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I N D E X

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But first, Bill Kovacic.

MR. KOVACIC: I want to start this morning by thanking all of our participants for this two-day program, and indeed our participants yesterday for

in this area.

Let me start by looking back a bit. As all of you are familiar, the U.S. competition policy system is distinctive for the open-ended nature of the substantive commands. We don't have industry-by-industry competition policy commands. We have very broad, generic declarations of authority, which place an absolute premium on the capacity of enforcement agencies and courts to adapt general principles and apply them sensibly in specific industry context.

In 1969, the American Bar Association report on the Federal Trade Commission, which in many ways is the modern watershed for the development of the Commission of the current era, suggested that the FTC had a unique role to play in applying competition policy principles to what the ABA called areas where issues of anticompetitive effects turn essentially on complex economic analysis.

Put another way, what the ABA was really telling the FTC to do is to take on the hard problems, to take on the hardest problems of competition policy and to devote its attention and effort to this area.

I would suggest to you in the now nearly 90-year history of this institution, the modern health care program is the single greatest achievement in the

competition policy field of this agency. Going back to the early 1970s where our legislative overseers strongly suggested that we take greater interest in issues associated with increases in health care costs, to the prosecution of the American Medical Association case, the complaint filed in 1975. Path-breaking work involving mergers in the HCA case in the 1980s, a plethora of studies in the field.

I would suggest that this area more than any other, and I'll make the assertion quite strongly, more than any other in the 88-year history of this institution has been the flagship program. This has been the best possible synthesis of our economic and legal learning, and, I think, our greatest success to date in taking on very difficult problems in an extraordinarily complex competition policy area.

In short, if I were challenged to offer one respect in which the FTC has truly fulfilled the destiny that Congress had in mind in 1914, I would advance our work in the health care area as being the best example.

What's the challenge looking ahead? The challenge is to make sure that our policy-making properly reflects marketplace realities. In this field in particular, to ensure that both price and nonprice attributes are given proper effect in the application of

competition policy rules.

I think this has a major implication for how we use our resources, and it involves a continuing change in the way in which we emphasize litigation and nonlitigation application of our resources. I think the basic implication is that we are going to be spending, as time goes by, more and more of our resources in what I would call competition policy R&D.

Back in my former life when I was an irresponsible academic and I enjoyed criticizing the agencies, I was fond of focusing on measuring outputs, such as cases. When I would show up at CLE programs and make smart-mouthed comments about what the agencies were doing, I gravitated towards discussing cases. Cases, after all, are what academics tend to teach in this field.

I've come to this job now, over the past 15 months, with a much greater sense of humility and appreciation for the extent to which the capacity to do good policy-making requires a basic investment in research and development. In other words, if we were a firm, I think we'll have to see ourselves spending more and more time simply on what a firm would designate as our R&D.

In short, the norms by which we ought to be

measured and evaluated over time include a greater willingness to invest in activities that increase our knowledge base.

Let me finish by simply identifying two key areas in which this type of investment, I think, increasingly is going to characterize our work: The first is this workshop. This is becoming an indispensable tool for staying attuned to the developments for academic scholarship in industry developments that are indispensable to our capacity to make good policy. To be willing on a regular basis in depth to hear from a variety of different constituencies about what's taking place in the marketplace.

Again, I salute David for assembling an absolutely superb vehicle for doing this, and to anticipate that this is something of which we'll do more in the future.

The second is an expanded research agenda, really of two types: The first is the willingness to do substantial empirical studies. David Scheffman has developed a wonderful internal empirical agenda, and you're familiar with outputs such as our generic drug study. The generic drug study required us to devote some of our best resources to gathering data and analyzing them. I think the result was an absolutely

superb report, but again, measured by the standards I would have applied in my former life, it doesn't generate a case, it generates a study. But a study, I think, again, that's crucial to our capacity to do good policy work in the future.

A second is our willingness to do retrospectives, looking at past cases. If the antitrust process itself was a form of health care system, it's a relatively remarkable one. For the most part, agencies have devoted relatively little of their resources to evaluating past effects. It's like a hospital that does surgery and never goes back and talks to the patients, but assumes that they're doing well.

As my colleagues described yesterday, especially with respect to hospital mergers, we're simply willing to spend now and are spending more resources to go back and look at actual consequences of consummated transactions. And if those consequences are benign or procompetitive, we'll make that known. If there are problems, we'll look further.

But making this kind of after-the-fact assessment, a core indispensable routine element of what we do, day in and day out, I think, becomes an increasing important element of the competition policy agenda looking ahead.

It's useful to pause for a minute, I think, and look and contemplate what's the meaning of even the title of the workshop. This is a workshop on competition law and competition policy in health care markets. It's useful to try to think, how is that different? How might that be different from a workshop on antitrust law, and antitrust policy?

I would suggest that the difference between those two might be useful to the FTC in trying to use a compass and formulate what its future role in this

So, inward-looking, and then we had a number of those issues explored yesterday, complicated issue, how is the most appropriate way to apply antitrust doctrine to this sector?

The second component of a competition policy is very much outward-looking. It's a recognition that competition or that antitrust policy and antitrust law is simply one component of a broader health care system. So the outward-looking component would try to reconcile the government's role as an antitrust enforcer, the government's role as the largest purchaser of health care services in the country, and the government's role both at the state and federal level as a regulator of health care services, with the goal of greater intrasystem rationality.

Thinking about how does the role of purchasing, how does the role of regulation affect competition in health care markets and trying to think of a competition policy that coordinates those various functions where antitrust law is one component, although a very important component of a broader system.

Within that role, I think the FTC could play a very important role, and is probably uniquely situated to engage in a variety of inter-agency type coordination to remind the government in its actions and various capacity of the impacts of different policies upon

competition. That's sort of what I think of a competition policy.

That being said, and Howard Beales from the consumer protection bureau of the agency was up here talking yesterday, I probably have violated norms of consumer protection in the title of this talk, because this is probably not an empirical look at competition policy, because realistically an empirical look at competition policy, no matter how long or how hard I looked under the microscope, might not reveal very much because I don't think we have a very sophisticated or networked competition policy.

A probably fairer title for my talk would be an empirical perspective on antitrust litigation, and what we're really going to be looking at and talking about today is the role of private and public antitrust litigation in the health care sector over the past 15 years, although I promise at the end of it to come back to this theme of competition policy and try to coordinate or at least think about what the empirical findings suggest in the goal of establishing the competition policy.

Attributions at the fore are appropriate, this

is a joint undertaking with Bill Sage at Columbia Law School who is equally responsible for the insights and the blunders that we may have accomplished together and it's supported by a generous grant by the Robert Wood Johnson Foundation as part of their investigator award program in health policy research.

This is just going to be kind of an infomercial, right, to try to give you a flavor of broader things. I'm not going to try to exhaust the resources, but if you're interested in some of the issues that are talked about, there are two recent publications that are helpful: The first is Antitrust and Health Care Quality in the Courts in the Columbia Law Review. So, if you want all of the tables, all of the data, the discussions of the methodology, that's where you would find it.

There's a second piece entitled The Copernican View of Health Care Antitrust that's coming out hopefully later this month in an issue of Law and Contemporary Problems, and that's our effort to try to take the empirical work and talk about developing this integrated competition policy for health care markets.

People here would probably be interested in that issue more broadly. It's put together by Clark Havighurst at Duke Law School and looks at the question of whether the health care revolution is over, and looks at the rise of managed care, the stall of managed care and the potential fall of

managed care from a variety of perspectives. So, people interested in the issues of this workshop would probably also find that symposium helpful.

What do I mean by empirical? This is, again, trying to vet out the possible misconceptions of the title of the talk. The economists in here are probably expecting me to say something very different when the title promises an empirical perspective of antitrust litigation.

So, what is it? It's a detailed study of health care antitrust enforcement. And why do that? The objective is really to try to assess judicial capacity to assess quality in nonprice concerns. If we're going to have a competition policy, we're going to have a realistic goal for antitrust law, we also have to have a realistic objective of how the courts can handle these types of issues and how far antitrust law and doctrine can be stretched to accommodate various quality in nonprice concerns.

What is it not? It is not an economic study of health care markets themselves, as an economist or an econometrician might do, although that type of research is vitally important in defining both an appropriate

antitrust policy and competition policy.

One caveat, however, at the very beginning of our study, we were very interested in trying to determine the extent to which courts use empirical studies of health care markets, economic research, the health services research literature, in resolving typical antitrust litigation problems. So, in the back of your mind, kind of have this open question in the past 15 years, what has been the role within litigation of this type of more economic empirical studies, and we'll shed some light on that question before we're done.

Again, a summary of the study objectives, more particularly it's to describe medical antitrust

and try to faithfully apply the coding instrument. That's a very different exercise than most lawyers, right? We're not reading the cases to determine what the law is. If that's even a meaningful question to ask or try to answer.

The data here really is the judicial opinion, and it's treated for social science purposes as a data base with a coding instrument. The important caveat there is whenever we had a quality-related code that we'll talk about later, the research assistants were instructed to highlight the quality portion of the opinion in yellow, and when we went back to tabulate and interpret the quality-related codes, we tried to do that in the context of the judicial opinion and not just simply flatten all of the cases into a spreadsheet format.

How do you find published opinions? Well, you go on Lexis and you do a very broad Lexis search, including not just simply doctors and hospitals, but pharmaceuticals, medical devices, allied health professionals, chiropractors, you name it, and you get an outrageously large number of cases, many of which have nothing to do with health care in particular. So, you screen those out. We coded about a thousand cases,

out of those, we reduced it to a data base of about 539 opinions concerned to be relevant. Obviously any one dispute can rise to a number of different numbers of opinion, so if you reduce that down, you have slightly over 400 separate disputes dealing with medical antitrust litigation in the 15-year period of the study.

You get the typical kind of pyramid that you would expect. The Supreme Court sitting on top doing a small number of cases, one percent over the 15-year period. You then have the nice kind of pyramid of about one-third of the cases being federal courts of appeals decisions, and about two-thirds of the opinions happening down in the trenches with the district courts.

We coded a vast number of things, including what are the allegations, what's the time to legal analysis, and for that, again, I would refer you to the Columbia Law Review article. Here I just want to simply try to focus on business conduct at issue. Who is suing whom? What are the kind of activities in the health care sector over the 15-year period that is generating opinions? In contrast, the sort of category of all opinions inclusive of private litigation, with the activities of the public enforcers.

Probably the most striking thing, if you look at the first two lines, staff privilege cases, and

exclusive contracting cases, in the private setting, account for almost two-thirds of the cases, right? Anybody who has already added up the totals and find out they go larger than 100, not uncommon you have multiple coding possibilities. These aren't exclusive, you can

portion of the public enforcement activity, and this is inclusive of the FTC, the DOJ and state attorney generals coded in the public category, has been merger activity. You had a number of discussions yesterday about the nature of the merger cases and I'll have some things to add to that subsequently in the presentation.

Other than that, on the public side, you see a fairly even distribution, all right, of challenging a wide variety of aspects of the health care sector, and in taking Bill's comment to heart, we'll also talk in a minute about how does one interpret a small number of public cases in light of the larger enforcement agency agenda, any impact that they may have in relationship to private cases.

Other striking factors, if you go down to the insurance and managed care category of cases, the network participation, joint contracting, unilateral contracting terms, you find out that all told, they reflect only about 17 percent of the allegations. Again, you kind of have to calibrate how much is happening on the public side? Huge amount within physician hospital relationships, relatively small amount of activity happening in the insurance sector and in the managed care sector in terms of private antitrust litigation.

Then there's a component here of what we call information type cases, gathering together a variety of things that say, what's the role of information in health care markets, that we also tried to isolate and to track.

Now, obviously you can try to break this down by periods, look at each five-year period separately and see if you have any interesting insights. Interestingly enough, the aggregate number of cases doesn't change substantially over the period. So, you don't have substantial increase or decrease in the amount of antitrust private litigation. You have again staff privileges and exclusive contracting cases being the biggest categories. You have a small decline in staff privileges cases in the last period.

You know, in 1986 you had the Health Care Quality Improvement Act that provided limited federal immunity for certain forms of staff privileges. You might be able to attribute the decrease to that, but then you would have to say, why does it take ten years for a federal law to begin to have marginal effects? And you can engage in story telling on either side of that question.

The last part of the study period, exclusive contracting cases, exceeds the number of staff

privileges cases as the largest category. Again, interestingly enough, you see an increase in merger activity, at least as represented in actual litigation.

If you now go down to the information cases, you actually see a decrease in the private credentialing and accreditation cases, which I find interesting, and I find that as a sign of saying that that war has basically been won. People recognize the value of information, a lot of plaintiffs no longer try to argue with various credentialing agencies or other forms of standard-setting within the industry, at least on antitrust grounds.

right? Not that the plaintiff ultimately wins in the end, but at least they have stalled the defeat that they might have suffered ultimately. Affirmances of appeals by defendants or reversals on appeals by plaintiffs are also substantial outcomes for plaintiffs. All told, they get substantial outcomes in only 15 percent of the cases that they bring. Defendants winning about two-thirds and about 20 percent of the cases being kind of neutral in terms of the disposition of the ultimate resolution of the dispute.

So, the private lesson is, unsuccessful plaintiffs. What about the public side, right? You might sort of say, wow, in comparison to the private litigants, at least the public litigants are much more successful. You see a success rate of about equal number of wins and losses on the way that we have sort of subjectively categorized it.

If you now go down to substantial outcomes for defendants in the public category and remove all of the losses in the hospital merger cases, you would have a substantial inflation in the government win rate, and so those merger cases, at least in the 15-year time frame that we're looking at, drive the government win rate down from sort of historic highs of the kind of high '70s, even if you go back to 1960s, 80 percent win rates

down to something closer to 50/50.

Again, you can try to break that down by forms of conduct. You tell some stories here that the antitrust lawyers in the room would not find surprising, staff privileges cases are the dogs of the dogs in terms of trying to win for plaintiffs with the lowest rates, exclusive contracting hitting closer to the mean of what the average is.

The other category, remember other now is anything that's not staff privilege or exclusive contracting, so that's all of the insurance cases, all of the managed care, all of the things dealing with medical devices and pharmaceuticals, higher win rate, relatively speaking for plaintiffs, although substantially lower in terms of what happens in terms of outcomes for defendants.

Again, sort of gives you a flavor of who is suing who and what some of the outcomes are.

I can sort of conclude this descriptive component and then we're going to shift over to talking about quality of care and quality of nonprice competition, although there are a couple of things that sort of encapsulate what I've already said.

Litigation is dominated by hospital/physician relations, right? That's kind of disconcerting for

those of you who expect to use private antitrust litigation as a vehicle for policy making. It's not effective, at least for the bulk of the cases.

Managed care reflects a small minority of litigated cases by comparison, and plaintiffs lose no matter how you measure that, although the public concerns and win rate is higher.

Interestingly, again, and it sort of questions how do you make the numbers? If you wanted to say that, boy, over a 15-year period, the government has only brought, you know, some 20 or 30 cases, what are they doing in terms of health care litigation? They are only a small part of the picture, right, in relationship to the private cases.

It raises interesting questions about who sets antitrust law, right? Is antitrust law being driven by private or public entities? Does bad case law on one side of the private/public divide influence the outcomes on the other side of the divide? Is one of the challenges public

public antitrust enforcement.

Here are the caveats that I think are appropriate and correspond to some of the things that Bill was talking about: Judicial opinions only reflect a small part of what an agency does, right? So it's unfair to try to generalize too much about public antitrust enforcement roles, simply by looking at

forum of private litigation.

Kind of shifting gears now out of the descriptive information of the private litigation into this discussion of quality and nonprice competition. It's hard, and a number of these things were reflected in the discussion we had yesterday, a number of them I'm sure will persist in the panel discussions today. What do we mean by quality? How do we know it when we see it? How is an antitrust or an enforcement agency supposed to prosecute or regulate in terms of protecting quality?

The first thing I think you have to let go of is thinking that there's a uniform view or that quality means one thing. The reality is, and if you look at the coding instrument, which was multiple categories, quality means many different things in many different contexts, you just have to get comfortable with that and therefore try to think about the many different meanings of quality.

Underlying a lot of this discussion are paradigmatic, you ask a health care professional what quality means, you get a fairly objective absolutist interpretation. You ask an antitrust lawyer and an economist what quality means, you get a very different understanding paradigmatically about what quality is.

I like sort of the distinction of saying that a lot of health care professionals view quality as something apart from competition, really separate from competition, whereas the traditional antitrust response and economic response is to say no, quality is a part of a competitive process, and that is one way to get a handle on sort of the conflicts that you often have between health care professionals and antitrust enforcers about the meaning of quality in nonprice competition.

Health services research literature provides a different window on the world, right? These are the people that are out there and make their lives studying the health care system in a very quantitative fashion trying to answer basic questions about what are the effects of various practices, organizational forums, and processes? In the health services research literature, you basically break down quality into the structure and process outcome paradigm, and if you come from the University of Michigan, you have to attribute that to Donabedian who was at the Public Health School at the University of Michigan for years and years.

That provides a whole different method of trying to understand quality. You measure the accreditation,

the ownership, the physical facilities. If you're talking about the structure components and the process components, you look at what tests are ordered, malpractice history, preventative services and outcomes. You say, well, what's the actual affect on morbidity, mortality? You have surveys, you have consumer rankings.

So, there's a rich area of literature out there that might measure quality in a quantitative way that

One thing we did in the survey instrument or the coding instrument is try to code what judges think about the effects of competition. What are their beliefs about the role of competition. Again, these are all in health care cases, variously defined. What we found is sort of two lessons you might take home: First is that most of the opinions don't expressly articulate views, right? So what we have here is 539 opinions in the background and we're generating things at the highest of sort of 58, 38, 7 coding things of courts actually expressly considering these considerations.

Of the courts that do express a particular view, orthodox beliefs dominate unorthodox beliefs. And by that I mean most courts believe that what most antitrust enforcers believe, that competition decreases prices, that competition decreases cost and that competition will in various ways increase quality, although what do we mean by quality? A more complicated question.

The unorthodox beliefs are out there, but they're really in a handful of cases. Six coded entries saying that competition will increase prices. Seven coded entries saying that competition will increase costs. That sorts of the medical arms race scenario that was discussed yesterday. Three entries saying that competition will decrease quality, which is really kind

of the larger policy issue and question at the fore of thinking about managed care in sort of the new millennium.

All right, so that's interesting. To say the courts at least express a view about quality, they adopt orthodox views and that the unorthodox views, despite the sort of losing trend in the merger cases, actually represent a minority view.

Other interesting sort of findings from the antitrust lawyers' perspective, the whole sort of set of Goldfarb era concerns. You know, that trepidation of approaching the profession of antitrust rules, that professions are different, you need different standards and you have all of these unique social and professional concerns, barely get lip service, all right? So at least in the sort of time frame that we looked at, 1985 to 1999, Goldfarb era concerns get very little attention.

One caveat there is at the end of our study period, what happens? We have California Dental Association decided by the Supreme Court, California Dental Association for the first time probably since Goldfarb was decided in the 1970s, raises the specter of Goldfarb era concerns again, and if that's going to take root within district courts or appellate courts, we

don't have a study window that allows us to answer that question.

All right. Overview on the quality characteristics. This is again going to give you a sort

distribution, although I'll go through a series of slides that gives you a more particular view of the entries that we considered.

If you're now looking at clinical structure, and again, remember, the end back there is 539 cases, right? So, this is really saying that these particular sets of issues are raised in really only a small handful of cases in practice.

If you want sort of two other numbers that are actually quite helpful: Thirty-six percent of all private cases raise at least one quality coded factor, all right, so you sort of say, in one-third of the private cases, at least one of the issues that we're coding for the many issues on quality, were addressed by the code, right? Which means that two-thirds of the private cases don't raise any of the quality factors that we look at.

If you look at the public side, interestingly enough, 71 percent of the public cases raised one of the factors relevant within our sort of quality nonprice coding instrument. So there's a greater tendency amongst the public cases to be paying attention to these various concerns than there are in the private cases.

Structural components, easier to understand why courts are trying to focus upon those and use those.

You can look at these things, I can try to measure them, and I can imagine theories one way or the other on why these factors might be able to increase quality and I might be able to think of the effect of competition and various levels of restraints in trade on these, all right.

So, it's the qualification of physicians, adequacy of staffing, continuity of care, adequacy of facilities, private accreditation, advanced technology. You know, these are not brain science, or sort of rocket science or brain surgery, these are bread and butter things that one would think if one were worried about quality in competition, you would have discussions related to these.

Some of them do occur, which I guess is an important finding, but not in a very sophisticated fashion, and not very often. Switch over to clinical process, we can tell a couple of different stories from these numbers. The first is, guess what wins? Unspecified process or quality concerns, right? When courts talk about quality it's usually done in an abstract level. There's a lot of hand waving, not a lot of efforts to try to be specific, and therefore on all the kind wastebasket categories seem to win in terms of the number of tabulations. This is not surprising.

Malpractice history gets 25 coded entries. Almost exclusively in the staff privileges cases that you might expect. And ironically, you know, people sort of well-versed in health policy and health law know that the malpractice history probably has very little relevance or correlation to actual quality, right? So, if you're looking for a measure of quality, the one the courts seem to latch on here, malpractice history, actually is not a very reliable factor.

Significantly, potential for clinical improvement is acknowledged in a small handful of cases, and I find that promising. And these are cases that talk about particular doctors or practices having unique approach to a typical type of medical problem, and underlying the protection of clinical innovation is not just simply concern for innovation but an underlying protection of choice, and we'll get to choice more directly in the market-level characteristics.

If you look at the losers here, rankings in quality surveys, outcome statistics. These are the gold standards of the health services research literature, right? This is what all the professionals will say, how do you measure quality? Talk about quality? Think about quality? What do I nel3ewo cnow thomarke ere-6k anre, rank

instrument in terms of what you find in judicial opinions. All right?

So, one significant finding of our analysis and our study, courts just don't deal with health services research literature. And what does that mean? That means that antitrust lawyers are not calling them as expert witnesses, are not trying to develop theories of the case that rely on that type of evidence, and rather rely upon these vague kind of abstract notions of unspecified quality concerns and hand waving when they deal with these issues.

I will go through this slide fairly quickly. General reputation for quality can have two interpretations: One, again, is further support for this kind of abstract notion of quality, trumping any specific notions, that's supported by the other category winning ten coded entries.

There's also a different story you can tell. Reputation in malpractice history are at least possible economic indicators of quality upon performance. Malpractice exposure, whether or not it's correlated with quality is correlated with potential liability exposure. General reputation for quality can be translated into notions of good will within a business school setting.

And one can say here that the things that are more likely to register on the antitrust metric of these opinions are quality considerations that can be translated into an economic parlance such as improving good will and reducing malpractice exposure. And one can say that courts are receptive to efforts, marginally

demonstrated that competence.

If you look at information, you have a smaller number of cases, but a sensitivity to the role and importance of information in making markets work effectively. And the thing about R&D innovation, small number, right? And that's kind of disappointing, if you think of a dynamic efficiency perspective, if you review innovation as an important nonprice concern or attribute of markets, courts seem to be less significant or less attentive to innovation as a separate concern.

Some preliminary conclusions, then: What can we say about some of the quality? One interesting thing is really that there is a return to orthodoxy here, and that orthodox beliefs trump the unorthodox beliefs. Why is that relevant? I think from that and from sort of the other things that we get from our instrument, no matter how much of a black eye the public enforcement agency has suffered from the hospital merger cases, they're an anomaly, right?

The same theories of the case that underlie the hospital mergers hasn't bled off into the other areas of antitrust law, right? So you can sort of view them as idiosyncratic, isolated incidents of judicial skepticism about the effects of competition, and I actually find it quite interesting that the same paradigm that motivated

the courts in those cases has not seemed to influence judicial decision making in a wide range of other private and even public antitrust enforcements, and I think that's significant.

There's a tension in these opinions, right? The tension is sort of back to this idea that there's many meanings of quality. There's a tension between courts as they try to view quality either as part of competition or apart from competition, and that tension is probably best illustrated between the staff privilege cases and the exclusive contracting cases.

All right, remember plaintiffs lose both of these things, but if you look at how they deal with quality concerns, there's a very different temperaments in the opinions. In the staff privileges cases, they view quality as a constraint upon competition. Similar to licensing, similar to malpractice histories, similar to self regulatory traditions within health care and are deferring to the assessments of quality of these other benchmarks, right?

So, they divorce quality from its sort of antitrust concern about competition, and treat this whole range of issues as apart from competition.

The exclusive contracting cases are the exact opposite. In the exclusive contracting cases, which are

again about one-third of the sample, courts expressly view quality, and now we're talking primarily about the quality of the hospital, vis-a-vis a particular set of anesthesiologists, or other sort of doctor shop as a

your clients, how do you articulate them better? Because you're not doing a very good job, or at least the courts are not being receptive to those arguments and there might be sort of areas to mind in bringing new resources and resources to bear in the context of litigation.

Courts are more likely to employ traditional antitrust heuristics of decision making, right? This is what we pick up in any antitrust textbook, the value of choice, right? The value of information, the value of innovation. By innovation I'm concerned here not just simply about technological innovation but forms of organizational innovation. And one can view managed care simply as a form of organizational innovation and a lot of the change in the health care industry in the last 15 years in terms of innovations in terms of organizational form.

