RESPONDENTS' OPPOSITION EXHIBIT 17

the bipartisan Consensus Managed Care Improvement Act.

How about the American Osteopathic Association? The American Osteopathic Association represents the Nation's 43,000 osteopathic physicians. Eugene Oliveri, Dr. Oliveri says, ''As president, I am pleased to let you know that the AOA endorses the Bipartisan Consensus Managed Care Improvement Act of 1999. Why? Because physicians are allowed to determine medical necessity. Health plans are accountable for their actions, a fair and independent appeals process is available and the protections apply to all Americans. Employers and patients,'' this letter says, ''are tired of not receiving the care they are promised, they pay for and they deserve, and H.R. 2723 will help bring quality back into health care.''

Here I have another letter of endorsement. This is from the American Dental Association:

''On behalf of the 144,000 members of the American Dental Association, we wish to endorse H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. This is the first truly bipartisan comprehensive patient protection bill in the 106th Congress.'' This was a letter to Congressman NORWOOD.

''By joining forces with Representative Dingell, you have breathed new life into the movement to establish a few basic rules to protect all privately insured Americans from unfair and unreasonable delays and denials of care.''

The letter goes on: ''We recognize that powerful groups that oppose managed care reform will continue spending millions of dollars in their relentless efforts to scare the public and badger lawmakers who attempt to improve the health care system. However, we will do all we can to make sure that our members know of your courageous efforts on behalf of them and our patients. Patient protection is a genuine grassroots issue that cuts across geographic, economic and political boundaries, and we believe that only bipartisan action will achieve the goal that you want.''

Here I have a news release from the American Academy of Family Physicians: ''Today the 88,000 member American Academy of Family Physicians announces its support for H.R. 2723.''

I have here a letter of endorsement from the American College of Physicians, the American Society of Internal Medicine: ''The American College of Physicians, ASIM, is the largest medical specialty society in the country, representing 115,000 physicians who specialize in internal medicine and medical students. The American College of Physicians believes that any effective patient protection legislation must apply to all Americans, not just those in employer plans, require that physicians rather than health plans make determinations regarding medical necessity, provide enrollees with a timely access to a review process that is independent, offer all enrollees in managed care plans a point of service that enables them to obtain care from physicians outside the network and hold all health plans accountable.''

Mr. Speaker, I have a letter of endorsement from the American Academy of Pediatrics: ''On behalf of the 55,000 general pediatrician-pediatric medical specialists and pediatric surgical specialists, I am writing to express our strong support of H.R. 2723. We are especially pleased that your legislation recognizes the unique needs of children and addresses them appropriately. Children are not little adults. Their care should be provided by physicians who are appropriately educated in unique physical and developmental issues surrounding the care of infants. You clearly recognize this, and have included access to appropriate pediatric specialists, and we are endorsing your bill.''

□ 2115

I have here an endorsement from the American College of Surgeons: ''We are pleased to note that H.R. 2723 requires health plans to allow patients to have timely access to specialty care and to go outside the network for specialty care at no additional costs if an appropriate specialist is not available in the plan.''

This is important. A lot of health plans have incomplete physician panels. If the patient ends up with a complicated procedure, they need assurances their plan will cover them.

This letter of endorsement from the American College of Surgeons goes on: ''If health plans continue to make medical determinations, then they should be held liable to at least the same degree as the treating physician. We are pleased to note that H.R. 2723 would allow patients to hold health plans liable when the plans' decisions cause personal injury or death. Additionally, the College agrees that it is reasonable to prohibit enrollees from suing their health plan for punitive damages if the health plan abides by the decision of the independent external review entity.''

Let me expand on this, Mr. Speaker. What we are saying in this bill is that if there is a dispute on an item of coverage, let us say a patient's physician recommends a type of treatment, the HMO says no, then the patient would be able to appeal that decision in his plan. If the plan still says no, then the patient could take that appeal to an external independent peer panel of physicians and say, I really think that common standards of practice show that I should get this treatment.

Under our bill, that independent panel could make that determination. If they say, yes, we agree with you, and the health plan follows that recommendation, then the health plan is free of any punitive damages liability. That is a fair, commonsense compromise on this issue.

Furthermore, in our bill we have a provision that says, you know, if an employer simply contracts with an HMO, the HMO makes the decision, the employer has had nothing to do with the decision, then the employer cannot be held liable, either. The responsibility lies with the entity that makes a decision that could result in a negligent harm to a patient.

What kind of problems are we talking about? Let me give one example. A few years ago a young mother was taking care of her infant son, 6-month-old infant son, in the middle of the night. The family lived south of Atlanta, Georgia.

Little Jimmy Adams had a temperature of 105 degrees. Mom looked at this baby and knew that baby Jimmy was pretty sick, so she gets on the phone. She does what she is supposed to. She is in an HMO. She phones a 1–800 number. She gets some voice from thousands of miles away and explains the situation.

The reviewer, the HMO bureaucrat, says, all right, I will let you take Jim. I will authorize an emergency room visit for little Jimmy, but only at this hospital. If you go to any other hospitals, then you are going to pay the bill.

It so happens that the hospital that was authorized was 70-some miles away. It is 3:30 in the morning. Mom and dad wrap up little Jimmy. They get into the car. They start to drive this long distance to the emergency room, even though Jimmy is looking really sick. But his mom and dad are not health professionals. On their way to Hospital X they pass three other hospital emergency rooms, but they are not authorized to stop there. They know that they would get stuck with the bill.

They do not know exactly how sick Jimmy is, so they drive on. Before they get to the designated hospital, little Jimmy has a cardiac arrest and stops breathing. Imagine, dad driving frantically, mom trying to keep baby Jimmy alive. They swing finally into the emergency room. Mom jumps out with baby in her arms, saying, help me, help me. A nurse comes out and starts mouth-to-mouth resuscitation. They put in the IVs. They give the medicines. Somehow or other they get little Jimmy back and he lives. But because of the medical decision that that HMO made, saying no, you cannot go to the nearest emergency room, Jimmy is really sick, you have to go 70 miles away, and he has this arrest because of that decision, well, little Jimmy is alive, but because of that arrest he ends up with gangrene in both hands and both feet, and both hands and both feet have to be implemented.

So I phoned Jimmy's mother recently to find out how he is doing. He is learning how to put on his leg prostheses. He has to have a lot of help to get on his bilateral hooks. He will never play basketball. I would tell the Speaker of the House that he will never

wrestle. When he grows up and gets married, he will never be able to caress the cheek of the woman that he loves with his hand.

Do Members know what that HMO is liable for under Federal law? Nothing, nothing, other than the cost of the amputations. Is that fair? Is that justice? I will tell the Members what, these victims of managed care, that the managed care companies just call anecdotes, if you prick their finger, if they have a finger, they bleed. They are our neighbors, or they may be our own families. I could tell hundreds of stories like this.

That is why these organizations say a primary part of this legislation should involve responsibility for an HMO that makes medical decisions.

Here I have a letter of endorsement from the American College of Obstetricians and Gynecologists: ''The American College of Obstetricians and Gynecologists is pleased to offer its support for the bipartisan consensus Managed Care Reform Act of 1999. This legislation would guarantee direct access to OB-GYN care for women enrolled under managed care,'' pretty important.

Here is a letter of endorsement from the American Psychological Association. ''The American Psychological Association expresses our strong support for H.R. 27. Broad bipartisan support for this legislation represents a major breakthrough on behalf of patients' rights. An analysis of the bill shows that the insurance and managed care industry could generate income of $280 million for every 1 percent of claims that are delayed over 1 year.''

That is the provision that is in the other body. Our provision in this bill makes for timely appeals. We appreciate the endorsement of the American Psychological Association.

The American Occupational Therapy Association endorses this bill. ''Over the August recess we have notified our members, asking them to talk to their legislators. Please let us know if we can assist you in your efforts to have comprehensive managed care legislation addressed on the House floor.''

The American Public Health Association, which represents more than 50,000 public health professionals, endorses the bipartisan bill because the bill would ''improve access to emergency services, allow more people to enter clinical trials,'' something the HMO industry has run away from, ''provide patients with a fair appeals process for denied claims, lift barriers to specialists, and hold plans responsible.''

''We understand,'' this letter says, ''that some within the managed care industry oppose any government regulation. But this issue is a very important one for consumers, health care providers, and the public health community. H.R. 2723 is a significant and welcome step towards achieving new patient protections for managed care patients.''

Here I have an endorsement by the American Association for Marriage and Family Therapy: ''On behalf of the 46,000 marriage and family therapists throughout the United States, we want to applaud Congressman Norwood and Representative Dingell for their effort to provide Americans with comprehensive patient protections. Provisions of significance to our organization include an independent review process for determination of medical necessity, the ability of people with special health care needs and chronic conditions to continue to access their doctors, such as a person who had a rheumatoid arthritis being able to continue to see their rheumatoid arthritis doctor.''

We have an endorsement from the American Counseling Association: ''H.R. 2723 provides a wide array of consumer protections, including key components for mental health providers and their clients.''

I have an endorsement from the American Academy of Ophthalmology. I am so proud of the provider groups who have given endorsements for this bill, because this bill is a patient protection bill. It is not a provider bill. There are issues that separate some of these groups. Not all of these groups see eye to eye on health care policy.

Here is an example. We have an endorsement by the American Academy of Ophthalmology and an endorsement by the Opticians Association. Sometimes these groups have policy disagreements, but on this issue they are in 100 percent agreement that patients need protection, basic protection, commonsense protection, from HMO abuses.

The opticians say, ''This bill gives basic, commonsense protections to millions of Americans, and it is certainly refreshing to see the bipartisan way it was approached.''

I have a letter of endorsement from the American Podiatric Medical Association, foot doctors, foot specialists. I have the same endorsement from the orthopedic surgeons.

I have an endorsement here from the Association for Oral and Maxillofacial Surgeons. We have an endorsement from the National Organization of Doctors Who Care. They say, ''We strongly support H.R. 2723 because it ensures fairness and accountability in our health care delivery system lacking in the bill that passed the Senate,'' and other legislation that has gone before, and they are referring to a bill that passed this House of Representatives in the last Congress.

They go on and say in their letter, and I think this is important, ''We are not against managed care. It does have a place. However, we are strongly against managed care plans not towing the line; i.e., not wanting to be held accountable for their medical decisions which adversely affect patient care.''

I have here an endorsement from Physicians for Reproduced Choice in Health Care. This organization is especially pleased that H.R. 2723 would ensure that medical judgments are based solely by health care providers. This is particularly important in that women should have direct access to women specialists.''

We have the National Patient Advocate Foundation endorsing this bill. They go on and say in this endorsement, ''Please note our strong endorsement of the bipartisan consensus Managed Care Improvement Act of 1997, our endorsement for each of the cosponsors of this legislation, and for each member of our United States House of Representatives who has contributed to this debate and to this resulting legislation in the last 3 years.''

They say, ''As one whose companion organization, the Patient Advocate Foundation, served over 6,000 patients last year who confronted insurance denials, of which more than 50 percent involved employer plans, our cases reflect an urgent need for a timely resolution and remedy for ERISA enrollees.''

Then we have an endorsement from the Patient Access Coalition. This includes a lot of groups. I cannot name all 128 of the groups under this umbrella organization, but I want to just go through some of them, because this organization encompasses a lot of patient advocacy groups, groups that work for patients, for instance, that have multiple sclerosis or arthritis.

Some of these organizations are the Digestive Disease National Coalition, the Epilepsy Foundation. Remember, these organizations which I am reading are endorsing organizations for H.R. 2723.

There is the Guillain-Barre Foundation, the Huntington's Disease Society of America, the Infectious Disease Society of America, the Lupus Foundation, the National Committee to Preserve Social Security and Medicare, the National Hemophilia Foundation, the National Multiple Sclerosis Society, the National Psoriasis Foundation, the Paget Foundation for Paget's Disease, the Pain Care Coalition, the Patient Advocates for Skin Disease Research, Scoliosis Research Society, the Society for Excellence in Eye Care, United Ostomy Association. The American Heart Association is an endorsing organization. The American Liver Association is, the American Lung Association. These are all organizations that have endorsed the bipartisan Managed Care Reform Act.

Continuing, there is the Amputee Coalition of America, the Arthritis Foundation, the Asthma and Allergy Foundation, the Cooley's Anemia Foundation, the Crohn's and Colitis Foundation, the American Diabetes Association.

□ 2130

These are just a few of the 128 organizations in this one umbrella organization that has endorsed the Bipartisan Consensus Managed Care Reform Bill.

Why are these patient advocacy groups endorsing this bill? One of the main things that they are interested

in, the American Cancer Society, the American Heart Association, the American Lung Association, the American Liver Association is because there is a provision in this bill that says, if a patient is getting standard treatment, and it is not working, the patient is out of luck, that that patient should be able to qualify for an experimental study; that the HMO would not incur the cost of the special treatment in that study, but that the HMO should be liable for standard care.

I am going to give my colleagues a personal example. Over the August recess, my father was in the hospital for 3 weeks with congestive heart failure. He had to receive intravenous medication in order to keep his heart pumping strong enough so that his kidneys would work. He could not get out of the hospital. Well, an HMO could have said, ''Well, his time is up. We are not going to authorize any payments for any treatment related to a clinical trial.''

