FEDERAL TRADE COMMISSION

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PANEL DISCUSSION:

PHARMACY BENEFIT MANAGERS

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I N D E X

P R O C E E D I N G S

DR. HYMAN: Good morning and welcome to the Joint Hearings on Health Care and Competition Law and Policy, jointly sponsored by the Federal Trade Commission and the Department of Justice.

This morning we're gong to be considering the subject of PBMs, or Pharmacy Benefit Managers. This afternoon, for those of you who are staying around, we're going to look at the subject of Prospective Guidance and how the guidance provided by the Department of Justice and the Federal Trade Commission, in all its various forms, is performing and how it compares to that provided by other entities in the federal and state systems.

But this morning, we're going to focus on drugs and how they're delivered to consumers, a matter of considerable significance -- as an economic matter, as a political matter, and as a policy matter.

And drug pricing is one of those perennials on the Washington scene. I actually was reading an article this morning that pointed out that in the mid-1950s the subject of drugs and how they were priced was extensively investigated by Congress -- the antitrust Subcommittee, which issued a report -- and there were a series of subsequent reports.

And we're hoping not to plow old ground, but to

summarize, analyze, and point to some new directions based on the Commission's particular interest in transparency, and probe the extent to which information is available about how PBMs perform and get a diverse array of perspectives on that subject.

We have a very distinguished panel, which we're quite pleased with. So distinguished that introducing them would consume most of the time that we have available this morning. So our tendency, if not our rule, is once sentence introductions of the entire panel, one at a time. And we have this handsomely appointed book outside that contains each and every one of the speakers' short biographies.

We're going to start at my right -- extreme right -- with John Richardson, who's Director of Medicare at the Health Strategies Consultancy. He focuses on pharmaceuticals, biotechnology, and medical devices. He's going to provide an overview of PBMs.

Next will be John Dicken, who's an assistant director for Health Care Issues of the General Accounting Office, specializing in health insurance and long-term care financing issues. He's going to go over a report that the General Accounting Office issued in January 2003, on the effects of using PBMs on health plans, enrollees and pharmacies in the Federal Employees

Health Benefit Program.

Immediately to my right is Jack Calfee, and one of our two frequent flyers on today's panel -- that is, he's appeared previously at the FTC DOJ sessions, and we're very glad to have him again. Jack is a resident scholar at the American Enterprise Institute, who's done lots of work on pharmaceutical-related issues, including direct to consumer advertising. He's going to talk here about the economics of the firm, and why PMBs emerged, and look at the way that they do. Is that a reasonable summary? Thank you, Jack.

Immediately to my left is Thomas Boudreau, who's Senior Vice President, General Counsel, and Corporate Secretary at Express Scripts. He is going to speak on behalf both of Express Scripts; and TCMA, the trade association of PBMs, providing that perspective.

Seated next to him is David Balto, who is a FTC alumnus, formerly the policy director of the Bureau of Competition; now a partner at White and Case; and our other frequent flyer today. He's appeared on several occasions at these hearings.

And David is going to, shall we say, provide a contrasting perspective on PBMs.

And then finally, Tony Barrueta, is Senior Counsel at the Kaiser Foundation Health Plan where he's

the primary legislative and policy analyst. Kaiser is obviously a health plan and they operate their own PBM. So we wanted to get that perspective as well.

And the basic framework here is that each of the speakers will have their allotted time. We'll take a break probably about two-thirds of the way through. And then, after everybody's made their presentations, we will have a moderated panel discussion among the panelists.

My job is to get them to discuss -- engage, but -- no fisticuffs.

And, as is always the case, these sessions are being transcribed and a transcript of the session will be posted on the FTC Web site within probably a month and a half, assuming our turn around time remains as it has. The PowerPoint slides and handouts that you'll see today will be posted much more expeditiously -- hopefully, within about a week. And the Health Care Hearings Web Site is reachable through FTC.gov.

So with all of that and no further adieu, let me just start with John.

MR. RICHARDSON: Thank you, David.

Good morning everybody. I'm going to attempt to summarize an entire industry, including a little bit about how PBMs work. It's a big task, but I'll try to move expeditiously thorough it. And hopefully, it will

be useful as well.

I'm going to cover these five areas. First, just go over the basics of what a PBM is, give you a snapshot of the PBM industry, talk a little bit about how PBMs work -- the key elements of their toolbox, and their key relationships with the other constituent parties of the health care system.

Then fourth, briefly touch on some of the current industry challenges; and then briefly summarize.

First, just a definition, a working definition, so we all kind of start from the same place. What is a PBM, or in plural, what are PBMs?

PBMs are companies that administer drug benefit programs for employers and health insurance carriers. I think it's important to remember that PBMs – about 10 or 15 years ago, many of them were what we would call third-party administrators that basically processed claims on behalf of health plans, or self-insured employers, or other entities that provided insurance. And I'll talk a little bit more about how they have changed quite a bit over the past decade or so.

And then the second part of the definition, equally important, is to give you a sense of the variety of contracts that PBMs have. They contract with everything from managed care organizations to state and

local governments acting as insurers -- such as FEHBP and the CalPERS Program in California. And their job, of course, is to provide managed prescription drug benefits.

Basically, the message is that PBMs are the sum of their contracting arrangements.

Just to give you some basic statistics about what a PBM -- or of the reach of PBMs, roughly 95 percent of all patients with drug coverage receive benefits through a PBM, but that doesn't mean that PBMs manage all the prescriptions in the United States. In fact, about 70 percent of the prescriptions are managed by PBMs; the remainder are managed by institutional pharmacies, in-patient hospitals, skilled nursing facilities.

And then the Medicaid Program also -- frequently states in their Medicaid programs will run their pharmacy benefits directly through their own fiscal intermediary. There'll be state staff who will serve the pharmacist function and -- I'll talk about this a little bit later -- this is an area where PBMs are starting to, given the cost pressures on states, talk to states about their capabilities and their services that would allow states to control their pharmacy benefit arguably better than they have in the recent past.

Pharmacy networks in -- the PBMs' contract with pharmacy networks to actually deliver the prescription

drugs -- and they typically contract about 90 percent of the pharmacies in a given area; and approximately 15 percent of the sales are through mail order.

Again, just statistics in terms of what the PBMs share of the prescription drug dollar is out of about $120 billion in prescription drug spending -- I'm sorry, they accounted for $120 billion in prescription drug spending in 2001 -- '02, about 80 percent of that total spending estimated by the Center for Medicare and Medicaid Services.

And finally, they are affecting the pharmacy benefits of about 200 million Americans. I think it's interesting -- the final statistic -- almost two-thirds of the country -- seniors -- about 76 or so percent of the Medicare beneficiaries in this country already have prescription drug benefits in some way, shape, or form -- either through Medigap, retiree health benefits, an M+C Plan, or Medicaid. And PBMs, through one of those mechanisms, actually serve about 65 percent of the country's seniors.

So just to go back to a point I made earlier on how the industry has changed over the last 10 years, yesterday's about 10 years ago, the primary business of most PBM companies was prescription drugs claims processing. There were about 150 firms. Most of them

were local and serving local and regional markets. And, in terms of the larger firms, there were of course some pharmaceutical companies that had an interest or ownership of the largest national firms. Eli Lilly, for example, owned PCS; and Merck and Medco is another example of that.

Today, the service offerings from the PBMs is much more extensive, much more clinical pharmacy management, and they've diversified into some other lines of business that weren't considered 10 years ago as something that they would think of as valuable business models -- specifically, disease management and more involvement in the delivery of specialty pharmacy.

Today there are about 60 firms -- 4 large publicly traded firms that I'm sure everyone in the audience is familiar with. But also it's important to remember, dozens of smaller PBMs -- and I'll talk a little bit more about how the market share is divided up amongst the large publicly traded firms and the smaller firms in a minute.

And in contrast to 10 years ago, most of the phenomenon of pharmaceutical company interest -- or ownership of the large firms anyway -- has changed with one notable exception which I'll talk about in a second.

So there are basically three different ways to

look at PBM market share. None of them are perfect, but I wanted to show all three to you because I think they all three give you a sense of how the market is divided. It really depends on the emphasis you want. And like any good policy analyst, if you were trying to make a certain point, you would pick one of the three and ignore the other two. But I'm going to show you all three just so you'll sort of have a broader picture of what the market share looks like.

If you look at it in terms of total drug expenditures that were at least controlled by PBMs -- remember I said a minute ago only 80 percent or so of total drug spending is touched by a PBM -- so this would be the diving up of that 80 percent.

Obviously, the 4 large, publicly traded firms -- Merck, Medco, Advance PCS, Express Scripts, and Care Mark -- are making up about two-thirds in total; but other PBMs -- and the reason it's estimated there -- my source document had a total expenditure and they do a survey of PBMs and they got information from the four major ones, plus National Prescription Administrators which has since been purchased by Care Mark -- and so they backed into the 35 percent figure.

But the four large ones there again are represented by two-thirds, the other PBMs a third.

If you look at prescriptions per year, the breakdown is similar, although there are two that appear on this list that didn't appear on the first one. First Health Services and Walgreen's Health Initiatives. And I suspect that Walgreens has gotten onto the list because they do a lot of mail order business and, with -- it's -- something as simple as an accounting issue, mail order prescriptions typically are for 90 days as opposed to 30 days for retail prescriptions. So each one of those counts three times.

If you don't -- again, you have to be careful when you're doing this kind of analysis, or looking at these kinds of figures, to make sure that you're comparing apples to apples. This one is a little bit distorted relative to the expenditures.

And then there's the covered lives. This one has its own unique -- I should say shortcomings, but things to bear in mind as you're looking at it. Again, you can see the 4 large, publicly traded PBMs there.

WellPoint Pharmacy Management shows up because WellPoint, of course, is the former Blue Cross of California, and there are now Blue Cross plans all across the country. They have their own PBM and have a lot of covered lives; but what I found interesting in looking at this statistic is that the AIS document found, from their

surveys, that PBMs have a total of 460 million covered lives, which, of course, is about 50 - 60 percent more than the U.S. population.

So, once again, how the PBMs count their lives -- people are counted multiple times. That's why I think it's useful to, when you're doing an analysis -- what is market share -- you really have to look at all three.

But one thing that's common -- obviously, the 4 large, publicly traded PBMs keep showing up as major players here, but there's also a large chunk -- anywhere from a third to almost a half in this one -- where the local and regional PBMs dominate, or provide a lot of the services.

And then just to get another cut to emphasize that point about covered lives, this is from a Wall Street analyst's report that divides the PBM industry into three big buckets. Again, the over $20 million group, you can see some very familiar names there. And then there's sort of a middle group and a smaller group that is primarily regional companies.

So just to touch very briefly on the publicly traded firms for a second, the view from Wall Street is that this is a favorable industry. It appears to have 20 percent plus revenue growth. It's not terribly capital-

intensive, at least for the firms that are publicly traded at this point. They've made the initial investments in their IT systems and other physical plant.

The untapped market opportunities -- one we're painfully familiar with -- and one I've been working on quite a lot for the last month of course is the Medicare prescription drug legislation moving through the Congress. There's clearly a role that PBMs will play in the delivery of that benefit to Medicare beneficiaries.

And, as I mentioned earlier, some states that had previously been comfortable relying on their fiscal intermediaries and state pharmacy staff to manage their prescription drug benefits are now starting to reconsider and think that perhaps a professional PBM could be useful to them as they try to get ahold of their Medicaid cost growth.

And there's also some specific growth areas that Wall Street analysts look at in terms of mail order, specialty pharmacy, and how PBMs can use their data integrated with medical data to help health plans and plan sponsors manage their medical costs.

And this just kind of summarizes what's been going on with the share prices of the firms. I apologize for the -- little bit hard to read there. I'll work on my contrasts next time.

You can see that Care Mark, Advance PCS, and Express Scripts have all done very, very well since about April of 2001 -- in October.

I think this is relative -- just to give you a frame of reference -- to the S&P 500 Index. And then also you'll notice Merck-Medco there has been -- its share price has been quite a bit lower. This is a cumulative percent change since the graph started. Quite a bit lower than the other three. I should take pains to point out that that is actually the share price, of course, for Merck-Medco Corporation, as a pharmaceutical company and the PBM part, which is Medco.

If you'll look at Merck-Medco's annual report for last year, at any rate, the revenue growth for just the Medco unit is much more consistent with the revenue projections -- or the revenue growth, I should say, for Care Mark, Advance PCS, and Express Scripts. It's unfortunate I wasn't able to do any kind of extraction of just Medco from the Merck-Medco entity, but if I was able to, I think it would look a lot more in terms -- of just the PBM share price, if that was being valued there -- would look a lot more like the other three.

And the point is that, at least from the point of view of Wall Street, these are very profitable and highly valued firms.

Now I just want to talk a little bit about some of the tools that PBMs use. There are really three levers that PBMs operate on to manage pharmacy benefits on behalf of the companies they contract with to do that. That's price, utilization, drug mix, and some combination of the three. And I'm going to touch on the basic -- the larger points on each of those.

But I think that one thing that we're all very interested in hearing about today is the formulary and how that exactly works. And the formulary is a good tool to talk about because it integrates the function of a PBM across all three areas -- price, utilization, and drug mix.

And a formulary works in those three areas basically by adjusting -- or working with manufacturer rebates in terms of price, a tiered co-payment structure, to affect utilization, and generic substitution to affect the mix of drugs actually delivered.

Just real quickly -- I'm not going to spend much time on this one -- there are different kinds of formularies. There's not just one basic formulary. It depends on the contracts that the PBM has with the plan sponsor or the health plan. And you can have varying ranges of how restrictive, or unrestrictive they are. The most restrictive are at the top of this chart and the

least restrictive at the bottom. And I'm sure we'll be talking more about those types of things later.

Just to talk about price for a second, manufacturer rebates is obviously something that lots of people are interested in how they work and it, in some ways, is quite straight forward. Manufacturers pay rebates to purchasers that successfully increase the market share for their products.

The rebate amounts are negotiated ahead of time into the purchasing contract between the PBM and the entity with which they do that -- again, whether that's a plan sponsor -- it's always important to bear in mind that these contracts are going to vary depending on the entity that the PBM is working for when the stated goals of the contract are met and then the rebates are paid.

The calculations are obviously very complex and, again, they depend on a wide variety of contractual arrangements between the PBM, the plan sponsors, and the manufacturers. If you're evaluating a rebate arrangement, there are three fundamental questions, we think, to look at. First, which party owns the rebates? It could be the plan sponsor, it could be the PBM, it could be the managed care organization, it could be the retail pharmacy providers. And in some cases where physician groups are capitated, or partially at risk for

pharmacy benefits, it could be the physician group.

Each contract is going to look a little bit different. There's an old saying, "If you've seen one contract for rebates, you've seen one contract."

What are the audit rights under the contract for each party is another key element. And then the third is what fraction of the rebates does the PBM retain as part of its administrative fee? A lot of PBMs don't retain any of the rebates; others retain a portion in addition to whatever percent of the revenue they will keep as their administrative fees.

So again, that's going to differ in each arrangement that is out there.

In general -- a general rule, if I can give you something general to latch onto -- is that purchasers able to more closely manage the pharmacy benefit are likely to receive greater rebates than those who do not. I think that's kind of a truism.

And then the third point here -- I'm sorry, fourth point -- is that the rebates are back end in that the settlement of those does not take place until about 6 to 12 months after the actual dates of service have ended. And I think that that's an important thing to remember. These are not real time. They depend on a lot of data being reported back and forth; and again, it goes

back to the arrangement that was negotiated before the benefit period even started.

So that's the price.

And then the utilization effect -- how PBMs approach that is through a tiered co-payment structure. I was debating with myself whether to put a four tier co-pay up here because they are so rare, but I think that it's interesting to at least talk about them. But most PBMs use a three-tier co-pay. I'm sure that most of us are familiar with those from our own health insurance plan. It's the basic tiers where you have generic drugs, and brand name drugs with no generic equivalent, brand name drugs that have a generic equivalent, or therapeutical equivalent.

Obviously, the co-payments there are designed to create an incentive for the consumer to prefer the lowest cost alternative that still is clinically effective.

The fourth tier -- I am loathe to talk about it, but it's out there. I think some PBMs are offering this to customers. A lot of customers are not actually interested in this yet, but I also thought it was interesting that in the fourth tier you have the very newest types of drugs -- gene therapy and injectable biologics -- being combined with things like lifestyle

drugs -- hair loss, weight loss, nail fungus, all that kind of good stuff.

And it is something that could be more and more prevalent over the next couple of years as those types of drugs become more and more popular.

Another way that PBMs can drive utilization in certain ways is with mail order. And again, I think it's important to remember the role that this plays and doesn't play. It's generally used for patients with chronic conditions who need maintenance medication.

As I mentioned earlier when I was talking about the counting issue, there are typically 90-day supplies; and this is where PBMs clearly can use the tools for therapeutic and generic substitution. In 2001 -- just to give you an idea of how prevalent this is -- large employer groups were offering mail order services to 87 percent of them and the Health and Human Services report to the President a couple of years ago estimated that the rebates that PBMs could drive through mail order was on the order of 2 to 25 percent.

One last item of the toolbox here is generic substitution and therapeutic interchange. And I think that there'll be a lot of discussion about this from other panelists in terms of how this is used. But I just wanted to lay out the definition so we all kind of had a

common understanding of what we're talking about.

Generic substitution is a clear one where we're talking about a generic substitute for a brand name drug which is exactly chemically the same. Therapeutic interchange is arguably a little more controversial, but still used by PBMs in a clinically driven manner by pharmacists where there are therapeutic equivalents for different types of drugs.

One example would be for Cox II drugs that are used to treat arthritis or other pain, such as Viox and Celebrex, versus the older, but in many cases equally clinically effective, non-steroidal, anti-inflammatory drugs -- that that's an example of therapeutic interchange.

And then finally, just a couple of -- the PBM value-added services -- because pharmacy claims are so heavily -- in fact, almost exclusively -- done electronically now, the -- at the point of service, the point of sale at the pharmacy -- PBMs have programs that allow the pharmacist to check for other drugs that the patient may be on. Of course, this presumes that the patient is getting all of their drugs through the same PBM. But they are able to check for drug interactions, the dosage utilization, other factors; and the pharmacist is able to take that into consideration as they counsel

the patient at the desk, or at the counter, I should say.

And then some PBMs -- particularly the larger ones -- also offer their clients pharmacy case management services where because the claims data is so rich -- especially relative to hospital and physician claims -- and having worked at a Medicare mass care organization for the past six years before I came here, I can say with great confidence that if it weren't for the prescription drug data -- at least in the case of the health plan I worked for -- we'd have no idea what was going on. This was in California and most of the medical services were capitated; and I think it's not talking out of school to say that the ability of a fully capitated model to get counter data from its medical and hospital providers is -- the polite word is challenging.

So with pharmacy benefits though, and in this plan's case were fully at risk for pharmacy benefits and paid for it through a third-party administrator, we were able to -- Caloptima -- that is, the plan was able to identify patients where were taking too many prescriptions per month, were able to identify people who had co-morbidity, who were at risk for nursing home institutionalization.

I don't want to oversell that, but there is a lot you can do with just the prescription drug data. And

it's very accurate and it's also very current; and that makes it a very valuable tool for health plans and for PBMs to use if the health plan chooses to contract with the PBM for that.

Very briefly, talk about some of the relationships in which these tools are used. The PBM one could think of as being at the center of these relationships between a manufacturer and the PBM -- PBM retail pharmacy, and the PBM and the plan's sponsor, and -- in some cases -- with the health plan as well, if that's the direction the plan's sponsor has chosen to go.

Again, the PBMs are contractually responsible for assuring quality, safety, and cost containment. The contracting for this activity is very, very competitive and, as I hope I indicated with the market share discussion earlier, there are these 4 large, publicly traded PBMs -- but health care is a local and a regional service and the competition in those local and regional markets is very, very competitive among all the PBMs.

They generally do no assume insurance risk -- PBMs, that is -- but do assume performance risk. Again, trying to meet certain performance targets. It's all the things from service times, call waiting times, to those types of metrics. They can be paid through administrative fees, share of rebates, or some

combination and then there are firms like Mercer, which also helps the health plan or plan sponsors evaluate the performance of PBMs, in addition to their performance under the contracts -- whatever performance metrics those may have been.

Now the pharmacy-PBM relationship is one that is interesting, I think, is one word you could use for it. Obviously, PBMs contract with retail pharmacies to create a pharmacy network. And I wanted to be very candid about some of the reasons that there's some tension between the pharmacies and PBMs.

First of all, the PBMs' quality, safety, and cost containment programs do require additional administrative tasks by pharmacies; and this can be -- if it's not perceived as being something that's adequately compensated for, or something that the pharmacies are resistant to -- and also pharmacies can often obtain higher compensation from non-PBM customers. And, just very candidly, I think that's where some of the political tensions between the two industries have come from.

And I talked quite a bit about rebates -- and that's the main manufacturer-PBM relationship. I did just want to touch on this one more time -- particularly looking at the final bullet on this slide, which -- I just want to make sure everybody's aware and I expect

that we'll be talking about this as well later -- that the Department of Health and Human Services' Office of the Inspector General, in April of 2003, issued some guidance to the relationships between PBMs and manufacturers in terms of their participation in Medicare and Medicaid, which likely will drive a lot of the organizing principles for the industry across all their lines of business.

And then, let's see. Just talk a little bit about the role of PBMs in the pharmacy decision-making process. I think there's potentially some confusion about this. The prescription decision-making process is still driven by the physician and patient within parameters set by the PBMs. The formularies can be structured differently. And, as I indicated with the slide that showed that formularies can differ quite a bit in how restrictive or open they are, many types of formularies allow access for non-preferred prescription drugs through the prior authorization process, or higher tiered co-payments.

And lest we forget, there are lots of other influences on the physician's prescribing patterns from manufacturers and pharmacists as well.

So just to sum up here with some industry challenges. I think, especially in contrast to the slide

I showed you earlier where three of the four publicly traded PBMs are so highly valued by Wall Street analysts this time -- looking a little bit about the challenges that the industry faces, bearing in mind that that outlook isn't exactly all roses.

First of all, there's erosion of pricing power in the negotiations with employers and health plans who re demanding more and more accountability for PBMs with less willingness to pay.

There is increasing difficulty in differentiating the service offerings between PBMs. And this goes to the competition issue I talked about earlier. Purchasers are not seeing much difference between PBMs and so they're not hesitant to switch if somebody can offer them a perceived lower price.

There have been some merger and acquisition activity in the last couple of years that has certainly petered out in the last year. A lot of that had to do with the business line diversification I talked about where PBMs were going into other lines of business like disease management and specialty pharmacy, but that seems to have more or less played itself out.

And, of course, enrollment growth is flattening out because of the market saturation as the actually number of uninsured continues to grow a little bit. The

ability of PBMs to go into new markets is basically constrained unless they can figure out a way to get into the government markets -- Medicare and Medicaid.

There are also some other business models out there which refer to with shorthand as the provider synergies business model which peels off some of the functions of a PBM and offers them to health plans and plan purchasers that are willing to do their own claims processing but need the clinical expertise to develop a formulary, for example. And of course there are several potential legal, political, and resulting PR threats out there.

I'll skip the summary. You just heard the presentation, so I don't need to summarize it.

And if you have any questions for me later, I'll be up there. Thank you.

[Applause.]

DR. HYMAN: Next is John Dicken from the General Accounting Office.

MR. DICKEN: I appreciate the opportunity to participate in this morning's panel discussion on pharmacy benefit managers.

I think John Richardson provided a nice overview of the PBM industry and some of the tools that PBMs use; and so my comments will focus on the actual

application of PBMs within the context of the Federal Employee Health Benefits Program, or FEHBP.

As David mentioned, this is based on work that the General Accounting Office issued in January of this year, looking specifically at the effects of using pharmacy benefit managers on FEHBP plans, enrollees, and pharmacies.

FEHBP is the nation's largest employer-sponsored health benefits program covering more than 8 million federal employees, retirees, and their dependents and gives a choice of about 13 national plans -- mostly PPOs -- and about 180 local plans -- predominantly HMOs.

We did our work at the request of Sen. Dorgan from North Dakota, who in part asked us to update a prior 1997 report that had looked at the cost savings that PBMs achieved for several FEHBP plans.

The Congressional interest in PBMs, as you well know, goes beyond FEHBP. It includes issues that PBMs are, as David mentioned, administrating the pharmacy benefits for most employer-sponsored health plans; and that as we speak Congress is considering a Medicare drug proposal and considering the roles that PBMs could play, or other private entities could play in administering that Medicare drug benefit.

Some have turned to FEHBP as drawing lessons

for how that could work within a Medicare context, but the FEHBP link also was key for the General Accounting Office for people to have access and a unique ability to look at what would otherwise be proprietary information.

As Congress' audit, evaluation, and oversight agency, we're able to track the federal dollar; and so by looking at the federal program, we were able to review contracts, financial statements, and pricing information that would not otherwise be available.

I do have to note though that GAO's ability to shine a flashlight on PBM operations was specific to the FEHBP contracts. It didn't entail the entire book of business that PBMs would have. And we respected the proprietary information that PBMs would have on their overall book of business.

Just very quickly, our study had four key objectives. First was to examine to what extent PBMs achieve savings for health plans. Secondly, how PBMs use affects FEHBP enrollees. Third, the effect on pharmacies. And fourth, how the PBMs were compensated for the services that they're providing to FEHBP plans.

Again, John gave an overview of the tools that PBMs use, so I won't dwell on this, but just note that the types of services that the PBMs are providing to the FEHBP plans include administrative claims processing.

They negotiate price discounts on behalf of the plans with the retain pharmacies. They also negotiate with manufacturers for rebates and discounts. Some operated mail order pharmacies; and they conducted a variety of clinical intervention programs, including drug utilization reviews, prior authorization programs, therapeutic interchange, and generic substitution.

Looking at the Federal Employees Health Benefit Program, we look particular at three large FEHBP plans. The first was the largest FEHBP, Blue Cross and Blue Shield's Federal Employees Program, which has more than 4 million enrollees and nearly half of the total FEHBP enrollment.

One interesting feature about Blue Cross is contracts with PBMs -- they actually had two PBMs. They contracted with Advance PCS for retail services and then with Medco Health Solutions for their mail order services.

We also looked at one of the other large national FEHBP plans. The Government Employees Hospital Association, which is a unique plan within FEHBP -- and they also contracted with Medco Health Solutions.