Much higher chance that if you can get a theory of the case that fits into one of those heuristics, the courts will respond, than if you're trying to get the court to sort of wander further out on the boundaries of nonprice and quality competition. And kind of remind you that antitrust law, again, sort of from the private perspective has played only a minor role in addressing quality-related concerns in managed care in the

imposes a challenge most of the public enforcement agencies and to the courts to say, can this sort of set of rules that govern the economy be applied appropriately in the context of sort of basic antitrust litigation.

So far, I would say the performance has not been stellar. I think you can point to sort of small trends and instances that might be able to be reproduced and emulated, but a lot of work still needs to be done to sort of rethink antitrust law in a way that can appropriately be applied in a lot of medical settings.

If I'm now kind of changing hats, right, and going from the inward-looking sort of how do I revise antitrust law to the outward-looking of how do we have antitrust law work in conjunction with a wide variety of other sort of government actors, regulation purchasing antitrust enforcement, one of the things that we argue for in the Copernican piece that comes out in long-term temporary problems is the need to get away from the

I'll highlight a couple parts of interesting doctrinal concerns that a competition policy is going to have to wrestle with in the future. One is the substantial limitations that the Noerr Doctrine has in enabling antitrust to be freed up to take care of manipulation of political processes, all right? I think a lot of the generic drug enforcement cases recognize that private parties can manipulate public regimes in ways with substantial anticompetitive effects.

One way to attack that is to attack that directly as the FTC has done. The other way is to free up private parties to enable them to bring similar types of actions if there are abuse of the pharmaceutical industries or the regulatory parameters, but what we find is that the Noerr Doctrine prohibits a lot of that. So at least what I would provide as a challenge is can we rethink the parameters of the Noerr Doctrine to free up antitrust laws to challenge greater degrees of manipulation of public processes or are there ways to go outside of the antitrust paradigm to get these agencies such as the FDA or the FTC more effectively governing and releasing manipulation of public property.

Second, there's a need for more unified treatment of state regulation and professional self regulation. In the Copernican piece, we make the bold

proposition that we should actually get rid of the State Action Doctrine and subject the state regulations to forms of substantive antitrust scrutiny in similar ways that we would do with private regulation and private self regulation. So I think we can rethink the parameters of the State Action Doctrine in ways to get a more coherent competition policy.

As Professor Brewbaker suggested yesterday, there's always a contention in health care markets

cite the GPO contract.

The idea is that by pooling the purchases, they can negotiate a lower price than an individual hospital can on its own. There's also other supposed cost savings that they can provide hospitals. For example, the hospitals all don't have to negotiate themselves with every manufacturer, and the same time, manufacturers don't have to do some of the marketing and sales to reach every single hospital by virtue of the GPO being in existence.

So, after the GPO negotiates the contract and the hospitals -- and some of them, they're primarily voluntary relationships. So, just because they're negotiating on behalf of several hundred hospitals doesn't mean those hospitals are going to buy everything based on that contract. But after they do buy purchases, the vendors will pay a portion of the sales back to the GPO as administrative fees. This is how the GPOs pay for their operating expenses.

the hospitals that they negotiate for. Not always, in some cases there are individual independent investors that own the GPOs, but often hospitals and other health care organizations actually own the GPO itself.

So, those are the two basic things. They are contract negotiators, they don't buy or sell on their own, and they charge administrative fees, and that's how they make their money. But beyond that, they really vary a great deal in how they do that, and whether they do it nationally or regionally, what other services besides contract negotiation they offer, and while they are primarily private for-profit companies, whether they are again owned by member hospitals or not.

Just for a sense of the size, the GPOs in our study basically reported that using their contracts, the generated sales are between $1 billion and $14 billion, so even though the relationship is voluntary, there's a lot of money going through these contracts.

Then the next two things I am going to say are things we didn't really talk about in our study or look at, but just background information. There are guidelines put out by the Department of Justice and Federal Trade Commission that help GPOs gauge whether or not they might be an antitrust concern. Basically just because you meet the two tests that are included in the

guidelines doesn't mean that you are not a concern. There could be extraordinary circumstances which make you a concern.

Just because you don't meet the test doesn't mean that you are also a problem. But basically the first test looks at whether there's enough purchasing going through the GPO that it can effectively exercise increased market power, and drive prices below the competitive level. The second one is really looking at

they have to disclose in writing to each member the amount of money they actually got from the vendors based on the purchases made either by that member or on behalf of that member.

So, that's background information. And what we did was a pilot study, and it was done at the request of the Senate Judiciary Committee, Subcommittee on Antitrust. It was a very narrowly focused study. The context of the study was that there were concerns that

paid when they used a GPO with the price the hospital paid when they bought on their own. Because it turns out most of the 18 hospitals in our study did belong to a GPO but they almost all also bought outside of the GPO contract.

That's the first question. The second question was looking at whether they were buying from small manufacturers or not, kind of a representation issue. Basically based on the data that we got, from the 18 hospitals, for pacemakers and safety needles, we found that the hospitals using the GPOs did not always get a better price for the member hospitals.

When we first looked broadly at anybody everybody, and compared to hospitals that used the GPO, those buying on their own, always got better price for five models of safety needles we compared. They ranged from one to five percent, though. The hospitals using the GPO contract paid one to five percent more. For pacemakers, the ratio was much greater and basically hospitals using the GPO contract for one model paid 25 percent less than the other hospitals, and for another model, paid 39 percent more.

So, the variation was great, but more than half of the time the GPO, the hospitals using the GPO contract did worse than the hospitals buying on their own in this

case.

We also looked at all the hospitals and then looked just for large GPOs, and those we defined whose sales are of $6 billion or more per their contracts. Basically we found the same thing. The hospitals using the large GPO contracts did worse for the five safety needle purchases we could compare and did worse about half the time for the pacemakers.

We then looked at the size of the hospital and found that small and medium-sized hospitals were more likely to have price savings with GPOs, using the GPO contract. Basically small hospitals using the GPO contracts, those with 200 or fewer beds always did better, and this is for pacemakers, when they used the GPO contract than those who purchased pacemakers on their own, the small hospitals on their own.

Conversely, large hospitals always did better buying on their own, they rarely did better when using the GPO contract.

The third comparison that we did was we looked at hospitals using large GPO contracts versus those using small. And we found that it varied by the device. The hospitals using the large GPO basically did better for virtually all those safety needle purchases, but when they bought pacemakers they were less likely to get

hospitals, and for other medical surgical supplies and devices between the pacemakers and safety needles. That's it.

(Applause.)

MR. HYMAN: Thank you very much, JoAnne.

We now have a panel on hospital group purchasing organizations, if everyone from the panel could come up.

MS. DeSANTI: Good morning. My name is Susan DeSanti, I'm Deputy General Counsel for Policy Studies, and next to me is my colleague, Matthew Bye, who is also in the Policy Studies Shop in the General Counsel's Office.

I want to welcome everyone to today's panel and I particularly want to thank our panelists for their time and effort in coming, we very much appreciate having you here, and we think we're going to have a diverse and balanced group of presentations today on hospital group purchasing organizations.

I'm going to start by briefly introducing each panelist, moving down the table, and that's the order in which they will make their presentations. Each panelist will make a presentation and then we'll have time for discussion at the end, and I do want to emphasize, David has obviously been keeping the time moving swiftly, and I think will continue to do so. The presentation is

President Materials Management at Sentara Health System, an integrated delivery system of hospitals, clinics, nursing homes and managed care insurance markets in Norfolk, Virginia. He has 23 years of materials inventory systems integration project management and solution development experience.

Then we move to Bob Burns, who is the James Jugin Kim Professor, and Professor of Health Care Systems in the Wharton School at the University of Pennsylvania. Bob is also a director of the Wharton Center for Health Management and Economics, and Visiting Professor in the Department of Preventative Medicine at the University of Wisconsin School of Medicine.

Then we have Cliff Goodman. Cliff is a Senior Scientist at the Lewin Group, a health care policy and management consulting firm based in Falls Church, Virginia. Cliff has more than 20 years of experience working with government industry and nonprofits in health care evaluation.

Next to him we have Steve Latham, who is Assistant Professor and Director for The Center for Health Law Policy, Quinnipiac School of Law where he teaches health care business law, business organizations and administrative law. He is also a lecturer at the Yale School of Management where he teaches business

ethics.

Next to him we have Larry Holden who is the President of the Medical Device Manufacturers Association in Washington, D.C. Prior to joining MDMA, Larry was chief of staff to Congressman Christopher Shays of Connecticut.

Finally we have Robert Betz. He is president and CEO of the Health Industry Group Purchasing Association. He has spent more than 20 years representing health care organizations in Washington, D.C. Prior to forming a private health care consulting management and lobbying firm, Robert worked for the American Hospital Association in Washington and the Louisiana Hospital Association in Baton Rouge.

With that we will get started with our presentations, and you may go first.

MR. CLARK: I am pleased to be here with you today, ladies and gentlemen.

As was mentioned, I'm Bruce Clark, I'm here on behalf of the American Hospital Association and represent specifically Intermountain Health Care, which is my employer. We're an integrated delivery system operating in Utah and Idaho. We have 22 hospitals. We operate about 100 health care centers and clinics. We have a health plan division with a group of insurance

products ranging from the traditional indemnity up through managed care, serving principally the residents of Utah and Idaho.

Just a disclaimer, and I begin my presentation. I'm not a professor, I'm not an attorney, I'm not an economist, much of what I say may seem pretty simple, but what I will share with you here today is our perspective as a provider organization on group purchasing, how it works for us and why we're involved in it.

I would like to just begin with a statement about the environment that we as hospitals operate in currently. About a year ago, in November 2001, the American Hospital Association released survey data that indicate that as of the year 2000, the end of the year 2000, one-third of U.S. community hospitals had negative margins, sixty percent had negative Medicare margins, and nearly two-thirds of U.S. community hospitals lost money on patient care services.

So, almost two out of every three community hospitals were relying either on investment income or endowments or some other income stream to make up for losses in their patient care services, or were in the process of going under.

In that environment, hospitals are reaching for

both the provider and the supplier. The supplier benefits in that their marketing activity and the cost to promote their products to all of the members of the group purchasing organization can be significantly reduced as the group purchasing organization publishes the contracts and promotes the contracts to its membership.

The health care provider can benefit by not having to spend time negotiating contracts and being able to divert those scarce human resources to focus on supply chain activity purchasing, receiving, storage, distribution activity, and looking at opportunities in their internal processes to take costs out of the system. If effectively done and with appropriate automation and electronic links, the transaction costs for both parties can be reduced.

Almost all U.S. hospitals participate in at least one group purchasing organization. An article in the Wall Street Journal Online just last month estimated that up to 98 percent of hospitals participate in group purchasing associations, in at least one GPO. It's been estimated that up to 75 percent, 50 to 70 percent of all products purchased by hospitals flow through group purchasing organizations.

One point that I think is important to remember,

because there have been some concern about what market power GPOs may exercise. It's important to remember that hospitals are free to join or not join group purchasing organizations. No one is required to be a part of a group purchasing organization. I'm free to join any group purchasing organization, or to join several group purchasing organizations.

The GPOs have to compete for my business, and for hospitals' businesses, and they are free to select GPOs that best represent their interests. Many providers belong to more than one group purchasing organization.

Intermountain Health Care belongs to a single GPO, in our case that's Amerinet, approximately 85 percent of our nonequipment purchases flow through the group purchase organization. Amerinet offers generally two or more contracts in each supply category, so we're able to choose, again, between more than one supplier for any category of supplies that we're dealing with, again, facilitating choice and competition.

We believe in the right of first refusal. We will purchase on GPO contract in every case possible, and every case where a contract supplier has a product that meets our clinical criteria. In the event that there's not a supplier meeting our clinical criteria, we

will sit down with the contract suppliers, offer them an opportunity to understand how to meet those, and then only if they're unwilling or unable to meet those criteria then do we look off contract.

Our clinicians and our care process models drive the selection process for the products and services and suppliers that we utilize. There are multiple opportunities through surveys, through advisory boards, advisory groups, for us to have input into the suppliers that are selected for contract in our group purchasing organization.

In conclusion, we've also found that in a number of cases, group purchase contracts provide a better deal than we can negotiate on our own. A recent example of that was with respiratory products where we participated in an Amerinet/Elite comparative contract process. The resulting contract provides a six percent improvement over the previous best price that we had negotiated as a system.

I would just conclude by saying that our experience has been that as we participate in group purchasing, and as we do it appropriately, we're able to reduce costs, we're able to improve the quality to the patients and the communities that we serve.

Thank you.

(Applause.)

MS. DeSANTI: Thank you, Mr. Clark.

Next we'll hear from Mr. Manley.

MR. MANLEY: Good morning. I've chosen this morning not to use overheads, I thought I would try a low effect presentation. I'm sure we will hear a lot about equipment technology later.

Like Bruce, we're a vertically integrated, horizontally managed integrated delivery managed network located in Norfolk, Virginia. We have a full line of products, including a new hospital, short and long-term stay facilities and a lot of products in the insurance marketplace through the managed care.

We have developed our environment in an urban area and we do have some advantages there. We are a member of a GPO, and we currently purchase about 30 percent of our total spends through thatoTed.

I've come today and I thought rather than just talk about Teds in general and our position, I thought I would talk a little bit about whatoI see as trends in the industry, whatoI see as some problems in group purchasing and some areas where we could possibly look for improvement.

The industry is changing, I think today the industry has an extreme imbalance. If you look atoit,

those folks that cannot help themselves to manage the cost is a value. So I think they will have a place in the industry, I think that place will be harder to manage as you see more and more of the integrated network technology take place.

I think there's some interesting issues out there. One of the issues that we deal with is the cost of change. The question you ask do incumbents have an advantage? Absolutely. Change costs money. It costs a lot of money. It is very difficult to change a thousand bed hospital or a thousand hospitals. I think to that area, sometimes we get stuck with the current manufacturers because their cost in changing those products are not of value to the industry.

So, do you ask me if GPOs get manufacturers that they stay with for a long time? Absolutely, and I think there's a reason for that. I think there's a cost reason. That said, does the quality versus cost equation have a place in the industry? Absolutely. Most IDNs, most GPOs, most people use the model I think we use which is ESP which is efficacy, safety and price, it's a three dimensional evaluation. Our IDN will always evaluate quality of product. We will not buy a product just because it is a low-dollar proposal. We will often select products that are not the low-dollar

proposal simply because we are meeting a standard of quality to meet our need.

I think the policy that GPOs pick low cost items for low quality does not exist because I don't think the (rcR btryeeyre8y-24oeanlep

the ability to select products and services, put them in a market basket that meets a need and that need will go forward from there.

If there is a bundling concept, I think those bundling relationships will exist directly between manufacturers and new larger IDNs as a partnership function rather than a GPO-driven function.

Those of us that can manage our own costs versus those of us that need help in managing our costs. Whether that's a national strategy versus a regional strategy has to be determined. Whether that is a threshold strategy of dollars versus volume, that needs to be determined. But they need to continue to evolve and in my estimation need to evolve a little bit faster to meet

MR. BURNS: Thank you. I want to thank David for inviting me down here today to speak.

I am going to give you an academic's perspective on group purchasing organizations. I'm not going to go through all of this because some of this has already been covered. But just to summarize a little bit of the different roles that GPOs play in the health care value chain, the roles they perform for their hospital members, and then I think what's more of germane for this audience is to look at the industry structure, GPO revenues and market structure, the concentration of this GPO industry, and see what conclusions we can draw from just a simple industrial organization analysis of the industry as to whether it's competitive or noncompetitive.

Finally, just some views of hospitals of the GPOs. You've heard two already. I had the privilege of conducting a four-year field study of not only GPOs, but hospital integrated delivery networks, manufacturers, distributors, e-commerce companies that were trying to disintermediate the supply chain, and in a little bit of shameless self promotion, I have shown you the cover of the book here that was published earlier this spring. But I am from a business school and I actually have brought flyers that offer you a 15 percent discount if

you buy it. But that's just the Wharton way of doing things.

Basically what the health care value chain is is the following: We have a very complex system. What our field research focused on were the providers, the hospitals which you've been hearing about, the large integrated delivery networks, dealing through a series of intermediaries, whether they're wholesalers on medical/surgical and drug side, or group purchasing organizations purchasing products on their behalf dealing with the whole series of product manufacturers.

What our book dealt with was this whole right side of the equation. I think it's helpful to just to have this picture in mind, because you need to view the GPOs in context and what they are is essentially an intermediary. As an intermediary, they are subject to a lot of market pressures, because in a number of industries, there are trends towards disintermediation, or cutting out the middle man.

We see that right now with a number of the large integrated delivery networks trying to act either as their own GPO or their own wholesaler or in sometimes both. So the GPOs are quite cognizant of this, and they're facing a number of market pressures from their own hospital members over here who are trying to

hospitals may join.

So, it's a huge important difference to understand. There are also membership differences, whether or not they represent hospitals, there's the physician or alternate site markets, geographic differences. They're subject to antitrust limits on how big they can be. And often times it's hard to distinguish the GPOs from the integrated delivery networks that you've been hearing about.

Intermountain Health Care is one of the three largest shareholders of Amerinet, and so to some extent they're indistinguishable.

This is a slide from our book in terms of looking at the GPO revenues and market share. You can see why the attention in the New York Times article was so heavily focused on Novation and Premier is because they have a whopping share of the hospital market. These are the big five on the nonprofit side and the big two on the for-profit side.

Now, it's interesting, if you look at how concentrated the GPO industry is, you can do it one of two ways: First you can do it as a percentage of the medical supply and pharmaceutical spending that GPOs actually penetrate. And going back to my prior slide, we're looking at this $47.7 billion that GPOs actually

penetrate. The top four GPOs, they constitute $36 billion of that or almost 76 percent of the GPO penetrated spend is accounted for by four top GPOs, with a very high concentration level.

However, if you look at the concentration of the GPO industry in terms of the total amount that hospitals spend on their medical and pharmaceutical supplies, you will see that the picture is quite different. The total supply is estimated to be roughly $67 billion, and like a true academic, I have, you know, an upper and lower bound estimates here, and a footnote, the top four GPOs account for $36 billion of that, which is only 54 percent accounted for by the top four GPOs, with a concentration level which is roughly half of what you see in the top panel.

So the numbers you use to look at the concentration of this industry are extremely important. Why the big difference between the upper and lower panel? Well, a number of the reasons have already been mentioned. First, hospitals can direct contract with manufacturers for their supplies and totally circumvent their own GPO.

Secondly, the GPOs actually only account for a percentage of all the medical supplies and pharmaceuticals that hospitals buy. It varies by the

type of product. Of that percentage, hospitals only comply with the contracts a percentage of the time. So what the GPOs are actually intermediating is a percentage of a percentage, and that's why the lower panel on the prior side is so much different than the upper panel, because the GPOs only contract for a percentage of a percentage.

There's also, as JoAnne mentioned, extreme variation among the GPOs in how well they monitor these contracts. In addition, as has been mentioned, hospitals belong to multiple GPOs, with multiple GPO memberships, you have divided loyalties and hospitals can shift membership share from one GPO to another, although that has not yet been documented how extensively or quickly that takes place.

As we can see, hospitals can purchase directly through their own integrated delivery networks and act as their own GPO. Finally, hospitals will act independently of their GPO, even when they're shareholders of the GPO when it's in their own self interest to do so.

So, in my view, the GPOs really have a challenge in trying to control their hospital members who have voluntarily joined them and I think the biggest challenge they have is just acting as a coherent body.

Mr. Goodman?

MR. GOODMAN: Thank you very much to the FTC and to David in particular for having me here.

The Lewin Group was commissioned by the Health Industry Purchasing Association to conduct a study, a survey study of the clinical review process conducted by group purchasing organizations and health systems. I'll tell you a little bit about it.

Here's a summary of our approach: It involved surveying five major health systems and six GPOs earlier this year. We interviewed a set of purchasing managers, administrative officers and medical officers of the health systems, upper-level executives, clinical operations directors of GPOs, conducted the interviews primarily by telephone using a detailed interview guide that was sent to all participants prior to the calls.

We developed this interview guide with input and comments by HIGPA, and left out of the study were proprietary aspects. We did not ask about contract terms, financial arrangements and business tactics, we were primarily concerned about the clinical review process.

Here are the GPOs that we surveyed. You can tell from the previous presenter that these GPOs account for a significant portion of the market. Here they are.

And I wanted to get just go right into our main findings.

Now, the most interesting thing I found in doing this study was really the breadth of technology attributes and impacts that are incorporated into clinical review processes. What one might expect typically is you'll see right in the middle there, economic attributes, because we think that GPOs are largely about price, but when quizzed on this, the people that run hospitals and make these decisions and the GPOs themselves tell us the kinds of factors that you've got to bring to bear to make decisions about these kinds of technologies.

I think Dr. Hammer referred to them as nonprice concerns. Nonprice concerns are quite present and prominent in these decision processes. Look down the list, technical properties and performance: Does the thing work or not, you know, when you plug it in. Safety to patients and health care workers, efficacy and effectiveness, economic attributes themselves are not confined to price.

Cost, cost effectiveness, cost utility, cost benefit, charges, ability to be reimbursed by a variety of third party payers. Those fall under economic attributes alone. Acceptability to patients and

clinicians, you know, ergonomic concerns, risk of liability, potential for standardization.

We're not done. Impact on market share and competitiveness, work flow considerations, reputation support provided by the manufacturer, and this one came up a lot, capacity of a vendor to provide sufficient and reliable supply. If you look at just what the price is, you're only getting a small bit of the story.

One of the challenges that the hospitals and GPOs face is to how to incorporate and weigh and interpret these various factors in making these decisions.

Our first main finding, though, is the clinical review processes of health systems, GPOs rely upon comprehensive systems of expert committees. It's not a one-person decision-making operation, and one of the interesting things that I found in particular, because I deal with technology assessment efforts around the United States and the world, is increasing multinational interdisciplinary processes in bringing together the right set of experts to weigh in on all of these issues. This is really held in common by the groups that we talked to.

They also, interestingly enough, used some of the same recognized independent technology assessment

resources. I know that groups, hospitals and other purchasers, providers, payers, use ECRI and Hayes and other technology assessment vendors. They use Medline and other databases, and lo and behold those are the kinds of things that we found.

As a matter of fact, I think it's a consortia that provides access to the Hayes technology assessments to all of its member institutions to help not only those member institutions but to help the consortia itself in weighing these decisions.

The health systems and GPOs have functions for monitoring and incorporating what we sometimes call break-through and other novel technologies. One of the great challenges here, I must say, is the great wealth, or I should say the width of the new technology pipeline. There's a lot of bandwidth of new technology here, and part of the issue is trying to identify these truly novel and break-through technologies and trying to keep track of these and the various ways in which GPOs and the large hospital systems try to track these things.

These functions include the capacity to respond to initiatives from the technology companies and vendors themselves as well as actively seeking out, that is horizon scanning for new technologies.

But of course consideration of such technologies is still subject to the same bits of demonstrating safety, effectiveness, cost effectiveness, reliability of

systems.

One of the most interesting ones that I came across was one GPO has a clinical technology service. They're kind of the guys in the garage if you will looking under the hood that undertake repair, maintenance and upgrade from any types of capital equipment. They have a communication capability with other aspects of the clinical review process in that organization.

To exchange information about how well do these things work in practice, what kind of feedback are we getting? Are there any kinds of problems? This feedback group is important.

I'll break to the sixth. GPOs interestingly enough can facilitate trials. I think there's more potential here for this than has been realized to date. But the fact that you've got organizations dealing with many, many hospitals across many different product lines, and many suppliers, they're obviously interested in the marketplace among the innovators, the purchasers, the clinicians, patients, payers even, to get rolling clinical data about the effectiveness of these technologies in the field.

In that sense, and to a small sense thus far, GPOs are in a position to facilitate clinical trials.

Interesting.

Now, just some quotations that I think help summarize some of the observations. There truly is an inclination towards evidence-based evaluations. This is not, you know, just a story by GPOs and health systems, throughout health care decision making. There is an inclination towards evidence-based policy, evidence-based decision making that draws upon some of the same technology assessment outfits and the same information sources as everyone else out there.

As one of our interviewees said, the GPOs are not locking out newer cusp technologies. They evaluate products on the merits, they do trade-offs of cost and effectiveness and use best evidence.

So, this is not unique to GPOs and health systems, but it's important to point out that in our observation, GPOs and health systems are part of this wave of evidence-based decision making.

Much of the clinical review activity is devoted to technologies that are recently FDA approved or whose approval is imminent. One fellow said that mostly we see the break-through products of these clinical review processes and he mentioned pulse oximetry as originally looked at as a kind of commodity, but if there's a new feature in a device like that that makes it not just a

commodity or not just a me-too product, but potentially a break-through, these are the kinds of things that should come to the attention to the clinical review processes.

Every single case that hits these clinical review processes, with this GPO in particular, it involves an extensive financial analysis. They used to not be so rigorous about this, but they're getting more rigorous, as are other decision makers in the field. So, these require a focus in how they change care, pair

that HIGPA has copies of our study as well.

With that I will close.

(Applause.)

MS. DeSANTI: Professor Latham?

MR. LATHAM: The panelists yesterday stayed seated at the panel and I thought that getting to sit might be a reward for not bringing PowerPoint. So, I'll try and collect on that.