Fortunately, my dad is not in an HMO like most Americans are, so he was able to qualify for an experimental study in which a special type of cardiac pace maker was inserted into both sides of his heart which, when it was turned on, gave his heart enough boost so that, within about 24 hours, he made a remarkable recovery; and he is now out of the hospital, and he is walking in the malls.

A lot of HMOs would say, ''Well, that is experimental treatment. We are not going to even cover the cost of the hospital room.'' But our bill says that, if a patient has no other options, then the HMO has to pick up routine costs, not the costs of the device or the medicine, but the ancillary things like the cost of the hospitalization or the cost of the blood work. That is fair and reasonable. But HMOs, they look at the bottom line.

I had a pediatrician once who worked just outside of Washington come into my office. She is now working in the National Institutes of Health. She had managed a pediatric intensive care unit.

I said, ''Why did you decide to go back into academic medicine?'' She said, ''I just could not put up with the HMO bureaucracies anymore. Let me give you an example. A few years ago, we had a little boy come into our intensive care unit. He had drowned. He was still alive, but he was a victim of drowning. We had him on the ventilator. We had the IVs running. We were giving him special medication. And the doctors and the parents and the family were standing around the bed praying for signs of life. He had only been in the hospital like 4 hours, and the phone rings in the ICU, and it is some bureaucrat in an HMO saying, 'Well, how is this little boy doing?' 'Well, he is on the ventilator. Chances, you know, are he is not going to do too good.' Well, the answer came over the telephone, 'If he is on the ventilator and his prognosis is poor, why do you not just send him home on a ventilator?'''

Now think about that for a minute. One is a mom and dad, and one's little boy is drowned. He is now in the hospital. He has been there a few hours. People are fighting to save his life, and an HMO bureaucrat is saying, well, his prognosis is not good just send him home. Our bill would prevent that type of abuse.

Here we have another letter of endorsement from the Paralysis Society of America. They represent 20,000 people with spinal cord injury and disease. This letter says, ''Particular attention is given to those portions of the legislation covering freedom of choice, specialists, and clinical trials.'' Very important issue for them.

Here I have a letter of endorsement from the American Cancer Society, and it is a good letter. I would like to read all of it for my colleagues, but I do not have the time. ''On behalf of the American Cancer Society and its 2 million volunteers, 2 million volunteers, I commend you for sponsoring H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. More than 140 million insured Americans are in some kind of managed care. This includes many of the approximately 1.23 million people diagnosed with cancer each year. In addition, the National Cancer Institute estimates that 8 million Americans today have a history of cancer. Your legislation adequately addresses our concerns in a way that will help individuals affected or potentially affected by cancer be assured access to the care that they need.'' That is their endorsement.

Here I have an endorsement from the National Association of Mental Illness. ''On behalf of the 208,000 members and 1,200 affiliates for the National Alliance of the Mentally Ill, I am writing to express our support for your legislation, the Bipartisan Consensus Managed Care Improvement Act.'' ''This protection,'' this letter says, ''is critically important for people with serious brain disorders such as schizophrenia and manic-depressive illness who depend on newer medications as their best hope for recovery.''

Here I have a letter of endorsement from the American Federation of Teachers. This is from Charlotte Fraas, Director of Federal Legislation. ''I am writing on behalf of over 1 million members of the American Federation of Teachers to urge you to support H.R. 2723, the Bipartisan Consensus Managed Care Empowerment Act of 1999. The AFT is proud to represent over 53,000 health care professionals who know such protections for patient advocacy are essential for quality health care.''

I have a letter of endorsement from the Service Employees International Union. ''On behalf of the 1.3 million members of Service Employees International Union, I am writing in support of the Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723.

''As a union representing over 600,000 frontline health care workers, we know how important it is to protect health care workers who speak out against patient care deficiencies. Employers should be prohibited from firing or retaliating against such workers if we are going to encourage health professionals to report patient care problems.''

I mean, do my colleagues want their nurse or their health care professional gagged? This bill will help prevent that.

Here I have a letter of endorsement from the American Federation of State, County and Municipal Employees, AFSCME. ''On behalf of the 1.3 million members'' we thank you for your leadership on the Bipartisan Consensus Managed Care Improvement Act. They are endorsing this bill.

I have a letter here of endorsement from the Center from Patient Advocacy. ''Since our founding in 1995, the Center for Patient Advocacy has been a leading supporter of strong enforceable managed care reform legislation. Every day we work with patients across the country who have experienced problems with managed care. We know firsthand the barriers to care that patients face, including limits on access to and coverage for specialty care, emergency room care, arbitrary medical decisions based on cost rather than a patient's specific medical need and the lack of a timely independent and fair appeals process. Most alarming, however, is that managed care plans, not patients and their doctors, continue to make medical decisions without being held accountable for their decisions that harm patients.''

I have here a letter of endorsement from the Friends Committee on National Legislation. This is a Quaker lobby in the public interest. This letter from Florence Kimball says, ''I am writing on behalf of the Friends Committee on National Legislation to express our strong support for the Bipartisan Consensus Managed Care Improvement Act of 1999.

''The Friends Committee on National Legislation supports a health care system whose primary goal is improving health in the population. In recent years, managed care has taken over as a dominant health care delivery system. Managed care organizations are under strong pressure to keep costs down. They operate on a for-profit basis. We are sensitive to the economic issues in health care, but we believe that reform and regulation are necessary in order to ensure that managed care organizations hold the interests of patients as their prime focus.'' I would add to that not, necessarily the bottom line.

I have here a letter of endorsement from the United Church of Christ. This is a letter to the gentleman from Georgia (Mr. NORWOOD). ''I am writing to thank you for your leadership in sponsoring the Bipartisan Consensus Managed Care Improvement Act of 1999.

''The United Church of Christ, Office for Church in Society, endorses the bill

as written.'' This is important, and I appreciate Dr. Pat Conover's letter here from the United Church of Christ. He says that, ''In the event that the bill is weakened, or if 'poison pill' amendments are added, such as Medical Savings Accounts, it is likely that we would then oppose the bill.''

This speaks to the fact that we need to pass a clean patient protection bill, not something that has untried ideas such as Healthmarts or association health plan extensions of Federal law that would enable more people to escape quality oversight by their State insurance commissioners.

I think that we could add, for instance, a provision to this bill that would improve the tax status for purchasing one's insurance. I think we could get bipartisan support for that. But if we start adding a lot of extraneous items, then I think we weaken the bill.

I have here a letter of endorsement from Network. This is a National Catholic Social Justice lobby. It is a letter to the gentleman from Georgia (Mr. NORWOOD). ''A National Catholic Social Justice Lobby supports the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). Having participated in the lobbying for patient protections over the past 2 years, Network applauds your efforts and those of Representative Dingell'' and myself ''and the cadre of Republican physicians in facing down the serious opposition from the House GOP leadership. You have stood firm against this and other daunting forces mobilized against you. We commend you for your efforts.''

Network affirms the Catholic social teaching and the UN Declaration of Human Rights that health care is a basic right. We support H.R. 2723, and we wish you luck.

I have here a letter of endorsement from the National Partnership for Women and Families. This is from the letter: ''For women and families, few issues resonate as profoundly and pervasively as the need for quality health care. Survey after survey shows Americans' growing dissatisfaction with the current health care system. Many feel the system is in crisis. We need common-sense patient protections to restore consumer confidence and tip the balance back in favor of patients and the health care providers they rely on.''

That is an endorsement by the National Partnership, and I want to build on that statement. None of us who are sponsoring this organization want to see the demise of HMOs. Some HMOs are providing good care for their families. I think people ought to have a choice. It may be that an HMO is a good choice for that family. But because of this past Federal law that was past 25 years ago, really for pensions but then expanded into health plans, we have a situation where the regulatory oversight was taken away from the States, and nothing was put in its place at the Federal level. This has enabled a few bad actors to do some truly horrible things to their patients like the decision that cost little Jimmy Adams his hands and his feet, for instance.

So I think that, actually, contrary to what the HMO lobby says about this legislation, I see this legislation as improving patients' choices. People will feel more comfortable with a managed care company knowing that there are some guidelines that apply to it and that that managed care company cannot just arbitrarily deny them the kind of care that they deserve.

I have here a letter of endorsement from the National Association of School Psychologists. ''The National Association of School Psychologists is an organization that represents 21,500 psychologists. If H.R. 2327 is passed, this provision will have an important positive impact on health care provided to adults with severe mental health illness, children with serious emotional disturbances, and other people with significant mental disorders who are increasingly being served in managed care settings.''

Here is a letter of endorsement from the organization Alliance for Children and Families. The Alliance and International Nonprofit Association representing child and family serving organizations supports this important legislation. Alliance members serve more than 5 million individual each year in more than 2,000 communities. We support your bill because it includes needed patient protections, strong reforms in managed care, and due process protections.

□ 2145

I have here a letter of endorsement from an organization called Patients Who Care. This letter says: ''We support the Bipartisan Consensus Managed Care Improvement Act of 1999. We strongly feel it ensures fairness and accountability. These qualities have been lacking in what the House and Senate have passed in previous legislation.''

I have here a letter of endorsement from Families USA, the Voice for Health Care Consumers: ''Dear Congressman Norwood: Congratulations on the introduction of the Bipartisan Consensus Managed Care Improvement Act. We are well aware of the efforts you and others have made to make this bill a reality. As you know, the American public is losing faith in our health care delivery system. Managed care companies that began with a promise of providing high quality care at an affordable price are not always delivering on that promise. Unfortunately, this has resulted in consumers being worried that they will not get the care they need even though they are covered with health insurance.''

And I would add to this letter that everyone here, either through deductions in their salary or just out-of-pocket, is paying a lot of money to those HMOs. Now, that is fine as long as we and our family members stay healthy. But what happens if we become sick? We may have an experience like Helen Hunt did in the movie ''As Good As It Gets'', where she describes to a physician the abysmal care an HMO has given to her son with asthma. I cannot repeat on the floor the words she used, but those who have seen the movie can remember that line very well because it got a standing ovation from most of the audience.

I have here a letter from the National Black Women's Health Project: ''We are strong supporters of your legislation. It offers significant protections for all Americans. Of great import is the improvement of patient access to medical treatment and therapies, including clinical trials, and this is highly significant for women of color.''

I have here an endorsement of our bill from the American Association of University Women. They say in this letter: ''H.R. 2723 is particularly important to women because it ensures that women have direct access to OB–GYN services. It ensures that pregnant women can continue to see the same health care provider throughout their pregnancy if their provider leaves the plan. It ensures access to specialists when appropriate, specialists outside a network's plan. It ensures access to clinical trials for new treatment options that may save women's lives.''

I have here a letter of endorsement from the National Breast Cancer Coalition: ''On behalf of the National Breast Cancer Coalition and the 2.6 million women living with breast cancer, I am writing to thank you for your leadership in offering H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.'' This was sent to the gentleman from Georgia (Mr. NORWOOD) and the gentleman from Michigan (Mr. DINGELL). ''The National Breast Cancer Coalition is a grass roots advocacy organization made up of more than 500 member organizations and 60,000 individual members dedicated to the eradication of breast cancer through advocacy and action. One of our top concerns has been access to clinical trials, and your bill has that in it.''

I have here a letter of endorsement from the American Lung Association: ''Health consumers deserve quality health insurance. Far too often we hear of cases where health insurers have obstructed or denied insured patients the care they need. Your legislation will help end many of the abuses.''

Well, Mr. Speaker, I have gone through just some of the letters of endorsement that I have received and others have received in endorsing H.R. 2723, the bipartisan patient protection legislation. But the hour is getting late. We have another speaker who has come to do a special order, so I will just close with this comment to my colleagues on both sides of the aisle.

It is now September. The Speaker of the House, the gentleman from Illinois

(Mr. HASTERT), indicated back in July that we would see a full and fair debate on this floor in July. It did not happen. We have had our August recess. The Speaker has said now that he expects we will see a full managed care debate on this floor in September. Those are the words of the Speaker of the House. I think we should hold the Speaker to his promise.

This is an important issue. There are lots of patients out there at this very moment that may not be getting the type of treatment that they need to save their lives because we have not passed this legislation. Mr. Speaker, I call on my colleagues on both sides of the aisle to support a bipartisan bill that can be signed into law; that can go a long ways towards correcting the abuses we hear about from our constituents.

Mr. Speaker, I include for the RECORD the letters and other documents I referred to earlier.

