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ON HEALTH CARE AND COMPETITION LAW AND POLICY

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I N D E X

NOERR-PENNINGTON/STATE ACTION

LONG-TERM CARE/ASSISTED LIVING FACILITIES

**P R O C E E D I N G S**

MR. HYMAN: I'm going to ask everybody to take their seats. My name is David Hyman. I'm special counsel here at the Federal Trade Commission. I'd like to welcome everyone to the latest in our ongoing set of hearings on health care and competition policy, jointly sponsored by the Federal Trade Commission and the Department of Justice. Seated to my right is David Kelly, representing the Department of Justice. And he'll have a few remarks in a moment.

I would like to start by acknowledging the hard work of other people at the Federal Trade Commission and Department of Justice that have made this set of hearings possible, including Sarah Mathias and Cecile Kohrs, as well as Kanithia Felder, Bruce Jennings, Barri Hutchins, and a variety of other people who make it possible for us to put these things on.

We have a very distinguished panel for you today, so distinguished that their introductions would take up most of the time that we have allotted. And instead of doing that, we've bound their one-page bios into this handsomely appointed book, available on the tables outside at no charge.

And so our rule here is one-sentence introductions for people, which we'll do all at the

outset, and then sort of individuals will speak from the podium, and then at the very end we will convene the panel up front to have a moderated roundtable discussion, moderated by myself and David Kelly.

The order in which people will be speaking is left to right as the audience sees it, and in the order in which I'm about to introduce them.

John Delacourt, our first speaker, is assistant director of the Federal Trade Commission's Office of Policy Planning. That is one of several research into policy R&D shops, as we call them around here. And John has been working hard on the issues that we're going to be discussing today, state action and Noerr-Pennington, in connection with his position at the OPP, as we call it, the Office of Policy Planning.

The second speaker, participating by the miracles of telecommunications, is Professor Clark Havighurst, a professor of law at Duke University Law School, who has spent much of his extended career focusing on health care and regulatory antitrust issues.

The next speaker is Meredyth Smith Andrus, who's an Assistant Attorney General in Maryland working in antitrust enforcement, primarily in health care.

Following, depending on scheduling, availability, the next speaker will probably be

Dr. Kenneth Kizer, who is the president and CEO of the National Quality Forum, which works on setting standards for measuring and reporting health care performance data. Dr. Kizer is not going to be speaking about state action and Noerr-Pennington, but the larger set of hearings relates to quality and consumer information, and this simply happened to coincide with his scheduling and availability.

Then Dr. Brenda Lyon will speak. She's a member of the National Association of Clinical Nurse Specialists and a professor at the Indiana University School of Nursing.

And then finally, Dr. Mark McClure, a dentist at National Integrative Health Associates, with offices in Maryland and the District of Columbia.

And rather than hear me continue to talk, let me turn things over to David Kelly, and then we can get started with John Delacourt's reaction.

MR. KELLY: I just want to welcome everybody this morning and thank you for your attendance here at these hearings.

Before we get under way, I'd just like to give a brief recognition to a couple of my colleagues who were an extraordinary assistance in the working group getting this together: Bill Berlin and Julia Knoblauch in my

office, and Ed Eliasberg from the Office of Legal Policy, and Leslie Overton from the front office. Those folks were great contributors to getting these hearings together. And again, on behalf of the Department of Justice, I welcome you all. Thank you.

MR. HYMAN: Okay. Now, John? John will be showing us one of our several PowerPoint presentations for today.

MR. DELACOURT: Thanks. Thanks very much for that introduction, both Davids. Thank you. I appreciate that.

My role this morning will be to discuss the work of the two FTC task forces on antitrust immunities, and those are focusing on both state action and Noerr-Pennington issues. Before I start, though, I will offer the usual disclaimer, which is that the views expressed in my presentation this morning are my own views. They do not necessarily reflect those of the FTC or any individual Commissioner.

And with that, I suppose I'll start at the beginning by offering a few words about the origin of the two task forces. And I guess we've got PowerPoint on one screen, anyways.

MR. HYMAN: The miracles of modern technology don't always do what they're supposed to.

MR. DELACOURT: There we go. Perfect.

Chairman Muris' arrival at the FTC in 2001 brought a renewed focus on both state action and Noerr-Pennington immunity. Although both doctrines are intended to prevent the economic objectives of the antitrust laws from encroaching on the political arena, they are also intended to achieve a rational balance.

Expansive interpretations of the doctrines by some courts have raised concerns that this balance has been upset. Although both the state action and Noerr-Pennington doctrines protect important political rights, expanding the scope of the doctrines is not necessarily an unambiguous good.

After a certain point, incremental increases in the scope of immunity no longer offer any meaningful additional protection of political conduct. At that point, the doctrines merely immunize additional anticompetitive conduct without offering any countervailing benefit.

In order to address these concerns on a systematic basis, the Chairman assembled two task forces of FTC staff in the Summer of 2001. Both the state action and Noerr-Pennington task forces have endeavored to address immunity issues through law enforcement actions, amicus briefs, and competition advocacy, and

continue to do so today.

So I will begin with the work of the state action task force. The state action doctrine was first articulated by the Supreme Court in Parker v. Brown. The Parker case is rooted in federalism, and holds that in passing the Sherman Act, Congress intended to protect competition, not to limit the sovereign regulatory power of the states. Therefore, the court held, regulatory conduct that could be attributed to the state itself is immunized from antitrust scrutiny.

This rule seems clear enough at first, but becomes substantially less clear when applied to delegations of state authority to private parties. It is clear, for example, that the Sherman Act was not intended to reach the conduct of a state legislature. It is less clear that it was not intended to reach, for example, the conduct of a state board of professional licensure, which may be dominated by market participants with a vested financial interest in particular regulatory outcomes.

The Supreme Court provided some guidance on this issue with its 1980 opinion in Midcal. The Midcal case sets forth two important limitations on the scope of state action immunity, both of which are intended to ensure that the conduct at issue is truly that of the state itself.

First, the proponent of immunity must demonstrate that the conduct in question was in conformity with a clearly articulated state policy. And second, the proponent must demonstrate that the state engaged in active supervision of the conduct.

So with that background, I will now turn to some of the problems associated with the doctrine. Since Parker, the scope of the state action doctrine has increased considerably. Among other possible explanations, the work of the state action task force suggests that steady erosion of existing limitations on the doctrine has been a contributing factor.

A review of recent state action case law suggests that some courts have substantially expanded the doctrine through interpretations of Midcal that weaken both the clear articulation and active supervision requirement.

With respect to clear articulation, this trend is best exemplified by the willingness of some courts to infer a state policy of displacing competition from a legislative grant of general corporate powers. States will often empower subsidiary regulatory authorities to enter into contracts, to make acquisitions, and to enter into joint ventures.

Although it is clear that the exercise of such

powers merit no special antitrust treatment in the private sector, some courts have reached the opposite conclusion when the powers are granted through legislation. Thus, courts have concluded that exclusive contracts are the foreseeable result of the general power to contract, and other courts have concluded that the exclusion of competitors is the foreseeable result of the general power to make acquisitions.

With respect to active supervision, the problem has not been sins of commission so much as sins of omission. Because of a lack of guidance as to what this factor actually requires, it has not functioned as a significant limitation on grants of immunity.

In Midcal, for example, the court held that the state must engage in a pointed reexamination of regulatory conduct. In Patrick v. Burget, the court clarified that a state is required to exercise ultimate control. And most recently in Ticor Title, the court noted that a state must exercise independent judgment and control.

Without guidance on how to implement these various verbal formulations in terms of actual state regulatory procedures, the active supervision requirement has continued to have a minimal impact. So those are some of the problems with the current doctrine. And I

will now turn to some of the potential solutions that the task force has been exploring.

State action task force is currently considering a number of possible approaches, and some of the most promising are those that are outlined on this slide.

First, clarify the proper interpretation of the clear articulation requirement. The goal here would be to ensure that the state truly intended to displace competition by authorizing the anticompetitive conduct at issue.

Second, elaborate clear standards for the active supervision requirement. This will ensure that the requirement has teeth, and will prevent private entities from restraining competition free from meaningful government oversight.

Third, advocate a tiered approach to govern the application of the clear articulation and active supervision requirements. The goal here would be to ensure that these tests are applied most strictly where the threat to competition and consumer welfare is greatest, and less strictly when the threat is less severe.

And finally, consider explicit recognition of a market participant exception to state action immunity.

This approach would be rooted in the Supreme Court statement in Omni Outdoor Advertising that immunity does not necessarily obtain when the state acts not in a regulatory capacity but as a commercial participant in a given market.

So having focused a bit on some of the things that the task force would like to do, I will now move on to some of the things that the FTC has actually done in the state action area. And I'll focus this morning particularly on the recent activities in the health care area.

I should begin by noting that in addition to bringing law enforcement actions, the Commission has a long tradition of engaging in competition advocacy. Occasionally, decision-makers at both the federal and state level will request the Commission's views on the likely consumer impact of a particular law or rule. A number of the Commission's most recent competition advocacy efforts have involved potentially anticompetitive state regulation, including regulation in the health care area.

One of the task force's first efforts in this area involved the sale of replacement contact lenses. Early last year, the Connecticut Board of Examiners for Opticians opened a proceeding to determine whether

various categories of contact lens sellers should be required to obtain a license before selling to Connecticut consumers. Although the issues raised by the proceeding were broader, FTC staff limited their participation to the issue of whether such a requirement would actually benefit consumers.

In March 2002, staff filed an activity comment with the board. The comment reviewed current federal and state prescription requirements, and concluded that they were sufficient to address any potential health concerns.

The comment further noted that enacting additional requirements would raise prices, reduce consumer convenience, and potentially endanger consumer health as consumers would be inclined to replace their lenses less frequently than recommended. Finally, the comment noted that unnecessary regulatory hurdles could serve as a significant barrier to the expansion of e-commerce in the State of Connecticut.

Because the board is still deliberating and has not yet enacted, much less attempted to enforce, any particular rule, this matter has not yet blossomed into a full-fledged state action case. The same is true of a second competition advocacy matter, although it nevertheless managed to raise an interesting active supervision issue.

This second matter involves state legislation rather than a board rule. Over the past two years, three states -- Alaska, Washington, and Ohio -- have requested the FTC's views on legislation that would create an antitrust exemption for physician collective bargaining with health plans.

In each instance, Commission staff filed a comment asserting that the proposed legislation was likely to harm consumers, as it was likely to raise prices without necessarily improving the quality of care.

Each of the state officials requesting the FTC's views, however, also inquired as to whether physicians acting in conformity with the legislation, that is, physicians engaging in price-fixing, would potentially be subject to antitrust liability.

On this issue, the staff comments uniformly asserted that the key issue is one of active supervision. If the physicians could demonstrate that they were being actively supervised by the state, their conduct would be immunized. However, the staff comments also conveyed the concern of the state action task force that the exact requirements of active supervision had not yet been defined with sufficient clarify.

The Commission subsequently returned to the issue of active supervision and attempted to address this

continuing lack of clear standards in its most recent state action effort, which, if you all will indulge me, is a non-health care matter but it does address the active supervision issue, and that is the Indiana Movers case.

The Indiana Movers case involved conduct by Indiana Household Movers and Warehousemen, Inc., an association representing approximately 70 household goods movers. One of the association's primary functions is to prepare and file tariffs on behalf of its members with the Indiana Department of Revenue.

According to the Commission's complaint, however, the association exceeded its role as a mere tariff-filing agent. The complaint alleges that the association actively engaged in the establishment of collective rates to be charged by competing movers. It further alleges that the association coordinated meetings between its members for the purpose of establishing uniform rates.

Although the case was resolved by consent order, thereby obviating the need to litigate the state action issue, the Commission nevertheless took the opportunity to advance one of the proposals being considered by the state action task force. Specifically, in the analysis to aid public comment that accompanied

the proposed consent order, the Commission endeavored to elaborate clear standards for the active supervision requirement. As the analysis states, the elements the Commission will look to in future cases to determine whether the active supervision requirement has been satisfied will include those that are elaborated on this slide.

So that would be, first, the development of an adequate factual record, including notice and an opportunity to be heard; second, a written decision on the merits; and third, a specific assessment, both qualitative and quantitative, of how private action comports with the substantive standards established by the state legislature. The analysis further clarifies that the third factor -- that is, this assessment of qualitative and quantitative compliance with state policy -- is not an attempt to impose federal standards on state decision-making. Compliance with the state policy, whatever it may be, remains the benchmark. However, if the state policy expressly encompasses protecting competition or protecting consumer welfare or similar criteria, the Commission will look for something resembling an antitrust review.

So I believe with that, I've covered the waterfront with respect to state action, and I will now

turn for a moment to the activities of the Commission's Noerr-Pennington task force.

Unlike the state action doctrine, which applies to delegations of government authority, the Noerr-Pennington doctrine shields a limited range of private conduct from antitrust scrutiny.

The doctrine was first articulated in a pair of Supreme Court cases, holding that a party's genuine efforts to petition government are immune from antitrust liability. The Noerr case involved efforts to petition a legislature, while Pennington involved efforts to petition the executive branch. The doctrine was subsequently extended to efforts to petition government through administrative and judicial proceedings as well, including the filing of lawsuits.

Like the state action doctrine, the goal of the Noerr doctrine has always been to prevent antitrust enforcement from halting or even chilling legitimate political conduct. As interpreted by some courts, however, the expanded doctrine shields from the antitrust laws conduct that, by reason of misrepresentation, fraud, or simple government non-involvement, has no political content whatsoever.

So I will now once again spend a moment on some of the problems with the doctrine as it's currently

articulated. The task force's review of recent Noerr case law suggests that the expanding scope of Noerr immunity has a familiar cause. While certainly not the sole cause, as in the state action context, the erosion of existing limitations on the doctrine appears to be a significant contributing factor.

The first of these limitations in the definition of petitioning itself. This definition, the first and most fundamental limitation on the scope of Noerr immunity, has in many instances been pushed to its limits.

In Coastal States Marketing, for example, the Fifth Circuit held that mere threats of litigation, whether directed to specific parties or published generally, constituted immunizable petitioning. These were communications that entailed no government involvement whatsoever.

While other courts have retreated from the view that immunized petitioning may entail no government involvement at all, they have yet to specify the precise level of involvement that is required.

Some litigants have suggested that in order to qualify as petitioning, pre-litigation conduct must be a proximate prologue to actual or imminent litigation. Others have suggested that it must be indispensable to

litigation. To date, however, no court has adopted either rule or proposed an alternative formulation. As a result, the category of conduct immunizable as incidental to litigation continues to grow.

While the definition of petitioning continues to grow, the other key limitation on the scope of Noerr immunity, the sham exception, continues to shrink. The sham exception, which was first articulated in the Noerr case itself, was most recently revisited by the Supreme Court in Professional Real Estate Investors. The PRE court set forth the well-known two-pronged test for sham petitioning. First, a party must demonstrate that the petitioning effort is objectively baseless. If this objective prong is satisfied, the party must then satisfy a second subjective prong by demonstrating that the petitioning effort reveals an intent to use the governmental process, as opposed to the outcome of that process, as an anticompetitive weapon.

Due to some courts' extremely restrictive interpretations of the first prong, that is, the objectively baseless prong, the sham exception has increasingly been limited to a single step.

The Eighth Circuit, in Porous Media Corp., for example, has held that mere denial of a defendant's summary judgment request conclusively demonstrates that a

petition is not objectively baseless and precludes the possibility of sham. In practice, PRE's first prong has almost always proven insurmountable for a single petition.

So again, with those problems with the doctrine as the background, I will now turn to some of the approaches for clarifying the doctrine and improving its functioning that the task force has been exploring. Like the state action task force, the Noerr task force is currently examining the feasibility of promoting certain developments in the law. To date, these efforts have focused primarily, though not exclusively, on clarifying the validity and scope of various non-sham exceptions to the Noerr doctrine. Some of the most promising are outlined on this slide.

The first would be to apply a more restrictive view of the varieties of conduct that constitute immunized petitioning. This would involve looking to cases concerning tariff filings and private settlements, and applying the definitions of petitioning developed in those situations to broader contexts.

Second, apply the Walker Process exception to Noerr beyond the patent prosecution context. In Walker Process, the Supreme Court created a Noerr exception that was broader than the traditional sham exception. The

Court's decision was based in part on the fact that the Patent and Trademark Office has limited information-gathering capabilities and consequently relies heavily on the accuracy of parties' representations. Applying Walker Process in other contexts simply recognizes that these limitations on information-gathering capacity are not unique to the PTO.

Third, advocate full recognition of an independent, material misrepresentation exception to Noerr. The goal here would be to confirm the continuing existence of a misrepresentation exception, separate and distinct from the two-pronged sham analysis set forth in PRE.

And finally, clarify the parameters of a pattern or repetitive petitioning exception to Noerr. Pursuant to this approach, the Noerr exception would be rooted not in the objective baselessness of a single petition, but rather in a pattern of repetitive petitioning without regard to the merits of individual claims.

Well, for better or for worse, since the formation of the two task forces, the FTC's docket has involved many more cases involving Noerr issues than state action issues. And as a result, the Commission has had many more opportunities to advance the objectives

that were outlined by the Noerr task force. And so the task force, in conjunction with the Commission's litigation staff, has had some degree of success in doing this.

Today, the Noerr-Pennington issues raised by the Commission's actions have tended to arise most frequently in the context of Food and Drug Administration approvals for the marketing and sale of generic drugs. In particular, the Commission has been involved in a number of cases addressing anticompetitive gaming of the Hatch-Waxman regulatory framework.

Because the operation of Hatch-Waxman is substantially complicated, I won't attempt to describe it in detail today. But I will note that -- two aspects of it. First, the Act requires innovator drug companies to list certain patents in the FDA's Orange Book, and the consequence of this is that the listed patent can then be used to trigger an automatic stay of FDA approval, which can bar a competing generic product from the market for up to 30 months. So this was the backdrop for the Noerr task force's most successful effort to date, which was the FTC's amicus participation in the In Re Buspirone case.

The Buspirone case involved allegations that an innovator company, in this case Bristol Myers Squibb, had

foreclosed generic competition with its branded drug, BuSpar, by knowingly listing in the Orange Book a patent that did not satisfy the statutory listing criteria.

BMS argued that its communication with the FDA was petitioning and therefore protected by Noerr. In response the Commission filed its amicus brief that asserted that Orange Book filings are purely ministerial and involve no exercise of governmental discretion. The court agreed, holding that Orange Book filings are analogous to tariff filings and simply do not constitute petitioning.

The court then advanced a second objective of the task force by holding that even if Orange Book filings did constitute petitioning, application of the Walker Process exception would nevertheless preclude a finding of immunity in this particular case. Notably, the Buspirone case, which addressed conduct that was before the FDA, is one of the first to extend Walker process beyond the PTO context. In addition to its amicus participation in the Buspirone case, the Commission recently announced its own independent enforcement action against Bristol Myers. On March 7th, this matter was resolved by consent order. The Commission's action against BMS was substantially more complicated than In Re Buspirone, and encompassed a

variety of anticompetitive conduct with respect to three different drug products: First, the anti-anxiety medication BuSpar, which I had mentioned previously, as well as two anti-cancer medications, Taxol and Platinol.

The Commission alleged a complicated course of conduct, which is set forth on this particular slide, and included the following acts. First, the Commission alleged that during the patent prosecution process, BMS deceived the PTO to receive unwarranted patent protection. Second, that during the new drug approval process, BMS deceived the FDA by listing on the Orange Book patents that did not satisfy the statutory listing criteria. Third, that BMS filed meritless patent infringement actions. And fourth, that BMS entered into inclusive agreements to further delay generic entry.

Because the case was resolved by consent order, the Noerr-Pennington issue was not litigated. However, as in Indiana Movers, the Commission used the analysis to aid public comment that accompanied the proposed order to provide substantial guidance on the immunities issue.

The analysis sets forth independent reasons why each of the four types of conduct alleged against BMS is not subject to Noerr immunity. However, it also states that: "The logic and policy underlying the Supreme Court's decision in California Motor Transport support

the application of a pattern exception and provide a separate reason to reject Noerr immunity in this case."

The analysis further states that "just as repeated filing of lawsuits brought without regard to the merits warrants Noerr immunity, so, too, do the repeated filing of knowing and material misrepresentations with the PTO and the FDA."

So taken together, the Buspirone and BMS cases have encompassed three of the four recommended approaches of the Noerr task force. Although the fourth approach, advocating recognition of an independent misrepresentation exception, has not received much attention it may have a role to play in the Commission's recently filed Unocal case, which again, if you'll indulge me, is a non-health care matter.

The Unocal case is the most recent in a line of FTC cases seeking to impose antitrust liability for so-called patent ambush conduct. Specifically, these cases involve the nondisclosure and subsequent enforcement of intellectual property rights in conjunction with industry-wide standard-setting proceedings.

The allegations against Unocal are thus similar to allegations against Dell, and more recently Rambus, in prior FTC cases. The principal difference is that while Dell and Rambus involve private standard-setting

organizations, Unocal involves a government SSO, the California Air Resources Board. It is consequently likely that Unocal will argue that its conduct is protected by Noerr, and indeed, recently Unocal did assert a Noerr defense.

In addition to presenting an issue of utmost importance to California consumers, the Unocal case presents an opportunity to clarify some fundamental aspects of the Noerr doctrine. As previously mentioned, the facts alleged in the complaint could potentially support application of an independent misrepresentation exception to Noerr. Also, like In Re Buspirone, they could potentially support a non-PTO application of the Walker process exception.

So with that, I believe I have covered the waterfront with respect to Noerr as well, and I believe I've come to the end of my time, so I will turn the program back over to David.

MR. HYMAN: Thank you, John.

Clark, are you there?

MR. HAVIGHURST: Yes, I am.

MR. HYMAN: Okay. Give me a second to get your PowerPoint up.

MR. HAVIGHURST: Okay. Can you hear me well enough?

MR. HYMAN: Yes. Okay.

MR. HAVIGHURST: I appreciate your indulgence in letting me participate in this manner. I realize it's a little more difficult for everyone to hear me and to absorb whatever I might have to say. I suppose if we use PowerPoints and you turn the lights way down, you can pretend that I'm there in person, even if I'm not.

A couple things, just to introduce myself. I spent a year at the FTC in '78-'79 in a capacity somewhat like David Hyman's status this past year. That was, of course, a time when the Commission was just getting its act together in terms of what to do about antitrust violations in the health care sector, and I was privileged to be part of those discussions.

I had earlier in that decade filed an amicus brief in the Goldfarb case, arguing at the stage where the court was considering whether to grant certiorari that this case was really important from the standpoint of the health care industry as well as the legal profession, and that the court ought to hear it on that basis, which, obviously, it did.

So I have a certain proprietary feeling about the whole antitrust enforcement campaign in the health care sector, and David gave me the chance to participate in these hearings at some point, and I decided that state

action immunity was a topic on which I might have something to add.

I had not known at the time, until quite recently, that the staff was preparing a report in this area and would be coming out shortly with some well-considered views on the matter. And so what I can add, I don't know. What I provide here may be a little late in the game from the staff's point of view, and we'll just have to see.

I'm going to talk mostly about state action and not much about Noerr-Pennington, though I have one comment at the end. And these are quite random comments. They come under, I think, ten headings, and if you lose the thread on one, you can probably pick it up on the next one.

These are things that have been -- have struck me about state action immunity over time, and several themes emerge, I think, that may be helpful to the staff and to others in thinking about these extremely interesting questions.

I mean, they are truly fundamental to our federal system and to our whole antitrust and competition policy. And so they are -- I enjoy teaching these matters, and I enjoy thinking about them from time to time, though I've never made this a principal area of

research and writing.

The first slide, I take it, is up. I thought I'd say a few things about the general nature of state action immunity. The key is, and I think the staff report says as much, from Mr. Delacourt's comments, that this is a -- the doctrine flows from an interpretation of the statute.

It is not directly, at least, a result of some constitutional limit on congressional power. Indeed, Congress has the power to regulate interstate commerce and could do so more extensively than the courts have deemed it to have done.

So we have here a statute that is now regarded as limited by an implied intention by Congress not to preclude legitimate state regulatory activity. And that seems to me about right.

Now, the Parker against Brown case and the Eleventh Amendment both say that the state itself is not subject to private suits in federal court for Sherman Act violations. But the doctrine of Parker against Brown is a whole lot broader than the holding in Parker against Brown.

It's always seemed to me that the doctrine of -- state action immunity doctrine potentially immunizes not subordinate state agencies that don't

qualify as the state itself, but even private parties that are exercising powers that the state has somehow conferred.

And that immunity results from reading the statute narrowly so that the general federal policy favorable to competition in the whole economy doesn't override the prerogative of states to carve out specific sectors for regulation under the police powers. And that seems to me a happy outcome, way of resolving this potential conflict.

When you understand the doctrine this way, as an effort by the court to leave room for states to regulate responsibly in the interest of consumers but not irresponsibly by empowering private interests to harm competition and harm consumers, then that supports the view that the stringency of the clear articulation and the active supervision requirement shouldn't -- should vary with the circumstances, and should expressly vary with circumstances, though particularly the circumstances that affect the ability of private interests to harm competition.

So I think of this doctrine as an accommodation between the federal preference for competition and the state's freedom to choose alternative ways to protect consumers. Under the doctrine, it seems to me important

to remember federal policy, federal antitrust policy, still operates to the extent of requiring first that the states take clear responsibility for setting competition aside, and second, that if the state directly or indirectly empowers private interests to restrain trade, then it must provide oversight to preclude abuses of those powers, to protect consumers in a way other than the ways in which competition would protect them. And it seems to me that conceptualization should be kept in mind as we proceed.

The next slide, please. I wanted to comment on the parallels with the McCarran-Ferguson Act, which limits the reach of the Sherman Act in the insurance industry, in the business of insurance, insofar as that business is regulated by a state.

Now, interestingly, the statutory test in McCarran strikes me as being very close to the one that the court subsequently adopted as the general rule to provide for other cases, where a state has substituted regulation for competition.

Because McCarran was enacted well before the Supreme Court devised the Midcal test, it seems to me that the state action doctrine can reach as far as the McCarran doctrine does. In other words, the fact that this McCarran test is embodied in explicit legislation,

there's no reason to read it any more broadly than the state action doctrine is read. So I think of McCarran as a legislative precedent that confirms the court's ascribing to the Congress of an intent not to displace responsible state regulation.

Next slide, please. Comity. Well, in international law, you find the principal of comity dictating deference by one sovereign to the policies and concerns of other sovereigns. And the state action doctrine presumes comparable deference on the part of Congress to the legislative policies of states, and provides some principles for defining the extent of that deference in particular cases.

Interestingly, the Hartford Fire case from 1993 is a case in which the Supreme Court gave a whole lot less deference to a foreign government's policies governing its reinsurance industry than comparable state policies receive under the McCarran Act or under the state action doctrine. You'll recall that Hartford Fire held that reinsurers in the U.K. were not immunized by a clear and strong U.K. approval of their anticompetitive activities. And the court said that as long as you can comply with both U.S. antitrust law and the law of the U.K., then there's no problem in applying U.S. law, that there has to be an actual direct conflict

that's more or less the sovereign compulsion defense rather than comity.

Anyway, one interesting thing about the Hartford case is that Justice Scalia would have read the Sherman Act to incorporate notions of international comity just the way the state action doctrine presumes congressional respect for the values of federalism. And that always seemed to me a much more sensible way to deal with the problems of conflicts with the law between U.S. competition policy and the laws and policies of other nations.

And I think the notion of comity ought to be kept alive in talking about the state action doctrine, but the contrast in the way it's been handled in the international sphere is, I think, notable.