From the panelists you've seen so far, you might not be aware that there's actually a lot of controversy about GPOs. Everyone so far has been very optimistic about the value of GPOs and what they add to the quality chain and so on. It's my unfortunate duty to inject a little bit of the dark side, but I do it from my point of view as an independent, nonconsulting law professor with special attention to the existing guidelines.

I know, by the way, that they aren't "Guidelines," but when I say the word "Guidelines," I just ask you all to imagine or pretend that I said "Statement of Department of Justice and Federal Trade Commission Enforcement Policy." I'm talking about specifically number 7 of those, the one that deals with joint purchasing arrangements.

That statement is -- well, it was being developed about a decade ago, and it's actually quite

optimistic about joint purchasing arrangements. It begins with a sweeping statement, "Most joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns." It repeats things like this throughout, and its structured in a way, it doesn't carve out safe harbors, it basically announces that the sea is safe, and it carves out two sort of danger harbors, if you like.

The two danger harbors are these: First, the enforcement agencies say that they will be concerned if GPO purchases account for more than 35 percent -- if a given GPO's purchases account for more than 35 percent of total sales in a relevant market. Here they're talking about sales from product vendors through the GPO to the hospitals.

The concern there basically is with monopsony power. Are GPOs large enough to have monopsony power to be able to drive down the prices of the goods they're purchasing on behalf of their hospital members to subcompetitive levels? If they are, the concern with that would be that we might see some reduction in production of those products, because of the subcompetitive returns, we might also see reduction in quality of those products as the vendors try to sell products at subcompetitive prices.

There's a fixed number -- roughly -- of tongue depressors and needles that the world needs and it may be that the vendors depress quality if they can't reduce numbers of output. The other concern that the existing statement has is the possibility that competitors in the same market will purchase so much of their -- well, it refers to 20 percent, an amount equal to 20 percent of their revenues -- purchase so much product through the GPOs that that common purchasing between competitors will have a tendency to stabilize competitors' price structures in a way that will facilitate price fixing. Or perhaps even that GPOs will communicate between competitors in the course of purchasing so much of the competitors' supplies that that will give rise to anticompetitive price fixing.

So, there are basically two unsafe harbors in the otherwise pleasant sea of group purchasing on the model in statement 7, and these are the possibility of monopsony power and the possibility of stabilization of cost structure across competitors.

Now let me turn to what some of the allegations are now that you might have read about in the New York Times about anticompetitive GPO affects, and I want to see how well they fit with the existing concerns in statement 7. And I want to be agnostic. I'm delivering

out of given hospitals to confine market share.

In addition to this, there are related allegations that although, for example, hospitals can belong to multiple GPOs, the GPOs may have contractual provisions tied and enforced to these rebates that say that you can't purchase goods from a different GPO if our GPO offers a good in that class, or say that you can't purchase goods from outside the GPO without losing rebates across multiple products or multiple years if we offer a good in this class.

exclusionary contract practices.

How does this set of allegations, whether true or not, fit with the concerns of the existing statement 7? And the answer is they don't fit at all. Because none of these allegations are predicated on the idea that there is market power causing subcompetitive pricing, and none of these are based on the idea of cost standardization among competitors.

So, the existing guidelines really have not S1rwD (,mpet

What kinds of contract provisions really are out there? Are these allegations about tying discounts to bundled goods and tying them over years, are these false? Are they true? What kinds of competitive justifications are there for the contractual provisions that are out there? What kinds of possible anticompetitive effects might provisions have in the alleged provisions are out there? Are there exclusivity provisions? Are there adequate provisions about disclosure?

One interesting feature about the whole GPO market as we heard from the GAO earlier is that these are purchasing agents for hospitals, but they're funded by administrative fees from the device makers. They're not -- in other words, there's a principal/agent relationship, but the agent is not being paid by the principal here. We need to see whether such exclusionary provisions as there might be make adequate reference to the principal/agent relationship and also fit well with competitive concerns.

Are there limits to economies of scale here? One way of interpreting the GAO data is that -- and the idea that larger groups break free from joint purchasing or group purchasing organizations is that at some point, you just don't get to save a lot of money beyond growing

to a certain size, and yet we see a couple of the larger

were representing nonprofit hospitals and everything is hunky-dorey. Even in the hearings themselves, we heard quite a bit about the good nature of the GPOs and how they're here to save the world. Now we're starting to see the GPOs come around the corner and agree that they have been involved in some contracting practices that are harming industry and harming patient care, and we're seeing that through the codes of conduct that they're now starting to develop in both Premier and Novation, the primary players here that I'll talk about today have put forward codes of conduct of how they're going to do business in the future that will create a better environment.

As a note to those codes of conduct, HIGPA also has a code of conduct more of an industry-wide. They're a good start, but we've got a long way to go with those.

The bottom line is what you have in the contracting processes, and again, I'm going to speak today more specifically what is happening to companies that I know about in the marketplace. You have sole sourcing agreements, 95 percent compliance. Some of them are 100 percent compliance. You have bundling of products that are unrelated.

I'll just give you an example here. The spectrum opportunity program at Novation bundles

adhesive drapes, tapes, dressings, sterility products, blades, sutures, gloves, these are all bundled together into one contract, and I'll point out how that can actually have a detrimental effects in a moment.

Exclusionary pricing has already been mentioned. Rather than the volume of products that you buy will, you know, get you a better price, it's done on percentage. As long as you stay within a compliance percentage within that contracting group, then you get your bonus, you get your check at the end of the month, but it's not on how much you buy.

Vendor fees, GPOs have talked about their vendor fees being below the three percent ratio. That's true only to the extent that if you only count administrative fees, what they consider administrative fees, and if you look into the fee structure that's going from vendors to the GPOs far exceeds three percent in many times.

And the price controls. We have companies that have actually gotten contracts with the GPOs and they have been told to basically increase their prices making them less marketable to within the structure of the agreement.

I'm going to detail a couple of companies and I'm going to kind of go fast here, because we've got several that I want to talk about. Masimo is somewhat

of a poster child from the Senate hearings and also from our association, but you had a company that had 50 independent studies. We heard earlier today about the effective use and these clinical groups that are going to evaluate products.

Masimo is a company that had a new product, they had 50 independent -- independent, not paid-for-by-Masimo studies -- saying that their product was superior. They actually had, I will show you a slide in a minute, they had a lower price than the incumbent vendor, and they failed to get on contract.

So, at some point within this framework, you have to start asking yourself if we have clinical groups and we have pricing and other issues to look at as far as how do you evaluate a product. If you have the superior product and you have a superior price and you can't get on contract, that begs a few questions.

Bundling is really where we're seeing the major problem here. I mentioned some of these products before that are bundled together. In Masimo's example, if a hospital purchases a Masimo product, it not only loses their structure within the spectrum opportunity or their pricing structure, they may have to repay savings from previous years up to five previous years back to the GPO.

So, you have a structure that's not only a bundle, but there's a penalty for changing products that can actually travel years back. In Masimo's case, I think at the end of the day you have to look at pricing, which is the GPO's role is to save money, bring the best products at the best price to the market. That market should be free and open. It should be an open marketplace. If you have a marketplace where with non-GPO hospitals you win almost every time, you have the superior product at the best price, but within the GPO realm, you can't seem to get a contract, and your competitor is more expensive, again, I think it begs questions.

This is a specific example. Masimo had a bid, they were the lowest price. They have 50 independent studies, including the Internal Clinician Group thought Masimo's product was better, and what happened was, Tyco Nellcor offered to give basically a rebate on sensors back to Novation for every time the hospital bought a sensor. Meaning about $6 million per year back to Novation. So, Tyco got the contract.

Again, I have gone through some of these things. In this particular product, you have 12 unrelated products bundled. Ninety-five percent compliance rate. I will caveat that only with Ethicon's endomechanical

Over the last ten years, I don't know if it was 100, I haven't been in this field for ten years, but you had a multitude of Trocar manufacturers. Today you have ten. In Masimo's example, I believe there were over 20 oximeter makers in the United States ten years ago. Today there are two or three.

So, what you are seeing is exactly what some of the professors and the analytical minds are talking about, is there market pressure from their contracting practice that are changing the market? Without question.

Retractable Technologies, I'm going to go through fairly quickly. Retractable Technologies makes a safety needle. They had a hard time getting onto contract again, got on the contract through a subcontractor, not on the bundle, not able to get market share beyond a certain percentage. And that is a perfect example.

Baptist Health Systems, San Antonio, if they buy even one box of Retractable Technologies products, they will lose $300,000 in rebates. So, is it voluntary to join a GPO? Is it voluntary to join the Spectrum program? Yes and no. If you need sutures, J&J, they control over 90 percent of the marketplace. If you need syringes, Beckton Dickinson controls over 90 percent of

the marketplace. That's the Spectrum bundle.

So, if you're a hospital and you need any average commodity product, you are probably going to get into a Spectrum bundle. The price you are going to pay is any price down the line and you are going to have to stay within that compliance ratio or you are going to have to repay the money saved.

Utah Medical, I am going to go fairly quickly because I am running out of time. Utah Medical provides a device that you put in the uterus during pregnancy and during birth that measures the pressure of the womb. They were the first company in the marketplace, they had a superior product. Premier did not believe that they were a big enough company to actually contract with them. They wanted to go with a Tyco subsidiary because they could bundle other Tyco products.

Premier contracted with Tyco in '97, without bidding, and you can see what happened to Utah Medical's -- Utah Medical was the leader in the marketplace. They had the number one device. You can see what happened to their marketplace after Premier set up a '97 bid without contract or contract without bidding.

I think what I am hoping that you pull from my part of the presentation is that we can talk about the

general sense of the law and we can talk about the general sense in the spirit of what happened in '97, but what we need to look at is the marketplace and who's being affected by this. Eventually it's the patients who are affected. Again, I think some of these anticompetitive effects we've already discussed. At the end of the day, what you have to look at, there are fewer companies coming out with new products, fewer innovations, and the companies right now, the ability of a company to start out, create a device, and go to the marketplace is severely hampered by GPOs' long-term, sometimes seven-year contracts with primarily the top 20 manufacturers of medical devices in this country.

And two more slides here. Basically, again, they have become gatekeepers for access to these hospitals. The bottom line is, at the end of the day, if you have Tyco, Beckton Dickinson, J&J who control over 90 percent of these markets and they are bundled together with other products, then it makes it very difficult for companies to get into this marketplace.

I will just leave this up here for a second. If anyone wants a copy of this presentation, they can contact any of these folks.

(Applause.)

MS. DeSANTI: Mr. Betz?

MR. BETZ: As the last speaker on today's panel, I feel a little bit like my old friend Bob Merkle, right before he went up for his fifth wedding. I asked him how he felt, he paused and looked at me and he said, "Robert, he said I know what's expected of me, I just don't know how to make it new."

But I would like to visit with you today, we will cover some of the points that my esteemed panel has made.

That was a picture of my grandfather.

What I would like to visit with you about is briefly talk with you about an overview of our industry, the savings that we contribute to health care organizations today. I want to mention the code of conduct our industry has developed, I would like to touch briefly and follow up Ms. Bailey's comments about our views on the GAO report and then talk with you about what we are doing to add to the body of knowledge through an industry assessment.

We are the purchase agents for the buying cooperatives for hospitals and other health care providers. Most group purchasing organizations in this country are owned by hospitals, all are ultimately responsible to hospitals. The FTC, I believe, was created in 1914, four years before that, the first group

purchasing organization was established in New York City.

What do we do? We aggregate buying power to negotiate discounts, we survey the marketplace for clinically desirable products, we negotiate and administer contracts on behalf of hospitals, we lower hospitals' operating costs, we streamline the purchasing process, and we promote safety and quality of care.

Seller-based fees and buying cooperatives are widely accepted competitive business models in many industries. I would call to your attention they exist in agriculture, real estate, insurance, and are used extensively by the United States Government.

Groups typically return fees in excess of expenses to the hospital members. In 1986, Congress sanctioned the GPO model for health care programs by exempting supplier-paid administrative fees from Medicare and Medicaid antikickback statutes. In 1991, adding to the statutory exemption, the safe harbor regulation requiring disclosure to members of the vendor fees paid to GPOs was added, but it allows competition to determine the level of those fees.

Let me talk with you about -- you heard, I believe, yesterday, from the American Hospital Association and from some of the earlier speakers about

expenditures in one year by $886 million, increase spending by state and local governments by at least $249 million. A one percentage point decline in the rate of GPO savings would increase Medicare and Medicaid spending by $1 billion annually. Veterans Affairs would face an additional calendar year expenditure of at least $61 million.

Our code of conduct. There have been recent concerns expressed regarding the business relationships between group purchasing organizations and vendors that pointed out the need for us to tell a better story, to reassure the public that the industry does and will continue to practice the highest ethical standards.

Our code focused on several areas. And again, this is included in your written materials. Eliminating the appearance of conflicts of interest, ensuring open communication between members and vendors, establishing guidelines for the use of contracting tools. In addition, reinforcing full disclosure to members of all vendor payments that are received, establishing a reporting and education programs, including surveys, that quantify the value of a group purchasing organizations, and then finally demonstrating the value of our cost savings.

Our code of conduct is a baseline for the

industry. We believe it is a historic document, the first time that the health care supply chain has ever come together in such a fashion. It is now in the implementation phase. We are looking for a full rollout in January.

Individual group purchasing organizations are moving ahead adding their own principles to the GPO baseline business practices.

I want to say a word just about our friends over at the General Accounting Office. GAO is conducting a new study of the industry. I think Ms. Bailey's comments earlier today about their first study being limited is indeed correct. They were under a difficult timeline and under difficult circumstances in doing this. We are looking forward to working with the GAO as they conduct a more comprehensive study.

This study, I believe, we're contributing information and working with the GAO staff hopefully in

also the Lewin Group, as mentioned by Cliff Goodman earlier. HIGPA has commissioned a study that has concluded that GPOs facilitate significant expert clinical input into group purchasing decisions. Again, that study is available to you as well.

This is my forecast: I believe that groups are going to continue to attract interest from many sectors in the government, but we believe that the end game will be a re-affirming of our fundamental value that we provide which we believe are the best products at the best price for the patients that we ultimately serve.

In closing, I just would call your attention, I don't know how many of you are readers of U.S. News and World Report, they come out every year with a listing of the 100 best hospitals in the country. If you get an opportunity to look at it some time, I would urge you to. I know that I find it interesting that everyone of those 100 hospitals belongs to and is an active participant in a group purchasing organization.

Thank you all very much.

(Applause.)

MS. DeSANTI: Thank you all. We've covered a lot of ground here, and we're going to try to have some discussion. I think first we would like to take a step back and take a broader look at the issues.

Matthew, do you want to start?

MR. BYE: We've been mainly discussing short-run implications here and I would like to switch to the long run. What I am interested in hearing about is market structure innovation and the effect that GPOs may have on these.

MS. DeSANTI: When you want to respond, could you just turn your name tent up on end like that. Okay, another demonstration, I'll do it again.

Yes, Cliff?

MR. GOODMAN: Yes, an important question. Are GPOs in the long run a factor in technological innovation? Yes. However, before we leap to GPOs, let's look to other factors that I think in my opinion have a greater influence on innovation today and in the future. That is the technology market is a very tough one, and it needs to be.

Before we even consider the role of GPOs, it's tough enough to get proof of concept. It's tough enough if you're a device, drug or biotech, to get approval from the world's toughest regulation agency, the Food & Drug Administration. It's tough enough if you've made it that far to show that you're going to get third party payment from the world's largest third party payer, Medicare. Aside from not tens, not hundreds, but

very smart about this. It used to be the VCs -- the VCs follow the same model I recently just did. You aren't going to get upfront support without some promise of proof of concept. Then they start saying, well, how do you look for FDA approval, what's your glide path for that? The smart ones over the past several years are saying great, FDA approval, can you show me that there's going to be a payer market out there for you? And yes, the GPO issue is coming up, but I see it as coming subsequent to these other larger hurdles.

MS. DeSANTI: Professor Burns?

MR. BURNS: Yeah, a different set of issues with regard to market structure. It's my impression from having studied the GPOs over the last few years that the largest GPOs have actually reached the antitrust limits in terms of how big they can be, in terms of the number of hospitals. If you look at Novation and Premier, they're not really adding more members these days, they've pretty much hit the 30, 35 percent cap that was stated in the FTC and Department of Justice guidelines. They're actually looking to grow in other ways.

So if you're to look down road, long-term, in terms of the market structure, they wouldn't necessarily change in terms of the number of hospitals that belong to them, what they would like to do is increase the

So, from a purely market structure point of view, this is a fairly competitive industry. Now, some of the other, you know, issues raised here deal with things other than strict market structure.

MS. DeSANTI: And let me ask you, just as long as I have you, from your research, are you at all aware of the extent to which bundling and other exclusionary types of contracts are prevalent among GPOs these days?

MR. BURNS: Yes, we actually studied bundling from a number of different perspectives. Not only the GPOs' perspective, but also the manufacturers who are trying to bundle these products and use them, as well as from the hospitals and purchasing bundles. Bundling is not a clear-cut issue. The manufacturers would love nothing better than to bundle products and get hospitals to buy them.

However, when those bundled packages include items that are high in clinical preferences, and you have a number of different physicians on staff who have different preferences, product bundling breaks down. This happens at the micro level in the hospital, at the clinical floor, when multiple physicians have different preferences and you can't get one bundled package to suit them.

So, bundling is one of those things that GPOs

and manufacturers would like to do, but here again it's resisted at the micro level when clinicians are ordering and using these products. I'm not convinced that that's a good long-term strategy either, and I think you have heard some of the other panelists say here, that's a road that's been already traveled and they are going to look elsewhere.

MS. DeSANTI: Mr. Clark?

MR. CLARK: I would like to just reinforce what Lawton just said regarding the introduction of new manufacturers and technology into our system. Our experience is a bottom-up process, and no GPO, unfortunately no hospital administrator can control who's visiting with our physicians about which product or which technology.

Those things continually get exposure, and many of the contracts that we currently operate under in our group purchasing organization result from strongly expressed clinical preference working its way up through our process. We don't have GPO bundled agreements that drive anything. We're not penalized in terms of fees or anything for what we might purchase either on or off2rm-uwher. te

those are determined by our clinical staff at the micro level, as was set, and that works its way up, and that determines what we purchase.

I might add that, you know, Masimo was mentioned. Our group purchasing organization was the first, I believe, to contract with Masimo, and we have an active process of looking at new technology in our system and through our GPO.

MS. DeSANTI: Professor Latham?

MR. LATHAM: I feel like Orson Bean here. I would like to take your question and use it to -- of course I would -- to reinforce what I said earlier.

MS. DeSANTI: Of course.

MR. LATHAM: Which Commissioner Riley gave a speech in which she talked about the FTC's turning to address short-term versus long-term considerations, questions about short-term pricing benefits to be balanced against questions of longer term benefits from innovation.

We've heard a lot today about the plight of hospitals and what the good things that GPOs do for hospitals that are in this difficult financial situation, and that might be in tension with questions about the effects of innovation on the hospitals but more importantly on their patients long into the future.

So, again, rather than trying to answer the concrete question about whether there's that tension right now, I do get the sense sitting here that, you know, we live in the post-modern world where the number of different market shares for GPOs that have been announced by various members of the panel were just wild.

So, I am not qualified to have an opinion on which of these things is true, but I do urge the FTC to start thinking about whether the guidelines in this area are taking account. For example, there's nothing in the statement on group purchasing that has anything to do with injuries to innovation over the long-term. The statement is designed only to address short-term price equilibrium types of problems. The economics world has moved past that and the GPO world has moved past it in terms of industry concentration in GPOs and industry concentration in device manufacturer.

So, back to you.

MS. DeSANTI: Thank you.

Mr. Holden?

MR. HOLDEN: Short-term/long-term, I think without question as Ves Weatherman [phonetic] said during the hearing, there is an impact to the venture capital community providing funds for young companies if

they believe that they're not going to get through the GPO. The FDA, I think it's a telling statement that one of the most burdensome federal agencies, the FDA, is just one of the factors along with GPOs that venture capitalists look at to determine whether they're going to fund a company.

So, I think that's a telling statement. The issue down from the other end of the table, are all GPOs bad? No. Are even Premier and Novation, you know, do they provide a value? I think they do. The question becomes, is that standardization? If it's across the country, is that going to harm innovation and is that going to in the long-term bring about market effects

were already here in what Lawton said. I think technology is alive and well especially in the innovation marketplace, because technology is a patient/physician process. And only patients and physicians work with that process.

It's difficult to manage across six hospitals and get a technology standardization to believe that a GPO is going to be able to sell stents from Dallas and convince somebody in Norfolk that that is the product to buy just doesn't exist. Technology today is a relationship that's basically a peer pressure between physicians and the skilled sets, of course, of the idea is to be able to develop a mechanism to work with the physicians and standardize them. But the technology as a GPO given the knowledge that is standard in this industry today.

MS. DeSANTI: Thank you.

Professor Latham, we take your points about the guidelines. I think it's certainly true, and I'll add this just so the audience has the benefit of some thinking from the FTC. The guidelines were developed in 1993. The first time that innovation theories and theories about innovation and competition showed up in other guidelines was in 1995 with the intellectual property guidelines.

These are theories that the agency has been developing over the past several years. Certainly no investigation in any area is necessarily constrained by existing guidelines in terms of if there are further developments. Those will always be assessed. Exclusionary stories are ones that have been difficult to articulate in guidelines because of conceptual differences and different types of fact patterns, but certainly they do exist in antitrust.

If you look at some of our cases, they are ones that are used from time to time, and guidelines are very costly effort for the agencies, but it's certainly true, and you're making a fair point, that the anticompetitive stories that are currently covered by statement 7 don't include the types of stories that we're hearing about today, and that's a very important point. I just wanted to add the other points about how the agencies tend to approach things.

I would like to ask one other basic point and maybe, Mr. Betz, you could respond and I'm sure others will have insights into this as well: I'm wondering about how the basic structure that presumes that administrative fees are coming from the vendors rather than from the hospitals, how that was determined. It's certainly true, the point that you made in your

presentation was that seller-based fees are a common phenomenon, and that's certainly true. They can also be controversial, and since I'm working on a study on slotting allowances now, I can tell you that in the retail industry, they are sometimes controversial, and they raise the same kinds of issues in terms of possible exclusion stories.

I'm just wondering, if it's the case that administrative fees are basically based on fees from the vendors, presumably they are giving you discounts through those fees, in essence they can give you a discount or they can pay you a fee. Why is the model that you get fees from the vendors rather than simply getting the largest discount that the vendor would give you and then relying on the hospitals to take some portion of that fee to pay the administrative cost of the GPO? What are the advantages of a seller-based fee model?

MR. BETZ: First of all, seller-based fees exist, as I mentioned in my comment, in other industries. And I would again emphasize that it is utilized by the federal government, the Department of Defense, the Veterans Administration, what's the other one? General Services Administration. I would say to you that these fees -- first of all, group purchasing

organizations historically back 32 years ago when I first got into health care, group purchasing organizations were of two types: Those that were supported by fees generated from the hospitals and those of administrative fees. Dues-based organizations as opposed to administrative fees-based organizations.

Hospitals and the continuing challenges that they have had have looked for ways over the years through shared services activities and through group purchasing organizations to reduce administrative costs. Particularly in the seventies and eighties, group purchasing organizations moved towards fees with the

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organization provides for their organizations.

Also, they provide rebates and distribution of the fees back to the individual hospital. Some of those fees are used for the uncompensated care issues and to provide greater services. Finally, for those fees, they are providing quality, safety and standardization.

So, I guess my response in summary to your comment is that they do both. They provide a discount and they also provide an administrative fee that offsets those costs for the hospitals, and that's why hospitals are so wildly supportive, we believe, of the function, either group purchasing activity or through IDNs.

MS. DeSANTI: Thank you.

Mr. Clark?

MR. CLARK: I guess from my perspective, hospitals paying the fee either directly or indirectly, but that three percent aggregated at the GPO level then allows that administrative burden of tracking and managing sales volume rebates, the whole nine yards, to be handled in one place on a group level much more efficiently than if I had to be worrying about that and every one of my 22 hospitals and if every hospital had to do on their own, then the burden of just the administrative burden of handling that process would be very difficult. So, that's just another service that

has been aggregated at the group level.

MS. DeSANTI: Mr. Holden?

MR. HOLDEN: I think we can look at fees and say, well, you know, aggregating purchasing into one location will certainly save hospitals and networks money. The question is should it be on the backs of the vendors? And I think in an ideal world it would not be or that fee would come from savings rather than the selling of the actual product. But we're not living in an ideal world and we understand in the whole spectrum of the marketplace that hospitals are under very heavy constraints trying to stay profitable or at least break even.

So, I think the concern with the fees are one, where do they come from, and by them coming from the actual sale of the product, a three percent fee on how much product goes through the door versus the how much you save a hospital, I think that creates some disincentive for GPOs to actually save money.

If on a contract you have company A and you're purchasing a million dollars worth, and company B can actually bring that product, the same product or equivalent product to the hospitals for less money, the GPO collects less money, it collects less fees. That's the nature of the dynamics.

So, for these GPOs to give away money by signing contracts with vendors for lower pricing is a disincentive to do it. So, there's some concern with that fee. Again, speaking to the nonlinear pricing, these are not based on volume, they're based on compliance percentages, not on volume. And I think therein lies part of the problem.