And then third, we looked at an HMO, Pacific Care of California, who contracted with Prescription Solutions, which is actually a sister corporation as

they're both subsidiaries of Pacific Care Health Systems.

Combined, these three plans covered over half of the 8.3 million FEHBP lives. They paid $3.3 billion to the PBMs in 2001 for their prescription drug costs and dispensed over 65 million prescriptions.

Turning first to the effect that PBMs had on cost savings. As many of you may know, the pricing for prescription drugs in contracts with PBMs is often based on what's known as the average wholesale price, or AWP. However, GAO, and another of other analysts, have expressed concerns about the average wholesale price because despite it's name, it's non-average of any actual transaction and it's not a wholesale price. It's really a retail sticker price.

So in lieu of looking at the AWP, we conducted a survey of 36 pharmacies in California and North Dakota and Washington, D.C., area to get the actual cost of an individual walking into that pharmacy and paying full price for the drugs without any insurance coverage.

Looking about 18 commonly used drugs, we found that a cash-paying customer would pay about $88 for 14 brand name drugs. The FEHBP plans, through PBMs, would negotiate discounts at the retail pharmacies that were about 18 percent below that full cash-paying customer price.

And then if it went through the mail order pharmacies for the same drugs, the discounts were even deeper at about 27 percent. Generic drugs are obviously much less expensive and the discounts were deeper, with discounts from the cash-paying customer price at retail of about 47 percent for the FEHBP PBMs, and about 53 percent for the mail order generic drugs.

Discounts are only a part of the pricing story for the PBMs. As John mentioned, they're also negotiating rebates with drug manufacturers based on their ability to include drugs on formularies and to increase that manufacturer's market share.

Looking at a four-year period for the three plans we reviewed, we found that the rebates that the PBMs collected and then passed through to the FEHBP plans effectively reduced the plan's spending by 3 to 9 percent.

The other area where PBMs attempt to achieve cost savings is through a variety of utilization controls -- things like drug utilization reviews and prior authorization programs. Here I have to acknowledge that estimating savings was more difficult, that the PBMs did not maintain consistent systems to be able to evaluate the cost savings of these; but we did work with the PBMs in being able to provide data that would give

some sense of the extent of savings from these program.

For example, one PBM cumulatively reported that these intervention programs saved about 14 percent of total drug spending. The largest source of those savings were predominantly from drug utilization review programs where two plans estimated savings of 6 to 9 percent. That was primarily from individuals going into pharmacies -- perhaps they were refilling their drug too soon, or there was a duplicate drug therapy; and the PBM would send to the pharmacy edits saying not to dispense that particular drug.

In addition, programs for prior authorization saved 1 to 6 percent primarily for a few fairly expensive drugs where the PBMs would require the enrollee, or the pharmacy, to contact the PBM before it could be dispensed.

Therapeutic interchange where there were exchanges between brand drugs that were therapeutic equivalents -- the PBMs report savings of 1 to 4 and 1/2 percent.

And then for generic substitution, one plan reports fairly small savings of less than 1 percent. I need to define the generic substitution here was fairly narrow. This was only in those cases where the PBM actually contacted the physician and changed prescription

that was to be dispensed as written to allow for generic to be dispensed.

But looking more broadly at the use of generic drugs by the PBMs we found that the use of generics was higher, notably higher, at the retail pharmacies than at the mail order pharmacies. About 45 percent of the drugs that were dispensed for our three plans at retail were generics, compared to 34 percent through the mail order pharmacies.

It's important to note though that the mix of drugs that are dispensed through mail order will be different. They tend to be more maintenance drugs for longer term use. And so if you look at only where generics were available, the difference between retail and mail order was much narrower -- 89 percent versus 87 percent.

Let me turn now to look at the effect of the PBMs on FEHBP enrollees. We looked at three areas. First was enrollees' access to retail pharmacies; secondly, their access to formulary drugs; and then third was the out-of-pocket cost sharing that enrollees paid.

The plans that we looked at required the PBMs to maintain fairly broad pharmacy networks so that nearly all enrollees would have access to a pharmacy within a few miles of their residence. As a result, and I think

this is consistent with what John indicated for other PBMs, the PBMs we looked at had more than 90 percent, nearly 100 percent, of licensed pharmacies participating in their networks for the three plans we reviewed.

In addition, the three plans maintain fairly broad drug formularies. In order to compare the drug formularies, we compared the FEHBP formularies to the Department of Veteran Affairs national formulary. The Institute of Medicine has determined that the VA national formulary is generally non-restrictive and so provided us with a steady bench mark to compare the FEHBP formularies.

In making that comparison, we found that over 90 percent of the drugs that were on the FEHBP formularies were either also on the VA formulary or had a therapeutic equivalent in the minority of cases.

The FEHBP plan formularies also covered nearly all of the therapeutic classes covered by the VA national formulary, with a few exceptions typically being areas where the FEHBP plan did not cover those services.

And then even if a drug was not covered on the formulary, each of the plans provided coverage for non-formulary drugs either through higher cost sharing requirements for the enrollee, or sometimes through a prior authorization process.

As far as whether the savings that PBMs achieve for the plans were passed on to enrollees, it depended on the plan's benefit design. In general, the plans designed their benefits so that if enrollees went to mail order pharmacies they would have lower cost sharing than if they went to the retail pharmacies.

Whether or not the enrollee benefitted from the discounts that the PBMs were negotiating depended again on the benefit design. For example, Blue Cross/Blue Shield would offer 25 percent co-insurance rate so that if there was a deeper discount the enrollee would get to share in some of that discount; whereas the other plans would have flat $15 or $30 co-payments, so that now the discount was irrelevant to the enrollee's cost sharing.

The rebates are, of course, paid directly to the plan, so don't reduce the enrollee's cost when they go to a pharmacy; but they are indirectly given back to enrollees in terms of reduced premiums. Because the FEHBP plan's premiums, at least for the PPOs, are based on their prior claims experience, the rebate payments to the plans would then translate, we estimate, to about 1 percent reduction in the future year premiums.

Pharmacies have raised a number of concerns, as John mentioned, about working with PBMs, and we examined some of these concerns as well. One of the concerns

deals with the discount payments that PBMs are paying to retail pharmacies. We examined how those FEHBP plan payments compared to the actual costs that pharmacies would incur for acquiring drugs. We found that there is not good existing data on what those actual acquisition costs are, so, after talking with various pharmacy associations and experts, came up with a proxy of the wholesale acquisition costs plus a 3 percent mark up.

In looking at that difference, then found that the FEHBP payments to the pharmacies are about 8 percent above what the wholesale acquisition costs plus 3 percent would be. It's important to note that these are gross margins. They do not include the rebates or discounts that pharmacies may be able to get to lower their acquisition costs, nor the overhead costs that the pharmacies must build into that margin.

Pharmacies have some concern about the administrative burden with working with PBMs; and some surveys have shown that pharmacies do spend 20 percent of their staff time dealing with third-party payment activities. This may be of particular concern to independent pharmacies where they may have fewer non-pharmacist staff available to perform these third-party payment activities.

Pharmacies were also concerned that they

believe that PBMs may steer, in some cases, their customers to mail order. Some of the PBMs we looked at do send mailings to their enrollees indicating that they could save money if they got their drugs through mail order instead of through the retail pharmacy.

And it's interesting to note that the three FEHBP plans that we reviewed do have a somewhat higher use of prescription drugs through mail order than the industry average -- about 21 percent compared to -- our data is showing 5 percent. I think John showed a little bit higher, about 15 percent.

But despite these concerns, still most retail pharmacies, as I noted, do participate in the PBMs networks; and it's really because of the large market share the PBMs are bringing. It's really something that pharmacies are not able to not participate when an estimated 200 million Americans are receiving their coverage through the PBMs. And they rely on these enrollees for access to their sales for prescription and non-prescription products.

Finally, we looked at the way that the PBMs were compensated for the services that they provide to the FEHBP plans. This diagram is showing the three broad ways that PBMs could receive compensation for their services, both through health plans, as well as through

drug manufacturers.

The thicker shaded lines represent the major revenue sources. For example, health plans can pay administrative fees directly to the PBMs for their services or, in addition rather, health plans will make payments for the retail mail order drugs.

Much of this is, of course, passed through to the retail pharmacy, or to the pharmaceutical manufacturer for mail order drugs, but some of it could be retained by the PBMs.

And then finally, through payments from pharmaceutical manufacturers, both in the forms of rebates and payments for other education or clinical services made to the PBMs. Again, some portion of this, or most of it, may be passed on to the health plan, but the PBM may also retain a portion of this.

Looking specifically at the three plans we reviewed and how they received compensation from each of these sources, administrative fees, on average, represent about 1½ percent of the total plan drug spending as far as what the PBMs receive from the health plans and administrative fees.

As far as the payment for retail drugs, we found that in the FEHBP plan cases that nearly all to all of that was passed through. It was a straight pass

through from the plan to the PBM, and then the PBM to the retail pharmacies. Now the PBMs did acknowledge that that may be different for other clients. For the FEHBP clients, this was a straight pass through, but for other clients there may be some revenues that are retained there.

As far as the mail order drugs, there was compensation that the PBMs retained, that the full costs were not sent on to manufacturers; however, this was one of the areas where the costs of the drugs, the mail order to the PBMs, was based on the entire book of business and so we were notable to quantify exactly what the compensation was due to the mail order retained portion.

The other major area is rebates and we broke this into two areas. First are those rebates that are directly attributable to the FEHBP plans and part of the contractual arrangements between the FEHBP plan and the PBM. As John mentioned, some of those contracts -- not all, but some -- would have the PBMs retaining some portion of those rebates to cover their administrative services.

On average, for the three plans we looked at, that represented less than 1/2 of 1 percent of total drug spending. However, the PBMs receive other rebates and manufacturer payments based on their entire book of

business of which FEHBP is just a small part.

While again this was broader than we were able to look at, looking specifically just at the FEHBP contracts, PBM officials and filings with the Securities and Exchange Commission indicate that these manufacturer payments are a large part of PBM earnings.

In conclusion, I just want to highlight some of the trade offs that FEHBP plans and PBMs face. We continue to be in a period of double digit premium increases and prescription drugs are still one of the cost drivers behind those premium increases.

The FEHBP plans may have some advantages over smaller plans in that these are very large plans, the largest employers sponsored program, and so that may allow them to generate more leverage as far as discounts and rebates. However, I know that they also maintain fairly broad formularies and plan networks and that may reduce their leverage with drug manufacturers and retail pharmacies.

So as there continues to be tension in trying to further control costs in FEHBP and other programs, the plans and programs could consider using more restrictive formularies which would allow them to get higher rebates from drug manufacturers; but enrollees would be less likely to have unrestricted access to all drugs.

Furthermore, they could consider having tighter networks with retail pharmacies. Again, that may leverage their ability to get higher discounts from the pharmacies, but those more selective networks would again pose more restrictions for enrollees and availability of local pharmacies.

As a matter of fact, Blue Cross has recently offered basic option -- has chosen to offer a more restrictive pharmacy network so that this tension is bearing out in the FEHBP program as we speak.

The reaction to the GAO report has been decidedly mixed. PBMs have touted the report as demonstrating savings from PBMs activities, where pharmacy associations raise some strong concerns that the report, they believe, did not fully address some of the relationships between PBMs and drug manufacturers, and whether that creates incentives for PBMs to promote higher cost drugs.

What we think is a very positive outcome from our report is an announcement earlier this year by the Office of Personnel Management, which administers the FEHBP Program, that it intends to have increased oversight of FEHBPs' PBMs. They've indicated that in 2004 contract year they intend -- expect the plans to make sure that they are achieving what they consider is

maximum savings from their PBMs, that they're going to require that the plans have processes for annual plan audits, and they're going to enhance their own ability through their internal Office of Inspector General to conduct oversight.

So, as I indicated, there'll be continued interest and oversight of the FEHBP plans as we continue to be in a period where there's a lot of focus on the PBMs and higher drug costs.

I appreciate the opportunity to present the findings from our report and look forward to the representations of the other panelists.

[Applause.]

DR. HYMAN: Next, Jack Calfee, who's going to go low tech.

MR. CALFEE: I don't have a PowerPoint. There was a bit of confusion about my appearance today and so it was only rather recently that I learned that I would be speaking today. But I have at least a little bit to say.

I'm going to talk more generally about PBMs in general in the larger phenomenon of what one might call intermediaries or middlemen.

As far as I can tell, all large markets -- and, in fact, lots of small markets -- spontaneously generate

middlemen, intermediaries, whatever one might call them. I will refer to them as middlemen, even though that's often a term of opprobrium. And the generation of these organization is simply a part of the search for efficiency in markets.

Ronald Coase wrote a rather provocative article about the role of middlemen, more or less, back in the 1930s, and that short article was a major reason why he received the Nobel Prize in economics some 40 or 50 years later. And essentially, he just pointed out that in many situations a completely vertically integrated firm is far less efficient than a situation in which you have products passing through a series of firms, some of those firms being, roughly speaking, middlemen.

Traditionally, the middlemen have been attacked, often vilified. And basically the suspicion is that middlemen don't add very much value to the product that's being sold, that essentially they just interpose, or cause the reaction of a wedge between the price of production and the price that the consumers actually pay for the product.

And I think that this suspicion -- in some cases almost a vilification -- is natural and will always occur; and a major reason it will always occur is because the operations of middlemen are always obscured. They're

always conducted with a considerable amount of secrecy and I'll say a little bit more about that later on.

But the criticism is always there and the criticism wasn't always from the ultimate consumers, but it's often from the producers. And a classic example is farmers who often resent the fact that what they are paid for a tomato is a lot less than what you and I pay for a tomato when we go to the Safeway, and they resent the idea that someone is taking so much of the money along the way.

So it's not surprise that PBMs are often under attack. And I would add that it's no surprise that managed care, which in some respects operates as an intermediary -- managed care organizations -- are under even more attack than PBMs.

There are certain kinds of functions or roles that middlemen perform in general in markets. As far as I can tell, they always perform an important role in logistics -- that is just moving your product where it is supposed to go. There's always a great deal of price bargaining.

There is this thing referred to as the wholesale price, which has been subject to about as much myth-making as anything in economics, largely because relatively little is known by the general public as to

what a particular wholesale price -- and even what the price is conceptually.

Middlemen often perform another service, which is to provide either advice -- or one might say even more than advice -- on product selection because small neighborhood stores, rather than trying to figure out exactly which brand they will carry in every product category will rely strongly upon the middlemen or, in this case, the wholesalers, to make those decisions, or at least provide compelling advice.

And then all middlemen do special things which the content of which depends upon the nature of that particular market, the state of technology, the maturity of the market, et cetera. And a lot of these specialized services are strongly dependent upon the kinds of information that middlemen are able to obtain, which often they can obtain more efficiently and more completely than can any other operators within the market.

Which brings me to PBMs, but I won't say much about what PBMs actually do for the simple reason that the previous two speakers have told you much more than I will ever know about the role of PBMs.

There are a few things that I think are worth discussing in particular. One of them is the question of

whether or not middlemen in general, and PBMs in particular, are a source of what one might call market failure -- that is endemic inefficiencies in a market. When one thinks about middlemen in general and the question of market failure, I think the starting point is to remember that middlemen are created by the market and they're created spontaneously.

Again in the search for efficiency, I think that as a general rule there should be a presumption that middlemen are serving a purpose and that not only is there a reason for their being there, but it's almost certainly true that the market works more efficiently and that ultimately prices are lower rather than higher because of the presence of middlemen.

And the implication is that the market which creates these organization also enforces considerable discipline over these organizations -- in other words, it's a competitive market and competitive markets discipline all the actors within those markets, including middlemen.

Here a natural question is whether PBMs are somehow special, somehow an exception to how middlemen work. In general, I think that on the whole there's not a lot of reason to worry about that. Let me mention three potential sources of market failure that might

apply to PBMs and their role as middlemen. One of them is the prevalence of third party payments -- that is the people who receive the product are not really paying for it directly, which of course is a source of many problems in health care markets generally.

In the case of PBMs and middlemen, in a sense that is their natural role. The middlemen, almost by definition, are being paid by someone other than the ultimate consumer of their product. Wholesalers are not paid by consumers, they're paid by retailers, et cetera.

So that the mere fact of third-party payments, I think, is probably irrelevant to the question of whether PBMs are a source of market failure.

Another natural question is entry restrictions -- the potential for monopoly. As far as I can tell, the PBM market is pretty much wide open. There are very little in the way of entry restrictions. We heard from one of the earlier speakers that there are roughly 60 PBMs in the markets. There are three that are quite large; none of them have anything approaching a dominant market share. In fact, if you have 10 or 15 percent of the market, you are a big player in this particular market.

And there are competing organizations in the form of large in-house PBMs, such as the one operated by

Kaiser, or what I gather are quasi or partial PBMs operated by such formidable organizations as WalMart and WellPoint.

And then our third potential source of market failure might be -- if not an absence, but a relatively small amount of public scrutiny of these organizations, which again is a by-product of the fact that much of what they do is necessarily going to be conducted more or less in secret.

Here I would emphasize that if you look at middlemen in general, PBMs are probably -- probably operate less anonymously than middlemen do in most other markets. There aren't many middlemen or intermediary institutions which are the subject of as much in the way of hearings; GAO reports; medical journal articles in JAMA, Health Affairs, and elsewhere; as are PBMs.

And I noted that, in fact, walking into this room, there were more than one publicly available articles about how PBMs work, including a much-noted, long and critical New York Times story which came out a month or so ago about PBMs, and especially about pricing.

I think that from the standpoint of public scrutiny, that PBMs again are probably more open to public scrutiny than is generally the case with wholesalers and intermediaries and middlemen.

I think we have to look ultimately here at how the market judges the operation of PBMs. We have to look at the basic market test and I think one of those market tests is "What happens, what changes when there are revelations about how PBMs actually work?"

And we've had some events that are more or less in the form of the disclosure of considerable amounts of information that was previously not too well known. I mentioned the New York Times story. Another notable example would be the numerous stories on Merck-Medco and its operations; and now a considerable amount of litigation is bringing quite a bit of information into the public arena.

And a natural question when those kinds of things occur is how does the market adjust? Do clients drop these organizations, especially in Merck-Medco? Do they by-pass them, do they get out of the business of using PBMs, et cetera? And if they don't do that, and they haven't as far as I can tell, that's suggests that the revelations really have not significantly changed the market's assessment of how these organizations have been working. It has not caused the market to adjust its expectations that they are getting genuine efficiencies out of PBMs as the market generally does with the middleman in general.

Let me say a little bit about one final topic, which is the matter of transparency. In general, markets do generate a fair amount of transparency on their own. Buyers and sellers often demand information from each other. In the case of PBMs, sometimes this information disclosure extends beyond buyers and sellers to consumers and other interested parties. And this is partly because PBMs find themselves in the position where they have to maintain a reasonable level of confidence -- not only from their direct clients, but from their indirect clients, including the physician community who PBMs have discovered need to have a decent amount of respect for the basic medical judgment of what the -- involved in what the PBMs do.

An example of how the PBMs cater to these demands is the tendency, as far as I can tell, a strong tendency towards highly independent formulary boards. Nonetheless, there is considerable murkiness in the PBMs market just as there is in all middlemen markets; and this is just the way all middlemen markets work, as far as I can tell, and the secrecy would tend to apply to pricing; to how products are selected; to the conduct of market research, which is an important function of all middlemen, but especially PBMs; to their assessment of potential changes in the supply of their products, which

in this case means not knowing the arrival of new drugs, but the research is being conducted on new and old drugs.

And I think that when one thinks about these characteristics of this particular market, that one has to beware of the dangers of inducing or forcing too much transparency in this market -- and I think that inducing or forcing transparency could do a considerable amount of mischief -- one would lead to diminish price competition. It's pretty well known that highly competitive markets are markets in which a lot of the price cutting is done below the board in ways that people don't see because that way one particular agent can get away with a price cut and gain market share and get some profits out of that before the competition realize that their prices have been undercut. And if you remove the secrecy, if you make prices more open, you can greatly reduce the incentives to cut prices in the first place.

Too much transparency would also tend to diminish competition in terms of information collection, market research, and the other activities which can be quite important for PBMs, as it is for all intermediaries. And the reasons are pretty clear, which is why should you go to the trouble to collect a great deal of very useful information if you're going to have to turn all that information over to your competitors?

And I think that a down side from too much transparency could also arrive in connection with formulary development, disease management, and related activities, that, again, are highly dependent upon information which in many cases is proprietary. And again, too much transparency would reduce the incentives to engage in these activities.

These considerations, I think, suggest a few things and these will form the concluding portion of my remarks.

One of them is that there's obviously a considerable amount of intellectual property associated with the collection and especially the use of information in this particular market. Intellectual property is something that promotes investment, of course, and I think that intellectual property needs to be respected even though we're not at the level of either patents or copyrights.

Second point is that, notwithstanding the natural tendency towards what one might call secrecy, secrecy in these activities, the market does generate a considerable amount of transparency and I think that those tendencies should again be respected and understood.

And then finally, I think that this is a

situation where there is no single optimal level of transparency, that this is something that has to be sorted out by the market and therefore it is no surprise. And in some cases PBMs have quite public formularies; in other cases, their formularies are not nearly as public; and I think that that's something the market can sort out and can work reasonable well.

So those are my general remarks, David. Thank you.

MR. HYMAN: Thank you, Jack.

[Applause.]

MR. HYMAN: Next will be Tom Boudreau.

MR. BOUDREAU: Good morning. I can hardly imagine a better introduction to my remarks than Jack's; and I can tell you that we didn't speak before this presentation. But he touched on the general role that PBMs play in the pharmaceutical marketplace and I'd like to give you a little bit of a window into how that actually works on the ground, so to speak.

I am speaking this morning on behalf of PCMA, the Pharmaceutical Care Management Association, which is the trade association for our pharmacy benefit managers, which includes not only the larger, publicly traded PBMs, but also a number of very substantial affiliated PBMs such as WellPoint, Prescription Solutions -- which is a

Pacific Care subsidiary -- Anthem, and others.

PBMs, as John indicated earlier in his presentation, administer the prescription drug benefit for approximately 200 million Americans. So we play a key role in the pharmaceutical marketplace. Our fundamental mission is to harness market forces to help our clients control the cost of prescription drugs.

Why do PBMs exist at all? This slide gives a lot of the answer, I think. You'll see direct-to-consumer advertising by brand manufacturers has increased dramatically -- $2.7 billion in 2001. Physicians report that increasingly patients come into their offices requesting a specific branded product which they have seen advertised in the general media. So there's an increasing level of information about prescription drugs from the producer side, from the manufacturers' side.

Per-member drug spent on an annual basis has been increasing substantially. We prepare an annual drug trend report which tracks the increases in prescription drug prices. And in an unmanaged environment, you can look forward to prescription drug cost increases in the range of anywhere from 13 to 16 percent a year; and some years it's been higher. We now estimate that in 2007 per-member annual prescription drug spend -- this is -- I should say this is our book of business, so it's

essentially a commercial population with some mix of retirees and seniors -- we anticipate that per-member drug spend will increase to approximately $1200 per year.

Senior drug spend, of course, increases much faster and by 2010, the estimate from the Prime Institute, is that per-member drug spend for seniors will be in excess of $2800.

One point I'd like to make -- when both John Richardson and Dicken spoke, they talked about what PBMs do, the PBM formulary, the PBM -- you know, the PBM administers the program.

I want to emphasize initially that it is the client's program that the PBM administers. We serve in a consultative role with our client. We sit down with our client, we help them analyze what their needs are for benefit design. Certain clients have an incentive or feel the need to have a more member-friendly benefit, others are more cost-control oriented. The role of the PBM is to consult with the client to help the client select the plan design features that best serve the client's needs.

So we sit down and we will do a customized formulary consultation, a network consultation. Express Scripts administers literally hundreds o customized formularies and hundreds of customized networks for our

clients.

The PBM's fundamental mission is to control costs by providing -- by harnessing market forces. We aggregate the buying power of our clients. In the role of the middleman, as Jack refers to us, I have to say our executives wince every time they hear the word middleman, but for purposes of today's discussion, I think it's fair to adopt that.

Our role is to aggregate the buying power of our clients and their many millions of members and to negotiate to help organize that market and to foster price competition in the supply chain. We negotiate on behalf of our clients with pharmaceutical manufacturers and with the retail distribution network to reduce prices for our clients.

In short, we harness -- our mission is to make prescription drugs both more affordable for out plan sponsors and also to increase the safety element in the use of prescription drugs by members of these plans. And I'll talk about that a little bit later.

I'm not going to dwell on this -- I'm going to move through this rather quickly right now because John Richardson earlier gave a good overview of what PBMs do and what the nature of their relationships are. But in essence, PBMs serve -- negotiate ingredient cost

discounts with pharmaceutical manufacturers, typically in the form of rebates. We negotiate ingredient cost discounts from the retail supply chain. In addition, we will be paid typically an administrative fee by our client.

And those are the primary sources of revenue for PBMs then. And the models do differ PBM to PBM, but the primary revenue sources that PBMs achieve are through manufacturer rebates and associated administrative fees; through pharmacy network margin; and finally, through administrative fees paid directly by the client.

This is not a black box to our clients. PBMs actually disclose quite a bit of financial information to their clients and our clients understand the components of what we do and the mix. And just to give you one example, we had one large client that challenged us to find a way to essentially give them the benefit of manufacturer rebates at point of sale, at the time the member actually gets the prescription drug.

The way we did that was to offer that particular client a very deeply discounted network price such that we lose money on every network transaction as it comes through.

The client then says, "You keep all the rebates and our dispensing cost at the retail level will be

adjusted on an annual basis based on your rebate key." So that client comes in, audits rebates annually; we adjust the dispensing fee, so that the client's getting the benefit of the manufacturer rebate at the point of sale.

And it's our job then -- and we have a strong incentive obviously to go out and negotiate the best deal with the manufacturer that we can possibly get because if we don't recover the negative spread that we're experiencing on every retail transaction, we will lose money on the account.

These are the key market forces that PBMs try to harness to help our clients control their prescription drug costs: Formulary development, manufacturer contracting, point of sale claim or plan design consultation, which emphasizes low cost brands and generics, mail pharmacy services, and retail network contracting.

I'll talk about each of these in order.