Next slide. The treatment of municipalities. The Supreme Court has been quite generous in providing antitrust immunity to municipalities. There are a lot of cases, but what's emerged is a willingness to treat foreseeability of anticompetitive regulation in the exercise of general municipal powers conferred by the state on the community as being sufficient to meet the first prong of the Midcal test. And in addition, again in the Town of Hallie case, the court relaxed the active supervision requirement because municipalities are, I

think, deemed to be supervised by local politics.

Indeed, it's been my thought that the leniency towards municipalities should be linked more explicitly than it usually is to the accountability of municipalities to public opinion, the media, and to voters in the municipal elections. The local politics provides a kind of active supervision, if you will, and indeed a presumptively reliable kind. And this may not be the kind of active supervision we usually look for in applying the state action doctrine, but I think in this context it should be deemed to be quite adequate to meet the concerns of the court in establishing the active supervision requirement.

And I think many people have recognized how fundamentally the direct political accountability of municipalities distinguishes them from state agencies and boards, especially those that are beholden to the very interests they regulate. And we'll say more about that as we go along.

Next slide, please. I wanted to say something about the Earles case in the Fifth Circuit. I've included that in -- I think we may include it in our casebook on health care law because it's such a bad example. We often include cases because they state the law so badly or make such interesting mistakes that they

are rewarding for teaching purposes.

At any rate, this case extended the Town of Hallie reading of the state action doctrine from municipalities to state boards. And I find that highly problematic, and I hope the staff report will find it so as well.

One thing that they did was to overrule a 1978 case or '79 case called U.S. against Texas State Board of Accountancy, where the Department of Justice found a state board to have violated the law in adopting a regulation against competitive bidding.

I think the state board was clearly controlled by the accountants, and they even put the rule out for vote by the accountants before they adopted it. This is, of course, similar to the restraint in the Professional Engineers case, and was, I think, a sensible outcome.

Now, the Earles case involved a restraint that was perhaps less egregious than that one, and you might be able to argue still in the Fifth Circuit that if the agency issues a blatantly anticompetitive rule like the one in Texas Board, then they're not immune unless they have explicit legislative authority.

But it's still -- the case troubles me because it seems to give much too much weight to federalism values and too little weight to antitrust policy. And I

hope the staff report will quarrel with the statement the court made to the effect that: "The public nature of the board's actions means there is little danger of a cozy arrangement to restrict competition."

Gosh, I think that's a naive view of the way state boards operate, and the notion that their activities are highly public and therefore protected. I mean, it's quite distinguishable, it seems to me, from the cases of the municipalities.

Indeed, I think the error in this case was in borrowing from the Supreme Court's lenient treatment of restraints imposed by municipalities. Indeed, I think it makes no sense at all to equate state licensing and regulatory boards that are controlled by the people they regulate with municipalities in deciding how explicit the legislature needs to be in empowering them to limit competition.

So in cases like these, I would say the clear articulation requirement should be enforced with special rigor. Obviously, the foreseeability test, which may be appropriate for municipalities, is clearly inappropriate in dealing with state boards. Indeed, few things are more foreseeable than that empowering a trade or profession to regulate itself will yield anticompetitive regulations that harm consumers. So that's a case that

has troubled me and was actually one of the main reasons I wanted to appear at -- to talk at this hearing.

Next slide, please. The supremacy clause: These cases are always discussed in terms of whether a state or its officers or agencies has violated federal antitrust laws. And it doesn't often come up in the more straightforward form of the question of whether the state law or regulation is preempted by federal antitrust policy. But in some cases, the action at the state level may be so offensive to federal policy that it's invalid and unconstitutional under the supremacy clause. And so I've long thought it might be possible to invoke the Sherman Act in preemptive terms when a state has created a regulatory board that's so dominated by the regulated interests that it amounts to a self-regulating cartel, precisely what the Sherman Act was designed to prevent.

And the court has said several times that states can't just authorize dangerous combinations of competitors or -- I think the Midcal court said you can't cast a gauzy cloak over a cartel. And so when states appoint regulators that are nominated by the regulated interests, I think federal policy could be invoked to trump the federalism concerns and invalidate the program.

Now, that may not really happen. But I think

in a report like the staff is preparing, they might want to throw out the possibility that some states could go so far in that direction to have their statutes preempted as opposed to going through the full state action analysis.

Next slide. Just to comment on why lower courts seem to have misused the state action immunity doctrine so often, and Mr. Delacourt's comments indicate that there's a lot of misuse, what you find, I think, is that the lower courts use state action immunity as a way to avoid addressing antitrust issues they prefer not to confront.

They've done this in other respects, too, and with other doctrines, too, interstate commerce for a while, and there are two or three others where you can sort of see the courts jumping at easy ways to get rid of cases that they don't want to hear -- staff privileges cases, for example.

In some cases, they simply are looking for an easy way to grant summary judgment because they don't want to try this time-consuming case. And in other instances, I think they think they could be incorrect but they may think that the law would require them to condemn some arrangement that they regard as either innocuous or so unimportant as not to be worth their time.

At any rate, the courts' decisions to use the

state action immunity doctrine are often a reflection of their confusion over antitrust doctrine, and reluctance to get into those questions when, in fact, if they did, they perhaps could resolve the cases in a much more satisfactory way.

So I think clarifying antitrust doctrine would sometimes enable them to deal with these cases more confidently on the merits, and that they would be less inclined to -- but you need to give them, you know, safe harbors and some rules that allow them to act summarily in cases where real competitive harm is not really apparent.

Okay. The next slide brings us to hospital staff privileges, and particularly in public hospitals. There are a lot of cases here, and I haven't read them all. But the risk is, as always, that the medical staff will administer privileges in the interest of its members, particularly their interest in avoiding competition, and not in the interest of the hospital itself.

Now, one finds, of course, that the public hospital's authorizing legislation usually authorizes denial of staff privileges. But that is not enough to immunize the hospital from suit because not all denials of privileges are necessarily suspect under the antitrust

laws.

Indeed, one should think of the hospital in deciding whether to allow a doctor to use their facilities as being in a vertical relationship as either a purchaser of the doctor's services or as a supplier of facilities to the doctor, whichever, but in a position where he can -- the hospital can refuse to deal or not for reasons of its own, commercial reasons of its own, and there is usually no antitrust issue.

Indeed, it is competition itself that is operating here, the hospital deciding whether to deal with a particular doctor and the doctor deciding whether to deal with a particular hospital. This is the market at work and not something anticompetitive.

In addition, of course, the statutory authority of the hospital to deny privileges shouldn't have any immunizing effect on anticompetitive actions the medical staff might take because the staff, of course, comprises private parties with commercial interests of their own.

Next slide. I would suggest -- and I think this is a new thought, and maybe it isn't, but if it is, I hope someone will take a note and think about it -- the thought is that the active supervision requirement could be used to ensure that the hospital's governing body, state-appointed governing body, oversees the actions of

the medical staff, and does so with enough care to ensue that the public goals or the hospital's goals are being furthered rather than the interests of the doctors.

And as far as I know, no court has yet viewed the medical staff of the hospital as a combination of competitors whose actions need to be actively supervised by the hospital to establish their immunity under the state action doctrine.

I also happen to think that active involvement by a hospital governing board should defeat antitrust claims on the merits, even by summary judgment. And that should be the case with private hospitals as well as public ones. The key factor is whether this is a vertical transaction or one in which the competitors of the applicant are the principal decision-makers.

Next slide. Staff privileges in private hospitals: I don't have a lot to say there, but I do think the Patrick case -- I've never known how to pronounce the second party in the Patrick case; Burget, I guess.

The case is interesting and it might be mentioned in the staff report in this respect because I think the Supreme Court created some confusion by skipping over the first prong of the Midcal test to the second one in finding no immunity for the private

hospital's actions in curtailing the privileges of the plaintiff doctor.

And that left the impression that the first prong test was satisfied. It was not an appropriate impression, but necessarily people seemed to assume that the reason you go to the second prong is that the first prong test is satisfied.

Now, the Oregon law in that case, which the hospital invoked, didn't contemplate any restrictions on competition that would contravene federal antitrust policy. Indeed, the Oregon legislature expressly gave the responsibility for screening physicians for maintaining the quality of care in hospitals to the hospitals themselves, and not to physicians that were acting on their own. And thus the statute provided, I think, no predicate for the exemption argument in that case.

The next slide. A little more on this. It's always seemed to me regrettable that the court chose to rest its decision on the lack of state supervision since in doing so, it seems to suggest that all privileges are somehow at odds with antitrust policy. And what I've been trying to say is that they really aren't, and that it would have been healthy for the lower courts to understand a little more clearly that this is not as

fraught with antitrust risk as it might seem if the hospitals are making the decisions and not the doctors.

So the case could have provided a good opportunity to observe that the problem in Patrick was physician domination of the privileges process, that the state law wouldn't exempt or didn't exempt that domination from scrutiny under the antitrust laws, and finally, that antitrust law is appropriately invoked when and only when the applicant's competitors are making the decision rather than the hospital itself.

Okay. The next slide, please. Comment on provider cooperation laws. The staff report, I think, should refer to the several laws in several states where the states have sought to enable health care providers, mostly hospitals, to merge or otherwise collaborate without being subject to federal antitrust laws.

And they do this by trying to satisfy the two requirements of the Midcal doctrine. They first express very clearly the legislature's desire to override federal competition policy. And second, they try to provide some form of state oversight, usually by the state attorney general, of any anticompetitive actions that providers might take pursuant to the authority the states give them.

Now, these laws haven't been much used, as far

as I know. And that may be because the hospitals haven't found that the option of being actively supervised by the state AG is particularly attractive, and that maybe they think their merger is more likely to pass muster with the feds in any event, and they can then go forward without being supervised thereafter.

But I've been curious as to whether the FTC and the Justice Department, in looking at mergers of hospitals, feel somewhat constrained by the possibility that the parties can go to the state if a merger is not approved. And I'd be kind of interested in some comment on whether the FTC has been inclined to -- I guess they wouldn't admit it, but I'd be interested in the dynamics here.

The idea of approving borderline mergers to prevent the parties from taking an end run around the authority of the states, it seemed to me that rather than having their authority avoided, they might approve the merger in the first place. And I guess I'd be interested. I hope the staff report will say something about those laws.

It does, I gather -- and the next slide, please -- I gather from what Mr. Delacourt says that they're going to say something about the statutes that allow doctors to engage in collective bargaining with

their health plans. These statutes seem to permit collective bargaining, at least in circumstances where competition among health plans is somehow deemed insufficient to prevent the exploitation of doctors.

But they stop short of authorizing strikes or concerted refusal to deals or group boycotts of health plans. And that seems to be a significant limitation on their effectiveness in solving the doctors' problems, as doctors see them.

If the doctors lack both the right to strike and also the protections of federal labor law, then it's unlikely that payors will be willing to sit down with them and actually negotiate with them in good faith over whatever agreements they may have.

But the Commission has opposed these in a number of instances and should continue to do so. And I continue to be interested in how serious these laws are as exceptions to the usual antitrust rules.

Okay. The last topic in the next slide, please -- a word or two about educational crediting. And I was kind of hoping that the staff report will say something, express some concern about the ability of private interests to limit and raise the costs of entry into the various licensed occupations by virtue of the state agency's reliance on private accrediting of

educational programs.

The typical case, of course, involves the state making successful completion of privately accredited training a prerequisite for licensure in the field. And that provides the -- gives the private interests an important role in defining the field and in setting the terms of entry.

No one seems ever to have doubted that the state action doctrine permits state regulatory boards to delegate control over educational programs to private interests. And the current law now seems to privilege the sponsors of accrediting programs under the Noerr-Pennington doctrine by treating their collaboration as exempt petitioning activity. I haven't read all these cases, but this seems to be the rule from the Massachusetts School of Law case, and is troubling to me.

Next slide. There is an example of the abuses that can occur that has been on my mind for some time, and I've never seen the FTC take an interest in it. And I think it's a glaring instance of a profession putting one over on the public in a way that should not happen.

The pharmacy profession has succeeded over the last ten years in raising the minimum training for pharmacists from five to six years. And they did this without any public debate or affirmative government

approval.

In other words, the states did not say we're going to increase the requirement for getting a license as a pharmacist from five to six years. They said, we approve -- we only license people who've gotten accredited training. And the accreditors raised the standard from five to six, so everybody is now a doctor of pharmacy. There are no more bachelors degrees, at least after 2004. I think we will see the last of those programs.

So the point is that there's now a huge shortage of pharmacists, and this has raised the costs and has contributed to overwork, to burnouts. I think the quality of service has declined. And this is a direct result of a restraint imposed using the licensing system by the pharmacists themselves.

So I think this is an example that demonstrates the need for antitrust law to impose some limit on the ability of private interests to control education and training in their respective fields.

Last slide suggests that there may be some doctrinal solutions available here. First, I would question whether the state action doctrine permits a state to delegate accrediting authority to a private body that's both subject to capture by special interests and

not subject to active supervision by a state agency that's independent of the occupation being licensed.

Second, I question whether the Noerr-Pennington doctrine protects a narrowly based joint venture that monopolizes accrediting in a particular field. Petitioning government is one thing, but domination of the supply of information and opinion concerning educational programs is something quite different.

And I think antitrust law should be available to challenge dominant joint ventures in educational accrediting that exclude from participation all interests other than supply side interests.

In other words, the American Council of Pharmaceutical Education, the ones that raised the standards in training requirements in pharmacy, that council could, I think survive attack under the antitrust laws if it included, what, chain drug stores, included health insurers and HMOS, pharmaceutical companies.

All they include, however, are the practicing pharmacists. And, of course, their view is that the more training the better, and higher costs and wages are not a concern of theirs at all.

So I think there's a role here for antitrust. I've written about this in the past but nobody has ever seemed to take it seriously, as I think they should. And

the pharmacy case, I think, is illustrates the seriousness of the problem.

That's my comments on these things. I hope they're helpful to somebody. I enjoyed being a part of this, and I'll try to stick around for the discussion later.

MR. HYMAN: Thank you, Clark. Now you hear why law professors labor in solitude, never knowing the effect of their articles. It's not just you, Clark.

Okay. Next is Meredyth Andrus.

MS. ANDRUS: Hi. I'm Meredyth Andrus. I'm an Assistant Attorney General in the Office of the Attorney General for the State of Maryland. The views that I'm going to express today are those -- mine entirely. They do not belong to the State of Maryland, the Attorney General, or to any other state official. I'm going to talk today about state action immunity, and in a couple of different contexts.

First, the state attorney general in Maryland and in other states has two basic roles. The first is that of -- at least in the antitrust enforcement context. First is that of a prosecutor. We enforce the antitrust laws, and that is both the federal and the state antitrust laws. And the second role is as counsel or representative of the state itself, and that includes

state agencies, state officials, and state licensing and regulatory boards.

Maryland has a unique program, and I'm quite certain that it's unique because I have talked about it quite a bit at National Association of Attorneys General meetings, and that is we actually counsel our regulatory and licensing boards on the antitrust laws.

In the health care area, the Department of Health and Mental Hygiene assigns an assistant attorney general to each licensing board in the health care profession. So each board is represented by an AAG, and each AAG at the Department of Health and Mental Hygiene is tutored by the antitrust division on both antitrust violations and state action immunity. Also, each board is counseled by the antitrust division when problems arise. And that is my job, one of my jobs, that I've been performing for about twelve years.

Now, licensing boards are creatures of statute. Their powers are enumerated in the statute. Their authority is subscribed by the powers that the legislature has given them. Board members are appointed by the governor and board members and competitors of the licensees they regulate, and that creates a certain amount of anticompetitive tension. There are on all boards also consumer members who sort of serve as a

buffer, give the voice of reason, if you will.

For licensing boards, the Midcal test -- because licensing boards are quasi-state agencies or entities, it's not absolutely clear whether they need to satisfy both prongs of Midcal. And the Supreme Court has not been very helpful in clearing that up for us.

We know that they have to satisfy the first prong of Midcal, that is, the clear articulation prong. The question comes to me, when a board is considering taking a certain course of conduct, the first area that I look at is what does the board's enabling act say? What gives us the statutory authority?

If the conduct is in the statute itself explicitly, I have no issue. There's no problem. The board can do it. The problem areas are when the statute does not explicitly authorize the conduct that the board wishes to take. And in such a situation, while it's not clear whether or not the foreseeability test of Town of Hallie and Omni apply to regulatory and licensing boards, that is what I counsel them.

In other words, if the statute does not explicitly authorize the conduct, it must be at least reasonably contemplated within the statute itself. If it is not, I advise my board to take other action, and in very difficult situations, to actually go back to the

General Assembly and request an amendment of a statute.

Active supervision has never been required, at least as far as I know, in the case of licensing and regulatory boards. I will say, however, in Maryland, that were the Supreme Court to decide that regulatory and licensing boards need active supervision, they get it.

The problems that we encounter in the health care professions are in those areas where the health care professionals perform certain procedures or operations that may overlap with those performed by another profession. I put a couple of examples on the slide for you.

We've got physical therapists competing with chiropractors competing with massage therapists competing with personal trainers. Obviously, dentists compete with dental hygienists and oral surgeons and plastic surgeons.

In the mental health arena, we have psychologists, professional counselors and psychiatrists. Dietitians and nutritionists overlap. And physicians, physician assistants, nurses and anesthetists and yes, nurse anesthetists. We have areas where one board may be regulating the professions of a number of different professionals and sub-specialties.

The types of actions that boards take that may raise particular antitrust or anticompetitive concerns

are in the area of licensure requirements -- that is, what education requirements, what experience requirements, what examinations are you going to take in order for you to be able to take an examination to obtain a license in the state. The regulation of out-of-state licensees has often been an issue in board regulation. Regulations, as I said, governing sub-specialties and practice limitations raise anticompetitive concerns.

Advertising restrictions: If the board determines to take action against a practitioner who is advertising in a particular way that the board feels is beyond the scope of their professional authority, it might take action.

One example that I'd like to use here, because I think that it illustrates the problem for you, prior to my tenure, I guess in the late '80s, in the state of Maryland we had the emergence of a new profession -- it was probably emerging all over the country at the same time -- and that is massage therapists.

And in Maryland, the board of physical therapists found that the massage therapists were, in fact, advertising their services and advertising utilizing the word -- using the word "therapy." The Physical Therapy Board ascertained that the use of the word "therapy" was not allowed by massage therapists, who

were not licensed or certified at that time, and therefore sent out cease and desist letters to all massage therapists practicing in Maryland.

The Maryland Association of Massage Therapists sued the Physical Therapy Board and the state in state court, alleging an antitrust violation. Now, the case was ultimately settled. I was not involved in the case. But it seems to me fairly clear that the word "therapy," which was not explicitly defined in the physical therapist statute as pertaining only to physical therapists, you can't restrict the use of the word "therapy" in someone's advertising.

And so how we counsel the boards is that as a regulatory board, your parameters are you may not restrict advertising that is truthful and not misleading to the public.

In addition, this was mentioned by Professor Havighurst, the delegation of board authority to non-state organizations such as trade associations or accrediting programs. I think that, yes, I mean, the state can by statute delegate authority, for example, for an examination to an accrediting program or educational program.

My concern is in the trade association and how closely the trade addition is aligned with a particular

regulatory board. Bottom line, my counsel is, it is the board who must make all decisions and not a trade association.

Obviously, a trade association is welcome to consult with and advise regulatory boards, and they offer valuable insight in many situations. But again, bottom line, it is the board who must make the decision and not the private trade association.

And disciplinary proceedings. These are licensed revocations, suspensions, et cetera, that pose an anticompetitive impact maybe for one practitioner, but yes, it's a competitive impact.

This is relating to statutory authority that relates to the first prong of Midcal. And again, I have counseled my boards that if they find that the authority is not explicit, it must be at least reasonably contemplated.

I also counsel the boards that they must record all actions in minutes, and obviously, by statute, the meetings are open to the public. Board counsel must be present at all board meetings. And again, if the law is inadequate, it must be amended by taking it back to the General Assembly.

The promulgation of regulations is another area that we have to look at. When boards regulate specific

areas of practice, we have to remember the regulations are not law for the purposes of state action immunity.

Change gears a little bit. For the past couple of years, we've been litigating a case. It started in the federal district court in Maryland and went to the Fourth Circuit twice.

This case, TFWS versus Schaefer -- Comptroller Schaefer is the comptroller of Maryland -- involves a very large liquor retailer who challenged the state and the state alcohol and tobacco agency alleging that the state liquor laws are a violation of the Sherman Act.

The two portions of the laws, or the one relating to no volume discounts, and the second one is a price-filing regulation -- that is, the liquor retailer must price its product and then hold that price for a month. Can't change the price. Can't respond to a competitor across the street's lower price. Must hold that price. At the end of the month, they can change their price.

But again, they must hold that price for a month. It's called a post-and-hold process. The TFWS alleged that this particular scheme was anticompetitive, a violation of the Sherman Act, and would not survive antitrust scrutiny.

We defended, the state defended, on three

grounds. The first was the Eleventh Amendment. The second was state action immunity. And the third was the 21st Amendment. The Fourth Circuit rejected both the Eleventh Amendment and the state action argument. And the state action argument is really what I want to talk about. The case has now been remanded for trial on the 21st Amendment. But I want to talk a little bit about the state action analysis that was performed in this case.

The state action defense -- and we've already talked about it -- state officials, state agencies, have to pass the first prong of Midcal. A statute is -- in this particular case, in the Article 2(b) in the Maryland Code, the liquor laws clearly articulate an anticompetitive scheme and that is notwithstanding any anticompetitive effect. The General Assembly acknowledged this was anticompetitive, acknowledged that it did not comport with the antitrust laws, and enacted it, anyway.

In the TFWS lawsuit, there were no allegations whatsoever of any private conduct. No collusion, no agreements, no discussions about pricing at all. Nevertheless, the Fourth Circuit held that this was a hybrid restraint, a per se violation of the Sherman Act, and there was -- the reason was it was not immunized is

because there was no active supervision.

Now, the court did articulate a preemption test, that is, that the particular law in question -- if it either mandates or authorizes conduct which constitutes an antitrust violation in all cases, or it places an irresistible pressure on private parties to violate the antitrust laws in order to comply with the statute, it articulated that test. But it didn't apply the test.

What it did say is that because there was no active supervision -- and it didn't even say of whom -- there was no immunity, and therefore the statute would fall under the antitrust laws. Now, I do read the case because I think it's very interesting. And I'm not saying that I disagree entirely with the result of the case. But I think that the analysis is a little bit incomplete.

In conclusion, I'd like to say state licensing boards, in my view, must pass the first prong of Midcal; that is, there must be clear articulation and affirmative expression of state policy. And secondly, the authority, while it must not be explicit in all respects, it must be reasonably contemplated by the board statute.

I think Professor Havighurst said that perhaps the Town of Hallie test for foreseeability should not

apply to state regulatory boards, but I wonder if that means that a state board's authority should be explicitly set forth in statute in all respects. I mean, the board would be frozen if every single act or decision that they had to make had to be so explicitly outlined in the statute. I think it's unworkable.

Thirdly, I believe that boards must be counseled by the state.

And finally, I think that challenges to state law as a per se violation of the antitrust laws should not be confused with challenges to state agencies or private parties.

Thank you.

MR. HYMAN: Next will be Dr. Lyon.

DR. LYON: I'm Dr. Brenda Lyon, and I'm here on behalf of the National Association of Clinical Nurse Specialists. I want to thank you for the opportunity of sharing our concerns today. The focus of our testimony is on what we believe to be Noerr-Pennington doctrine violations, a little bit different twist from some other stances that we've heard yet this morning, and anticompetitive actions of the National Council of State Boards of Nursing and its member boards to create insurmountable barriers for clinical nurse specialists that substantially limit the economic and professional

opportunities of this practitioner. And just as a basis for moving forward, to make sure it is clear, the National Council of State Boards of Nursing is an association and not a regulatory body.

Before I get into our concerns, I think it would be helpful to share with you some background information on clinical nurse specialists as advanced practice nurses. A clinical nurse specialist is a professional nurse, registered professional nurse, who holds a masters degree in nursing from an accredited school of nursing that prepares clinical nurse specialists for specialty practice in nursing. The essence of clinical nurse specialist practice is specialty practice, unlike nurse practitioners, who are educationally prepared as generalists in primary care.

There are currently over 40 specialty areas of practice that have evolved to meet societal needs for expert nursing care. And just some examples of these are oncology, orthopedics, HIV/AIDS, rehabilitation, women's health, incontinence, diabetes, and pediatrics.

It's estimated by the Division of Nursing and the American Nurses Association that there are over 60,000 CNSs in the US. CNSs have been providing expert nursing services to the public for over 50 years, practicing within the scopes of practice authorized by

the R.N. license, which include autonomous nursing practice in the provision of nursing care -- not medical care but nursing care -- and delegated medical authority.

CNS practice is characterized by the provision of expert research and theory-based direct patient care to patients who have specialty needs. It bridges the gaps between new knowledge and actual practice at the bedside by staff nurses, thereby advancing the practice of the discipline for the benefit of patients. And it facilitates system changes on a multi-disciplinary level that help hospitals and other health care facilities improve patient outcomes cost-effectively.

There are some CNSs -- psychiatric, congestive heart failure, diabetes, for example -- who have obtained prescriptive authority so that they may order medications to help patients manage or control symptoms or functional problems in conjunction with an M.D. specialist. You must be clear here that this prescriptive authority for medications extends beyond the scope of practice authorized by the R.N. license, and therefore additional regulation such as licensure beyond that license for these CNSs is warranted.

Currently, there is a critical shortage of CNSs in the U.S. Some hospitals are now offering $20,000 sign-on bonuses. Recently the number of universities and

colleges offering masters degree programs preparing CNSs to meet this need has increased from 187 to over 200.

Now to the regulatory credentialing issues. Some state boards of nursing -- for example, Texas, Ohio, Minnesota, and Arkansas -- are requiring all CNSs to obtain a second license to practice. This requirement represents over-regulation for the vast majority of CNSs, who do not want or need prescriptive authority and who hold an R.N. license.

It also creates insurmountable barriers for the CNS to practice with or without prescriptive authority when obtaining the second license requires specialty certification as a CNS by exam only, thus denying the public access to needed services. And that will be made clear in just a moment. I'm going to speak to each of these issues separately.

In terms of over-regulation, there is no evidence over the past 50 years of a public safety issue regarding CNS specialty practice. The level of regulation needed for CNS practice without prescriptive authority is designation recognition.

This level of regulation would provide for title protection and to make the practice of CNSs clearly distinct from that of nurse practitioners. This title protection helps assure that people do not represent

themselves as CNSs when they have not been prepared as such, and also to help CNSs meet third party payor requirements for reimbursement for CNS services.

The issue of insurmountable barriers: The requirement to obtain a second license and to be certified by exam as a CNS adversely affects the majority of CNSs who practice within the domains authorized by the R.N. license they already hold. There are over 40 CNS specialty practice areas. Only nine CNS specialty exams exist.

Therefore, the vast majority of CNSs will never be able to obtain certification in their specialty area. It is not economically feasible to develop exams in areas where there are not large numbers of nurse practitioners. It takes a minimum of $100,000 to develop an exam, and then almost an equal amount to maintain it per year. Thus, is it impossible for the vast majority of CNSs to meet this regulatory requirement.

Some examples of the consequences of these insurmountable barriers: In states such as Texas, Ohio, and Arkansas, there are hundreds, if not collectively thousands, of CNSs who have stopped practicing as CNSs because they cannot obtain recognition to practice, or are forced to go back to school to take nurse practitioner courses to learn competencies not used in

their CNS practice.