One final thought, while the GPOs, the larger ones, you know, Novation and Premier, do provide some very good services in consolidating, I think there's some concern. I mean, if you look at the financial incentives for some of the mid-level and senior-level managers at Premier and Novation in the way they receive their salaries. You know, these guys are making a half a million dollars a year to over a million dollars a year to be executives in these organizations and yet the primary purpose is to save the health care system money. I think we should be questioning that as well.

MS. DeSANTI: Professor Burns?

MR. BURNS: Yeah, let me just follow up on what Larry mentioned in an earlier comment by Steve about economies of scale. The hospital industry has been searching for the elusive economies of scale for the last 20 years, and that's why they formed hospital systems, that's why they formed hospital networks,

that's why they have these large integrated delivery networks, and almost all of the econometric evidence to date points that those economies of scale are limited and achieved at a very early size. And we actually published a review of this in Health Affairs two months ago.

Given that, hospitals are hard-pressed to find economies in other areas of scale, the one area where they seem to have found it has been in the group purchasing side, which is on the administrative side rather than the clinical side, where hospitals have never been able to achieve any economies.

So, group purchasing serves as the one tangible area that I can point to where hospitals have achieved some economies of scale. Now, going to Larry's comment about exerting it on the small device manufacturers, hospitals, if you go back to my slide on the health care value chain, hospitals are squarely in the middle of the health care system. On the one side, what we call

care. That game has pretty much played itself out.

Now hospitals are using their GPOs, and acting independently as integrated delivery networks to push on the other side of the value chain, upstream toward the manufacturers and the distributors. This is a game that everybody in the health care system plays, okay?

Unfortunately for the small manufacturers, when everybody else is consolidating, you're at a relative disadvantage. But this is what has been taking place throughout the entire health care system. You look at manufacturers, you look at distributors, you look at hospitals, you look at physician groups, you look at managed care organizations, you look at employers who are forming purchasing coalitions, everybody has gotten big to push back on people upstream and downstream to get the best rates they can. This is just the way our system works. Smaller manufacturers are at potentially a disadvantage at that.

Now, the one thing I would say is that on the product manufacturing side, we have the most innovative set of product companies in the world, probably fueled by our reimbursement system, but I don't see any diminution in the innovativeness in the medical device and technology sector, a lot of those firms form, develop and proceed and then get bought up by the larger

manufacturers. That clearly exists, but I don't see innovation having been impeded in some portion of the medical device sector.

of potential with a better mouse trap. Smaller companies with a true, novel break-through technology need not pass through the GPOs' doors to get attention. They can go directly to the chiefs of cardiology, radiology, orthopedic surgery, so forth. They can be published in peer review journals. They can have Internet sites. There are many ways to access the decision makers, especially for the high-end technologies that will demand those as chiefs of cardiology, other leaders, other clinical so forth leaders. That's what gains attention.

Secondly, insofar as demonstrating how good a technology is, whether it's safety, efficacy, cost

value of your technology to the people that will try to acquire it, whether it's through a GPO or otherwise. The avenues are not closed for innovation.

MS. DeSANTI: Others who want to make a final comments from Mr. Clark, we'll start with you.

MR. CLARK: Well, I would just echo what was just said. I don't feel any lack of new technology coming through our doors, people seeking our attention, and visiting with our physicians. I think that door is open, as I mentioned earlier, I think in our experience, the product contract selection process is an upward process, and I believe that properly done, both the manufacturer, small, large or otherwise, and we as the provider benefit from the process, and I believe that we ultimately, directly or indirectly, end up paying that fee.

So, I think if it's approached properly, we don't lose contact with those small innovators. There are many of them.

MS. DeSANTI: Mr. Manley?

MR. MANLEY: Again, I will pretty much echo what everybody else has said. Technology is an issue that's solved best at home and solved best at the hospital. We have not ever seen an instance where technology has been

systems, most hospitals don't try to act as their own GPOs, and those who have in the past often failed. Like distributors. Nobody wants to do what distributors do. They make a one percent margin or less, why do this? But they provide a value-added. I think GPOs do, too, to some extent.

MS. DeSANTI: Professor Latham?

MR. LATHAM: I ate lunch upstairs yesterday at the FTC cafeteria.

MS. DeSANTI: Please forgive us.

MR. LATHAM: And believe it or not, I didn't feel that I was faced with a lack of choices about things that I could eat, but is there a world in which the menu up there might be a little bit bigger? Certainly. I don't know how you feel the lack of technologies that have not made it into a marketplace. I think we have to think when we're thinking about what the FTC should be looking at, and what the guidelines in this area should address themselves to, we do have to be thinking along the lines that Commissioner Riley was talking about, about the existence of possible uncomfortable trade-offs between current short-term price advantages for hospitals and longer term and perhaps more speculative benefits to patients down the road from innovation.

It's great that there's a lot of innovation going on now. The question is whether there might be more in the absence of certain kinds of contracting. I would add finally, I didn't mean to be so harsh on GPOs when I came today, I meant to be talking only about the structure of the guidelines. I want to say that there are obviously hundreds of GPOs, and the various allegations that I have been sort of recounting are attached in the press at least to only a very, very few of them. I think there is no doubt but that GPOs save hospitals a great deal of money and perform a really valuable service. As the GAO study showed, particularly to the small hospitals that just don't have the wherewithal or the scale to do this for themselves.

So, in that sense, I applaud it, but I do wish that the FTC would look at whether in the presence of GPOs helping and gaining market share and doing joint purchasing, whether there's a threat to innovation from specific contracting practices that are associated with only a few of the GPOs out there.

MS. DeSANTI: Mr. Holden?

MR. HOLDEN: I would just echo a lot of what was just said. I think the problem that we see is inherent in the fact that you have two GPOs, the ones that we are hearing about the New York Times, the ones that we are

talking about in the Senate hearings, that those are also the two GPOs that are controlling the vast majority of the marketplace. So, it begs the question, have they reached that point where they are creating some problems within the marketplace?

I would just point out that 90 percent of the innovation in the medical device field comes from companies of 50 employees or less. The companies that are getting GPO contracts, if you look at that suite A bundle I mentioned all those contracts, 3M, Beckton Dickinson, Bard, Ethicon, which is J&J, okay, that's who's getting the primary. That's who's getting the lion's share. These are the top 20 medical device companies in the United States.

Are we losing innovation? Those top 10 companies, if you look at their annual reports, they don't do R&D anymore, they buy out small companies. If those companies aren't there for them to buy out, innovation is being harmed. It's being harmed because there are groups of GPOs, primarily Premier and Novation and some of the contracting practices of others that are excluding small and innovative companies from the marketplace.

It's not always that break-through technology. Again, a large portion of the medical device field, it's

incremental increases in knowledge that changes people's lives, and you're going to lose that if there's not some sort of change in the market dynamic.

MS. DeSANTI: Mr. Betz?

MR. BETZ: Thank you.

First of all I would like to say, and I think I speak for the rest of the panel, when I say thank you to the FTC and particularly to Mr. Hyman for all of the arrangements that have been made, and on behalf of my organization anything that we can do to assist you in further workshops or additional presentations, don't hesitate to holler at us.

I would just like to close on the matter of access and innovation, if I could. I would like you to just keep a couple of thoughts in your mind. First of all, you need to differentiate between high clinical preference items, and a whole lot of me-too products. If I am out in a garage somewhere creating what I consider to be an innovative product, in my eyes, it may be an innovative product, but to the clinicians that evaluate on behalf of group purchasing organizations, for the hospitals, they may not think this is an innovative product. They may think that it is simply a me-too. So, I think we need to differentiate those in our thinking.

I would also ask you, I understand how difficult it is for a small manufacturer as it is in any industry to succeed; however, some of the charges that have been made have come from companies that I find it interesting to look at their shareholder lists and also their SEC filings about the contracts that they do have. On the one hand they compete and complain about group purchasing organizations, but yet in their filings for investors, and with the SEC, they tout their relationships with these same organizations.

Group purchasing organizations do push back for hospitals against manufacturers. Some of which I believe after some study do demonstrate oligopolist tendencies. I think that hospitals have a true value in this country and we are their advocates and will continue to be such, but I do not know of particular examples of products that are being foreclosed from the marketplace.

We've heard allegations that certain products are being foreclosed from the marketplace by group purchasing organizations. It is clear, I think, from some of the comments that have been made here and from the literature that the market in which groups operate is highly competitive.

In conclusion, keep just one thing in mind, if a

group purchasing organization does not provide products that the member hospitals demand, another group purchasing organization will. They are very highly competitive with one another. Individual hospital members of these organizations have considerable choice in their purchasing decisions of the best products at the best price for the patients that we are here to serve.

Thank you.

MS. DeSANTI: Thank you all very much. I really appreciate the wealth of experience and information that this panel has brought to us. We will reconvene at 1:15, and the FTC does have a cafeteria, it's up on the seventh floor, if you want to go for a swift lunch. I actually can recommend it.

Thank you again.

(Whereupon, at 12:20 p.m., a lunch recess was taken.)

AFTERNOON SESSION

MR. HYMAN: If everyone can take their seats,

how important I think this kind of activity is.

Unfortunately, I can not attend many of the sessions of this program or the other programs that we have had here, but I promise you that I do read transcripts, and I read presentations, and they are tremendously helpful to me.

I can not help digressing just a minute today and thinking about a meeting we had in this very

Bear in mind that the famous Standard Oil case had been decided just three years before. The general public thinks of the Standard Oil case as the case that broke up the Standard Oil trust, and it is important for that, but it is also important for the creation of a so-called Rule of Reason in antitrust law. You have to determine whether or not a particular practice was legal or illegal based on a variety of factors.

There was this level of uncertainty in the business community about what is legal and what is not legal. One of the ideas behind the creation of the Federal Trade Commission is we will have a body of supposed experts to give guidance. I don't think of the expertise as residing where I am. I think of the expertise as being in the staffs that we've accumulated in this building, who try to inquire as to what might or might not be reasonable and then provide some guidance to the outside world.

That is what these meetings are all about. This particular aspect of our mission was somewhat neglected for many years, and to his great credit our former chairman, Bob Pitofsky, revived it in 1995 with a series of very extensive and comprehensive hearings on international, high tech competition. That tradition has been expanded upon by Tim Muris, the current chairman. I can't tell you how gratifying it is to me personally

and how important I think it is that the Federal Trade Commission continue these efforts.

Now, what do we do with the learning that's accumulated in this room. Well, there are a number of things we do. It informs our prosecutorial judgments. We bring cases or we don't bring case based on what we learn here. It informs comments that we make to other government bodies at the state or local level. We are very frequently asked to comment on various matters of concern, and we draw on information that we get from workshops like this one and others.

We just are winding up a very significant one on the patent antitrust interface, for example. We have got one coming up on problems caused by public and private impediments to the development of ECommerce. All of these issues are issues that do not just concern the Federal Trade Commission and our particular authority but concern a variety of other government authorities. To the extent that they will listen to us, we provide our particular perspective on these issues, informed by these meetings.

I think that those of you who have attended this meeting, or have attended some of the others we have had

-- whatever your responsibilities may be in the public or private sector -- walk away with a renewed appreciation of the difficulties and the complexities of a lot of issues that we deal with.

We say our competition policy and really our consumer protection policy is informed by economics, but the economics of the health care business are somewhat odd. You have got the third-party payor problem. You have got the problem that an identifiable human life is regarded as having almost infinite value. It makes it very, very difficult to think of cost effective ways to deal with health care because the minute it's personalized -- either because of something you read in the newspaper or because of your own personal experience -- economics goes out the window.

So, there are unusual challenges in dealing with this particular subject. I think that even if we can not provide bottom line solutions as a result of a meeting like this, at least the debate will be enriched and people will have a heightened appreciation for what the other guy has got to say.

I just have to tell you that the longer I live and the more experience I have in the world at large,

the less sure I am that I am right about anything. For me, the process of growing up and maturing as a human being is the process of appreciating how difficult and how complicated problems are in this world.

So with that, I wish you well. I hope you have a good session this afternoon. I can not be here but, as I said, I promise you, I will read what you have to say. Thank you.

(Applause.)

MR. HYMAN: Thank you, Commissioner Leary. Our first speaker of the afternoon is Michael Wroblewski from the Office of Policy Studies, who is the principal, author along with lots of other people at the Commission of the Generic Drug Study, copies of which are outside -- there seem to have been a run on the market, but we're trying to get some more.

MR. WROBLEWSKI: Thank you, David, and good afternoon. I was asked to give a 15 minute thumbnail sketch of the Generic Drug Study that the Commission just released in July of this past year that really reviewed experience to date under the Hatch-Waxman Act.

As most of you already know, the Hatch-Waxman Act established a regulatory framework that sought to balance incentives for continued innovation by brand-name companies and to encourage opportunities for

market entry by generic drugs.

ANDA, an Abbreviated New Drug Application is what a generic drug applicant files with the FDA to get approval of its generic version of a brand name drug product. In that ANDA, it has to show that its product is bioequivalent to the brand name product that it is making a generic version of. It gets to rely on the safety and efficacy data of the brand name product. It doesn't have to prove that again, but it just has to show bioequivalence.

One part of the application of the ANDA is a Patent Certification, and what we're going to be talking about today are really the Paragraph IV certifications, and those are the certifications that the brand name or the generic applicant has to make relating to the patents that cover the brand name product.

Now, Paragraph IV certification is one in which the generic applicant says that the patents are either invalid or not infringed by that particular ANDA. Obviously by its name Paragraph IV certification, there are paragraph I, II and III certifications that we're not going to talk about this afternoon that really deal with patents that have already expired or generic applicants that seek to enter the market prior or right after the patents expire.

The Orange Book, the Orange Book is where the

general public can go and look up a brand name product and find which patents cover that particular brand name product.

The 30-month stay, the 30-month stay is really a 30-month stay of FDA approval of an ANDA. It is invoked if a brand name company receives notification by the generic applicant of an ANDA that it has filed with the FDA that contains a Paragraph IV certification. If the brand name company files suit, patent infringement suit, within 45-days, the FDA is prohibited or is stayed from approving that ANDA for 45 days from that notice.

Last the 180-day exclusivity is awarded to the first generic applicant to file an ANDA containing a Paragraph IV certification. The 180-day exclusivity starts to run on one of two events, either when the generic applicant begins commercial marketing or a court decision.

During this time period, the FDA is prohibited from approving a subsequent or a second or a third or a fourth generic applicant for the same drug product.

Let me give you a quick little scope background of the Commission study. We announced in October of 2000 our intent to undertake a study of how generic drug competition has developed under Hatch-Waxman. We undertook it really for three reasons: One is that at

that point the Commission had taken law enforcement action against some allegedly anti-competitive agreements between brand name companies and generic applicants, and we wanted to see if those agreements were isolated instances or were they more typical.

We had been asked by Congress to look at this issue. And over the next several years, there's a substantial volume, a sales volume of brand name drug products that are coming off patent. The Commission wanted to ensure that there were no roadblocks to generic drug competition developing for those brand name products.

We received clearance from OMB last April, April 2001 to conduct the study. We issued nearly 80 special orders pursuant to Section 6 (b) of the FTC Act to brand name and generic companies. We focused the special orders on brand name drug protects that were the subject of Paragraph IV certifications filed by generic applicants, and we looked at those NDAs, those New Drug Applications, that had a Paragraph IV filed against it between 1992 and the end of 2000.

That resulted in a 104 drug products that are in our study as measured by unique NDA numbers, and they include such as blockbuster drugs such as Cardizem CD, Claritin, Pravachol, Xanax, Zantac, Zocor, Zoloft.

The responses to the special orders were generally completed by the end of last year, and we produced the study, and we released it this July.

The rest of the talk I want to talk about first will be the 30-month stay and then the 180-day marketing exclusivity provision. The study sought to determine the frequency by which brand name companies sued generic companies within that 45-day period, which then invokes that 30-month stay.

As I mentioned, this is actually figure 2.1 that's on page 15 of the report, so if you want to look through it in here. As I indicated there were 104 NDAs that are part of the study. For 29 of those brand name drug products, the NDA holder, the brand name company, did not sue the generic applicant.

FDA approved those ANDAs on average in 25 months and two weeks 25 months, 14 days, for FDA to approve those 29 ANDAs that had not been sued but had contained a Paragraph IV certification.

In 75 instances, the brand name company sued the generic applicant. As of June 1, this is when all this data is taken as of, a snapshot is of then. As of June 1, 22 of those patent infringement suits are still pending. In 15 of those the initial 30-month stay has not yet

patents.

This compares to only 1 of 9 blockbuster drug products as to which the brand name company filed suit against the first generic applicant prior to 1998 for more than three patents, and usually only sued on one or two patents, in most cases only one. In the future this may portend a result that the patent litigation will take longer than the 25 months and two weeks for the litigation to be resolved.

The second phenomena that we observed was an increase in the listing of patents in the Orange Book after an ANDA has been filed. We noticed that it has occurred since 1998, and it's happened for eight drug products. By listing patents in the Orange Book after an ANDA has been filed, brand name companies can obtain additional 30-month stays of FDA approval, and this can occur under the following scenario:

An ANDA has been filed for a particular drug product. Brand name company lists an additional patent in the Orange Book. The generic company makes a new certification, a Paragraph IV certification saying that that particular patent is either invalid or not infringed. It then has to notify the brand name company.

It notifies the brand name company. The brand

name company sues within 45 days. An additional 30-month stay is then instituted. So what happens is you have 30-month stays that are now stacked upon each other, and for these eight drug products where this occurred, the additional delay of FDA approval, beyond the first 30 months, has ranged from four to 40 months.

In all four cases so far with a court decision on these later listed patents, the patent has been found either invalid or not infringed by the ANDA.

The interesting thing is in these eight cases, most of the later-issued patents raised questions about whether the FDA's patent listing requirements have been met. The study describes three categories of patents that raise significant listability questions.

These are all described in Appendix H in excruciating detail, so if you want to read further about them, you can. Briefly they are patents that may not be considered to claim the drug formulation or method of use; a product by processed patents; or patents that constitute double patenting.

The problem is that recent court decisions have held that Hatch-Waxman doesn't provide generic applicants a basis to challenge the listing of any of these patents.

So to remedy the harm caused by these late

listed patents, the study recommends that Congress permit only one automatic 30-month stay per drug product, per ANDA to resolve patent infringement disputes over patents listed in the Orange Book prior to the filing of an ANDA.

This we thought was reasonable, one, because as we've noted that historically it took FDA about 25 and a half months to approve an ANDA with a Paragraph IV certification that hadn't been sued. It took about 25 and a half months and may be taking longer for a District Court to obtain a decision or for a District Court decision to be rendered, and so that the first 30-month stay wouldn't cause any additional delay other than what would occur otherwise.

We were thinking that this would eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. The study also recommends that Congress clarify when brand name companies can sue generic applicants for patent infringement by overruling the Allergan case.

We raised some additional concerns about patent listings. As I mentioned earlier, currently the FDA doesn't review the propriety of patents listed in the Orange Book, and courts have ruled that applicants don't have the ability to challenge one of them, to seek a

delisting of them.

The lack of such a mechanism can have some real world consequences in that the Commission is aware of at least a couple instances in which a 30-month stay, the first 30-month stay has been generated solely by a patent that raised legitimate listing questions. At a minimum, it appears useful for the FDA to clarify its listing regulations.

Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in patent infringement litigation that's already in progress. In this way, the dispute could be resolved in the same forum, in the same District Court that the patent infringement litigation is already underway.

I'm going to switch now to the 180 days and give you first a couple of facts about how frequently the 180 days has been awarded. Prior to 1992 it had been awarded for three particular drug products. Between 1993 and 1997, it wasn't awarded at all, and since 1998, the FDA has granted the 180-day exclusivity for 31 drug products.

As I mentioned earlier, the running of the 180 days can be triggered either by commercial marketing or by a decision by the Court. In 19 instances, it was by

the commercial marketing by the generic drug applicant, and in the other 12 instances it has been a court decision that has triggered the exclusivity.

In most instances, the generic applicants have waited to enter the market until at least a District Court has held that the patent covering the brand name drug product was invalid or not infringed by the ANDA.

The recent antitrust issue that has arisen is how these patent settlements can affect generic entry. As I mentioned earlier in that schematic of how the 104 cases have been decided, remember there were 20 cases that have settled, so there were 20 final settlement agreements, and they really broke down into three types of agreements.

The first type of agreement was one that involved a brand payment. Typically there was a brand payment from the brand name company to the generic company, and the generic company would not enter, in most instances, until the patents had expired, in one or two instances, slightly before the patent had expired.

Seven of the agreements were license agreements where the brand name company licensed its patents to the generic applicant in exchange for a royalty payment based usually on net sales or some type of sales figure, so that the generic applicant could use those patents

prior to patent expiration and enter the market prior to patent expiration.

The last two agreements we saw were supply agreements where the brand name company would supply the generic applicant with its products. So that the generic applicant would be marketing the brand name product rather than seeking approval of its product under the ANDA.

The problem is that 14 of these agreements had the potential to park the 180-day exclusivity for some period of time, and what I mean by that is that because it was a settlement agreement, there wasn't going to be a decision of a court, at least with that first applicant, and if there was a delay in when the generic applicant would begin to market, it would preclude FDA from approving any subsequent eligible generic applicants that were ready to come, so it could act as a bottleneck.

To mitigate against the possibility of this happening, the study recommends that Congress enact S 754 which is the Drug Competition Act as introduced by Senator Leahy to require brand name companies and generic applicants to provide copies of certain agreements to the Commission and to the Department of Justice.

We also have three minor recommendations based on the conduct observed. The first one is to clarify that the commercial to marketing trigger for the 180 days would be triggered, and I mentioned earlier that there were two agreements where it was a supply agreement where the brand name company was supplying the generic company with product. If that's the commercial marketing that the generic company is engaging in, that should constitute commercial marketing such that it triggers the 180 days, and it doesn't preclude FDA from approving a subsequent eligible applicant.

The second and third clarifications really deal with, if you have somebody who's second or third ready to go, the 180 days shouldn't be acting as a bottleneck. So the second clarification is to say that if there's a court decision, regardless of whether it's the court decision hearing the first applicant's court case, that that court decision would constitute a court decision to trigger the 180-day exclusivity.

The last one is to clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a court decision, and that's really what happened in the Ticlid case involving Teva and Hoffman La Roche.

In conclusion, Hatch-Waxman has been generally successful in encouraging generic entry, but the 30-month stay and the 180-day marketing exclusivity should be amended to ensure that the provisions are not gained to delay or deter generic entry.

Thank you.

MR. HYMAN: Thank you, Michael. Our next speaker is Jarilyn Dupont from the Food and Drug Administration. Jarilyn informed me I think late yesterday that I erroneously capitalized the P in Dupont, and she is not related to the wealthy DuPonts, so I managed to correct it on her name tag but pretty much nowhere else.

MS. DUPONT: Good afternoon. Although I'm following Mike's commentary, originally I was not supposed to, so I don't want to mislead anyone and think that I'm going to respond to the FTC recommendations in their report. I assure you that's not my function at this particular time.

We clearly appreciate the work that's been done by FTC, and we certainly feel that it has confirmed some of the perceptions that FDA has had with respect to the increased number of patent filings and the increase in related lawsuits.

With respect to FDA action on any of the FTC

recommendations, we have two things that are going on. We have a citizen's petition that FTC filed with us last May, and that will be responded to. I know they're wondering when, and it will be at some point in the future, as everyone knows how quickly we do respond to citizen's petitions. We will be responding to that and working on it. I think part of it was we were waiting for the report to come out.

The second thing is last year's appropriations bill required us to file the response, a report to Congress with respect to the FTC report eight months after the report was filed, which puts it at about March. The new appropriation bills are trying to shorten that time, but we are working on that response, and we will be filing a report to Congress on the FTC's recommendations that are in the report.

Let me start by saying, going to the bulk of my speech, I'm afraid Mike gave you part of it, so I think I'm probably going to bore you on some of this, and for those of you who are experienced with the FDA process, you may be doubly bored, but I'm going to go into a little more detail about the whole system of the Orange Book.

As I told someone before this, the most critical point on this is why is it called the Orange Book, and

so that every one will know and everyone has asked that no other colors were available in the printed copy, and therefore they picked orange, and it is orange even on the web site.

If most of you don't know the correct title of it, it's the Approved Drug Products for Therapeutic Equivalence Evaluations, and it includes other information in addition to these patent listings, but it is obviously commonly known as the Orange Book, and it's difficult to getting away from calling it that, if you're familiar with it.

With respect to our perspective on generics and branded pharmaceuticals, obviously the agency and the administration are committed to assuring that the approval process works well and is balanced. As Mike pointed out the original act had, it balances both innovation of new drugs against access to generic drugs, and that is a very hard sort of avenue to take, and it's very difficult to do that to everyone's satisfaction.

I don't think we'll ever get it to everyone's satisfaction, but it's certainly something we're trying to accomplish.

Let me go to the process. Under the FDNC Act, the provisions which were implemented by the Drug Price Competition and Patent Restoration Act of 1984, which is

either known as Waxman-Hatch or Hatch-Waxman, and since I have a former Waxman staffer sitting in the audience and a current Hatch staffer sitting in the audience, you can all take your pick as to what you call it.

Those particular provisions require that as part of a New Drug Application for an innovator or supplement to a New Drug Application, information on any patent that claims the pending or approved drug or a method of using the drug and for which a claim of patent infringement could reasonably be asserted must be filed

someone could file an action with respect to these particular patents.