Each of the PBMs has a slightly different business model. We've come from our origin -- the origins of these companies are different and so different companies emphasize different aspects of this chart. But essentially the core services are similar.

There's a lot of interest and speculation,

frankly, about formulary development. It's difficult and it's complex, and it's -- as Jack mentioned -- there's frankly a lot of intellectual property in the form of know how and experience that goes into this. But the general concept is not terribly difficult.

I'd like to walk you through an example of how we might make a formulary decision in a single therapy class. First of all, every formulary process starts with an independent pharmacy and therapeutics -- a P&T committee -- which is composed by independent physicians, not employed by our companies, who assist us in evaluating drugs for both clinical effectiveness and safety.

Jack mentioned the need for some secrecy in our industry. We don't publicly disclose the names of the members of our P&T committee because we want to shield them from the influence of particular manufacturers who might seek to lobby for their drugs. But these are 17 -- in our case, 17 physicians who are typically in academic settings, and private practice settings, cover a range of specialties. They usually are very well regarded in their field with a number of publications and so on; and they take a real interest in pharmaco-therapy.

So they tend to serve. And I've talked to members of our P&T committee about why they do this and,

as often as not, the reason is that this is just intellectually stimulating. They want to participate in this process.

The P&T committee makes -- actually, at the end of the day, they do a very simple thing. There's a complex intellectual analysis that underlies it, but they tell us with respect to any new entrant into the pharmaceutical market that we should treat it on our formulary in one of three ways: It's either a mandatory include -- this is a drug that's -- it either -- you know, it's new, it's novel in its class, or it comes in with a clinical profile that is so much better than drugs that are already available in that class that any clinically sound formulary must have this drug available to members.

So they could tell us we must include the drug. They could tell us that we should exclude the drug because they are concerned about its safety, typically because they're concerned about its safety profile. And I can tell you there have been a couple of cases in which our P&T committee recommended exclusion of a particular product that the FDA had approved for out-patient use and those products were later withdrawn for the very safety concerns that our P&T committee had expressed. So we think they add a lot of value in terms of patient safety.

And finally, and this is true for the majority of new agents, they'll tell us that -- they may tell us that it's an optional drug. In that particular therapy class there are other agents that are efficacious and perfectly good, so you can either -- you can include the drug or exclude the drug. That's where the formulary development process now comes in because if the P&T committee tells us that it's a mandatory include, it's on the formulary; end of discussion. If it's an exclude, it's out.

Now we can take the next step with the optional -- with the drugs that are designated as optional and construct an appropriate formulary for our clients.

The first step that we take is to rank order the agents in a class. And this is just a schematic of a hypothetical therapy class that contains six agents. The small "C" represents a generic product in that class.

We first rank order the agents according to their clinical effectiveness. This reflects both the P&T committee's input and also the input of our clinical pharmacy staff. We have a very large staff of Pharm D's, graduate pharmacists, who study the clinical profile of pharmaceutical agents.

For instance, drug B might be preferred from a

clinical perspective, because its dosing is one a day, whereas drug F, for instance, might be three times a day. Those are the kind of considerations that the clinical folks take into account.

Then we take those agents and we spread them along a horizontal axis which is cost. And there's a little bit -- down at the bottom here, it says -- it's a cost of a 30-day supply, AWP. It's really AWP net of rebates. This is the net cost of the product to our clients on a 30-day course of therapy basis, not obviously by pill, but by course of therapy for 30 days.

So now we've spread them out across both the horizontal and the vertical axis on the basis of cost and clinical effectiveness. Now we have to ask ourselves, you know, okay, this -- it might -- you could draw some conclusions from this chart, but we have to deal sort of in the world of possible. What is actually happening in the marketplace today with respect to these agents and what can we hope to achieve if we're going to prefer certain drugs over others?

So then we take a look at the current market positioning of the products. And the size of each bubble represents the relative market share of those products.

Obviously, if product F occupied 80 percent of the market in this particular class, we would have a

different decision in this class because it -- the -- if you had to move all of the members of a health plan who are using product F to a lower cost product, you would have a very difficult time doing that. There'd be a lot of member disruption, the health plan client would be disinclined to undergo that level of disruption. So we take a look at the relative market shares of the product and finally we draw a line and separate the preferred products in that class from what we will designate as the non-preferred products in the class.

Typically now, this means not that the non-preferred products are not covered -- although there still are a few closed formularies out there, they're quite rare -- what will more often happen is that if there's going to be a product that's excluded completely, it may be one product in a class.

For instance, product A might be excluded by a client simply because its clinical value is so low that they don't want to encourage the use. They're going to be more inclined to encourage their members to us a clinically more efficacious product.

But typically this would be the way we would draw the line. We'd include the generic of the products which both have high clinical efficacy and relatively lower cost. And this is how we would develop, therapy

class by therapy class, a national formulary that we might recommend to our clients.

Having said that, what the Express Scripts formulary, or the PBM formulary actually is is a recommendation. It is a recommendation that's based on a book of business analysis. And so we have, at our company, something we call our national preferred formulary and this would be the exercise, more or less, that we would go through.

We also, however, and this is true of our competitors, have clinical specialists who will go out and sit down with our clients -- particularly larger and more sophisticated health plans -- and do this analysis, therapy class by therapy class, for the plan. Because those bubbles may be positioned differently for a plan and they may, for instance, want to have product F covered if F happens to have a large market share for members of that plan in particular.

So as I indicated, we literally administer hundreds of custom formularies which we sit down and design with our clients, hand-in-hand.

The second market force that PBMs try to bring to bear is plan design incentives which encourage the use of the preferred products. You can see in 1997, 80 percent of the formularies that we administered were

essentially open with minimal incentive to use lower cost brands. In 2002, we now see that a majority of clients are using three-tier formularies which have a lower co-payment for preferred brands, a higher payment for the non-preferred brands in that class.

We also try to emphasis the use of generic drugs. Right now, most plans do offer lower co-payments for generic drugs, but the co-payment for generics is actually a higher percentage of the total ingredient cost.

Our recommendation to our clients is that you really ought to be thinking about lowering the co-payment on generics to a very small amount so as to incentivize members of those plans to use generics at a higher rate.

The generic opportunity is huge. And there is -- you know, I've heard one -- you know, from a number of sources, the suggestion that PBMs favor higher AWP brand drugs because somehow we make more money on that. Well, speaking for Express Scripts, I can tell you that we find generic drugs to be, across the board, more profitable to our business than brand drugs; and, in fact, as we have said publicly on a number of occasions, across our entire book of business we actually lose money on brand drugs.

In our network contracting, the prices that

we're paying to retail pharmacies for the branded products are actually higher than our clients are paying us in reimbursement. So we have a terrific incentive to assist our clients and their members in moving to the generic products and to lower cost brands.

This chart shows the -- in our book of business -- the generic utilization rate. John Dicken mentioned that in mail order, the generic utilization rate was lower than at retail. There's a very simple reason for that. The mix of products in mail and at retail is quite different. Mail order handles exclusively maintenance medications.

There are fewer generic substitution opportunities in the maintenance medication classes, whereas at retail there are classes like the antibiotics as a whole group in which there are quite a few generic substitution opportunities. Mail order does very little in the way of antibiotics because those are drugs that are needed for an acute condition as a general rule.

But you can see that the generic utilization is increasing and we expect generic utilization to exceed 50 percent within the next couple of years.

The third market force that we try to harness is mail order pharmacy. It's a low cost, high convenience option for members often incentivized by the

plan so that -- because the -- typically, we're going to -- mail order will provide a cost savings of 10 to 12 percent to the plan sponsor over retail.

And then finally, we negotiate discounts with retail networks. As Jack, or excuse me, as John Dicken mentioned, there has been some static between retail and PBMs recently. There are some benefits to the PBM contract with retail that don't often get mentioned. And it was an important factor as these networks were first created in the mid-90s.

The PBM contract takes away the credit risk. We assume the client credit risk. The PBM guarantees payment to the pharmacy, at least that is our business model certainly, so that once we adjudicate the claim and tell the pharmacy it's good to go, it's our contractual obligation to pay the pharmacy even if our client doesn't pay us.

It speeds up the cash turns for retail. And finally, there's no paper claim involved. It's done all point of sale and electronically.

In addition to the purely economic benefits that we bring to our clients, PBMs add a great deal of safety to the use of prescription drugs through -- and this was mentioned earlier -- through DUR messaging. Very briefly, last year our company sent 33 million -- we

handled approximately 300 million retail claims. We sent 33 million safety-related DUR messages. We're not talking about therapy substitution or generic substitution opportunities here. Thirty-three million safety-related DUR messages resulted in over 500,000 prescription changes for safety-related reasons.

We think that's huge value to our health plans and to consumers. We're actually trying to work to take some of the noise out of that. We think that's too many messages and we have a project underway right now in which we're attempting to focus on the really high impact messages so that we can make sure that that information's getting through to the pharmacy and to the prescriber.

And then finally, three of the PBMs -- Express Scripts, Advance PCS, and Medco -- have formed a joint venture called Rx Hub, which is intended to promote electronic prescribing. We think this will be a terrific advance in patient safety. It will both -- it will put the DUR information -- which is now only available to the pharmacist after the prescription's been written and the member's standing at the counter expecting to get the product -- will put that DUR information in the hands of the physician at the time of prescribing so that the physician can take appropriate action, and it will eliminate medication errors due to illegible and

misunderstood handwritten prescriptions.

That is in beta testing right now. It will be open architecture which will be available to any PBMs, health plans, pharmacies that want to plug into it.

I see I'm out of time. I'll just add a couple of final notes. I emphasized earlier that what we're doing is administering the client's benefit program. So whether the level of control, price control, is high or low, that's a decision that the client makes after we walked them through their various alternatives.

There's a tremendous amount of financial transparency between the PBM and the client. We've -- we make extensive financial disclosures about our relationship with manufacturers, our relationships with retail. Our clients understand how we do this business.

More importantly, the consultants who serve the bulk of our clients -- the Mercer's, the Tower's, the Hewitt's -- fully understand these relationships, understand how this works. It's an incredibly competitive marketplace. Although there are few -- as Jack pointed out -- a couple of national PBMs, there are dozens and dozens of smaller competitors; and there aren't many national PBM contracts truly. Most of these contracts are local or regional in nature. There are a lot of players in this marketplace.

Almost all of the major cases that are awarded are done so in a competitive bidding environment, typically run by the consultants. Our clients understand very well indeed how we do our business and how we make our money.

So I'll just wrap up by saying we believe that PBMs are the market-based solution. We think we're adding a real financial value to our clients. We're adding both financial and safety value for the members of their health plans. And we welcome the opportunity to be able to discuss what we do and how we do it and to open up the window for you just a little bit more.

Thank you very much.

[Applause.]

DR. HYMAN: Thank you, Tom.

At this time, we're going to take a 10-minute break and we'll reconvene at 5 after the hour to hear from our final two panelists.

[Recess.]

DR. HYMAN: Our next speaker is David Balto from White and Case.

MR. BALTO: Thanks. I really want to commend the FTC for holding these hearings on PBMs.

There really isn't sufficient information known about pharmaceutical benefit managers and how they work;

and too often the debate about PBMs, like many health care issues, doesn't go beyond the level of caricatures. I think it's really important for the FTC to hold this hearing and begin to dialogue on the kinds of issues, more nuts and bolts issues, about PBMs.

I'm not here to criticize the role of PBMs, though for those people who want to buy what the first four speakers sold hook, line, and sinker, I suggest that you read several newspaper articles and the complaints and two lawsuits that are out on the front table there.

I guess it's important to read the newspaper articles because Jack Calfee has informed us that the New York Times serves as the bulwark to make sure that the PBM markets are transparent and protect us from competitive harm. But these articles detail several instances where PBMS haven't quite delivered on their promises. But that's not the subject of my talk today.

I think that this panel fits in well with the rest of the FTC's hearings, which seek to struggle with the issue of how health care markets can work more effectively and how consumers can be better protected by having better sources to consumer choice and information.

I think the bulwark of these hearings is the concept of consumer sovereignty, that markets work best when consumers are fully informed about the variety of

choices they receive and about the alternatives in terms of quality, and price and service.

When consumer sovereignty exists, when there's real transparency in markets, that's when we expect markets to work much more effectively.

Now I think, as Jack Calfee has pointed out, there is the potential for problems in agency relationships. And I think those -- and those problems come about oftentimes because of a lack of transparency. In this case, I think the general public perception is we don't know who the PBM is the agent for. Is it the agent for the manufacturer, is it the agent for the plan's sponsor, does it have conflicting agency relationships, and where in the world are consumers in this equation in this pharmaceutical supply chain?

Now my own experience in dealing with PBMs was as an attorney at the FTC, where the FTC brought two important enforcement actions against PBMs in the mid-1990s. Then the idea was that pharmaceutical manufacturers would buy PBMs and use them to push their drugs to more effectively market their drugs. And that's why pharmaceutical manufacturers were willing to pay an astronomical amount of money for these PBMs. Lilly paid $4.2 billion for PCS. It eventually sold it for $1.6 billion. Beside myself, I think most of the shareholders

of Lilly wish we had blocked that merger.

Anyway, the complaint in the Lilly PCS case was that -- and there are critical concepts which I don't think are that different now that there was a market for national PBMs and that the acquisition of -- Lilly's acquisition of PCS might enable them to foreclose rival manufacturers of drugs in drug categories where Lilly had market power. And it also might facilitate collusion among vertically integrated pharmaceutical manufacturers.

To resolve these problems, the FTC consent order took three approaches. On transparency, the FTC consent order required that an independent formulary be created and that PCS must accept -- and that independent formulary would make determinations on which drugs would on the formulary -- I'm sorry, an independent P&T committee would establish -- would play that role.

You know, it's nice to see regulation really help move the market. This is a case where the FTC had a good idea and it helped move the market so that most PBMs adopted similar provisions.

On the potential foreclosure issue, they required PCS to maintain an open formulary for consumers, but allowed PCS to offer a closed formulary. And on potential collusion, it created firewalls to protect from potential collusion between PCS and other PBMs.

A couple years later we brought a similar -- the FTC brought a similar enforcement action against Merck and Medco. Again, the concepts were really similar.

One important here was that the ability of Merck to exercise market power through their PBM didn't just create a static competitive harm, but a potential dynamic competitive harm that drug manufacturers, knowing that Merck would control the formulary over Medco, which was a -- which had only something like 20 percent of the market -- would diminish the incentives for firms to engage in research and development where they knew they might have to compete against Merck and Merck could use its Medco muscle to keep them from being able to effectively compete. And the consent order basically took the same approach. I think there was somewhat stronger evidence of potential for collusion in the Merck case.

I wanted to mention just one of the public antitrust -- one of the public suits brought because I think it's indicative of some of the kinds of suggestions in the public mind about why there are competitive problems here.

ASFME has brought a lawsuit against the four largest PBMs. Under California unfair competition law --

let me pause for a moment and mention to all my friends in the FTC here today that the California Unfair Competition Law is the first cousin of the Section 5 of the FTC Act; and everything you can do under Section 5 of the -- under the California Unfair Competition Law, you can do under Section 5 of the FTC Act.

Anyway, what AFSME has alleged is that consumers pay inflated prices, and this is partially due through the manipulation of the AWP and that oftentimes, because of a lack of transparency, consumers don't receive the full benefit of the rebate savings that PBMs receive.

Like most class action complaints, the complaint seeks money and injunctive relief to assure somewhat greater transparency.

You know, there's a very interesting case decided under the California Unfair Trade Practices Act involving credit card foreign exchange fees in which a violation was recently found because of the lack of transparency of pricing. So I think there is some -- there are elements to this that I think will be very interesting to watch as they're played out.

Now are there competitive concerns in the PBM industry? I still think that the FTC's analysis in those earlier cases is correct. The market has become more

concentrated since then. Four large firms have approximately 70 percent of the market. The FTC defined a market of national PBMs services in which there were relatively few competitors. And even though Merck and PCS had a relatively modest market share, something like 20 to 30 percent, the FTC believed that enforcement action was necessary.

Those concerns, I think, should be greater because there's substantial concentration, increased consolidation, there's been no successful PBM market entry for -- at a national level -- for a long time. And, in addition, I believe that switching costs are rather substantial, that it isn't easy for plan sponsors to switch from one PBM to another.

This creates an environment -- not an uncompetitive environment -- but an environment where there can be competitive problems, an environment where you cannot necessarily expect that if there's market failure that the market will necessarily correct itself. That's especially true when there is a lack of price -- when there is a lack of transparency.

And that's the major topic that I want to address.

The reason why transparency is important, and we know this from Economics 1, is that it assures a

greater level of competition. It gives consumers information with which they can use to play different rivals against each other. Armed with information about rebates and the PBMs setting, buyers can encourage PBMs to compete more aggressively to secure lower prices.

Transparency also plays an important role from the perspective of other manufacturers. Transparency can prevent discrimination. Secret rebates can ultimately end up in encouraging choosing higher priced drugs.

Now there are theoretical reasons I'm sure the rest of the panelists will have about why this doesn't occur. But it seems to me from reading the articles in The Wall Street Journal, or the complaint in the case, that's precisely what at least has been alleged. Rebate disclosures allow buyers to monitor what's going on in a market more carefully and prevent different types of price discrimination.

Now is this a new concept? Hardly. Congress has enacted anti-kickback legislation in a variety of health care settings to prevent conflicts and possible discrimination because it realizes the potential for abuse of agency relationships. So Congress, in order to -- and HHS -- in order to get the discounts safe harbor, the anti-kickback law requires that firms provide information about rebates and price concessions. And of

course, some of these rebates are the subject of government investigations.

Now again, let's go back to Economics 1. Two Chicago-School economists, two of my friends -- Dennis Carlton and Jeffrey Perloff – put it well: "Why do we care about transparency? Because firms obtain market power from consumer lack of knowledge about prices and quality. Limited information can lead to monopolistic price on what otherwise would be a competitive market."

And the antitrust enforcement Agencies and the Supreme Court have realized that year over year. If I had only another 25 minutes I'd repeat to you, all of the antitrust enforcement actions brought by the Agencies that focus on price transparency, but we could start at Bates v. Data Bar of Arizona. For some reason attorneys thought it was improper to advertise prices. Justice Blackman, who liked doctors but didn't like attorneys, wrote a decision striking down the ban on lawyer advertising. And many of his observations, I think, are critical. He said that the disclosure of prices and other dimensions of competition perform an indispensable role of the allocation of resources in a free enterprise system.

And in the health care markets, the FTC has recognized the importance of transparency. In FTC versus

Indiana Federation of Dentists, the FTC brought suit to challenge an association's decision not to provide x-rays to managed care providers so they could determine whether or not certain procedures were appropriate.

The FTC challenged that because that kind of transparency would have led to more competition, greater choice, and better quality of service.

I don't have to repeat the rest of the things that Justice Blackman said. You know, there's dozens of studies and court cases that show that where there's greater pricing transparency, prices are often dramatically lower than they would be when it's not there. And transparency is important to all aspects of the transaction.

The Supreme Court has suggested that it's all the elements of a bargain -- quality, service, safety, and durability -- that the antitrust laws seek to protect.

The FTC has taken action to assure transparency in situations often involving agency relationships, often involving consumers who aren't fully informed, often involving situations where there is the potential for market failure and the potential for people -- even with small market shares, even with almost minuscule market shares -- to act anti-competitively and abuse the

competitive process.

Two examples: The funeral industry rule in which the FTC requires the industry to provide consumers with detailed pricing information for all products and services they provide. A more recent example, the telemarketing rule which has similar provisions.

And the most recent example, a letter that was issued by the FTC staff back in December of last year involving Internet search engines in which they instructed that Internet search engines would be wise -- let me repeat wise -- to provide information to people suggesting what payments they receive from companies that advertise on their Web site.

And that kind of disclosure can make consumers better informed and lead to a more competitive marketplace.

So I guess the interesting part of our discussion will be where the transparency line should be drawn. I can't imagine that there's any kind of controversy that transparency is the kind of good like competition -- which is like ice cream -- you can never have too much of it.

Thank you very much.

[Applause.]

DR. HYMAN: Finally, Tony.

MR. BARRUETA: Thank you.

Well, unlike ice cream, I do think there are circumstances when transparency can go too far -- particularly in a marketplace like we have for prescription drugs; and that in fact, while transparency is certainly useful and necessary to promote an effective agency relationship -- and that type of transparency can be worked through in the form of contractual relationships between the agents and their customers. And what is fundamentally a monopoly/oligopoly market for prescription drugs, there's actually value for consumers in being able to maintain the confidentiality of the prices that they negotiated.

Mr. Calfee mentioned the benefits and the challenges to competition in discounting, if, for example, a manufacturer of a brand of drug cannot be assured that the price it offers to a particular purchaser might be held confidential.

And it really does involve getting into some pretty good depth about how the prescription drug marketplace works to discuss this. And I'll touch on it a little bit. It's not exactly what the Commission asked me to talk about, but I think in the discussion, we'll probably get around to some discussion around that.

So let me -- just by way of introduction, let

me tell you a little bit about Kaiser Permanente and why I think I'm here. Kaiser Permanente is the largest integrated delivery system group model HMO in the country. We serve about 8.4 million people across 9 states and the District of Columbia.

In terms of our role in the prescription drug market, we buy about $2.5 billion worth of drugs every year. Just in California, to give you a sense of the magnitude, we dispense more than 50 million prescriptions a year for more than 4 million different Kaiser members. So more than two-thirds of our members in California are actually using their drug benefit and we put enormous resources into managing a drug benefit -- both in terms of how physicians within the organization select preferred drugs, how physicians put in place methods in order to cooperate and collaborate in terms of managing effective use of drugs, and how pharmacists are used -- pharmacists who work for the health plan and for our hospitals organization -- to support the physicians in their efforts to use drugs in the most cost-effective manner.

So I think I'm here a little bit to talk about that different model of an internalized PBM. We don't really refer to it as a PBM, but it's certainly a pharmacy benefit management function.

But at the same time, we do have networks around the country. About 2 percent of our benefits are delivered through network arrangements in which we are required to be able to provide access to be able to make benefits available to our enrollees through either community pharmacies or physicians practicing in the community.

And in those circumstance, we find that it's far more efficient to out-source that function; and so we do have a contract with a third party PBM, who manages the contracting with pharmacies.

And so, I think, in our organization, we really do -- and I really enjoyed Dr. Calfee's comments about this because in some respects there are efficiencies in internalizing function; and in other respects, there are much greater efficiencies if you out source and select a middleman to take care of things that would be much more expensive and much more difficult for you to take care of.

I just want to make a couple points about the prescription drug market and then I'll talk a little bit about formularies and how I think they work in the market -- both from my perspective. How it works within the PBM industry, but also internally.

I think as I suggested when I started, the

prescription drug marketplace is unique and it's important when we're talking about PBMs that we put this entire discussion in the context of what's going on in the prescription drug marketplace.

The prescription drug market operates unlike any other market, both in terms of supply and demand. One would expect that there's some diminution of competition in any market like the prescription drug marketplace where you have very strong intellectual property protection and very strong market exclusivity protection. It causes the market to operate differently than you have in commodity markets, whether that is dentists, doctors -- in many markets, most of the types of markets that were discussed, for example, in the cases that David raised a few minutes ago.

I do think that the prescription drug market is really fundamentally distinguishable from most of those markets.

So you expect a little bit less competition in general, but competition's even more fragile than it should be because it's been undermined by an inherent market dysfunction based on how third party coverage of prescription drugs works, who prescribes drugs, who dispenses drugs, who pays for drugs, who consumes drugs -- these are all different parties. And again,

that's another unique nature of the demand side of the prescription drug market.

There has been occasional collusion. That's been appropriately addressed, I think. And one thing that we shouldn't leave out -- and I hope that we'll have a little bit of discussion about this, although it might be -- if there's going to be a later meeting on the prescription drug marketplace generally, it would probably be more appropriate for that, but there are a number of governmental policies that have been put in place that actually promote an anti-competitive marketplace.

And so we really do need to think about what's going on in the market? If the complaint is drug costs are going up and PBMs are failing in their job, I think we really need to look at other factors that are making the drug market less competitive and driving up drug costs.

Of all the problems in the prescription drug marketplace, I would say that PBMs are not only the least of our problems, they're probably the primary potential solution to most of the problems. And I think that it's important when we start thinking about what types of government interventions might be appropriate.

And this is coming up a great deal in the

context of the current debate over the Medicare drug benefit -- that there is a need to be very subtle and very delicate about what the government will require PBMs to do -- particularly in terms of transparency and disclosure -- to make sure that any transparency isn't done in an unwarranted fashion that might actually have the effect of undermining market competition.

Let me talk a little bit about formularies because I think that's the -- that was the primary issue that I was asked to come and talk about.

Really, formularies -- and again, I should say that the presentations that we had this morning are really a wonderful exposition on what's going on in the PBM marketplace, what PBMs do. So I think all I'm really doing is adding a little bit of amplification on a couple of different points.

You know, formularies are really the central component on the demand side of the market, the central component of the infrastructure to create competition among drug manufacturers. I think of the prescription drug market as being in different stages where when you -- when there's a new breakthrough drug -- and the example that I sometimes think to talk about is Prozac -- when Prozac came onto the market in 1989, it very quickly became recognized by physicians as being so superior to

the existing anti-depressants that it became a must-use drug.

And during that period of time, which I think avoids the first stage of a drug market, is when there's a new drug that is essentially a blockbuster drug. The manufacturers have almost pure price-setting capability. They can set the price wherever they want, wherever they think the supply and demand curve meets for a particular drug. And because there's no effective alternative, they can set the price at their whim.

It's not until follow-on similar chemicals that are different drugs become available that we have a situation where there is an opportunity for making the manufacturers compete with each other on price. And in the absence of an effective mechanism for competition on price, what's typically happened in most of these markets, as these follow on drugs -- in this case it was Zoloft, Celexa, Paxil, a couple of other similar drugs -- they all essentially shadow priced at least list prices and the cash paying prices at that same level.

The challenge is can the demand side of the market be put together in such a way that physicians can be encouraged to drive utilization or patients can encourage their physicians to drive utilization to one among the others; and then is there an infrastructural

capacity for a PBM to go out, or a health plan like Kaiser Permanente to go out and then negotiate with drug manufacturers on price.

And what I think happened was the PBMs adopted the Kaiser Permanente, and other integrated delivery strategies, and applied it to a broader marketplace, to the network-based marketplace, rather than simply the closed model. Which brings me back to formularies again.