GROUPS ENDORSING H.R. 2723, THE BIPARTISAN CONSENSUS MANAGED CARE IMPROVEMENT ACT OF 1999

1. Alexandria Graham Bell Association for The Deaf, Inc.
2. Allergy and Asthma Network-Mothers of Asthmatics, Inc.
3. Alliance for Children & Families
4. American Academy of Allergy and Immunology
5. American Academy of Child & Adolescent Psychiatry
6. American Academy of Facial Plastic and Reconstructive Surgery
7. American Academy of Family Physicians
8. American Academy of Neurology
9. American Academy of Ophthalmology
10. American Academy of Otolaryngology-Head and Neck Surgery
11. American Academy of Pain Medicine
12. American Academy of Pediatrics
13. American Academy of Physical Medicine & Rehabilitation
14. American Association for Hand Surgery
15. American Association for Holistic Health
16. American Association for Marriage and Family Therapy
17. American Association for the Study of Headache
18. American Association of Clinical Endocrinologists
19. American Association of Clinical Urologists
20. American Association of Hip and Knee Surgeons
21. American Association of Neurological Surgeons
22. American Association of Oral and Maxillofacial Surgeons
23. American Association of Orthopaedic Foot and Ankle Surgeons
24. American Association of Orthopaedic Surgeons
25. American Association of Private Practice Psychiatrists
26. American Association of University Women
27. American Cancer Society
28. American College of Allergy and Immunology
29. American College of Cardiology
30. American College of Foot and Ankle Surgeons
31. American College of Gastroenterology
32. American College of Nuclear Physicians
33. American College of Obstetricians and Gynecologists
34. American College of Osteopathic Surgeons
35. American College of Physicians-American Society of Internal Medicine
36. American College of Radiation Oncology
37. American College of Radiology
38. American College of Rheumatology
39. American College of Surgeons
40. American Counseling Association
41. American Dental Association
42. American Diabetes Association
43. American EEG Society
44. American Federation of Teachers
45. American Federation State, County, and Municipal Employees
46. American Gastroentrological Association
47. American Heart Association
48. American Liver Foundation
49. American Lung Association
50. American Medical Association
51. American Medical Rehabilitation Providers Association
52. American Nurses Association
53. American Occupational Therapy Association
54. American Orthopaedic Society for Sports Medicine
55. American Osteopathic Academy of Orthopedics
56. American Osteopathic Association
57. American Osteopathic Surgeons
58. American Pain Society
59. American Physical Therapy Association
60. American Podiatric Medical Association
61. American Psychiatric Association
62. American Psychological Association
63. American Public Health Association
64. American Society for Dermatologic Surgery
65. American Society for Gastrointestinal Endoscopy
66. American Society for Surgery of the Hand
67. American Society for Therapeutic Radiology and Oncology
68. American Society of Anesthesiology
69. American Society of Cataract and Refractive Surgery
70. American Society of Dermatology
71. American Society of Dermatopathology
72. American Society of Echocardiography
73. American Society of Foot and Ankle Surgery
74. American Society of General Surgeons
75. American Society of Hand Therapists
76. American Society of Hemotology
77. American Society of Nephrology
78. American Society of Nuclear Cardiology
79. American Society of Pediatric Nephrology
80. American Society of Plastic and Reconstructive Surgeons, Inc.
81. American Society of Transplant Surgeons
82. American Society of Transplantation
83. American Thoracic Society
84. American Urological Association
85. Amputee Coalition of America
86. Arthritis Foundation
87. Arthroscopy Association of North America
88. Association of American Cancer Institutes
89. Association of Freestanding Radiation Oncology Centers
90. Association of Subspecialty Professors
91. Asthma & Allergy Foundation of America
92. California Access to Specialty Care Coalition
93. California Congress of Dermatological Societies
94. Center for Patient Advocacy
95. Congress of Neurological Surgeons
96. Cooley's Anemia Foundation
97. Crohn's and Colitis Foundation of America
98. Diagenetics
99. Digestive Disease National Coalition
100. Endocrine Society
101. Epilepsy Foundation of America
102. Eye Bank Association of America
103. Families USA
104. Federated Ambulatory Surgery Association
105. Friends Committee on National Legislation
106. Gullain-Barre Syndrome Foundation
107. Huntington's Disease Society of America
108. Infectious Disease Society of America
109. Lupus Foundation of America, Inc.
110. National Alliance for the Mentally Ill
111. National Association for the Advancement of Orthotics and Prosthetics
112. National Association of Medical Directors of Respiratory Care
113. National Association of School Psychologists
114. National Black Women's Health Project
115. National Breast Cancer Coalition
116. National Catholic Social Justice Lobby
117. National Committee to Preserve Social Security and Medicare
118. National Foundation for Ectodermal Dysplasias
119. National Hemophilia Foundation
120. National Multiple Sclerosis Society
121. National Organization of Physicians Who Care
122. National Partnership for Women & Families
123. National Patient Advocate Foundation
124. National Psoriasis Foundation
125. National Rehabilitation Hospital
126. North American Society of Pacing and Electrophysiology
127. Opticians Association of America
128. Oregon Dermatology Society
129. Orthopaedic Trauma Association
130. Outpatient Ophthalmic Surgery Society
131. Paget Foundation for Paget's Disease of Bone and Related Disorders
132. Pain Care Coalition
133. Paralysis Society of America
134. Patient Access Coalition (represents 129 of the groups on this list)
135. Patient Advocates for Skin Disease Research
136. Patients Who Care
137. Pediatric Orthopaedic Society of North America
138. Pediatrix Medical Group: Neonatology and Pediatric Intensive Care Specialist
139. Physicians for Reproductive Choice and Health
140. Physicians Who Care
141. Pituitary Tumor Network
142. Renal Physicians Association
143. Scoliosis Research Society
144. Service Employees International Union
145. Sjogren's Syndrome Foundation Inc.
146. Society for Cardiac Angiography and Interventions
147. Society for Excellence in Eyecare
148. Society for Vascular Surgery
149. Society of Cardiovascular & Interventional Radiology
150. Society of Critical Care Medicine
151. Society of Gynecologic Oncologists
152. Society of Nuclear Medicine
153. Society of Thoracic Surgeons
154. TMJ Associations, Ltd.
155. United Church of Christ
156. United Ostomy Association

MEMBERSHIP LIST OF THE PATIENT ACCESS COALITION

Allergy and Asthma Network—Mothers of Asthmatics, Inc.

The Alexandria Graham Bell Association for the Deaf, Inc.
American Academy of Allergy and Immunology
American Academy of Child & Adolescent Psychiatry
American Academy of Dermatology
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Physical Medicine & Rehabilitation
American Association for Hand Surgery
American Association for Holistic Health
American Association for the Study of Headache
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Oral and Maxilofacial Surgeons
American Association of Orthopaedic Foot and Ankle Surgeons
American Association of Private Practice Psychiatrists
American College of Allergy and Immunology
American College of Cardiology
American College of Foot and Ankle Surgeons
American College of Gastroenterology
American College of Nuclear Physicians
American College of Osteopathic Surgeons
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American Dental Association
American Diabetes Association
American EEG Society
American Gastroentrological Association
American Heart Association
American Liver Foundation
American Lung Association
American Medical Rehabilitation Providers Association
American Orthopaedic Society for Sports Medicine
American Osteopathic Academy of Orthopedics
American Osteopathic Surgeons
American Pain Society
American Physical Therapy Association
American Podiatric Medical Association
American Psychiatric Association
American Psychological Association
American Sleep Disorders Association
American Society for Dermatologic Surgery
The American Society of Dermatophathology
American Society for Gastrointestinal Endoscopy
American Society for Surgery of the Hand
American Society for Therapeutic Radiology and Oncology
American Society of Anesthesiology
American Society of Cataract and Refractive Surgery
American Society of Clinical Pathologists
American Society of Colon Rectal Surgery
American Society of Dermatology
American Society of Echocardiography
American Society of Foot and Ankle Surgery
American Society of General Surgeons
American Society of Hand Therapists
American Society of Hemotology
American Society of Nephrology
American Society of Pediatric Nephrology
American Society of Plastic and Reconstructive Surgeons, Inc.
American Society of Transplantation
American Society of Transplant Surgeons
American Thoracic Society
American Urological Association
Amputee Coalition of America
Arthritis Foundation
Arthroscopy Association of North America
Association of American Cancer Institutes
Association of Freestanding Radiation Oncology Centers
Association of Subspecialty Professors
Asthma & Allergy Foundation of America
California Access to Specialty Care Coalition
California Congress of Dermatological Societies
College of American Pathologists
Congress of Neurological Surgeons
Cooley's Anemia Foundation
Crohn's and Colitis Foundation of America
Cystic Fibrosis Foundation
Diagenetics
Digestive Disease National Coalition
The Endocrine Society
Epilepsy Foundation of America
Eye Bank Association of America
Federated Ambulatory Surgery Association
Gullain-Barre Syndrome Foundation
Huntington's Disease Society of America
Infectious Disease Society of America
Joint Council of Allergy, Asthma and Immunology
Lupus Foundation of America, Inc.
National Association for the Advancement of Orthotics and Prosthetics
National Association of Epilepsy Centers
National Association of Medical Directors of Respiratory Care
National Committee to Preserve Social Security and Medicare
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization of Physicians Who Care
National Osteoporosis Foundation
National Psoriasis Foundation
National Rehabilitation Hospital
National Right to Life Committee
North American Society of Pacing and Electrophysiology
Oregon Dermatology Society
Orthopaedic Trauma Association
Outpatient Ophthalmic Surgery Society
The Paget Foundation for Paget's Disease of Bone and Related Disorders
Pain Care Coalition
Patient Advocates for Skin Disease Research
Pediatric Orthopaedic Society of North America
Pediatrix Medical Group: Neonatology and Pediatric Intensive Care Specialist
Pituitary Tumor Network
Renal Physicians Association
Scoliosis Research Society
Sjogren's Syndrome Foundation Inc.
The Society for Cardiac Angiography and Interventions
Society for Excellence in Eyecare
Society for Vascular Surgery
Society of Cardiovascular & Interventional Radiology
Society of Critical Care Medicine
Society of Gynecologic Oncologists
Society of Nuclear Medicine
Society of Surgical Oncology
Society of Thoracic Surgeons
The TMJ Associations, Ltd.
United Ostomy Association

ANA Endorses Bipartisan Managed Care Bill

ANA encourages Congress to continue working together & pass bipartisan bill

WASHINGTON, DC.—The American Nurses Association (ANA) today applauded the introduction of a bipartisan consensus bill that would reform managed care. The bill, H.R. 2723, ''The Bipartisan Consensus Patient Protection Bill of 1999,'' was introduced on August 8, 1999, by Rep. Charlie Norwood (R–GA). Rep. John Dingell (D–MI) is the lead co-sponsor.

''The American Nurses Association is pleased to endorse this bill and encouraged by the cooperation and compromises made to achieve real progress on managed care reform,'' said ANA President Beverly L. Malone, PhD, RN, FAAN. ''It is heartening to see Congress working together to solve problems—this is how Congress should be working.''

ANA has been a strong supporter of managed care reform legislation and believes every individual should have access to health care services along the full continuum of care and be an empowered partner in making health care decisions. Given the nursing profession's preeminent role in patient advocacy, ANA is particularly heartened by the steps proposed to protect registered nurses (RNs) and other health care professionals from retaliation when they advocate for their patients' health and safety.

''As the nation's foremost patient advocates, RNs need to be able to speak up about inappropriate or inadequate care that would harm their patients,'' said Malone. ''Nurses at the bedside know exactly what happens when care is denied, comes too late or is so inadequate that it leads to inexcusable suffering, which is why we need to maintain strong whistleblower protection language in this bill. Nurses want to see strong, comprehensive patient protection legislation enacted this year.''

AMERICAN MEDICAL ASSOCIATION,
Chicago, IL, August 30, 1999.

Hon. CHARLIE NORWOOD,
House of Representatives,
Washington, DC.

DEAR CONGRESSMAN NORWOOD: The 300,000 physician and student members of the American Medical Association (AMA) strongly urge the House of Representatives to begin debate on and pass meaningful patient protection legislation.

The AMA has endorsed H.R. 2723, the ''Bipartisan Consensus Managed Care Improvement Act of 1999,'' introduced by Representatives Charles Norwood and John Dingell, which would guarantee meaningful protections to all patients and enjoys broad bipartisan support. The AMA also continues to work with Representatives Tom Coburn and John Shadegg, who are in the process of drafting patient protection legislation. Whichever bill becomes the vehicle for reform, it must include the following key provisions, embodied in H.R. 2723, that ensure genuine patient protections.

External Appeals

All patients must be guaranteed access to an external appeals process whenever a denial of benefits involves medical judgment or concerns medical necessity. All patients deserve access to an independent external review entity if they have been improperly denied a covered medical benefit. External reviewers must also be independent from the health plan or issuer. For the external appeals system to work in a fair and unbiased manner, external reviewers must not have a conflict of interest with the plan or issuer. In addition, treatment decisions or recommendations made by physicians must be reviewed only by actively practicing physicians (MDs/DOs) of the same or similar specialty. External reviewers must be properly qualified to ensure a meaningful external review process.

External reviews must be conducted on a timely basis, not to exceed specified time periods, with shorter periods applicable under

exigent circumstances. Plans and issuers cannot be permitted to intentionally delay an appeals process—or ''slow-walk'' enrollees who are seeking benefits to which they are entitled. The external reviewers' decisions must also be binding on the plans and issuers. Unless external review entities' decisions are binding, any right to an external review would be worthless for the patient.

Medical Necessity

Truly independent external reviewers must decide ''medical necessity'' according to generally accepted standards of medical practice. External appeal entities, when making ''medical necessity'' determinations, should not be bound by arbitrary health plan definitions. In addition, ''medical necessity'' determinations and other decisions involving medical judgment must be made by physicians (MDs/DOs) who are independent from the plans and issuers.