The ANDA process permits approval of generic versions of approved innovator drug products. That was Title I of Waxman Hatch. The timing of the approval depends in part on patent protections for the innovator drug, and let me point out something that may not be clear is that with respect to these generic applicants, they can file them many months, whatever years, before the patent expires, so that you will have this particular patent -- excuse me, generic application sitting there for some time before actually there may be any movement on it, or there may be movement on it, but it certainly can only get a tentative approval until the patent or any exclusivities have expired with respect to that particular patent or some of the other activities occur, the court decisions, commercial marketing or the court decisions are taking place.

Consequently, what happens is is when they file an application, however early it is, they must contain a certification for each patent listed in the Orange Book, and there's four different certifications. I know we've concentrated on Paragraph IV, but there's one other that actually is relevant to this, but the four are that the required patent information relating to such patent has

not been filed; that such patent has expired, which is number II.

Number III is that the patent will expire on a particular date; and IV is that the patent is invalid or will not be infringed by the drug for which approval is being sought.

The last is that Paragraph IV certification. The important part here is that the third one is that the patent will expire, and what happens obviously is that a generic will file that and say the patent will expire on a certain date, and in the meantime, a new patent will be filed for listing in the Orange Book to which they then have to then file a Paragraph IV certification. So they have to amend it basically and file a Paragraph IV certification.

If they submit this Paragraph IV certification, they've got to notify the NDA holder, and the NDA holder then has 45 days within which to file a patent infringement action. If they file within that 45 days, then the 30-month stay is imposed. If the court decision is before the end of the 30 months, then the 30 months expires before 30 months.

If no action is filed, again as I explained, you can issue a tentative approval for the drug, but it cannot be a final approval or a complete approval

patent information is withdrawn or amended by the NDA holder, and as you know that has led to quite a lot of litigation.

We don't assess whether or not the patent claims an approved drug or whether the claim of patent infringement could reasonably be made against an unauthorized use of the patented drug.

As we've maintained since the implementation of the Act, we have no expertise or resources with which to resolve complex questions of patent coverage. The agency role is totally ministerial, and the courts have upheld that this ministerial role since forever -- most recently in July of 2002.

The process of patent certification, the notice to the ANDA holder and patent owner, the 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay does mean that there is the possibility of considerable delay in the approval of an ANDA.

These delays, the type of patents that are submitted and our role in maintaining the Orange Book have prompted much litigation, the Generic Drug Study and much Congressional interest. There are several pieces of legislation going through right now that do address some of this.

As I noted before, we're working on the report to Congress and a response to the FTC's citizen's petition. When these are available, there will be more information on FDA's position with respect to the recommendations. Thank you.

MS. MATHIAS: I believe next we have the panel, and let's get everyone pulled up and get that set up to

PANEL 4: GENERICS and BRANDED PHARMACEUTICALS

Panel Members

Ashoke Bhattacharjya, Jensen Pharmaceuticals

Greg Glover, Ropes and Gray

Bill Schultz, Generic Pharmaceutical Association

Sarah Lock, AARP

Amanda McCluskey, Families USA

David Reiffen, Treasury Department

Michael Kades, FTC, Moderator

MR. KADES: Good afternoon. It's not surprising that this panel is about pharmaceutical industry and competition. I'll be moderating it. My name is Michael Kades. I'm an attorney in the health care division of the Bureau of Competition. Hopefully you will hear little from me and most from the panelists.

Each of the panelists will have ten minutes for

Just so you'll know, the order of presentation will be alphabetical, so you can't read anything from the tea leaves of the order of the presentation, so I think with that, we'll begin.

Our first speaker is Ashoke Bhattacharjya who is the Senior Director of Business Information for Jensen Pharmaceuticals, which is a wholly owned subsidiary of the Johnson & Johnson Company.

DR. BLATTACHARJYA: Good afternoon. I would like to thank the FTC and David Hym0dhnati72en

as well as the other legal issues, but I will focus, as I said earlier, on the economic aspects.

I will also talk a little bit about the economic impact of the Hatch-Waxman Act and other market dynamics that have accompanied the time period since its inception. In particular, I will spend a few minutes on the dynamics and variety of competition. This, I think, is the crux of my presentations in any case, and follow up with some findings from key academic and government sources, including the FTC report itself, and then briefly allude to some general J&J, Johnson & Johnson positions on Hatch-Waxman reform.

Overall, there are some facts in here that may be familiar to some, but I think they something bear reiteration and have been already alluded to in the FTC report, but the market has grown tremendously over time, and the question is, and this is an interesting issue which often gets drowned out in some of the rhetoric that the companies sort of discuss: What has contributed to the tremendous explosion of the health care market overall and the growth in expenditure in pharmaceuticals? Without going into a lot of detail, what will be available on the web site later on, the key point recognizes that prescription drugs account for about 9.7 percent of overall health care expenditures at this point in time.

If you look at historical trend going back all the way back to 1960, it was about 10 percent in 1960. It declined to about, I would roughly say, 5 or 6 percent, and then it's climbed since, but it is at a level which we have seen before, but more importantly, this growth has been driven primarily in the last six years by volume and mixed growth, and about one fifth of it is attributable to price change over that period of time.

This is a key issue, which I think is actually well documented and may be found in a number of sources, including the one that is noted at the bottom in a footnote.

The growth of pharmaceuticals is also attributable to the dramatic impact on improving health care as well as the cost effectiveness, which I think has been talked about earlier during this workshop. There's a growing body of evidence, both in the clinical and the economic literature, on pharmaceuticals that are cost effective, and relative to other forms of health care interventions, they often end up reducing total costs associated with an illness by replacing sometimes less effective and more expensive treatments.

Indeed, the President's report from this year, 2002, alludes to this very fact in quite some detail,

and I direct you to page 182 in particular.

The growth of pharmaceuticals is also explained by the tremendous increase in third-party insurance and Medicaid versus out of pocket payments. It's about to up to about 70 percent now if you combine the two versus I think approximately 18 percent in 1970.

Again this is background. That's the sort of the perspective. That's the context in which we can evaluate quickly the Hatch-Waxman Act. Overall, the existing Hatch-Waxman Act provides what we believe are an appropriate set of incentives for innovation by research based companies and for market entry by generic pharmaceuticals.

I will not belabor the points in terms of the data, but I think you've already heard the generics do account for about 47 percent of all pharmaceutical prescriptions now. This is up from about 13 percent in 1980, and 19 percent in 1984.

Market penetration by generics have become increasingly rapid. There are several case. The most spectacular in this particular context being the case of Prozac where within one week, 80 percent substitution occurred within at least the Merck Metro system.

The Congressional Budget Office has done a study, I think it was done about a couple of years ago,

in 1998, and there's a lot of discussion in that study on the impact of the Hatch-Waxman Act, the economic impact. It's estimated there were 8 to 10 billion dollars saved from generic substitution in the mid 1990s, and the study also concluded that expected returns from marketing new drugs have declined 12 percent because of this act, and this is from the CBO study.

As I said, in the few minutes that remain, the crux of the idea is that there's more than just price competition in this market. Price competition is clearly

The therapeutic competition, the notion of that is that even for branded products that are on patent, there are a tremendous amount of competition that is not always fully appreciated certainly in general discussions and certainly in the popular press, and there's been a number of examples, and there's some remarkable shifts in market dominance, even among patented drugs.

I think the case of Lipitor is well known. There was another product which was the first product, Zantac, this goes back in time, which was a major anti-ulcer drug that superseded the first drug in that category, and they were all considered to be highly innovative drugs, so clearly there's no first mover advantage.

There's a tremendous amount of product differentiation among brands and their attributes. Patient tolerance and efficacy are not uniform, and they're all well served by increased variety, and that variety is provided by a number of branded products in the therapeutic class, and that's a major source of competition. There are also a number of publications on this particular topic.

Then there's this dynamic or Schumpeterian competition. This is the one that's in the President's

report. Specific examples that are cited in that report is the case of PPIs, which is a class of GI or gastrointestinal, anti-ulcer type products but advanced called pump inhibitors, and they replaced H 2s, which is the class of drugs like Zantac and Tagamet and the PPIs like Prilosec and Prevacet and so on, and this particular class came and replaced and surplanted an existing therapeutic class, an established class, which was on patent.

The supersession occurred before patent expiration. This is a key point that one needs to recognize, and there are other examples I think in the case of statin versus calcium channel blockers may also be a relevant one.

The costs of innovation versus imitation I think is well discussed in some context, but I think I would like to remind the audience and others that it's a long and intensive drug development process that takes about 12 to 14 years. It's highly risky. Only about 20 in 5,000 compounds that are screened enter pre clinical testing, and then about one in five clinical trials receive drug approval, that go into clinical trials that receive drug approvals.

The cost of R&D on average, and I would like to emphasize the average, recognizing failures, dry holes,

successes, when you average it all out, it works out to about 800 million dollars per new chemical entity. This is from a recent Tufts University study that was published late last year I suppose.

The cost of failures or delays are devastating. I won't get into specific examples, but the impact on market value as a consequence of any failures or delays are enormous.

By contrast, as was said, generics have to establish bioequivalence. Which requires about one to two years, and the costs, as I understand it, are up to 2 million dollars, and this is this is from a well known expert in the field, Henry Grabowski of Duke University.

The importance of pharmaceutical innovations, basically the idea is that economic studies have found umpteen number of times that patent protection or intellectual property rights are critical. It's kind of well known, but the length of the market exclusivity is more important in pharmaceuticals than in other high tech industries, and contrary to popular misconception, on average, and again on average, many marketed products do not recover their R&D costs.

The source of this is a number of papers by Henry Grabowski and John Vernon that have been established, and I can provide the sources in detail

of due process and no forfeiture provisions for failing to bring suit within 45 days. Normal statutes of limitations should apply, no forfeiture of right to trial by jury. There's legislation that effectively deprives patentees of the right to have juries hear of validity and infringement issues in ANDA cases, and no private action for delisting from the Orange Book

of the Pharmaceutical Research and Manufacturers Association of America, also known as PHARMAA.

MR. GLOVER: Good afternoon. I'm pleased to participate in this panel on generic and branded pharmaceuticals. I'm a physician and an attorney with the law firm of Ropes and Gray, specializing in representation of the research based industry on the relationship between intellectual property and FDA regulatory law.

My presentation will focus on innovation as an essential driver of competition in the pharmaceutical industry. Innovation is the primary source of competition in the pharmaceutical industry. Innovation produces new products that compete with products of other research based companies in a given therapeutic area.

To the extent that innovation does not occur, research based companies and generics alike will have fewer new products, and less competition will occur. Both initial and sequential product innovation are important features of the research and development process in the pharmaceutical industry.

As you can imagine, innovation does not occur in predictable consistent manner. Sometimes it occurs quite serendipitously. In many cases the innovation

that first appears incremental can turn out to be fundamental.

Innovation by brand name manufacturers has provided new dosage formulations that permit changes from intravenous to oral formulations, changes from four times a day to once a day dosing and changes from prescription to over the counter versions of products.

Moreover, product innovation results in a variety of different drugs with the same therapeutic class that have different clinical and side effect profiles.

All of these innovations give physicians more options to fit the drugs to the needs of the individual patient. Even after the introduction of lower priced generic copies of earlier versions of pioneer drugs, the demand for improved variations, a test to the immediate competitive significance of these innovations, as well as to the related to the consumer benefits. In addition, subsequent generic copying of these new versions further expands their competitive impact.

Robust patent rights for initial and sequential product development are needed to promote innovation and related competition. These rights enable development of government approved marketable drug products.

By providing research based manufacturers an

opportunity to benefit financially from the innovations they develop, these rights also provide the necessary incentive to promote further investment to support the research, development and refinement needed to discover future treatments and cures to protect the public.

The full range of patent protection is critical to achieving the full benefits of innovation. While patents are significant to innovators in most industries, they're absolutely crucial to the pharmaceutical industry. Without current levels of intellectual property protection, there would be no significant pharmaceutical industry, at least not in its current form, and neither would there be a significant generic industry because fewer drugs would be developed for generic companies to copy.

Effective enforcement of these patent rights is essential. Although the Hatch-Waxman Act prevents a pioneer company from bringing a patent infringement action, against a generic company during the generic product development testing phase, the Act enables effective enforcement of patent rights at the time a generic applicant files its application.

By providing up to a 30-month stay on FDA's approval of a generic copy of a patented product, the Hatch-Waxman Act enables patent owners to have a limited

time to defend their intellectual property rights before the generic product receives final approval from FDA.

Enormous investments are necessary to support pharmaceutical innovation. It is aehtf8Wnsitcei,rt33 3trt333

dramatically reduced prices, as they have done at increasingly high rates. Since the law's passage, the generic industry's share in the prescription drug market has jumped from less than 20 percent to almost 50 percent today.

An additional impact on pioneer generic competition arises from reduced effective patent terms. That is the time between FDA approval and patent expiration. The full patent term in the United States is 20 years from the date a patent application is filed. Accordingly, innovators in most industries who do not need regulatory approval before going to market typically receive up to 18 and a half years of effective patent life.

In contrast, pharmaceutical companies have a strong inducement to apply for patents early in the development process. As a result of this incentive and of the lengthening development and FDA review times, effective patent lives for pharmaceuticals have declined.

The average period of effective patent life for new medicines introduced in the early to mid 1990s for patent term restoration was only about 10 to 12 years. This trend also works to accelerate generic market entry.

Thanks to the cycle of innovation supported by effective intellectual property rights, the pharmaceutical industry is characterized by substantial and increasing competition. As pharmaceutical companies

I want to take a moment to explain AARP's interest in these issues. We are a nonprofit, non partisan membership organization of more than 35 million members aged 50 and older, and we work to foster the health and economic security of individuals as they age, including ensuring access to needed health care and prescription drugs. To that end, AARP supports efforts at the state and national levels to increase access to more affordable drugs.

Now, when David invited me to participate, he asked two questions. He said, Can you describe what the general need and benefit to AARP's constituency will be if we get quicker access to generics, and can you tell us why AARP participated in litigation against the industry?

So as to the first, I want to address it on two levels. One would be the macro level of the general numbers and statistics that drive our need to get involved in the issue, and the second is on a micro level of the individuals whose story we hear every day.

Access to prescription drug treatment is particularly important to the older population which, because of its chronic and serious health conditions, has the highest rate of prescription drug use.

For example, Ms. McCluskey's organization,

Families USA, has reported that people over 65, although only 13 percent of the population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs.

The rising demand for prescription drugs has been, as we have heard, accompanied by a dramatic increase in prescription drug costs, leading AARP to support access to generic drugs, which has proven to be a benefit to consumers by lowering the cost of medication.

From 1993 to 1999, prescription drug spending rose by 94 percent, over 2 and a half percent the increase for total national health spending, which grew by 36 percent over the same period.

A University of Maryland study predicts that the increase in pharmaceutical spending will increase, estimating the increase to be between 15 and 18 percent per year from 1999 to 2004, more than doubling from 105 billion in 1999 to 212 billion in 2004, and the rise in spending may be even greater than the Maryland study estimated because we have information from the National Institute for Health Care Management that spending of prescriptions rose 18.8 percent in 2000, reaching the total cost of 131.9 billion dollars last year, with an average cost to fill a prescription being $45.27.

Now, prescriptions account for approximately 19 percent of the average total out of pocket spending on health care by Medicare beneficiaries. This does not include home health care and long-term nursing home costs by beneficiaries, and prescription drugs comprise the largest category of Medicare beneficiaries health care expenses after premium payments.

Medicare beneficiaries were predicted to spend an average of $480 out of pocket on prescription drugs in 2000. Those who are in poor health or lack drug insurance pay considerably more. Those who were in poor health spent $685. Those without drug coverage spent $715, and those who are severely limited in their activities of daily living spend $725. Research has shown that uninsured, older and chronically ill people do without drugs when cost become too great a factor.

A 2002 AARP study reveals that for Americans age 45 and older, more than one in five report that they do not fill prescriptions prescribed by their doctor because of the cost. The cost of the drug was the primary reason people cited for not getting their prescription filled. Of particular concern is that the proportion of people who say that cost is the main reason for not getting prescription filled is rising.

It's up from 13 percent in 1986 to 32 percent

this year. Without a doubt increasing access to lower cost generics is one way to ensure that consumers will fulfill the prescriptions their doctors have ordered. Because generic drugs are priced much lower, they're a source of substantial savings.

Recently, the rate of generic market penetration has slowed and declined, and although Michael and two of our panelists have discussed the rate of market penetration at approximately 47 percent, it is clear that since 1984, the rate of generic penetration is declining.

Generic drugs market share, as a percentage of total dollar sales, slipped from a high of 12.2 percent in 1985 to 8.6 percent in 1998. As the FTC's Bureau of Competition has pointed out, consumers save most on prescription drugs when multiple generics enter the market.

The average price of a generic drug declines as the number of manufacturers of that drug increases, and it makes sense that the sooner more companies offer the same generic product, the greater the competition, and the lower price consumers pay.

Now, a Brand I study in 2002, which was a study supported by the generic industry, indicated that if generic drugs were more widely available and utilized,

every person age 65 and older would save an average of $270 for prescription drugs, but these figures that I've just rattled off are talking about the national macro level, speaking to averages and the national problem.

When you hear the stories that our members call us with, then you will begin to understand what savings on the cost of prescription drugs means to them and what faster access to lower cost drugs would do to improve their lives.

AARP members call in and tell us about how much they spend on prescription drugs and how their savings keep going down. Many members call and say they can't afford to take their medication, that they have to do without or sacrifice in order to pay for their prescriptions.

Some members call in tears explaining their stories as they struggle to make ends meet, and many are angry because of what they see as the increased cost of prescription drugs greatly exceeding the cost of living and what they see as the reasonable profit margin for

Maine and Michigan, which seek to provide discounts and coverage for seniors for medically necessary drugs.

We are joined in litigation with consumers and consumer groups affiliated with the Prescription Access Litigation Group, an effort by community catalysts and others to bring systemic change to prescription drug competition. These cases, which we have joined, have several things in common. First, they are cases of national impact involving important drugs used by older people.

They each allege that generics and name brand manufacturers have reached settlement agreements resulting in the delay of generic competition. One member has told me that she spends 10 percent of her income on Pador alone. Another woman says that the Tamoxifen medication keeps her alive, but she can't afford to pay for her other necessities of life.

As we've heard about and intuitively understand, the amount of competition between drug manufacturers has a direct correlation with the cost people pay for medication, and the cost of medication has a direct correlation with whether people can afford to purchase them and get the benefit of these drugs.

Any delay in the availability of generic prescription drugs means that consumers' access to life

saving and health enhancing medications is being diminished.

Thank you.

(Applause.)

MR. KADES: Thank you, and our next speaker is Amanda McCluskey, who is the Director of Health Policy of Families First, a nonprofit, non partisan consumer advocacy organization.

MS. MCCLUSKEY: Thank you. It's actually Families USA.

MR. KADES: I'm sorry.

MS. MCCLUSKEY: That's okay. I believe there is an organization out there called Families First, but that is not us.

Thank you very much for the invitation to be here. I'm delighted to be here and participate in this discussion on an issue that's of such great importance to so many Americans.

I would like to focus on three different areas related to the questions outlined in the agenda. First, I would like to look a little bit at the market from the perspective of the consumer, particularly that consumer that doesn't have prescription drug coverage and is paying the full price for the prescription when they go to the pharmacy counter.

while the rate of inflation during the same period was 2.7 percent. The story's the same if you look at the price increases over five years as well. Over the five-year period from January '97 to January 2002, prices rose on average 27.6 percent or more than two times the rate of inflation.

Among the drugs on this list of 50, ten are generics, and 40 are brand name. In the last year, prices for the generics most frequently used by seniors increased by 1.8 percent, a rate less than the rate of inflation. During this same period, prices for the 40 brand name drugs most commonly used by seniors increased an average of 8.1 percent.

In addition, the generics not only rose slower, but their prices are significantly less expensive. The average of the 40 brand name drugs, the average price was over 1,100 dollars per year for annual treatment using these medications compared to 375 dollars of an average for the generics.

Numerous studies have conducted head to head comparisons of brand to generic drugs and show significant savings for brands and generics within the same category. Clearly, competition from generic drugs offers seniors significant savings off of the brand name price and generics are increasingly -- particularly as

that manufacture these 50 most commonly prescribed drugs, and there are nine companies that are based in the U.S. and that are publicly held and therefore obligated to file with the SEC.

So we looked at those nine companies, and all of those nine companies reported a profit in the last year based on their SEC filings. Six of the nine companies, and the six include Merck, Pfizer, Bristol Myers Squibb, Wyeth, Lilly and Schering-Plough, had profits exceeding their spending on R&D, and on average the nine companies reported profits of 18 percent of total revenues, but only 11 percent of total revenues was allocated to R&D.

We also wanted to look at other areas of spending where we felt maybe direction was being diverted from R&D and taking potentially money away from that and a problem for why we weren't seeing any interest in lowering prices or moderating prices.

So we also looked at spending on marketing advertising and administration, and all nine companies spent considerably more on marketing advertising and administration than they spent on R&D.

Now, I don't want to go into this in great detail because that's the conversation for the next panel, but I did want to mention it is in the report. The report is on the web site, again at Familiesusa.org.

So I want to close this off by saying that while I think it was Mr. Glover, Dr. Glover, who mentioned that this is a very risky industry and that drives a lot of what the industry does. At the same time, this is also a very profitable industry. Fortune 500 has ranked this industry the most profitable for the last ten years, and it's the most profitable by a large margin.

In fact, in the last year alone, the average profit margin for a Fortune 500 company was a little bit over 3 percent compared to around 18 percent for the pharmaceutical companies.

I want to move on to the specific questions about the loopholes. You can imagine as an organization that advocates on behalf of consumers, seeing these high and rapidly rising prices, seeing the difficulty that individuals have accessing generics, and this is particularly frustrating.

So Families USA is very supportive of efforts to close the loopholes in Hatch-Waxman. In particular, we believe efforts to limit brand name manufacturers to one

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the Orange Book in a timely fashion. We also believe it's important to require both brand name and generic companies to report agreements and agreements that they have made about marketing of generic drugs and that these areas need to be aggressively monitored to ensure that the 180-day exclusivity for the first generic isn't parked, to use the FTC's language.

Once the patent exclusivity is expired, every effort should be made to get the generics to market as quickly as possible. These delays have tremendous financial implications for consumers.

Finally, I want to comment on one other area,

and I have been thinking about this a fair amount lately and have sort of likened it to me-too drugs manufactured by the same manufacturer as the original drug.

I think Claritin and Clarinex and Prilosec and Nexium sort of give it away in their names to some extent, but I think they're two great examples where the manufacturer has gone to great lengths to make fairly modest modifications in the drug to the extent that it's unclear what the added value is for the patient and, at the same time, have successfully protected the patent and the exclusivity of the drug that they've initially introduced.

So I just raise that. I know part of this hearing was to sort of raise those other areas and look at the FTC study, and I raise that as one other possibility and one other area that I think is worth looking at.

I just want to close by saying that we do value the innovation and the innovative work of pharmaceutical companies, but I think it's important to point out -- and I guess before I go there, I want to say not only do we value it, we believe it should be rewarded, and patent exclusivity is certainly one way to do that, but we believe that we should be rewarding true innovation, not simply modifications to an existing drug or me-too

drugs, but really true breakthroughs that offer real advances in the treatment of care for individuals.

Thank you.

(Applause.)

MR. KADES: Thank you. Our next speaker is David Reiffen, who is a staff economist in the Office of Economic Policy at the Department of Treasury. He is formerly a staff economist at the Federal Trade Commission, and he's authored a study on the generic drug industry or coauthored a study.

MR. REIFFEN: Thank you. I would like to thank the FTC for inviting me today, and as was noted, I work at the Treasury Department, and I have to give the usual disclaimer that whatever I say today is my opinion and not that of the Treasury Department.

As several earlier speakers discussed, recent FTC enforcement actions have focused on certain behaviors by innovator drug companies with respect to generic firms, specifically as alleged, that innovator firms colluded with generic firms to delay entry. For example, in several cases the innovator and the initial generic agreed to delay the introduction of the generic product, typically in exchange for a payment by the innovator, and that was discussed at some length today.

This is particularly important because certain

to obtain any additional FDA approval. It can simply bring its product to market even before the patent expires and certainly as soon as the patent expires, so in combination, by introducing its generic product before any independent generic firm can get FDA approval, the innovator firm can take away a lot of the profits associated with entering as a generic producing drug.

That, in turn, can have a fairly substantial effect on the number of entrants, so that was kind of the hypothesis that we came up with, and in doing our research for the study, we actually came across a quote by a fellow named Morton Katz, who was then Chairman of the National Association of Pharmaceutical Manufacturers, which was very much in the spirit of what we were talking about. So he's basically saying the same thing, that the innovator comes in first. It will be very difficult for any generic to make any money, an independent generic.

So what we were doing in the study was to try to estimate the magnitude of this effect, and so that comes down to two questions. First, how big are the profits that the first approved generic firm can expect to get as a percentage of all the profits that can be made producing a generic drug?

It turns out for the typical drug in our sample, we estimate that a little more than half of the profits go to the first entrant.

Then the second question is: What's the effect of the number of entrants of removing this profit from that available to the generic producer, so if a lot of the profits from entering decline, they decline by the amount we said, how many fewer generics will apply?