In states such as Texas, there are schools of nursing who are closing much-needed CNS programs because there is no certification exam in the specialty area. The most recent example in Texas is that a little over -- oh, about two years ago, hospitals in the Austin area and surrounding area came to the University of Texas at Austin requesting the school to develop a women's health CNS program. Now, women's health is a specialty CNS area existing for many, many years. And to meet this need, the University of Texas at Austin got this program approved. They had 32 applicants to the program to begin this fall, and the executive director of the Texas State Board of Nursing visited the school informing them that the Texas Board of Nursing would never recognize women's health CNSs because there is no certification exam, and therefore the school is no longer pursuing that degree.

It is also imperative to note that requiring certification by exam for entry into a specialty area precludes the evolution of new specialties to meet evolving societal needs because certification exams are not developed in an a priori manner. I just want to insert here as a sidebar that there are other ways to demonstrate competency besides exam.

These insurmountable barriers only worsen with

the new compact language passed by the National Council of State Boards of Nursing, again an association, in August of 2002. This compact language is called, titled, the "Uniform Advanced Practice Registered Nurse (APRN) License/Authority to Practice Requirements."

The multi-state compact language for the recognition of advance practice nurses, including clinical nurse specialists, nurse practitioners, registered nurse anesthetists, and nurse midwives, only recognizes certification exams as the mechanism for demonstration of competence.

Now, the intent of this compact language is admirable. One is to increase uniformity of regulations for advanced practice nurses across states. The problem is the National Council of State Boards of Nursing treats these different, very distinct, different practice areas as the same, and then therefore in part creates insurmountable barriers, which again I will get into again.

The important matter here is that the NCSBN, as an association, has developed language that the regulatory bodies, the state boards of nursing, must adopt in order to be part of this compact. The National Council of State Boards of Nursing advanced practice registered nurse task force has proposed that if there is

not a CNS certification exam available in a particular CNS's specialty area, that a more general exam, such as the medical/surgical CNS exam -- and note, this is just one of the nine specialties, and it's a specialty in itself -- can be taken as evidence of competence.

We believe there are important legal defensibility questions of requiring or accepting an exam that does not test for competencies in the specialty area, and there are multiple examples of this that just, frankly, in our view make it nonsensical.

The effects of the regulatory barriers described are devastating to thousands of CNSs and result in: first denying the public's access -- and we define public both in terms of patients as well as CNS employers -- to much-needed CNS services; schools of nursing not developing new graduate degree specialty programs to meet societal needs; and wasted dollars, with CNSs taking unnecessary additional course work to become nurse practitioners. In essence changing the scope of CNS practice to include competencies they do not use, to achieve advanced practice recognition so that they can provide CNS services.

Currently, the National Council of State Boards of Nursing advanced practice task force is advocating the development of a standardized, generalist exam to

evaluate safe advanced nursing practice. No other nursing group is supporting development of a uniform generalist examination for advanced practice.

The actions of the NCSBN as an association, in our view, raise important Noerr-Pennington concerns, which are: The association, made up of members of state boards of nursing, has undue and inappropriate control over state regulatory processes. The association process does not allow for input of other organizations. Others may comment, but those comments are not incorporated into deliberative processes. The association has a vested economic interest in changing the licensure process, examination or certification development, as it develops and provides testing products.

These are our Noerr-Pennington-related questions: (1) Is it appropriate to provide an association which provides testing products to state licensing agencies and mandates membership to obtain the testing products with unfettered access to state licensing agency staff and appointed members? (2) Is it appropriate for such an association to develop policy, lobby its membership for the adoption of the policy, and subsequently develop the required products for sale to its membership? (3) Is it appropriate for the association to develop the policy which would require the

use of uniform standards for licensure and the use of a standardized exam, and subsequently force the state boards of nursing to use its product by limiting access to a national disciplinary database, or alternatively, work to undermine other competency certification products?

We do not believe the Noerr-Pennington exemption was created for this purpose. We believe that the NCSBN has exceeded the boundaries of the exemption when it developed policy inconsistent with state goals related to regulation, that is, protection of the public, health and safety of the public, while not creating barriers to block -- unnecessary barriers to block the public's access to needed services.

The National Council of State Boards of Nursing, in our view, has exceeded the boundaries of the exemption through its development of policy that would support NCSBN products for sale to state boards of nursing. State licensure boards, not the NCSBN, were designed to address the health and safety of the public.

Policy developed by an association with ties to state boards of nursing that can be anticompetitive, discriminatory, and is unrelated to the primary standards of licensure, that is policy established for administrative ease rather than evidence of harm, is

subject to antitrust challenges.

A primary anticompetitive concern is changing the scope of CNS practice and/or creating insurmountable barriers to practice substantially limits the economic and professional opportunities of this practitioner without providing a clear scientific or legal basis to do so. We believe this is anti-competitive and we have one piece of case law cited.

We respectfully recommend that the FTC should clearly speak to the role and limitations that should be placed on associations which mandate membership of government appointees to. Number one, adopt anticompetitive policies for regulation of CNSs; and two, to obtain products and services. Furthermore, the FTC should also address appropriate boundaries on association conduct related to policy that enhances their own ability to create, structure, or limit the market for providing services to that government agency.

Thank you very much for the opportunity to testify.

MR. HYMAN: Thank you, Dr. Lyon.

We will take about a ten-minute break, and then we will reconvene at 11:00 and Dr. Kizer and Dr. McClure will speak at that point. And then we will go into the moderated roundtable.

(A brief recess was taken.)

MR. HYMAN: We'll continue now with Dr. Ken Kizer from the National Quality Forum, and then batting cleanup will be Dr. McClure, who's been waiting patiently since 8 a.m. And then we will go directly into a moderated panel discussion that will be completed no later than 12:30.

Dr. Kizer?

DR. KIZER: Thank you. Good morning. Thanks for the opportunity to say a few words about the National Quality Forum.

Let me just preface my further comments with reiterating what I suspect you well know and have heard lots about already, that there's a paradox in American health care at this point in time, as there indeed has been for some time. There's lots of good things that we do in health care here in the U.S. as far as training of our practitioners; having lots of diagnostic and treatment technology diffused throughout our community; our biomedical research program is the envy of the world and the engine that's driving development throughout the world; and lots of technology. We spend, by any measure, more than anybody in health care and clearly, some people get very good care.

But we also know that things aren't all that

rosy and that care is fragmented and too difficult to access. Lots of people don't have guaranteed or predictable access to care. There are growing questions about the value of the care, or all the money that we spend on health care. There is an increasing dissatisfaction with the system from all perspectives -- patients, providers, payors. And we certainly know from a number of major studies since 1998 in particular that the quality of American health care is not what many had thought it was prior to that point in time.

Now, in the few minutes I have with you, I'm not going to talk about the state of American health care quality or the lack of information that consumers and purchasers ideally would have for a real health care market to operate and what many of the barriers are to improving health care quality because it's my understanding that those topics have already been covered in sufficient detail already.

What I will talk about in quick fashion is the National Quality Forum, how it came about, what it is about, what some of the work is that we currently have underway, and then just end with a few of the challenges that currently confront the National Quality Forum.

What is the NQF? Well, we are a private, nonprofit, voluntary consensus standard-setting

organization. I have to confess that three or four years ago, if someone came up to me in the street and said, "Hi, I'm from a voluntary consensus standard-setting organization," I would have probably asked about their Haldol level and kept walking.

But voluntary consensus standards, while they are new to health care, are certainly not new elsewhere. There are tens of thousands of them. They exist in most other industries. But they are not -- have not been used previously in health care to any significant degree.

More specifically, the National Quality Forum was created to standardize health care performance measurement and reporting to come up with an overall national strategy for how quality of care would be measured and reported. And then finally, to do other good things to make it all happen.

The specific genesis of the forum is that we came out of a presidential advisory commission where the consensus of that group was that the issue of quality of American health care should be vested in the private sector. The commission also proposed the creation of a federal entity that would work in many ways like the SEC. Indeed, the SEC was the model that most closely parallels the thinking behind the creation of the National Quality Forum.

The commission released its report in 1998. Subsequently, a committee was convened by the White House to plan a governance structure and some basic operational details of the forum. This resulted in the forum being incorporated in the District here in May of 1999. And subsequently, I joined the organization and we became operational in February of 2000.

I might also note that the corresponding federal or government sector entity that was recommended has not progressed. Indeed, there has been no expression of interest by either the prior or the current administration, or by anybody in Congress in creating the council that was recommended as setting national priorities and other things that was viewed as being a partner with the forum.

The intellectual thinking behind the creation of the forum is not terribly profound but worth mentioning, that basically, if we want to have wholesale quality improvement, which everyone agrees is needed in American health care, we need a systematic approach.

To have a systematic approach, you need a strategy. You need performance measures. You need reporting. You need national goals. Those measures need to be standardized and reliable and meaningful. And finally, then, we have to get alignment of all of our

structure, process, et cetera, with that, and somehow we have to build accountability into the system.

A few things about the structure of the forum. We are a membership organization. As of last month, we had nearly 200 organizations that belong to the forum. This ranges the gamut from all the usual health care suspects like the American Medical Association and the American Hospital Association and the American Nursing Association, et cetera, to General Motors and Ford Motor Company and Glaxo and Merck and a number of pharmaceutical companies and lots of other entities in between.

We are in essence an organization of organizations, to try to bring all the parties to the table. One of the ways of thinking about the forum is that it is an experiment in democracy. It's an experiment in democracy in a number of ways.

How do we bring government and the private sector together? How do we balance the common good against the individual agendas of the various organizations? How do we achieve equity between the various stakeholder entities, like consumers and purchasers and providers?

Indeed, all of the members of the forum, all the organizations -- and there are individual members as

well, I should say, but fundamentally we're an organization of organizations -- but all the members belong to one of four councils, consumers, purchasers, providers, and research and quality improvement organizations.

That's notable in that each of those councils then elect a chairperson who then has a seat on the board of directors. The determinative body for the forum is the board of directors.

The board at the current time is composed of 29 individuals. There are 23 voting and six non-voting. For all intents and purposes, though, it's not a real distinction since we have yet to come to closure on a matter where it was so close that the difference between voting and non-voting members would have made a difference. The heads of three federal agencies sit on the board of directors, the administrator of CMS as well as AHRQ, and then the head of the Office of Personnel Management, which purchases health care for federal employees.

We have representatives of the states insofar as there's someone who represents state health officers and the Medicaid programs. And then the rest are private sector representatives. As I've already said, each of the four member councils have a representative on the

board.

The six liaison or non-voting members include the Joint Commission on Accreditation of Health Care Organizations, the National Committee for Quality Assurance, the Institute of Medicine, the National Institutes of Health, FACCT, who I understand you'll be hearing from, and the physician consortium on performance improvement of the American Medical Association, which in essence represents the specialty societies.

By our bylaws, consumers and purchasers constitute a majority of the board, albeit a slight majority. But this is done in recognition that historically these entities have not been at the table or felt to have a voice at the table as much as it's viewed that they should have.

We're unique in a number of ways. One is that anyone can join the forum, any individual or any organization. It's open to everyone. There is both public and private sector representation on the governing board, and as I'll come back to in a moment, that is not only allowable under relevant federal statutes but is overtly encouraged because of the nature of the organization.

As I've already mentioned, there's an equitable status among the stakeholder sectors. We are not focused

on hospitals or hospice or nursing homes or home care or any other individual part of the continuum of care, but all parts of it. And indeed we place a priority on looking at performance measures or standards that go, like patients do, through the continuum of care, one day maybe at home and the next day in the hospital, in a nursing home, et cetera.

Finally, the thing that most distinguishes the forum is that we have this formal consensus process and what we produce are known as voluntary consensus standards. This is governed by a specific piece of federal law known as the National Technology and Transfer Advancement Act of 1995, which defines what is a standards-setting body. Five attributes that have to be met to meet that test. The significance of voluntary consensus standards is that they actually have legal status, which is different than most standards in health care and what we typically think of as quality of care standards or other standards.

Indeed, under the National Technology and Transfer Advancement Act, the federal government is obligated to adopt voluntary consensus standards when they are setting standards in an area, or specifically justify why they are doing something that is government-specific.

Likewise, the law encourages, explicitly encourages, as does OMB Circular A-119 and other pieces of -- well, other things that amplify the law, that encourages the federal government to participate in the voluntary consensus standard process. That's why CMS, AHRQ, and OPM sit on the board, as well as NIH.

Some of the activities that we are currently involved in are included on this in the next slide. And this is not a complete list, but it gives you some sense of the range of activities.

One of the first things we were asked to do was to identify a list of those things that -- in the terms of the letter from CMS and AHRQ – the serious, egregious, preventable adverse events in health care that should never happen. That is a little bit much to say without taking a breath, so we call them the never events. Some people objected to that, so we finally came to the more politically neutral term, serious, reportable adverse events in health care.

This is a consensus document, and I'm pleased to say while this consensus document was released in March of 2002, the State of Minnesota, the governor signed a law last week that puts this list of reportable events as mandatorily reportable in the State of Minnesota, the first such state to do this. We know

about 20 states that are currently looking at doing this.

We were asked to also come up with a list of "safe practices." What are those practices that health care facilities should have in place to minimize the likelihood of errors? We released a few weeks ago a set of 30 practices that meet that criteria.

The appeals process, and part of built into this national -- or the consensus process, is a formal appeals process after something has been endorsed by the board. That will run its course next week. We will at that time send this over to CMS, who contracted for it. Whether this ends up being a condition of participation or whatnot remains to be seen. We know that many of the private entities, like Leapfrog and others, are already operationalizing this.

We were asked to develop a set of national performance measures for hospitals, acute care hospitals, so that we would actually be able to compare the performance of hospitals in Portland, Oregon versus those in Portland, Maine and places in between.

That again, I'm pleased to say that we completed work on that a few weeks ago, and there are 39 measures there. You may recall seeing a voluntary hospital reporting effort launched by the American Hospital Association, the Federation of American

Hospitals, and the Association of American Medical Colleges last December for ten measures. Those ten measures are part of the 39. Indeed, part of that agreement is that they will use NQF-endorsed national performance measures.

Last October we endorsed a set of performance measures or consensus standards for the outpatient care of diabetes. Those are just now being re-looked again. We have worked with CMS on the nursing home performance measures. As you know, CMS is now reporting information on all 50 states to the media and to the public on performance measures in nursing homes.

We worked with them on the pilot. We are currently under contract to re-look at the initial set of measures. Likewise, we have a contract with CMS to develop or to endorse performance measures on home health care. We expect to start work on that probably in October or November.

We've done some work with NCI and are in hopefully the final throes of negotiating a large contract with NCI on quality of care performance measures for cancer, and seven specific areas in particular in cancer.

We're funded by Robert Wood Johnson Foundation to develop standards for mammography for consumers, or

what things should consumers look for when they are seeking to get a mammogram.

We're working with the Society of Thoracic Surgery and a number of other entities on national performance measures for cardiac surgery. Likewise, we're funded by the Robert Wood Johnson Foundation to develop performance measures for nursing care. It is somewhat astounding that given the importance of nursing, that there are not nationally endorsed performance measures for nursing.

We currently are working with a number of entities to come to closure on an agreement to develop performance measures in behavioral health care. We're working with JCAHO and NCQA on standardizing the credentialing process. Or at least coming up with an idealized method of credentialing physicians and other independent licensed practitioners that would get rid of much of the waste and incredible duplication of effort that currently is involved in this process.

And there's a bunch of other things, but I think that this gives you a sense of the scope of work that the forum is currently involved in.

Just in closing, the last couple of things: In the three years that the forum has operated, a number of issues have come to the fore. One of the -- on the list

of six things here that I would just highlight is financial support.

We are a private nonprofit. Everyone agrees that the work that we are doing is both of high quality and good and long overdue and very much needed, but no one is rushing to pay for it. Indeed, it's the only instance I know where the federal government explicitly notes in their contracts that they are under-funding the contract because they would like to see the private sector partners step up to the plate as well.

Some of the other issues we're confronting is how do we coordinate with other standard-setting bodies like the Joint Commission and NCQA and a myriad of others, from CMS to the state licensing boards to the American Board of Medical Specialties, and go down the list of other folks who are involved in setting standards and overseeing quality of care and overall health care performance, and providing information to the public.

What's the role in establishing national priorities? As you probably know, the Institute of Medicine has recommended some priorities to AHRQ and, in turn, to the Secretary of Health and Human Services.

In many ways -- well, let me just send on an editorial note comment that lots of good people have been working very hard for many years to improve the quality

of health care, but in many ways if one were to look at it from an objective, dispassionate view, it looks a lot like Brownian motion in that the activities are all over the board with no coherent underlying strategy for how or where we're trying to go.

There are no goals to the effort, no prioritization of effort. Steps are being taken to try to address that through the IOM and HHS. There has been considerable sentiment that the forum, given our role in bringing people together and the unique attributes that we bring to the table, should be involved in that process.

What should be the role of the forum actually in the implementation of performance measures and standards? Originally, as the forum was thought about and how it was conceived, it was felt that this should be left entirely to the private sector or regulatory bodies or accreditation bodies. And indeed, that is happening. Many of our performance measures are now embedded in contracts that the various purchasing groups and others are putting in play. But there seems to be a sentiment, particularly by many of the provider organizations, that the forum should have a more active role in the actual implementation of things that come out of our endorsement process.

And we're trying to work through what is actually a role that would be complimentary to all the other good work that is being done by others, what should be the role of the forum in actually collecting and reporting information on the various standards that are endorsed by us. And then finally what role can we play in devising or in defining an overall coherent, coordinated, and consistent approach to health care quality improvement.

Again, lots of entities doing lots of good work all over the board, but rife with redundancy and waste of effort and an undue burden on providers in many cases. How could we bring some coherency to this as well as perhaps some efficiency?

Those who would like to know more about the forum, you can go to our website. I would note, though, that as a membership organization, there are two portions to the website, the public and the members-only portion. The members-only portion is much more robust than what is on the public side, although there's lots of information on the public side as well.

And finally, I would just close with this quote from the Institute of Medicine quality of care committee that notes: "Fundamentally, what we need to be looking for in health care is a new system, a new way of

approaching the work. The business of health care has fundamentally changed in the last 30 or 40 years. However, our method of delivering care has remained the same. There is a fundamental disconnect that result not only in incredible inefficiency and waste and a system that's not very user-friend, but also one that results in errors and sub-optimal quality of care."

With that, thank you.

DR. McCLURE: My name is Mark McClure, and thank you for allowing me to talk to you about this very important topic, mercury and dentistry and the potential consumer fraud and antitrust problems of organized dentistry surrounding this issue.

As you can see from my resume, which you can't see because I don't know how to operate e-mail in time, I'm a practicing local dentist and involved in integrated medical education. Twenty-five years ago I worked with the FTC on advertising and organized dentistry's roadblocks to implementing capitation, or HMO dentistry, as we called it then. Now we're calling it managed care.

The work of the FTC at that time -- history reveals accelerated competition and change into the medical and dental industries. I come before this Commission to help you understand another consumer problem perpetrated by organized dentistry, which

involves purposeful restriction of information that dental patients should know to make informed decisions.

As some of you in this room probably know, there's a controversy in dentistry according to the -- concerning the use of mercury in filling materials implanted into yours and other patients' mouths. Other governmental groups, namely, Congress, FDA, EPA, are charged with investigating the personal safety and environmental toxicity of mercury in dentistry. The real professional work on any controversial issue like this should be in the scientific and clinical arenas.

I further realize that safety and efficacy of dental fillings is not your mission. But antitrust enforcement and consumer protection is. Giving patients full access to scientific and clinical information through their dentist and any other means is why this Commission needs to know some of these issues.

First, I'd be willing to bet that there is not a single dental patient in this room who has ever heard a dentist describe a mercury filling or a mercury amalgam. No, dentists describe them as silver fillings, silver amalgams, or just plain amalgams.

Secondly, would you be concerned if I informed you that 50 percent of your amalgam filling is mercury; that mercury is a highly -- mercury in the filling is

highly volatile, continuously leaching out throughout the life of the filling. Elemental mercury that gases off from your filling when you chew is absorbed into your mucous membranes and lungs very efficiently at the tune of about 80 percent. The mercury accumulates very tenaciously in all the tissues of your body, especially brain and nerves, passes through the placenta if you are pregnant or your milk if you are nursing; and that mercury is the most toxic non-radioactive metal to biological tissues?

Now, if some of that was true, and there are thousands of articles in the world medical toxicology literature to support this and much more, should I as a dentist, who has researched and practiced mercury-free dentistry, be able to mention any of this to my patients, to you, or to any others?

These are the problems, and I'm thrilled the FTC is conducting these hearings to take a look at these. The American consumer is being deceived about the mercury amalgam filling, and it's evident that the ADA, my professional organization, is complicit in the fraud and coverup.

Now, how does that happen? The public is deceived by the word "silver" to describe dental fillings that are primarily mercury. Dental amalgam is 50 percent

mercury. The silver component is less than 30. The ADA continually characterizes such fillings as silver fillings. Number two, the controversy exists about the safety of mercury fillings. But it's hidden from the consumer when organized dentistry uses the term "silver."

It's also important for consumers to know that mercury -- that the amalgam is mainly mercury, that mercury, as I mentioned, is the most toxic non-radioactive material, is very volatile, is banned and phased out of most other health products. Dental offices are the largest polluter of mercury in waste water. And the FDA, Health Canada, major amalgam manufacturers, have recommended that mercury fillings not be given to children, pregnant women, kidney, and hypersensitive patients. The ADA has taken no position on this.

However, the mercury filling controversy remains relatively unknown to the public. And a recent poll stated that the safety of amalgam debate is still unknown to about 60 percent of the public.

Number four, the ADA has a vested economic interest for promoting -- for the promotion of mercury as silver, and fails to disclose its royalties from amalgam manufacturers. The ADA has a seal of acceptance program undisclosed in its promotional brochures. The ADA claims

through this seal of acceptance program that is it has researched the safety of mercury amalgam and found it to be safe. There are no peer review articles but only anecdotal claims that the product must be safe because it's been used for the last 150 years. The ADA publishes a brochure calling the fillings "silver," burying the mercury content of amalgam and then making scientifically unfounded comments about its safety.

Number five, the FDA should stop the ADA, in my opinion, from the deception of promoting filling material as silver. The safety is not within the scope of the FTC, but the Commission has frequently acted to stop misleading claims of drugs and devices that the FDA has approved, and I think we've had examples of that today.

If all patients, but especially pregnant mothers and patients of young children, knew that these fillings were mostly mercury, it is unlikely that many would choose alternative materials -- or it is likely that many would choose alternative materials.

Furthermore, the ADA is explicit in suppressing information about mercury fillings. Through its tripartite structure, the ADA at the national, state, and local level, information and approval plows from top down. The ADA controls what is taught in dental schools through its accreditation process, and the toxicology of

mercury is certainly not taught in the dental educational process.

The ADA has intertwined the state dental boards. The American Association of Dental Examiners is actually located inside the ADA headquarters. The ADA, through the state boards, controls what is approved for continuing education by dentists, and in some cases seeking license and renewal, like Maryland, my state. The mercury controversy has never been presented to dentists or in any other kind of ADA-sponsored meeting or publication that I can see.

The ADA is intertwined with federal agencies responsible for regulating the safety in dental devices as well as directing dental research dollars. The National Institute of Dental and Craniofacial Research from NIH reveals that it has funded 543 studies related to amalgam since 1972. Yet only one NIDCR study has ever been published.

The ADA adopts ethics rules that deems it unethical or fraudulent for dentists to tell their patients that removal of mercury amalgam dental fillings removes a toxin from your body. That's Ethical Rule 5(a), which I'm paraphrasing. "Removal of amalgam for alleged purposes of removing toxic substances from the body, when performed solely at the recommendation or

suggestion of the dentist, is improper and unethical."

The gag orders have been instituted by some dental boards to prosecute or intimidate mercury-free dentists from informing patients about the existence of mercury in dental fillings and the risk of such fillings. Maryland is one of those states.

In summary, the issues that we are bringing before the FTC is that your consumers and our dental patients are: one, not properly being advised that the metal fillings that are being placed in their mouths are mercury mixtures; two, the ADA has, through its promotional materials, falsely and misleadingly called the dental amalgam silver fillings when silver is only 25 to 30 percent of the mixture; and three, consumers are unaware of the highly toxic mercury being placed in their mouths and contributing to their toxic load. Dentists who wish to inform their patients of the fact are subject to ethics violations and regulatory action.

Now, this is some specifics about what I have just talked about. As far as the antitrust and restraint of trade, there are specific examples of sub-groups of the ADA using the ethics power to stop dentists from advertising that they are mercury-free. And I cite an example of a Dr. Sadloff in Massachusetts and Dr. Levy in New York.

By the way, my written testimony is available to anybody afterwards. I'm not on PowerPoint, but anybody that has that in, as well as any collaborating information that documents where we're coming from on this.

We have specific examples of dental boards enforcing their gag rule to stop dentists from advertising they are mercury-free. Currently, Alabama dental board is prosecuting a Dr. Fraser for such an advertisement. A few years ago, the Virginia dental board reprimanded a Dr. Rice for saying mercury fillings have a toxic substance, but backed off when on appeal. The Maryland dental board still has a gag rule, in writing, although enforcement has temporarily been abated.

In summary, the FTC should be interested in the ADA's mercury ethics and state dental boards' gag rules because it has the result of keeping consumers and dentists in the dark, and it violates the First Amendment rights of mercury-free dentist advocates.

Number two, the consumer protection: The FTC's mission is consumer protection. The public trusts dentists to tell the truth to the best of their knowledge about oral and health issues. The ADA breaches that trust with its pro-mercury amalgam position in its

brochure calling the fillings "silver."

The ADA is not some neutral organization that simply advocates. The ADA has complex financial agreements with manufacturers of dental mercury and other dental products where manufacturers pay the ADA and the ADA puts its stamp of approval on the product. The AMA, by the way, considers such practices to be unethical.

I want to thank you for your attention and interest and any additional -- as I mentioned to you, all the -- my testimony is on hard copy.

MR. HYMAN: Thank you, Dr. McClure.

I'd now like to involve all of the panelists to sit where their names are, and then we can have a moderated discussion. Since I've been doing most of the talking, I'm going to let the other David have the first question.

And I would just point out to the panel generally, although a question may be directed at a particular person, our goal is to try and get a discussion going among the panel. So if you want to get in on the fight, feel free to let one of us know, or just start talking.

MR. KELLY: I'll direct the first question to Meredyth. You were talking about the TFWS case and how the court dismissed the state action part of it by

finding there was no active supervision, and you felt that that may have been an incomplete analysis.

What do you -- do you think that the -- there really is, obviously, no place for supervision of a set regulation like that. What do you think the court was looking for?

MS. ANDRUS: And I think the court did indicate what they were looking for. They were looking for that if this was to be immunized under the state action doctrine, I think what the court would have sought was the state actually setting the prices or at least ascertaining that the prices were reasonable.

And because the state did not do that, allowed retailers to set their own prices, and the state was not actively monitoring what those prices were for reasonableness, that therefore there was no active supervision.

And I found that the analysis was incomplete because it didn't solve the issues that I had about well, was there an agreement in the first place? I mean, were the private parties actually setting prices or simply complying with the statute?

And that's why I said, David, I thought it was more relevant for a preemption analysis than a state action immunity analysis.

MR. KELLY: Thank you.

MR. HYMAN: This is for John Delacourt. I first wanted to give you the opportunity to respond, if you wanted to, to anything that Professor Havighurst or Ms. Andrus said, and then second, wanted to invite you to talk a little bit more about the competition advocacy project and the extent to which it's been successful or not in persuading both state and federal authorities of the merits of the Commission's views.