Accountability

All patients, even those covered by ERISA plans, should have the right to seek legal recourse against managed care plans when the plan's negligent medical decisions result in death or injury. Health plans must be held accountable for their decisions. Employers who do not make medical treatment decisions should not be held liable.

Point Of Service

All patients must have the opportunity to choose, at their own expense, an option that allows them to seek care from outside the network of health care professionals chosen by their employers. If an employer selects a small, closed-panel HMO for its employees, the employees should be able to obtain medical treatment from a physician outside the panel and bear any additional costs.

Emergency Services

A ''prudent layperson standard'' must be the basis for determining when emergency medical services are appropriate and require coverage by a plan. Establishing this as a standard is not only fair, but essential for protecting patients. For instance, a patient who is suffering severe chest pain and honestly believes he or she is having a heart attack should be able to go to the nearest emergency room and be covered for treatment received.

Prohibition On Gag Clauses

Health plans and insurance issuers must be prohibited from including gag clauses within their contracts with physicians. Gag clauses seek to prevent physicians from discussing with their patients plan or treatment options or disclosing financial incentives that may affect the patient's treatment. These clauses strike at the heart of the patient-physician relationship and can create real conflicts between patients and their physicians.

Information Disclosure

Group health plans and health insurance issuers must be required to provide enrollees with important and basic information about their medical coverage. Plans and issuers should identify the benefits offered—including covered benefits, benefit limits, coverage exclusions, prior authorization rules, appeals procedures, and other basic information. Patients deserve to know exactly what they are paying for.

In conclusion, the AMA appreciates the bipartisan efforts by House members to introduce legislation that would promote fairness in managed care. We urge you to support legislation containing these essential protections for all patients and to request prompt floor action on managed care reform legislation in September.

Respectfully,

E. RATCLIFFE ANDERSON, Jr., MD.

AMERICAN ACADEMY OF FAMILY PHYSICIANS,
Kansas City, MO, Sept. 7, 1999.

HEALTH CARE STEPS TAKEN

PATIENT CARE REMAINS PRIORITY

WASHINGTON, D.C.—The 88,000-member American Academy of Family Physicians (AAFP) today announced its support for two major managed care reform bills that are likely to be considered by the U.S. House of Representatives this fall: H.R. 2723, The Bipartisan Consensus Managed Care Improvement Act of 1999, introduced by Representatives Charles Norwood (R–GA) and John D. Dingell (D–MI); and for Health Care Quality and Choice Act of 1999, to be introduced by Representatives Tom Coburn (R–OK) and John Shadegg (R–AZ) when Congress reconvenes in September.

''Both bills go a long way to address the patient protections that are needed in today's health care system,'' said Lanny R. Copeland, M.D., president of the AAFP. ''We are very appreciative of the work of the authors of these two bills and of their willingness to listen to our concerns.''

Both bills contain provisions that will allow patients to get the best healthcare and physicians to provide it:

All plans: Patient protections apply to all health plans, not just ERISA plans.

Gag clauses: Both bills would prohibit contract provisions between physicians and health plans that restrict or prevent medical communication between physicians and their patients.

Patient advocacy: Both bills contain some protections for physicians who advocate on behalf of a patient within a health plan or before an external review panel.

External review: Both bills would establish external review mechanisms independent of health plans.

Medical necessity: Such external review processes would not be bound by the health plans' definition of medical necessity.

Liability: Both bills permit patients to sue in state court.

Women's health care: The Coburn/Shadegg legislation would include family physicians among those designated as qualified women's health providers. H.R. 2723 would not preclude patients from going to family physicians for their women's health needs.

Children's health care: The Coburn/Shadegg legislation includes family physicians among those designated as qualified primary care physicians for children H.R. 2723 would not preclude patients from going to family physicians for their children's health needs.

''These legislators are being responsive to patients and to the public good,'' said Copeland. ''We urge the House of Representatives to expeditiously pass legislation reflecting these principles.''

PATIENT ACCESS COALITION,
Bethesda, MD, August 16, 1999.

Hon. GREG GANSKE,
U.S. House of Representatives, Washington, DC.

DEAR REP. GANSKE: On behalf of the 130 patient advocacy and provider organizations that comprise the Patient Access Coalition, we deeply appreciate and acknowledge your demonstrated commitment to moving strong and meaningful patient protection legislation to the House floor for consideration this year. Your support of this issue has unquestionably sparked a new level of dedication and enthusiasm amongst your colleagues for making patient protections a top legislative priority when the House reconvenes in September.

Because the health of millions of Americans is dependent upon the care provided by managed care plans, the issue of patient protections is one of national importance and urgency. It is clear that the only way to achieve passage of strong patient protection legislation this year is with the bipartisan support of Congress, and we are pleased that you are working toward that end.

The Patient Access Coalition has been working tirelessly for the past six years, in a bipartisan manner, to guarantee basic federal protections for all patients who are enrolled in managed health care plans. We believe there is now a very strong consensus in the country and in Congress to do so, and our commitment to reach that goal remains stronger than ever.

We look forward to working with you and other members of Congress to ensure that meaningful patient protection legislation is enacted into law this year.

Sincerely,

NANCEY MCCANN,
Co-Chair.
CAMILLE S. SOROSIAK,
Co-Chair.

NETWORK, A NATIONAL CATHOLIC SOCIAL JUSTICE LOBBY,
Washington, DC.

Hon. CHARLES NORWOOD,
House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: NETWORK, A National Catholic Social Justice Lobby supports the Bipartisan Consensus Managed Care Improvement Act of 1999 (HR 2723). Having participated in the lobbying for patient protections over the past two years, NETWORK applauds your efforts and those of Reps. Dingell (D–MI), Ganske (R–IA), and the cadre of Republican physicians in facing down the serious opposition from the House GOP Leadership. You have stood firm against this and the other daunting forces mobilized against you. We also commend those who bolstered your efforts.

NETWORK will lobby in support of HR 2723, hoping that the bill will be strengthened in the process. Our membership nationally has already been alerted. But we wish to stress, Representative Norwood, that NETWORK believes that the long journey toward HR 2723, and hopefully its passge, further underscores the need for a national dialogue on health care.

The prolonged debate which began with the President's Commission on Patients' Protections, the subsequent introduction of patients' protection legislation and the militancy and funding of those who championed opposition to strong protections are proof positive of the dangers we face as a nation in the commercialization of health care.

When HMO's/insurance companies and pharmaceuticals begin to shift priorities from the rights of the patient to the success of the stockholder, we have entered a dangerous zone in human rights. The situation calls for a national ethical moral debate on what constitutes an authentic health care system.

NETWORK affirms the tenet of Catholic social teaching and the U.N. Declaration of Human Rights that health care is a basic human right and that the government has an obligation to protect that right out of responsibility for the common good. Consequently, we have supported past initiatives to protect that right through legislation which would provide for all citizens access to affordable quality health care.

That those initiatives have failed is a travesty of justice, leaving us the only industrialized nation in the world without a guarantee of health care for all its citizens.

Sadly, at this point, the nation's non-system is hopelessly fragmented while the number of uninsured grows daily. As the need for patients' protections indicates, even those privately insured under a variety and complexity of health care plans—the details of

which often elude them—are not guaranteed necessary, timely and quality health care.

Therefore, as we support HR 2723, we urge you to use the lessons of these two years as a launching pad toward universal access to quality, affordable health care. Universal access to affordable quality health care will be for NETWORK and many of our allies a critical election issue.

Sincerely,

KATHY THORTON, RSM,
National Coordinator.
CATHERINE PINKERTON, CSJ,
NETWORK Lobbyist.

NATIONAL PATIENT ADVOCATE FOUNDATION,
Newport News, VA, August 19, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of our patient and health care constituents, I write to commend your leadership in bringing a Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723) to the United States House of Representatives. Many members of the House of Representatives have sought to support reform that would improve patient access to care and patient autonomy in decision making with their physicians during their medical experience while assuring patients access to independent, external review and offering plan accountability for decisions made. Each member who has contributed to this debate has achieved success in the form of the Bipartisan Consensus Managed Care Improvement Act of 1999.

The Bipartisan Consensus Managed Care Improvement Act of 1999 reflects an understanding that insurance should not dictate or control health care of Americans rather it should facilitate and finance health care for Americans. Our organization strongly endorses H.R. 2723 citing specifically the following advantages:

The Bill is one of bipartisan consensus and it does reflect the health care matters that have long been debated on both sides of the aisle with resulting legislation that serves patients and medical providers fairly and equitably while supporting our managed care industry through the development of a clearly defined set of critiera that health plans must meet to conform to the federal law as defined in H.R. 2723.

The Bill affords protections to all people with employment-based insurance (including state and local government workers) and people who buy their insurance on their own which we feel affords an equitable opportunity for regulation and enforcement of industry standards for the majority of insured Americans.

The Bill establishes a uniform standard of accountability for health plans who make coverage decisions which is consistent with the level of accountability that exists for every business and industry that provides service to Americans and that becomes legally accountable for poor business practices or judgements that cause harm to our citizens. With 79 percent of our citizens in an ERISA plan that currently offers few venues of remedy for those citizens whose benefits are denied, the Bipartisan Consensus Managed Care Improvement Act of 1999 does offer improved remedy and uniform regulations. As one whose companion organization, the Patient Advocate Foundation served over 6,000 patients last year who confronted insurance denials of which more than 50 percent involved ERISA plans, our cases reflect an urgent need for timely resolution and remedy for ERISA enrollees. This Bill improves the system of clarifying responsibilities, systems of appeal and opportunity for timely remedy. Patients confronting life threatening conditions must have timely, external, independent review and closure to their cases.

The Bill assures that medical judgements are being made by medical experts and their patients.

It is our position that the provisions of this legisation that assure patient access to Clinical Trials, access to prescription drug not on the HMO's predetermined formulary when the treating physican deems the medication as needed for optimum benefit of patient care and the provision that doctors and nurses will not confront retaliation when they report quality problems all combine to assure higher standards of quality care for patients that will enhance disease survival and extend life.

Please note our strong endorsement of the Bipartisan Consensus Managed Care Improvement Act of 1999, our endorsement for each of the co-sponsors of this legislation and for each member of our United States House of Representatives who has contributed to this debate and to this resulting legislaiton over the course of the last three years. It was our recent pleasure to honor both you and Congressman Dingell with our National Health Care Humanitarian Award July 22, 1999 in Washington. Certainly the leadership that you both exhibit in the development, sponsorship and negotiation of this bill as you seek to position it on the floor of the House for debate is consistent with our evalution of each of you as recipients of our award. Thank you for your noble leadership in addressing the matters embodied in this Managed Care Improvement Act. We encourage House Speaker Dennis Hastert to place this Bill on the floor of the House for debate and to allow your peers in the House of Representatives to vote their conscience in support of H.R. 273.

Respectfully submitted:

NANEY DAVENPORT-ENNIS,
Founding Executive Director.

AMERICAN COLLEGE OF SURGEONS,
Washington, DC, August 31, 1999.

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the 62,000 Fellows of the American College of Surgeons, I am pleased to offer the College's endorsement of Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723. This legislation encompasses all of the provisions that the College believes are critical to ensuring that all privately insured patients have access to the most appropriate medical care. This legislation stands in stark contrast to the inadequate managed care reform legislation that the Senate passed in July.

The College believes that all patients should have timely access to appropriate specialty care. Patients should not be forced by their health plan to endure unnecessary delays in accessing specialty care nor should they be forced to receive care from a specialist who does not have the appropriate training and experience to treat their condition. We are pleased to note that H.R. 2723 requires health plans to allow patients to have timely access to specialty care and to go out-of-network for specialty care at no additional cost if an appropriate specialist is not available within the plan.

Once a patient is able to see an appropriate specialist, health plans are frequently restricting the patient's care by unilaterally determining the most appropriate medical treatment. This determination often is contrary to the advice of the patient's treating physician. It is also often formulated on the basis of cost rather than the patient's best interest. H.R. 2723 would protect patients by requiring health plans to offer their enrollees an opportunity for independent external review of their case. The external reviewer would then produce a binding determination. The College further commends you for including a requirement that the independent external entity determine the appropriate treatment by considering the recommendations of the treating physician along with other reasonable evidence and to do so without being bound to the health plan's definition of medical necessity.

Another issue of deep concern to our Fellows is that surgeons and other physicians being forced to bear all of the liability involved in providing health care services when health plans are often restricting the services they can provide and the setting in which the care can be provided. If health plans continue to make medical determinations, then they should be held liable to at least the same degree as the treating physician. We are pleased to note that H.R. 2723 would allow patients to hold health plans liable when the plan's decisions cause personal injury or death. Additionally, the College agrees that it is reasonable to prohibit enrollees from suing their health plan for punitive damages if the health plan abides by the decision of the independent external review entity.

All of these provisions, along with the numerous other provisions included in H.R. 2723, address critical patient needs in our nation's changing health care system. Once again, the College is pleased to offer its support for the Bipartisan Managed Care Improvement Act of 1999 and we look forward to working with you, the Republican and Democratic leadership, and, in fact, all the Members of the House of Representatives to ensure that comprehensive managed care reform legislation is enacted this year.

