana (the top nine hospitals)

Clearly, we need more of the quality of care offered to patients at doctor-owned

hospitals, not fewer.

Physician-owned hospitals are improving access to health care services by sometimes "rescuing" existing hospitals that are struggling financially. Frequently, physicians are purchasing hospitals that are threatened with bankruptcy or being let go

by larger systems that don't find them profitable enough. Physicians are spending their personal money, putting themselves and their practices at risk, to make certain that hospitals are kept open and that communities continue to have local access to healthcare. Many of these hospitals are in rural or inner city areas that would not have access to care if the local physicians did not step up and take action. If the pending legislation passes, this option will no longer exist.

Large, multi-specialty hospitals have argued that physician-owned hospitals, especially those that specialize in cardiac care, are taking the less sick and most profitable patients and leaving them with more complex cases and more uncompensated care. But the Centers for Medicare and Medicaid Services (CMS) released a study in 2005 analyzing this claim. Two key facts emerged from the report: "The notion that specialty cardiac hospitals are systematically screening out more severely ill patients using the ED [emergency department] is not supported by our findings." And the notion that physicians are profiting from these referrals certainly is called into question: "The average ownership share per physician in a cardiac hospital is only 0.9 percent, based upon hospitals in our study," CMS said.

The health care system needs more competition, efficiency, and specialization, and

The health care system needs more competition, efficiency, and specialization, and specialty hospitals offer all three.

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