Formularies were used within an organization like Kaiser Permanente since the 1940s. Hospitals used them even before that. And really what they were designed to do was simply to limit the number of drugs that had to be dealt with in any particular institution. It became pretty well know through the 60s and 70s that at least in the out-patient marketplace they were a useful tool for organizing competition with an organization like ours where there were competitive drugs.

PBMs adopted the formulary concept; and because they don't have practicing physicians within their plan as we do -- we have -- our medical groups actually manage the formulary without plans using the assistance and analytic support of the pharmacists who work within the health plan to make formulary decisions. PBMs have had to establish separate committees to do this.

The real distinction that you see -- and if you look at the formularies, they're not that different in the final analysis. They cover essentially the same types of drugs, they go through the same analytic process; but what you find when you have physicians involved is that there's much greater confidence in the formulary and the physicians are far more willing to prescribe in accord with the formulary.

And so what you see in an organization like Kaiser Permanente is we have about 97 or 98 percent prescribing in compliance with the formulary. What that means for us is that we're able to go to the manufacturers in any particular instance and say, "Our physicians have really bought into a particular decision that we've made; and based on the evidence, we think that we can start 80 percent of our patients in a particular class on a new drug," or "We think we can move 95 percent of our patients from drug A to drug B."

And it is this nature that -- it's the nature of potential competition that allows us to go out to the manufacturers and effectively put that business out to bid.

In the network arrangements where they have similar formularies, they have less buy-in by the physicians and so they're relatively less able to have

that kind of market power.

However, it does work to some extent and that is why PBMs are able to negotiate rebates realizing a lower price on particular drugs.

I really do think that, you know, there have been frequent criticisms of formularies, particularly that they place economic considerations ahead of clinical considerations. And there a couple reasons why I think that's an ill-founded concern. And the first of -- you know, the primary of which I think is a practical concern.

In order to go through this analysis of how much market power can you as a purchaser bring to bear on a particular class of drugs, you need to know the clinical information about those drugs. You need to go through the analysis to figure out what you're able to deliver for the manufacturers in terms of their growth of market share, which is what they care about, or their avoidance of your taking their market share away, which is how I generally like to think about it because somehow that seems more frightening with them.

But you need to know that. So you -- no matter what you do, you have to go through a clinical process to understand what the evidence seems to show in order to indicate how competitive a particular class might be.

So just from a very practical standpoint, I really do think that there's a sequencing of decision that clinical safety and effectiveness issues have to come first before you can get to the cost considerations because you don't even know what the costs are going to be until you figure out how competitive the particular drugs might be.

There is a particular complication, I think, around formularies; and this ties back to some of the criticisms that have been made about pharmacy benefit managers that I've read about in the newspapers -- and everybody else has read about in the newspapers. And that is the manufacturer's strategy to preserve their market share in particular drug classes by introducing onto the market follow on chemicals that would be -- would maintain their market exclusivity after the predecessor chemical becomes generically available. And so there are some classic examples of this: Prilosec and Nexium being one, Claritin and Clarinex being another.

So this is actually a very interesting situation and an interesting problem; and I don't have any information about this, but do I personally think that there's some nefarious plot going on to shift patients to newer, more expensive patented drugs? No. I think that there's a difficult business decision that

needs to be made by any payor for drugs about whether it makes sense to go with that switch if the manufacturer of the new drug is going to offer a lower price.

And so what you have is a situation -- on the newer drug -- what you have is a situation is you have to make a very difficult decision about how far out do you think you're going to have the ability to move patients to a generic drug; and will moving to the newer drug make it more complicated to do that?

What I think that says is more about the need for open communication and transparency between the PBM and it's client. It says a lot about that and the need to make sure that those decisions are made in collaboration because they certainly can be mutually beneficial, but it's an entirely different issue from saying that any type of price negotiation in this context should be widely -- you know, made widely available on the Internet, or something, so that consumers can see all of the arrangements that are going on. I think that's a fundamentally different issue.

And I think that there is some question about the hyper-regulation, both in terms of some legislation that I see introduced in the states, or litigation that's been put forward now. I think that that may actually just muddy the water more, rather than really getting

down to whether this will support competition in the marketplace.

And, you know, the real last pitch that I have on all this is it gets back to this notion of competition in the prescription drug markets is very fragile. The PBMs came into being and grew because there was a gap in the market where purchasers generally were not able to collectivize their market power. And the PBMs provided the conduit for dis-aggregated consumers to come together to aggregate their market power; and it works out, as you've heard today -- you know, everything that you've heard today is essentially the infrastructure that's been developed to permit consumers to realize lower drug costs both in terms of the premium costs that go into drug benefits, and also the absolute drug costs.

Are we all the way to where we want to be in terms of better competition in the marketplace? Certainly not. But I think that hamstringing the PBMs and their activities, which some people have advocated for -- and I do think that transparency -- this notion of wide-spread transparency of prices is one of the things that would hamstring PBMs from being able to negotiate lower prices -- would actually exacerbate rather than enhance competition. It would exacerbate the problem rather than enhance competition in the market.

But those are just some thoughts that I have and I really look forward to the discussion, which something tells me will be a little bit lively. So.

[Applause.]

DR. HYMAN: Thank you, Tony.

Well, we've got a reasonable amount of time and one of the consequences of this format is that subsequent speakers made comments on earlier speakers and so our general practice is to start off by allowing the early speakers to respond to anything that had been more or less specifically directed at them, or take off from an observation made by a subsequent speaker -- I know, Jack, put your hand down -- and we'll follow the sequencing order and just walk our way across.

And then I have, as predictable, a whole series of questions that we can use for discussion as well.

But first, John?

MR. RICHARDSON: Question for David, I think, on the issue of the market shares; and you know how you talk about the consolidation of power.

I'm very interested in this distinction between the volume defined by prescriptions, or covered lives, or expenditures -- if you look at it as a national phenomenon versus the way I understand that these contracts were let, which is in a local or regional

health care market where there may be, and arguably is, more competition for the PBM services between the four nationally publicly traded firms and the smaller, more niche players.

MR. BALTO: Well, I think that's a good question. I haven't investigated it recently. I mean, the -- when the FTC investigated in those two cases, they were willing to sort of buy onto a notion of a more -- of a market that was segmented. And by the way, that isn't at all unusual from an antitrust perspective. The antitrust agencies oftentimes segment markets, depending upon consumer demand and also supply alternatives into, you know, more national players, or more local and regional players.

And I think a lot of whether or not that characterization is correct would depend upon whether there are a set of consumers for whom these are the four key alternatives; and they agree that these four firms collectively might be able to raise price, which would include not decreasing prices as fast if they acted collectively.

I think the fact that there is a lot of competition -- in other words, even though there's a lot of competition on the local level, I don't think that resolves the issue.

MR. DICKEN: No, I think all the presentations were very insightful and informative, I think, even though there were some differences in perspective in the role in transparency. Generally, that reflects the trade-offs and the tensions that exist in the current market and the PBMs as far as the role they're playing.

MR. CALFEE: Gee, one comment on David's talk and one question.

I'm not a lawyer, but my impression of such cases such as Bates, Virginia Pharmacy, and so on, is that they all pertain to retail prices; and specifically pertain to attempts to suppress information about retail prices.

I just want to make perfectly clear that I'm not proposing or defending a situation in which consumers are deprived of information about the prices that they pay at retail, nor would I suggest that it would be a good idea for Kaiser, for example, to be deprived of information about how much exactly they pay for whatever they purchase.

My question, David, is is it -- your proposal that if Pfizer cuts a deal with Kaiser to reduce the price of Lipitor -- either directly or through a rebate -- are you suggesting that we would be better off if Pfizer's competitors and Kaiser's competitors all knew

right away exactly what kind of deal Pfizer was trying to cut with Kaiser?

MR. BALTO: No. And maybe what I should have done is clarified a little more of how -- what I was aiming for in terms of transparency. I'm looking at transparency so that plan sponsors have a much better idea of the rebates that manufacturers are receiving.

When I go into a grocery store, I don't really -- it may not be that important for me, it's probably not important at all for me to know how much Giant acquired their milk for. But, you know, I think it's important for Giant, in order to effectively bargain for the lowest -- milk's probably not a good example -- but the lowest prices for some goods, to know what acquisition costs of the intermediary may be.

And so I think that it's, you know, it would help a great deal if the plan sponsors knew this. And I don't think that's necessarily going to stifle the ability of firms to engage in selective discounting.

MR. CALFEE: So you're -- what you're suggesting is that -- and let's drop Kaiser for the moment and move to some organization -- group health association -- someone that actually uses a PBM. Your suggestion is that an organization, provided the uses of a PMB, they should know what the -- what kind of deals

the PBM has with their providers?

MR. BALTO: That's correct.

MR. CALFEE: Is that right? And I presume there's no barrier to them negotiating an arrangement in which they do have that information, or they can move onto some other PBM that does provide that. Is that right?

MR. BALTO: You know, there -- no, there's nothing that prevents them. In fact, as of July 1st -- the wonderful thing about the market, Jack, is that it's really resilient and it typically works a lot faster than regulators do.

And there is a new entity in Minnesota called Prime Therapeutic which is offering what they say is a consumer-friendly, or something like that, PBM in which they, as a matter of course, will provide these disclosures to their plan sponsors. So, hopefully, you know, maybe that's a sign that the market will take off in a more open fashion.

MR. BOUDREAU: Well, David raised some pretty hair-raising concerns about PBMs and I would be concerned too if there were a factual basis for any of them.

First of all, just in terms of characterizing the relationship of PBMs to our clients, we -- at least our company, and I think this is true of other PBMs --

don't characterize ourselves as an "agent" technically and literally. We have a contractual relationship. It's a very detailed document that goes through, you know, our relationship has a lot of financial disclosure in it, but it -- I would not characterize it as an agency relationship.

P&T committees were not, with all due respect to our host today, an invention of the FTC. They were in existence for sometime prior to the Lilly acquisition of PCS -- basically drawn out of the hospital setting, I think -- and I can say for our company that we had an independent P&T committee from day one, as soon as we started to develop formularies.

With respect to the litigation to which David referred, as there are matters in litigation I'm constrained from detailed response, but the complaints are -- contain a lot of factual errors as a complaint in litigation often does.

In particular, the California statute has been so abused by the plaintiff's trial bar in California that even the California legislature is considering a number of proposals to bring that particular statute back and draw some limits around it.

I might add that in a lot of those cases, the parties that have initiated that litigation are actually

not directly PBM clients. Our clients, the people with whom we contract and to whom we deliver our financial benefits are by and larger very, very happy with us. We have high retention rates, we have high member satisfaction rates.

And I'll not go further into my analysis of what the point of trial bar can mean to an industry. There are plenty of examples of that that you can read about yourself.

With respect to concentration in our industry, we don't see it. None of the PBMs that publicly report their profits are reporting what I would consider anything like monopoly rents. PBMs generally derive a profit that's in the 2 to 3 percent range of sales. It's a very, very low margin business.

And with respect to entry into the marketplace, not only are there -- as I mentioned in my remarks -- a number of smaller, sort of below the radar, but nonetheless relatively effective competitors already in the marketplace -- there are a number of potential entrants that we should be aware of. There are a number of health plans -- Aetna, Cigna, for instance -- who have very substantial, full-line, full-service PBM capabilities which they now utilize only for their own health plan clients.

If the PBM marketplace became a marketplace in which you could achieve monopoly profits, they could very easily move into that marketplace. So they sit on the sidelines and serve certainly to discipline prices in that marketplace.

But the real price discipline comes from, frankly, a competitive bidding environment in which PBMs do have to win most of their business and it's pretty brutal. There is -- the consultants are smart and they know how to run a process that produces a very, very good bottom line result for their clients.

The PBM contract and service is not really a consumer product. We are selling our services to sophisticated health plan sponsors. We delivery some of those services directly to members. We add value to those members. We believe in a form of safety, convenience through the mail, service, and so on. But our contract terms are negotiated with a highly sophisticated counterpart who knows exactly how to get the best deal for itself.

I certainly hope everything that Tom says is true. I hope it increasingly becomes true. You know, markets perform -- I don't think there's any disagreement that with sophisticated buyers and sufficient information, you can make firms effectively compete with

each other.

I'm not going to get into the top of whether or not PBMs make a lot of money. I'm sure there are people who could, you know, take another point of view on that and whether or not they exercise market power. I see the players and their market shares, especially in the national market, as being very stable.

And I would tend to think that among most people they'd be in agreement that there are some practices that have created problems. Tom's company itself has now promised not to take rebates from manufacturers to push drugs in certain fashions. I think that's very laudable, I think it's partially in response to a large degree of consumer discomfort. It's in response to the fact that it caused discomfort in the agency relationship, or whatever the relationship is, that he had with -- he has with his customers. And if the market is truly competitive, as Jack would suggest, we would see the other PBMs moving to take a similar response.

That's basically it. Let me just note, in case Tom's stomach isn't upset enough, in the credit card case where the court decided that the credit card company's failure to disclose their conversion fee rates was a violation of the California Unfair Trade Practices Act,

MasterCard and Visa are on the line for over $800 million in damages.

MR. BARRUETA: It's interesting -- we were litigating the tablet splitting case in superior court in California, in the same courtroom where the Visa MasterCard case was being heard, with the same judge, and that's why it took him two and a half years to get around to our case because he was working on the Visa-MasterCard case the whole time.

No, I think that, you know, we're sort of the party here's who's both a competitor to the PBMs, because the PBMs look eery way that they possibly can to try to carve out our members from the drug benefits that we provide. We have to deal with that at Calpers every couple years. You know, wherever we are.

And I don't blame them. I mean, it's -- if we're doing something that -- if people can buy a better product for a lower price, I think that's great and I'm gratified that virtually never have they been successful and we've had the opportunity to go in and explain why we provide a better benefit.

But we are a competitor, at least for our membership, with PBMs; and we're also a customer of PBMs. You know, we're not a PBM.

And our perspective really comes from -- I

mean, a lot of our perspective, I think, comes from the experiences that we had in the mid to late 1990s. And I do personally feel that something went wrong in that market. And I personally blame the customers of the industry who basically took a very short-sighted perspective that -- and Tom is exactly right to say that these customers are very well attuned to knowing what's going on.

There was not one customer during that time for whom rebates were a surprise, that there were rebates in the industry. They all knew this was going on. But customers, for the most part, were interested in paying zero administrative fees; and they were happy to let the PBMs keep the rebates instead, because they took a short-sighted view that, you know, they just didn't want to have to -- however it is they want to manage their books, they just didn't want to pay any administrative fees.

We went out to bid for this business at the same time that all of this was going on. And we made the decision at that time, we said, "We're going to pay our full freight of administrative fees because we want to know -- we want to make sure that there's no rebate arrangement going on that would counter our larger goals in terms of drug utilization management, how our physicians think that our patients should be managed;

and, economically, we want to make sure that we, you know, are in there and there's nothing running in cross directions.

And that was the basis on which we bid. We got bids on that basis and we bought services on that basis.

I think a lot of the complaints going on about what happened then is, frankly, a lot of sour grapes, that people made bad decisions purchasing services back in the 1990s, and they were shocked -- shocked to find that rebates were going on, and now they've decided that they're going to try to recoup that money through litigation.

So I -- there may be some facts -- I mean, some of the factual allegations in some of these cases are pretty bad allegations. If they're facts, then there probably ought to be some recourse. But the nut of these cases is this notion of, you know, whether it's economic agency, or who's operating in whose interest -- these are not being -- were a surprise to people when these transactions were entered into.

And so my view is that rather than, you know, focusing like we're going to wind up focusing for the next three years on how terrible the PBMs treated their customers until the litigation is done, what we really ought to be doing is figuring out, as purchasers of

pharmaceuticals -- as people who prescribe them, take them, pay for them -- how can we all get rowing in the same direction? And I worry that the litigation is going to distract us from doing that.

DR. HYMAN: Okay. Anybody else want to --

MR. BOUDREAU: I want to make just one comment sort of following up on something that Tony said.

You know, one of the issues that we face when we try to sell our services to our clients is that we do have a view to the future -- where pharmaceutical pricing is going, where products are going to be coming in -- that our clients don't have. That's information that we try to bring to the table and value that we add to their decision-making process.

But the clients and the consultants, in particular, tend to lag a little bit, even when you're putting that information on the table. One of the things that we're dealing with right now, as we try to sell new cases, is to point out to clients that with all these new generic introductions that we're projecting over the next few years -- I showed you the slide -- it's a large amount of money -- rebates are going to come down because generic products aren't rebated. Brand rebates are going to drop.

Clients are still pushing for rebate guarantees

in many of our contract bids. That's not necessarily to the client's advantage to have the PBM guaranteeing a certain level of rebate. What the client wants to think about is the net cost of the plan.

And a rebate guarantee doesn't create the same incentive to drive to generic utilization that a net cost arrangement does. So we try to educate our clients.

You know, our value proposition is we're going to help you control your prescription drug costs. We can see the generic train coming down the road. We think it's great. We'd like to get our clients focused on that; but, you know, the marketplace is still lagging that a little bit.

And we've got a job to sell our clients on the proposition that, you know, the focus on rebates is not necessarily in their financial interest. You know, we are, you know, it's one of many different pricing components that the client needs to take into account.

The consultants, however, like to spreadsheet the PBMs. They like to have us all throw in a bid that they can put into an (inaudible) spreadsheet and push the button and say this is the best deal. It's a little more complicated than that and, you know, that's one of the jobs that we've got to do, to educate our clients as to what is in their best financial interests.

And we think that's real value added that we bring to these discussions.

DR. HYMAN: Okay, let me throw out a question.

There's been a consistent theme pretty much throughout that the clients for PBMs are health plans or a variety of other aggregated entities of individual patients -- although the patients are, of course, the ones that ultimately take the pharmaceuticals. There doesn't seem to be a compelling reason to think there's transparency problems between the PBM and the client, but a lot of the discomfort that has been alluded to relates to lack of transparency when it flows down to the individual patient, or consumer level.

And so the question that I just want to put on the table is "Does that change the analysis any when it comes to transparency, when it comes to disclosure, or do we just view -- and I hate to use the word, “agent,” given that Tom doesn't like it -- but should we just view PBMs as adequate agents for patients and leave it at that?

Anybody have any thoughts on that?

MR. CALFEE: I don't see why PBMs should be seen as agents of patients at all. They're just, you know, an organization that's contracted with, between the managed care organization and the pharmaceutical firms.

And I think that if there's an agency relationship, it's further downstream, it's between the patients and the managed care organization, because they're the ones that are exercising a great deal of discretion.

DR. HYMAN: Yeah, fair enough. I mis-spoke. I meant "Should we assume that the transparency between the PBMs and the health plans -- where the health plan is acting as the agent for the patient" -- using that in an economic term. We'll basically sort out any of the issues that we might have here.

So does that change your answer any?

MR. CALFEE: Yeah. My impression, and I found what David had to say a little bit confusing on this point, is that I assume that there's quite a bit of transparency between the managed care organizations and the PBMs. I gather from what David said that's not necessarily true, but it is at least true, I think, that the managed care organizations at least have some appreciation of whether or not there is transparency upstream, whether or not they know exactly what kind of deals are being cut.

And if that's the case, well then the market can sort that out pretty well. If you want to have more transparency, you can go to a PBM that offers more transparency.

At the patient level, I think we're still left with a situation where they're interacting purely with the managed care organization and they will never know what goes on upstream and they won't really care very much.

MR. BOUDREAU: David, if I may. We do not have carte blanche to communicate with the members of these health plans. Our contracts limit our ability to communicate because the health plans, I think rightly view them as their members. They want to be able, to a large extent, to control the communication. And, you know, frankly this is -- this gets very pointed when we're asked to give, you know, various kinds of, you know, a rebate guarantee, for instance.

That's all fine and good, but we'd like to be able then to be able to communicate formulary preferences to the members in a way that we think is effective. If we're going to be sort of put on the line to deliver a rebate, we want to have -- be able to have a conversation with a member. And that is negotiated aspect of this transaction. How much will the plan sponsor permit us to speak to these members?

MR. BARRUETA: Yeah, I think on the transparency issue, and I assume that primarily what we're talking about is the transparency of the rebate

arrangement between the manufacturer and the PBM, or the client, and, you know, the price that's inherent in that. And if there's more transparency, then we can talk about that, but let me just take that on for a second.

You know, if I really thought that that would create more competition in the marketplace and lower drug prices, I'd be the first one in line to say, "I'm all for that; that's a great idea." However, I think that in fact this issue of transparency comes with an agenda, just like many issues have come with an agenda as it relates to prescription drug pricing.

I mean, it reminds me tremendously of the debate around the Medicaid best price formula, the Medicaid rebate formula, which basically requires drug manufacturers to provide the statutorily defined "best price" to the Medicaid programs based on whatever the "best price" is that they offer in the private marketplace.

You didn't have to do a Medicaid rebate program with that formula in order to provide savings for Medicaid. If you had just said, "You get 25 percent off of the average price," Medicaid programs would be much better off than they are using the best price.

The reason that the private proponents of that approach supported that approach, and at least the

manufacturer who supported that approach is on record as explaining this in the popular press, was that what they wanted to do was eliminate discounting. They wanted there to be a single price policy in the marketplace so that there would be less discounting, so that they would be protected from competitors who wanted to come in with lower prices.

I think the transparency issue is very similar. It has the same groups of people who are interested in absolute price transparency because what they're really interested in is making sure politically that everybody pays the same price -- not that there's greater competition, but that there's actually less competition, that you would be forced -- that you will get no benefit by going to any particular retail or other supplier of drugs because all the suppliers of drugs are going to be paying the same price because everybody knows what everybody else is paying. And you'll quickly move to one price.

And I strongly suspect if you were to quickly move to one price, you're going to move to the higher price, not to the lower price.

MR. BALTO: Well, I'm an antitrust lawyer and I love selective discounting and I think it's really critically important; but I think this is really

different.

First of all, I don't agree that there's transparency between the PBMs and the plan sponsors -- not the degree of planned transparency I think that you really need for these markets to be competitive. But beyond that, I think there's a big difference between going and having something like a mandatory, you know, most favored nation's price like in the Medicaid legislation; and something where there's disclosures with individuals.

Certainly, if those disclosure about individual rebates were made generally public, they would have the impact of dampening selective discounting. But, you know, I don't think that's the kind of transparency that's being envisioned.

DR. HYMAN: I have a whole series of questions and now I have to decide which one I want to ask.

Well, let's talk a little bit about market entry, and switching costs, and market definition. I mean, David's made a very strong argument in favor of national PBMs being the starting point for the analysis and argue that there are going to be significant costs in transitioning among different PBMs.

On the other hand, you look at John's chart and there are 60-odd local ones that have 50 percent of the

market, depending on how it is you actually slice the pie. So what's the relevant market and how hard is it to just drop one and move to another? And how does the presence of formularies affect that as a variation?

MR. CALFEE: Well, as Tom mentioned, you have national PBMs, but you don't have much in the way of national contracts. It's very much a regional market, so whatever questions there are about market share, switching costs, and so on, is definitely regional. It's not national. I assume we can assume that, right? I mean, that seems to be the case. I'm not sure anyone disagrees with that.

DR. HYMAN: You certainly asserted it.

MR. CALFEE: Right. I haven't heard anything to the contrary at this point.

DR. HYMAN: Okay. Tony?

MR. BARRUETA: Yeah. As a purchaser, we do have a national contract for PBM services with other than one of the three large PBMs, so you can get those services from other than the very large PBMs. And, you know, as we go through our process of revisiting our contract, we look forward to, you know, anybody who wants our business to give it to us for free; and, in fact, pay us money back for using them. But, no. So I think you actually can get that.

I think the formulary question is really a good one. We had to work that out with out PBM because we don't want them using their formulary because that would have a counter-productive effect for us since we have our own formulary for the rest of our business; and much of our network strategy, of course, is to transition people eventually to come into our system as we grow, hopefully, and expand. Although we don't seem to be moving in that direction anytime soon.

So. But the notion is that is it possible for a PBM -- you know, I do see this as a potential switching problem. Can the new PBM help with the transition from the old formulary to the new formulary? And I suspect they could. I suspect they could adopt the old formulary and, over time, transition to a new formulary.

But even in that case, the formulary's not that necessarily difficult a barrier because virtually every state has a law, and plans are written in such a way, as to provide certain protections for their enrollees who are on a particular drug. And simply changing the formulary, you don't necessarily have to change that particular patient to the new drug.

It's an interesting issue that should be looked at pretty closely, but I would expect if that -- that actually would be a competitive selling point, I would

think, for a plan going after somebody else's business to come up with a more flexible formulary strategy to say, "We have a transition strategy for you which is going to be relative seamless for your enrollees."

But I don't know if Tom has some comments on that.

DR. HYMAN: Yeah, I actually wanted to ask Tom explicitly on that, "Tell us about business you've taken away from other PBMs and business you've lost to other PBMs."

MR. BOUDREAU: Well, the first is a subject near and dear to my heart.

As I sit here today as an industry representative, I don't want to get too much into the competitive dynamics of ourselves versus your competitors, except to say that it is very competitive.

But the transition issue is, for any large plan, a subject again of pretty considerable negotiation. Indeed, the big plans, or the big cases, will require both implementation guarantees in terms of timeliness, and lack of error in set up, and a variety of things; and, in addition, they often ask for the PBM to subsidize the cost of the move through an implementation payment, which takes that cost off the plan, or at lest partially takes that cost away.

So that is, you know, that's another term of the contract that we negotiate as -- you know, if it's take away business, that's the discussion we have.

With respect to the formulary change, whether or not that's difficult is very case-specific. Again, I've got to reiterate, it's the client's formulary. We're not imposing a formulary on the client. We may have the conversation that is something like this: "If it's this formulary, then this is the pricing that we can give you; if it's this formulary, then this is the pricing we can give you."

But we don't have a gun to the head of our clients requiring them to adopt a particular formulary. So the client may say that "We don't want to change this class or that class, or the formulary at all." And then, you know, we sit down with our financial people and we figure out what that, you know, how we can bid that case if we're not going to be using the, you know, what we would consider the more favorable contracts with manufacturers.