Sincerely,

GEORGE F. SHELDON, MD, FACS,
President.

OFFICE FOR CHURCH IN SOCIETY
UNITED CHURCH OF CHRIST,
Washington, DC, August 10, 1999.

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: I am writing to thank you for your leadership in sponsoring the Bipartisan Consensus Managed Care Improvement Act of 1999.

The United Church of Christ, Office for Church in Society, endorses the bill as written.

In the event that the bill is weakened, or if ''poison pill'' amendments are added, such as Medical Savings Accounts it is likely that we would then oppose the bill.

Thanks again for your effort to help protect patients from inappropriate denial of care and to make sure that the services promised in managed care contracts will be fully available from competent health professionals.

Sincerely,

REV. DR. PAT CONOVER,
Policy Advocate.

AMERICAN COLLEGE OF PHYSICIANS,
AMERICAN SOCIETY OF INTERNAL MEDICINE,
Washington, DC, August 12, 1999.

Hon. CHARLES NORWOOD,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: The American College of Physicians-American Society of Internal Medicine (ACP–ASIM) is the largest medical specialty society in the country, representing 115,000 physicians who specialize in internal medicine and medical students. ACP–ASIM is in a unique position to evaluate patient protection legislation as our members represent the full range of internal medicine practitioners. We believe

that any patient protection legislation must be comprehensive and provide patients with the necessary basic rights and protections they need.

ACP–ASIM believes that any effective patient protection legislation must:

Apply to all insured Americans, not just those in ERISA plans.

Require that physicians, rather than health plans, make determinations regarding the medical necessity and appropriateness of treatments. ACP–ASIM supports language that defines medical necessity in terms of generally accepted principles of professional medical practice, as supported by evidence on the effectiveness of different treatments when available.

Provide enrollees with timely access to a review process with an opportunity for independent review by an independent physician when a service is denied.

Offer all enrollees in managed care plans a point-of-service option that will enable them to obtain care from physicians outside the health plan's network of participating health professionals, and

Hold all health plans, including those exempt from state regulation under ERISA, accountable in a court of law for medical decisions that result in death or injury to a patient.

In addition to these protections, we also believe that it is important to address the need to ensure access to affordable health insurance coverage for all Americans. Patient protections are meaningless if patients lack health insurance coverage. ACP–ASIM calls on the Congress to guarantee the most basic right of all Americans—the right to insurance coverage—by crafting legislative solutions that will reduce, with a goal of eventually eliminating, the growing numbers of uninsured citizens.

As the U.S. House of Representatives considers this legislation, ACP–ASIM encourages the continuation of a bipartisan approach. We thank you for sponsoring the Bipartisan Consensus Managed Care Improvement Act, H.R. 2723, containing the key elements needed for effective patient protection and demonstrating the bipartisan support for such legislation in the House. ACP–ASIM looks forward to the consideration of a comprehensive bill on the floor of the House in September that will be fully capable of providing Americans in managed care and other health plans with needed protections. We stand ready to assist in this effort.

Sincerely,

ALAN R. NELSON, MD, FACP,
Associate Executive Vice President.

AMERICAN ACADEMY OF PEDIATRICS,
Washington, DC, August 9, 1999.

Hon. CHARLIE NORWOOD,
House of Representatives,
Washington, DC.

DEAR CONGRESSMAN NORWOOD: On behalf of the 55,000 general pediatrician, pediatric medical subspecialist, and pediatric surgical specialist members of the American Academy of Pediatrics, I am writing to express our strong support of your recently introduced legislation, the Bipartisan Consensus Managed Care Improvement Act of 1999 (HR 2723). We look forward to working with you and other members of Congress to ensure that strong patient protection legislation becomes law this year.

We are especially pleased that your legislation recognizes the unique need of children and addresses them appropriately. Children are not little adults. Their care should be provided by physicians who are appropriately educated in the unique physical and developmental issues surrounding the care of infants, children, adolescents and young adults. You clearly recognize this and have included access to appropriate pediatric specialists, as well as other important protections for children, as key provisions of your legislation.

Thank you for your efforts and we look forward to working with you to enact strong patient protection legislation. Please do not hesitate to contact me or Graham Henson of our Washington office if we can be of assistance.

Sincerely,

JOEL J. ALPERT, MD, FAAP,
President.

AMERICAN PSYCHOLOGICAL ASSOCIATION,
Washington, DC, August 10, 1999.

Hon. CHARLIE NORWOOD,
House of Representatives,
Washington, DC.

DEAR DR. NORWOOD: On behalf of the 159,000 members and affiliates of the American Psychological Association (APA), I am writing to express our strong support for the bipartisan Consensus Managed Care Improvement Act (H.R. 2723), which you have introduced with Representative John D. Dingell.

Broad bipartisan support for this new legislation represents a major breakthrough on behalf of patients' rights. You bill covers all persons with private insurance and includes much needed patient protections, strong reforms of the managed care industry and due process protections for providers. APA is especially grateful that you have continued to champion our top legislative priority, removing the ERISA shield from health plan legal accountability. As in your previous bills that APA has endorsed since 1996, H.R. 2723 permits persons who have been injured by decisions of health plans that delay or deny care to hold them legally accountable. We believe that removal of this special exemption will be a strong incentive for health plans to deliver clinically necessary care, obviating the need for lawsuits.

Improvements to an appeals process without legal accountability clearly would not be sufficient. A new analysis of the Senate-passed bill, S. 1344, shows that the insurance and managed care industry could generate interest income of $280 million for every one percent of claims that are delayed for the full 377 days permitted. This PricewatershouseCoopers analysis helps refocus the debate on the need for incentives to ensure that correct decisions are made by health plans to begin with and that health plans do not abuse an appeals process.

H.R. 2723 also includes the requirements that those in closed panel health plans be offered a point of service plan at the time of enrollment, enabling care outside of a network. The bill reflects a procompetitive provision banning health plans from excluding a class of providers based solely on licensure. Medical necessity decisions would be made by clinical peers in a fair and independent appeals process, moving the system away from some of its worst abuses.

APA appreciates your continued leadership on these vital issues and will continue to work with you to win enactment of comprehensive managed care quality legislation.

Sincerely,

RUSS NEWMAN, Ph.D., J.D.

SERVICE EMPLOYEES INTERNATIONAL UNION,
Washington, DC, August 19, 1999.

Hon. CHARLIE NORWOOD,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the 1.3 million members of the Service Employees International Union, I am writing in support of the Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723.

We are very pleased that a truly comprehensive bipartisan patient protection bill has been introduced. This is a bill that addresses the concerns that many working families have about the failure of managed care plans to ensure access to quality health care and puts medical decisions in the hands of medical experts not insurance company bureaucrats. Unlike the Senate bill, H.R. 2723 would:

Cover all Americans who have private insurance's.

Provide true access to emergency services, specialists, continuity of care, and clinical trials

Provide for an internal and an independent external appeals process that ensures a timely process for consumers for whom health care is denied or withheld

Hold health plans accountable for treatment decisions that result in injury or death.

Additionally, H.R. 2723 includes a vitally important patient advocacy/whistleblower provision. As a union representing over 600,000 frontline health care workers, we know how important it is to protect health care workers who speak out against patient care deficiencies. Employers must be prohibited from firing or retaliating against such workers if we are going to encourage health professionals to report patient care problems.

We commend you and your leadership in putting forward a bill that provides real patient protections. SEIU looks forward to working with you to pass H.R. 2723.

Sincerely,

ANDREW L. STERN,
International President.

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
Washington, DC, August 11, 1999.

Hon. CHARLES NORWOOD,
Longworth House Office Building,
5Washington, DC.

DEAR CONGRESSMAN NORWOOD, The American College of Obstetricians and Gynecologists (ACOG) is pleased to offer its support for the Bipartisan Consensus Managed Care Improvement Act of 1999. This legislation would guarantee direct access to ob-gyn care for women enrolled in managed care.

Women need the assurance that they can receive care for their women's health needs from their ob-gyns without the added time, expense, and inconvenience of first having to get permission from their primary care physicians. Your legislation would ensure this fundamental patient protection to all women in managed care plans.

Today, many managed care plans require women—even pregnant women—to get permission slips from their primary care physicians before they can see their ob-gyns. Sixty percent of ob-gyns in managed care plans report that their gynecologic patients are either limited or barred from seeing their ob-gyns without first getting permission from another physician. An astounding 28% report that their pregnant patients must first receive another physician's permission before seeing their ob-gyns. To make matters worse, nearly 75% of ob-gyns report that their patients have to return to their primary care physicians for permission before their ob-gyn can provide necessary follow-up care.

Direct access to ob-gyns for all covered obstetric and gynecological follow-up care, as under your plan, will help to ensure quality health for women, including pregnant women and their infants. Thank you for your leadership and commitment to these vital goals.

We look forward to working closely with you as this legislation moves toward enactment.

Sincerely,

RALPH W. HALE, M.D.,
Executive Vice President.

CENTER FOR PATIENT ADVOCACY,
McLean, VA, August 9, 1999.

Hon. CHARLIE NORWOOD,
Longworth House Office Bldg.,
Washington, DC.

DEAR CONGRESSMAN NORWOOD: The Center for Patient Advocacy is pleased to support the ''Bipartisan Consensus Managed Care Improvement Act of 1999.''

Since our founding in 1995, the Center for Patient Advocacy has been a leading supporter of strong, enforceable comprehensive managed care reform legislation. Every day the Center works with patients across the country who have experienced problems with managed care. We know first-hand the barriers to care that patients face, including limits on access to and coverage for speciality care and emergency room care, arbitrary medical decisions based on cost rather than a patient's specific medical needs, and the lack of a timely, independent and fair external appeals process to name a few. Most alarming, however, is that managed care plans—not patients and their doctors—continue to make medical decisions without being held legally accountable for their decisions that harm patients.

The Bipartisan Consensus Managed Care Improvement Act is a common-sense approach that addresses these problems. In this era where the pressure to reduce costs often comes at the expense of the patient, it is not only appropriate, but imperative that Congress act and pass legislation to protect patients from managed care abuses.

We commend your continued leadership in the managed care reform debate and your tireless efforts to secure a strong, enforceable and bipartisan solution to the problems patients across the country are facing. As we have continued to emphasize, patients are not calling on Congress to pass a Republican or Democrat bill. They are calling on Congress to pass bipartisan legislation that will truly provide them with needed protections and empower patients and their physicians with the decisions affecting their health care. And we believe that the Bipartisan Consensus Managed Care Improvement Act will do just that.

Sincerely,

TERRE MCFILLEN-HALL,
Executive Director.

AMERICAN OSTEOPATHIC ASSOCIATION,
Washington, DC, August 27, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR CONGRESSMAN NORWOOD: The American Osteopathic Association (AOA) represents the nation's 43,500 osteopathic physicians. As President, I am pleased to let you know that the AOA endorses your bill, the ''Bipartisan Consensus Managed Care Improvement Act of 1999'' (H.R. 2723).

The AOA advocates, on behalf of patients, for Congress to enact strong, meaningful, and comprehensive protections. After six years of debate and delay, we believe that H.R. 2723 is the bipartisan legislation that will ensure the AOA's long sought principles. These include: physicians allowed to determine medical necessity; health plans held accountable for their actions; a fair and independent appeals process available to patients, and protections which apply to all Americans.

Over the last two decades, managed care has become less interested in delivering quality healthcare to patients. Instead, the focus seems entirely on the bottom line. It is time to bring the focus back to our patients and away from HMO profits. Employers and patients are tired of not receiving the care they are promised, pay for and deserve. H.R. 2723 will help bring the quality back into healthcare and allow osteopathic physicians to care for our patients in accordance with the high principles guiding our profession.

Again, thank you for your leadership on this critical issue. We are encouraged by the broad bipartisan support your legislation has received. The AOA pledges to work with you and all Members of Congress to ensure swift enactment of H.R. 2723. Please feel free to contact Michael Mayers, AOA Assistant Director of Congressional Affairs, in our Washington office with any further comments or questions.

Sincerely,

EUGENE A. OLIVERI, D.O.,
President.

AMERICAN DENTAL ASSOCIATION,
Washington, DC, August 13, 1999.

Hon. CHARLIE NORWOOD,
1707 Longworth House Office Building, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the 144,000 members of the American Dental Association, we wish to endorse H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. This is the first truly bipartisan, comprehensive patient protection bill in the 106th Congress. By joining forces with Representative Dingell, you have breathed new life into the movement to establish a few basic rules to protect all insured Americans from unfair and unreasonable delays and denials of care.

We recognize that the powerful groups that oppose managed care reform will continue spending millions of dollars in their relentless efforts to scare the public and badger lawmakers who attempt to improve the health care system. However, we will do all we can to make sure that all of our members know of your courageous efforts on behalf of them and their patients.

Patient protection is a genuine grassroots issue that cuts across geographic, economic and political boundaries. We believe that only bipartisan action will solve the problems in the health care system, and your bill represents a major, positive step in the right direction.