So what we do is we estimate a number of structure relationships, which basically describe competition within the generic sector, not competition between generics and branded but from within, to answer these questions, and they describe how competition develops among the producers of specific kind of drugs.

As it turns out, although we developed those estimates for the specific goal, that you can answer a variety of policy questions with these same kind of estimates.

So I'm going to turn first to the specific question of what happens when these branded firms bring out their generic firms, the innovator brings out his generic product.

It turns out the size of the effect depends on the sales volume of the drug, so if you have a drug that had relatively small sales before patent expiration, the

the drug before a patent expiration.

For the large volume drugs in our sample, the effect is much smaller. As you can see here the difference between the two lines is much smaller. On average over the three years, it seems like maybe it's only 5 percent or something, maybe less, and the reason is for a typical large drug, you might have a dozen independent generic firms applying in the base case.

So if you have a reduction of three in the number of generic entrants, they still have nine, and moving from 12 to nine has a much smaller affect on price than moving from five to two, and we're estimating that, but that's part of what we're doing here.

So as I said, we estimated a bunch of structural equations, and all these equations are describing in what is going on in the industry, and none of them are interesting in and of themselves, except perhaps the relationship between the price of the generic drug and the number of generic competitors, and that relationship has been estimated elsewhere, but we were interested in a specific aspect of it.

What we wanted to know is, we know generally the more competitors there are the lower the price will be, but we were interested in the question of when does that effect go away.

As we say we think a second firm will always lower -- having two firms will always introduce a lower price than having one, but will seven have an effect on price, seven rather than six have an effect?

So we estimated this relationship in a way that will allow us to answer that question, and what we find is somewhat surprising to us. The effect of additional generic competition seems to persist, even as you move out to six and seven firms.

Certainly it starts to flatten out. At about ten, you get to about as low a price as you can, as you're going to get, which is why the early result that in large markets moving from twelve to nine doesn't have much of an effect, but moving from five to two, you can see what happens has a very big effect on price.

Now, I should give a few caveats here. We estimated this in a number of different ways with different measures of price. They don't all look exactly the same, but the general picture is kind of similar which gives us some reassurance, but I wouldn't swear by these values. So that was what we did in analyzing this previous practice.

If you look at the paper, you'll see we discussed some other applications of these same kinds of estimates, and the message that comes out of the paper

often seems there's very little we can agree on. We haven't even been able to agree on the name of the statute. Is it Hatch Waxman or Waxman Hatch?

As a former Waxman staffer, I call it Hatch-Waxman, and I understand some of the Hatch staffers have agreed to put Mr. Waxman's name first.

One thing I think there is general agreement on is that the report by the Federal Trade Commission is really very helpful. It provides a lot of information that many of us have tried to get for quite awhile, but have been unable to get. It puts it together very well, and while I guess we all draw our own conclusions from the report, I don't think there's any disagreement that this is going to be very valuable as we consider these issues and particularly as Congress considers the issue this year and probably next year as well.

We're also not arguing about the value of patent rights. I don't think anybody is suggesting that patents aren't very important as an incentive to pharmaceutical research. Nobody's contesting that there used to be a 17 year patent. Now it's a 20 year patent. There's a five year patent extension granted in 1984. There's a six month pediatric extension.

None of this debate is really about those patent rights. The issue instead is: What happens after the

patent expires? What happens if the generic successfully challenges a patent and is able to show that it's invalid? And these turn out to be very, very important issues because, as everyone in this room knows, generic drugs have saved tens of billions of dollars since 1984, and as I think most people would acknowledge, there's potential for them to save much more in terms of prescription drug costs.

I'm going to cover three or four of the issues that seem to be key and just discuss a little bit about what's at stake. The first one that you keep hearing about is the so-called 30-month stay.

In any other industry, if a company such as a generic company wanted to challenge a patent, it would infringe on the patent. It would find itself in litigation, and it would generally have the choice of whether to go ahead and sell its product during the litigation. Now, selling the product can be a very risky course because if you lose, then you can pay treble damages, and in this industry you literally often would be betting your company.

So as the FTC report recognizes, even when there's no stay of FDA approval, the generic companies generally do not start marketing their product during litigation, but there's one situation where you can

imagine a generic company would want to market its product, and that's where it makes the assessment that this is a very, very weak patent, highly unlikely to be upheld. I think as a public policy matter, you want the generic to be able to market its product in that case.

The 1984 Hatch-Waxman Act basically tells FDA that once the generic files its application and says it's going to challenge the patent, FDA can't approve the generic drug for 30 months, and the Federal Trade Commission report says that one 30-month stay is okay, and the reason is that it takes 24 or 25 months typically for FDA to approve the application, so there's not much impact of that 30-month stay.

The original Senate legislation would have eliminated the 30-month stay, and I think as you'll see, that is the far simpler way to deal with this. This state creates all kinds of complications. I guess I would say in response to the point made in the report, if the average time is 24 or 25 months, there are

30-month stay, appears to be very weak, but the issue that's grabbed everybody's attention is something really of more recent vintage. No one ever imagined in 1984 where the first 30-month stay is about to expire, and so the brand comes in and somehow manages to get a second patent issued from the patent office, files it with FDA in the so-called Orange Book and gets another 30-month stay.

Under the law, as FDA has interpreted it, allowed it to be implemented, there could be a third, a fourth, a fifth, and in one case there actually have been quite a number of 30-month stays, and almost everybody who's looked at this is troubled by it.

The Commission was certainly troubled by it. The legislation to pass the Senate would eliminate that second 30-month stay and say there could only be one. I don't know anybody who will seriously argue that the 1984 Act contemplated more than one.

That leads us to the Orange Book. The significance of the Orange Book is that you get your 30-month stay only if you list your drug in the Orange Book, so it becomes very important whether the patent is actually listed in the Orange Book or not.

If we eliminated the 30-month stay, we could save everybody trouble about arguing about the rules of the

Orange Book because they wouldn't matter so much, but if we're going to have 30-month stays, then whether the patent can go in the Orange Book or not matters.

Now, it's only supposed to go in the Orange Book obviously if the patent claims the drug, if the patent is tied to the drug, but the rules, as FDA have implemented, basically are if the company wants to put the patent in the Orange Book and certify that it's valid, then the FDA treats its job as ministerial. As Jarilyn said, it says, Do you really mean it, but if the company certifies it again, the drug is in the Orange Book.

The courts haven't been any more help because they've said that the generics can't challenge the Orange Book listing, so even if you have the best case in the world, there was one case where the FDA had essentially said that the drug did not match the patent. It had gone ahead and listed it in the Orange Book, and the courts said you can't challenge it.

Now, the legislation would do what to me seems like a pretty small thing, which is to allow a generic company that wants to challenge this Orange Book listing to do so, not to have to do all this massive patent litigation, but to simply say, Look, that patent doesn't match the drug, I'll argue about its validity somewhere

else.

This has been, like everything else, very, very controversial, and it's going to apparently be some Bonanza for trial lawyers according to those who argue against it, but the bottom line here I think is the Commission said that where there have been patent challenges, the generics have prevailed 73 percent of the time.

So we're talking about real issues here. We're talking about creating a situation where drugs can come on the market long before the patent expires, if the patent is invalid, and creating a real structure that allows that to happen.

One provision in the law that's designed to encourage this is the so called 180-day stay, and basically what it says is the first generic to break a patent gets a reward. It gets to be the only generic on the market for 180-day days. The FTC study I think supports this as an incentive. It suggests some modifications, but I think they're minor enough that they really don't merit discussing here.

Where the issue has really become interesting is in these settlements, which the Commission says has sometimes had the effect of blocking other generics. I want to just say two things about that. One is whatever

the only one to advertise that use.

One of the brand name companies had gotten a six month extension for pediatric exclusivity, and one of their lawyers thought of the bright idea: Well, let's try to convert that to three and a half years; we should get three years for our entire drug because nobody else can put a pediatric claim on its label.

Congress addressed that in legislation last summer, but they addressed it only for pediatric populations. Undoubtedly, someone will try this for a label having to do with some other type of population because the pharma companies were very resistant to sort of a broad fix of this issue.

Third issue is biologics. The '84 Act really deals with chemical drugs, but today and in the future, there will be increasing drugs made from living substances, which are called biologics. There isn't a generic system for them in place. Much hard thought has to be given in the future to how you create a system to allow pharmaceutically equivalent biologics. Otherwise the patents on those drugs could be almost infinite.

In terms of the Commission's role, I assume it will continue to play the role it has. I don't know that the main issues are going to be so much antitrust issues or the kinds of issues that the Commission

typically looks at, as they're going to be competitive issues, and I think for the foreseeable future, the main forum for those is going to actually be Congress.

In conclusion, the '84 Act was enacted because at that time there were two imbalances in the marketplace. The first is Congress concluded that the brand name companies were losing too much patent time due to FDA requirements and FDA approval, so upfront there was too much patent time being lost, and Congress gave a five year patent extension.

It also said the brand name companies were gaining too much patent time at the back end. In other words, it was unhappy that there were was such a lag between the time the patent expired and the time the generic drugs could come on the market, so to address that, it created the generic drug program at FDA and the whole ANDA process.

The whole theory of that program was give the brand companies extra patent time, but the day the patent expires, position the generics to come on the market.

Today, there are new imbalances arising that are creating delays in the times generics can come on the market, and while the statute has been a great success story as the report recognizes, there is need to make

more adjustments.

Thank you very much.

(Applause.)

MR. KADES: Thank you. Well, I think we've pretty much heard from representatives of the major participants in the pharmaceutical industry, either as makers or buyers, and we've heard the representatives' views.

What I would like to start out with is to maybe try to turn the tables on the speakers a little bit and discuss the issues that are not the ones that other speakers have raised, so, for example, obviously the representatives from PHARMAA and from Johnson & Johnson talk about innovation. The representatives from the consumer groups talk about access and cost.

Maybe I thought it might be worthwhile to ask them each to respond to the issues that were raised by each other, and I thought we would start by, I'll throw this out to either one of the two representatives from consumer groups, which is from your perspective, what are the benefits of innovation in the pharmaceutical market, and how is it that we should weigh those benefits in making either policy decisions or enforcement decisions in antitrust actions?

MS. LOCK: I'll jump in. Of course innovation

is -- as Bill pointed out, there's certain agreement amongst manufacturers and consumer groups that innovation is vitally important, and we support those protections. The balance has to become, and Hatch-Waxman certainly tried to strike this balance between allowing competition and respecting those rights.

From our perspective at AARP, we see the overwhelming costs being continually driven up, and there's got to be an examination as Families has done in I think in some of their studies, maybe Amanda would like to address this, between the balance between profits and reasonable expectations of profits and when the prices become so out of reach that most people can't afford them.

MS. MCCLUSKEY: I'm happy to do that. I think obviously I agree with Sarah, and I think I made it pretty clear that we value innovation, and I think part of it is how you define innovation, but I think the trick here is balancing the notion of rewarding this innovation.

I think a 20 year patent puts a pretty high price, is a lot of 2t.3Iauea pretty high7

think there are loopholes in the existing laws, and I think the companies have been very clever in maximizing those to their advantage.

It goes directly to the point about profits, and I think we are not here, I'm not here to say that the companies are too profitable or what the right profit margin is, but it's hard for me to deal with issues around prices for people who can't afford drugs and to hear companies say they can't absorb any reduction in price, that they need more time, more maximizing of their profits, of their exclusivity on the market when people can't afford the product.

As far as I'm concerned, if people can't afford the product, then the innovation doesn't exist for them, and so I think there's a very delicate balance there, but I think what we've seen in the work that the FTC has done, we have done a number of our own, we have done a series of work ourselves, again it's on our web site. You're welcome to go and get that, if you want to give me a card here, I'm happy to send it to you, looking at where the companies have potentially used these loopholes to go too far.

What that really means is people aren't getting access to these innovations, so what does it matter? If they don't exist, they might as well not exist if people

can't afford them, so I think it's really important to say we're not saying they shouldn't be profitable. We're not saying that we don't believe innovation should be rewarded, but that's the point of the current patent system.

That's why we give the companies a 20 year patent, and we're talking about beyond that. I think what Bill pointed out made a really good point. The issue is what happens once the initial patent expires, and that really is the question, and I think I can very clearly say that Families USA feels that's enough, that these companies are making billions of dollars a year on these drugs.

I've got numbers. Lipitor, the manufacturers of Lipitor made more than 6 billion dollars on that drug just last year.

MS. LOCK: I would just like to emphasize that when the money and the profits and costs are so incredibly extreme, it becomes a good business decision to make settlements and make million dollar settlements to your would be competitors not to compete. That's when there's a real problem in the system.

MR. KADES: I would like to give a chance to either of the members from the branded pharmaceutical to respond to that and perhaps add these two additional

ideas to the mix, which are, one, is it conceivable that a system could put too much emphasis on innovation, and secondly, some of the facts and statistics that were raised by Ms. Lock and Ms. McCluskey such as the fact that one in five elderly are not filling a prescription due to costs, are those facts relevant to determining whether the system is providing enough, too much or too little incentive for innovation?

MR. GLOVER: Both of the statistics that were raised as well as the comments that were recently made as well as the statements made by Ms. McCluskey and Ms. Lock when they first made their statements principally addressed issues concerning access to medical care, and PHARMAA, as well as these organizations, support a prescription drug benefit.

That is, in fact, what they said they were talking, and that is, in fact, what the principal issue is. We do not believe that the issue of innovation is inconsistent with access. We believe that it's very important that the patients they described, the constituency that they represent, continue to have both access as well as the benefits that will come from new developments by benefnRtTD rTD (snct, what they o m6cp 7hee fTj -

have in the past and have the benefit of reducing overall health care cost because it allows the patients to, for example, stay out of hospitals or to stay out of higher cost types of medical care, so we think both of those are important.

With respect to the question of: Is it possible to have too much emphasis on innovation? As I said, I do not believe that this is a challenge or a contest between innovation and anything else that we're trying to achieve. Clearly, where you have, as a general matter, a view that you're competing between incentives for innovation versus incentives to allow generics to go on the market, that is fine.

I do not think, as they say, that we're truly talking about what happens after the patent expires, but because the language that we're using today is not very precise, what the debate truly is, is whether what we view as genuine innovation that is respected in the marketplace, that physicians like, that benefit patient care, is viewed by others as being innovation of the type that needs to be protected, and whether what we are doing in terms of an industry is what other people will respect as being important.

We do not believe that we are always clairvoyant enough to know whether the innovations that we make are

indeed overwhelmingly important to the public health or they are incremental innovations. We simply don't know. We're not that good at predicting, and similarly, I don't think other organizations can look at what we do and say: Some of that is good innovation and some of that is worthless innovation.

MR. KADES: Let me turn to maybe a more specific topic. One of the proposed reforms that has been discussed here today deals with the 30-month stay, and Mr. Schultz discussed his view that he did not think that anyone envisioned multiple 30-month stays back in 1984 when Hatch-Waxman or Waxman Hatch was first passed.

I thought I would give the opportunity to pharmaceutical manufacturers, and Bill can respond, as to whether that was indeed envisioned and whether getting rid of multiple 30-month stays is a good idea or a bad idea.

MR. GLOVER: In 1984, I don't think anyone contemplated any pharmaceutical industry of the degree of sophistication and complexity that we have now, and I

this last January, stated in some circumstances so-called multiple or stacked or what we've referred to as nonconcurrent 30-month stays are appropriate in certain circumstances.

We should also, however, take a look at why you have these so-called nonconcurrent 30-month stays. There is one view that says that this is the result of the pharmaceutical companies getting more and more patents on their products. And, indeed, the trends will demonstrate that as we've gotten more sophisticated in our research and development, that we do find aspects of our products that are patentable, and often these patents and innovations for the products occur, hit several stages, and therefore you have multiple patents.

As we also know, regardless of the number of patents that exist on a product at the time an ANDA applicant files its application, there's only going to be a single 30-month period in which all the 30-month stays run concurrently, so the real debate is not so much why are there multiple patents on pharmaceutical products, but why is it that some of these patents are being issued by the patent office and subsequently listed in the Orange Book after the ANDA applicant files its application.

There are going to be two things that lead to that. One is that, as always occurred, innovation for the large pharmaceutical companies occurs on a step-wise basis. There may be patents that you are filing for throughout the development process up until and perhaps even beyond when you first file your NDA or your NDA gets approved.

Those patents will be issued by the patent office in due course, and indeed some of those patents will be issued by the patent office some years after the drug first goes to market.

The second thing that is occurring, however, is that contrary, as you may have seen from some of the data in the FTC report that was presented here today, there seemed to be a change in activity in 1998. One of the reasons there was a change in activity in 1998 is because there was a new interpretation of the law relating to when generics were eligible for the 180-day market exclusivity.

Prior to 1998 and from 1984 basically to 1998, the interpretation was the generic had to be both first, and they had to successfully prevail in a patent infringement suit against the pioneer in order to get the 180-day exclusivity. In 1998, this was thrown into question, and eventually we have settled upon a role

approved.

It's on the market, and at some point a generic company decides that the patent may be invalid so it challenges the patent. That's then litigated for 30 months in District Court, Court of Appeals or whatever, and as that 30 months is about to expire, lo and behold, the pharmaceutical company finds another patent that it lists on that drug that was patented years and years ago.

Nobody is suggesting they shouldn't be able to get that patent, that they shouldn't be able to modify their product, but the question is: Should the generic be able to match the old product with the old patent or should this new patent be able to block it?

I want to emphasize, we are talking around the edges now. We're not talking about fundamental change. We're not talking about cutting down patent time. And I think it's quite interesting that there's been only a small number of companies really that have engaged in these abuses.

There are plenty of brand name companies that have been very innovative and very profitable without this kind of maneuvering, and I suggest that that alone is some evidence that there's something wrong here.

MR. KADES: Well, I think that concludes our

time for this panel. I want to thank you all for taking time and giving us your thoughts, and we wish you the best.

MR. HYMAN: We're going to continue. First let me just mention there are additional copies of the Federal Trade Commission Generic Drug Study outside, so if you didn't pick one up earlier, they're now there. They're at both the fourth and fifth floors. I'm not sure about the third floor.

I would like to now introduce from the Food and Drug Administration, Lesley Frank, to give us an overview of direct to consumer advertising before we have our last panel on that subject.

MS. FRANK: Thank you, and good afternoon to all of you. I'm sorry to say the CD I brought in is not working, so there's no PowerPoint. Sorry about that, folks.

I'm going to try to give you an overview of the direct to consumer promotion of prescription drugs. We have FDA regulation for drug promotion and take enforcement action to ensure that the FDA regulated parties comply with the so-called promotion provisions of the federal Food, Drug and Cosmetic Act.

I want to be clear when I talk about FDA regulated parties, I'm talking about manufacturers,

packers, distributors, NDA holders, investigators even, and anyone who works on behalf of those parties, and we have essentially within FDA Center for Drug Evaluation

letter. Instead it's to provide information to all regulated parties as to our enforcement activities and rational so they can avoid the same kind of violations, the concept many people believe is false.

If you see direct to consumer promotion of prescription drug on television, and you get a brochure or see an ad in Time Magazine, that this material has been cleared by FDA. This is not true for the most part. We do not pre clear the vast majority of all promotional materials.

Therefore it's important to understand that our enforcement actions are in essence taken after the fact. That's because with the exception of drugs approved under what's called Subpart H, you're accelerated approval drugs on HIV drugs and those drugs distributed through restricted access, they have a requirement of submitting terms ahead time, but that's more of a pre submission requirement we can review if we have the time and generally we do.

Not all NDAs -- two copies of form 2253 get sent to the agency. We get over 30,000 pieces a year. We will review launch material when requested by the company. This is not a requirement. There is no pre clearance requirement.

We can only regulate that promotional material

that falls within the legal definition of labeling and advertising, and FDA defines labels as any written printed or graphic matter upon or accompanying the drug product, and in contrast to what you have on a drug bottle, you get your prescriptions, that's the label.

Labeling is a little more expansive, and to be construed as a label, it need not physically accompany your little bottle of medication. It need only supplement, that is, explain it.

What I'm saying is a drug product can be shipped from New Jersey to Florida, and a brochure about the drug by the same manufacturer is shipped from Texas to California, and that piece of labeling is deemed to accompany the drug for our jurisdictional purposes.

Advertising, on the other hand, is not defined in the statute. The Act does say that advertising doesn't apply to anything that's been previously determined to be labeling, and you go to the regulations, and they give you have examples that include advertisements in published journals, magazines, periodicals, broadcast through media such as radio, television, telephone communication systems.

Those aren't the limit but good examples. Okay, why do we do this? Why do we regulate promotional labeling and advertising? The fact is false, misleading

unbalanced, unsupported information may increase risk to consumers. Consequently that false, misleading, unbalanced information causes a drug to be misbranded in violation of the Act.

Our job at DDMAC is to protect and guard against false, misleading advertising, protect public health, by our complements of enforcement and educational program.

Now, in order to be compliant with the Act, promotional and labeling, advertising materials may recommend or suggest drugs only for those uses contained in the approved product labeling. That's the PI, package inserts.

Claims made in promotion cannot be inconsistent with that. They can't be -- promotional material can't be false, lacking in balance, omit material facts or otherwise be misleading.

Basically what the law calls for and what we should see in an ideal world is the dissemination by FDA regulated parties of truthful, informative labeling and

a significant risk to the consumer. Yes, they do also provide the significant benefit, but this information needs to be communicated.

When I talk about false or misleading, what am I talking about? Well, promotional material can't state or imply a prescription drug is safer or more effective than shown by the clinical evidence. It can't state or imply that it's more effective for a broader range of populations, again demonstrated by the scientific evidence.

Now, you have a general idea sort of what we do and why we do it, and I want to turn specifically to DTC promotion. In the early 1980s, it looked like DTC promotion of prescription drugs was going to be the wave of the future.

sufficient safeguards to protect consumers.

Up until the 1990s, what did you see? Manufacturers were really trying to get the information to the patient after the drug was prescribed through the physicians, through the pharmacists, through health care professionals in general. The material itself was designed to be used after the prescription was received.

There were also things called health seeking or disease oriented promotion. Now, this tried to increase the number of consumers going to their doctors, asking about a particular problem. The ads disclosed that the particular health condition or medical problem existed, revealed that doctors have treatments for this condition, and it urged the effect that consumers see your doctor.

We saw reminder ads, the name of the drug. Reminders ads are exempt from the agency's advertising regulations because all they do or are supposed to do is call attention to the fact that the drug exists. They're not full prescription drug ads. They can have things like the drug's name, dosage form, package type price. Any mentions of drugs effectiveness or safety triggers a balancing requirement of risk information, brief summary, et cetera.

nature of broadcast media such as TV or radio, the regulations actually do modify the requirements in the case of a broadcast ad.

Yes, you have to have your indication. That's your benefit, but they also have to reveal the major risks of the prescription drug. Internally we call this the major statement, and by regulation, it has to be in either the audio or audio and visual portions of the broadcast ad, and then -- oops, I've got the stop, and can I just add?

MR. PAHL: Please finish off your remarks.

MS. FRANK: You've got benefit. You've got risk. You can either scroll the brief summary which you see on print ads, which no one is going to buy the time for, I have to admit, and in a way that someone can actually read it. In the alternative, the regulations say you can make adequate provisions for disseminating the PI.

And we put our heads together, tried to figure out what did that mean. We talked to industry. We talked internally, and we basically came up with a four component approach, and we came up with a guidance. A guidance just means it's not binding on us. It's not binding on regulated parties. It's just our thinking.

Certainly we need a very good reason to deviate

from it, but we said, okay, you've got a multi faceted audience, you have to address this audience, you need a diverse approach, you've got people who are technologically not sophisticated, people with privacy interests. They don't want to leave their names. They don't want to leave their addresses. They don't want the material mailed to them. It's a matter of health, they don't want people to know they're asking about this drug.

So with all these concerns, okay, we have a reference in the ad we see on T.V. to a toll-free telephone number. A person could request a PI be mailed or read over the phone. People don't want their phone numbers picked up by some sort of caller ID at the other end and registered so people don't do that.

Then reference the fact that health care providers can provide more information, certainly we want to encourage that. The listing of an Internet URL. A lot of people have Internet. A lot of people just like to go on and check. There are a lot of people who don't have Internet access, don't want it and are afraid to be identified with cookies or anything else.

That's why we also have reference in the ad to a concurrently running print ad so a person in their own private way can go to a place that they normally access,

whether it's a library grocery store, pick up a magazine, open it, and there it is, and there's the risk information.

Basically what this all assumes, however, is that you've got truthful information, consumer friendly, in context with -- you can't omit material facts. The limitations have to be disclosed for use with diet and exercise, only for use with med, again consumer friendly language. The whole idea is that you're providing a sufficient basis to enable the consumer to discuss the prescription drug product with his or her health care provider.

Now, just very briefly the type of enforcement we do, we have entitled letters. They're typically less severe violations of the Act. Warning letters, on the other hand, they're more severe violations of the Act. They're egregious, repetitive behaviors, violations that could actually lead to enforcement actions right away if not promptly corrected.

Additionally in the enforcement arena we have, under certain circumstances, entered into consent decrees with pharmaceutical companies to require submission of promotional material before they went out with it, not pre clearance, again pre submission requirement.

None of those I would like to say were a DTC, and finally seizure of the misbranded product is always an option. It has not been used in recent memory in the area of violative prescription drug promotion.