We have a very flexible system. Our company in particular has a very flexible system; and, as I mentioned earlier, we administer literally hundreds of different formularies for our clients. So the formulary -- I'll tell you where the formulary transition

issue becomes important is if the client is asking for some form of rebate guarantee, because then, you know, we have a certain of arrangements with manufacturers. They differ from our clients -- or from our competitors' arrangements with manufacturers.

If they want a rebate guarantee, then we have a much more detailed discussion about what we're going to ask the client to do by way of a formulary shift so that we can give them the financial deal that they want.

MR. BALTO: Four competitors, yeah, the four major traded companies have had relatively stable market shares. I'd be interested in knowing the degree that those folks lose business to the small people, but that wouldn't be dispositive in my mind.

You know, there are, you know, if these firms are larger, you know, for a reason and it may be that there's -- I don't want to become too antitrust-y, but, you know, maybe that there's significant difference between them and their rivals, such that, you know, for some significant group of customers these are the, you know, the only four alternatives.

This is, you know, a concentrated market in the terms that the, you know, antitrust Agencies typically look at markets.

MR. BARRUETA: Yeah, just to -- on the

formulary issue, and that's just following up on that, you know, one of the things that's really interesting about this market is that this notion of the rebates. The rebates really are a potentially pretty small component of the overall cost. And I think Tom made that point in terms of what you're really interested in is the net cost.

There are some drug classes where, depending on the PBMs' performance in terms of driving utilization to, you know, and somebody else raised the Cox II inhibitors example earlier. But that's a wonderful example, that even if you assume you have a 25 percent rebate, or whatever, on Cox inhibitor A versus Cox inhibitor -- Cox II inhibitor B, that savings that you would get, or that savings that you would forego by moving from one to the other, is dwarfed by the impact that you would obtain by actually having appropriate utilization of that drug.

So, you know, that's one of the things to factor in and it's not -- you really don't want to just look at the formulary and the rebates. Much more important, I think, and I haven't looked at the spreadsheets on this stuff, but is the ability of the plan -- of the PBM -- to actually move people to generics, to be able to use appropriate drugs within certain classes. And there's a pretty limited set of

classes that you can get an enormous benefit out of.

So I am interested in the notion of the change in the formulary. And certainly that is a switching cost if, you know, you go right over to their formulary, you're going to get lower prices than if you don't go right over to their formulary. I mean, it's a cost, but I think it needs to be put into context of the potential opportunities that exist in a change in general.

MR. CALFEE: Just one comment on -- the Cox II is an interesting case actually. We fund a research group that does research on how prescription drugs are actually utilized after post introduction, which is an area that's not studied very well.

And what we found is that there's a very, very high percentage of the Cox II's that are prescribed for which the indication for use is not apparent.

Now the only benefit of the Cox II's over the other meds, including a lot of OTC products, is that it tends to reduce gastrointestinal complications. When you're looking at a prescription for a Cox II for a 30-day supply, you have to ask yourself why. In 30 days you're not likely to develop a -- you know, these are being prescribed, in other words, for acute, short-term problems, like an injury, not really a clinically appropriate use of a Cox II -- unless the patient has a

history of an inability to tolerate the other products.

So one of the things we're talking with our clients about is the potential to prior authorize the Cox II's through a step therapy program which requires the use of the OTC or generic product before you move up to what are the very expensive Cox II products.

That's not a rebate-driven plan design for the PBM, I might add because typically the manufacturers won't pay rebates on prior-authorized products. So we are looking to drive -- you know, we're trying to focus our client on net cost reduction; and the Cox II is an interesting case of how that might be done.

DR. HYMAN: Let me throw out one other question and just ask people to react to it. It seems to me that PBMs can either be paid through administrative fees, or rebates, or some combination; and in that regard they're really substitutes for one another.

So the question is, apart from the history, particularly given the controversy that seems to surround rebates in the current environment, what's the logic of continuing to rely on rebates? Is it that it gives a performance incentive to the PBM? Is it that it prevents arbitrage? Or is it something else?

MR. BARRUETA: In terms of the use of rebates generally or the retention of rebates by the PBM?

DR. HYMAN: Well --

MR. BARRUETA: Because the use of rebates -- I mean, it's the mechanism by which price reductions are realized in the network model.

DR. HYMAN: They used to do that with ex ante discounts as opposed to six to nine, or even a year later, rebates, right?

MR. BARRUETA: I'm not sure how you would do that actually, because the structure of the market is a negotiated reimbursement rate with the pharmacy. There's no direct sale of the drug from the manufacturer to the PBM except in the mail order context. And you can see, you know, the relative benefits of doing that based on some of the data that was shown.

But I don't think you are going to get away from rebates because it is the most probably expeditious and least complicated way to realize price discounts in the market, when you consider that most of the drugs are going to flow through another party, the retailers.

MR. BOUDREAU: I think ideally a client would like us to -- would like our financial interest to be aligned with the client's financial interest. So, as I pointed out in my presentation, there are generally three potential sources of revenue in a PBM agreement -- three major sources -- the network margin, the difference

between what we pay the pharmacies and what the client pays us for the network script; manufacturer rebates and the associated administrative fees, or related fees; and then, finally, there's the administrative fee the client pays. Also, there's the mail order margin.

You know, a well-informed and well-advised client will try to get an alignment of interests on all of those issues, so that we have an incentive to maximize rebates, we have an incentive to negotiate the very best discount in the network that we can, the client can pay a reduced administrative fee, and so on.

Clients have different approaches. I mentioned the example of our client earlier that really wanted rebates up front, so to speak. And in that case, we're able certainly move those pieces around. The dollars are, in a sense, fungible as far as we're concerned, but we have an ability to move those pieces around to meet the client's requirement. And, in that case, in effect the client gets the rebates at point of sale.

DR. HYMAN: Anybody else?

MR. RICHARDSON; Just a comment. Thinking about a point that Tom raised earlier about the coming change of a number of brand name drugs to generics over the next 7, 8, 9 years; and given that rebates are driven by brand name drugs, it's going to be interesting to see.

The dynamic may change for reasons beyond, you know, is it the right business model just because the source of funding is going to change significantly.

DR. HYMAN: All right. Well, I'd like to thank the panel for a really excellent set of presentations and a lively discussion.

And we will reconvene at 2:00 to talk about prospective guidance and I'll ask the audience to join me in a round of applause for the panel.

[Applause.]

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A F T E R N O O N S E S S I O N

MR. BYE: Good afternoon and welcome back to the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy.

My name is Matthew Bye and I will be co-moderating this panel with Eduard Eliasberg from the Antitrust Division of the Justice Department.

Today we're going to examine the provision of health care related prospective guidance. We'll focus on the processes by which guidance is provided, including the issuance of advisory opinions by the FTC, business review letters by the Justice Department, and guidelines.

We'll also consider the provision of prospective guidance by the State Attorneys General and the U.S. Department of Health and Human Services.

We have eight distinguished panelists this afternoon and we've only got until 5:00 p.m. So very briefly, I will introduce each of the panelists in the order they will give their presentations. The panelists' complete biographies are available in the handouts.

Jeff Brennan is the Assistant Director for Health Care Services and Products in the Bureau of Competition at the Federal Trade Commission.

Claudia Dulmage is a member of the Department of Justice Antitrust Division's Health Care Task Force,

and has authored many business review letters in that capacity.

William Cohen is Assistant General Counsel for Policy Studies at the Federal Trade Commission, and an author of the "Antitrust Guidelines for Collaborations Among Competitors."

Jeff Miles is a principal at Ober, Kaler, and Chair of the American Health Lawyers Association Antitrust Practice Group.

Clifton Johnson was vice president/general counsel of an Ohio teaching hospital before becoming a partner and chair of the Health Economic Practice Group at Hall, Render, Killian, Heath & Lyman.

Joining us by phone, Warren Grimes is a professor at Southwestern University School of Law and is currently on leave as a senior research fellow at the American Antitrust Institute.

Ellen Cooper is Chief of the Antitrust in the Maryland Office of the Attorney General. She's also chair of the Health Care Working Group of the Multi-State Antitrust Task Force of the National Association of Attorneys General.

Vicki Robinson is Chief of the Industry Guidance Branch at the Office of the Inspector General, the U.S. Department of Health and Human Services. She's

active in reviewing health care fraud and abuse issues.

Panelists will be talking for 10 minutes today.

Cecile Kohrs has green, orange, and red signs to indicate time. And just also note that two of our panelists will have to leave early today. They weren't able to join us for the panel discussion.

I'll ask Jeff Brennan to start with your presentation.

MR. BRENNAN: Thank you. Good afternoon. I appreciate the opportunity to talk today about the advisory opinion process at the FTC, particularly in the Health Care Division, which is the shop where I am. And we seem to get the most requests for advisory opinions of any in the bureau.

The overall topic is prospective guidance and I thought it would make sense at least to mention it's not just advisory opinions, but the Commission has a host of resources and sources for folks outside the agency, and inside the agency for that matter, to learn about FTC policy and approaches to different enforcement and antitrust issues.

Our Web site is www.ftc.gov, and whenever I speak to groups, I usually tout the Web site because I personally believe it's outstanding and there's really a wealth of information on the Web site about the entire

agency and our -- the enforcement actions and so forth at the agency. And the health care page, in particular, has a wealth of information.

This first slide just is a -- you can see the page there and there's several resources listed for health care antitrust issues for people to go. The statement of antitrust enforcement policy in health care, of course -- our actions in health care services and products over the years, a separate site to our pharmaceutical practice area -- Commission actions -- advisory opinions -- and so on.

If you click on advisory -- well, first if you click on the guidelines, of course, there's several guidelines that guide us in the Health Care Division. The health care statements are where we would turn the most, I suppose, but there are certainly other resources that we turn to on the staff, the collaboration guidelines -- particularly, with respect to the pharmaceutical industry, cases that we address.

The license of an intellectual property guidelines are another source that are on the Web site that are sources of guidance both for the staff and for practitioners.

With respect to advisory opinion, we have a link on our Web page there, on our Web site, for all the

advisory opinions that the staff has issued, or the Commission, since 1982, when the data was accessible and available. And they're all listed in this index.

And you go into the index and you can see a list, again on the Web site, of all the advisory opinions that go back in time. This page, obviously the most recent ones in the last year or two.

Some common questions that folks ask when they enquire. Occasionally, clients will ask their lawyers about "Can't we get some insight from the FTC on this issue?," and it's not infrequent when I'll get a call, or colleagues of mine in the office will get a call about "How does this advisory opinion process work? What do we have to do?"

An advisory opinion is a statement of a legal opinion of the Commission or its staff with respect to a party's proposed course of action. And "proposed" is an important modifier there which I'll talk about in a second.

Usually, most advisory opinions come from the staff and, in the course of the analysis laid out in the advisory opinion, the staff will summarize in a sense as to whether or not the proposed course of conduct would be something with respect to which the staff would recommend that the Commission take an enforcement action -- or not,

for that matter.

Who can request? This is right out of the FTC rules. Any person, partnership, or corporation may request advice from the Commission with respect to a course of action which the requesting party proposes to pursue.

A few important caveats there. The request must relate to future, as opposed to ongoing, conduct; and it must relate to prospective conduct of the requesting party. We don't respond to requests for advisory opinions about the outrageous conduct of one's competitor, for example, or something terrible that its customer is doing, or supplier. It has to be conduct engaged in by the actual requestor.

It's important to note that it's free and there are no filing fees or other types of charges.

I came to the Health Care Division two years ago and I never appreciated the tremendous service that these advisory opinions are till I saw first hand the amount of work that goes into them. Lawyers in private firms get paid a lot of money for writing advisory opinions to their clients and the Commission staff engages in the same rigorous-type analysis for the same types of clients. The big difference is, it's free.

And so I had to see first hand, I guess, to

really appreciate what a service they are and I know it's the same in the Antitrust Division.

The difference between a Commission and a staff opinion. Again, right out of the Commission's rules, the Commission may issue an opinion where the matter involves a substantial and novel question of fact or law and there is no clear Commission or court precedent, or the subject matter of the request and consequent publication of Commission advice is of significant interest.

The Commission has authorized the staff to consider all other requests for advice. Now in practice, the large majority of the advisory opinions that have come out of the agency are staff opinions. There's 93 opinions laid out in our Web site index, again commending in 1982; and all of 8 of those are staff opinions. Ninety-three are staff opinions and 8 are Commission opinions; and there hasn't been a Commission advisory opinion since 1994.

There are limitations on whether an opinion would be available. We don't answer hypothetical questions. We answer questions with respect to actual proposed conduct. A request will normally be considered not appropriate where the same or substantially the same course of action is under investigation by the staff, or is or has been the subject of a current proceeding

involving the Commission or another government agency.

It would also be unlikely that we would issue an opinion, or not likely, or not -- an opinion would not be forthcoming if an informed opinion can't be made or could be made only after extensive investigation, clinical study, testing, or collateral enquiry.

Again, that would go beyond the purposes of the advisory opinion process and probably would eviscerate the service that they provide were such an opinion solicited that would require this kind of detailed factual investigation.

And as I mentioned, the conduct must be proposed rather than ongoing. We do not give advisory opinions on conduct that persons in industry have already chosen to engage in.

What must you disclose if you request an advisory opinion from the staff? Not surprisingly, enough information for us to evaluate the conduct. Our rules require that you state clearly the questions that the applicant wants resolved, cites the provisions of law under which the question arises. It's typically Section 5 of the FTC Act, of course. And it's usually their -- obviously, conduct that would involve an agreement among competitors most of the time. And of course the requestor must submit all relevant facts that it believes

would be material.

The identities of the companies or other persons must be disclosed. We don't respond to anonymous request for advisory opinions. The request letter and material submitted by the requestor are placed on our public record when the opinion letter is issued. That's again right directly out of the Commission rules.

And in those letters that, again, become public, staff discloses basic facts and they do so to third parties as well from whom we seek information during our consideration of a request.

We do, from time to time, if there's an advisory opinion that comes in with respect to certain conduct in a certain area, contact third parties in that area to help assess for our own purposes -- both factual questions that may come up, as well as to help us develop our analysis as to the legal implications of the proposed conduct.

Can information be protected on a confidential record? Yes. If the information is exempt from disclosure under FOIA or some other law, you have to ask for confidential treatment and specifically describe your basis.

We do not issue confidential opinions. They must be made public right out of our rules and it we must

describe the proposed conduct in sufficient detail to support the analysis. There's certainly the function of an advisory opinion not just to the requesting party, but also to other interested persons in industry and law, and so forth. That's an important function of our advisory opinions and so we need to be able to state sufficient facts publicly to clarify what it is we're actually providing opinion about.

Opinions are not binding on the Commission. There's a long quote in the slide here which I won't read. But it's 16 CFR, Section 1.3(b).

The Commission would give advice without prejudice to the right to reconsider the opinion at a future time. And there's rights built into the party to give the party, for example, a chance to stop the conduct and so forth.

The Commission can rescind staff advice and, where appropriate, commence an enforcement proceeding even after a staff advisory opinion has been issued. And with that standard language in the advisory opinions that the staff issues that it's without prejudice to the Commission.

To my knowledge anyway the Commission has not rescinded any advisory opinion that's been issued heretofore.

There's a time component to an advisory opinion. The health care statements, the Joint FTC-DOJ Health Care statements lay out certain time frames which trigger, after all necessary information is received, 90 days regarding any matter addressed in the statements, except for hospital mergers outside the safety zone, and with respect to multi-provider networks. And as to those networks, 120 days; and same time period for other non-merger health care matters.

Now in practice, the amount of time it actually takes from the initial request to the issuance of the advisory opinion turns on how much information is necessary for us to make an informed judgment and how complex the issues are. Pretty obvious, I think.

What is reasonable to expect an opinion to do? Our process is best suited to questions concerning our analysis of particular types of conduct where facts concerning market definition are fairly clear and market power is not likely to be present.

Questions about what is the relevant market, or where assessments of market power would be required are, you know, largely and usually factually intensive; and again, that's beyond the true function of an advisory opinion.

We don't routinely investigate to verify

information that's provided to support market definition or market share and the conclusions in the opinion letter are conditioned on the accuracy of the facts made in the request. And if one was to go into the Web site and look at some of the advisory opinions that have been issued, I think they always made clear that the staff is relying on the representations made by the incoming letter, usually by counsel, as to factual issues relevant to the requested analysis.

As I mentioned earlier, sometimes we do ask for information on a voluntary basis from third parties to help us assess fully the nature of the conduct that's at issue. We don't compel, and we can't compel, compliant third-party cooperation.

The Commission doesn't issue subpoenas and so forth in the advisory opinion process; and so we may not have access to all information from all relevant sources, but we do the best we can. And as I said, we do largely rely on the facts that are proposed to us in the incoming letter, or submitted to us in the incoming letter, and the opinion that we issue turns on the accuracy of the facts that are represented to us.

Just in the remaining time, we went back and made a few bar graphs and so on to take a look at the advisory opinions.

Well, the number of them is what this slide shows. It tracks advisory opinions annually since 1982, which is when the advisory opinions are first -- the first year in which they're compiled in the Web site. And it's kind of interesting to see the ebb and flow of advisory opinions by year. The highest bar is in 1994 -- '94, '95, '96 was a period of spikes in the issuance of these advisory opinions; and the vertical axis is literally number of letters. So the top line there is 12 in the year.

Now those periods coincide with just before, during, and after the issuance of the health care statements; and there may or may not be a correlation between the demand for the statements and their issuance and the request for advisory opinions.

They seem to fall off in '98 and '99. In 2003, where we are now, the number of incoming requests and issuance of advisory opinion seems to track fairly consistently with the non-spike years over time.

Distribution. We also played around with the advisory opinions. Again, these are all taken right out of our Web site to try to assess by category the types of requests that we've received and the opinions that have issued since 1982.

Now these do some double counting in a sense.

If a request for an advisory opinion and the actual opinion covers a couple of different issues that we segregate out, they're counted under the different columns there on the horizontal axis.

So there's a little double counting; it's not a whole lot.

You can see network joint ventures. It's by far the area where we've had the most advisory opinions over the years.

The Robinson-Patman Non-Profit Institutions Act requests come in in second place; and just in the two years that I've been in my current position, we've had three or four NPIA requests. So it's just an interesting -- they don't -- there's no NPIA references in the health care statements and there's not a lot of enforcement activity in that area, of course, but the requests do seem to come in with some regularity.

And just in these remaining slides, what we did is we looked -- during some years when the requests were high -- what the breakdown was. 1997. Again, network joint ventures was the leading topic area of advisory opinions. Then one each in different categories, you'll see there.

1996 was a big year for the NPIA requests; but again, network joint ventures was -- with three, which

was high for that year. Network joint ventures again in 1995, led the pack in terms of the topic area.

I don't think that's probably too surprising to practitioners in this field that those are the areas where the competitive issues can be most complicated many times and where there's been a lot of activity in the last decade or so among joint venturers -- particularly among providers -- in putting together network joint ventures. And the request for guidance reflect that.

Now we didn't go back and check the DOJ business review letter statistics, but I wouldn't be surprised if the topic areas were pretty much parallel to the topic areas that the commission received during these periods.

Same kind of thing in 1994. Went back to 1984, which was another year. We had 8 advisory opinions that year. Network joint ventures, 3; providers -- collective provision of free related information also had 3; and so on. So.

We broke out 1985 and that's the end of my slides. So in conclusion, I just -- I do think that these advisory opinions are an immense service and we take them exceedingly seriously. We put a lot of effort into trying to come out at the right place. And I expect we'll be facing more in the coming months and years.

Thank you.

[Applause.]

MR. BYE: Thanks very much, Jeff.

Claudia Dulmage will give the next presentation.

MS. DULMAGE: I'd just like to clarify at the beginning here that following Matthew's brief bio's that he gave that I'm no longer in the Health Care Task Force because the Health Care Task Force does not exist any more at the Department of Justice; and about half of the members of the former Health Care Task Force are now part of the Litigation 1 section, which is where I am these days.

I'm very honored to be among this group of distinguished panelists to talk about prospective advice today; and I just wanted to preface my remarks by stating that these comments reflect my personal views and are not necessarily those of the Department of Justice or of the Antitrust Division.

As we all know, in September of 1993, the Department of Justice and the Federal Trade Commission issued six statements of their antitrust enforcement policies regarding mergers and various joint activities in the health care area.

At that time, the agencies also committed to

issuing expedited Department of Justice business reviews and Federal Trade Commission advisory opinions in response to requests for antitrust guidance on specific proposed conduct involving the health care industry.

Policy statements and the expedited specific agency guidance were designed to advice the health care community at time of tremendous change and to address as completely as possible the problem of uncertainty concerning the agencies' enforcement policies that some had said might deter mergers, joint ventures, or other activities that could lower health care costs.

So here we are now 10 years down the road and it seems to me that the question we should be asking today is "Have the agencies accomplished their goals in this area?"

Based on the number and time timing of business review requests submitted to the Department, and as we saw, I think this also applies to advisory opinion letters at the FTC, I think the answer to that question is a resounding yes.

The number of business review letters issued after the first publication of Joint DOJ-FTC Guidelines in September of 1993, were 12 in 1994 -- fiscal '94 -- 10 in fiscal '95; 17 in fiscal '96; 11 in fiscal '97; and then the numbers drop for all subsequent years to 3, 1,

1, 2, 2, and zero.

And we have put together a little graphic as well to show what this looks like in chart form. And as you saw with Jeff's presentation, the FTC's experience is somewhat similar with number dropping off sharply after 1997.

Now the conclusion I draw from the numbers here are that clearly the health care community used the business review letter procedure heavily during the time when the guidelines were new -- a period that stretched over three years as revisions continued to be made.

During that time, the health care providers, and payers, and their counsel were clearly testing the waters with numerous requests for advice regarding specific situations that may or my not have fallen within the parameters of the safety zones or the anecdotal examples provided in the guidelines.

What also seems clear is that with each new issuance of advice the whole health care community, or at least the health care legal community, was paying attention. They were all reading the business review letters and advisory opinions that were issued and adding them to their store of knowledge and understanding about the lines that were being drawn at the Department with regard to collaborative health care activities.

As a body of knowledge about potential problem areas and the agencies approach to them developed, there was less and less need for industry players and their counsel to seek advice on how to interpret either the antitrust laws in general or the guidelines in particular.

Accordingly, the stream of requests for advice has now slowed to a trickle. Indeed, there have been no requests for the Department's advice for over a year.

In my view, this points to a successful public education campaign; thus, we would now expect only the occasional request when parties are planning something unusual or innovative and they do not feel comfortable relying on past business review guidance, or the guidelines themselves before proceeding with their plans.

On the other hand, it's always possible that activities that are clearly anti-competitive will deliberately not be disclosed to us, or in the alternative the parties may believe that it's easier to obtain forgiveness than permission.

And in those instances, of course, we rely on members of the public adversely affected by such activities to report them to us so that we can ascertain the facts.

Let's talk a little bit about the ones that

don't appear on the chart. I just point out here that these statistics do reflect only the number of business review letters that were issued. As you may be aware, that number does not coincide with the number of requests received which is somewhat larger.

The difference represents the number of requests that were either withdrawn or for which the Department declined to provide business review advice. The business review procedure, as codified in 28 CFR Section 50.6, allows the Department to, in its discretion, refuse to consider a request, or to decline to pass on the request.

While I have never known the Department to simply refuse to consider a request, we have certainly declined to give advice on a number of occasions. In virtually every instance, this denial was based on the fact that the request violated Section 2 of our procedure which states that the Division will consider only requests with respect to proposed business conduct.

That is, our investigations determined that the proposed conduct had already been implemented in one form or another. And despite the fact that paragraph 10(d) of our procedure allows the department to issue a press release disclosing the names of the requesting parties and the nature of any action taken by the Department in

response to the request, I've never know the Department to do so when it has declined to issue advice.

The CFR procedure also allows the requesting parties to withdraw their request at any time. Generally, this occurs when the requesting parties begin to sense that the business review they receive will be a negative one.

At that point, almost everyone chooses to withdraw rather than suffer the public disclosure of their proposal and our negative reaction to it. Thus, there are only four instances over the last 10 years of issued negative business review letters. The reasons that these letters were actually issued and saw the light of day, rather than the parties withdrawing their requests can only be surmised.

However, I'm glad that at least this handful of negative letters was issued because I believe the health care community much more valuable learning from the negative letters than from the positive ones.

I'll just briefly mention here the differences between the FTC and the Department of Justice approach to prospective advice. I don't think I'm giving away any secrets when I say that the approaches are somewhat different, a fact that is no doubt based on our historical practices. When the two agencies decided to

jointly publish guidelines and to expedite their response to written questions, they did not institute a joint procedure for giving that prospective advice. Rather, each agency relied simply on the procedure it already had in place.

For us, that was the business review letter, something that had grown out of the so-called railroad release letters of the 30s and 40s; and for the FTC, it was the advisory opinion letter, a long-standing Commission procedure provided for in the FTC rules.

As I understand it over working with FTC staff and talking about these things over the years, FTC staff, as DOJ staff, generally review a request for advice. They seek clarification of statements that seem incomplete or unclear, as do we; and then issue a legal opinion as to whether the proposed conduct would violate the federal antitrust laws.

The Department of Justice, on the other hand, goes through the same initial procedure, seeking clarification from the parties, and then we do conduct an investigation to test the assertions in the request letter -- for example, regarding market definition or the number of viable competitors in a market.

This investigation can be fairly lengthy and complicated and can result in challenges to the facts as

presented by the parties. When we are satisfied that we know the facts, we state our enforcement intentions with regard to the proposed behavior.

The two agencies have conferred over the years about possible ways to reconcile these two quite different approaches. And I believe that the result has been an increased level of fact testing by the FTC, and on our side, a determination by the Division to rely more on the materials presented by the parties -- whether with the initial request or in subsequent productions at the request of staff, unless on contacts with third parties or mediation with request or whose proposals require extensive modifications to draw a positive letter.

Beyond that, the two agencies have maintained their separate and distinct framework for providing prospective advice.

In the end, I think these differences in approach probably stem from our formal rules long since adopted by each agency; and in the case of Justice, our procedure states at paragraph 5 that "In connection with any request for review, the Division will conduct whatever independent investigation it believes is appropriate;" while the FTC's codified procedure states that "Parties may seek advisory opinions for any activity that, among other things, does not require extensive

investigation."

While the public may have wished that an entirely new and standardize procedure be developed in 1993 when the agencies jointly introduced the health care guidelines and announced their willingness to provide prospective advice about them, I do believe that both agencies have done a commendable job of answering the public's questions about where the lines are drawn in collaborative health care ventures.