Sincerely,

S. TIMOTHY ROSE, D.D.S., M.S.,
President.
JOHN S. ZAPP, D.D.S.,
Executive Director.

PHYSICIANS FOR REPRODUCTIVE CHOICE AND HEALTH,
New York, NY, August 30, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: Physicians for Reproductive Choice and Health (PRCH) is pleased to support the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). We applaud your leadership, as well as that of Representative Dingell and the additional supporters of the legislation. The mission of PRCH is to enable concerned physicians to take a more active and visible role in support of universal reproductive health. We represent more than 3,000 physicians and non-physician supporters from around the country. PRCH is committed to ensuring that all people have the knowledge, access to quality services, and freedom of choice to make their own reproductive health decisions, and we believe this legislation is an important step toward that goal.

The American health care system is changing rapidly. PRCH believes it is vital that those changes do not come at the expense of quality care for patients. The Bipartisan Consensus Managed Care Improvement Act includes many important patient protections. As a physician membership organization, PRCH is especially pleased that H.R. 2723 would ensure that medical judgments are rendered solely by health care providers, who are in the best position to guard the interests of their patients. Other particularly important provisions would assure that women have direct access to ob-gyn care from their choice of participating health care providers; protect health care professionals who report quality problems from retaliation by insurance plans and others; and prohibit health care plans from financially rewarding health care professionals for limiting a patient's care.

We commend your leadership in the struggle to ensure that patients' rights are established in federal law.

Sincerely,

JODI MAGEE,
Executive Director.
SEYMOUR L. ROMNEY, M.D.,
Chair.

AMERICAN CANCER SOCIETY,
August 27, 1999.

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR CONGRESSMAN NORWOOD: On behalf of the American Cancer Society and its 2 million volunteers, I commend you for sponsoring H.R. 2723, the ''Bipartisan Consensus Managed Care Improvement Act of 1999,'' legislation that meets the needs of cancer patients. As the largest voluntary health organization dedicated to improving cancer care, we urge support of such legislation that would help ensure patients, especially those affected by cancer, access to quality and appropriate medical care. Specifically, we are pleased that the provisions in your legislation will benefit all 161 million Americans in private health insurance and employer-sponsored plans and that your legislation provides patients with direct access to clinical trials.

More than 140 million insured Americans are in some kind of managed care plan and this includes many of the approximately 1.23 million people diagnosed with cancer each year. In addition, the National Cancer Institute estimates that 8 million Americans alive today have a history of cancer. While managed care has greatly improved access to needed prevention, early detection, and cancer treatment, we are concerned about some of the gaps that remain in getting quality care to the patient.

Your legislation adequately addresses some of our concerns in a way that will help ensure that individuals affected or potentially affected by cancer will be assured improved access to quality care. H.R. 2723 grants patients with life threatening diseases access to specialists, including an out-of-network specialist if one is not available within their health plan; ensures continuity of care if an employer switches to a plan that does not include their physician who is providing on-going treatment or if a treating physician is no longer with the health plan; and permits for a specialist to serve as the primary care physician for a patient who is undergoing treatment for a serious or life-threatening illness.

Most importantly, your bill includes a clinical trials provision strongly supported by the American Cancer Society. H.R. 2723 recognizes that coverage of the routine patient care costs for patients enrolled in any phase of high-quality, peer-reviewed clinical trials affords people with cancer and other serious or life threatening disease the opportunity to seek the best and most appropriate care while helping to advance scientific knowledge. This access is integral to possibly extending life, reducing morbidity, and

increasing medical knowledge. As you may know, in many cases, coverage for routine patient services for patients who wish to participate in a clinical trial are often denied, thereby creating a major barrier for patients who would like, or need, access to these treatments. For these patients, the clinical trial offers a critical opportunity to receive state of the art cancer treatment—therapies that may be their best and most appropriate treatment option and their only chance at survival and an improved quality of life. In addition, without sufficient enrollment in clinical trials, we as a nation lose an opportunity to collect data about the safety and efficacy of a new therapy or technology that could potentially benefit future generations of patients and save the health care system money. We firmly believe it is essential that cancer patients have access to these oftentimes lifesaving therapies that can reduce suffering and prolong life and are very supportive of the provision in H.R. 2723.

The Society commends you for sponsoring this legislation that provides access to clinical trials for all patients with serious and life threatening diseases. Due to the nature of research, life-saving treatments for one disease are often found in clinical trials of a drug aimed at treating another disease. Recently, clinical trials of Rezulin, a diabetes drug, showed that the drug may slow rapid cell growth in some cancers. Similarly, research has shown that the cancer drug, endostatin, may help heart disease. By providing broad access to clinical trials, your legislation will help advance the state of research for many diseases by allowing for the cross-pollination of research—cancer patients will benefit from clinical trials in AIDS, diabetes, etc., and vice versa.

While we are very pleased with your leadership on this issue, we are concerned that H.R. 2723 will not help patients who want to enroll in privately sponsored pharmaceutical trials—the type that is most frequently provided through the Food and Drug Administration. We would greatly appreciate your consideration of increasing access to these types of clinical trials for managed care patients.

The diagnosis of cancer is devastating—not only must patients confront an array of medical decisions, they must deal with financial and emotional burdens as well. We thank you for sponsoring legislation ensuring that cancer patients, irrespective of type of health insurance, will face fewer financial worries as they consider their treatment options. Please call Megan Gordon, Legislative Representative, for any additional information you or your staff may need.

Sincerely,

KERRIE WILSON,
National Vice President, Policy Advocacy.

AMERICAN ACADEMY OF OPHTHALMOLOGY,
Washington, DC, August 30, 1999.

Hon. CHARLES NORWOOD,
Longworth House Office Building,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: The American Academy of Ophthalmology (AAO) would like to thank you for your introduction of H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. Your bill contains the core patient protections the AAO supports and believes should be a part of all managed care plans.

AAO is the world's largest educational and scientific organization of eye physicians and surgeons (Eye M.D.s), representing over 26,000 members, dedicated to the treatment and diagnosis of disorders of the eye.

AAO supports H.R. 2723 on the basis that it would guarantee the following six protections to the millions of Americans enrolled in managed care plans:

1. An out-of-network (point-of-service) option at the time of enrollment;
2. Timely access to specialty care;
3. A fair and expedited independent appeals process;
4. A consumer information checklist;
5. A ban on financial incentives that result in the withholding of care or a denial of a referral; and
6. A ban on ''gag clauses'' which prohibit a provider from giving patients certain information, including treatment options.

We look forward to working with you to ensure passage of a strong, comprehensive and meaningful patient protections bill this Congress. Again, thank you for introducing your bill and for championing this issue in the House of Representatives.

Sincerely,

WILLIAM L. RICH, III, MD,
Secretary for Federal Affairs.

FRIENDS COMMITTEE ON NATIONAL LEGISLATION,
Washington, DC, August 26, 1999.

Re Managed Care Improvement Act.

Representative CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: I am writing on behalf of the Friends Committee on National Legislation (FCNL, a Quaker lobby in the public interest) to express our strong support for the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723).

FCNL supports a health care system whose primary goal is maintaining and improving the health of the population. In recent years, managed care has taken over as the dominant health care delivery system. The shift to managed care has reflected the belief, particularly within the business community, that managed care does a substantially better job of controlling health care costs than does traditional fee-for-service insurance. Thus, managed care organizations are under strong pressure to keep costs down. In addition, many managed care organizations operate on a for-profit basis which exerts pressures to reduce outlays. These changes in the structure of health care insurance have created an environment in which patients' interests can (and sometimes do) take a back seat. While we are sensitive to the economic issues in health care, we also believe that reform and regulation are necessary in order to ensure that managed care organizations hold the interests of patients as a prime focus.

Following are some of the provisions of H.R. 2723 that are of particular importance to FCNL.

Scope of coverage: We support extending managed care protections to all 161 million people in the U.S. with private insurance. This would complement the protection already afforded to those in Medicaid and Medicare managed care.

Access to care: We strongly favor efforts to reduce and eliminate bureaucratic obstacles that some patients have faced as they seek access to physicians and needed health care services. For example, we support access to closest emergency room, without prior authorization and without higher costs; guaranteed access to needed health care specialists, outside the network, if needed; access to pediatric specialists; the right of women to directly access ob/gyn care and services; and access to quality clinical trials for those with no other effective option.

Protection of Doctor/Patient Relationship: We oppose limitations placed on physicians by HMOs or insurance companies that reduce their ability to treat or communicate with patients. For example, we believe that legislation should prohibit gag clauses that restrict the freedom of health care providers to discuss all treatment options with patients; limit financial incentives to withhold care; ensure continuity of care so that patients in the middle of long-term treatment plans do not suffer an abrupt transition of care if their physician or other provider is dropped from the plan; and assure that health care professionals who report deficiencies in the quality of health care services will not experience retaliation by the plan.

Accountability: We support the right of patients to timely appeals of health plan decisions and to be able to hold health plans accountable for decisions. Examples of such rights include access to internal and independent external appeals processes that are fair, unbiased, and timely; and a mechanism that holds health plans legally accountable when their decisions harm patients.

FCNL applauds your efforts and the efforts of your colleagues to pass legislation that would provide these and other related protections to patients in managed care plans.

Sincerely,

FLORENCE C. KIMBALL,
Legislative Education Secretary.

AMERICAN FEDERATION OF TEACHERS,
Washington, DC, August 20, 1999.

U.S. HOUSE OF REPRESENTATIVES,
Washington, DC.

DEAR REPRESENTATIVE: I am writing on behalf of the over one million members of the AFT to urge your support for bipartisan patients rights legislation, H.R. 2723, the Bipartisan Consensus Managed Care Empowerment Act of 1999. Hopefully, when Congress returns from its August recess, the House of Representatives will have the opportunity to vote on this important bill.

This bipartisan measure, introduced by Representatives Charles Norwood (R–GA) and John Dingell (D–MI), is compromise patients' rights legislation that retains essential features of the Patients Bill of Rights, H.R. 358, that AFT has also supported.

The bipartisan bill (H.R. 2723), which applies to all 161 million Americans with health insurance coverage, has these essential features;

Ensures access to emergency care without prior authorization, following a ''prudent lay person'' standard;

Authorizes direct access to OB/GYNs and pediatricians to be primary care physicians;

Provides access to pediatric specialties;

Provides for continuity of care when there is a change of plan or change in the provider network;

Provides for an independent external appeals process;

Authorizes patients to sue health plans in state courts, but disallows punitive damages if a plan complies with an independent external appeals decision;

Provides that doctors and nurses can report quality problems without fear of retaliation from Health Maintenance Organizations (HMOs), insurance companies and hospitals.

AFT is particularly pleased that H.R. 2723 contains protection against retaliation for health care workers acting as patient advocates. The AFT is proud to represent over 53,000 health care professionals who know such protections for patient advocacy are an essential component of quality health care.

H.R. 2723 offers the House a very real opportunity to enact legislation on a bipartisan basis that will improve the quality of managed care. The American Federation of Teachers urges you to co-sponsor and support this vital legislation.

Sincerely,

CHARLOTTE J. FRAAS,
Director of Federal Legislation,
Office of Government Relations.

AFSCME, AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL–CIO,
Washington, DC, August 18, 1999.

Honorable CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the 1.3 million members of the American Federation of State, County and Municipal Employees (AFSCME), I am writing to thank you for your leadership in introducing the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). This compromise legislation provides meaningful reform of managed care with significant and enforceable protections for consumers.

In particular, we are pleased that the bill extends patient protections to all of those who are covered by managed care plans rather than just limited segments of the insured population. Importantly, the bill holds all, rather than just some, plans accountable for treatment denials which result in the injury or death of patients. But the liability shield now enjoyed by self-funded plans is removed in a balanced way, providing that there will be no punitive damages where the plan has followed the recommendation of an external review panel. Further, the bill makes clear that employees cannot be sued unless they intervene in treatment decisions.

Of particular interest to AFSCME members who work in health care, H.R. 2723 includes important protections for physicians and nurses who raise concerns or warnings about the care of patients. Although limited, these protections will allow health care professionals to speak, without fear of reprisal, to appropriate public regulatory agencies, appropriate private accrediting bodies, plan administrators or their employers. The provision protecting patient advocacy will help accomplish the bill's overall goal of improving the quality of care for patients.

In sum, H.R. 2723 would accomplish reform in a meaningful, yet balanced way. We thank you for co-sponsoring this important legislation.

Sincerely,

GERALD W. MCENTEE,
International President.

AMERICAN THORACIC SOCIETY
AND THE AMERICAN LUNG ASSOCIATION,
Washington, DC, August 24, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the American Lung Association and its medical section, the American Thoracic Society, I want to congratulate you for introducing the Bi-Partisan Patient Protection legislation (H.R. 2723). The ALA/ATS strongly support this important legislation.

American consumers deserve quality health insurance. Far too often we hear of cases where health insurers have either obstructed or completely denied insured patients access to the care they need. Insurers, by design or default, are preventing patients from getting the care they need.

Your legislation will help end many of the abuses in our nation's health insurance system. Your legislation will give all of our nation's insured individuals access to specialists, a swift appeals process and legal recourse for denied care, and will ensure physicians—not insurers—determine medical necessity. These important patient protections are needed to restore confidence to our nation's health care system.