I would like to thank you for inviting me to speak here today, and I would be happy to answer any questions. That's it.

MR. PAHL: Thank you, Lesley.

(Applause.)

jurisdiction over DTC advertising, Federal Trade Commission also has jurisdiction over DTC advertising although pursuant to a memo of understanding between the two agencies, FDA has primary jurisdiction.

The other thing I would note is that in 1996, when the FDA adopted its current approach to DTC advertising, the FTC staff filed comment with the FDA opining that the DTC approached being considered and which is subsequently being adopted was likely to increase consumer welfare.

Among other things, the FTC staff comment said that such advertising was likely to provide timely information regarding medical advances, remind consumers about good health practices and supply information needed by consumers to understand and evaluate their physician's recommendations.

I guess the question our panel is going to address here is whether DTC advertising has met these high expectations, and I look forward to hearing from all our panelists on that topic.

Without further ado, I think it's time to hear from our distinguished panelists. Each of them will have ten minutes to provide some opening remarks, after which if there's any time left, I will pose some questions about DTC advertising, and it's been a very

long hard day for everyone, so I hope we're going to try to finish up at five o'clock as we're scheduled to do.

So without further ado, our first panelist will be Rebecca Burkholder from the National Consumers League.

MS. BURKHOLDER: Good afternoon. It's a pleasure to be here today. The National Consumers League is a national not-for-profit organization that has represented consumers and workers since 1899, over a hundred years, and the League has long been involved in

FTC posed, including: Is there evidence that DTC advertising is harmful or beneficial to consumers; and what consumer protection issues are raised by DTC? I'll focus on the following, the sources of health information, communication between health professional and the patient/consumer, consumer response to DTC promotion, are DTC affords effectively communicating risks and benefits and prescription for reform of DTC promotion.

and going on down there.

The AHRQ survey further looked at the degree of trust consumers place in the sources of information. The results seemed to show that although consumers had broad information seeking habits, in the end they trust very few with their own health.

According to the AHRQ survey, consumers trust the following sources a lot to provide accurate information about prescription drugs. As you can see, doctors are at the top of the list, pharmacists, and then at the bottom the DTC ads 6 percent.

Prevention Magazine's 2000 survey of consumer reaction to DTC ads reported similar skepticism for everyone and everything, save a consumer's own physician and pharmacist. That survey showed that only 5 percent trusted print or broadcast ads of prescription drugs a lot.

So in short, consumers seek and obtain information from a variety of sources, but they are skeptical of claims in DTC promotion and are most likely to place the greatest trust in their own health care professional.

Second, the impact of information on the patient physician relationship. The National Consumers League recently explored how consumers increased access to

health information is changing the doctor patient relationship by conducting a series of focus groups with patients and doctors this last year and this year.

Both doctors and patients acknowledged in the groups that patients were taking on a greater role in managing their health and that the patients actually wanted to become a partner with their doctor, and what happens to be driving consumer's interest and comfort in this is increased access to information, especially the Internet, which provides consumers with speed access to huge quantities of information. While many doctors in the focus groups welcome the informed and engaged patient, other doctors found such patients threatening.

Patients also talked in the focus group about doing their homework before a medical appointment. This process includes reading magazines and tearing out articles and advertisements about over the counter or prescription drugs, containing online searches and gathering information by word of mouth from friends, family and co-workers.

Doctors discussed the impact of this information. Doctors talked about feeling frustrated when they walk into an exam room and see the patient holding a stack of papers from various web sites and

magazine ads that may contradict his or her own professional judgment, and when faced with all this homework, physicians are often frustrated by the credibility of that information.

Physicians were concerned that patients take much of this information as scientific, regardless of the source and whether there was any research or evidence to support the findings, and most of the culling of the good information from the bad occurs in the exam room where time is already scarce.

Yet the solution is not to shut off this river of information. Patients probably cannot determine on their own whether the information gathered is applicable to their condition, and every patient is entitled to an informed conversation with his or her physician.

The solution lies in facilitating an open, unrushed exchange between the patient and the doctor, not in abandoning the communication that prompted and fielded the discussion in the first place.

Third, consumer response to DTC promotion. DTC promotions are reaching consumers and prompting discussion and information seeking behavior. 70 percent of respondents to the Prevention survey stated that they asked their doctors for more information as a result of

the DTC ad while 28 percent asked for the specific prescription.

The Prevention survey also estimates that as a direct consequence of DTC promotion, as many as 21 million Americans discussed a medical condition or illness with their doctor that they had not discussed before.

Similarly the FDA's 2002 patient survey on direct to consumer advertising reported that as a result of drug ads 18 percent of consumers talked to their doctor about their own medical condition or disease, something they had not done before. As you can see that has dropped off in 1999 where there were 27 percent. Overall, the data show that doctors are prescribing the advertised medications when consumers ask for them.

The Kaiser survey reported that of the 30 percent who talked to their doctor about a medicine they saw advertised, 44 percent gave the prescription asked for. FDA's recent survey reported an even higher result of the 23 percent of the consumers who saw an ad and talked to their doctor. 69 percent of those who asked for a specific brand received it.

It is difficult to draw conclusions about DTC advertising based upon increased utilization alone. More drugs are being prescribed for many reasons. Drug

promotion is one factor. In NCL's view, the appropriate prescribing of medications results in a healthier, more productive population. Increased utilization is worrisome if it's due to unnecessarily, improperly prescribed prescription drugs.

Ultimately the responsibility rests with the physician to choose among treatment alternatives and prescribe an appropriate medication, and DTC advertisers bear the responsibility to present useful drug information in a manner that is truthful, complete, understandable and does not create unreasonable expectation.

DTC advertisers have done much to educate and inform consumer about how prescription drugs can improve health. They have been much less successful in communicating the risk.

Is DTC advertising effectively communicating risk and benefit information? Under current FDA regulations, prescription drug promotion must fairly balance the positive information about safety and effectiveness against the negative information about the drug's side effects and contraindications.

Yet consumers are not taking away important information from DTC advertising that otherwise technically complies with all legal requirements. DTC

advertising is not communicating risk information effectively, and even benefit information could be conveyed more clearly.

The DTC ads do seem to raise awareness of certain prescription drugs. Over two thirds of the respondents to the League's '98 survey always or sometimes increased their knowledge of medicine and also increased their knowledge of disease, and the Kaiser survey report concluded that the three drug ads shown to consumers were effective in communicating very basic information, the name of the drug and what it treats.

However, the Kaiser survey also found that consumers did not gain much knowledge beyond that. Even after seeing a DTC ad, 70 percent of consumers reported that they knew little or nothing more about the health condition for which the drug was indicated. 59 percent knew little or knowing more about the medicine.

As for conveying important risk information, DTC advertising is especially lacking. The Kaiser survey report noted that FDA guidelines require that television prescription drug ads include a major statement formerly disclosing all the risks associated with the drug.

As the report states, just because the ads included this information, it is not necessarily successfully communicated to viewers, with the exception

of one of the side effects mentioned in one ad, about half or more of the respondents could not correctly identify the potential side effects after having just views an ad.

For print ads the Prevention survey that over 50 percent thought print advertising did only a fair or poor job of communicating serious warnings.

In addition the brief summary has failed to communicate useful risk information to consumers. Required to accompany all print advertisement, the brief summary is frequently nothing more than a reprinting of the warnings, indications, contraindications and side effects from the drug product's full package labeling which is written for health professionals.

It is dense, printed in minute type, highly technical and contains every single side effect ever potentially associated with the use of the drug. It is typically neither legible nor comprehensible.

The FDA 2002 survey reported that among those interested in a drug advertised in the print media, that's those interested, 54 percent reported that they read about half, little or known of the brief summary, and 55 percent found the brief summary somewhat hard or very hard to understand.

Lastly, I will discuss just a few alternative

models for disclosure of risk and benefit information in DTC promotion that will better advance consumer welfare and public health.

First of all new regulations. FDA must either amend the old 21 CFR Section 202.1 or promulgate a new regulation that specifically addresses DTC promotion. This regulation was written to advise sponsors on how to promote their drugs to the medical profession. The new regulation specific to DTC advertising should incorporate lay consumer comprehension into evaluative criteria.

Reformat the brief summary, the brief summary must be formatted to provide important risk and benefit information, a consistent balance format and be written in plain language a lay consumer will understand. The summary should include important use and safety information, identify who should and should not use the product.

The brief summary should not include, as it must now, every single risk in the full product labeling, but emphasize the most serious and most frequent side effects.

Third, standardize format for risk and benefits. In NCL's view the format for presenting risk and benefit information for prescription drugs should be

standardized as it was for over the counter drugs and foods, and this way consumers can become familiar with the single format and learn how to use it to obtain important health information.

The drug facts and nutrition facts formats provide excellent models for a standardized presentation for important risk and usage information.

Lastly, include health professionals. DTC can be a surprise intrusion into the physician patient relationship. Thus drugs sponsors should include health professionals in advertising campaigns so they're prepared to address consumers inquiries and health professionals should not be threatened by the empowered and curious patient.

The patient inquiry is a request for a dialogue, and the health care professional should respond with information about the drug, its risk and benefits, about generic availability and therapeutic alternatives.

So consumers have gleaned health care for a variety of sources, but for all these rich and varied sources, they continue to trust their health to medical professionals.

Thank you.

(Applause.)

MR. PAHL: Thank you, Rebecca. Next we'll hear

from Dr. Jack Calfee who is a resident scholar at the American Enterprise Institute.

MR. CALFEE: Thank you. I don't have a PowerPoint, and it occurred to me maybe I could just talk from here.

MR. PAHL: That would be fine.

MR. CALFEE: Minimize transaction costs, as it were.

I provided outside, I'm sure most people missed it, a brief one-pager outline my remarks. I'm going to follow that. Essentially I want to make six points about DTC advertising, and the first is strictly background, probably a point with which everyone in this room agrees which is consumers need to take more action on their own behalf than they used to in connection with health care, and specifically in connection with getting drug therapies that can be a value to them.

I would point out this is not just a matter of the growth of managed care and less time with the doctors and that kind of thing. This has been going on for 20 or 30 years, and this trend is reflected explicitly in FDA policies, and I would mention two, one being the -- I wouldn't call it an avalanche but certainly a long and very large stream of conversion from prescription to over the counter status for drugs,

not just in connection with arthritis but often in other connections often, and the other one being the side effects of cancer therapy. The side effects of chemotherapy can be quite severe, and again there are drugs that can help with that and again consumers are often lacking in the information about these drugs that could be of value to them.

Point number 3, advertising and promotion is a demonstrated mechanism for overcoming the gap in information between what the literature says and what

The FDA has conducted two consumer surveys. Prevention Magazine has conducted at least three, with a fourth now under design. There have been several other surveys. All these surveys, the ones that I have in mind, are large, representative surveys of consumers. All of them are well designed. They're quite informative, and they're surprisingly consistent across the different surveys.

Point number 5, this evidence now permits us to reach some kind of preliminary assessment of the costs and benefits of DTC advertising. Let me focus first on the potential harms from DTC ads. So far, the evidence tells us that the harm from DTC ads is minimal. It may have been very, very slight indeed, and this appears to be true in connection with several specific items of concern.

One is inappropriate prescribing. A second is the possibility of deceptive advertising and its effects. Third, the potential distortions in the relationships between doctors and patients and finally the impact of DTC advertising on prices.

I won't go through these in detail. In my handout I did cite and provide a link for a paper that goes through these items in probably more detail than you would like to encounter.

previously expected , and you would expect to see doctors prescribing these drugs more aggressively.

So far we haven't seen much of that, and that is one reason why with all the debate about pharmaceutical prices and pharmaceutical access, the main topic of discussion right now at least in political terms is how to assure access to these drugs rather than how to curtail prescriptions that should not be written.

Also let me mention briefly on the question of deceptive advertising, and here the point that I think is worth making is that the FDA standards for deceptive advertising are extremely stringent, far more stringent than those in the FTC in the halls of this particular

their own standards is quite limited, and the effects, if any, seem to be very, very small.

Finally, point number 6 in my brief list is what the evidence tells us so far about the actual and potential benefit of DTC advertising, and what we've seen so far is those benefits seem to be quite varied and they appear to be fairly substantial, at least at this point. Advertising certainly increases consumer and physician awareness of the potential benefits of pharmaceuticals, in other words, it is helping to close the information gap.

The advertising is prompting more discussions between patients and doctors about drugs as one or two speakers have already mentioned. There's considerable evidence that something on the order of 20 percent of the population, maybe a little bit more than that, has been motivated by DTC advertising and talked to a doctor about a condition they had never previously discussed.

If this were the only effect of DTC advertising, that would be a very large and very important benefit when you consider the kinds of drugs that are being advertised for osteoporosis, depression, elevated cholesterol, et cetera, conditions that people often don't discuss with their doctors, and if as a result of the DTC advertising they are discussing these

conditions, the benefits of doing so can be quite substantial.

DTC advertising is increasing consumer awareness of both risks and benefits of drugs. It seems to be making people feel more comfortable about the drugs they have been prescribed. They seem to be, if anything, more aware than they have ever been that drugs are inherently dangerous, that they should be treated with caution but they can also be beneficial and that, they, along with their doctor, should be balancing these things.

The evidence suggests that DTC ads are probably increasing compliance with drug therapy. If this again is the only thing DTC advertising were to do, the benefit can be very, very substantial given that noncompliance with drug therapy is one of the most stubborn and difficult problems that the medical profession has encountered, and they have not come close to solving the problem of noncompliance with drug therapy.

I think it's possible that five years from now, ten years from now when we look back at the DTC advertising, a lot of us may think that the effects of DTC on compliance may be the single most important effect and the most important benefit of DTC

advertising.

Oddly enough DTC advertising has increased consumer awareness of non drug therapy for important medical conditions, and if you think about it, the reasons are pretty obvious. If you advertise a drug to treat obesity or cholesterol or other conditions, several other conditions, the first thing that will happen if your ad causes someone to talk to the doctor, that person will receive lifestyle advice, and the survey, not just consumer surveys but surveys of doctors show that is exactly what happens.

When people go in to see their physician about diabetes, for example, the first advice they get is lifestyle advices, and it's pretty far down the road before they start getting any kind of drug therapy.

What this means if one looks at the attention to non drug therapy and the effects on compliance, that DTC advertising may be having important positive externalities or positive spill over benefits for the market, and by that I mean benefits that go to consumers but are not captured by the brands doing the advertising.

Finally, DTC advertising substantially reinforces industry standards to develop new drugs and to research new uses of existing drugs. Thank you.

MR. PAHL: Thank you, Jack.

(Applause.)

MR. PAHL: Our next panelist is Dr. Steven Findlay. He's the director of research for the National Institute of Health Care Research and Educational Foundation.

MR. FINDLAY: Good afternoon. We're pleased to have the opportunity to participate today. I would also like to make six points. Jack and I didn't coordinate on that, but it just seems a good round and short number, and I'll try to make my remarks as brief as possible to get to the discussion.

I would like to make six points and then four specific recommendations pursuant to the questions posed to this panel by the FTC staff that did a great job in the last two days of bringing us all together. I've been through most of the last two days, and it's been terrific.

First, to state the obvious, DTC ads are very visible. That visibility has focused media attention on the ads, and both of these, the visibility and media attention, has tended to obscure other forces contributing to the increase in prescription drug use and spending.

The fact is DTC drug ads are but one factor in

the rapid rise in prescription drug spending since 1995, '96, '97. Earlier today we heard about some of those other forces, but just to tick them off, increased insurance coverage of drugs, more drugs being approved, an increase in the diagnosis of many chronic conditions that afflict millions of people, and an increase in the markets to physicians and the free samples particularly provided to physicians.

All these forces at the same time that DTC ads have come to force since about the mid 1990s, and particularly after the 1997 clarification -- all these forces overlap, and that makes it, has made it quite difficult to tease out the independent effect of DTC ads.

In particular, in the last few years, we think there's a strong synergy between DTC ads and a rising volume of free samples the doctors gave patients. Literally some people see an ad, ask for the drug from their doctor, and the doctor says or can say right there, here's a sample, try it for a few weeks. That's a powerful synergy, and as most of you probably know, the increase of DTC ads is matched by the increase in the volume of samples that are going to the doctor's offices.

Point 2, because of this confluence of forces,

the magnitude of DTC's effects has not yet been accurately quantified. That includes effects on such things as the demand for drugs, prescribing trends, consumers' perception of drug safety, which I think is an important issue, the public's health and of course costs.

There is suggestive evidence both ways, that DTC ads have a significant effect and that they have a relatively minor effect so far, and in fact some of the same evidence has been spun both ways, and Jack referred to some of the evidence, and Rebecca as well to the various surveys.

For example, I'm citing a survey that Rebecca also mentioned, some observers cite survey data to emphasize that only about 3 to 6 percent of people in the U.S. have gotten a drug because of an ad. Sounds small, but in fact that represents 8.5 to 12 million adults, American adults in 2001 who received a drug as a direct result of an act. Rebecca presented that data. But wait, it sounds like a lot of people, but that's out of 850 million physician visits in 2001 and 3.2 billion prescriptions.

So it depends a lot when you look at this data on how you want to spin it, and you really can interpret it both ways, and it has been interpreted both ways.

Third, data linking drug advertising to higher

improved access to prescription drugs through managed care and particularly through PBMs. They've made it much easier for us all to take our card and get a drug.

As that was happening, we have seen more and more drugs ads, and of course some drugs have become household names, so it's a real interaction. It's worth noting here, though, that the pharmaceutical industry is well aware that DTC ads also promote the purchase of prescription drugs outside an insurance system.

Witness Viagra. Many men pay for Viagra out of pocket, some with a prescription and some apparently without. Viagra is also widely available on the Internet.

Point 5, with respect to the FTC's question on which drugs are being advertised and why, I would like to stress one point which harkens back to the first panel today. It's brand name drugs, not generics. Question, will this change? I think it's possible we'll see some generics being advertised to consumers in the next few years as more blockbuster brands go off patent, but it's highly unlikely that generics will ever be promoted to consumers to the degree brand drugs are, and I think that's unfortunate.

One other point here, DTC ads foster the blockbuster system of drug discovery in marketing, and

that's not entirely bad, as Jack alluded to, but it's not entirely good either. Many analysts, including us, think companies have poured too much lately into preserving and marketing their blockbusters.

Sixth point, and this is the critical question: Are DTC ads harmful or beneficial on balance? The fact is we just don't know. We don't know what the balance is. Putting costs aside, the ads obviously have positive effects, and Jack referred to some of those, helping to educate consumers about diseases and alert them to new drugs. That's obviously going on.

Just as obviously, some people are getting prescriptions for drugs they don't need because of a DTC

more resources into monitoring the content of DTC ads. I think the FDA would agree with that, and there's universal consensus that they're just not spending enough.

Recommendation 3, the FTC and FDA should more formally combine forces to more carefully measure and track consumer response to DTC ad including assessment of problems understanding the risk information that Rebecca referred to. Again the FTC and FDA should more formally and more carefully measure and track consumer

Still though to sit around and hear conversation that seems to work from the assumption that what is truly motivating the pharmaceutical industry to DTC ads is the desire to educate people. I don't think really anybody believes that. We can talk that way. There may be some incidental benefits. There may be some people who learn some fragments of information.

But the fact that some people learn something is not necessarily evidence of benefit. The question is what do they learn, how selective is what they learn, do they learn one thing instead of something else.

Dr. Inglefinger who was the editor for the New England Journal of Medicine for a number of years said plainly, advertisement should be overtly recognized for what they are, an unabashed attempt to get someone to buy something, although some useful information may be provided in the process.

It's really hard to hear people sympathetic to the pharmaceutical industry talk about their desire to get information to patients when for years we've been monitoring drugs in which the industry has consistently tried to prevent the most dangerous of adverse drug reactions from coming to public attention.

It's hard to sit there especially when the industry objected to the patient package insert program

back in 1991, which would have been not the only way but a very important way to get information about drugs to patients.

We have to ask ourselves if the purpose of all of this truly was education, why wouldn't you work on the drugs of greater public health benefit? Why wouldn't you work on the places where you really could make a difference in people's lives?

But instead we don't see that. We see what's completely predictable. We see an emphasis on the conditions that are incurable, an emphasis on conditions that are chronic, an emphasis usually on a crowd of therapeutic classes, although sometimes an exception is there for the cosmetic or lifestyle drugs, which simply aren't the world's greatest public health priority.

We see an emphasis on the new over the old. As Steve said clearly we see a complete emphasis on the brand name over the generic. We see an emphasis on efficacy over safety. One of the earlier tricks in the DTC campaign was to put the side effects of the adverse effects of a particular drug in white against a white background. That's a good way of not letting everybody quite see what's going on from a safety point of view.

Efficacy stuff of course is bright and center. We've also seen a linguistic twist on this where an ad

for Rezulin had the benefits in English. Sorry, this was in a Spanish language magazine called El Tempo, and the benefits were in Spanish since it was a Spanish magazine, but the brief summary appeared in English.

All of this suggests that the best way to understand what this is all about is not about education at all but really about profit, and I think unless we can talk honestly about it, I don't think we can really have a fair conversation about DTC advertising at all.

What are consumers perceptions of DTC ads? We've heard something about this already. Kaiser Family Foundation found that 70 percent of the TV viewers that they surveyed learned little or nothing about the disease, and 59 percent learned little or nothing about the drug.

Similarly, a study in the Journal of Family Practice in 2000 showed that of the possible 11 point educational score, the average educational score for 320 DTC ads that they looked at was 3.2, and often missing, not surprisingly, were information about duration of use, alternatives, especially behavior alternatives to drug therapy.

In a number of cases of course, either the efficacy data was presented in a misleading fashion, so the old trick of using the relative benefit of the drug over the absolutely benefit of the drugs is an old trick

in pharmaceutical and other advertising. That's a frequently recurrent thing.

Of course the consumers themselves are confused, as was alluded to earlier. The 1999 survey showed that 43 percent of consumers believed that only, quote, completely safe drugs could be advertised through DTC and that 29 percent believed that drugs had to be, quote, extremely effective in order to appear in a DTC ad.

50 percent even believed that they had to be pre approved by the government, and we've heard quite clearly that that is not the case.

The cost element of this is also important. The amount of expenditure on DTC ads is well known to people in this room, some of who are spending this money, sky rocketed to 791 million dollars in 1996 to 2.5 billion in 2000 and now 2.7 billion.

The consumer pays at both ends. First we have to pay for the advertising, and secondly because, as I outlined at the beginning of this there's a shift for newer and more expensive drugs, pharmaceutical companies really don't make money on the others to the same extent, we pay again because of the shift in expenditures as well.

I count the cost element of this is actually one

of the dimensions in which the evidence is most clearly in.

I did give a bit of thought to the regulatory scheme under which FTC and FDA are operating here because in a way that does seem to be the theme of this panel. I'm a physician, not a lawyer, so perhaps not the best person to be talking about this, but my understanding of the regulatory scheme is we should remember that DTC ads, although we talk about them as prescription ads, they're not necessarily prescription ads.

They're over the counter that are in principle DTC ads that go directly to consumer. Same thing is true for dietary supplement ads. The agreement between FDA and FTC says that prescription drug regulation belongs with FDA, and supplements in over the counter direct consumer ads, again not as important, have fallen to FTC, and so my recommendation with respect to the FTC would be to at least put their effort where they can which would be with over the counter drugs and with supplements, and there's no shortage of misleading information that goes out in the dietary supplement area, that's for sure.

Where the real power enforcement-wise is, is really with FDA. As has been pointed out before,

despite at least 15 years of people defining such, we still have no regulations for DTC ads, and we're still relying on guidelines and the like that were written back as a result of the 1962 efficacy amendments. These are way out of date.

The second problem is that there are no civil monetary penalties so all we get is this notice of violation letters, warning letters, et cetera. Of course the companies are fully aware by the time the letter gets issued that already a few million people will have seen the ad if it was on T.V. It's well worthwhile to take the chance. The worst you get is notice of violation or warning letter, which really doesn't really have any strong teeth at all.

Indeed even when there are repeated violations resulting in repeated warning letters, there still is no opting for the final option which the FDA has which is criminal prosecution. At least eight DTC violations for Claritin, at least eight Flonase and Flo-vent, and still all they get is yet another notice of violation or a warning letter, still no criminal prosecution despite a demonstrated pattern of conduct.

What really worries me about that is that there's a decline in enforcement at FDA. For all of our hope of what FDA might do, the fact is under the current

counsel's office, there is hostility I believe toward really clamping down on improper advertising, and that is becoming now clear in the enforcement records at the FDA.

Notice of violation warning letters were 158 for advertising, not only direct to consumer, this is for everything, in 1998. But by 2001 they were down to 73, and I checked the FDA's web site this morning. They have data through August or so, and I extrapolated to the end of the year. It will be down to 23, 23 in 2002 compared to 158 in 1998.

This is a matter of discretion. In fact there was even a point at which the number of employees at

America and the former and founding CEO of the National Osteoporosis Foundation, and I'm here today to represent perhaps those conditions and diseases that have not been heard on the subject of direct to consumer advertising and promotion.

As documented in the AARP survey, there exists a health information gap, which includes a medication information gap, and of course as we've all said today DTC advertising is really only one of many efforts to address this problem.