MR. DELACOURT: Well, I guess on the first point, which was, you know, if there was anything I wanted to follow up on with respect to Professor Havighurst's testimony and Meredyth Andrus's testimony, and I guess it would be to point out one area where there was some divergence, and that was with respect to active supervision of state boards.

And it appeared to me from Professor Havighurst's testimony that he was more of the view that such boards were not analogous to municipalities, that they had very different sorts of electoral accountability, that the fact that a city government is directly responsible to voters makes it a different animal from a state board, and therefore would put the state board in the category of active supervision where a municipality is not. And if I understood Meredyth

correctly, you would have a different view from that.

I guess I would -- as far as the debate is concerned, I would come out more on the side of Professor Havighurst. And I think that's one of the fundamental issues that the task force has really looked into, is what is the function of the active supervision requirement, and have the opinions found in the Supreme Court's opinion in Hallie really gotten away from what the active supervision is all about.

I would contend, with Professor Havighurst, that active supervision is about electoral accountability. And with that as the standard, I think you have a situation where state boards and other subsidiary regulatory authorities, which are not looking to public approval, at least directly, would need to be supervised by a higher government authority.

MS. ANDRUS: May I clarify my position, John, just --

MR. DELACOURT: Sure.

MS. ANDRUS: I don't -- given the two choices, whether you have to pass the active supervision prong of Midcal or not if you're a state regulatory board, I come somewhere in between. I think there should be a more rigorous scrutiny placed on whether or not a board is acting within its statutory authority than is placed on a

municipality for those very reasons that Professor Havighurst cited.

But I do not believe that a state board rises to the same level of scrutiny as, say, private parties do when you're talking about whether or not the state must actively supervise. So I think there's a middle ground, and I think state licensing boards fall into that.

MR. HYMAN: Do you want to --

MR. DELACOURT: Yes. With respect to advocacy, I think we -- just briefly on that, I think we have had very good success with the Commission's competition advocacy program. One of the particular matters I mentioned was state physician collective bargaining legislation, and I think we have a fairly strong track record there.

Two of the pieces of legislation we commented on ultimately were not enacted into law, and a third was enacted only after significant limitations were placed on the collective bargaining in the form of more rigorous active supervision by the state attorney general's office. So I think that is -- that particular example is characteristic of the overall success we've had.

MR. HYMAN: Let me just ask a follow-up on that. To what extent have you had better results when your involvement -- when the Commission's involvement was

invited as opposed to that of, as we law professors would say, an officious intermeddler?

MR. DELACOURT: Right. Well, it is the official policy of the Commission to only participate where we've received an invitation from an authorized state legislator or other interested state official. So in all instances, we've had an invitation.

However, I will -- you know, I think your point is still well taken in that in some instances, we've had an invitation from an individual who is clearly in the minority as far as the particular piece of legislation is concerned, and certainly have a tougher row to hoe there.

But I think, by and large, that policy has been a good one in that when our comments are submitted, typically they have been sought and are given some significant scrutiny before action is taken.

MR. HAVIGHURST: A point of information on that, if I may?

MR. HYMAN: Sure.

MR. HAVIGHURST: Some years ago, I remembered some amendments proposed -- I'm not sure they were ever adopted -- to the FTC Act, or your authorization or appropriation bill or something that would have limited you to commenting -- spending appropriated money on commenting on something where you hadn't been invited.

Is that still in place, or is it just a policy that the Commission has adopted, or do you know?

MR. DELACOURT: I don't know the answer to that question. As far as I know, it is a Commission policy, but it may in fact have the pedigree you're describing.

MR. HAVIGHURST: I was always kind of amused by that provision in the Congress, telling you that you can't spend their money that way, telling people -- giving people unsolicited advice about the effects of state action and state legislation on competition. I think it is a perfectly legitimate role for the Commission to play, but I guess that prudence might dictate not acting as an officious intermeddler.

May I go back to the question earlier about the active supervision and so on? I think I would -- it's never seemed to me easy to imagine an effective method of supervision of the activities of state boards that are essentially accountable to the people they're regulating rather than to any state -- in any effective way to the state legislature.

So I've always been inclined to put more emphasis on the clear articulation requirement, and, in fact, quite demanding. And Ms. Andrus thought that I was too demanding. I think we might be able to find a common ground.

But I think the point I was making is that the state legislature really ought to take real and clear responsibility when they are authorizing regulation that is significantly anticompetitive, and to so not in a general way but in a specific way in order that somebody is politically accountable for what's being done. I'm not sure we could ever make these state boards accountable in an effective way, and so I guess I'd require the legislature to step up and be clear.

Now, Ms. Andrus says her test is whether the anticompetitive regulation is reasonably contemplated in the legislation. I think that's too generous. The foreseeability test is clearly too generous in that, of course, we can foresee that if you give power to a cartel, it will act as a cartel.

So something else is necessary. I suppose a clearly contemplated test might satisfy me. But I would think that the legislature ought to be expected to be accountable on these matters and to not give boards open-ended authorities on the grounds that somehow, well, we knew they'd do this. That's not good enough for me.

MR. KELLY: I'll throw this question out to John, Meredith, and Clark.

Professor Havighurst talked earlier about how he could possibly see a supremacy clause overriding the

state action doctrine if there was a particularly anticompetitive state action. I think we could all see that in terms of a multi-state metro area, where the state said, to advantage our accountants or our chiropractors, we're going to do the following, that that might be viewed as anticompetitive and overridden.

Yet there are some other state actions that could be seen as relatively anticompetitive, yet within some reasonable stretch of the mind could be seen as regulation. And where really would the line be with that?

What comes to mind is the vast differences that some states have in admitting out-of-state lawyers, to the point where local counsel is a cottage industry in some states, and there doesn't necessarily seem to be any reason for that other than the strength of the local bar in those states.

Where would we see the line between the acceptable behavior and what would clearly trigger the supremacy clause?

MR. HAVIGHURST: My idea was to focus particularly on these boards that seem to be created in a way that makes them accountable to the licensed profession. I suppose it's impossible to think that nominations for board membership would not be vetted with

the professional associations in the field. But somehow, when the statute says that the nominees shall come from a list submitted by the association, that bothers me a lot. I would probably call that -- I would say that's preempted.

It's a good way of sending a signal. And I think that the staff and the Commission ought to at least raise concerns about that kind of thing and sort of threaten using the antitrust laws that way, even if it's not likely a court would agree.

As to other things, I don't suppose the supremacy clause is going to be useful very often. I don't think you could use it to deal with the problem of out-of-state lawyers trying to get admitted on motion to another bar.

But I certainly agree that -- with the statement of the problem. And again, I think a clear articulation requirement of some kind would perhaps help there. I have no further thought on that.

MS. ANDRUS: On the thought about the nominations of a state board being legislatively mandated to come from the trade association, I think that's not a prudent policy. But if the state decides that that is the policy they wish to promote and follow, I think that's the state's right.

Whether it rises to the level of supremacy challenge that would be successful, I don't have the answer to that. But I think that the states -- it is the state's right to decide whether or not it wants to take that action.

MR. HAVIGHURST: But it flies right in the face of federal antitrust policy. Now, that would be argument, and I think that at that point the state's rights should be preempted.

MS. ANDRUS: I think that's -- I think you exactly stated it, and that's what I was talking about in the TFWS case regarding whether or not this would be a preemption issue. You would analyze it a little bit differently.

MR. DELACOURT: I guess I would add to that that I don't know that I would move immediately to the supremacy clause argument. And I would note that the particular issue of interstate spillovers is a big one, and the answer -- the example you used of lawyers being restricted from moving from one state to another I think is a good one.

Perhaps a better example is the Parker case itself, which involved a raisin marketing program, and 90 to 95 percent of the raisins that were affected were sold outside of the state of California. So clearly the costs

of that program were borne by people outside the state.

So this has been a continuing problem with the way the state action doctrine has been implemented. And by way of improving upon the doctrine, and perhaps addressing that problem, I would make two recommendations.

One would be referring to the tiered approach that I'd addressed during my presentation, which would be to look to various factors that would counsel applying the clear articulation and active supervision requirements with greater rigor. And I would say that the presence of interstate spillovers, particularly significant interstate spillovers, would be one factor counseling in favor of such an approach.

MR. DELACOURT: And I agree with that.

MR. HAVIGHURST: While we're still on that point, let me make one observation about the Parker case, which has always struck me as a quite peculiar decision because it appeared that federal agricultural policy at that time expressly contemplated and approved exactly the kind of marketing orders that the California pro rata program was involved in. And thus you didn't have, in fact, the kind of conflict between federal policy and state policy that is necessary to trigger a state action issue.

Now, in other words, I suggest you reread Parker and you'll discover that there really isn't the conflict that is essential to any case where the doctrine, so-called doctrine, of Parker against Brown is to be applied.

MR. HYMAN: Okay. I have a question for Dr. Kizer. It relates to the NQF. As I listened to your description of what NQF does, I kept hearing public good, public good, in the sense that economists use that. And so it was interesting, certainly, to hear that the federal government is not all that keen in funding you and is encouraging you to seek out private funding for your efforts, when the characteristic of a public good is that they are under-funded by private sources.

So I guess I have two questions I'd like you to at least talk about. One is the extent to which you have been successful at attracting private funding, and two is, to the extent you know, how other standard-setting organizations are financed, the other 18,000 or 1800 of them that you had mentioned. I've lost a decimal somewhere.

I thought you mentioned that standard-setting organizations are very well-known. There are lots of them out there in other industries. And how are they financed, if you know?

DR. KIZER: Let me first -- perhaps if I said it incorrectly, the federal government has been a very good customer and they have been perhaps our principal customer. They have acknowledged that for many of the projects they've funded, though, that they would like partners to step up to the plate.

And to date, that has been -- it's hard to find many instances where that has materialized. A number of foundations have contributed their funds to the work or are paying for contracts that we have underway. But as far as either unrestricted grants or other sorts of things, they have not yet materialized.

We recognize that we came about during a downswing in the economy, which certainly hasn't helped in this effort. And we'll see where it goes in the long term. But much of what we do -- I mean, clearly it is in the public good. I mean, it falls in the category where -- and I know there is interest in a number of our members in pursuing a strategy of perhaps more dedicated federal funding since what we're doing benefits, certainly, a variety of federal programs who are either providing funding for care or directly providing care or otherwise involved in the health care process. So it benefits those entities directly, but also benefits all the public. So it does, in fact, meet

the general good of what is in the public good.

In some ways, the work that we're doing is on a much higher timeline. If you compare our process and the degree of transparency, accountability, and rigor of our process against, say, some of the ANSI or ANISTA, we have a more explicit process laid out. It's very clear, or it's clearer, how things are done. And we typically talk about accomplishing work in a period of months as opposed to years.

My experience with ANSI and other groups is that they are paid for usually by the members, who are directly involved or who have a direct and material interest in the standards being pursued, and that those often take many years to accomplish. What we're trying to do, I think it often has a much greater sense of urgency associated with it.

MR. KELLY: I'll throw this out to the panel generally. Dr. Lyon expressed concerns that the certified nurse specialists have about the state nursing association's role in multiple areas where they set standards, develop tests, and then market the tests. And in some ways you can understand where those concerns come from.

My question is, in terms of a Noerr-Pennington problem with the association, the state nursing

associations group, advocating that they be permitted to do these things and that these tests be put in place, even though that is, in a sense, advocating for possibly anticompetitive benefits for their own members, isn't that something that they're entitled under Noerr-Pennington to do? Or should there be some limits on their ability to lobby that?

DR. LYON: Just to clarify, the association that we're concerned about, again, is not -- it's not state nurses association, but the National Council of State Boards of Nursing, which we referred to as an association rather than a regulatory -- it is an association rather than a regulatory body.

MR. DELACOURT: I guess my analysis there would be the relationship between the association and the state board or other authority that is actually passing the requirement into effect.

And I guess perhaps the distinction would come back to this issue of what in fact constitutes petitioning, and whether the government authority is really doing anything or whether they are just ministerially passing on what the private association has done.

DR. LYON: Right.

MR. DELACOURT: I think if you have a situation

in which the private association essentially works with its members and establishes a rule and then passes that on in a recommendation that is merely put into effect by the government authority, you may have a situation in which that is not petitioning. And I think you've got an analogy there to the tariff-filing cases, in which the private associations decide what the rate would be and then merely file that with the government authority.

However, if there is a lot of political content to what the association has done, that may be a tougher row to hoe.

MR. HYMAN: If I could follow up on that question, and this is just revealing my ignorance of the consequences of the different ways that this can come out. But is what's at stake here whether one can hold oneself out as a clinical nurse specialist, or whether one can perform as a clinical nurse specialist, or both?

DR. LYON: Both. Both.

MR. HYMAN: Okay. And what are the consequences of not taking an exam that doesn't exist and then advertising and performing? Are we talking professional discipline that will result? Revocation of license?

DR. LYON: Revocation of license.

MR. HYMAN: Revocation of license? Okay.

David, did you want to -- okay. I actually had a question now for Dr. McClure. And I guess the first question I wanted to ask you is, you made the point several times during your remarks that the American Dental Association has economic interest in the continued use of amalgam through their branding program, for lack of a better word.

And I guess the question that I would have is, assuming that there's an alternative material available, are you aware of a reason why they wouldn't similarly have some economic interest in branding the alternative material --

DR. McCLURE: They do.

MR. HYMAN: -- and collecting fees for doing that as well?

DR. McCLURE: They do. They have it with all materials. I mean, unlike the AMA, the ADA puts their seal of approval on certain materials that go through their process. And my point is that that inherently puts them in a different position. It also gives them -- gives this particular issue, as far as the dentist and our patients, a certain safety that we've looked at this process and we've endorsed this material.

MR. HYMAN: No. I guess I understood that part. Let me start with a narrow question, though, which

is, does the ADA have a similar branding arrangement with the materials that mercury-free dentists use?

DR. McCLURE: Absolutely.

MR. HYMAN: Absolutely?

DR. McCLURE: A full range of materials are looked at by the ADA, not only just filling materials but impression materials and other things.

MR. HYMAN: Well, then, I guess the obvious question that I would have is why are they sort of unenthusiastic about dissemination of information about the full range of options when they have branding and presumably royalties or license fees regardless of what filling material is used? Have you ever discussed that subject?

DR. McCLURE: I think it's a political problem, and I think it's an economic problem. I think that the liability for -- I mean, what's evident here is that the liability that the organization may have for any type of promotion of mercury, and the toxicity that may result from that is something that is something that is of concern.

So that's my reason -- I mean, you're giving my --

MR. HYMAN: No. I understand. I'm asking you for what their position might be, but --

DR. McCLURE: Yes. I think it's trying to keep the lid on the pot.

DR. LYON: Before we -- David, could I go back to the National Council of State Boards of Nursing for just a moment? And just to again reiterate, for clarity purposes, that this National Council of State Boards of Nursing produces testing products that are sold to state boards. So this association has an economic vested interest in creating requirements that, in essence, will generate income for them, and then requiring state boards to, in essence, purchase these products and use these products.

So, I mean, it puts another wrinkle in in terms of what our concerns are that I addressed in my presentation but didn't spend a lot of time on. I mean, does that not raise another concern?

MR. HYMAN: Well, let me ask a follow-up question to that before I try and answer it in the long-standing tradition of law professors of answering questions with questions.

DR. LYON: Which I'm not.

MR. HYMAN: But I am. You said that NCSBN requires the individual state boards to use these tests. Is that correct?

DR. LYON: Correct.

MR. HYMAN: But is it exclusive, that is, they prohibit them from granting authorization as a CNS on anything for which there is not a test?

DR. LYON: Yes.

MR. HYMAN: And what's the sort of political dynamic within the state that is looking at the loss of individual CSNs?

DR. LYON: Clinical nurse specialists.

MR. HYMAN: Nurse specialists, yes.

DR. LYON: Well, the dynamic varies. And frankly, I didn't get into this in the testimony, but when state boards of nursing have advanced practice nurses on the board, 98 percent of the time that advanced practice nurse is a nurse practitioner. Sometimes they're a psychiatric clinical nurse specialist, but that's pretty close to a nurse practitioner.

And those individuals, unfortunately their lens is pretty narrow. And there's a political difficulty here in that they view the future of the discipline as being nurse practitioner practice, and in essence substituting for the practice of physicians, and not clinical nurse specialist practice.

MR. KELLY: This would go to John and Meredyth. We talked a little bit about physician collective bargaining and some of the problems that that can result

in. Obviously, that meets the first standard. It would take explicit legislation to authorize it. But the active supervision could be extremely difficult in terms of how the state would supervise the process of the physicians negotiating.

But my question really relates more to a related issue. I've had physicians tell me on several occasions that rather than collective bargaining for the actual price they're paid, it might be better for them if they could simply collectively deal with the government and some of the private payors in regards to how they're treated in non-economic issues -- timely payment, standardization of forms, and those kind of issues.

And I'd just like to see what John and Meredith see about the problems with implementing that kind of a program as opposed to a full-blown physicians collective bargaining.

MS. ANDRUS: Just to clarify what the question is, the physicians then would collectively bargain with the government? Is that what you're saying?

MR. KELLY: They're saying not to collectively bargain, but just to work together to resolve paperwork issues and standardization issues with the government and with large insurances, not the actual economic factor.

MS. ANDRUS: I mean, I may be dense, but I'm

not seeing a problem with that.

MR. DELACOURT: I would second that Meredyth is indeed not dense, and also note that that argument frequently comes up with these pieces of legislation. And the way we've dealt with it is to suggest that if the physicians are merely interested in coordinating on factors that don't affect price, then an antitrust exemption is not necessary.

And furthermore, these types of arrangements, including messenger model type of arrangements, have been endorsed by the FTC/DOJ guidelines on health care, or the health care statements I guess is the term for it.

MR. HYMAN: Meredyth, when you spoke, you made a point that in Maryland, the board is counseled by a state AAG, and further, that Maryland is the only one that actually does this. And I guess the obvious question that raises is what's going on in the other 49 states, given your involvement in the National Association of Attorneys General?

I wonder if you could speak about that a little bit, and then talk about the risks of alternative models from the one you've outlined.

MS. ANDRUS: Okay. I can generally. I can generally. My understanding is that the attorney general for the most part does represent the state licensing

boards in other states. To that end, if each is -- I don't know the answer to this, but if each is assigned an assistant attorney general in their respective health departments to counsel the boards, that's great.

What I was saying is unique about Maryland that I am fully confident is not going on in other states is an ongoing instituted program whereby the antitrust division goes to the boards and says, you guys got a problem or potential problem and this is how we're going to fix it. That's what I'm thinking is not happening in other states.

And the risk of that is -- I mean, there's a couple of problems. First, your AAGs, who are counseling the boards on contract issues, on promulgation of regulations, or whatever it is, are not versed -- they're not -- they don't understand the antitrust laws. So they would not necessarily recognize a red flag if it was raised in the course of counseling the board.

Our assistant attorneys general in Maryland do know when to call me and say, we have a potential problem, because I've been on them for over ten years about potential anticompetitive issues that confront the board. And they confront them over and over again because you have a revolving membership. So you have to keep educating over and over again about what the

potential pitfalls are and how not to run afoul of them.

In other states, I think that they do -- on a case-by-case basis, as a problem arises, the attorney general or the antitrust division or bureau or section or whatever it is would come in and probably take care of the problem, or represent them if they were sued. But I do not believe that they instituted an ongoing problem-shooting situation, which I think we're ahead of the game in that and I'm proud of it.

MR. HAVIGHURST: May I ask a question on that? Meredyth, is it your thought that your involvement in this activity constitutes active supervision of those boards for purposes of the state action doctrine?

MR. HYMAN: Clark stole my next question.

MS. ANDRUS: I know. I know. Well, you know, we haven't articulated clearly what active supervision would constitute for this type of entity. But I certainly believe that I am actively supervising the board with respect to any issues that raise competitive concerns, yes. MR. HAVIGHURST: The question is whether you're giving policy advice or simply telling them not to violate the law and counseling them as to what it takes. And I think maybe you're a little in the latter category. But it wouldn't take much to have the attorney general office passing judgment in terms of

competition policy on some of these new regs that they're proposing, for example. MS. ANDRUS: Well, we do, Clark. We do review all the regs that go through before they go to AELR. That's the administrative and executive and legislature review part of the General Assembly. Before the regs get sent down there, they're passed by the antitrust division and we review those.

So I think we're closer to the active supervision than you think.

MR. HAVIGHURST: Yes.

MR. KELLY: I address this to John. John, you talked about several activities that the FTC might undertake as a result of the state action and Noerr-Pennington reports when they're prepared.

In terms of both of those, where do you see the greatest potential for improvement in prosecuting anticompetitive behavior if the FTC is able to fully implement their agendas?

MR. DELACOURT: Well, I guess before answering that one, I'll reiterate the disclaimer that these are my views and not the views of the Federal Trade Commission.

But one area has been already teed up with the last question posed to Meredyth about whether the AG's office in Maryland is engaging in active supervision. I mean, I think that's a very useful role that can come out

of the task force's efforts, and our recommendations in the upcoming report is to get the state AGs thinking about these types of programs. And if Meredyth could be out there carrying the banner or, you know, encouraging others in the National Association of Attorneys General to be talking about what sorts of conduct would provide adequate supervision, that would be great. And the reason I say that is that in our Indiana Movers case, we attempted to set forth the elements that real active supervision would entail, but we're kind of doing that at a very high level and we need input from the state AGs to say what the specifics would look like. I think they have a much better idea of how active supervision can be carried out efficiently and how it can be carried out with minimal burden. So I think that's one area where we can see a lot of movement forward. MS. ANDRUS: Can I second that, too, and also mention the fact that the states and the federal government, both the Department of Justice and the Federal Trade Commission, are working very cooperatively together. And I think that that suggestion is a very good one.

MR. HYMAN: Let me follow up with Dr. McClure. There's obviously been a fairly extensive array of private litigation about these issues against state boards and, I gather, the American Dental Association as

well. And you were involved, I gather, in one such piece of litigation in Maryland.

I wonder if you could just talk very briefly about how you all have fared in the private litigation, including the one that you were involved in.

DR. McCLURE: Could I refer to Charlie Brown to --

MR. HYMAN: Well, why don't we start just by talking about the one you were involved in.

DR. McCLURE: I believe that's in -- I believe that's been -- I'm not sure. I'm not a lawyer so I'm not sure about the legal terms here. But I believe that's been put aside. I don't think that's proceeding through the courts right now, the one that I'm involved in.

MR. HYMAN: Okay. And that terminated how long ago, if you recall?

DR. McCLURE: I think it was in the last year.

MR. HYMAN: The last year? Okay. Let me follow up on that question and just a somewhat more narrow one. As I understand the various ethics rules that the American Dental Association has, and I'm not going to get the language exactly right, but their position seems to be that it's unethical or fraudulent for a dentist to advise a patient that the fillings that they have should be removed and replaced with mercury-

free fillings.

DR. McCLURE: Or they could be toxic to them.

MR. HYMAN: Or using the magic -- what we in antitrust call the nine no-nos, the language that is problematic. Maybe we should put it that way. But they've also sought to limit advertising just generally of mercury-free dentistry?

DR. McCLURE: That's correct.

MR. HYMAN: Now, do you see a distinction between patients who come in needing fillings and the option is given to them at that time, versus patients that come in with fillings and the dentist counsels the patient about the, from your view, toxic nature of those fillings?

DR. McCLURE: The problem is that a patient coming in with the request to the dentist to be able to remove fillings, the dentist is perfectly able to be able to proceed on that from an informational standpoint as well as a, you know, procedural standpoint.

But the dentist is not able -- as I read the ethics rules and try to abide by them, the dentist is not able to mention the toxicity of mercury if that's not brought up by the patient. So it puts an uneducated patient at a decisive disadvantage to be able to advance that agenda.

Secondly, it puts the dentist who is -- that is involved in these issues at a disadvantage to be able to promote the fact that they're mercury-free outside of somebody bringing the issue to them. And so for that part of it, I mean, that's the major point that I'm trying to make, is that the consumer is left in the dark. This scientific and academic debate is being squelched by -- you know, in my -- by the ADA in this particular situation.

MR. KELLY: How would you deal with a patient who came in and asked what kind of filling he could get, and you tell him, you can get the mercury or the other, and he says, well, gee, which one is better for me? I mean, are you allowed to --

DR. McCLURE: Sure. Once they bring it up, I'm allowed to take care of that, to answer the question. And in my situation, since I've been mercury-free for 20 years, I have a different population base that comes in to me. However, I'm kind of carrying the banner for people that are just getting into this process that don't have -- that don't realize, you know, that this person -- that they have a choice.

MR. KELLY: I'll get back to John. That was an excellent answer on the state action part of the question. Let me give you a chance to give us a response

on the Noerr-Pennington side.

MR. DELACOURT: Right. Well, I guess on the Noerr-Pennington side, I think perhaps the development in the law there that would be potentially the most useful would be clarification of the continuing existence of an independent misrepresentation exception.

I think right now establishing that a piece of litigation or some other petitioning effort is objectively baseless is so difficult that those sorts of efforts are virtually never successful. And so scaling that back to a misrepresentation analysis I think not only will achieve the result we're looking for, but in addition to that I just think it's properly related to the goals of the Noerr-Pennington doctrine.

The Noerr-Pennington doctrine is directed towards protecting communicating with government, and those are viewed as having some sort of political content. But when you've come to the position of filing a lawsuit or otherwise engaging in petitioning that is infused with misinformation and misrepresentations or key omissions, I think that clearly that sort of conduct no longer really has any bona fide political function and really can be viewed under the auspices of the antitrust laws.

MS. ANDRUS: One additional clarification to

Noerr that I would love to see is in the context of the patent and generic pharmaceutical litigation, the patent infringement lawsuits, where the two parties settle an infringement suit and then take the settlement and have the court essentially rubber-stamp it and then call it therefore Noerr protected. I would like to see that particular position disqualified as deserving of Noerr protection.

MR. HYMAN: I've got another question for Dr. Kizer. When you described what NQF does, it sounded like they divide broadly into two distinct categories. One is developing performance measures and the other is developing standards for treatment.

And I don't have a sense of the sort of comparative size of those two categories, but my question is really directed at the second category, that is, treatment standards or guidelines. A complaint that we've heard repeatedly is that there are too many guidelines out there, and the problem is figuring out which ones you should use, and particularly when you get into a litigation setting.

But the specific question I wanted to ask you to address is the comparative advantage of NQF in developing defensible guidelines or standards. You've already spoken of one, which is the speed with which you

can develop them. And I just wanted to give you an opportunity to talk a little bit more about NQF's advantage in developing these things.

DR. KIZER: Yes. Let me clarify some terminology there. First of all, we have not engaged in actually developing treatment guidelines or quality of care standards, if you will. By definition, as a voluntary consensus standard-setting body, what comes out of our pipeline are consensus standards. That's often confusing to the provider community because those are often confused with -- the consensus standard may be a performance measure or quality indicator or other terms that often have just -- have different meaning based on nuances of language but are not really quality of care or standards of care, which is what people often think of in terms of standards.

So we're not engaged in that. The endorsing -- and likewise, while we have recently taken on some projects to develop some performance measures, most of our work is focused on endorsing performance measures that either are tied to national priorities or what will reasonably be expected to be national priorities when those are set, where there is an evidence base supporting them and some other criteria.

There's a plethora of standard-setting groups

out there. One of the problems is that there are so many that there's a lot of confusion. I hope that we can contribute to this by endorsing a set of national performance measures that has agreed-upon specifications, et cetera. These standards will both reduce the burden and increase the value and the meaning of what comes out of that pipeline because they will have been agreed to during the endorsement process.