The American Lung Association and the American Thoracic Society are ready to work with you and other Members of Congress to quickly enact this important legislation. Again, thank you for your leadership on this important issue.

Sincerely,

FRAN DUMELLE,
Deputy, Managing Director.

NATIONAL BREAST CANCER COALITION,
Washington, DC, August 24, 1999.

Representative JOHN DINGELL,
Representative CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVES: On behalf of the National Breast Cancer Coalition (NBCC) and the 2.6 million women living with breast cancer, I am writing to thank you for your leadership in offering H.R. 2723, The Bipartisan Consensus Managed Care Improvement Act of 1999. Passage of this legislation would ensure that patients in private health plans have access to legitimate patient protections.

The National Breast Cancer Coalition is a grassroots advocacy organization made up of more than 500 member organizations and 60,000 individual members dedicated to the eradication of breast cancer through advocacy and action. We have long been committed to working with Members of Congress to enact meaningful healthcare reform. While many versions of ''patient protection'' legislation have been discussed in the past, we appreciate your leadership on introducing strong and comprehensive bipartisan legislation that brings us one step closer to achieving our goal.

One of NBCC's top concerns is breast cancer patients' access to clinical trials. Women with breast cancer often seek participation in clinical research studies as their best treatment option. It is unconscionable that their health plans would deny payment for even routine patient care cost like physician and hospital charges merely because patients are receiving treatment in the context of a clinical trial versus standard therapy. H.R. 2723, which would require health plans to cover routine patient care costs for cancer patients enrolled in approved clinical trials, is a critical step in including greater participation in clinical trials.

We also want to thank you for including access to specialty care in the Bipartisan Consensus legislation. This provision is extremely important to ensure that individuals in private health plans have access to the specialty care they need—an essential component of a meaningful patients' bill of rights. We are pleased that this legislation would allow breast cancer patients to go straight to their oncologists should that be medically appropriate.

Finally, NBCC appreciates your recognition that a right without strong enforcement is no right at all. By holding plans accountable when their decisions to withhold or limit care injures patients, H.R. 2723 ensures that insurers are subject to the same rules and legal penalties for injuries as any other industry. Strong enforcement is absolutely essential to any meaningful managed care reform, and we are pleased that the Bipartisan Consensus bill incorporates this provision.

Thank you again for your outstanding leadership. We look forward to working with you to get H.R. 2723, The Bipartisan Consensus Managed Care Improvement Act, enacted into law this year. Please do not hesitate to call me or NBCC's Government Relations Manager, Jenifer Katz if you have any questions.

Sincerely,

FRAN VISCO,
President.

AMERICAN ASSOCIATION OF UNIVERSITY WOMEN,
Washington, DC, August 24, 1999.

PROTECT WOMEN'S HEALTH IN MANAGED CARE REFORM

DEAR REPRESENTATIVE: On behalf of the 150,000 members of the American Association of University Women (AAUW), I urge you to support the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723), introduced by Reps. Charlie Norwood (R–GA) and John Dingell (D–MI), when the House considers managed care reform legislation. AAUW believes that H.R. 2723 will ensure accountability of managed care plans and a health care delivery system that fully meets the needs of women and families.

AAUW believes that only H.R. 2723 will significantly improve managed health care for all consumers, and especially for women. H.R. 2723 covers all 148 million privately insured Americans and addresses a broad range of issues that will provide quality, timely, and appropriate health care to all consumers; ensure patients' rights; and meet the needs of women and their families. H.R. 2723 guarantees that patients can have a health plan's decision to deny care reviewed by an independent medical expert, and holds managed care plans accountable when their decisions to withhold or limit care cause injury or death. H.R. 2723 is particularly important to women because it: Ensures that women have direct access to ob-gyn services from the participating health care professional of their choice; Ensures that pregnant women can continue to see the same health care provider throughout pregnancy if their provider leaves the plan or their employer changes plans; Ensures access to specialists, including, when appropriate, specialists outside a plan's network; and Ensures access to clinical trials for new treatment options and that may save people's lives.

Once again, I urge you to support H.R. 2723 to ensure accountability of managed care plans and a health care delivery system that fully meets the needs of women and families. If you have any questions, please call Nancy Zirkin, Director of Government Relations, at 202/785–7720, or Lisa Levine, Government Relations Manager, at 202/785–7730.

Sincerely,

SANDY BERNARD, *President.*

NATIONAL BLACK WOMEN'S HEALTH PROJECT,
Washington, DC, August 24, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN NORWOOD: The National Black Women's Health Project (NBWHP) is writing in support of the Bipartisan Consensus Managed Care Improvement Act (H.R. 2723). NBWHP is the only national organization solely dedicated to improving the health and well-being of America's 17.8 million Black women through wellness programs and services, information, and advocacy. We have been and continue to be a strong supporter of managed care reform. The proposed legislation offers significant protections for all Americans, and the specific implications for women and women of color are vitally important. Of great importance is the inclusion of patient access to medical treatments and therapies including clinical trials. This is highly significant as women of color are often under-represented in clinical trials. In addition, the inclusion of access to all prescription drugs is crucial as women would have assured access to coverage for contraceptives.

There is an urgent need for consumer protections in the health care and insurance system, and we feel that this legislation is a

progressive action in this regard. We appreciate any opportunities to work with you. If you have any further questions, please feel free to telephone our office. Shelia Clark, our Public Policy Associate, is our contact person. We look forward to the passage of this legislation.

Sincerely,

JULIA SCOTT,
President and CEO.

NATIONAL ALLIANCE FOR
THE MENTALLY ILL,
Arlington, VA, August 24, 1999.

Hon. JOHN DINGELL,
Hon. CHARLES NORWOOD,
U.S. House of Representatives.
Washington, DC

DEAR REPRESENTATIVES DINGELL AND NORWOOD: On behalf of the 208,000 members and 1,200 affiliates of the National Alliance for the Mentally Ill (NAMI), I am writing to express our support for your legislation, the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). As the nation's largest organization representing people with severe mental illnesses and their families, NAMI believes that federal standards are necessary to ensure that access to the most advanced treatment is not compromised in the name of cost savings. We support your efforts as an important step forward in protecting the interests of consumers and their families in the health care system.

In particular, NAMI is especially pleased that your legislation will address critical issues that are of great concern to people with severe mental illnesses and their families including use of restrictive prescription drug formularies and meaningful external appeals. NAMI is grateful that your legislation will protect the ability of patients and their doctors to go beyond a health plan's limited drug formulary when it is necessary to find the most effective medication. this protection is critically important for people with serious brain disorders such as schizophrenia and manic-depressive illness who depend on newer medications as their best hope for recovery.

NAMI also strongly supports your proposal for external grievance procedures that would require that decisions of independent review panels be legally binding upon health plans and prevent health plans from being able to select the independent third-party review panel. Patients and their families should be able to take their claim of an unfair denial of treatment coverage to an unbiased process for an adjudication of their rights.

NAMI also supports key provisions in H.R. 2723 regarding access to medical specialists. Health plans should be required to provide access to covered specialty care within a plan's network and allow consumers unobstructed access to a specialist, such as a psychiatrist, over a longer period, without repeated and unnecessary pre-authorizations from their plan. Finally, NAMI would like to thank you for including in your bill strong protections for consumer access to medical treatment costs associated with clinical trials. For many people with severe mental illnesses, clinical trials on new medications are the best hope for successful treatment. Health plans should not be allowed to deny patients access to these trials by refusing to pay for routine medical care.

NAMI is grateful for your efforts on behalf of people with severe mental illnesses and their families. Your bipartisan approach to this difficult issue is an important step forward in placing the interests of consumers and families ahead of politics. NAMI looks forward to working with you to ensure passage of meaningful managed care consumer protection legislation in the 106th Congress.

Sincerely,

LAURIE FLYNN,
Executive Director.

FAMILIES USA FOUNDATION,
Washington, DC, August 11, 1999.

Hon. CHARLIE NORWOOD,
Longwood HOB, Washington, DC.

DEAR CONGRESSMAN NORWOOD: Congratulations on the introduction of the ''Bipartisan Consensus Managed Care Improvement Act of 1999,'' H.R. 2723. We are well aware of the efforts you and others made to make this bill a reality.

As you know, the American public is losing faith in our health care delivery system. Managed care companies that began with the promise of providing high quality care at an affordable price are not always delivering on that promise. Unfortunately, this has resulted in consumers being worried that they will not get the care they need even though they are covered with health insurance. Your bill is a reasonable compromise proposal that can bring back balance to our health care system.

We look forward to working with you to make the ''Bipartisan Consensus'' bill the law of the land.

Sincerely,

RONALD F. POLLACK,
Executive Director.

NATIONAL ORGANIZATION OF
PHYSICIANS WHO CARE,
San Antonio, TX, August 24, 1999.

Hon. CHARLIE NORWOOD,
Longworth HOB, Washington DC.

DEAR CONGRESSMAN NORWOOD: I am president of Physicians Who Care, Inc. (''PWC''). It is a not-for-profit organization which is devoted to protecting the doctor-patient relationship and ensuring quality health care. Formed in 1985 in San Antonio, Texas the organization has approximately 4,000 members, most of them doctors in private practice. PWC believes the responsibility for medical care belongs first and foremost to physicians and patients. We affirm the right of the physician, as the provider of care, to diagnose, prescribe, test and treat patients without undue outside interference. We affirm the right of the patient, as the person most affected by care, to choose his or her own physician and help determine the type of treatment received.

On behalf of PWC and its board of directors, I am writing to you now. As you know, one of the major issues facing our country today is our health care delivery system—quality, access, delivery, accountability and fairness. We are apprised that this issue will come before the House of Representatives next month after Congress reconvenes from its summer recess.

We have reviewed H.R. 2723, the bill introduced into the House by Representatives Norwood and Dingell. It is known as the ''Bipartisan Consensus Managed Care Improvement Act of 1999''. We strongly support it as it insures fairness and accountability in our health care delivery system that has been lacking in what the Senate has passed and other legislation that has gone before (H.R. 2723). We ask that you vote in favor of it.

Now is the opportunity to vote on legislation that will support the ability of patients to receive proper care from their providers and provide providers with measures of confidence and comfort not known by them since managed care and managed care plans were foisted upon patients and physicians.

We are particularly impressed by the wording in H.R. 2723 relating to external appeals, the ability of patients to sue their health plans and managed care organizations like HMOs (just like they can physicians, hospitals and others who make medical decisions in patient care), excluding employers from liability unless they are involved in the same medical decision-making that presently exposes physicians, hospitals, nurses and the like.

Moreover, we are mindful that opponents of this type legislation raise costs as an issue or that employers will not be able to provide health insurance to their employees if the ERISA preemption is lifted or even that lifting this preemptive effect will cause more lawsuits. To these points, we respectfully and firmly disagree! Opponents are using emotion and ''scare tactics'' to avoid fact and the ability of all patients to receive proper and quality health care.

We are not against managed care; it does have a place. However, we are strongly against managed care plans not ''toeing the line'', i.e. not wanting to be held accountable for their medical decisions that adversely affect patient care (all over the country managed care plans are failing, 200 in California alone).

Now may be the last time that you have to provide effective relief to patients and their providers alike. If you do not, our court system may do it for you (as recent decisions in the last few years seem to strongly indicate.)

Please vote what is right, fair and just for all patients; we sincerely ask that you support H.R. 2723.

Thank you.

Sincerely,

RONALD BRONOW, M.D.,
President.

PATIENTS WHO CARE,
San Antonio, TX, August 24, 1999.

Hon. CHARLIE NORWOOD,
Longworth HOB, Washington, DC.

DEAR CONGRESSMAN NORWOOD: I am president of Patients Who Care (PtWC). It is a non-profit 501(c)3 organization of approximately 20,000 members and is dedicated to promoting through education an understanding of issues affecting access by patients to the highest quality health care possible. We believe in preserving quality medical care, affordability of care and care reimbursement plans, and preserving the doctor/patient relationship. We also feel it is the right of patients to choose their own physician and determine the type of treatment received. Finally, we try to help patients understand their rights in the health care decision-making process.

On behalf of PtWC and its board of directors, I am writing to you now. As you know, one of the major issues facing our country today is our health care delivery system—quality, access, delivery, accountability and fairness. We are apprised that this issue will come before the House of Representatives next month after Congress reconvenes from its summer recess.

We have received H.R. 2723, the bill introduced in the House of Representatives Norwood and Dingell. It is known as the ''Bipartisan Consensus Managed Care Improvement Act of 1999''. We strongly support it as we feel it insures fairness and accountability in our health care delivery system. These qualities have been lacking in what the House and Senate have passed in previous health care legislation. We ask that you vote in favor of H.R. 2723, and do all you can to help this bill move quickly to passage.

Now is the opportunity to vote on legislation which will support the ability of patients to receive proper care from their providers. It will also give providers a greater measure of confidence and comfort in treating their patients since managed care and the managed care plans were foisted upon patients and physicians many years ago.