In closing, I would just observe that this program seems to have followed the pattern of several other government initiatives that have offered the business world various forms of comfort with respect to the antitrust laws.

Web business associations, export trading companies, certificates of review, and notifications pursuant to the National Cooperative Research and Production Act of 1993 are all examples of comfort-giving programs that saw a flurry of activity when first enacted, followed by significant drop-offs in public interest over time.

In all these cases, the patterns are hopefully a sign that the public has come to understand the law, to generally know its limits, and to require little further guidance from the antitrust Agencies.

Thank you.

[Applause.]

MR. BYE: Thanks very much, Claudia.

William Cohen will give the next presentation.

MR. COHEN: I'm very pleased to have this opportunity to speak with you. I have in the past, several times, served as a moderator for panels such as this, but this is the first time I've been a panelist, so it will be a somewhat new experience to be able to use sentences that end with periods rather than question marks.

With the power of the period though, I think comes the need to offer the standard disclaimer that the views I'm expressing are my own, and they're not necessarily the views of the Commission or of any individual Commissioner.

I think I've been asked to talk to you because I've seen the drafting process for a number of guidelines from varying perspectives. I was one of the drafters of the Competitor Collaboration Guidelines and I worked within the Chairman's office on all the other guidelines projects between 1989 and 1995 in the competition area. That includes the Merger guidelines, the Guidelines for the Licensing of Intellectual Property, the Competitor Collaboration Guidelines which I've already mentioned,

the International Operations Guidelines and the Health Care Statements -- the Competitor Collaboration Guidelines, of course, coming later.

I'll try to give you some insights regarding what the agency confronts when they're undertaking a guidelines process and I'll be speaking generally rather than just in the context of health care.

Essentially, we have a set of costs and a set of benefits here. I'm going to start with the benefits, but I'll probably spend more time talking about the costs simply because they may not be as well understood by people who have been outside the guidelines preparation process.

Let's examine the benefits. Clearly, there's the obvious benefit of guidance; and this guidance may be very helpful for businesses in planning their conduct and for their attorneys in counseling them how to proceed.

Typically, this guidance is directed towards satisfying an identified need for guidance that's come -- that's developed. In the case of the Competitor Collaboration Guidelines, for example, the need, I think, is identified in the 1995 hearings on global and high tech competition wherein we were told time and again that one thing that the agencies could do that would be very helpful would be to give further guidance on joint

venture activity.

The health care statements flowed from a recognition of rapid market changes and developments and a business need to understand the antitrust landscape.

When need is identified, guidelines can help fulfill the agency's responsibility to aid the public in understanding competition laws; and the implications of those laws for business activities; and for removing, to the extent possible, any mis-perceptions that might deter lawful conduct.

Guidelines have a further value in providing a common framework for discussions when we meet with outside counsel. The fact that guidelines are in place and the counsel has read them helps ensure that the arguments go to what we really want to learn about and it helps counsel to understand where the agencies are coming from in the discussions. And, of course, if guidelines are persuasive, they may influence the courts. They may be a way to shape the law.

A second set of benefits may be less obvious than the giving of guidance, but guidelines -- the drafting of guidelines in preparation for guidelines can be very useful to the agencies in helping to think things through. This can be just even at a very basic level of terminology -- an example from the Competitor

Collaboration Guidelines context.

You often read in court cases that deal with these issues discussion of ancillary restraints. Well, it's not until you sit around a table with people and try to draft examples, or try to write up sentences dealing with the concept of ancillary that you realize that everybody has a slightly different idea in mind when they use that term.

Is it talking about what's reasonably related to the venture, is it talking about what's reasonably necessary, what contributes to the venture? When you have to actually put it down in guidelines, you have to go through a thought exercise. It's very useful to the agencies.

Going to both of these benefits, I think that guidelines are sometimes most successful when they cause us to encapsulate and convey a very basic thought process, such as the core principles that are stated at the start of the intellectual property guidelines, principles such as "Agencies don't presume market power from the existence of intellectual property;" or when the guidelines explain a method for analyzing a recurring issue, major recurring issue such as how do you define irrelevant market set out in the merger guidelines?

Let's turn to the costs. One obvious one is

that guidelines are very resource intense. Speaking from the perspective of the collaboration guidelines, many, many hours went into identifying key issues, gathering and assimilating the best thinking on each, bringing in the litigation perspective, and the policy perspective, and the case law and the economics; and sorting through where you'd want to come out, putting it all into precise words that convey what you want.

And after all that's happened, then it first leaves the drafter's desk, the first drafter's desk; and there's the whole process of coming to agreement with others in the enforcement agencies that this is the best approach to take and that these are the best words.

And, of course, there's experience that accumulates. Even after you have the guidelines in place, you may want to add guidance, you may want to update or extend the guidance to make sure that the guidance remains useful. I think we've seen this over the years with the health care guidelines, the health care statements.

This takes a lot of time and it takes some of the time of the best, very best people in the agencies; so you can't undertake these processes lightly.

A second type of cost flows from the fact that even if you're willing to spend the resources and come up

with guidelines with very good information in them, there is still potential of temporary confusion and unintended incentives.

Under the heading of "confusion," I'm thinking of a phenomenon that we've sometimes referred to as "seeing ghosts." Even if the guidelines are drafted very precisely, different readers -- readers will have different perceptions and they'll attach differing connotations to the words. They'll read your language with those perceptions and connotations in mind and sometimes they'll see things that no drafter ever thought were there.

Certainly, this can be dealt with and frequently it's dealt with through post-guidelines speeches and the confusion ultimately resolves itself.

Perhaps a little bit more difficult to resolve though is the problem of the unintended incentives. I think safety zones are a good example of this. They pose a problem that sometimes is difficult to deal with. Boundaries set in the safety zone inevitably will be placed at a level that gives maximum assurance to the agency that there won't be a competitive problem; yet, once you tell a firm that as long as conduct stays within given boundaries that conduct is going to be okay, the inclination -- the natural inclination will be to play it

safe and stay within those boundaries. We've seen this in the Competitor Collaboration Guidelines with a 20 percent safety zone; and I think we saw it in the health care statements with a 20 and 30 percent share safety zones for exclusive and non-exclusive networks.

So a safety zone intended to free up business conduct actually can discourage some firms from taking full advantage of flexibility they really have. All the agencies can do is stress repeatedly that conduct outside the safety zone will often raise no competitive concerns and hope that over time this message will become understood.

A third and final set of costs that I'd like to talk about flows from the aspects of the process that make giving good information difficult. There are four factors here.

One is -- to begin with, there's a natural tendency to be very cautious. What ends up in the guidelines is sometimes the least common denominator of the thinking of those who had worked on it. On one hand there are litigation concerns. Anything that in some manner, shape or form can be used, even if twisted or distorted, against the agency and come back to hurt us, the litigators are obviously going to say perhaps shouldn't go into the guidelines and will resist that.

There could be differences of opinion often with the result of limiting the guidance to the areas where there's agreement. Consequently, what's most interesting, or potentially most interesting, sometimes might get left on the cutting room floor.

Second, there's a problem of dealing with issues where state-of-the-art analysis doesn't yield many definitive conclusions. Here there's a difference of views. Some argue that it's better to say nothing if you can't give thorough guidance on an area; but others would take the approach that even knowing that it may not fully satisfy readers, you should say what you can. Perhaps you can identify the factors that you've considered, or that you will consider, even if you're not at a point where you tell how you can weigh them.

A third barrier to giving useful guidance can be the possibility of differences between litigation frameworks and the analysis employed in determining whether to bring an enforcement action. Case law can take time to respond to advances in thinking; and this poses something of a dilemma. You want the guidelines to reflect the way you actually analyze an issue; but litigation must proceed in terms and using a framework that a court, working from case law, will understand and accept.

Another factor is that assignments of burdens are often very critical in litigation. They play a much lesser role in many guidelines context.

The problem is limited in one sense in that the results, under the two ways of looking at things, are generally -- ought to be the same, but the format of the explanations as to how you get there may differ. I say the results generally ought to be the same because there's always some room for prosecutorial discretion.

And again, this poses a problem for guidelines writers. To the extent you give guidance as to how you exercise, or are likely to exercise, this discretion, there'll be tension with any litigation posture. To the extent that you don't give guidance in this area, you've limited the transparency that the guidelines permit.

This is just a tension the guidelines writers always have to face.

Finally, I'd like to flag an issue that's out there in defining what is good guidance. Guidelines may go to more than one audience; and to the extent that the audiences vary in sophistication and in need, what is useful for one may not be ideal for another. If you don't reach the cutting edge of analysis, practitioners with sophisticated specialized antitrust practices may respond that these guidelines present nothing that's new.

Yet the same set of guidelines may be tremendously valuable to others. Corporate counsel knows its clients from time to time need basic antitrust counseling.

In closing I'd like to add a couple words about one other guidance format and that's reports on hearings such as these.

It's interesting because it flags a difference from what guidelines can present. The report format permits expressions of thinking in the format on the one hand and on the other hand; and, at least in some instances, ambidexterity may have some virtues.

The report format permits you to identify a problem and set out the pro's and con's of all the best alternatives. Sometimes this can help advance thinking far enough to go on to issue guidelines. This is what happened with the efficiency guidelines in the merger context which flowed from the report on the 1995 hearings. And sometimes the report itself can add very great value just on its own.

Thank you.

[Applause.]

MR. BYE: Thanks very much, Bill.

Jeff Miles will give the next presentation.

MR. MILES: Thank you very much, Matthew.

I guess if there's no other point that I get

across today, I think the point I want to get across is that except with regard to enforcement actions by the agencies, I think the advisory opinions that both issue are the most important thing they do.

They're certainly the most important part of putting together the advice that I provide clients and I'm very appreciative to have them.

But, as some people have mentioned, the forms of perspective advice the agencies provide go well beyond the advisory opinions: Certainly the complaints the agency files, the consent orders and the consent decrees provide perspective advice; speeches of agency officials; Congressional testimony by agency officials; letters from the agency staffs to state agencies -- such as the Sladell Hospital Letter that the FTC issued recently -- the advisory opinions themselves; and, of course, the different sets of guidelines.

And in health care we have the statements, but also the collaboration guidelines and the merger guidelines are extremely helpful as well. And I guess I would point out that perhaps you should not overlook old guidelines or statements. In 1981, the FTC issued a statement on physician control of pre-paid medical plans, which I still find helpful today with regard to physician merger work, network work, and similar types of work.

So, as Jeff Brennan mentioned, there's a substantial amount of guidance out there.

The other thing I think worth remembering is the federal agencies are not the only ones who have advisory opinion processes; a number of the states do also. But one of the problems, I think, is I find it difficult -- and I hope Ellen will talk about this -- I find it difficult to identify those states that do have advisory opinion processes. I also find it difficult to find the procedures that the different states have.

And, Ellen, I might suggest, as you probably know, the Trade Regulation Reporter prints all of the various state antitrust statutes and I'm wondering if the states could suggest to CCH that perhaps if they have opinion -- advisory opinion processes, they might be added to each state's section.

And then finally, as I discovered a couple of years ago, it's very difficult to actually put your hands on state AG advisory opinions. Our law firm got an opinion from Ellen's office a few years ago, but I don't know that it's published anywhere.

There are a number of state advisory opinions that are published in the trade cases; and Might also suggest that perhaps NAG could put together a compendium of state advisory opinions in the antitrust field, or the

AGs or NAG could again suggest to CCH that these advisory opinions be printed in the trade cases. I think that would be a big help to all of us.

Look -- turning now to the federal advisory opinion process, I don't want to embarrass Judy Moreland, but back in 1997, Judy gave an presentation to I guess what was then the National Health Lawyers Association outlining how the advisory opinion process works and also providing some of her own thoughts on how to go about obtaining advisory opinions from both the Antitrust Division and the Department of Justice. And the outline that she presented is as worthwhile today as it was then; and if you look at my attachment, that outline is attached as part of that.

The advisory opinions of the agencies to someone in my position in private practice are crucially important. I can't believe a day goes by that -- in some way, shape or form -- some of the advice that I provide is not related to some of the advisory opinions that the agencies have provided.

If my count is correct, and it may not be, I think since 1990, the agencies together have issued about 122 advisory opinions. About 69 of those have been on networks and sometimes I think the agencies, or at least some staff members at the agencies, underestimate the

importance of these advisory opinions to those of us in private practice. Often they discuss issues on which there are no case decision; and often they're the only legal guidance we can obtain; and sometimes subconsciously, I think some of us look at the advisory opinions as "the law" on particular issues where there is little guidance.

I've always been impressed with the willingness of the staff members I've dealt with to help out with advisory opinions in the sense of making suggestions that are very helpful in the process. The Federal Trade Commission, for example, in one instance suggested that I submit a request in draft form, which I did. The staff had a number of helpful suggestions for how the request letter could be improved and we subsequently requested what I thought was a vastly improved request.

The staff members appear always willing to sit down and flesh out the issues of the letter. I can tell you the sessions with the staff members, I have found very educational from a personal standpoint and enjoyable. The staff members have always seemed candid, and open, and not trying to push a particular position; and, in some situations, the staff members have actually been able to suggest improvements to the program or the proposal that I've brought to the agency for its review.

And then finally, I would mention that some people have indicated that the agencies tend to be overly conservative in the conclusions they reach in staff advisory opinions; and, frankly, if you look particularly at recent opinions -- the PriMed opinion from the FTC; the MedSouth opinion from the FTC; the Washington State Medical Association opinion from the Department of Justice -- I don't see how anybody can look at those opinions and take the position that they represent and overly conservative approach. They seem candid and well analyzed to me.

So I guess you can tell, overall, as far as the advisory opinion process is concerned, I don't have a whole lot of problems. I have a couple of questions. I wonder, for example, if those requesting opinions should be permitted to withdraw the opinions because frankly negative advisory opinions are very helpful. For example, the Antitrust Division, if you look at the Children's Health Care Network advisory opinion, which resulted in a negative opinion, it's a very well analyzed letter and very helpful; and the same is true of the Allentown Gastroenterologist Physician Practice merger letter.

So I suppose I'd like for the -- I realize there are costs to not letting requestors withdraw

opinions, but I'd like the agencies to at least consider whether, once a decision is made to request an opinion, the requestor should be permitted to withdraw it.

And then the only other thing I'd mention about advisory opinions themselves is, I do wonder if in some situations the process might be sped up to some extent. And that's really -- I wonder sometimes if the agencies give the opinion process the priority that at least I think it deserves.

I'd like to make a few other suggestions, or at least raise a few questions with regards to some of the other mechanisms for advice.

With regard to the health care enforcement statements, I think the agencies ought to consider whether they ought to re-examine that portion of Statement 8 and Statement 9 on clinical integration. I don't know whether it should be deleted, but I think at a minimum there needs to be more discussion on clinical integration in the guidelines if it's going to remain; and particularly situations in which joint negotiations might be ancillary to a clinical integration program.

In Statement 9 I think the agencies should consider a more in-depth discussion of messenger models because we continue to see networks -- either intentionally, or unintentionally -- violating messenger

model principles, very frequently in similar ways.

Especially in light of the 9th Circuit's recent decision in international health care management, I think there ought to be more discussion in Statements 4, 8 and 9, on the extent to which networks of competing providers can negotiate non-price variables, including what non-price variables are.

I think also the statements ought to make some mention, perhaps even if as a footnote, of the potential liability of health care consultants and attorneys representing competing providers when competing providers negotiate with third-party payers.

I'd like to see a little more transparency in some of the investigation decisions the agency make with respect to, for example, why certain cases weren't brought. There's perhaps a too-detailed explanation of the cruise line decision; there's an interesting discussion in the Indiana Warehouseman's case of the FTC's position on what constitutes sufficient state action exemption compliance.

And what I'm thinking about specifically when I make this suggestion is Chairman's Muris' comments back in November that the Commission investigated a clinically integrated network and decided not to bring an action. Those of us who work in the network area would be

substantially helped if we had a better understanding of that network, how it worked, and why the agency decided to take a pass on it.

And then finally, as far as future guidelines are concerned, I think it would be nice to see more input from private practitioners in the development of guidelines. When the '96 health care guidelines came about, I can remember being herded over into the Antitrust Division's office; a set of the guidelines, to exaggerate only slightly, was thrown in front of me; I was told to read it, make comments, and leave. And it's very hard to spend time giving the degree of thought something like that deserves in that type of environment.

So I think it might benefit both sides if private interests were given a little more opportunity to provide input into guidelines such as the health care guidelines.

Thank you very much.

[Applause.]

MR. BYE: Thanks, Jeff.

Clift Johnson will give the next presentation.

MR. JOHNSON: Thank you, Matthew.

It is indeed a pleasure to participate in these joint hearings today. I'm especially pleased to be able to provide a perspective from outside the beltway on the

practical importance of continuing the commitment to prospective guidance.

Bottom line: The agency's commitment to collaboration and public disclosure clearly makes for good government; and, in my opinion, must also engender a higher degree of antitrust compliance in the private sector than what we'd otherwise have.

This afternoon I'd like to dial down to some of the details, discuss some of the issues I ask my clients to consider before seeking an advisory opinion, offer three concrete examples of the practical impact that some decisions have had, and highlight a few issues that might be ripe for additional government commentary.

First, why would a client ever request a formal advisory opinion from any enforcement agency? Clients generally are not interested in inviting investigation. I'm sure that we'd all agree that a sound opinion of counsel will usually suffice; and we'd also agree that if it was a close call, the Agencies will probably take a more conservative approach than perhaps private counsel would.

So when might a client be well advised to request a formal advisory opinion? To put that question into context -- we were talking about costs a little bit ago -- one must acknowledge that an antitrust

investigation, let alone litigation, is extremely expensive to defend. It consumes massive amounts of time from management and management energy, it tracks executives from their key operations, and can lead to some rather nasty public relations problems. In the end, an ultimate victory in court may be a shallow victory.

On the other hand, significant expenditures of financial resources and political capital can be avoided by the client in those situations where a project might be viewed with disfavor or subjected to restructuring by the reviewing agency.

It has been my experience that a formal advisory opinion is most helpful when the proposed conduct raises with a novel legal question or the client is especially risk adverse. For these clients a favorable review provides comfort and some degree of certitude.

Nevertheless, there are several potential risks and inconveniences that must be weighed against the incremental comfort that one obtains from a favorable review.

If the issue is novel, or tends to expand existing legal interpretations, one might rightfully anticipate a conservative reception from the government. Although opinions are well-reasoned and becoming more

accommodating, one has to expect an enforcement agency to lean on the conservative side in their opinions.

Second, clients must be prepared for the intense level of scrutiny that can be associated with a request for an advisory opinion -- and rightfully so.

Dr. Ellen Briquette of MedSouth IPA participated in these hearings in September and presented a glimpse of the exacting examination that can be brought to bear on a cutting edge issue. Similarly, we've seen data regarding the number of provider network requests that have been submitted. Whenever a provider network issue arises, the agencies are going to have to look at the level of clinical and financial integration; they're going to be looking at patient origin data, alternative source of supply, and interviewing purchasers. This takes time and clients need to understand that.

Finally, the business review process itself can be excruciatingly slow for business leaders accustomed to making quick strategic decisions. Even the relatively acceptable 3 to 4 month response time can be an eternity for a hospital CEO. I've had occasion where an opinion may take in excess of a year. And unfortunately, the requesting party is not in a position to demand a prompt review. I think we know the response we'd get if we tried to do so.

So the program description asks "Are parties discouraged from obtaining formal advisory opinions?" Yes, I think so to some extent, but rightfully so. The agency should not serve the role of antitrust counsel for private parties. Nevertheless, staff advisory opinions and business review letters are valuable components of the government's overall antitrust enforcement efforts.

The processes ensure compliance by the requesting parties, frequently with implementation of competitive safeguards that private counsel might not have deemed necessary. Further, and perhaps more importantly, publication of detailed reviews allows private practitioners to better counsel their clients, discourages submission of duplicative requests, and fosters enhanced antitrust compliance at relatively low cost.

The more detailed the guidance, the more beneficial the guidance will be to third parties. Three practical examples of how the agencies' prospective guidance facilitates antitrust compliance come to mind.

The first example is actually a tribute to a footnote. During the late 80s and the 90s, a lot of hospitals were developing joint managed care contracting strategies with their physicians. We're all familiar with the PHO model and we're all familiar with the uses

of contracting committees within PHOs.

Many well-intentioned health care attorneys believed that the antitrust risks associated with PHO contracting to be relatively low because each participating physician made a unilateral decision to accept or reject a proposed fee schedule or manage care contract.

The agencies' position on this point was address in Statement 9 of the 1994, and then 1996 enforcement guidelines. Statement 9 addresses multi-provider networks, but some of us found Footnote 65 particularly significant. You may recall that Footnote 65 asserted that the use of an intermediary to negotiate contracts, or the use of an opt in/opt out type of provision in a contract did not negate the existence of an agreement.

Footnote 65 was particularly prophetic in light of subsequent enforcement actions.

The second example I'd like to reference are the two staff advisory opinions issued by the FTC on July 5, 1994. I think everyone knows where I'm going with this. If you're dealing with physicians and trying to explain financial integration, the use of a withhold is commonly used. Regardless of the level of withhold the counsel suggests, there will be a physician in the

audience who will try to put you on that slippery slope and come down to a more narrow withhold.

The use of the two FTC advisory opinions, each addressing a 15 percent withhold and coming to different conclusions, have been extremely helpful in each of my presentations with clients.

Finally, the third example of a watershed advisory opinion would be the one issued to MedSouth IPA. I'd always thought that the hardest question I had to ask was "How much financial integration is enough integration?" That question's been overshadowed now by "What constitutes clinical integration and how much do we have to do in order to negotiate prices collectively?"

The MedSouth model has generated much commentary in the industry and will continue to be watched closely by health care attorneys. Of particular interest will be the resolution of the practice question "Will consumer perception of enhanced quality -- regardless of whether real or imagined -- be sufficient to justify premium pricing in the health care industry as it is in virtually every other industry?"

Or perhaps a more stimulating debate will be the examination of whether collective price negotiations are reasonably necessary to effectuate successful medical management programs.

There are many other examples of the valuable role that the agencies play. Despite the shortcomings, the private bar would suffer a terrible loss if the agencies were to curtail their commitment.

In the future, those of us outside the beltway might benefit from additional guidance regarding the agencies' enforcement policies in several areas -- first, with respect to messenger models. Messenger models contemplate third-party evaluating managed care contracts and educating payers about a provider's willingness to accept different fees.

At what point does that education become negotiation? Is coercion the key? How does a messenger model present rates to a self-insured plan when development of a fee schedule is in itself inconsistent with the messenger model?

With respect to physician practices and integration, are productivity based physician groups -- eat what you kill type of compensation model -- integrated for antitrust purposes? Anesthesia groups bring particularly difficult questions to the table. When does a demand for volume based pricing become an impermissible MFN and to what degree will the Agencies consider non-economic factors in their respective analyses?

These and other issues will inevitably give rise to future guidance. The Agencies are to be commended for their commitment to prospective guidance in the health care industry. I hope that they will never rue the day that they got into the guidance business.

Thank you.

[Applause.]

MR. BYE: Thanks, Clift.

Warren Grimes will now present by phone hook up.

MR. GRIMES: Can you hear me?

MR. BYE: Yes, we can.

MR. GRIMES: I have some slides for you, so if you could just give me the heads up when they're ready to go. While we're waiting, let me just make a preliminary disclaimer. I was asked -- Matthew Bye asked me to make a brief presentation this afternoon because I have done some thinking and writing about disclosure and antitrust enforcement.

Earlier this week I presented a paper at the American Antitrust Institute Conference on this topic. There was no special focus in my work on health care and I have no specialized expertise in the health care area, but I have done some thinking and I've written this longer paper on transparency issues in antitrust

enforcement.

Are you ready to go with the slides?

MR. BYE: We are.

MR. GRIMES: I'm sorry, yes?

MR. BYE: Yes, we are.

MR. GRIMES: Oh, good. Well, let's move to the slide entitled Transparency Disclosure of Information about Enforcement. On the general topic of disclosure, the antitrust enforcement agencies, of course, disclose information in a lot of ways -- and this has already been mentioned in other statements -- through speeches, guidelines, advisory opinions, business review letters, testimony. And obviously for health care, I think a number of panelists have pointed out that the advisory opinions and business review letters are a critical part of this effort.

In the next slide I talk -- I want to talk for a second about the benefits of disclosure in general -- as why is it important for the agencies to disclose what they're doing. In a law enforcement decision, where they're conducting an investigation, if the agency knows that its decision must be explained, this can improve pre-decisional process and inject some discipline into the decision-making process itself.

A second benefit is fostering agency

accountability after the decision is reached. If we know why the agency did or did not bring an enforcement action, that can be very helpful to the private bar. It also is of interest to academics such as myself who want to write about the area.

Third benefit is enhancing knowledge of and compliance with the law. And this is obviously a key purpose behind advisory opinions and business review letters.

One point I want to make here is that when there is inadequate disclosure, we have a greater likelihood that specialty law firms will develop to the exclusion of antitrust lawyers who might have an interest in practicing in an area but can't get access to the information. I think this shows up most obviously in merger enforcement where the inadequacy of disclosure of decisions about whether to challenge or not challenge a particular merger means that only those law firms who handle a lot of mergers have this knowledge at their fingertips; and this gives them an entry advantage that makes it more difficult for others to even practice merger law.

I don't know whether this is occurring in the health care area so much, although obviously we do have some significant hospital mergers and other joint

ventures going on that might be reviewed under the Hart-Scott-Rodino Act.

The fourth advantage of disclosure is that it fosters fairness and public confidence in government. Obviously, if a law enforcement investigation is going on and there is some public knowledge of this, those who are interested in and would be affected by the decision have a chance to make their views known.

And I might mention a final point on this slide about the benefits of disclosure. For many merger investigations, disclosure of what the enforcement agency is doing is important for the stock market. As a former FTC attorney who handled preliminary injunction cases in the merger area, I know that we would get constant calls from arbitragers who wanted to get an information advantage over the rest of the market. And it always bothered me that the Commission -- and I think the same is true at the Division -- did not make more routine and effective disclosure at each step of a merger investigation.

All right, moving on to the fourth slide, Disclosure in the Antitrust Context, I think that the agencies do a good job in speeches and guidelines. A second point would be that the agencies don't do so well in enforcement decisions.