MR. KELLY: I'd like to do a follow-up back to Dr. McClure. With your litigation that you were involved in, you indicated it's no longer going through the court system. How did it end?

DR. McCLURE: I'm not versed in the legal -- I believe that it was put -- you know, the legal term for it, it was dismissed, probably, or it was put aside because there wasn't enough -- they didn't feel that they should be getting into the -- there wasn't enough value for them to enter into the argument, I believe.

MR. HYMAN: It was dismissed on ripeness grounds. Mr. Brown is helping us on the record here.

I have a question for Professor Havighurst. In your PowerPoint, you had one slide that said you thought the governing body of is the public hospitals should oversee staff actions. And I guess the question I wanted to ask was how, and somewhat more tendenciously, why?

Obviously, leave aside the antitrust elements of it. But the logic of delegating these sorts of things to medical staff in the first place was a lack of expertise and knowledge on the part of the executive body of the hospital. So if you don't like "why?" I think you can just focus on the "how?" part of it. And then explain in a little more detail what the governing board is going to be able to do to prevent the anticompetitive possibilities of having the medical staff making the decisions.

MR. HAVIGHURST: Sure. You recall that I said that I think this is both a requirement of subsequent antitrust law as well as the state action doctrine. It would apply to private hospitals as well as public ones. And so the question you ask is, well, what should boards do to minimize the risk to competition posed by putting the doctors in charge of their competitors' access to the hospital?

Well, there are a lot of things. I mean, each case presents a different set of problems. Sometimes the issue is what happened in the operating room on the night of such-and-such, and you have to interview the nurses and you have to -- and the stories go on and on. And you can rely on the medical staff for their version, but it might also be useful to have a committee of the board

talk to those nurses and see if the true story is the one that they've been hearing from the doctors.

Sometimes, in getting -- making a judgment about whether a doctor is competent or not, it would be useful to get an outside doctor's opinion, get somebody else to review the charts and see if the medical staff's view is the same as the outsider. There are probably many other things. It depends on the case. But what you're looking for is conscientious attention by the board to the interests of the hospital the board should make sure that the doctors its getting are good doctors, that they are doctors that it wants for its own commercial reasons.

I've seen cases where the medical staff wanted to get rid of a doctor, but he was a big admitter. And the board might have had a very different view based on the economics, the incentive presented by the chance to get all these patients. There's a tradeoff there, but the hospital's judgment is more reliable, to my mind, and more appropriate than that of the medical staff. I think there's a lot a board can do and the conscientious counsel could tell the board how to handle each case to make sure they're doing their duty. And on the other hand, if you've found over time that your medical staff is highly reliable, then you don't have to do as much.

But I think there is a need for that oversight, both as an antitrust matter and as a state action, community matter.

MR. KELLY: How would that be different in the case of a private hospital?

MR. HAVIGHURST: I don't think it would be much different. The question you're asking is a little different, but I think the private hospital can escape virtually all of the antitrust risks that are involved in credentialing if the board has taken its responsibility and made a hospital decision in the hospital's interests on the matter.

And I think those cases should be dismissed summarily if the hospital has done its duty in that regard. Most hospitals historically have not, but this is a way in which antitrust law can make sure that hospitals are taking charge of this matter in the ultimate sense, relying on their doctors for advice but not letting them call all the shots.

MR. KELLY: I guess my follow-up question would be even if you were to establish that as the case, you're always going to have some doctor come along and say, well, that's all true, but in my case they really conspired against me.

MR. HAVIGHURST: Yes. That's -- but that's

nonsense. I mean, the way to think about this whole thing is to think about the hospital and the medical staff are independent entities engaged in a joint venture. And they set up the joint venture using the least restrictive possible alternative, namely, that the hospital ultimately makes these decisions rather than the medical staff. So once you've set up that decision-making process, and assuming you follow through on it, then these cases -- there's no conspiracy. There's simply a joint venture doing its job, running a hospital with medical input on one hand and the hospital's inputs on the other.

And I guess those cases ought to be thrown out real fast if the hospital board has done its duty and can show that it exercised independent judgment. That defeats the conspiracy claim. And it should be possible for counsel to tell the board what it takes to defeat that claim and get the hospital board then to do its duty.

MR. HYMAN: Well, the two Davids have lots more questions, but we've colluded together and we're going to let each of the panelists speak briefly, quite briefly, to sort of round this out. So we'll do it in the reverse order in which people spoke. So Dr. McClure, if you had any brief closing remarks that you'd like to make.

DR. McCLURE: Well, just in summary, when you have two competing interests in any professional organization, you're going to have problems. And in our situation, you know, I can see that through the dental -- the American dental societies. There's a competing academic interest here or practice interest, and there are problems. And I think that the -- I think the FTC has a legitimate concern to try to make sure that the public doesn't become a victim of that.

MR. HYMAN: Thank you. Dr. Kizer?

DR. KIZER: I don't have much to add to what I've already said. I appreciate the opportunity to be here and I hope the Federal Trade Commission as well as the Department of Justice will look to the forum as a potential resource when it's wrestling with some of these issues in the future.

MR. HYMAN: Dr. Lyon?

DR. LYON: Just to summarize briefly, again, we have concerns about the National Council of State Boards of Nursing establishing policy that they're mandating state boards to adopt that is based on really nothing more than opinion, not fact. Additionally, we are facing competing interests in the discipline. Currently clinical nurse specialists are being substantially denied economic and professional opportunities in the

discipline, with their license as an R.N. being threatened. And these are grave concerns of ours.

MR. HYMAN: Meredyth?

MS. ANDRUS: First, I want to applaud the Federal Trade Commission's task force on state action and Noerr-Pennington immunities. I think that's excellent work being done and will clarify some issues for all of us, both prosecutors and defense counsel for the state.

One issue that I think is left unresolved in my own mind, and the discourse with Professor Havighurst has got me thinking a lot now about the clear articulation requirement of Midcal for licensing boards. And Professor Havighurst, I haven't decided whether clear articulation -- I mean, clear contemplation is too much and reasonably contemplated is too little, but perhaps it's somewhere in between.

MR. HYMAN: Clark?

MR. HAVIGHURST: Well, that's progress. I appreciate your letting me participate in this way, and I hope it's been not too inconvenient or difficult to follow. I've gotten a good deal out of it at this end, and I guess I would say that the staff's work is highly timely. I think these are interesting and important problems and the FTC is just wonderfully positioned to clarify some things that have gotten quite

confused. And I'm glad to see this effort, and I'll look forward to the report.

Now, if there's anything I can do in the meantime, I'd be glad to help. If the staff wants me to clarify anything I've said or embellish my thoughts, I'd be glad to do that. But I will look forward to seeing what they produce. Thanks for letting me be involved.

MR. DELACOURT: Like the other panelists, I'd like to thank you for inviting me to participate. I guess as a final thought, I would like to note that both the work of the state action task force and the Noerr-Pennington task force are motivated by the premise that both of these immunities have been expanded too broadly.

And I think that, you know, perhaps it's too simple, but one way I think that we could get back to the appropriate scope of these immunities is to import a notion from the constitutional law context, which is that of narrow tailoring. And if we look to the political objectives that are sought to be advanced by these two different immunities, in the case of state action, that would be advancing the state policy, and in the case of Noerr that would be advancing the right or protecting the right to petition. I think we can get back to the place we need to be by looking to see if particular efforts or particular regulations are narrowly tailored to advance

those objectives, or whether they've been inappropriately expanded beyond those goals.

MR. HYMAN: David?

MR. KELLY: I'd just like to take this opportunity to thank all the panelists for taking time out of their busy schedules to join us today. And just add as a belated disclaimer that if anyone thinks they construed a point of view from my questions, I assure you it's my point of view and not that of the Department of Justice.

MR. HYMAN: I associate myself with David's remarks, although substitute Federal Trade Commission for Department of Justice and we're there. I'd like also to thank all of the panelists, and ask you to join me in a round of applause.

(Applause.)

MR. HYMAN: And we will reconvene at 2:00 to discuss long term care issues and consumer information.

(Whereupon, at 12:31 p.m., a lunch recess was taken.)

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

MS. MATHIAS: I'd like to try to start on time and end on time. It's to the benefit of the audience, which includes people listening in on the -- we do have a teleconference call-in number that people are able to listen in on. And we think it's important to everybody's schedules to stick to a schedule.

Like I said, or at least I hope I already said, welcome. We are glad you are here today at the FTC/DOJ Health Care Hearings on Competition Law and Policy. We are spending this afternoon from 2:30 to 5:00 -- I mean 2:00 to 5:00, excuse me -- looking at long-term care and assisted living facilities. And this does, of course, also include nursing homes.

We are trying to develop issues that look at the quality that's found in the long-term care situation, the information that consumers are able to find, whether there are better avenues to get that information to them, and the other issues that we have listed in our description.

I would like to introduce our panelists, who are very -- who without this we couldn't have a panel today. We don't spend a lot of time on the introductions because we want to spend more time on the questions and answers and the presentations. So we do have a handout

outside that has everyone's biographies in it.

But as a quick introduction, and this will be in the order of our speakers, we have Jan Thayer, who is the chair of the National Center for Assisted Living, and is president and CEO of the Excel Development Group, which manages Midwestern long-term care and facilities.

Next we have Keren Brown Wilson, who is president of the Jessie F. Richardson Foundation and an associate professor at the Portland State University.

Third is Karen Love. She's founded the Consumer Consortium on Assisted Living, which is a national education and advocacy organization supporting consumers of assisted living.

Fourth is Barbara Manard, who is vice president of the -- at the American Association of Homes and Services for the Aging.

Next is Toby Edelman. She's an attorney with the Center for Medicare Advocacy, advocating on behalf of the needs of nursing home residents.

And finally, we will be joined by Dr. Barbara Paul. She is director of the quality measurement and health assessment group at CMS. Her team's work is getting an award this afternoon, which she is accepting, so she's juggling her schedule and will be here just a little bit later.

Just a couple of ground rules, to make it all easier. For the panelists, when you come up here, this podium does lower and raise so that you can make it easier on yourselves to see the audience. There's a height button right here.

For the people who are listening in, it's very important that you speak into the mike, and also for our court reporter to be able to get all of your words and well-thought-out thoughts.

We will have a series of the presentations. We will then take a short break, finish with the presentations, and move into the moderated roundtable. I will be asking questions, and then we hope that it leads to a discussion among the panelists.

Sometimes the questions will be directed at a specific person; sometimes they'll be open-ended. One of the ways I find that makes it easier for me as moderator to make sure I'm calling on everyone is if you will turn your tent sideways, which I'll show you what that means. If you turn it like this (demonstrating), then I will not fail to recognize you and we can make sure that everyone's voice is heard.

We will, as I said, end at 5:00. If you could please turn off any cell phones so that they won't interrupt. I do find that it's kind of hard for the

speakers to -- maybe they're having a brilliant moment of revelation and they get interrupted. And so we do appreciate courtesy to them.

And also, Cecile, over to my right -- your left -- will be keeping time. She will put up a little notecard that says five minutes, then two minutes, and then time. We do like to respect everybody's property rights on this so that we can also make sure there's plenty of time for discussion.

With that, I think I've hit everything that I needed to, and so we will start with Jan Thayer. Thank you.

MS. THAYER: Thank you, Sarah. Good afternoon, ladies and gentlemen. It's a pleasure for me to be here today on behalf of the National Center for Assisted Living.

My name is Jan Thayer, and I have been a provider of a variety of long-term care services over all of my professional life, dealing as I am, as a trained registered dietitian and also as a nursing home owner and administrator. I no longer own the nursing home, but have now moved into the ownership of assisted living and retirement communities, and also as the president and CEO of a company that manages, develops, and consults with assisted living facilities and other kinds of retirement

communities. So indeed, it's a pleasure for me to be here today.

What I would like to bring to you is a discussion about the long-term care spectrum and the role that assisted living plays in that long-term care spectrum. Obviously, you see that for most of us, we spend a lot of our life in independent living. However, as we move into our later years and as we begin to see our needs increased, we enter many times into independent living on a retirement campus.

There are a variety of services that are supportive that can occur at that level, but most of them begin to occur as we see the second and third box. The acuity increases as we move to the right of the slide, with those services that are available to people in assisted living, where we still see lots of choice, where we still see lots of independence.

And when people come to me as I was sitting in the chair of the executive director for my facility, they would say to me, what's the difference between assisted living and a nursing home? And I used to explain it the best way I knew how to lay people who were shopping for the first time: In assisted living, we assist you to take care of yourself. In a nursing facility, primarily we take care of you.

And I found that the public understood that. There was lots for them to read and lots for them to absorb, but that, I thought, was a phrase that they could take home and remember.

Obviously, when we have needs that are so increased that we cannot meet those in an assisted living facility, along the long-term care spectrum the next logical step is the nursing facility and then the sub-acute and moving on to the acute care area. We also know that there's a very large place in the long-term care spectrum for home care, adult care, hospice care, all of the variety of community-based services that can be brought in.

It would be interesting for you to know that there are about 36,000 assisted living licensed residences in the United States. The average residence houses 40 to 50 residences, but many are much smaller than that. We see lots of three- and four-bed units. And we see those that are very small, very homelike, in fact, take place in a building that looks like a large family home that maybe our grandparents occupied at one time in their lives.

Statistically, it shows that about 60.5 percent of the units that are available for folks are studios. That means that they are simply large rooms, but they are

private rooms, almost always with a private bath. And that's what people like about assisted living. About a third of them are one-bedroom, and then a little over 8 percent are two-bedroom.

Our statistics tell us that across the country, there is about an 87 percent average occupancy rate, and that it costs about $26,000 a year to live in these facilities. However, fees can vary, and that is something that we emphasize that people need to find out when they're doing their search and their comparison. This fee schedule varies quite significantly depending upon whether it's in a rural area of the country or a more urban area of the country.

I want to show you some pictures of some typical units in which we are involved, our company has worked with either development or ongoing management. This is a facility in Lincoln, Nebraska. It houses about 68 residents, and we do have double occupancy. And this is, as you can see, a lovely building. It's warm and welcoming on the inside.

One of the differences that we're seeing in nursing facilities and assisted living is how many of their own furnishings people are able to bring with them. And this is a living room in one of those. You can see -- here's a -- in this picture, somebody has even

brought their own collection of dishes. This particular facility is -- and you might see those lacy curtains at the window. This is in a Dutch community in Orange City, Iowa. There are those curtains again, in their bedroom.

Typically, we serve meals to folks in a dining room-type setting, restaurant-type setting. And we do lots of other things that are fun. Here's Main Street, and it actually is built to look like an outdoor Main Street, where you have storefronts. And, of course, we have to have the beauty/barber shop.

One place I visited called this the magic shop. And I said, why is it the magic shop? And they said, well, because you go in looking like you do on a bad hair day, and you come out and you're magically transformed. This is the magic shop. And, of course, who could do without ice cream and popcorn?

We're going to spend just a little bit of time talking about the activities of daily living. ADLs, we talk about, those of us that are in this business. Eating, bathing, dressing, toileting, and transferring are the things that people begin to need help with as they age.

And it might be an interesting tidbit for you to know that bathing is the most common activity of daily living that nursing home residents and assisted living

residents both need help with, in varying degrees, but that is the one thing that we see in common, along with the other items, but that the most.

Transferring, we simply mean being able to move from one chair to another, or from a chair to a bed, or to get up from bed in the morning.

There are approximately 900,000 assisted living residents, of whom 69 percent are female. The typical resident, about 83 years old, needs assistance with 2.25 ADLs. However, it's interesting to note that 19 percent require no assistance whatsoever.

Nearly two-thirds of these folks have incomes of $25,000 or less, and so if we look at the -- and remember the statistic on the previous slide, where it costs about $26,000 to live in a facility, one of the challenges we have in this country is to find a way to provide affordable assisted living for many, many of our residents.

Where do residents come from when they move into assisted living? The majority, as you see on the slide, from home. Other assisted living facilities. Hospitals. Nursing facilities. Skilled nursing. Independent living. And all of the rest of that percentage, which is about 3 percent, is made up from other sources. And the NCAL 2000 survey is the source of

this information.

What happens when residents move out, or why do they move out? There are about 33 percent who go to a nursing facility. Twenty-eight percent actually die in the assisted living facility. Go to, about 14 percent, to another assisted living. Twelve percent get better and go home. Eleven percent to hospital. And other, 2 percent.

The average length of stay is two to three years. Depending upon the source of information that you look at, you'll find that to be the average across the country. And certainly it's borne out in our own facilities.

Multiple factors can determine whether a consumer chooses an assisted living facility or a nursing home. Both settings provide assistance with activities of daily living. Both also offer varying degrees of health-related services. But it is often the level, the intensity, and the frequency of health care services that differentiate an assisted living facility from a nursing home.

So if we look at the dependence, you can see the numbers and the percentages there for yourself that even -- you see, as I stated before, bathing is the most common ADL for which residents need assistance. But you

can see from what I said the intensity is that which changes.

On the other hand, how about the activity of daily living independence? About 28 percent of people can bathe themselves in assisted living facilities, while only 6 percent in a nursing facility, and on it goes down the line. As I said, only about 2.25 activities of daily living we need to assist people with in our assisted living facilities, where that's about an average of 3.8 in a nursing facility.

It also would be interesting to you, I think, to know that nursing homes and assisted living facilities vary in nature depending upon the state in which they're located. They also vary depending on the overall policies and procedures of that assisted living facility. We insist and coach our people all the time with not only what we publish but in all of our communications, how important it is to be able to carefully spell out what it is that our facility does.

Only about -- about two out of every three nursing home residents require and depend upon Medicaid to help support them in a nursing facility, while another 10 percent rely upon Medicare. And conversely, only about 10 percent of assisted living residents receive any kind of support through government assistance.

Typically, that's SSI payments and Medicaid, based on our statistics.

What are the forces that are driving the long-term care marketplace? The age of the elderly and senior affluence. People are growing older faster than ever before in this country. They are living -- I hear people say to me all of the time, I didn't believe I would ever live to be this old. And that's happening not only in the United States, but in lots of areas of the world.

There is growing consumer awareness of long-term care options. People know what's out there. Fifteen years ago, when I opened my first facility, I had to explain to doctors what an assisted living facility was. People are becoming very, very good shoppers and very well-informed.

There are changing consumer preferences for how and where care is delivered. People want to make their own choices, and that's only going to be enhanced. I laugh every time I think about how the singalongs used to be conducted, with us singing, "Oh Susanna." What we're doing today, and I suppose in ten, twenty, thirty years, we're going to have to be playing hip hop music at the intersections because that's the only place I hear it now, and I suppose I'll want that when I go to a facility.

Seniors are less disabled today than they used to be. We know that according to the study published by the National Academy of Sciences in the USA, seniors have become an average of 15 percent less physically disabled in the last 20 years, meaning there is a lesser need for the highest of medical care options for them. We are beginning to say it makes sense for us to take care of ourselves.

The assisted living work group was a two-year exercise that was -- just finished its work. And any discussion of assisted living must be prefaced by mentioning this report. It was about assisted living quality, and it was presented to the U.S. Senate Special Committee on Aging on April 29th.

In 2001, then-chairman Senator John Breaux asked assisted living stakeholders to develop recommendations designed to ensure more consistent quality in assisted living and in those services nationwide. And as a result of this, the assisted living workgroup was organized with nearly 50 organizations, stakeholders representing providers, consumers, long-term care and health professionals, regulators, and accrediting bodies.

Meetings began in 2001, and a report was presented that was entitled, "Assuring Quality in

Assisted Living: Guidelines for State Regulation, Federal Policy, and Operational Models." And many of those recommendations adopted by the ALW related to consumer protection, and we'll reference those today.

In 1999 there was a report issued by the General Accounting Office that found that some assisted living providers were not disclosing all of the information deemed important for consumers in order for them to make informed choices when choosing a community. The assisted living profession took that very, very seriously, and in order to be able to answer that, NCAL did some important things. One of them was to issue "The Power of Ethical Marketing," which is part of our testimony.

The kind of disclosure that we believe in builds trust between the residents and the consumer, and marketing materials are extremely, extremely important. Here's an example of another kind of document that we have produced in order for us to be able to inform our marketers when they are out looking. That brochure is enclosed for us.

The American Health Care Association and the National Center for Assisted Living have a number of consumer websites in order for consumers to tap in and see what they can learn. And we have many, many hits a

month on that.

There are various state regulatory issues and approaches. Several models of assisted living exist in response to consumer demand. And these expectations are change as new generations of elderly need services. Here is something that's also in our testimony, which is a state-by-state comparison of regulations as they exist today.

Defining quality, which is something that we're all about, is not simple. We say in our workgroup, and we say it in the National Center for Assisted Living, that it's very, very hard for us to judge quality because we don't have enough research yet. We promote research, and we're saying you are out shopping, how can you really determine whether or not what you're looking for is going to be met? It's a challenge to provide an environment where residents feel the greatest satisfaction possible and also have the greatest kind of independence.

So are we to judge on a process or an outcome measure? Despite the challenges that we have, we need to continue to look at how we're going to measure quality in the future.

According to a recently published issue brief, there are these kinds of issues that -- I see my time is running out, and I don't have time to explain all of them

to you. But there are some realities of growing old which leave a potential conflict between external and internal uses of customer satisfaction.

There are things that are going to happen as we grow older. Our health is going to decline. We can't cure old age. And so we have to be very sure that we communicate exactly with family members, with others, so that we can define what it is that we are able and what we are not able to do.

Despite challenges, the outcome measure will be critical. And we want to be able to find several states who are interested in testing some of the theories that are out there. Some processes are absolutely important. They will always be measured by state regulators. But the outcome process and what we measure may not necessarily be that which provides customer satisfaction.

As a registered dietitian, process is important to me when I say food needs to be stored safely. It needs to be prepared safely. It needs to be served safely. But if I write a menu that my residents don’t like, when they do a resident customer satisfaction survey, they're still going to say that the food is terrible.

So there was -- I just want to tell you that according to a recently published brief, "Using Outcome

Measures" -- that there is a recently published article called "Using Outcome Measures in Assisted Living." It was prepared by Dr. Margaret Wilde. And she says there are currently two types of outcome measures used by assisted living residences: resident assessment interest instruments, and satisfaction surveys.

And she goes on to say that those two can have potential inherent conflict, and that we must identify areas for improvement that are candid, not based on giving the caregivers the guideline, the picture, for what they need to do to have a very good grade because then they will aspire to that, just like we did in college. Tell me what I need to do and I can give it back to you. Instead, we need to find a way that we can have candid, non-influenced feedback that will allow us to do the best thing for residences -- for our residents, excuse me.

I wanted to go on to say with the last slide, choosing a lot of -- choosing an assisted living facility requires a lot of involvement by the consumer and the family. It's a process that involves the choice of home and staff who provide services.

It involves being very candid on both sides of the issue, with what you need and what the person can provide. And if you refer to the assisted living

workgroup, you'll see that there is a whole variety of bullet points there stating that we recommend to each of our providers, these are the things that they tell consumers when they come in to observe and to choose.

And in closing, I would say that a high involvement decision is one that requires in-person visits, being sure that you have all of your answers -- or questions answered, to observe personally residents and staff. Because it's a complex process. Individual values, needs, and preferences must always be considered by all of us when any time we are making a decision as important as choosing an assisted living facility.

Thank you.

MS. MATHIAS: Thank you, Jan.

And next we have Keren Brown Wilson.

MS. WILSON: Thank you. I was going to use PowerPoint, but I have a notorious reputation with messing it up. So I decided I'd better spend my precious few moments speaking directly to you.

In the name of time, I'm going to forego part of the written testimony that I have copies for you regarding specific reasons to the questions posed by the Commission. Rather, I'm going to spend a few minutes talking about some recommendations because I think ultimately that's what we're most interested in here

today.

I thank you for the opportunity to speak here today and to provide some of my thoughts on assisted living. As you know, my name is Keren Brown Wilson. And a friend of mine, Rosalie Cain, said, be sure to give them your bona fides.

So my bona fides are: I've been in this business 25 years. When I was working on my PhD in the early '80s, I had a conversation with my mother. And some of you that know me very well know about this conversation. But when I told her I was going to be a gerontologist, her first question was, what's that? And then the next question after I answered that is, she says, why don't you do something to help people like me?

Those were prophetic words in my life, which have guided both my personal and my professional life since that time. In the ensuing years, I have been an academic, a researcher, a CEO of a publicly traded company, a CEO of a not-for-profit charitable company.

I have been a direct caregiver, for my mother-in-law, for my mother, and now most recently for my sister. I have visited countless nursing homes, countless assisted livings, and I've had more than my share of experience with home care, and expect to continue to have those experiences as I move forward in

my life. So I think that I bring to the table today a number of perspectives. And I hope that what I share with you will represent what I have learned from playing all of those roles.

I'm not speaking for any association. I'm not speaking for any one person. I'm speaking from a perspective, a perspective that I hope shows how I believe that we have to look differently upon the issues before us today.

I do believe that assisted living is at a crossroads in its development, and I want to look today at specifically some recommendations about how to explore that. We just received some great statistics on assisted living. The ironic thing to me is that fifteen years ago, the truth of the matter is you could have discussed pet rocks with as much knowledge as you could have assisted living.

Today, you can read about assisted living in Reader's Digest, Dear Abby, and Consumer Reports. The growth has been phenomenal. It has, in fact, become now the new word for, I have to make a long-term care decision for a loved one. What should I do about assisted living? Not, what should I do about a nursing home, but what should I do about assisted living?

So what I want to talk today are five specific

recommendations. But first, I want to talk to you about something which I think has kept assisted living from evolving as we would like it to. And I think that unless we deal directly with these challenges, we will continue to be mired down in approaches that are not likely to yield us what all of us want, which is quality of care and quality of life.

What are those challenges? Well, it seems to me that they rest on five competing sets of values. And this is a theme that some of you may have heard me talk about before. But let me tell you explicitly what I think those competing values are and why I feel they are so important to assisted living.

The first of those is safety versus autonomy. Many of you know that I have studied and thought about this particular set of competing values for quite a while. But it is central to many of the discussions about regulation and oversight.

In our society, we want to maximize, which is virtually impossible. A good friend of mine, Bob Appelbaum, who is very well known for his work in quality and long-term care, said, what we want most for ourselves is autonomy, and what we want for those we love is safety. And that's very true.

The problem is, we seldom can have the maximum

of both. And yet when we approach how to deal with risk, how to deal with independence, how to deal with choice, we act as if we can. So we must find ways of dealing with the conflict inherent in maximum safety and maximum autonomy. The second set of competing values are the rights of the individual and the rights of the community. We're all familiar with the issue of resident rights. We're all familiar also with the concept of what it means to live in an institution or to work in an institution, whether that be a church, a school, a family, or other organization to which we belong. We find ourselves often wanting things or needing things that others don't care about, others don't agree with, that others find disruptive to their life. And we find ourselves having to balance what we want, what we prefer, what we need, versus what others want, need, and prefer.

And when people live on a long-term basis in a setting, those that live there and those that operate them face the same challenge of balancing competing and often conflicting desires, needs, and preferences.

The third challenge -- and this is really a difficult one that many states are experiencing a bitter lesson, including my own state, about how to deal with -- this is what I call the expectation of standards versus the ability to pay.

I've often said that we have champagne taste and a beer budget. Literally, many states are confronting so severe crisis that even minimum standards are at risk. And yet minimum standards do not satisfy many, or any. So the dilemma that we have is that we have and we want things that we are not or cannot pay for.

The fourth challenge that I think that we face, and despite the valiant efforts of the assisted living workgroup I believe we still face, is what assisted living is and who it serves. Many would say that a three-bed-unit house is not assisted living. Others would say that you only have assisted living if they have the capacity to deliver XYZ services. So we have not yet reached consensus at any level about what assisted living should be, how it should be defined, and who it should serve.