I want to give you a little bit of background and talk a little bit about diseases because that's what DTC advertising is really addressing. First I want to describe briefly a disease that is poorly understood by the general public and by physicians alike, lupus.

Lupus is a complex autoimmune disease in which the immune system goes into overdrive and begins to attack normal healthy cells and tissues. It's the body attacking itself. The results can be devastating because no organ system is safe from this attack, the joints, the heart, the brain, the lungs, the kidneys, the skin, to name a few organ systems that may be affected by the disease. The effects of lupus can range

suffer from this disease that affects both genders, although 90 percent of those affected are women, especially women of color. Lupus also strikes children.

The bone thinning disease, osteoporosis, accounts for more than 1.5 million fractures each year, including fractures of the hips, spine, wrists and other bones. This disease exacts pain and disability and disfigurement and death. There are more than 50,000 deaths each year due to bone fractures, especially the hip fracture.

These deaths are primarily due to infection or pneumonia or blood clots that occur as a result of the fracture or as a result of the surgery to fix the fracture.

I cannot begin to tell you how challenging it once was to alert consumers about osteoporosis or how challenging it is today to gain public and professional understanding about lupus.

In osteoporosis, direct to consumer advertising made a major contribution to educating patients and health professionals about the risks, about the diagnosis and about the treatment of osteoporosis. My remarks today are going to relate to two questions posed by the FTC, namely the role of physicians and

pharmacists in advertising of prescription drugs and evidence that DTC advertising is harmful or beneficial to consumers.

Many of us can remember when physicians used to be the key resource in communicating information about medications to their patients, but in today's health care environment, physicians have too little time to spend with their patients. We've all said that today, and we all know the prescription is written at the very end of the visit, many times as the doctor hurries out the door to see the next patient.

Here is where DTC advertising I think has been most effective. It has helped to inform the patient about major conditions and treatments and encourages them to schedule a physician's hurriti TD7redilsto nt

if you live in Washington to think DuPont Circle CVS, as I speak about the role of education with respect to medications and pharmacists. I don't know what your experience has been, but I think mine is pretty typical. You take your prescription to the pharmacist, and if you want, you can wait 30 to 45 minutes or you can wait an hour for it to be filled or you can come back.

In both cases it's very unlikely that the pharmacist will have any time at all to speak to you. If your decision was to come back for the medication, you'll stand in line and just be happy that the prescription is filled when you get to the counter.

If you had questions about your medication at that point, these are replaced by other questions such as: Did my prescription drug program cover the medication; and by the way, what is that copay? So I do think that there are issues around the time that physicians have and the lack of time the pharmacist has have to speak to us about our medications.

Unfortunately, the AARP underlines this conclusion because the study points out that almost half of all patients have little or no communication about their medications with either of these two health care professionals. Certainly policies and programs that

require physicians and pharmacists to discuss medications with their patients are needed.

There is no question but that DTC advertising messages could be even more educational. In many cases, the ads do not describe the symptoms of the condition the drug is designed to treat. The FDA regulations mandate that information on adverse effects and risks be presented as part of the ad, and in my view, inclusion of some of this information is necessary.

However, I think in many cases, too much information is presented, and the ad's educational value and impact is diminished. DTC ads should tell the balanced story, and physicians and pharmacists should have the primary responsibility for discussing risks and advertise effects with their parents.

After all, it's the physician who knows the patient's medical history and can put this information into context for that individual patient. Asking consumers to figure out whether risks and adverse effects are relevant to them I think is asking too much.

Now, is there evidence that DTC advertising is

campaigns to reach the millions of people who are at risk for the disease. When funds became available and the organizations did produce those ads, they were aired at the time the country slept. It was primetime DTC ads that educated the American consumers about the existence of bone density tests and treatments that made the difference.

With respect to this disease and others, I would respectfully suggest that if DTC ads were ever to be eliminated there would have to be a corresponding redefinition of the public service mandate of network television to allow nonprofit organizations to air health messages in prime time. Of course, that's not the role of the FTC. It might be the role of the FCC.

Over the past five or six years, many factors converged to establish a role for DTC advertising, not the least of which was the emergence of a health care system that fundamentally changed the role of the physician and all other health care providers.

When you factor in the Internet and its potential to educate and the quickened pace of pharmaceutical innovation that produced more life saving and quality of life enhancing drug therapies than ever before, it is no surprise to me that the role and responsibilities of consumers have also changed. In

order for consumers to benefit from the new health care system, they are called to play a much more proactive role in their own health care.

Finally, I believe there is a need to balance DTC ads with more educational messages and foster requirements that enable physicians and pharmacists to discuss medications and their risks with consumers.

In addition, the public and private sector must initiate major health information campaigns on diseases that include material on available tests and treatment.

Thanks.

(Applause.)

MR. PAHL: Thank you, Sandra. Last we'll hear from Richard Samp who's the chief counsel of the Washington Legal Foundation.

MR. SAMP: Thank you. The Washington Legal Foundation is a group that has been actively involved over the years in promoting free speech rights under the First Amendment, particularly commercial speech, and that is how we first really became involved in FDA issues at all.

We have been involved over the years in litigation with FDA on First Amendment issues and have won a court judgment against FDA requiring FDA to relax restrictions on dissemination of information about off

label uses of drugs, and in fact FDA has had a pretty solid record of losing virtually all of its First Amendment cases in recent years.

I think it's that record that has caused FDA to recognize that it does have to rethink what it does in terms of imposing regulations in this area, so unlike Dr. Lurie, I'm not looking for increased enforcement in the area. Rather, I would hope that -- I think the increased recognition at FDA of the important of free speech is something that continues.

Now, I was going to spend a good portion of my remarks talking about the efficacy of advertising and how it does really make a difference. I think everybody here is pretty much in agreement on that point. Dr. Findlay is maybe not 100 percent convinced, but most people here seem to think it makes a real difference.

Rather, the disagreement perhaps that we have most strongly is whether or not it's a bad thing that people have to end up paying for advertising. Dr. Lurie says that the consumer ends up paying, and I guess that's not surprising.

I think we are in agreement that if you have advertising, it's because you think you ultimately can make it up in increased sales later on. Manufacturers are not in the business of giving away free information

about their products. Rather they really think they have something to gain.

And I believe what we are seeing now in terms of some increased opposition to direct to consumer advertising is primarily driven by this cost factor, that many states, the national government, many HMOs are very concerned about rising health care costs, and they really don't have any concern whatsoever about the fairness and balance of ads. They don't really think there are consumers who are dying as a result of improper misleading information that they've gotten from ads.

Rather, their concern is that health costs are being driven up, and you see, therefore, legislation in Congress, for example, to try to get rid of the tax deductibility of advertising expenditures, and they're obviously aimed at trying to cut down on speech, and frankly I haven't seen a single proposal of this type that would pass a First Amendment challenge.

In fact at the end of this week, I think most of the organizations represented here will be filing comments with FDA. We will certainly be doing so, and I think that you will see a good number of the comments suggesting that there are serious First Amendment concerns if what we think ought to be done is cut back

on advertising because of the fear that it leads to increased costs.

Now, it's not inevitable that you'll have overall increased costs because of advertising, and the fact that you do suggests that advertising is fulfilling a real need, that people are seeing ads on T.V. and are realizing that there is a product out there that, for example, can treat their allergies without causing them to be drowsy while they're at work, and that's a significant contribution.

You see a lot of ads for Claritin and similar products, and what you don't see is the product saying, We're just as good as Claritin but we cost 30 percent less, and the reason you don't see it is essentially FDA bans that kind of comparative advertising.

Unlike FTC which just simply requires that you have some substantiation for what you claim in your advertising, FDA requires that you have done two well controlled studies, which are the sorts of studies that are required to get your product approved in the first place.

So to make a comparative claim, to say that your product is better than the other person's product or to say that your product is just as good but you're charging less, so therefore people should buy your

product requires the kind of studies that simply aren't going to get done.

So we don't have comparative advertising, and so to the extent that advertising doesn't lead to competition in decreased costs, in part that is a problem caused by the kinds of FDA restrictions you have now on comparative claims.

Now, a concern that is raised from time to time is that ads are not properly balanced, and pretty much balance is the only complaint you hear because I don't think anybody can seriously claim that ads that you are hearing now are really false and misleading, but FDA, for example, has complained that the ad is somewhat unbalanced because it shows somebody who has used a product who's out riding a bicycle and perhaps somebody who is suffering seriously from arthritis wouldn't be riding a bicycle.

So we really ought to be cutting back on advertising of that sort. In fact, these kinds of imbalanced claims are primarily the claims of people who don't like the advertising in the first place.

Now, one of the chief features of direct to consumer advertising is a lot of it tends to be prescription advertising, which means that, of course, you cannot get the product unless you get a doctor to

generic equivalents.

The fact is that the price of the pioneer drugs will drop precipitously and the share of the market drops precipitously despite the lack of advertising for any generic drugs.

Finally, I just want to say that people want the drugs that are out there because they work, because there are conditions being served by the drugs that are available, and Dr. Calfee is 100 percent right. Every survey shows that direct to consumer advertising is increasing public awareness of the availability of drugs, and we ought to be very thankful that that direct to consumer advertising has now gone up to 2.7 billion dollars a year, and hopefully we'll have more of it in the future. Thank you.

(Applause.)

MR. PAHL: We have a few moments, ten minutes or so, before the end of our time, and I guess what I would like to do at this time is pose a question or two to the panel, and I'll probably pose it to a particular panel member, but after that person has responded, the other

didn't do what the manufacturers had hoped, and as I recall the latest data show that the spending in 2001 was not a whole lot more than it was in 2000.

I don't know what it is so far this year, but the last I heard it was definitely not sky rocketing. I don't know what the numbers are for 2002. So I think that the implication of your question is right.

It is still a fairly small factor in this market. Whether it will become a large factor I think really remains to be seen.

MR. FINDLAY: I substantially agree with that, although I use an example to show how DTC advertising can really drive some markets in some therapeutic categories, and it's already been referenced Claritin, Allegra and Zyrtec, the three oral antihistamine drugs, they comprise over 90 percent of that market. It's a huge market. Those are widely, widely available drugs.

Millions of people suffer from allergies, and DTC advertising I think with those three drugs has had a profound impact on the market, driven sales and use up significantly. I think just everyone agrees with that.

Now to your question of competition, the three of them are advertising quite widely, although it's been sort of up and down since '98. Some of them one year spent 150 million and down to 70 million the next year,

et cetera.

I think there is competition between those three and DTC.

MR. CALFEE: It's going to be over the counter advertising for Claritin.

MR. FINDLAY: That's right, will become over in December. I think that's an example of how DTC advertising can enhance competition. Those three were really neck and neck with each other, although Claritin had the bulk of the market.

MR. LURIE: Well, that's certainly true. These are drugs of no great repute really. They're not any great innovation in medical care in this country, either first because the disease is not life threatening at all. Secondly, because there are lots of quite effective drugs that are being generic for many years that could have been used.

I think the other area of course is in non steroid anti-inflammatory drugs where there's been enormous promotion of Cox two inhibitors, explicit or implicit claims of superiority over the Cox one inhibitors, and a drive to the use of Cox two inhibitors where it really simply isn't justified, and that has clearly driven the market and the price of health care up.

MR. PAHL: This question I also would like to pose to Dr. Findlay to start, and it relates to one of the ideas you had for something the FTC should study, and that's: Do manufacturers of branded prescription drugs which are about to go off patent and face competition from generic drugs -- do they use DTC advertising to try to maintain their market position, and if they do, is that advertising characterized by false or misleading claims?

In effect is it true advertising that's intended to maintain the market position, or are you seeing false and deceptive advertising that's being used to try to maintain market position?

MR. FINDLAY: What we're seeing, is it was alluded to in the panel earlier today, the tactic is really not to -- once your brand drug is about to go off

advertised drug, but Nexium will certainly be one or two most advertised drug in 2002, and those are both follow up drugs to ones that dropped off patent or about to drop off patent.

So that's the strategy of the pharmaceutical industry.

MR. PAHL: Have you seen anything in the ads that looks like they're false or misleading or do the claims appear to be true and substantiated?

MR. FINDLAY: I'm not an expert on the content of these ads. I sort of have a personal view on that like we all do. I find the ads to be quite good, and I find them to be relatively fair and balanced, not enough side effect information for me in some of them, but I'm not an expert on the content.

I don't think that they're -- I would say they're not terribly misleading, either of those.

MR. CALFEE: Tom, could I add something.

MR. PAHL: Sure, definitely.

MR. CALFEE: A couple of things. One these follow on drugs typically have a broader indication than the ones they're replacing because they've done research to get more on the label so the advertising tends to emphasize that.

The other thing is that it remains to be seen

whether this strategy is going to work. I mean, right now Nexium and Clarinex and so on, they're not facing generic yet. They're not facing over the counter versions yet.

The only recent case I'm familiar with where a little bit of this has happened is with a development by Eli Lilly of once a week Prozac, but Prozac has gone generic. The managed care firms converted physicians to generic Prozac very, very quickly as we saw in the last session, and once a week Prozac, which is actually a fairly significant innovation, that's a valuable drug for a lot of people and it has done terrible in the marketplace.

Lilly is hardly selling anyone on once a week Prozac. It remains to be seen whether in Clarinex, et al., will do well when they have their real battle which is the battle against the PBMs that are converting people to generics.

MR. LURIE: I would dare say you're somewhat a victim of the direct to consumer advertising because Prozac isn't that great a drug. The data don't substantiate that.

MR. CALFEE: No, I'm comparing it to the older Prozac.

MR. LURIE: I see. It's the new one that's

opportunity for the last word, if they would like one.

MR. FINDLAY: I'll respond to Peter making a point, that I agree that the basic phenomena here is some of the drugs that are going to -- only about a hundred drugs that are advertised to consumers, a hundred per year, not the same hundred.

It was 92 in '98, '99. It went up to 105. It's about 103 now, so it's a relatively small number of drugs. Are all of those drugs going to be great clinical breakthroughs and represent real effectiveness for patients over previous drugs or other drugs that are not being advertised? No.

Are some of them going to be, in fact, better drugs from which the public can benefit from knowing about them? Yes. So I think it's a mixed bag.

MR. PAHL: Okay. Thank you very much for your helpful comments.

MR. HYMAN: All right. A couple of announcements. First as people are leaving, if they brought stuff in with them, if they can just sort of insure that there's no net gain of stuff in the room, I would appreciate it because we end up cleaning it up after you all leave.

Second, let me remind people that the deadline for comment and response to the Federal Register notice

is September the 30th, so if you have the desire to submit written comments for the record, by all means feel free.

Let me introduce our last speaker at the end of what has been an interesting and provocative two day workshop. I also want to thank everyone for coming, and thank all of the people on the Commission who helped to make this workshop possible, and the people that aren't on the Commission including speakers and panelists and moderators and our partners in the various enforcement agencies.

Now it's time to introduce our last speaker for this two day workshop, Tim Greaney, professor of law and co-director of the Center of Health Law Studies at St. Louis University.

One of the things you see prevailing in employment markets is that compensation is back loaded for all sorts of good incentive reasons, to encourage people to stay around and motivate optimal performance. The family version of that is spinach first, dessert later. With this in mind, I picked Tim Greaney to give our closing remarks.

Tim has written a number of insightful and provocative papers on antitrust, one several years ago on hospital mergers which appeared in the American

Journal of Law and Medicines called Night Landings on an Aircraft Carrier, and the paper, Whither Antitrust, that will form the foundation for his remarks today, which appeared in Health Affairs several months ago. He'll take it from here.

MR. GREANEY: Well, thanks to David and to the FTC for really stimulating a couple of days. It's been a great program. I think this is what the FTC is all about is bringing together people and developing a base to operate from, and it's really a credit to David and the staff who have done all this, and to this brave stenographer who's handled two days worth, thank you very much.

Let me make a couple remarks. First of all, I give you a personal disclosure about my personal health history. I have a genetic defect. I'm a life long Red Sox fan, and that makes me constitutionally incapable for me to see the glass as half full, and I'm afraid I'll have some gloomy assessments about antitrust enforcement, and I offer that by way of excuse.

My normative perspective though is, I won't repeat it, I'll just incorporate by reference what Bill Kovacic said earlier, one of our really outstanding law professors in the area and someone who knows what he's talking about, when he says health care antitrust

enforcement has been the FTC's crowning achievement, I agree with that completely. I think it's a feather in the cap of what the FTC has done.

There are countless economic studies I think

what antitrust can do about it.

Let me first deal with probable claims for antitrust relief, relief from antitrust law. It's something that is not new. I think it's something that has occurred in every era of antitrust. In the late 70s and early 80s when antitrust in health care was just beginning, we heard claims that it was needed. You needed special exemptions, et cetera, to preserve professional sovereignty, to preserve the supremity of state and federal regulation.

In the 1980s the ground shifted a little and we heard that there was legislation regulation needed so PPOs could form. Maricopa was said to be blocking PPOs.

They produced the FTC/DOJ policy statements. They also helped contribute to state hospital cooperation laws, state laws regulating managed care, physician collective bargaining laws more recently.

How do we appraise those results? Well, I've given them grades. I give the Health Care Quality Improvement Act a B, policy statements A minus, cooperation laws C minus, managed care laws C plus, and the collective bargaining laws an F.

I'm a pretty easier grader as it turns out. I'm going to do what law professors don't do which is tell you why they give the grades. We're sort of a black box. We don't have to disclose what we're grading on, and here's my grading key, and really it's one of the best articles I can commend to you. It's actually a chapter in a book soon to be published by Peter Hammer called Medical Antitrust Reform, Arrow, Coase, and the changing structure of the firm.

He says we have to change the competitive norm against whether it is doing something that promotes consumer benefit, promotes consumer welfare, by ameliorating some kind of market failure, and is it well designed to advance social welfare.

I'm not going to have to go into why I think one does and one doesn't, but I think you can see there's

really questions about whether some of these state laws are really addressing a real problem, what the market failure, their design it at best ambiguous, and the remedy is certainly not designed to correct a market response.

Anyway, that's my norm. Those are my grades and I'm sticking with them, but I'll talk more about the policy statements because I think they are a major development and something that needs to be talked about.

Let's start with some success stories about antitrust. I have a picture here of someone -- I didn't bring my seating chart. I should call on someone. Anybody who knows who that is? It's not the poster guy for diet in a bottle. You might have thought that.

That's former Judge Taft who wrote Addyston Pipe, one of the great decisions in antitrust history, and I thought that would be a good frame for our success stories.

The success stories I think, and I'm going to go very quickly through them because I want to dwell on the negative, the policy statements really have contributed to understanding advanced knowledge, spread the word outside of the Beltway and I think improved the functioning of the legal advising system which is really what we're about here. We're about improving lawyers'

ability to advise clients.

Antitrust has done a great job in weeding out the chaff. Don't forget it has dealt with those hundreds and hundreds of staff privileges cases, which I share with Peter, probably the only one in the room that's read all of them. I read them for writing my treatise. They're spurious, and antitrust, there's been four successful cases in those hundreds of cases, encouraging integration, promoting means by which firms can integrate, a need to do it, curbing cartel activity. I think the FTC in particular, its activities its repeated cases in this area really are an important contribution.

I think the pharmaceutical industry, things we've been talking about, are exactly what this agency is supposed to be doing. If we want to apply the merger guidelines phrase, timely, likely and sufficient, that's the kind of enforcement I think you want. It was timely. It was likely to improve competition, and it was an important step forward.

Finally I'll just say the staff here is really something to be proud of and something that has really improved the way things work.

Well, what have we heard the last couple days? I think we've heard a little bit of the murder on the

Orient Express here. We've heard the blame being pushed around as to who's responsible for competition's failure to curb costs in health care, and we've had sort of the physicians, the hospitals and managed care pointing to each other, Don't sue me, sue the guy behind the tree.

We've heard them talking about whose concentration, whose activities have spurred the spike in health care costs.

Let me offer some other places where we can look, not that they are not to blame in some sense. I mean, there is higher pricing of people who have either acted through cartelizing or in response to natural forces of their increased market concentration, but let me mention some problems we have.

We have a problem with respect to the concentration spike because of problems of detecting mergers, joint ventures, detecting cartels. If I want to leave a message today, I think the lack of litigation is a big problem. It is a big problem.

I know lawyers are not supposed to complain about the lack of litigation, but my tag line here is that advice, policy statements, speeches, advisory opinions, et cetera, have a diminishing shelf life if it is that not backed up by litigation. I think the policy statements are a great achievement, but I think not backed up by litigation you can see their weakening

that extent, and the piece I'm working on now really talks a little about or friends from Cook County, Illinois, the Chicago school, and what they're teaching has done to infiltrate thinking, and I'm afraid in the health care area, adhering slavishly to the Chicago template is a mistake that the courts are making, and I think given market failures and other things, we have those problems.

In any event, the other bad news is antitrust has very little to say about some of the key areas that are affected now. Oligopoly for one, antitrust has almost nothing anything to do with oligopoly and monopsony has its own problems.

journal, St. Louis Law Journal, but it's a piece he wrote on the MedSouth decision, the MedSouth advisory.

He really does talk, I think, in very good terms about the problems we have with the Rule of Reason and the problems of what he calls an on off switch. It's either Per Se Rule and illegal or Rule of Reason and legal, the old defendant's paradise argument, and I guess this blurring of the standard is the problem we have, that Judge Easterbrook captured it well when he said, "When everything is relevant nothing is dispositive."

Okay. Well I don't want to leave out the private bar, and this brings me back to my message, How effectively are policy statements conveying what the boundaries of the law are? Is there a mentality out there that any merger is worth trying? We have almost negotiated rulemaking now. That turns into negotiated conduct. I'm all for advisory opinions and policy statements, but I think we need to go further.

You can look at this. I was asked to predict the future, and I've tried to list some of the areas where we see cases developing now. I'm working on a new edition of my case book, so I have to collect as many cases as I can.

But clearly we have provider cases, hospital

physician disputes. With concentrated markets we have exclusive contracting problems that really do fit the model of what is problematic. We have hospitals with significant market power engaging in exclusive contracting in areas where there is legitimate foreclosure in physician markets.

We see that in other areas, so I won't go through the litany of possible combinations there are out there, except to say there are cases that at least on their face really do make some economic sense, but I'm not sure private parties are sufficiently incented to bring them in all cases.

Where do we go? Can I cut the Gordian knot? Well, no, as I used to say when I worked for the Antitrust Division, that's beyond my pay grade, but I'll throw out a few ideas, a few thoughts here.

My bottom line which I signaled earlier was that policy statements, et cetera, are good but if they become advisories, if they become -- if everything is negotiable, I'm not sure that a message is sent that will really revitalize antitrust.

So I think the FTC has got to get involved as it has in the past in Amicus filing in trying to get the private cases that are meritorious, more successful. Again I'm an alumnus of the Antitrust Division, but I do

believe there is a law enforcement role to be played.

I have to say I've been hearing about criminal enforcement for many years since I left the division, and I'm still waiting to see it. I look at some of these physician cartels at least as described in some of the releases, and I'm wondering: "Where are the criminal referrals, where are the referrals to Justice for criminal prosecution?"

Some of these cartel activities are not all together different than some of the international cartels that the division prosecutes, and in some cases it certainly is appropriate to send a message, and if you want to change the nature of advising between lawyer and client, I think that is a way to do it.

In today's environment where we hear that the people at WorldCom and elsewhere are to be prosecuted to the fullest, I think people who knowingly and intentionally violate the law at significant costs to consumers should be prosecuted criminally.

Are there other avenues? I think the states have a role to play. I think the states really have their hand on the pulse of their local markets. They're perfectly situated to do it. A lot of states are increasing their staffs, but I think they need some help from somebody, and I know there have been cooperative

cases filed.

In the Whither antitrust piece in Health Affairs, I suggest the outrageous, that maybe even regulatory reviews by state agencies, maybe a second best alternative to litigation, since litigation is expensive and hard to come by. Maybe regulatory mechanisms like the State of California has for its non profit mergers is appropriate, returning to my theme that policy statements have some advantage, but guidelines I think are -- we may have reached the point where they are necessary.

There is a vast and increasing economic literature that's growing out there that might help inform thinking in these areas. There's a lot being written on market definition and integration that might be of help and also moving towards more targeted research. Final point -- supporting targeted research here that will help inform both courts and legislatures.

We have a problem of lag. Something gets written, but it takes years to turn into decisions in the Federal Courts.

Finally I have a note that there is a -- I think the rationalization of industries makes very good sense, and the FTC taking the lead in health care is a very, very good idea, but there is a concern with

jurisdiction.

70 percent of the hospitals are not for profit. Much of what they do will be out of FTC's jurisdiction, and somebody's got to watch that. Criminal enforcement is the Justice Department's responsibility. I hope those holes will be well plugged. I have a concern given frankly the Antitrust Division's history.

Well, at the end, I give you some reading to do, part shamelessly advertising my own reading, and Peter Hammer's article I mentioned is an outstanding piece, and once again Commissioner Leary has really put together one of the most thoughtful pieces I've read. I'm sure he would be willing to share it with you, even though we haven't published it. Yet we don't make any money on our law journal, so I'm happy for you to get it directly from him.

It really does deal with some of the key problems of assessing conduct in the health care industry, trying to appraise the influence of quality when you make the assessment of net competitive effects, and it really is an excellent, excellent article.

Thank you for your attention, and, David, thank you for a wonderful conference. It was a well conceived, well executed conference.

(Time noted: 5:23.)