They generally disclose little or nothing when investigation is dropped; and, even in cases that are settled, the "Fix-it-First" cases under the Justice Department, and the Part 2 Resolutions -- consent resolutions by the FTC, there's very seldom any disclosure of the near-miss issues. These consent explanations almost always are limited to explaining what the agency decided to act against. In other words, what's in the relief decree? Anything that's not in the relief decree is left out of the explanation.

Final point on this is that I think accessibility of advisory opinions, including in the health care area, could be improved -- and I'll get back to this in a second.

Arguments Against Transparency -- this would be the next slide. Many of these don't apply to advisory opinions or business review letters, but there have been a lot of arguments made against transparency. The first that too much visibility to agencies' actions could interfere with decision making. A second that if past decisions are know, they might constraint the agency.

I think that, by the way, this point is not a very good argument. Past decision of the agency are known to the insiders, to the law firms who handle these cases, and if they are the only ones who know about these

past decisions, again, this creates this phenomenon of the specialty law firm where other law firms aren't in on -- don't have the knowledge. And this strikes me as unfair and inappropriate.

Another argument against disclosure is the burden of preparing the disclosure statement. This is perhaps the number one argument given by the antitrust agencies as to why they don't disclose when they drop a merger investigation, or some other law enforcement investigation.

Two other arguments: The risk of disclosing confidential information. Obviously, this is a concern, but not an insurmountable one.

And finally, politicizing agency decision making. I'm not going to say much about this except to remark that antitrust is political and I think to use the risk of politicization as an excuse for not disclosing is not a very strong leg to stand on.

In the next slide I just bring up the example of the European Union. Those of you who have used the European Union's competition law site I think would probably share my view that it's a far more user-friendly web site than either of the web sites that the FTC or the Justice Department currently have.

And just as an example, let me cite the merger

cases. If you go to the merger link on the European Union Competition Law web site, you will find that merger decisions by the competition directorate and by the European commission, are indexed in multiple ways. They're indexed by date, by name of the parties, and by subject. So you have a subject matter index that may list the type of market involved, or the type of issues if it was a joint venture, and so forth.

So I think anyone who has used this web site will agree with me that it is much more user friendly than those that are at least currently offered by the FTC or the Justice Department.

The next slide, I mentioned the experience of other agencies, again, I used the example of the FCC and the Federal Reserve, all of which have web sites which I think are more accessible than the antitrust agencies.

These agencies, for example, disclose antitrust or merger investigations on their web site as soon as the investigation begins; and they would also offer explanations of the decision. And here's an important point -- that the European Union and these other federal agencies would offer opinions, or explanations, of why the agency decided to drop an investigation -- not only when they decide to pursue enforcement action.

Next slide: Issues Involving Advisory Opinions

and Business Review Letters. I think there are basically three issues here. The quantity of the opinions, the quality of the opinions, and the accessibility of those opinions.

As to quantity, do we have enough opinions? Do they cover the field? And I'm going to leave that question to others to resolve.

As to quality, are the letters clear? Do they provide a basis for accurate counseling? On this point -- well, maybe on both the first two points, I have followed with interest the comments of the panelists who said that negative letters -- letters that say that proposed conduct is not lawful, or would be challenged -- are very helpful and I would agree that that's a legitimate issue that should be looked at by the agencies. Perhaps there's a need to adopt different rules that limit a parties ability to withdraw a request for an opinion.

The last point, accessibility, I think I'm most qualified to speak on and I -- indeed, I already have. I think the -- if you look at the -- I took a look a couple of days ago at the FTC's listing of advisory opinions and health care and there was a long list on the web site; but again, the indexing of these opinions is not very helpful. I think it would be better if they could offer

multiple indexes along the lines of the European Union index.

My last slide makes this point. Accessibility, I think, is inadequate, or at least could be improved. It makes the point that the European Union's competition law web site does a better job.

I might make one last comment about the web sites and that is that the search engines have been criticized -- not so much by me, but by others who have tried -- who have been frustrated in using the search engines. Particularly, I've heard complaints that the search engine on the FTC's web site does not function very well and if you put in a party's name, or if you put in a topic in the health care area, that you get too many readouts and that it just -- it doesn't work effectively. So that's another point to look at.

Disclosures are important and I think the FTC has, through its advisory opinions; and the Justice Department, through its business review letters, has made an attempt to make the information available.

I'll just leave you with the major theme of my remarks, which is that let's make this information more accessible.

Thank you.

[Applause.]

MR. BYE: Thanks, Warren.

Ellen Cooper will give the next presentation.

MS. COOPER: Good afternoon. Before I start, of course, I have to make my own disclaimer; and that is that the opinions that I express are my own and not that of any attorney general, including my own attorney general.

Also, before I get started, I needed to talk a little bit about the roles of the Attorney General. And those roles are not just to enforce the antitrust laws, or to prosecute antitrust law; but also to prosecute health care providers for violation of licensing laws in health care area, to protect the integrity of charitable trusts -- and again, I'm just talking about the Attorney General's roles in the health care area.

They also represent state agencies; and, in doing so, they advise state agencies, but they also defend state agencies -- and that includes defending state agencies who are being sued for antitrust violations.

So in that context, what kind of perspective guidance do the attorneys general give? And what can I say about it? Whom do the attorneys general advise? What form may the advice take? Are there any constraints? And what are some examples of advice that

attorneys general have given recently.

Well, first of all, whom do the attorneys general advice? Principally, the attorneys general advise state officials -- and these include the governor; the legislature, including individual legislators who are contemplating filing bills or want to mend current legislation. They also advice state agencies in most states and political subdivisions in many states as well.

And then down, way down at the bottom of that list is interaction with private parties.

Next, the question is "What form may advice take?," and I'm dividing this into formal advice and informal advice. The most formal advice is an opinion of the attorney general. And this opinion is, generally speaking, required by the constitution of each state. Opinions are published and indexed, and they are generally also of some significant legal question.

The process of changing an opinion is available only to state and local officials.

Another formal form of advice is a report of the attorney general, and this may be self-initiated by the attorney general, it may be required by statute or just simply at the request of the legislature. It may be at the request of the governor, who may have issued an executive order; and, generally speaking, these reports

also are on significant issues and they are not often issued.

Advice can also be in the format of formal guidelines. The National Association of Attorneys General have adopted guidelines. These are usually drafted by staff attorneys, but adopted by vote of the membership -- in other words, at the attorney general level.

Also, an individual state may adopt guidelines; and an example of that are the antitrust guidelines for mergers and similar transactions among hospitals adopted by Massachusetts in 1993, and used by Massachusetts throughout the 90s in looking at hospital mergers.

Another form of advice that is formal is advice of counsel. This is not so relevant in these circumstances because this advice is attorney-client privileged. It's confidential and not subject to public document requests, which are the state FOIA equivalents. The process is again available on to state and local officials; and so there's a lot of advising going on as part of the attorneys general's jobs that's not available to private parties.

Finally, we get to antitrust business review letters; and I have to say -- in answer to your question, Jeff -- very few states issue such opinions.

Maryland, Ohio, Minnesota and Virginia are the only states that I'm aware of that actually have published guidelines for business review letters. And Maryland and Ohio have active programs that are modeled after the DOJ procedures; and have issued letters in the recent past.

Minnesota and Virginia issued letters in the past. They still have published procedures, but in speaking to current chiefs of those divisions, these procedures are not being currently utilized.

The final state that has a procedure is Florida. Florida issues antitrust no-action letters under the Florida Health Care Community Antitrust Guidance Act. So Florida issues these no-action letters only in the area of health care.

Finally, I would be remiss, coming from Maryland, if I don't mentioned that Maryland has a formal board review program. In the 1980s, the Maryland Antitrust Division reviewed the regulations and policies of state licensing boards to assure their compliance with the antitrust laws; and published actual formal board review reports.

And these were top to bottom reviews of all the regulations and policies of those state licensing boards.

However, since the 1990s, the Antitrust

Division attorneys have worked with board counsel on specific issues rather than top to bottom review; and these issues, of course, would be ones with potential anti-competitive effects.

I'd like to talk a little bit about informal advice because this actually is probably the most important part of advice that state attorneys general give.

Many states give non-binding, informal advice to private parties on request, on a case-by-case basis; but few states have established mechanisms for doing this. And many states will say "We are not permitted to give advice, but we'll discuss issues with counsel for parties."

Many states do educate the public on antitrust, and the attorneys general feel that they have an important educational role, and they distributed brochures, they conduct seminars, and some states have outreach programs to the business community. Unfortunately, because of the state of the economy right now, and the financial condition that a lot of states are in, a lot of this activity really is not going on very much at the moment.

The next question is "Are there constraints?" There is a very serious constraint, and that is,

attorneys general are not authorized by statute or constitution to give advisory opinions to private parties. And many, many attorneys general take this very literally, very seriously, and will not give advice if asked by private parties.

Many offices lack the resources to respond formally to every inquiry. As some of you know, some states have only a single person doing antitrust law and that person may be doing other kinds of work as well.

And many offices lack procedures. In other words, they have no authority to even issue regulations that would govern process in order to give formal advice.

So given all that, let me just really zip through some recent advice in these different areas.

Reports. There are three reports that I can refer you to. The Office of the Arizona Attorney General has issued a series of reports on prescription drug pricing within the state.

The Massachusetts Attorney General reported to the legislature on the Springfield health care market; and back in 1995, the Washington Attorney General reported to the state legislature on the role of antitrust immunity in the Washington State health care market. And that was quite a lengthy report to which many experts added advice.

I mentioned that many -- that the attorneys general all give formal opinions; and that's what I'm talking about here. I want to -- I've chosen two opinions to contrast what was happening. These are opinions that are on health care matters.

In Texas, this is advice, that I'm referring to, in 2001, to a state legislator who asked, "May a hospital contract exclusively with a single medical insurance provider?" Within the context of the question, the providers' names were given and there was some information given about the context.

Within that letter, the Texas AG wrote: "Generally, it is beyond the purview of the opinion process to construe contracts or scrutinize particular contractual arrangements, especially those between private entities, and to determine whether they satisfy specific statutory criteria or are otherwise legally permissible." "Nor," the Attorney General added, "may the Attorney General make finding of fact.

Nevertheless, in quite a lengthy opinion to the state legislator, the Texas Attorney General discussed the issues surrounding decisions about whether exclusive contracting might violate the antitrust laws or not -- concluding that the facts were not sufficiently revealed in the current context to give an opinion.

In contrast, the Arkansas Attorney General, in 2001, was asked again by a state legislator "Does the Arkansas Staffing Association plan to establish a credit reporting program violate Arkansas antitrust law?" And this is the answer almost in its entirety:

"Although the Attorney General is required to provide opinions on certain matters of state law to members of the general assembly, and various state officials, I am prohibited from engaging in the private practice of law. Consequently, I suggest the Association seek advice from private counsel or the United States Department of Justice."

There is another opinion, although I know time is short. I'm sorry, I can't resist.

This just gives a feel for the scope of advice. This is an informal opinion because it's not from the Attorney General himself, but it is from staff, advising the mayor of Sally, South Carolina, that -- and the answer is indeed an ordinance forbidding anyone other than the Town of Sally to sell Chittlins -- fried, boiled, or raw -- on the day of the Chittlin Strut does violate the antitrust laws.

I mentioned the Florida No Action Letter and there are two of them. I won't go into the substance of them. They both deal with dental networks and dental

society advice. They are both no action letters and they're both posted on the Florida OAG web site, which is myfloridalegal.com. You can find them both posted there.

And that's the second one referenced.

Two business review letters -- one from the State of Ohio -- dealt with proposed joint ventures between the Medical College of Ohio at Toledo, which, incidentally, is a state school, and St. Vincent Mercy Medical Center, with respect to academic and clinical pediatrics. And one from my office -- and I believe this is the one that Jeff Miles mentioned about a proposed network of 11 hospital-based home health care agencies.

So I hope this gives you an idea of the range of the kinds of opinions that the states give. And my conclusions about this is that although most states prohibit advising private parties, attorneys general perceive that they have a mission to educate the public; and so many, many states will meet with parties and provide informal oral advice to them. Very few states will provide written advice to private parties.

But even so, to the extent that the state attorneys general do offer formal prospective advice, I believe these procedures are under utilized. There just aren't that many letters out there.

Thank you.

[Applause.]

MR. BYE: Thanks, Ellen.

We'll take a short break now and then return with Vicki's presentation.

[Recess.]

MR. BYE: Now Vicki Robinson will give her presentation.

MS. ROBINSON: Good afternoon. It's a real pleasure to be here and I appreciate being invited to come and talk about the advisory opinion process at the Office of the Inspector General of the Department of Health and Human Services.

I'm very proud of the work we do and so it's a pleasure to come and tell you a little bit about it.

For those of you who may not know what the Office of Inspector General does, we're not antitrust folks. Broadly speaking, what we do is combat fraud, waste, and abuse in the federal health care programs -- including the Medicare and Medicaid programs. And, in that capacity, we have both an enforcement role and we have a guidance role.

And I think of the guidance role as sort of our preventing fraud, waste and abuse effort. I think it makes a lot more sense to try to prevent fraud and abuse up front than have to rely on the sort of pay-and-chase

method afterwards.

And so that's what my group does. We deal with the guidance function. And we issue a broad range of guidance actually. We issue fraud alerts and special advisory bulletins, we issue compliance guidance to aid the industry in developing compliance guidance programs, we issue safe harbor regulations, and other regulations, and we -- there's a variety of forms of informal guidance that we engage in.

But the centerpiece of our guidance efforts really is our advisory opinion process. And before I go too much further, let me mention that if you're interested in all of our guidance, we have a web page. I think it's a pretty good one. We're at OIG.HHS.gov, and you can find a lot more information than I'll have time to tell you about in 10 minutes.

The advisory opinion process for us was part of the Health Insurance Portability Act in 1996, it's statutory. And the industry really wanted it and, to be honest, the Office of Inspector General and the Department of Justice weren't so keen on having this advisory opinion process. But despite some initial skepticism on both side, I think about how well we would actually operate the process, I'm pleased to say that I think it's overall been a pretty successful program and

very well received; and we get reasonably positive feedback.

We started in February 1997. We have received -- as of yesterday afternoon -- 363 requests for advisory opinions. They come in about 50 to 60 a year, for formal requests. And we have issued, as of today, 101 advisory opinions. We think something like 15 to 20 a year. And I'll come back in a minute to what the discrepancy is in those numbers. It's not that we're behind 260 opinions, thank goodness.

So I'll take about 10 minutes. I'm going to try to discuss some of the key features of our process. I as asked to sort of focus on things that might be different about what we do than what the FTC and the DOJ does -- although I will confess that we cribbed liberally from their regulations when we wrote our regulations. If you compare them, you'll find some shockingly similar phrasing.

I'll try to mention what I think are some of the benefits to both industry and government from our process; and then I'll talk a little bit about what I think the challenges are for us -- particularly since we are largely opining about a criminal statute.

I do need to say that these are my personal views; they don't necessarily represent the views of any

government agency or official.

So let me talk a little bit about the process. I think one of the key differences about our process is that it is statutory. It's mandatory; we have to do it; although it is voluntary for the industry. So no one can go in and say, "Well, you didn't get an advisory opinion; you must have had bad intent." They can't use the opinions in that way. The government can't use the opinions in that way.

But we have to issue opinions to the industry; and we're required to issue opinions on several sections of the Social Security Act, sort of a variety of legal authorities, but in practice most of our opinions deal with the Federal Anti-Kickback Statute.

A couple of things you should probably know if you don't know what that statute is, in order to understand what we do -- the Federal Anti-Kickback Statute is a criminal statute that says it's illegal -- this is nutshell version -- it is illegal to purposefully pay anything of value to purchase federal health care program referrals. You can't buy business in the federal health care programs.

It is a statute which the Department of Justice Criminal Frauds Section, and the U.S. Attorneys Offices -- they actually prosecute the criminal cases.

But we have jurisdiction to proceed administratively against kickback violations, and we also have statutory authority to issue safe harbor regulations that describe business practices that would be deemed to be immune from prosecution -- that don't come under the statute. And we also have the authority to issue the advisory opinions under this statute.

We issue reasoned opinions and we issue them both for existing and proposed arrangements. Again, a difference from what the FTC and DOJ do. We do both existing and proposed arrangements, but to be truthful, we don't get many requests on existing arrangements because of the law enforcement implications if we, in fact, find a kickback arrangement going on.

We get quite a few requests on potential arrangements, but we don't do hypotheticals, and we don't do opinions on what your competitor, or somebody else, is doing; so the person that requests it has to be a party to the arrangement, or if it's a proposed arrangements, they've got to certify a good-faith intent to enter into the arrangement. So we try to make sure that it's real.

Another really key distinction about our opinions is that our opinions are legally binding by statute. They're legally binding on the requesting party and on the Department of Health and Human Services. And

what that means is that if someone gets a favorable opinion, they can legally rely on that opinion so long as they conduct their arrangement in accordance with the facts that they gave us and that they disclosed all the material facts. And we can't bring a case against them for that conduct.

As a result, it's a very valuable thing to have a favorable advisory opinion from us, and the bar for getting a favorable advisory opinion is, frankly, very high. We are very conservative and very cautious in issuing these because of the binding nature of the opinion.

The statute does require that we consult with the Department of Justice; and in our case, that's with the -- we consult with the criminal fraud section. And we have a very good working relationship with them.

The statute gives us 60 days to issue these advisory opinions. Now that is an administratively difficult and short time frame. As a practical matter, the time it actually takes to issue the opinion really varies widely based on the complexity of the arrangement, the complexity of the legal issues, the quality of the information that we're getting, the submissions. We often get difficult issues at first impression, so it actually ends up varying quite a bit.

The short time frame also makes it impossible for us to conduct any independent investigation of the facts and we do not. We rely entirely on factual submissions from the parties that request the opinion and it sort of leads to two things. One, we ask a lot of question, we file a lot of requests for additional information if we need it, we look behind any kind of cursory statements in the initial submission. We may as for follow up information, underlying documents, anything we think we need.

We also require that all the facts be certified under penalty of perjury and we have a certification form that's required to be used.

Another thing that's quite important because of the mandatory nature of the process, we don't pick and choose the advisory opinion topics. We answer whatever questions come in the door. And so sometimes there is a tendency, I think, on the industry's part to see the issuance of an advisory opinion as some sort of indicator of our enforcement priorities; and that is not necessarily the case. Because again, if no one writes in on something we think is really important, there's not going to be an opinion issued about it.

As I said earlier, we issue fewer opinions than we get requests. In fact, it tends to work out about one

in every three requests results in an actual published opinion. The others are either rejected or they're withdrawn. Our regs allow folks to withdraw their opinion request at any time.

The typical reasons for rejecting an opinion would be that the subject matter is outside the scope of what we're authorized to do; the same, or substantially the same subject matter is (inaudible) in the course of an investigation or a government proceeding; or that we could only make an informed opinion after really extensive investigation or clinical study.

I think we cribbed that language straight from the FTC regs.

The typical reasons for withdrawals are that people get wind, from talking to us, that they're likely to get a negative opinion and they don't want that; or the business deal has fallen through for reasons wholly unrelated to the advisory opinion. That happens quite a bit.

We put all our opinions up on our web page. We put them up redacted. We take out all the identifying information and we do not make the submissions part of the public record, although they are subject to FOIA requests and they are dealt with that way.

The statute does require us to charge for the

cost of preparing an opinion. Our fees end up being very modest by law firm standards, particularly; but that's -- it is a required -- I should point out the money goes to the general treasury, it doesn't come back to my agency.

So my time is short. Let me just hit on what I think are sort of two big benefits to the industry, one to the government. The benefit to the industry, I think, depends who you're looking at. For the individual requestor, it's the legal certainty with respect to their particular arrangement.

But there's a different interest with the industry as a whole and that's to get some insight into how we think about things. A log of our opinions include lists of bench marks, or guidelines, or factors that others can apply in their own situations, although the opinions themselves only apply to the requesting party.

From the government's point of view there's lots of benefits, but one that I think was somewhat unexpected -- and has been, I think, a real benefit to us -- is that this opinion process has given us a real window on the health care industry -- and particularly on the developments in this very fluid and dynamic industry. What's coming down the road? What new business arrangements are developing? And because we have a very interactive process with the requestors, we learn a lot,

which means our opinions are better informed, our other guidance is better informed. I think all of our decision making is better informed and we've become a lot more knowledgeable.

I will use my last 30 seconds to just say that there are a number of challenges in our advisory opinion process, the chief one being is that we are opining on a criminal statute. And there were a lot of concerns by my agency and the Department of Justice that the opinion process could be misused.

People might use opinions to thwart their investigations of them; they may use opinions to say that they're just like someone else and they don't have criminal intent, because, look, someone else got to do something kind of like it; or they may take sentences or phrases out of opinions that are then used against the government.

And what -- that has not happened. Knock on wood. It has not happened. The dire predictions haven't happened. We are very careful. We vet opinions carefully with our law enforcement partners, we vet them -- we read them incredibly carefully trying to -- someone mentioned the ghost before -- you thought something said something and then someone reads it differently. We try very hard to avoid that problem.

We take comments from our Justice Department partners, for example, very seriously. We address them; we work with them on language. And so we're working hard to avoid some of the misuses that people have predicted might have happened. And I'd be happy during the discussion to address any other questions that you all might have about our process.

And thank you very much for inviting me to come and talk about it.

[Applause.]

MR. ELIASBERG: Thank you very much, Vicki.

I get to ask the first question. But before that, let me second something that Jeff Miles said.

I, too, highly recommend the paper that Judy Moreland did on the overview of the advisory opinion process at the FTC. It also has discussion of the Justice Department's business review process. It is available at the FTC's web site, under the antitrust and the health care advisory opinions; and is just an excellent guide for use.

With that, let me start by sort of doing a blunderbuss first question. And I'm going to ask Claudia -- I don't know if you have any colleagues -- anyone -- I guess, no one's left from the FTC here but Clift Johnson and Jeff Miles.

And actually, Vicki, I'm going to include you in on this one too.

MS. ROBINSON: Okay.

MR. ELIASBERG: I got it from what you just said a minute ago. And the question is "Should parties be allowed to withdraw business reviews, or advisory requests?" A couple follow-up questions to that -- I'm never one to ask just one question -- "If so, what are the costs or benefits of having the agencies publicly disclose it back to withdrawal?" And "Is there a happy medium by refusing to allow withdrawal, but simply redacting who the parties are, or who the party was who's withdrawing the letter?"

So, Claudia, now you are the only person on my right hand side. Why don't we start with you?

MS. DULMAGE: All right. Well, as I've said to a couple members of the panel, do believe that if we took away -- we'd have to literally change our rules to not allow parties to withdraw, since it's specifically stated in our rules that they may withdraw.

But I think that -- this might be a moot point since we're getting so few requests these days, but I think it would have a chilling effect on people asking for advice if they knew that they were locked in and that, you know, come what may, you know, their proposed

business conduct was going to be the subject of a letter or a press release and that even if we, you know, took a grave disliking to it, that it was going to become public information.

I think the fact that they are allowed to sort of pull out at the last minute does, you know, allow people to sort of jump in there, test the waters, figure out if what they're doing is unacceptable. And I think that -- I mean, unless people just have a death wish -- I mean, I think that having, you know, gotten the notion from dealing with the staff at the agency that we really would frown on this behavior.

I don't think they're probably going to go ahead and just, you know, after withdrawing, you know, implement the behavior -- particularly, I think, from the Department of Justice's perspective, when we tend to go out in the market and talk to payors. And I think payors would feel quite, you know, comfortable coming back and complaining later on if they knew the behavior that we were looking at was taking place.

And so I think there's a couple drawbacks, not only formally having to change the rules -- and I don't even know what that entails -- I mean, I don't know what happens, what hoops we'd have to jump through to do that.

But then I think you might discourage people

from coming in and trying to get advice from us.

MR. ELIASBERG: Jeff or Clift?

MR. MILES: Can I ask Claudia a question? Or do you want me to answer?

MR. ELIASBERG: Why don't you answer this one first, then you can ask --

MR. MILES: Okay.

MR. ELIASBERG: But first things first.

SPEAKER: I think you have to answer the question.

MR. MILES: I think Claudia's right. I think it would put a damper on the -- let's call it the demand for advisory opinions -- if you could not withdraw it because it's always -- I mean, I know from my own standpoint. It's always -- I'm always happy to know that if I've totally screwed up and it's a really bad proposal I can always pull it.

I would hope, I guess, that there is some middle ground. I don't think there is any ground that totally solves the damper on demand problem. I mean, I suppose you could redact names, but that still -- I think that still is going to discourage some people from applying for a letter because they can be easily identified, number one, and number two, they know, even if everybody else doesn't, that DOJ frowns on what they

want to do.

I'm sure what the middle ground would be that would solve the lessening of demand. And I think the ability of people to ask for these letters is very important. I would not like to see something that would decrease the demand for advisory opinions.

MR. ELIASBERG: Clift?

MR. MILES: But I still want to ask Claudia a question, but I'll do it later.

MR. ELIASBERG: Right. We'll give you a chance.

Clift?

MR. JOHNSON: Well, I'm pretty much in agreement with Jeff. I would not want to see anything that would detract on the ability to request opinions or demand for those opinions. However, I think if you redacted names, and perhaps at some intermediate stage where the agency could go through the process, work with the requestor, find the information, and there are going to be requests out there that are pretty much going to yield a thumbs down. And perhaps at that point, the requestor could withdraw the request without any record of it having been made.

I did file a request once for Henry County Hospital regarding an NPI question and at the end of that

the client wanted the no opinion, the negative opinion, in the record because it showed somewhat of a boundary for others. They thought that was important.

I can see situations where it might be important if you are negotiating with a third party and you run a proposed transaction through, especially if you're dealing with a hospital versus physician groups, it might be helpful to have a negative opinion on record.

So I would think after some intermediate step, and once the time commitment, resource commitments are made by the agency, then, yeah, I think academically it would be helpful to have those negative opinions on the record.

MR. ELIASBERG: Finally, Vicki, the perspective from an outsider looking at these -- the world of antitrust and health care antitrust?

MS. ROBINSON: Well, I can tell you how we've thought about it. It's a question we have thought about -- we thought about when we designed our program and we do revisit the thinking about it from time to time. Although our regulations clearly provide that requests can be withdrawn and we would have to change the regulations which we have no plans to do.