So having said that, then, let me suggest to you what I will put forth as a recommendation. And bear with me because now -- I want to read this part because I think it will go faster and I'll be sure to say what I want.

Recommendation one: Recognize the value of and continue to develop uniform disclosure forms. First we should recognize that efforts taken to implement a

strategy of using consumer disclosure forms have been a step in the right direction. These efforts were undertaken in response to the 1999 JO report, as it's called, for written information regarding cost, service agreements, discharge criteria, and grievance procedures provided to consumers before a contract is signed.

Many states have developed instruments to access this information. Industry trade associations have largely supported these efforts. I believe this tool can be useful for states to weed out sites that are willingly -- and I underline the word willingly -- engaging in fraudulent behavior, and help consumers think through their options in an organized manner.

But disclosure is not likely to ensure consumers fully understand what they are buying or answer questions about what it will really cost, how much control they will be able to exercise over their care and their environment, or when they will be told they cannot live there any longer.

Second: Recognize the benefits of negotiated risk agreements and continue to develop a mediation process for consumers and providers to address and reconcile differences in service delivery decisions.

A second strategy worth further exploration in relation to aging with choice, as some have begun to call

attempts by consumers to assert their rights to age in place and exercise greater decisional autonomy. This strategy calls for investigating the various forms of a negotiated risk process.

States such as Michigan, Louisiana, and Texas have already adopted legislation designed to facilitate this negotiation at one level by saying that consensus reached between physicians, consumers, and providers about specific individuals remaining in assisted living could be legally honored.

At least 28 states have incorporated negotiated risk language in their regulations governing assisted living, recognizing them as a potential mechanism to facilitate discussion between consumers and providers when disagreement looms over what the consumer wants and what the provider feels can be accommodated both in terms of autonomy and individual rights.

This approach has been a topic of considerable debate. Some of my colleagues believe negotiated risk to be dangerous, misleading, and serves to protect providers of any liability if harm results from poor quality care. Others think they're hard to do, harder to implement, and make enforcing rules of any kind harder. But to me, what is truly dangerous is a categorical refusal to recognize that quality in the truest sense can never be achieved

for frail, disabled, and vulnerable consumers if we do not find ways to systematically explore and address how to achieve consensus about what to do in individual situations to balance conflict.

Some have written about negotiated risk assessment, have stressed the underlying issues associated with legal issues. But I am more persuaded by ethical arguments that sees negotiated risk as a process that facilitates systematic discussion of choices, options, and consequences.

Having a written, signed agreement, in my view, should be a mechanism to remind parties of their discussions and agreements. These agreements are signed both by the provider and the consumer in acknowledgment that a consumer has chosen to continue or discontinue a certain service or care plan even though doing so may result in a negative consequence. Consumers agree to accept some responsibility for outcomes that may occur under the agreement stipulations. The guiding principle behind such written agreements is that risk is a natural element of adult life and successful negotiations can occur to ensure a higher degree of autonomy for consumers as they exercise their rights. This does not mean that providers are or should be exempt from providing high quality of care. Community standards of care must still

be considered and efforts made to reduce the likelihood of negative outcomes related to poor quality care.

Third strategy: Facilitate and encourage familial advocacy. A third strategy to utilize is encouraging increased familial advocacy. In my experience, nothing keeps providers more on their toes than those family and friends who come often and work collaboratively to address issues or concerns about the quality of care and life of those they love. Assisted living has created a place that families are much more willing to encourage their elders to use, based solely upon the environmental improvements. What we need to do is make sure it stays that way.

Research has shown that family involvement can have beneficial impact on the quality of life for assisted living residents and can also create positive experiences for the provider as well. By tapping into this resource and finding ways to motivate and encourage the involvement of families and friends, we can address the controversies of negotiated risk agreements and ensure a higher degree of quality both for individuals and for others who call assisted living home.

Fourth strategy: Retool the existing survey process to include quality of life measures and to more accurately represent the findings of surveys. Retooling

the survey process to assess more meaningful holistic measures of quality is important. Robert Mollock in his review of state regulations describes the overwhelmingly process-oriented nature of current state survey methods. While anecdotal evidence abounds, little empirical evidence exists about what the actual survey results indicate for assisted living. In my own work, the evidence suggests that the state surveys seldom address quality of life, and quality of care citations often focus on process measures such as food storage and records documentation.

To complicate the issue more, the integrity of severity rating systems, which classifies at-risk consumers, are based upon the citations issued during a survey, are compromised when restricted distribution of scores indicated in such scales do not act to discriminate among providers.

Further, many times surveys are done in a manner that raises appeals against the citations the appeals are often successful and the citations are ultimately removed from the record. Many accessing public records are not aware of how this process works and may place too much confidence in their accuracy. Yet to my knowledge, nowhere are consumers made aware of the limitations of such information. In my view, the survey

process should be restructured to more accurately measure quality of care and account for quality of life.

Particular attention should be paid to the over-reliance on so-called quality reports that do not establish more precise parameters. States should be encouraged to evaluate rigorously the quality of information they have gathered. Consumers should be encouraged to engage regularly in their own sensory test evaluation.

Fifth and last, train family members, consumers, personal advocates, and surveyors to holistically assess quality measures, including quality of life and quality of care. Make more training available to family members, consumers, personal advocates, and surveyors to comprehensively assess quality of care and quality of life measures. Prospective residents and their families should have access to information that helps them become better sensory surveyors to help them inform themselves of what is really happening in residences.

We need to recognize that quality of life is an equal component in the quality of care and general quality indicators, which means accepting sometimes that providers will have to make a tradeoff between safest procedure, yielding to the needs of consumers that they

themselves feel are more important and for which they are willing to share responsibility.

The importance of this recommendation is in the training of consumer advocates and surveyors for a new generation of elders who won't be accepting of regulations that ignore quality of life and their firm belief in the continued autonomy in later life.

Thank you.

MS. MATHIAS: Thank you, Keren.

And next we have Karen Love.

MS. LOVE: I'll try this height thing. I'm a little taller here, so we'll see how this goes.

I've had the opportunity of working in the long-term care arena for over the past two decades, in nursing homes, home health care, adult day, assisted living, practically every one of the spectrums. And one of the most incredible parts of all this is that it's all about people.

I mean, we talk about outcomes. We talk about measures, all of that kind of thing. But it is about people that we're talking about. And the ALW that we just finished in the end of April, preparing -- or presenting the report, one of the wonderful components of that was it was something about people, by people, for people.

Let me talk a little bit today about assisted living. Jan mentioned a number of these studies. One is a study that was led by Katherine Haas, the national study on assisted living. And in part of her report, she notes that 90 percent of residents believed they were able to stay in an assisted living residence for as long as they wished. And we know that's not accurate.

Most were also uninformed about a facility's policies on retention and discharge. In 1999, the GAO report found a number of items relating to marketing: One, that consumers generally relied on the providers for all of their information; secondly, that providers did not always give consumers information sufficient to determine whether or not the assisted living residence itself could meet their needs; thirdly, that the marketing material, contracts, and other written materials weren't always complete and they were sometimes vague; and lastly, that 25 percent of facilities routinely provided contracts before a resident moved in. So that means that they didn't really have an opportunity to review the material ahead of time.

As I said, that was in 1999. And I think there has been a lot of progression and movement forward in that arena. A lot of these issues are relevant to all sizes of the assisted living residences, but the majority

of the residences in the country are small, are ten beds and less. And those residences typically don't hire a marketing staff. The marketing function is done by an owner/operator.

The Consumer Consortium has run a national help line since 1998, and it has manned a website message board since the beginning of 2001. So we have an opportunity to hear from people all over the country about, you know, what their experiences are, what their concerns are. And it's been our anecdotal experience through those two arenas that the marketing problems most often occur in the larger facilities, not so much the smaller ones. And typically, when I say larger facilities, these would be 40 beds or larger.

And we think that to a large degree, the reason that is is because the way the marketing operations are designed. And four specific areas: One, that marketing staff often aren't well-oriented to the care function of the residence.

A lot of time and attention is spent on the marketing component, you know, selling the actual facility, but not really so much on the other side. So there's a gap in understanding of what the services and support are that residents can -- this is so hard for me. At ALW, we really wrestled over, you know, do we call

them facilities? Do we call them homes? What do we call them? We decided on residence, with a C-E, but it sounds so much like resident. Secondly, that marketing staff can feel pressured by management to keep beds filled. And this can lead to sometimes marketing staff giving promises in order to lure people -- lure isn't the right word, but to attract people into their facilities to keep the census up.

Thirdly, that a high turnover in marketing staff can create an environment where the staff aren't there long enough to really know the residence and the population and what it can and can't do.

And then lastly, that the size and volume of a facility itself makes it harder for the marketing staff maybe to spend adequate time. So, for example, a marketing staff for a facility with 40 residents will have more time to spend than one that is trying to fill a 90- or 120-bed facility. So sometimes it's just a matter of time available to spend reviewing contracts, et cetera.

The assisted living workgroup that we've referred to had a number of recommendations that came out of it that I think were really fantastic. One is that it requires all assisted living residences to have a written contract between the residence and the residents.

Secondly, all information, written or otherwise, conveyed by the facility should be consistent with the contract.

Thirdly, that all prospective residents have the right to review the contract prior to admission, and that includes having a third party, maybe an elder law attorney or somebody else within the family, have an opportunity to review it.

And fourthly, that the majority of the ALW felt that providers should not use a universal standardized contract. Instead the recommendation was: here are the key issues of importance the contract should cover, and then allowing the residences themselves to customize and add.

But just to give you a little bit of statistics why we feel, CCAL feels, it's important to have at least some guidelines, 28 percent -- according to Robert Mollecko's report, 28 states do not require any kind of written material -- or any information about resident rights in their written material; 30 states do not require any information on admission or discharge criteria; 34 states don't require any information on grievance procedures; and 36 states don't require any information on termination of contract provisions. So there really is a need to give some push to those states

or areas that aren't maybe as good about giving information.

We also discussed a recommendation to develop a model for states to use in producing consumer reports. And this, unfortunately, did not reach majority consensus. A minority felt that this was a function that should be done through the public regulatory agencies.

CCAL did support that recommendation, though. We felt that that was an excellent opportunity to provide more information and help make it a little bit more available to the public.

Going back again to my over two decades of experiences, my experience and belief is that what really fosters and sustains quality of care in a long-term care environment is caring, enlightened leadership. For this strength, the most important foundation -- or from this strength, the most important foundation is staff. And a strong leader has the skill set, typically, to select, develop, and promote a strong staff.

Effective leaders often say things like, I'm not that smart. I just surround myself with smart people. The people who are appreciated and valued tend to appreciate and value and stay with a company, all of which are stepping stones to quality.

You can't provide quality, consistent care when

you don't know your residents, you don't care about your residents, you're there just to get a paycheck, you're exhausted, maybe you've worked a number of double shifts, and you're concerned about paying your electric bill. So these things are really important considerations as we look at how we're actually running and operating these facilities.

I have had the opportunity to run assisted living and nursing home facilities, and I found that instituting and maintaining a supportive environment, or what we often call culture change, costs no more. So there's no down side economically to doing this.

But often the money savings are in non-direct areas. For example, when you run a really wonderful facility, you tend to attract people, so your census is higher. When you don't have a lot of staff turnover, you're not spending the money in recruitment, hiring, training. When you've got staff that are happy and well-trained, you tend to have lower rates of workmen's compensation and unemployment insurance.

So where your cost savings are aren't maybe in the same direct areas in which you consider -- typically consider quality. But it does all work out. And typically, you know, it works out on the plus side.

We'll leave you with just one thought that many

of us kind of ponder, and that is, Toyota, in looking at other industries -- and Lynn's smiling at me -- Toyota is an example in the car industry of a company that has really exemplified strong leadership, tend to have a very happy workforce, and provide a good product, a whole line of products covering a wide range of prices. And what is puzzling is why there are no Toyotas in residential long-term care.

On the information side of assisted living, I just wanted to talk about two things CCAL has. We have a consumer publication that helps you make informed choices. It hopefully has enough information to prompt and guide for questions that suit your needs.

It's got room in the margins for notes, so it's meant to be taken with you. We think that's really helpful. And then it has a comparison chart so that as you go to a number of facilities, you know, it really prompts you to look and compare.

We're also in the process of producing a video on assisted living, a 20-minute informational video, to help consumers make informed decisions.

Thank you. I appreciate the opportunity to be here today.

MS. MATHIAS: Thank you very much, Karen.

Next we have Barbara Manard and a PowerPoint.

MS. MANARD: Good afternoon. Thank you for the opportunity to speak today. I am Barbara Manard, speaking on behalf of the American Association of Homes and Services for the Aging.

AAHSA is a national nonprofit organization representing more than 5600 mission-driven, not-for-profit nursing homes, continuing care, retirement communities, assisted living and senior housing facilities, and community service organizations. Every day our members serve more than one million older Americans across the country. I've been asked to address a number of questions and issues with respect to nursing homes.

First, a few words about the market in general. As of 2002, there were more than 16,000 licensed nursing facilities in the U.S., serving some 1.5 million patients or residents on any one day. Most, 65 percent of these, are proprietary, but a substantial number, about 23 percent, are privately owned nonprofits. The remainder are government-owned, typically by counties.

More than two-thirds of the residents are paid for by Medicaid, a joint federal-state problem. The federal program, Medicare, covers an additional 10 percent. Private payments contribute about half of facilities' revenues, although private payors make up

only about a quarter of the customers, including an estimated 2 to 5 percent covered by long-term care insurance.

After a decade of declining occupancy due to a variety of factors, including the growth of alternatives such assisted living and a healthier, wealthier elderly population, occupancy has stabilized nationally at a median of about 88 percent, exactly where assisted living is, I saw.

There are, however, wide variations across the nation with respect to nursing home occupancy. Hawaii, Minnesota, and Connecticut, as shown, are the top three states in the nation with respect to occupancy, with medians in the mid-90s, while Texas, Arkansas, and Oregon, the bottom three, are in the mid to low 70s. These differences tend to reflect a combination of public regulatory and payment policies.

Turning now to the specific issues you raised, the first inquiries about the type of information that consumers have about cost and quality. Disclosure of full and accurate information to consumers is not the same sort of issue in the nursing home field as it is in some other health care areas, including assisted living. There is virtually no debate over the appropriateness of full disclosure in the nursing home field.

The key issues have to do with the challenge of developing ways to collect and present accurate, meaningful information that consumers can use. Volume per se is not the issue.

This document, which is about 50 pages single-spaced, contains the federal regulations regarding a nursing home's obligation with respect to resident rights, many of which refer to information on matters such as covered services, associated charges, and access to federal assessments of nursing home quality.

We are not aware of substantial problems with regard to residents, potential residents, or their families having information about the cost of services, although understanding Medicare and Medicaid payment and coverage policies can be a challenge.

In addition, there is a wealth of information available on the internet, including the federal site, Nursing Home Compare, which I hope that Barbara Paul will describe in some detail. Nearly all states maintain similar sites, with at a minimum a link to the federal site.

As of last year, at least twenty of the state sites contained detailed information such as full survey reports on individual facilities. Several states, such as California, Texas, and Maryland, have developed their

own reporting systems incorporating quality indicators and other performance measures.

In addition, there are a number of useful -- numerous useful guides to choosing a nursing home produced by consumer groups, provider organizations, and government. These stress the importance of visiting a home several times if possible. In addition, they stress seeking out information from multiple sources such as those mentioned above, nursing home ombudsmen, and state regulatory agencies.

Those who are able to avail themselves of these resources should not lack reasonably adequate information to make well-informed purchasing decisions. On the other hand, those who need nursing home care are by definition frail, frequently suffer from cognitive impairments, and often lack informal supports to help them with decisions. We do not actually know how well-informed these and other consumers are when they choose a nursing home or how much more or better information would matter to their choices, though it may be important for other reasons such as general public awareness.

Research on consumer choices of nursing homes is limited, but consistently points to the primacy of location and affordability as key factors. Furthermore, nursing home residents rarely vote with their feet after

they are in residence. Transfers among residents are rare, about 5 percent of all admissions.

Those factors suggest the continued need for mechanisms in addition to publicly available information, consumer choice, and market forces to enhance and sustain nursing home quality. Some do hope that in the future, better information and decision support systems, among other things, might improve the operation of market forces in the nursing home field and hence improve quality. That, in fact, has been one of the driving forces behind implementation of the new federal nursing home quality measures across the nation.

Suffice it to say at this point that the quality indicators available, particularly through the federal efforts, to potential consumers available over the internet are generally state-of-the-art, although they have widely recognized limitations. These limitations, discussed later, are for the most part inherent in the state of the art itself in the complexity of the subject.

As efforts are made to improve the state of the art and quality of the information, so too should the opportunity be seized to determine the effect of the unique national experiment we have undertaken with publication of these measures.

The additional information widely acknowledged as highly desirable but not always available to consumers includes customer satisfaction surveys, staffing information, quality of life measures, measures to help consumers judge the suitability of services for special needs populations, and a variety of financial data. While much of this information is available from individual facilities and at some state websites, the challenge has been to develop reliable measures and uniform reporting formats for cross-facility comparisons. Research is underway to address these problems.

The way in which information is presented is at least as important as the quality of the information itself in terms of the effectiveness of the message. This is one area where problems are perhaps less a matter of lack of research than the inconsistent application of what is known. How can information overload be prevented without sacrificing a necessary degree of accuracy? We'd like to see the skills of information specialists more consistently applied to the development of public reporting systems, along with the integrative reliability experts.

I've already mentioned a number of issues and general concerns about the available nursing home quality measures. I should also stress one of their great

strengths. We are blessed in the nursing home field by a very rich database of clinical information about individual patients and residents. This comes from the federally mandated uniform assessment tool, the MDS.

Far more is possible in the nursing home field in terms of clinical quality measures using administrative data because this tool exists. But to some degree, our blessing is also our burden. This basic tool was state of the art 20 years ago when first conceived, but today, despite some updating in the tinkering sense, it does not fully capture the type of information that experts now believe is necessary to track and evaluate quality.

This is not a call for more questions appended to an already lengthy assessment form, but for investment in information technology that can ultimately make the collection, storage, retrieval, and use of clinical data for quality monitoring and other purposes seamless, accurate, and efficient.

In large part because of the existence of this MDS database of clinical information, recent developments in nursing home quality measurement have focused intensely on clinical outcome measures such as those published by CMS. The industry, including AAHSA, has strongly supported CMS in its quality initiatives, and

with equal enthusiasm we support continued research to improve the measures.

The key problems with the CMS measures and outcome measures in the nursing home field in general are related to the difficulty of finding ways to measure performance that is attributable to an individual nursing home rather than the types of patients it serves.

Does this home have more patients with decubidi than others because it specializes in treating those at high risk for skin breakdown or because it has failed to implement appropriate skin care and other clinical procedures? That's the real question.

The difficulty in finding appropriate measures to provide answers is in part related to the lack of clear linkages between care processes and outcomes. We know less than we all want to with respect to what works. In addition, where there is better information about the causal chain leading to adverse outcomes, we often lack the right information to develop optimal risk adjusters, given the administrative data at hand.

Additional issues include the challenge of dealing with instability over time and the general lack of objective benchmarks of expected performance. There are a number of other technical problems that researchers have attempted to deal with related to developing

measures that present fair comparisons among facilities. Most experts, including prominently those who developed the current CMS measures, would agree that entirely satisfactory solutions await further work.

For those who would be hard-pressed to define selection bias, attribution bias, or censoring, terms used by experts to describe various technical problems, one common-sense problem is apparent to any who scan the current measures available over the internet. It is typical for homes to score high on some quality measures and low on others. Does that reflect the multi-dimensional nature of quality and homes actually being better at some things than others, or does it further suggest problems with the validity of the measures?

Structure and process measures, such as the number of deficiencies or staffing patterns, also have known problems, some of which can be dealt with through multi-variant analysis, but some of which -- staffing is the best example -- require better data collection systems. Despite the romance of most people with outcome measures, we are actually less concerned about the risk of using structure and process measures than the risk of ignoring these potentially useful indicators.

Obviously, simply having nurses on duty does not make a quality home if the nurses do not know what to

do or do it poorly. But all things considered, many experts believe that where there are so many complex factors involved in clinical outcomes, as is generally the case in long-term care, structure and process measures may be preferable to outcome measures. The classic acute care example is aspirin given on presentation with acute MI. Similar measures need to be developed in long-term care.

There is substantial research, including CMS's recent study, linking one structural measure, nurse staffing, to quality, variously measured. Similarly sophisticated work needs to be done to identify evidence-based care process models in long-term care.

How would competition on quality measures affect cost, prices, and decisions by payors and customers? As noted, the nation has recently embarked on an experiment in which a set of well-researched, if not optimal, quality measures is widely available to the public. We do not know what effect they will have and hope that appropriate research will be addressed to the question you have posed.

Existing research suggests that the effect of these measures on cost and prices is likely to be minimal, in part because Medicaid, and to a lesser extent Medicare, are the dominant price-setters in this market.

Structural measures such as the number of nursing staff adjusted for case mix might have a more perceptible effect on patterns of spending, but these patterns, i.e. greater investment in nursing staff, are already known to be sensitive to incentives inherent in public payment systems. Attention to those payment systems, not just the amount of money but how the incentives are structured, may be a more certain way to achieve desired goals.

Despite recognized distortions in the operation of nursing home markets related to supply constraints, regulated prices, and imperfect, asymmetrical information, researchers have found evidence that these markets are not entirely anomalous. For example, a set of researchers from Brown University has recently found that substantial deficiencies on the federal survey predict low occupancy, low private pay use, and both voluntary and involuntary terminations from the program.

The study authors conclude: "This study provides evidence that public reporting may indeed be a mechanism to promote overall quality in the sense of forcing some facilities from the market, but the plight of the most at-risk facilities should not be ignored. Although many would no doubt prefer to help usher in the demise of chronically underperforming nursing homes" --

and AAHSA strongly supports exactly that -- "doing so without a clear plan concerning what long-term care options will take their place is not defensible. If we are to prune the tree of existing long-term care facilities, we must also make every effort to plant and nurture humane alternatives."

To that end, adequate compensation from the dominant public payors is essential. While the relationships are not entirely linear, research does find the better stuff costs more. But it also demonstrates that simply raising public rates does not necessarily translate into better quality -- more nursing staff, for example.

Public payment systems can, and AAHSA believes they should, be structured to encourage spending on direct care staff. Research on other types of performance-based payments in the nursing home field has not been encouraging, but that research was mostly conducted over a decade ago. Carefully conducted demonstrations with good evaluation components could be useful today.

Thank you, and I'll look forward to the discussion later.

MS. MATHIAS: Actually, what I think we're going to do right now, before we move on to Toby, since

we've all been sitting for a little over an hour and I think that in the afternoon it's always good to stand up, we'll take about a ten-minute break. Starting in at 3:25, we'll have Toby and Barbara, and then we'll move into the panel discussion. So feel free to go get a drink.

(A brief recess was taken.)

MS. MATHIAS: If everyone could have a seat, we'd like to go ahead and get started so that we have time for discussion afterwards, although it looks like there's good discussion still going on. If we could get started.

As I stated, we'll start with Toby next, and then move on to Barbara. Thank you.

MS. EDELMAN: Thank you for the opportunity to speak today on behalf of both the National Citizens Coalition for Nursing Home Reform, where I'm a longstanding member of the board of directors, and the Center for Medicare Advocacy, where I work.

Since 1977, my work as a lawyer has focused on issues involving institutional long-term care, and so I'm pleased to speak to you today about these issues from the perspective of consumers. I could just maybe sit down and say, I agree with Barbara Manard, but I spent a lot of thinking about these questions, so I'll try to

eliminate a lot of what I planned on saying and focus more on issues that I think maybe haven't been said by others before me.

I think it's extremely noteworthy that the FTC and the Department of Justice have combined long-term care and assisted living in today's hearing because from my perspective, the line between nursing homes and assisted living is blurring.

Assisted living is becoming less a housing option for relatively healthy and relatively wealthy older people and more a health care option for a population that is considerably less healthy and less wealthy.

In terms of residents' needs and their needs for assistance with activities of daily living, assisted living facilities increasingly serve a population that looks more like nursing homes than ever before. More than 100,000 of the one million people who live in assisted living facilities live there under Medicaid waivers. By definition, they need a nursing home level of care.

Despite the increasing similarities in the people in these two facilities and the increasing similarities in their needs, there are obviously still very significant differences between the two types of

facilities.

The regulatory structures are, of course, different. Nursing homes are largely creatures of the Medicare and Medicaid programs, and although participation in both programs is voluntary for most facilities, the overwhelming majority of nursing homes choose to participate in one or both. As a result, the primary locus of regulation has been the federal standards. These are set by the nursing home reform law and they're very prescriptive.

Assisted living facilities, in contrast, are a relatively new participant in the long-term care continuum. Residential long-term care settings have been around for many years and they have been known and continue to be known by a variety of names such as personal care homes, residential care facilities, adult residential care homes. Each state seems to have its own term.

Assisted living itself is a relatively new term, but it is a term, as anybody of people have already noted, that is without a common definition. It's not defined at the federal level. There are no federal laws that set out standards that assisted living facilities must meet.

What I want to talk about, though, this

afternoon is the availability and limitations of information as a method of assuring quality, and the effects of payment on quality.

I think nursing homes and assisted living facilities differ enormously in the availability and quality of information that's made available to the public. There is a lot of information about nursing homes, but people are often unaware of it or unable to use it. Ironically, in contrast, I think people want information about assisted living, but there's comparatively little information and the information that's available is not uniform or consistent from state to state or even within a state.

In the nursing home area, the federal government has made a tremendous amount of information available. As part of President Clinton's nursing home initiative in July 1998, HCFA developed a website called Nursing Home Compare that includes information about each certified facility, nursing staff, deficiencies cited by the state survey agencies, and the residents who live there.

Most of that information has been consistent since 1998. But what I want to focus on is the part that has been changed recently, and that's about resident characteristics. Resident characteristics is the part of

the Nursing Home Compare website that is self-reported information derived from the minimum data set. It is the assessment information that facilities complete about each resident as part of the care planning process.

One concern about the MDS information, as it's called, is that it's found to be inaccurate, sometimes willfully, but perhaps more often because of confusion on the part of facilities about how to complete the MDS. For example, facilities seem to be very -- have very different ideas about how to report whether residents are in pain. Some facilities identify residents in pain only if the pain is not controlled by medication. Other facilities identify residents in pain if they need medication to control their pain.

Facilities' different ways of completing the MDS forms makes it difficult to compare facilities. People might want to know about the care needs of people who live in facilities before they place a relative, but it's hard to know what the information actually means that appears on the website.

The resident characteristic portion of the website has changed the most since 1998. The nursing home quality initiative from the Bush Administration has added new risk adjustment measures to the resident data. The principle of using risk adjustment is, of course,

widely accepted. But it's the specific factors that are used to make risk adjustments that can be very controversial.

Last year at a meeting on the initiative, a nursing home administrator was very critical of the way the weight loss adjuster was used for residents who need assistance in eating. He said that many residents in his facility need to be fed, but residents don't lose weight because the staff feed them. He argued that factors within a facility's control should not be adjusted, and I think most people would agree with that.

The other very significant change in the nursing home quality initiative is how the resident assessment data are reported and publicly described. When the data were first introduced into the survey process in the 1990s, they were called quality indicators.

And HCFA stressed at surveyor training that the indicators were only intended to help surveyors when they conducted a survey. They would help surveyors identify potential care issues as well as specific residents whose care should be evaluated in depth during the survey process.

Under no circumstances were surveyors told should they consider the information a statement about

deficiencies or quality of care. The indicators were just pieces of information that needed further evaluation.

Today, under the new initiative, the risk adjusted quality indicators are called performance measures and they are reported publicly as describing the care provided by nursing facilities to residents. And I think that is an overstatement from the perspective of the Center for Medicare Advocacy.

When data are made available to the public and are described as statements about quality, they need to be more accurate and refined than when they are used by surveyors and facilities. At a meeting of the National Quality Forum earlier this spring, two very competing sets of indicators with very different research findings about their validity were discussed, and the members of the steering committee were choosing among the indicators for the public reporting.

It became very apparent, I thought, at the meeting that the quality indicators are political and philosophical as well as scientific. That information about resident outcome data, while available, really cannot be oversold as more valid and meaningful than it really is. I think this concern and some of the others led the General Accounting Office to conclude that

nationwide implementation of the initiative was a little bit premature.

Although there's been a lot of discussion these days about outcome measures, I think the distinction between process and structure and outcome is a false one, and there seems to be quite a bit of agreement among the people who've spoken so far today that we do need all. We shouldn't abandon process and structure as we move to outcome focus, although obviously the whole point of the system is to get good outcomes for residents. I think we all agree about that, and that process and structure are intended to make good outcomes more likely than not.

The additional information that I think most consumers would like to receive is information about staffing. Consumers intuitively know that having sufficient numbers of adequately trained and supervised staff is most important.

So they want to know how many staff are working in a facility, but in addition, they want to know about staff credentials, staff turnover, whether staff are permanent employees or from an agency, which staff in particular are responsible for family members' care.

They want to know about nursing staff, including professional nursing. And I think they also want to know about other health care professionals.

Factors such as these are significant predictors of health care quality, and while Congress has required that each nursing facility post some nurse staffing information beginning this past January, the detailed information that consumers want is not really available.

I've been discussing information solely from the perspective of nursing homes and that's because for assisted living, there's nothing comparable at the federal level. The primary source of information for consumers about what an assisted living facility provides is the contract, and as a number of people have already discussed, the GAO and others have found a lot of fault with the contracts that have existed and been in place.

And although I think there is agreement -- certainly, the assisted living workgroup agreed that contracts and marketing materials need to be the same, and Karen expressed very clearly the consensus recommendations of the assisted living workgroup on those points -- I think we're not there yet.

And the California Advocates for Nursing Home Reform found similar problems that the GAO has found and prior people who've looked at the contracts. California Advocates found these same problems in their March 2003 report. So we have made some progress by recognizing what contracts should be, but the contracts are not

there.

In the policy principles for assisted living, nine members of the ALW set out an alternative method for regulating assisted living. We felt we could not endorse the model that we thought the ALW was proposing, which set few standards of care and relied primarily on contracts to fill in the details. From our perspective, we thought such a model was inadequate and unfair to consumers. We think consumers need to be able to rely on a particular level of services set by law and should not have to negotiate independently and individually with facilities to establish a standard of care.

I think there are significant problems in stability, certainty, and continuity of care if standards are set by contracts because contracts are written. They can be rewritten and changed.

So I think information is important. It's extremely important for consumers. But it's insufficient. First, people don't have all the tools or the time to look at the information that's available. Few people plan to move to a nursing home, and placement is usually made at a time of crisis -- an elderly person falls, breaks a hip, goes to the acute care hospital, and the decision is made by the physician, the family, somebody, that this person can no longer live alone.

Then the hospital discharge planner says, your DRG days are over. You have to leave within days, if not hours. So it's a very difficult time and people have no choice but to take whatever facility is willing to admit them.

There seems to be some difference, I think, in advance planning for assisted living. Some people, especially the adult children, are looking in advance at assisted living facilities before they need to make a placement. I think the problems for these consumers are the lack of reliable information and the lack of consistent definition.

A second problem with a public strategy focused primarily on information is that people don't have full and complete choice about where they'll live. In the nursing home area, Medicare and Medicaid beneficiaries are often denied admission based on their source of payment.

The General Accounting Office and Inspector General reported delays in admission for Medicare beneficiaries under the new prospective payment system for people who needed high-cost drugs, ventilators, or other expensive services, and discrimination against Medicaid beneficiaries has been a common problem for decades. Nursing homes have always preferred higher

paying private pay residents to Medicaid beneficiaries.

I think a third problem with an information-based model is that families who are choosing facilities, if they have a choice, often and quite rationally choose a nursing facility nearby so that they can visit frequently. Families feel that being physically present for the family member who lives in the nursing home is important for assuring better care.

So people who might be able to use information and who might actually have choices about facilities will choose a facility for reasons unrelated to the information they have. I think families of residents in assisted living have many of these same concerns.

So what information would consumers like? I think they would like information that's timely, meaningful, and comprehensible. Simpler is better. They would like information about staffing. And I think, with all this information, they clearly need help in understanding and analyzing it. A strong long-term care ombudsman program at the state and local levels is quite critical to helping older people and their families understand the information that's available.

In my final two minutes, I want to talk to the questions about how payments for care affect quality. Payment, of course, has an impact on quality. But what I

would like to just highlight for you is several GAO reports issued last year that found that increasing reimbursement did not improve staffing or care for residents because I think the usual response, the industry generally says, we don't get enough money. Give us more money, care will be better. That's not what the GAO found.

In June 2002, the GAO looked at 1999 Medicaid cost data in Mississippi, Ohio, and Washington. It found that facilities' expenditures varied considerably in the three states, but the average share devoted to resident care was relatively stable.

Facilities that had more nursing hours had fewer deficiencies. We've heard that a lot of times before. But facilities with higher reimbursement rates did not increase their nurse staffing. Facilities that got more money spent the additional amounts on capital, operations, and administration, not on nursing.

Two months later, in August, the GAO issued another report that showed that nursing facilities changed their practices in response to the new Medicare reimbursement system. The GAO found that skilled nursing facilities classified more of their residents into the high and medium rehabilitation categories, where the nursing home industry described reimbursement as more

favorable. But despite the favorable reimbursement rate, residents actually got less therapy, a 22 percent decline in the amount of therapy received between 1999 and 2001.

In November, the GAO reported that nurse staffing changed very little after Congress increased the Medicare payment for the nurse staffing component in the year 2000 by 16.6 percent. The GAO found that facilities in four states did increase their nurse staffing by 15 to 27 minutes a day, a considerable amount.

But three of those states -- Arkansas, North Dakota, and Oklahoma -- had made changes to Medicaid payment or had made policy changes to raise the nurse staffing. So increased staffing came about because of state Medicaid payment or policy requiring increased staffing, not because Medicare rates were increased to pay for more staffing.

And finally, in December 2002, the GAO reported that Medicare payments exceeded costs for freestanding facilities, both as the new reimbursement system was enacted and later after Congress increased payments. But the GAO found that with increased reimbursement, facilities' costs went down and profits went up.

These repeated findings by the GAO, I think, are quite disturbing. They demonstrate that it is not enough to give the industry more money and hope that

facilities will provide care. And I would also say it is not enough to give consumers information and expect that the market will assure good care. Good reimbursement policies and good public information are critically important, but a strong regulatory structure is also necessary to help assure that residents in nursing homes and assisted living facilities get the care and services that they need. Thank you.

MS. MATHIAS: We will move next to Dr. Barbara Paul. I'll start her presentation. While it's coming up, I also forgot to mention that Keren Brown Wilson had left some handouts from her discussion on the edge of the table, and there are other handouts outside for anyone who wants them.

DR. PAUL: Good afternoon. It's a pleasure to be here. I come to this work as a physician and internist who, for 12 years, was in full-time practice taking care of many patients in nursing homes; also as a granddaughter of a 95-year-old grandmother in a nursing home in northern Wisconsin. And now I have the privilege of working at the Medicare program directing the quality measurement group and in that capacity direct the quality initiatives under Secretary Thompson and Tom Scully.

What I'd like to do -- let's see how we proceed here -- is to give you some of the big picture of the

agency's strategy for improving quality of care and then focus right in on the role of consumer information in our quality strategy.

This is a complicated slide that those of you who hear me talk know that I use it a fair bit. I'm not going to go through it in detail. But it is a useful construct. It really does explain how we as an agency, both as a purchaser and as a regulator, use a whole variety of strategies to be buying higher quality care tomorrow than we're buying today. And that's -- if you wanted to try to describe my job, I think that would be what it is: help the agency figure out how to buy higher quality care tomorrow than we're buying today.

In order to do that we have about seven different strategies that we employ and they're listed across the bottom of the slide. And I'm not going to go into all of those strategies today, but just to show you that right in the center there is consumer information. And under Tom Scully and Tommy Thompson, this truly is kind of the centerpiece of their strategy.

But it is always coupled with other strategies, such as giving plans, doctors, and providers technical assistance -- that's the quality improvement organization program that we fund in every single state -- and the one-two punch, I think, of consumer information coupled

with technical assistance from quality improvement organizations, I think, has been very effective, particularly in the last couple of years.

We also are increasingly employing the strategy of collaborations and partnerships. And the nursing home quality initiative is a very good example of that. We develop both national collaborations and partnerships as well as state and regional level. We people together around a table to talk about one topic and move in the same direction many of them who hadn't been talking about one topic or moving in the same direction for a long time.

So those three strategies in particular are very important to our work at the agency with these initiatives. Just to run through some of the others quickly, the strategy on the right: to establish and enforce standards. That's kind of the bread and butter of what we are as a regulatory agency. We also write in the conditions of participation and overseeing the compliance with the rules and so forth.

Rewarding desired performance is another strategy that is of particular interest to this administration. They believe very strongly that we should be paying more for superior care.

Structuring coverage and payments to improve

care, just to move left here -- that's really to say that we know that only we can write Medicare coverage policy and only we can write Medicare payment policy, and if we don't do it right, we're going to get in the way of the provision of high quality care. So we know we've got to get that right. We've worked very hard to do that. There are things about the structure of the program that get in that way, but we certainly focus on it and work very hard to structure coverage and payment.

And then finally, going way to the left, we support standard methods. This strategy just says that we believe, as a federal entity, that sometimes our role is to bring people together and get them all to agree on certain standards, and then let them go off and use those standards.

An example would be the work we're doing to establish standards for information technology, for IT transactions, where we can help to be the convener and a standard-setter. And then everybody can go off and create their own products and do their own thing.

So those are the seven strategies that we use with probably the three that particularly relate to the nursing home and home health initiatives.

To jump into the middle of the slide, though, also, to emphasize to you that none of these strategies

are possible without the underlying data and without the measures that are derived from that data. And it's because of differences in the data and in the measures that some of our initiatives look a little different.

Obviously, with nursing homes we have the MDS data sets, measures derived from that. With home health agencies, we have the Oasis data set, measures derived from that. What you'll see on the hospital side, we're working on launching some public reporting of hospital quality.

It's going to have a little different look and feel, at least for a while, because we don't have a robust data set to work from. We don't have that entire infrastructure of the data coming in and being able to be scrubbed and monitored and massaged as we do with MDS and Oasis.

So with hospitals, we're at a different place. It's going to look different for a while, and it really goes back to that box. And thus the reasons why we use different strategies, depending on the data and the measures.

So this is another way to explain what I just said, which is that we believe it is only by employing multiple strategies that we're going to move quality to the right, that performance on any particular indicator

of quality. The goal here is to move quality to the right and to reduce unexplained variation. And we know that the best way to do this is to use all sorts of strategies, particularly consumer information incentives and technical assistance.

The compliance strategy helps to assure a certain baseline level of quality and can certainly move some people to the right, but is not enough to move the whole population of performance to the right.

Secretary Thompson announced his quality initiative in November of 2001, with the twin goals of empowering consumers to make more informed choices and also to stimulate and support clinicians and providers in improving the quality of their care. And as I said, the centerpiece of these initiatives is consumer information. But it is complemented by additional tactics, particularly collaborations and partnerships, technical assistance, and ongoing maintenance of our oversight activities.

We do have a growing amount of information on the website on Medicare.gov, our consumer website. You've heard folks mention it several times today. We went live with this with managed care information in 1999 and dialysis facility information in 2001. Last year, under Tom Scully and Tommy Thompson, we launched the

enhancement to home health, Nursing Home Compare, with the quality measures as you've been hearing about.

Home Health Compare is being launched this year. We launched the skeleton of the website on May 1 of this year with detailed quality information for eight states on that day. We will launch that fully this fall. We haven't picked a date yet, but we will launch that fully this fall with eleven different measures of quality for every Medicare-certified home health agency in the country on Home Health Compare.

And these are searchable databases. Like on Nursing Home Compare, you put your zip code in, or I think you can use county, state, some other search criteria. It will bring up a variety of nursing homes. It's very useful to help a person in their search.

We do plan to build out Hospital Compare next year. We're working on that right now. And that is again much more developmental. What you'll see on hospitals, just to kind of let you know about that, is that you will see us go live with some quantity information on hospitals this summer on CMS.gov. We will then go to Medicare.gov next summer once we do some additional consumer testing and development because we're just not ready to go directly to Medicare.gov just yet.

Also, to make the point that there is lots of

other information on our website, this is just a list of a number of publications that can be downloaded from Medicare.gov. And we do emphasize on these websites that the information about these quality measures is just one piece of information and that there's lots of other information that people should use in choosing a nursing home or home health agency. And we have a whole staff dedicated to trying to figure out what that additional information might be for people.

Where are we going? On the nursing home side we are looking at creating a patient experience of care or patient satisfaction survey. And this probably would be both resident and family perceptions of care. And we are working -- this is very developmental now, but we're working with a number of stakeholders.

We're trying to learn from a number of states who already have instruments, and a number of researchers who already have instruments to try to figure out if we can develop, in collaboration with those who use these instruments, an instrument that is useful that would then provide information to go up on our website. So developmental, but we're definitely working in that direction.

Also, looking at staffing. That is something I think we're all very interested in. The challenges

there: if you go back to that first slide of mine, have to do with the data; and how do you get the data through; and what kind of measures do you construct; and what kind of case mix adjustment do you do?

So there are lots of steps along the way. But we're very interested in going ahead and getting started because right now what we have are kind of -- sort of just dueling points of view which don't get us anywhere. So we'd like to figure out what the science is that we need and go along that path to create some staffing measures that really hold up to scrutiny.

And right now, we're working on just funding some very developmental work in that regard: What is the data set we would need? How would we get it? How would we take MDS, sort of clinical information, and marry it with the staffing information to create some measures? And then, of course, we have to go test them. So that's where we are on that.

Quality of life measures. We also are looking for other measures that are less clinical to see if we can't find some other measures that resonate for consumers that talk about the quality of their experience of living in that home. And so we're working on that, again, kind of at the research level. But we'd love to get to the point where we have all of those things on the

website.

We also, besides the website, have lots of other avenues for getting this information out. We are using the media more and more, and I think this is again Tom Scully's style. And I think he has used it very effectively.

The ads that we used in the nursing home quality initiative last year were not -- they were sort of a small snapshot of information in and of themselves. But more than that, they were a stimulus to get people to go to the robust information, to the website, to the 1-800-Medicare, to their discharge planner, to the homes, et cetera. But the media is a part of our strategy to help to get this information out.

1-800-Medicare is our toll-free line for Medicare beneficiaries. They can essentially get the same information by phone that they can get on our website. We have customer service representatives there with lots of resources available to them.

We work with the state health insurance assistance programs throughout the country. We have regional offices in ten different locations in the country who have a variety of outreach efforts on this and other aspects of Medicare. Lots of partnerships, increasingly, and particularly the quality improvement

organizations, who are in every state.

We also find that there are lots of very wonderful state and other websites that we like to provide people with links to, and so we increasingly are trying to track those and provide links where appropriate.

So let me just now talk about consumer information and consumer research a little bit. The staff who have done this work have provided me with some information I think you'll find to be useful.

We definitely used consumer research to create the Nursing Home Compare and Home Health Compare websites, specifically to help us to choose the measures from those that were already currently available, being used in other ways, figuring out which measures to use for the websites for this activity.

So we went out to consumers, various consumers -- lay consumers, clinicians, discharge planners, et cetera -- and asked them which measures most resonated for them.

We have used this research to improve the understandability of the language that we use, to improve the design and look and feel of the website and its navigation, and to also identify the target audiences for promoting the website so that we are really focusing our

communications on the right target audience, depending on the information at hand.

With nursing homes, some of our findings. First of all, that we found that family caregivers and referral sources such as hospital discharge planners really should be our primary target audiences. They were the primary users of this information.

We also found that doctors and other clinicians were willing and did refer their patients to our website, which was helpful information to us. And we also learned that consumers don't use this information alone. They know right up front not to -- that this is not how to use it, and they do factor in other information.

On home health, a couple of things just to tell you about what we found with talking to consumers there. A little different. We found that, again, caregivers responded very favorably to this information and felt that they would be likely to use it.

Interestingly, consumers did not always even have a concept of what a home health agency was; a little different challenge for us communicating about home health quality if we first have to educate about what a home health agency is. A little different challenge than with nursing homes, where I think everybody kind of has this mental picture.

And many consumers did not realize that they had a choice in home health care agencies. They are being directed a lot of time by discharge planners, I would assume. I don't know kind of the guts behind this statement. But I would assume it's because they often are being directed at the moment of discharge by discharge planners. And I think it's useful in and of itself for people to realize that they do have choices.

We also are going -- doing a lot of ongoing evaluation. And just again, to give you some examples of this evaluation, on the nursing home side, we did find that the initiative successfully promoted quality improvement activities. And this is specifically talking about the pilot phase last summer or fall.

About half of the nursing homes in those pilot states sought technical assistance from the quality improvement organizations in that state. That's a very high number for something this new, to facilities that had not been used to working with QIOs at all. And about three-fourths of them reported making quality improvement changes themselves, regardless of whether they worked with a QIO, and indicated in great numbers that the nursing home quality initiative itself was a stimulant to getting them to go and to start to embark on some of those quality improvement strategies.

At this point, we have -- I just have some recent numbers that I just saw. About 20 percent of the nursing homes around the country are working intensively with our quality improvement organizations right now. We expect another 20 percent to begin working with us when we launch a couple of collaborations that we're finalizing, kind of a collaborative project. So that will get us up to 40 percent working quite intensively.

Another -- we also know, and I don't know the overlaps on all of this, that about 40 percent of nursing homes are participating in various technical conferences and onsite meetings and so forth, and that 70 percent of them are actively receiving information in the mail from our quality improvement organizations. So by using a lot of strategies we're having quite a deep penetration of outreach to the nursing homes from the quality improvement organizations.

We also know from our evaluation that the initiative increased the seeking of nursing home quality information by consumers. Phone calls to 1-800-Medicare regarding nursing homes and visits to the website increased dramatically right after our media events. They tailed back off again, but still remain at levels that are higher than before this initiative.

The Nursing Home Compare website is the most

popular sub-site on Medicare.gov. It gets 20 percent of all of our Medicare.gov traffic, which is about 200,000 page views a week. So we think that this is quite good evidence that people are coming to the site and finding -- and using the information.

And in fact, when we have queried those who came to the website, they were highly satisfied. They said that the information was clear, easy to understand, easy to search, and valuable. And on a scale of zero to ten over 40 percent of web users scored the information a ten on these dimensions, and 70 percent gave the information an eight or higher.

This is to remind you that we continue to evaluate. On the home health side, we will be evaluating the phased-in launch that we're doing on home health to assess the effect of that initiative on home health agencies, discharge planners, consumers, and others. We have a whole team at the agency who's dedicated to this kind of consumer evaluation and improvement long-term and we will continue to assess how it's going, what the information -- how the identification is being used, how it can be improved. And we will be working with many of you on that because we greatly value the input that all of our partners bring to us on that area.

So just to close, just to kind of wrap it up by

reminding you that this is -- consumer information is a centerpiece of where we're going, but we do compliment it with a variety of other strategies. And it's a very exciting set of initiatives to be working on and I'm certainly pleased to be here to talk to you about it today. And that's it. Thank you.

MS. MATHIAS: If I could invite the panelists up to the table. One of the ways we always like to start off is sometimes the later presentations will raise questions or ideas within the earlier presenters. So we like to give everybody an opportunity to respond to what they've heard, and I thought I might just start off with Jan, just to see if there was any questions or ideas or comments that you wanted to raise relating to what you've heard today. And we'll move down.

MS. THAYER: I think that the area of quality and measuring quality in its delivery in assisted living is a challenge that will be before us for the short run. However, I think it also brings us tremendous opportunities.

And, in fact, one of the outcomes of the assisted living workgroup was the idea that a center for excellence in assisted living would be created, which would be housed for the purpose of collecting information, collecting research and having a place to

record those best practices that occur throughout the country. We want to be able to share that research so that we could establish some standards that, through voluntary kinds of collection of information, would lead us to establishing guidelines, benchmarks, and to determine how we can indeed measure quality.

Those are the -- that is the logical next step, I believe, from where we finished that report, and I believe that all of us who were involved with that would certainly agree that that step needs to be taken.

We also need to find a way to look at how we measure finance and quality outcomes. And one of the things that I have noted in my experience is that even though we use somewhat standardized data to measure satisfaction, let's say a customer satisfaction survey, that in our own facilities, which we measure in three states, that we get a wide variety of information back depending upon the setting in which care and the housing takes place.

For instance, I find that there is a great difference in the satisfaction as it is rated in the survey system that we use, the satisfaction instrument, in whether the setting is urban or rural. Now, you might not think that would be the case, but you can ask yourself, why might that be true?

There are those persons who live in a more rural area who have not perhaps had some of the experiences that people have had in more urban settings. And to them, to a man who has grown up on a farm, working the soil, working in the rural United States, who perhaps has not married, to have someone help him with housekeeping, food, socialization, life has become heavenly in an assisted living facility. It would heavenly for lots of us.

And if we go to a more urban setting, where we might measure a woman of the same age group who has been very urbane, very worldly, very professional in her career, and has had lots of opportunities to travel and experience fine hotels, the same question will not be answered the same way. Because we all judge quality from our own perspective.

And so I think that we are very challenged and looking forward to finding methods where we can truly assess what it is that blends for us some process -- because I think all of us would agree around the table that some processes have to be measured. But then how do we translate that to the outcome that we want it to be with true and definitive information that will give us answers that we are looking for? And I believe that the center for excellence could be the way that we begin to

gather that on a voluntary -- in a voluntary manner.

Part of the attractiveness of assisted living to the consumer, I believe, is the independence and the choice that consumers are able to have. And therefore, states have written their own regulations and their own guidelines for what assisted living may be. And in the outcome work, the report, the assisted living workgroup report, we were able to define assisted living with an overall definition and then a couple of points for clarification.

Because as we work on a nationwide initiative, we all bring our own beliefs and our own experiences and what goes on in our states. And one of our challenges was to define assisted living. So I wanted to say that I believe we made huge strides in defining it for the public, and that we are looking to being able to find a way to measure quality, although we have certainly only begun that process.

MS. MATHIAS: Thank you. Keren?

MS. WILSON: I think that everyone agrees how important information is. And I think everyone agrees that most of the ways in which people use information makes it less than perfect in terms of their able to use it successfully and their ability to use it well.

I think we have some differences on what

strategies might be most useful to help actually empower consumers to use information effectively. And I am -- I will be most interested to see whether or not we can avoid literally trying the same way to address the issues of quality in assisted living that we tried in nursing facilities, which made some huge differences but had a great price, mostly in terms of quality of life for many people.

So what I hope we don't lose sight of here is that while we all agree upon quality, or everyone wants quality, that we have different opinions about what quality is; and we have different opinions about how we might measure it; and we have different opinions on what strategies might be more successful in allowing us to balance some of those competing values that we have not been very successful in balancing so far.

MS. MATHIAS: Thank you. Karen?

MS. LOVE: I wanted to applaud Dr. Paul. I thought that a lot of the work that you presented today, some of which I wasn't familiar with -- but I think you're really on the right path.

For example, you talk about quality of life measures, identifying that. And Jan, as you so aptly noted, it does, it varies tremendously depending on what your life experience is. Also, the staffing measures.

Staffing is the foundation. We hear that over and over again. But how do we determine what's adequate staffing? Especially -- it's hard in nursing homes, even more so in assisted living, because there's such variability there.

Plus I think all the experience and information you're getting from Nursing Home Compare, and I'm imagining your Dialysis Compare, et cetera, is producing a robust body of information that we can build on and look at to use in other entities. So I think you've got some good information that we can borrow and build on.

MS. MATHIAS: Barbara?

MS. MANARD: I think I'll pass. I had no -- mostly, unfortunately, we just agree on everything.

MS. MATHIAS: We're writing that down, Barbara.

MS. EDELMAN: That's very shocking to both of us, I think.

I think one thing that I did disagree with that was said today was Dr. Wilson's support for negotiated risk contracts. And what I would recommend to people is a very, very good article, I think, that Eric Carlson wrote in the NAELA Quarterly, the National Academy of Elder Law Attorneys --

MS. MATHIAS: Could you speak a little bit more into the mike?

MS. EDELMAN: Oh, I'm sorry. So I'd be happy

to make this article available to people, and I'll certainly send it to the FTC. It just came out this spring. And it's called, "In the Sheep's Clothing of Residents' Rights: Behind the Rhetoric of Negotiated Risk in Assisted Living." And what Eric points out is why he considers negotiated risk bad public policy; that from his perspective, and he said this quite a bit when we discussed this issue with the ALW, that he believes negotiated risk agreements are unnecessary, that people already -- residents already have the right to make choices, and that the only real purpose of a negotiated risk agreement is for a facility to be able to say, we're not liable for whatever bad outcomes happen to a resident.

MS. WILSON: That's not true.

MS. EDELMAN: Well, I think --

MS. WILSON: But we'll be answering.

MS. EDELMAN: Well, it is one of the very hotly debated topics in assisted living, and here's a new resource for people interested.

MS. MATHIAS: Okay. Barbara, you got to go last, so I'm going to ask you a question. One of the -- I think on what you defined as the complicated slide, one of the lower bars was that you are looking at -- where's my question? -- that you were trying to reward facilities

with, I think, incentive payments.

And how does that work, and are you seeing reaction to that? Are people -- has it been implemented? How are people responding to it? Are people trying to improve their quality to get better payments?

DR. PAUL: Yes. What we have sort of under that strategy right now is one thing in the field right on the managed care side of the shop. With our managed care plans, we have an effort in which we are paying them a little bit more -- it's a very modest bonus payment -- if they will report information to us about the quality of care they're providing for patients with congestive heart failure.

They'll report it, and they have to achieve a very high level of success, 80 percent success rate, on one of the measures they report, and 85 percent success rate on another. And if they report both of those, we will give them this little bonus. And last year we paid out about $25 million. It's a two-year project, $25 million last year.

Tom Scully, when he came on board and learned about it, he more than doubled the amount of money on the table because he was so enthusiastic about this project. So this year we're going to be paying about actually three times as much money to approximately the same

number of plans for showing superior care with heart failure.

That's what's already out there. We also have a number of demonstrations either in development or in the field. There's one for physician group practices in which we will be, for those practices -- without explaining the whole thing, to the extent that there's money saved in this demonstration, we will be sharing some of that money based on quality in that demonstration.

We have one that's not quite out of OMB right now -- it keeps getting reported in the newspaper, but it isn't quite out of OMB -- in which we would propose a demonstration with hospitals to pay a little bit more for demonstrating superior care.