I agree, first off, with Jeff that negative opinions sometimes contain our best advice. We can often

say more when we're saying no than when we're saying yes; and so I think there's a lot of value in a negative opinion to the industry at large.

I mean, I will say, as someone who spends a lot of time working on advisory opinions, it is frustrating to get pretty far down the road and then have the thing withdrawn and all your wonderful work and hard thinking has -- disappears into -- well, we keep it in what we call the bone yard and hope we can resurrect it for somebody else's opinion down the road because we grow very attached.

That said, I think we have to balance the interest of the industry and the guidance and the interest of the individual requestor who has asked for it, who in our case will pay for it; and I think these folks have a law enforcement risk.

Even with a proposed arrangement, I think some people feel there is a law enforcement risk because our statute covers the offering of a kickback; and so some folks may feel that they don't want to even take that chance if they had to stay in the game till the end.

I think there is the fairness issue of requiring someone to pay for an opinion that they don't want. I think there is -- I personally, think that's just a fairness issue -- I think there's -- you know, as

a practical matter, there's a resources issue. To the extent that we can focus our resources on doing opinions -- our resources on opinions that people want, I think that's probably a better use of our time to some extent; and we have limited resources, so you've got to balance that.

I think as a practical matter, to the extent we wanted to get additional information or needed it in order to finish the opinion, we're going to get less cooperation once someone decides they don't really want it; and our options of forcing it may be limited.

And I think the redacting, at least in our case, may not be effective. We redact voluntarily -- unlike the IRS, which has statutory exemption from FOIA, I believe, for their private letter rulings. But they redact and the names stay confidential.

Our redacting is voluntary, largely at the preference of the industry, as it was expressed to us, so the names of the parties are not necessarily going to be ultimately protected under FOIA. That would depend on a case-by-case review of the FOIA request and the matters requested. But I don't know that redacting would ultimately solve the problem in our case.

MR. ELIASBERG: Jeff, you honored your part of the bargain, now you get to ask a question but I will not

guarantee Claudia will answer.

MR. MILES: I think since around '88 there have been 5 negative business review letters. Have there been instances in which somebody wanted to withdraw a request knowing they were going to get a negative opinion and they were not permitted to by the Division?

MS. DULMAGE: Not to my knowledge. I believe that, since our rules definitively give people the right to withdraw at any time, I think we would be able to do that. But certainly I'm not aware of that.

MR. MILES: Do you know why some of these people did not withdraw? Or are you able to say?

MS. DULMAGE: I think that -- and at least to generalize on a couple of them that I'm familiar with -- without talking about any specific letters, I think that in one case there was -- it was almost like sort of a political thing where I think the -- certain representatives of the industry were kind of, you know, wanted the information out there that the Department had gone negative on -- and an instance where they thought they'd get maybe a lot of Congressional support or something to literally come back and change the law.

And I know that in one that I personally worked on -- I feel kind of guilty even saying this, but it's like I'm not sure that the counsel really did know that

they could withdraw. And I was surprised that, you know, they went to the end of the process and let the letter be issued. So those are the, you know, kind of two that I'm familiar with in general terms.

MR. BYE: I'd be interested in hearing the panelist's opinions on the differences in demand for letters from the Justice Department and FTC. It seems like there was a fairly substantial decline in demand for letters from Justice in the mid 90s.

And following on from that -- interested in hearing what factors private counsel consider when deciding whether to approach one agency or the other.

MR. JOHNSON: Well, for me, with respect to the Non-Profit Institutions Act, we always go to the FTC. Based on the requests I've had, I would be more inclined to go to the FTC just because they seem to turn them around a little more quickly than it's been my experience with the Department.

Having said that, I'd also try to look for enforcement actions that may have been brought on facts similar to what I was trying to present; and if it became apparent there's a problematic case, or whatever, from one agency or the other, I would probably want to go to that agency to make sure that I would have the opportunity to distinguish my client's situation on an

enforcement action. Thank you.

MR. BYE: Anyone else want to comment? Jeff?

MR. MILES: Yeah, I guess I'll comment. I think maybe in the 80s and the early 90s you -- I think you got a more in-depth analysis from the FTC, if that's what you were looking for, as opposed to simply a naked up or down. And I guess this answer is sort of stupid, but, I mean, in my own case, up until maybe three years ago, I had not had much contact with the FTC.

I had come out of the Antitrust Division; I knew some of the people there; and so I was more inclined to simply deal with them because I knew who I was dealing with.

MR. ELIASBERG: Kind of a follow-up for a variation on Matthew's last question -- I think for private counsel, though perhaps Ellen will have something on this, but let me zero in on Jeff and Clift. Let me zero in on Jeff and Clift.

Now, Jeff, that we've learned that you've spoken to Ellen and not just to the FTC and the Antitrust Division -- and Clift, I believe, you -- Ohio is -- when you were with the Antitrust Division, actually did some business reviews.

But under what circumstances might you advise a client to consider approaching say a state antitrust

office for prospective guidance on an antitrust issue, rather than going to one of the federal agencies?

MR. MILES: The situation that comes closest to mind to me is when I know there may be a difference in enforcement philosophy on the issue between the two.

And just to give you a concrete example, I'm involved in a matter now where a state attorney general has said that his office does not accept the concept of clinical integration regardless of whether you have a network that is clinically integrated or not; and if that's something the feds want to accept, that's fine, but he's not buying it.

So where you have a situation like that, I'm not sure I would look for an advisory opinion from him, but I would certainly go in and talk to him if I was representing a network that would involve at least, as one of its from of integration, clinical integration.

MR. ELIASBERG: Clift -- any thoughts on this, Clift?

MR. JOHNSON: Along those same lines, I think the differences in enforcement philosophies might lead me to go to the state AG. It's been my experience that the state attorneys general do not issue advisories, if you will, to the private parties, but they are open to discuss issues.

Three occasions -- or three different types of occasions where opinions have come up, if you will, all with respect to merger analysis. Some attorneys general will go through a merger analysis as part of their Certificate of Need process. Regardless of whether the CON statute actually implicates antitrust principles, they'll use that vehicle to get to the analysis.

More recently, on two or three mergers, the attorney general has used his or her authority, under the Charitable Trust Doctrine, to make like interesting from an antitrust perspective. And it's been "Show me that this is going to be a pro-competitive transaction and I might be more willing to let the monies flow where you intend them to flow."

In one occasion -- this was several years ago -- actually, I have to admit to some forum shopping. I think politically we had a better opportunity with state review than we did with federal review. We actually went to the attorney general and asked for an investigation and had the attorney general issue CIDs and conduct a full-fledged investigation of the proposed transaction with the hopes that once that investigation -- with the hopes that we could close the investigation successfully. And a closed investigation would probably dissuade the federal agencies from

reviewing the same transaction.

MR. ELIASBERG: Ellen, any thoughts on this?

MS. COOPER: There are a lot of transactions that are small. And, you know, they kind of fly under the radar of the federal agencies, but they may be of tremendous significance to the state attorney general once it's brought to his or her attention. And those are the kinds of issues that really need to be raised, I think, with the state attorney general.

There may also be cases where a state entity is involved in one way or another -- whether through the CON process, or just because one of the parties may have -- may be a state hospital or medical school, or something to that effect. And, in that case, the Attorney General is likely to have an opinion and maybe hear about it through the back end.

So I think in those kinds of issues, with those kinds of issues, it's very important to talk to the state AG.

MR. BYE: Would it be useful for opinions to be binding, and what impact might that have on demand?

MR. MILES: I don't think it would have much impact on demand at all because I think the Antitrust Division's position is if you get a favorable opinion and have been truthful, that guarantees you no criminal

prosecution, or something to that effect.

Claudia, is that right?

MS. DULMAGE: I think the history is that if -- that there has never been a criminal prosecution in an instance where there was a favorable letter.

MR. MILES: Right. And I don't believe -- I don't know of any civil prosecution on the heels of a business review letter. And --

MS. DULMAGE: We always reserve our right to go back --

MR. MILES: Right. Oh, yeah, I mean -- but I think we expect you to do that. And, from the FTC's standpoint, if there is a problem down the road, you'll get notice, I think, and the opinion will be withdrawn. I'm not aware of that happening. It may have happened.

But I think the way most of us in the private bar look at it is from a practice stand, it's as binding as anyone could reasonably expect. And, from listening to Vicki, I mean, they're not completely -- you're not totally safe, even if you get one of your opinions, it sounds like. There may be an argument that material facts weren't disclosed.

I mean, there's always some way around these things, it seems to me, if you want. You always leave yourself at least a little bit of wiggle room.

MS. ROBINSON: No. I mean, our opinions are -- the statute says they're to bind us in the department. As a technical matter they don't bind the Justice Department, they only bind the Department of Health and Human Services. We have similar language in all of our opinions that we reserve the right to rescind or modify or amend, but it's prospective and we can't go retroactively after somebody -- as long as they disclosed all the facts to us.

Now if they disclosed all the facts to us and we missed something, I'm not sure then what we -- that we would have any recourse. We have only on one occasion so far modified an opinion going prospectively, and we issued a modification. We have a procedure for notifying and so forth, and we posted the modification up on our web page. But it's only been one time that we've done it.

MR. MILES: I guess I can only speak for myself, but the fact that the opinions are not binding has not concerned me; and my clients have been aware they're not binding and they haven't been concerned.

MR. JOHNSON: I concur with Jeff on that, but I may be one of the few people who have ever had a situation where they've received a no-action letter on a transaction and then, two years later, had to re-fight

the transaction with a member of the Department of Justice actually seeking, or advising the front office, that a criminal investigation should be opened on the transaction.

And it was a little disconcerting when, in that transaction -- we were going right through all the documents; all the documents were being applied consistently through the two years -- and the investigating attorney said, "Well, we just misread the documents two years ago;" and that was a rather unfortunate situation.

As for making them binding, I -- even having gone through that experience, I would not recommend that the letters be binding. I think the government needs the ability to have -- needs that flexibility to pursue actions.

MR. MILES: I think that's especially true when you're trying to predict, based on ambiguous variables, what the effect of certain conduct is going to be in the future. I don't see how you can bind yourself not to bring an action if things don't turn out as you expect.

MR. ELIASBERG: Just to follow-up. The example you were mentioning, was that a business review context or --

MR. JOHNSON: It was not. It was actually

initially filed through the Hart-Scott process, not a business review letter.

MR. ELIASBERG: Again, we just keep picking on you, Jeff, but the purpose here is to try to help us to see what ways we can improve the process.

In your view, do Department and FTC business review letters, or advisory opinions, typically provide sufficient analysis? And if not, could you give us an example of an insufficient one and what additional discussion should have been included -- that would have made it more productive?

MR. JOHNSON: From my perspective, I think that the level of analysis is pretty good in the business review letters. Occasionally, there'll be some where they get to be a little repetitive; and frankly I can see why the level of analysis wouldn't be quite as thorough because the issue's been addressed in prior letters.

But I think the level of detail has been pretty good.

MR. MILES: I agree. I think -- again, early on I think there was some business letters that could have used some more detail, but certainly if you look at business review letters and advisory opinions, through the mid and late 90s and into this year, I think the analysis is sufficient.

The place I would like to see more analysis is in the examples to the Health Care Guidelines.

MR. BYE: Vicki, you mentioned that HHS has learned from people seeking guidance. I was wondering if you could -- whether you had anything else to add to that and also whether you could comment whether it's productive for the Justice Department?

MS. ROBINSON: Well, yeah, I do think that we learn a tremendous amount. You know, before we -- you know, pre-'97 -- and I actually wasn't in the office then, so I have to sort of speak from what I've heard -- I think it was sometimes difficult for out office to find out what new business arrangements, what developments were going on out there.

People weren't crazy about coming to talk to us, frankly. We were perceived, and we are a law enforcement agency. We are not -- coming and saying, "Well, here's what we want to do," I think maybe there wasn't a lot of that and I think we opened up a door or window here. Because we ask a lot of questions and we find that to issue an informed opinion, and to make a decision, particularly, as Jeff points out -- and we weren't, to some extent, being asked to speculate and to be a little omniscient and a little prescient, which we are neither, to figure out how things may play out in the

future.

We ask a lot of questions and have to get the context of the industry. You need to understand everything from how the parties may relate, how hospitals and doctors relate, how the reimbursement programs work, how the money's flowing to understand, frankly, where the kickback incentives may be, what may be driving arrangements that may cause kickbacks to arise? All of these things require context and we get a lot of it.

The advisory opinions have also had -- in a couple of cases have led to other kinds of guidance. In one instance, an infamous instance that I hesitate to even bring up for the fear of creating another stir, but we had an advisory opinion on something known as ambulance restocking, which was something that became the bane of my existence and we've, I think, issued more advisory opinions on this than anything else.

But this is -- you've seen it on ER. The ambulance company drives up, drops the patient, grabs some free bandages, and takes off.

And someone raised the question whether that might be a kickback insofar as the hospital was giving free things to an ambulance provider that was bringing a patient to the emergency room. And the first request we got -- the facts were framed in such a way that it was

potentially a kickback. I think they did that -- they wanted a negative opinion, actually. I think it was very expensive to have these restocking programs and it was very nice to be able to say, "Well, gee, we'd like to do this, but the federal government has a problem here."

This was very early on in our process. This was the sixth opinion we had ever done and we were not familiar with a few things that we now know. And so we issued this opinion that said this particular case, this is suspicious. And I believe I talked to a fire chief from every single state in the nation, including Alaska and Hawaii, because we weren't as familiar with ambulance restocking, didn't realize how wide spread it is, and how, in many cases, it is really not at all a problem. Most cases. Most cases of emergency restocking really aren't a problem.

We then received a slew of opinion requests and we kept answering them and kept saying, "Well, this one looks okay, and that one looks okay, and this one looks okay." And eventually actually did a safe harbor regulation -- went through the whole NPRM process, issued a final regulation to get this off of our plates really and to settle the question because people kept being so -- the risk-adverse folks out there were so nervous about it because it had been an advisory opinion.

And this gets back to my issue about our opinions do not necessarily signal enforcement priorities. But it was read that way. And so we have learned a lot and that whole experience taught me that we have to ask even better questions and we have to really do our jobs in understanding the industry that we're opining in, because we have a range of things we look at.

And in another case, and I won't give you the details, but we had a series of opinions come in on a similar type of transaction -- sort of known as gain sharing -- it's a hospital-physician relationship, which may have antitrust issues, I don't know -- but after a series of these requests, we actually issued a special advisory bulletin, because we had some concerns, and we do have some concerns about them, and we laid out those concerns.

Well, a lot of what we learned about these things came out of this series of advisory opinions. So they have been very helpful to us in formulating our guidance.

MS. DULMAGE: I don't think that requests for business reviews have necessarily brought a lot of unusual or unique, you know, business arrangements to our attention. I'm not aware that we've ever been sort of bowled over by, "Well, that -- whoever thought of that?

I mean, isn't that strange?"

But from my personal perspective, I can remember thinking often that, you know, seeing -- sometimes if you saw something come across your desk that, you know, you're -- just really didn't smell right, and it really didn't look good, and it, you know, it was like somebody was coming and asking about this. I know I always used to think these are people that actually came to us and said, "This is what we want to do," and certainly that must mean that this is the tip of the iceberg and how many of these arrangements are there out in the world that are just going on -- lively going on -- without our knowledge?

And, you know, back into my -- what I like to say, you know, people thinking better to get forgiveness than permission -- you know, they're not going to come in and ask us if they can do it and they're out there doing these kinds of things. I mean, it made me a little bit nervous about that, but I don't think that we were necessarily, you know, being really well informed about, you know, new, different types of business conduct in the health care field that we thought were very strange.

MR. ELIASBERG: Judy Moreland is graciously joining us, given that Jeff Brennan had to leave.

MS. MORELAND: I think there is a -- not in

most cases, but in some cases, a very useful feedback process between the request that we get in and the -- not so much the enforcement actions we take, but the guidance we give, particularly in terms of the policy statements. And some of these are matters that saw the light of day and some of them didn't.

But the revisions that we did to the policy statements in 1996 -- and this whole re-examination of the role of financial integration and other types of integration, from my perspective, grew directly out of my experience dealing with advisory opinion requests, maybe not involving physician networks, but other kinds of collective activity that pointed out some ways in which the analytical structure didn't necessarily apply to a lot of other factors -- situations where you would like there to be consistency.

So I think it's an important part. And this -- as we get more opinions relating to clinical integration, you know, they aren't fun, but I think it will shape the way we look at the issue; and might, in some form or another, allow us to provide more specific guidance.

I'm not promising to revise the policy statements ever again, however.

MR. ELIASBERG: Well, notwithstanding what Judy just said, let me go ahead and put the question out on

this. Again sort of looking at least for (inaudible) for an answer to Jeff and Clift.

Are there areas or activities that come up in your daily practice, as private counsel and giving advice, that are subjects that are not covered in the health care policy statements that you think should be covered? That is to say -- I'm not just talking about an example.

Jeff, you mentioned putting in additional examples with something like clinical integration and things like that; but are there other subject areas that you come across in your daily practice that are not addressed in policy statements that you think it would be appropriate to be covered if -- in spite of Judy's protests -- there was another iteration of policy statements?

MR. MILES: There are certainly many issues that come up daily that are not covered by the statements, but I can't think of any that really would be amenable to guidelines. They're too -- unique is not the right word. They're too sui generis, I guess, is the best way to say it.

The one area I can think of that might be amenable to some type of guideline analysis is the one that Clift alluded to with regard to physician practices,

which is basically -- and the same would apply to virtual hospital merger analysis -- and that is when -- how do you analyze whether these entities ought to be treated as single copperwelded entities, or as joint ventures?

MR. ELIASBERG: Just a follow-up question. Jeff, when you -- I gather you're saying that that should be something that's covered in the policy -- health care policy statement, notwithstanding the competitor's cooperation-collaboration guidelines?

MR. MILES: Oh, yeah. I don't think -- I really don't think that collaboration guidelines are any help on that particular issue. I don't think they're meant to be any help on that issue.

I guess the question in my mind is whether this provider copperweld issue is the sort of thing that would be amenable to a guideline. I think probably it's a close question, but certainly it's an issue I see very frequently that, to be honest about it, I need some help with.

MR. ELIASBERG: Clift?

MR. JOHNSON: I concur with Jeff on that as well. Perhaps maybe with the virtual mergers less so than perhaps with the physicians practice groups.

But the one situation I alluded to earlier, which was a come back for another evaluation, was

actually a Copperweld issue; and that was 10 years ago. So what had been a legitimate joint venture was, two years later, perhaps a per se price fix. So that would be helpful in that regard.

Perhaps even more simply, when one puts together physician groups, a physician group hires a new physician, or putting together two physician groups in a merger-type scenario -- physicians by nature tend to be very independent and their compensation arrangements tend to be very much productivity based. The physicians are employees under the same physician group, under the same corporate structure, but yet if you were to apply true antitrust principles to some of these groups -- and I'll use anesthesia as an example -- there is no overhead to share, other than maybe malpractice. There's no equipment to share. There's no offices. They're hospital-based physicians.

Yet, you'll have a group of maybe 20 physicians manning a medium-sized hospital. Are these physicians engaged in price fixing when they negotiate as a group? Interesting issue. It's difficult, I think, in the physician practice arena.

Another area I'd like to see some more guidance would be that with respect to most favored nation's pricing. The demands of payers. I know of one situation

where we have a payer that recognizes that they're not going to be as big as the first payer, so they're demanding pricing within 3 to 4 points of the big guy because they figure the big guy's so inefficient they can compete effectively with that much of a differential.

But yet they also want another 3 to 5 points differential between the next biggest guy. And it's just -- at some point, this volume-based pricing concept crossing the line and it's difficult to evaluate.

The final comment -- really -- not really for a new issue, but keep an eye on the effect of any of these pronouncements on rural health care. And there may be occasions where the community need outweighs a potential anti-competitive harm by having two OBs in a rural area negotiate together under one of these group-type of arrangements. So keep an eye on the impact on rural health care.

MR. BYE: Warren, are you on the line?

MR. GRIMES: (No response.)

MR. BYE: I'll persevere regardless.

How do advisory opinions compare to speeches and guidelines in terms of giving prospective guidance and also increasing transparency?

MR. MILES: Well, I'm not sure I'd make that comparison. The problem -- guidelines and opinions both

are very helpful. I think all else equal, the guidelines are more helpful simply because they are more broadly applicable.

The problem I have with agency speeches is I think there's too much pontification and too little substance. I'd like to see some of the agency officials come out and provide substance as far as their views are concerned, both from the standpoint of the specific issues their agencies are interested in and some of the analytical tools and analyses they use, instead of simply coming forth and saying "We enforce the antitrust laws; we believe in the antitrust laws; we believe in competition."

I mean, you know, all of us do. Let's -- help us with some substance with regard to the subjects you're interested in, that you're concerned about, that we can talk to our clients about; and if it's a relatively complex subject, to analyze how you're looking at these things.

MR. ELIASBERG: Vicki and Ellen, I don't mean to pick on you two, but you are the relative outsiders.

Given what you've heard here today, any thoughts on what the Agencies -- the federal antitrust agencies -- can do to speed up the process, make the advice more useful, and to reduce burdens? Anything that

comes to mind, given what you've heard?

MS. COOPER: You know it's funny. I think in part because we did actually model a lot of our program after what the FTC and the DOJ regs – it seems to me that one of the primary differences at least was where we are and where you are is volume; and I don't know enough about antitrust to know why the difference.

I mean, we get a tremendous amount of interest, though not as much as we expected when we first started. When they first started our program, there were predictions that we would get 500 requests a year. That was based largely on the number of informal phone calls that were coming in everyone -- "Well, we get this many phone calls, maybe we'd get that many formal requests." That didn't happen.

But we do get about 50 or 60 formal letters a year. We get a lot of phone calls from people who talk to us about submitting, but for one reason or the other don't. Sometimes we tell them their arrangement's a non-starter. We can tell in the first 5 minutes of talking to them that this is never going anywhere.

And I'm pretty straightforward with people on telling them "This is a non-starter; don't bother. You might want to re-think it and then talk to us again."

Some people decide they don't need one for one

reason or the other. So I don't know what the difference is given that the processes are rather similar in many respects. It may be that ours is a statutory program that was sought heavily by the industry. I don't know if that's made the difference.

But in listening today what strikes me as one of the primary differences is just the scope of the program.

MS. COOPER: Well, it struck me also, this volume issue, because our volume is even smaller than yours, as it seems; and I don't know whether it's for the same reasons, but most people are telling me -- you know, as I made some phone calls and had some e-mail correspondence with my colleagues across the country -- that there's been a diminution in requests at the state level as well for guidance.

And not just in the health care area, but just across the board. And, unfortunately, I can't help you in explaining why that has been other than to say that, to the extent it's helpful to you, we've been getting fewer requests than formally. And I don't know whether that's because antitrust is not on people's minds right now, but that certainly seems to be true at the state level.

So there are -- there seem to be fewer requests

as well for the informal processes that I described. At one time, although we weren't issuing a lot of business review letters, or even embarking on a business review procedure, and then having it withdrawn, which happens to us as well, we were getting a lot more requests for the informal kind of advice that I described where someone would come in and just have a conversation with us and try to get a sense from us of where our boundaries were. And that doesn't seem to be happening quite as much in this new millennium.

MS. ROBINSON: I might just add, I guess, one other observation because one thing that is -- when you say that, our requests for informal guidance are actually going way up right now. We're getting more phone calls, more inquiries.

And one of the things that may account for our volume -- which did rise over time -- it didn't start out the first year as 50 -- may be that more and more people became aware that we were available and that we're there.

We went out and did a lot of speeches and presentations, and a lot of talking up what we do actually; and I think that as word got out that this process was available, that we were open to approving things -- I think there was an initial skepticism that we would just say no to everything -- we actually take a

somewhat different approach -- and built up some credibility in the industry that we were going to do this in good faith. And I think that has, in some ways, contributed probably to the volume.

The other thing that may account to some extent for our volume is that the complexity of issues that we deal with ranges from the very simple, like this ambulance restocking, to incredibly complex financial business transactions. And so some of the opinion requests we get are rather short and simple, aren't terribly time-consuming to prepare the request, and actually we get quite a few do-it-yourselfers with no legal counsel at all who send things in.

And I don't think that's going to be the case with the subject area you're dealing in and I think the complexity of the arrangements you're dealing in probably means that you would have a smaller volume in thinking about it.

MR. MILES: How many people --

MR. ELIASBERG: Could you speak into the mike, Jeff?

MR. MILES: How many people do you have in your letter writing shop, so to speak? How large --

MS. ROBINSON: Well, that's an interesting question. Right now we are unusually small. We've had

some attrition and our original branch chief, left to go into private practice about -- I think I've had the job now for 7 weeks.

So I worked with him the entire time he was there, but he left and we've had some other attribution, that we haven't replaced. We are, at this point, with just three of us. We will be -- we've been as many as, I think, six. Relatively small and focused group, but that does enable us, I think, to do a couple things. One, to speak with one voice, to have consistency in what we do, because we're small enough to talk to each other and consult and we have a very -- a process for clearing things, but even so, it enables us to work closely together. And I think that's actually been a benefit.

We're unusually small right now and we're actually going to be increasing the ranks again. But it's a relatively small group and there are a lot more lawyers in our office that do other things.

MR. BYE: We're coming up to 5:00 o'clock, so I might as the panelists whether they have any final comments to add? Any concluding statements?

MR. MILES: I would just say to keep it up. I think the advisory opinion process is very, very important to us in the private field; and I just want to ensure that the agencies put the same degree of emphasis

on it that we do.

MS. MORELAND: Well, I guess, I can say one thing. We are actually -- the business at the FTC has not dried up. We've got a number of active advisory opinion requests going on, some of which I think probably will see the light of day. So it's -- our experience has not been the same as at DOJ.

And that's leaving aside the non-profit institution things that only come to me.

MR. BYE: I'd like to thank all our panelists for coming along today. It's been an excellent set of presentations.

Thank you.

[Applause.]

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C E R T I F I C A T I O N O F R E P O R T E R

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CASE TITLE: HEALTH CARE AND COMPETITION LAW AND POLICY

DATE: JUNE 26, 2003

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the tapes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JULY 8, 2003

LISA SIRARD

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

SARA J. VANCE