And just to sort of flag for you what that will be, assuming we can get all the I's dotted, is these hospitals would be using sort of an electronic data transmission -- again, if you go back to my complicated slide, the data part, they're going to give us lots of data. We're going to have lots of measures, probably about 30 -- I haven't counted lately, but roughly about 30 measures that will be publicly reported. And then the highest performers will get a little bit of extra money. So that's the demonstration that we're proposing that we

haven't gotten going.

Now, on the nursing home side, I think that philosophically, just in general, whether it's nursing homes or dialysis facilities or hospitals, philosophically this administration does definitely believe in paying more for superior care and, conversely, for paying less for, you know, very low quality care. That is the end game that they are looking at.

I think that people on the nursing home side don't really think that the measurement is quite there yet to be discriminating on that regard. And I understand that we published our payment update on nursing homes recently with a request for comment on the idea of how could we find ways to tie a payment and quality together because we just don't quite know on the nursing home side how to do it. So that's out right now for comment. We're looking forward to comment to see how we might do that on nursing homes.

So that's the spectrum of what we're doing on payment for quality right now.

MS. MATHIAS: Okay. I think that raised a comment or question from Barbara.

MS. MANARD: No. I have a comment. Because this is something that I've been involved in research on for some 25 or 30 years, is the issue of payment systems

in nursing homes. And remarkably, Medicare is the nursing home payment system that is divorced from quality. It has strong incentives to reduce spending on care, and you still get the money.

Now, that is in contrast, substantial contrast, to the state Medicaid programs, where all but a handful of state Medicaid payment systems actually have far better incentives. The problem in many of the Medicaid payment systems is literally that the pie isn't big enough. But they have worked much more carefully at figuring out ways to structure the payments.

And in general, what the better ones do is a combined of the kind of pricing approach of Medicare with something that actually looks at, did you actually spend money on nursing?

And we are looking forward to continuing to discuss that with CMS. It's more difficult on Medicare because you have so many facilities where there are literally only three or four Medicare patients at one time. So getting that payment system is sort of like the tail wagging the dog.

But it is interesting that that is the one payment system that is not -- so since there is a lot of challenge with the measures, as we know, but there is -- you would hardly find a debate about the importance of

nurse staffing. It's likely that that would be something that there's probably a line of reasoning where you might find more consensus.

Anyway, more in the future.

DR. PAUL: I hope you'll send comments in and --

MS. MANARD: You won't necessarily, get through that forum, but certainly through other forums.

DR. PAUL: We'll look forward to talking about it.

MS. MANARD: Right.

DR. PAUL: Because I think this administration is very interested in testing out new models of payment that really do incent quality. So to the extent that demonstration projects can be designed and things like that, we are very interested.

MS. MANARD: And the states have really been innovators in this area. And all of us have had numerous discussions over the years, consumers and so forth, although I think, you know, the industry won't be 100 percent together.

MS. MATHIAS: Toby, I think you raised your --

MS. EDELMAN: Yes. I was concerned about, I think, an important point from my perspective is making sure that the reimbursement systems support the

regulatory standards. And some of the Medicaid reimbursement systems haven't particularly done that.

When the early case mix systems came in and they wanted to recognize that more care might cost more money -- there's some logic there -- when they designed reimbursement systems to say, well, for each pressure sore there are additional points; if the pressure sores are bigger, there are more points, that's not consistent with what the nursing home standards are, that people shouldn't have pressure sores if they didn't come in with them, or if they have them, they should be improved.

And so I don't think we want to have the reimbursement systems creating different incentives from what the regulatory systems have as their incentives. And it's interesting that what Barbara says, that the Medicaid systems are doing a good job in -- at least they're trying to correlate care with the payment.

Because I know last summer when the Atlanta Journal-Constitution did a long series about nursing homes, they were concerned about the incentives in the reimbursement system where facilities got extra money for keeping costs down. So facilities that had very low staff got bonuses. They got incentive payments. But these were the same facilities being cited for low staffing. And that doesn't make sense, either.

So if we give incentives, we shouldn't be giving incentives to things that we are saying are not good care practices.

MS. MANARD: You have just described the incentives in the Medicare payment system. That's the Medicare payment to a T. And I read that Atlanta -- it's quite excellent. And the thing to understand is that payment systems for Medicaid vary across the country.

The only one that's similar to Medicare is the one that Texas had for 30 years and finally abandoned because the legislature got distressed at continuing to see a payment system that rewarded poor quality.

MS. EDELMAN: But there's also evidence that poor care costs more money than good care. And so there's something a little strange about giving extra money to provide good care if it's cheaper to do that. But, I mean, we certainly want to have high standards and pay for those standards to be met. I don't see how we could ever disagree with that important point.

MS. MATHIAS: Okay. Well, although we earlier heard that there has been a blurring in between the long term assisted living care and the nursing home, I think we've kind of focused on the nursing home.

So to turn a little bit to the assisted living care or assisted living facilities, if a consumer is out

there and trying to sort through the information, ask the right questions, maybe visit the facilities, you know, if they had to ask three top questions to help them make a decision, what would those three questions be? And I'll raise that to anyone, but maybe start on my right-hand side with the assisted --

MS. WILSON: I'm ready to answer.

MS. MATHIAS: Go ahead, Keren.

MS. WILSON: I'm ready to answer. I think the first question that they should ask is that -- and this is going to sound strange, but it attacks that balance question: Is this a place I feel comfortable in?

In other words, since you have to live there, this is a place that you're going to live and you're going to receive support, then I think there's a very important element when you're doing these visitations, apart from what kind of staff do you have, what kind of -- you know, are there credentials, you know, when will I have to move out, it's like, is this a place that I intuitively feel comfortable with?

And I'm going to tell you a very brief story to illustrate this point. I told you earlier today that my mother was in a nursing home. And I used one of those consumer guides to select a nursing home for my mother. And it had the top rating in all of the categories. It

had -- you know, everything that I was supposed to check, I checked, and it got a good score.

I went back to school and my mother moved herself to something that, you know, to my eyes looked like the most unsuitable, the most poor quality environment that you could -- and quality that you could ever imagine. And when I asked her why she did that, she said, because I like it here. It feels good to me. I can do what I want here.

And so that was a very important lesson to me, is that there has to be a good fit between the person and what kind of life they want to lead, and what it is that's offered in that environment.

The second thing that they should ask is, in fact, to find out the actual range of services and to talk to residents that live there now, or to families. They should ask for references. They should ask for residents or resident families to speak to.

And the third thing is that they should just sit in the common area and watch for a while. They should look at the residents' faces, they should look at the staff's faces, and they should use their ears, eyes, and nose to tell them, to inform them. After that, then they can look at the other kinds of information. If I were -- those are the first things I would do.

MS. MATHIAS: Thank you. Jan?

MS. THAYER: And I have to -- we're not going to disagree about what you need to look at when you go to a facility because it's very hard to limit it to three. But if I were going to search for a place for my mother, and my mother and father and mother-in-law all lived in assisted living, one of the things that I want to know, and I would ask it in a different way, is about your history.

And so I would ask to be shown any of the survey or regulatory reports that had been received by that facility as it was looked at from a regulatory agency. And I would probably ask for the last three years because I want to know what their performance has been from those who are judging it from a perspective that will be different from mine. Because the least that I want is for them to have lived up to certain standards. Then I will go from there.

I think it's absolutely critical for people to understand the fee structure when they are comparing and searching a facility because you need to know how you are going to be charged, if you are going to be able to meet those requirements, if someone is going to accept Medicaid. The fee structure is something that can create lots of concern. It can create lots of disappointment.

It can be a place where people have lots of misunderstandings. Then one of my important questions would be: How do you determine how my mother -- that my mother will be treated as an individual here? How will her needs be determined, and how will you address those needs, and what role will she have and will I have in determining those needs, and if we agree on how those needs should be met?

And I do have to give you a fourth because you absolutely must tour, walk through, the facility. I always am interested to know if residents look up at visitors. I think that is an indication that they have been having interaction with people who work there. I want to know how the staff looks. I want to know if the staff says hello to me. I want to know that the facility is clean. And most of all, I want to be there -- and perhaps this shows a little bit of my bias as a dietitian -- I want to be there at mealtime.

MS. LOVE: Can I just add quickly a couple things to that?

MS. MATHIAS: Sure.

MS. LOVE: Wearing both my hat from making a placement for my own father in assisted living, and running assisted living, and then helping to answer our help line to help people make informed choices, one of

the things that I would add, too, I certainly agree that absorbing the environment, feeling what it's like, talking to families, residents.

But I would also add, and we haven't -- and it's one of our tips in our checklist is, if you can afford it, have a two-hour discussion with the geriatric care manager because they know within a particular area what facilities are operating at what level. And, you know, who runs the facility and what the staffing is really, really promotes the quality of the place.

And then secondly, when I'm coming in, you know, for my just sitting and watching, I would recommend doing it 4:00 to 6:00 p.m. on a Saturday afternoon and seeing, what does the facility look like? Is it chaotic? Is it hectic?

MS. WILSON: Saturday is a good day.

MS. MATHIAS: One of the questions that was handed to me by another FTC person goes back to part of the discussion that Toby raised, which -- and I may not get this question exactly right because there seems to be some shorthand in it.

But you discussed the fact that there's some discrimination in the admissions of nursing homes against Medicare and Medicaid payments. And the question is, is that a discrimination in the source of payment, or is it

a discrimination in the amount of payment, and is that -- is it discrimination, or is it a functioning market? I mean, any of those questions?

MS. EDELMAN: Well, in Medicare, I think what has been in general found is that nurses from the nursing facility, from the skilled nursing facility, will -- it's the first time anybody ever heard this happening after the prospective payment system came in -- the nurses would go to hospitals with computers and calculate what the payment rate would be for the resident.

Depending upon whether they considered the reimbursement rate sufficient, people would get admitted or not admitted. So I guess you could say it's the amount of payment. But these are people who are eligible and covered by Medicare, and they're not getting admitted to nursing homes. They're people having to go to a facility that they might not choose to go to, but to some facility that would admit them.

Medicaid discrimination: Medicaid payments are lower than private pay rates. They're lower than Medicare rates. And so discrimination has always been -- it's always been an issue as long as I've worked on nursing home issues, since 1977.

And I think that it takes a variety of forms, that people just cannot -- they won't get admitted. And

what the reform law says is that a number of practices that facilities engage in are illegal. I mean, the law responded to the discriminatory practices. But it's still common. And I think what's disturbing to me is that there's an assumption that Medicaid just doesn't pay enough and that's the cause of the discrimination.

Some years ago, Catherine Haas did a study in California -- it might have been as many as fifteen years ago -- but she looked at all of the cost reports from California. And she concluded that the facilities that did the best financially were facilities that had about the statewide average of Medicaid beneficiaries living there. Facilities that had huge percentages of Medicaid, like 90 percent, didn't do well, and facilities that had very, very low percentages of Medicaid also didn't do well.

But taking people as they came, or allowing people to convert from private pay to Medicaid, was more financially valuable for facilities than discriminating against Medicaid people because even though the rate is lower, keeping beds empty and waiting for the elusive private pay person was a bigger problem than taking the lower rate, or other management decisions that facilities were more significant to their profitability than Medicaid. MS. MATHIAS: This question will show

some of my ignorance, but I guess that's why they need to be asked. And maybe everybody else already knows the answer.

It seems to me that with a lot of the -- and maybe I'm misunderstanding. The assisted living facilities have a very widespread amount of how their either -- standards of care may not be the right word but, you know, you go from three units to 60 units. And it seems to me that some consumers might assume that all of those are regulated either by the state or the federal, and they may not have an understanding if they are or if they aren't.

How is that information getting out to the public about what standards the assisted living facilities have to comply under, if there are any standards, or if it's just up to the contract of the assisted living? How can the consumer learn how it is protected, how it's not protected, in this kind of changing, evolving health care system that is seeming to give more and more care these days than it maybe originally was thought to be giving? Jan?

MS. THAYER: From the National Center for Assisted Living and the slides and in our -- in my testimony, we give the addresses of several of our websites which are intended to help the consumer to be

educated to the kinds of questions that they need to ask as they begin to research assisted living accommodations for their loved ones.

So I think that the responsibility at this time is certainly to access those kinds of guides that we have in order for people to learn how to ask the right questions. So we have published a consumer guide that's free of charge. I believe we're getting something like 10,000 hits a month -- is that the correct number? -- on our website of people asking questions.

And so education, because this is not such an old service in terms of comparison to nursing homes, is a very large process of education. And so from a national perspective, we can help people to learn how to ask the right questions, and then since these are state regulated, I think that you then have to go to your state and ask the same questions in your state. And you can also ask that in the facility where you are.

What are the basic standards to which you must adhere? And then you simply have to -- that's why I would suggest looking at the last survey because it at least will give a snapshot of how well you are performing based on what the state requires you to do in that state.

From then on, it is simply going to be a process of your doing your homework and touring and

checking and asking questions. And we advise that it not be a slow process -- excuse me, that it be a slow process and that you take your time to shop very, very diligently by asking questions, the same questions, in every facility.

MS. WILSON: I think that, first of all, most states -- I don't know for sure if all do -- most states are in fact publishing their rules online. So you can actually go in and read the rules for a particular setting. I don't know how many states out of all 50, but that is something that is available. What isn't available in those rules is sort of like what I would call the plain English version so that consumers can actually understand, what does the rule require?

So one of the things that might be helpful is if, in fact, states began to sort of simplify what it is that's required under the rules and had a plain English version of that online along with the rules.

The other thing is that when a consumer actually begins to contemplate a decision for move-in or admission, the very first question out of their mouth, it seems to me, once they've sort of zeroed in on a place, whether it's by accident or by referral or whatever, is to say, are you a licensed setting?

If the setting says yes, then they should say,

what kind of license? And then at that point they could go and find out from the state government what is actually required of that, and then go back to the source and ask questions about that.

But if it's not a licensed setting, which is actually sometimes a problem in assisted living because of the variety of definitions, then the problem is more difficult for the consumer because then they do have to rely more on the types of information that are available through the residence, through the community.

And there are guides, but consumers still need a lot more education about how to successfully use those guides. And that's the part that's really still missing, I think, is a good educational effort, particularly for non-licensed settings because there are a great many unlicensed settings that are described as assisted living in the United States.

MS. MATHIAS: In my preparation for this series of panels or this panel this afternoon, I actually did go on the CMS website to look at the chart, and kind of did a quick survey on how user-friendly, and found it was very user-friendly.

And my initial question was going to be, how do we make that information more available to, you know, for example, my Nana, who's concerned about even touching a

computer, more or less, not quite website savvy?

But I think Barbara did a great job of answering the various ways and avenues that you're trying to get the information out there so that everyone can figure out whether it's the person who's going to be either needing the nursing home or the family member. Because I do think it needs to be a unified decision or, hopefully, some joint decision-making going on in there.

But I've also read some concern about the fact that the definitions are not always uniform on how people are reporting, like restraints. Some people may only count physical restraints, whereas others may use chemical restraints as part of their tally.

And how do we get some of that information out so that people understand that it's a good source of information? It's not perfect, and never do we want the perfect to stop the good, or however that quote goes. But how do we make sure that people are using that information, but also are aware of some of the limitations of that information?

DR. PAUL: And first, on the accuracy of the information, we have a whole effort going on at the agency to help to educate the MDS coordinators at the nursing homes to answer their questions and to help to create more consistency about how they do their data

collection and coding.

We had a satellite broadcast -- it was either December, maybe -- in which we specifically were targeting the bedside nurses who do the MDS coding, and specifically were trying to answer and clarify any questions that there are about coding for the data elements that go into these measures in particular. I mean, all of them are important, but we decided to focus on those right this second. So we have a lot going on just to try to improve the data.

On the website, there is a -- just to speak generally, there's a law. I can't cite the law to you; I can certainly get it for you. But there's a law that was passed not long ago that talks about how the federal government has to assure the integrity, usefulness, accuracy, quality -- there's like five buzz words there -- of the information that it provides to the public.

And so when we look at our website, we kind of pass it through that lens with the folks at the agency who are kind of helping us track our compliance with that law. And one of the things that we do to be in compliance with that, which also just makes sense, is we try to write the right caveats around the information.

How is it useful? How is it not to be used?

You know, what is it meant for and what is it not to be meant for? What are the limitations of the information? And if you click into the website at Nursing Home Compare and you read about the various measures -- I'd encourage you, for example, to go to the pain measure because I know that one; we had to write lots of stuff around that measure -- you'll see how we tried to explain the limitations of that measure, and the limitations of how one might use it.

Hopefully, as we clean up and get better and better measures based on good data and with nice clean risk adjustment, we'll have to have less of those caveats. But right now you'll see how we've tried to structure that. And we will continue to do that, whether it's the home health measures or hospital or whatever.

MS. MATHIAS: Toby, you look like you had a comment?

MS. EDELMAN: No.

MS. MATHIAS: Okay. But Jan does.

MS. THAYER: Well, I must digress because I wanted to go back to your earlier question and you didn't have the opportunity to see me turn the nametag over.

MS. MATHIAS: I apologize.

MS. THAYER: And this is in regard to unlicensed facilities and the definition of assisted

living. And while in the assisted living workgroup it was very difficult to take out parochial and individual experiences, I am now going to relate one to you.

I think that it is extraordinarily helpful for the consumer to have a guideline such as we found helpful -- and it was done legislatively in my state, which is Nebraska -- and that was to say, in this state we have defined assisted living. And unless you meet these basic requirements, you may not advertise that you are assisted living.

So that the consumer in Nebraska at least knows, when they go into a facility that markets itself and that actually carries the assisted living license, that there is a basic set of requirements and services that will be available. And in my experience, as both a consumer and a provider, I think that is very helpful to at least give you a place where you may start and then do your comparisons from there.

It's just like you can't say you're a car unless you are -- and that's putting it very simply -- unless you are at least this. It gives the consumer a basic piece of information with which to start making an informed decision.

MS. MATHIAS: Are some of those smaller facilities, licensed or unlicensed, moving into the

marketing of their facilities at this point? And what do we see happening? Because it would seem to me that the small ones may not advertise anyway and may try to -- I want to say slip, but that's not the right word -- kind of just work on what I would call some of the smaller -- you have the daycare houses where it's in the neighborhood and they take in about four kids and take care of people. When I hear, you know, four units or four beds in assisted living care, that kind of image comes to me. And I'm just wondering, are those smaller units or assisted living care entities being monitored or watched, or are they assisted living care? I mean, we -- I know that the definition is quite broad.

MS. THAYER: May I answer? May I answer that and then --

MS. MATHIAS: I started it with you, yes, so please do, and then Keren and then Karen.

MS. THAYER: I believe that if they are of three, four beds or units, they may not be able to meet the standards that some states say you must meet in order to be assisted living residences. So they might be simply a place where people can receive board and room. And for some people, that is an extremely important part of a service that they can have offered to them in their lives, and they don't purport to be an assisted living

residence.

Different states have different names for different levels of service that they offer, and so I think that they would not be, at least in my state, marketing themselves as assisted living because, number one, it would be against the law to do it, and maybe that's not the only reason they would not, but they simply cannot offer that base of service.

So they don't even try. They say, my niche -- this is my niche and these are the folks that I will serve. MS. MATHIAS: Keren Brown Wilson?

MS. WILSON: Well, I think that a number of states have developed a separate licensing category for small homes -- adult family homes, foster care. So there is a licensing category.

But there's also -- and it's very state by state; for example, Florida has a huge number of unlicensed small homes. It also has a large number of unlicensed large homes. Many of the -- the large homes are unlicensed for a different reason than the small homes.

The small homes are unlicensed because they are operating as that sort of neighborhood service. And importantly, and this is important to hear, almost always they are serving people who are OSS or SSI clients who

can't be served in the licensed places because the licensed places can't do it for $833 a month, or $744, or whatever the rate is for a licensed OSS provider.

So they're basically serving clients who providers can't serve at the OSS or state rate, or who can't meet the regular private market rate. They are those crack people or gap people that we often refer to. And they also don't meet nursing home admission standards. So there's a huge market out there for these clients.

The larger unlicensed residences are doing it mostly as a matter of choice because they are using a different model. They are using a home health care model, or the regulations in their state prohibit certain kinds of services being provided and they want to be able to provide it. So they're using a home health model of service delivery.

And it's the -- or some states are actually using that model, where they're licensing the service and not the setting. So, you know, it's the service that's licensed and not the setting. So, you know, the larger places, they're unlicensed for a different reason.

But for the small places, in many cases it's because they're serving -- and states, quite candidly, don't really want to know a whole lot about these places

because that's on a state dollar.

MS. MATHIAS: Karen Love.

MS. LOVE: I want to echo what Keren Brown Wilson said. And as we're looking at states in increasingly difficult budget times, this is an area that's getting hit significantly.

You've got states, for example, like Maryland, you know, right here in our own back yard, that has a tremendous amount of these smaller homes, has a licensing category for the smaller homes, has a fairly decent set of regulations. But they don't have nearly enough manpower to do the oversight and the following up on complaints. And this is going to continue to be a challenge. I think it's a -- as you call, the gap or crack people, this is a huge, huge issue and there are no easy answers.

MS. MATHIAS: We've talked about a number of the different ways to measure quality, whether it's process or outcome, structure. It seems to me that one of the things I've heard -- and I hope to be corrected if I'm incorrect -- is that we need kind of a blending of various measures to figure out what is the best way to measure quality. You can't just rely on process. You can't just rely on outcome. You can't just rely on the structure of the facility.

But what I was wondering is -- and I'm not seeing any cards raised, so I'm going to hope that assumption is correct -- but is there one of those -- I mean, clearly certain ones are easier to look at.

But is there one that should get weighed a little bit heavier in the weighing of quality? Is outcome more important? Is process more important? And how do you use all of that to measure such a thing, like quality of life, which doesn't seem to have really a process that you could go through?

Start with Barbara.

DR. PAUL: Yes. I can bite a little bit on that. I think that fundamentally, though, you know, the measures should resonate for the users. And it kind of depends on who the user is. If the users are lay consumers making choices about nursing homes, then I think you're going to have different measures that are important than if the users are clinicians who run the nursing homes, perhaps.

I mean, you probably ought to have both but, you know, I think -- so the users really should drive some of these decisions. And we've certainly looked to consumers to help us with that.

What I hear from consumers a lot is that outcomes measures just resonate better for people. You

know, it's easier to understand infection rates or death rates, mortality rates or whatever, than it is to understand, you know, the measure that we have or one of the measures that we have on hospitals is -- you know, has to do with left ventricular systolic dysfunction.

And I'm sure I'm not going to be able to explain that in our Medicare.gov website. And that's a process measure. But on the other hand, doctors know what to do with that measure and know how to impact that, and that's good for the patient.

So I think we would see a whole menu of measures that address process, outcome, structure. And also, in the "Crossing the Quality Chasm Report" from the IOM, they talk ed about six aims for health care. And I probably will -- see how far I get -- efficacy, equity -- so these are measures. You can measure efficacy, equity, efficiency, which is certainly a big one and a very challenging one, safety, patient-centeredness, and something else.

MS. MANARD: That was excellent.

DR. PAUL: And, you know, I think if we can have measures that assess -- whether they're process, outcome, or structure, that address each of those six aims, I think you're going to have a very nice menu to choose from so that whoever you are, you can go to

whatever seems to resonate for you.

MS. MATHIAS: Thank you. I think you turned at about the same time, or at least I looked over. So we'll start with Keren and then move to Jan.

MS. WILSON: One of the things that I would hope that we wouldn't forget is that many times we confuse the word compliance with quality. And a lot of what we measure is compliance. We don't measure quality.

So I hope that as we try to struggle through what it is that we're measuring, we recognize there's a need to measure compliance. There's a need for regulatory oversight and there's a need to measure compliance. But I wouldn't want us to confuse compliance with quality.

And that does go to the issue of structure, process, and outcomes. For me, many of the structure and process things measure compliance, and many of the outcomes measure quality, at least from a consumer point of view.

And that's just my -- you know, I'm not saying that all process measures and all structure measures measure compliance. But in my view, from a consumer point of view, they measure mostly compliance, which may contribute significantly to quality. But is it necessarily quality itself?

MS. MATHIAS: Thank you. Jan?

MS. THAYER: I think that there is a great deal of exciting research that is ahead of us to determine how best to measure whether or not we are effectively delivering a quality of life, a quality of service, a quality of care from both the consumer's perspective and the provider and the regulator or surveyor's perspective.

One of the challenges that -- and we have states, we have some states, that are ready to begin to be sites where we can start to gather data to know whether or not we can arrive at questions and answers that are meaningful in determining this.

I think one of the challenges that we face when we care for older folks is that in the United States, we are still looking for the fountain of youth. We don't want to get old. We don't want to get disabled. And we want to do something about it as we do.

And so how well do we understand, how well do we accept, how well do we educate individuals and families about the life process that says, when somebody is in an assisted living facility or a nursing facility and with certain disease processes or even with a certain age that we are in life, there are things that are going to happen to us that no one can do anything about.

And yet in a nursing facility, if a resident

loses X amount of weight in X period of time, that is a deficiency for the facility when indeed there may be nothing you can do about it.

My own father died just through the fact that, as he told me, "I am wearing out." He was approaching 95 years of age. I tried to get him to get up and walk up and down the halls with me, and he said to me one day, "You know, you really must leave me alone. Do you know how many miles these feet have walked?"

And you know, I didn't bring it up to him any more. If he wanted to, we did. If he didn't, I didn't urge him to do something when he said, "Do you know how many miles these feet have walked in 95 years?"

And so we want to cure everything. And we can't cure old age. And I think we have to have some realistic expectations about the issue that there are some things that are going to begin to happen to us, and how do we then put that into something that we can look at not as delivering inferior service or care, but that we realistically together agree is just one of life's processes?

MS. MATHIAS: Toby, you had your tent turned.

MS. EDELMAN: I did. I did. I guess I wanted to say a couple of things about outcomes. I think that the demand for outcomes is certainly a consumer demand.

In the mid-1970s, a statewide class of nursing home residents sued Colorado and the federal government, saying the whole survey process is just focused on process and structure:

Does the facility have the potential to provide good care, not does it provide good care? Does it have nice diets? Are they written well? Not, does anybody eat the food and enjoy the food? So I appreciate and really think it's important to look at outcomes.

But I know from reading a lot of the decisions from the administrative law judges, when bad outcomes are cited and there's a deficiency because something has happened to a resident that the survey agency determines should not have happened with good care.

What the facilities frequently say is, it's not our fault. We did everything we could have done or should have done, but -- and so we did all the right process. We did all the structure. Don't talk to us about outcomes.

So we hear about it from -- I mean, I think everybody, consumers, providers, move in different directions on outcomes and process and structure depending upon what the situation is. But I think we all do agree that all of these things are important. It's just -- it's hard to pick one and say, this is the only

way to get there, because it doesn't really work for anybody. We need all of it.

MS. MATHIAS: Well, as I stated earlier, we do try to run the train on time. So I think Toby got the last word.

I wanted to thank the audience for coming, both here physically and the people on the phone. I especially wanted to thank our qualified panelists. They have given us a lot to think about and chew on as we eventually write this report. I think they deserve a round of applause.

(Applause.)

MS. MATHIAS: We will reconvene tomorrow at 9:15. We'll spend the morning looking at financing design and consumer information. In the afternoon is advertising. Hope you can come back. Thank you.

(Whereupon, at 5:03 p.m., the hearing was concluded.)

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**C E R T I F I C A T I O N  O F  R E P O R T E R**

DOCKET/FILE NUMBER: P022106

CASE TITLE: HEALTH CARE AND COMPETITION LAW AND POLICY

DATE: MAY 27, 2003

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the tapes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JUNE 11, 2003

LISA SIRARD

**C E R T I F I C A T I O N  O F  P R O O F R E A D E R**

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

SARA J. VANCE