We are particularly impressed by the wording in H.R. 2723 relating to external appeals, the ability of patients to sue their health plans and managed care organizations like HMOs (just like they can physicians, hospitals and others who make medical decisions in patient care), excluding employers from liability unless they are involved in the same medical decision-making that presently exposes physicians, hospitals, nurses and the life. We are also mindful that opponents of this type legislation raise ''costs'' as the issue, saying 'employers will not be able to provide health insurance to their employees if the ERISA preemption is lifted or even that lifting this preemptive effect will cause more lawsuits'. We feel this is a lesser concern than decisions that adversely affect patient care (all over the country managed care plans are failing—200 in California alone).

Now may be the last time you have to provide effective relief to patients and their providers. If you do not, our court system may do it for you (as recent decisions in the last few years seem to strongly indicate.)

Please vote what is right, fair and just for all patients; we sincerely ask that you support H.R. 2723.

Thank you.

Sincerely,

STEVEN C. JOHNSON, CLU, RHU,
President.

P.S. It is also our understanding that most ''individual'' health care plans, not currently under ERISA, will not be affected by this legislation, or be required to conform to H.R. 2723. please be vigilant of this issue which our members have raised.

ALLIANCE FOR CHILDREN AND FAMILIES,
August 24, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: We at the Alliance for Children and Families are writing to express our support for the Bipartisan Consensus Managed Care Improvement Act (H.R. 2723), which you have introduced with Representative Dingell. The Alliance, an international nonprofit association representing over 350 child- and family-serving organizations, supports this important legislation to protect patients' rights. Alliance members serve more than 5 million individuals each year in more than 2,000 communities.

Broad bipartisan support for this new legislation represents a major breakthrough on behalf of patients' rights. This bill provides essential protections for all consumers in the private health insurance marketplace. H.R. 2723 ensures that medical decisions will be in the hands of medical experts. It permits people to hold their managed care plans accountable when plan decisions to withhold or limit care result in injury or death. We believe that holding health plans accountable will be a strong incentive for them to deliver clinically necessary care, minimizing the need for lawsuits.

We support your bill because it includes much needed patient protections, strong reforms of the managed care industry and due process protections for providers. It ensures that patients have access to a fair and independent external review for cases in which care is denied. H.R. 2723 also ensures that patients have access to specialists, including, when appropriate, specialists outside a plan's network.

Thank you for your leadership in protecting patients' rights through the Bipartisan Consensus Managed Care Improvement Act of 1999.

Yours sincerely,

CARMEN DELGADO VOTAW,
Senior Vice President, Public Policy.

PARALYSIS SOCIETY OF AMERICA,
August 23, 1999.

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Longworth Building, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the Paralysis Society of America (PSA), I am writing to voice support for H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.

We are pleased to see that the consensus bill combines the patient protections found in the major managed care reform bills introduced in the House this year, including H.R. 216, the Quality Care Act, and H.R. 358, the Patients' Bill of Rights. We also note the importance of H.R. 2723 as a bipartisan bill. Legislators who support this bipartisan bill recognize the importance of a health care system that balances the cost of service delivery without sacrificing individual patient needs.

PSA's membership of more than 19,800 people consists of individuals with spinal cord injury or disease, their family members and caregivers, health care professionals, and others with an interest in the disciplines of spinal cord medicine and paralysis. As you can imagine, the outcome of patient protection legislation speaks directly to the vested interest in our membership.

Particular attention is given to those portions of the legislation covering freedom of choice, specialists, and external appeals, clinical trials and privacy. Also of interest to our membership are the sections covering continued care, freedom of communication, clinical trials reform, incentives to deny care, and privacy:

PSA members want the right to freely choose and/or change their doctor and hospital;

PSA members want the right to see a specialist if they and their doctor determine the need is paramount to managing the complex health care needs of people with spinal cord dysfunction;

PSA members want the right to a second and third opinion following denial of coverage by a health plan, at no cost to the patient;

PSA members should not be forced to change doctors and hospitals while in the midst of a course of treatment for a health care problem;

Doctors must be able to talk freely with patients without fearing repercussions from health plans. Every doctor should be free to discuss anything relative to a patient's health with the patient, even if the information may be negative towards the health plan. Health plans must not be permitted to use tactics that discriminate against doctors for cooperation in patient advocacy, such as threats of firing, disciplinary action and by providing incentives to deny care;

PSA members should be able to participate in clinical trials that may maximize their independence and quality of life without undue interference from their health plan; and

PSA members are concerned about their right to privacy. No medical information on a patient should be released without the patient's approval.

The right to quality health care and patient protection is of primary importance to the members of the Paralysis Society of America. PSA offers its support, and will gladly assist you in any way we can to ensure that H.R. 2723 is enacted into law.

Sincerely,

NANCY STARNES,
Director.

NATIOANAL ASSOCIATION OF SCHOOL PSYCHOLOGISTS,
Bethesda, MD, August 24, 1999.

Hon. CHARLIE NORWOOD,
Longworth House Office Building, Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the National Association of School Psychologists, (NASP) I am writing to express our strong endorsement of H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.

NASP is an organization that represents 21,500 school psychologists and related professionals throughout the world. NASP works to actively promote educationally and psychologically healthy environments for all children and youth. We work together with national coalitions to increase support and funding for primary prevention services and mental health programs that deter youth from delinquent activity, assist them with improved learning and provide them with experiences and role models to become successful in life. In health care, our goal is to increase access and affordability of health and mental health services for which coverage is often extremely limited or denied.

Developing a balanced compromise on the most controversial of managed care reform provisions, the Bipartisan Bill would provide essential protections for consumers in the private health insurance marketplace. The Bipartisan Consensus Bill maintains a strong utilization review process to require the oversight of trained personnel, assures fair appeals, guarantees access to emergency and urgent care services and holds health plans accountable for their decisions. Furthermore, this bill requires the development of quality criteria along with performance and clinical outcome measures for at-risk individuals and people with chronic and severe illness. If H.R. 2723 is passed, this provision will have an important positive impact on the health care provided to adults with severe mental health illnesses, children with serious emotional disturbances and other people with significant mental disorders who are increasingly being served in managed care settings.

Our efforts to improve mental health service delivery must include the elimination of insurance discrimination against people with mental disorders and the serious problems associated with the delivery of mental health care by HMOs. It is time to move beyond the impasse in this effort. The Bipartisan Bill creates a new ''Patients' Bill of rights'' which should pass the House with minimal dissension. Thank you for your commitment to reaching a workable compromise to finally provide consumers with the opportunity to appeal instances of discrimination or denial of care.

Sincerely,

SUSAN GORIN, CAE,
Executive Director.

AMERICAN ASSOCIATION OF ORAL, AND MAXILLOFACIAL SURGEONS,
Rosemont, IL, August 26, 1999

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Washington, DC

DEAR REPRESENTATIVE NORWOOD: On behalf of the American Association of Oral and maxillofacial surgeons (AAOMS), which represents the nation's approximately 6,000 oral and maxillofacial surgeons, I thank you for supporting provider nondiscrimination language as stated in Section 133(a) of the bipartisan ''Consensus on Managed Care Improvement Act of 1999''.

We fell that this bill has the strongest chance of being enacted, as it is a bi-partisan effort and is endorsed by President Clinton. AAOMS lends its strong support for the Consensus on Managed Care Improvement Act of 1999, and hopes that it is enacted into law.

Oral and maxillofacial surgeons in your district and across the nation believe that provider nondiscrimination is a key component of managed care reform. It is the top legislative priority of the AAOMS.

Thank you again for all your help in making sure that provider nondiscrimination language was included in this important piece of legislation.

Sincerely,

DAVID A. BUSSARD, DDS, MS,
President.

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.,
Bethesda, MD, August 31, 1999

Hon. CHARLIE NORWOOD,
U.S. House of Representatives, Washington, DC.

DEAR MR. NORWOOD: With regard to HR 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999, I am pleased to announce our unqualified support of the proposal. Embodying every principle the association has embraced as essential for meaningful managed care reform, we are convinced its enactment is in the best interest of all Americans.

The strong bipartisan support your measure has heretofore generated is compelling evidence that, given a fair hearing by the full House, a comprehensive patient oriented reform package can prevail. To this end we offer our understanding and enthusiastic support.

Best regards!

Sincerely Yours,

RONALD S. LEPOW, DPM,
President.

OPTICIANS ASSOCIATION OF AMERICA,
Fairfax, VA, August 24, 1999.

Hon. CHARLIE NORWOOD,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the Board of Directors and the members of the Opticians Association of America, I am writing to thank you for sponsoring H.R. 2723, the bipartisan managed care improvement bill.

This bill would give basic, common-sense protections to millions of Americans in managed care plans, and it is certainly refreshing to see the bipartisan way in which it was approached!

In addition, we are pleased to see that the bill contains a point-of-service option and anti-discrimination language which guarantee consumers the widest possible choice of providers.

We look forward to continued collaboration in the interest of America's health care consumers.

Sincerely,

JACQUELINE E. FAIRBARNS,
Assistant Executive Director for Government Relations.

AMERICAN OSTEOPATHIC ASSOCIATION,
Washington, DC, August 27, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR CONGRESSMAN NORWOOD: The American Osteopathic Association (AOA) represents the nation's 43,500 osteopathic physicians. As President, I am pleased to let you know that the AOA endorses your bill, the ''Bipartisan Consensus Managed Care Improvement Act of 1999'' (H.R. 2723).

The AOA advocates, on behalf of patients, for Congress to enact strong, meaningful, and comprehensive protections. After six years of debate and delay, we believe that H.R. 2723 is the bipartisan legislation that will ensure the AOA's long sought principles. These include: physicians allowed to determine medical necessity; health plans held accountable for their actions; a fair and independent appeals process available to patients, and protections which apply to all Americans.

Over the last two decades, managed care has become less interested in delivering quality healthcare to patients. Instead, the focus seems entirely on the bottom line. It is time to bring the focus back to our patients and away from HMO profits. Employers and patients are tired of not receiving the care they are promised, pay for, and deserve. H.R. 2723 will help bring the quality back into healthcare and allow osteopathic physicians to care for our patients in accordance with the high principles guiding our profession.

Again, thank you for your leadership on this critical issue. We are encouraged by the broad bipartisan support your legislation has received. The AOA pledges to work with you and all Members of Congress to ensure swift enactment of H.R. 2723. Please feel free to contact Michael Mayers, AOA Assistant Director of Congressional Affairs, in our Washington office at 202–414–0148 with any further comments or questions.

Sincerely,

EUGENE A. OLIVERI, D.O.,
President, American Osteopathic Association.

AMERICAN COUNSELING ASSOCIATION,
Alexandria, VA, August 27, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: I am writing on behalf of the more than 51,000 members of the American Counseling Association to express our strong support for your legislation H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. This bipartisan patient protection legislation will afford health care consumers the essential protections necessary to ensure the delivery of quality health care services.

H.R. 2723 provides a wide array of consumer protections including several key components for mental health providers and their clients, such as putting medical decisions in the hands of medical experts, not the insurance company bureaucrats; the ability to hold health plans liable when their decisions to withhold or deny care result in injury or death; adequate access to specialists; a continuity of care clause, and a provision to prohibit nondiscrimination against providers based on their type of license. In addition these protections would apply to all privately insured individuals, unlike other managed care legislation considered in Congress.

Representatives Norwood, we thank you for your continued advocacy on behalf of health care consumers. This legislation will make a difference to the millions of Americans with private health insurance. Please let us know if we can be of any assistance in your work.

Sincerely,

DONNA FORD, MS, NCC,
President, American Counseling Association.

AMERICAN PUBLIC HEALTH ASSOCIATION,
Washington, DC, August 10, 1999.

Hon. CHARLES NORWOOD,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: On behalf of the American Public Health Association, which represents more than 50,000 public health professionals around the country, I am writing to express our support for your new bi-partisan managed care reform bill, H.R. 2723.

This bill will provide patients with real, enforceable assurances that they will receive the care they need and have purchased from managed care companies. If passed by Congress, this bill will: improve access to emergency services; allow more people to enter clinical trials; provide patients with a fair appeals process for denied claims; lift barriers to specialists; and hold plans responsible for the medical decisions they make.

Furthermore, the bill's broad bi-partisan cosponsorship—and announced support from President Clinton—makes it Congress' best chance to complete action on this important issue this year.

We understand that some within the managed care industry oppose any government regulation, but this issue is a very important one for consumers, health care providers, and the public health community. Your steadfast commitment to reform and your strong leadership throughout this debate are commendable. H.R. 2723 is a significant and welcome step toward achieving new protections for managed care patients. We look forward to continuing work with you toward achievement of that mutual goal.

Sincerely,

RICHARD A. LEVINSON, MD, DPA,
Associate Executive Director, Programs and Policy.

NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES,
Washington, DC, August 13, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE NORWOOD: The National Partnership is pleased to endorse the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). This is strong, bipartisan patient protection legislation, and thanks to your hard work, we believe it can—and will—pass the House of Representatives.

For women and families, few issues resonate as profoundly and pervasively as the need for quality health care. Survey after survey reveals Americans' growing dissatisfaction with the current health care system, and many feel the system is in crisis. We need common-sense patient protections that will restore consumer confidence and tip the balance back in favor of patients and the health care providers they rely on.

There are many features of this bill that are especially important. First and foremost, this bill ensures that medical judgments will be in the hands of medical experts, not insurance bureaucrats looking at the bottom line. This bill:

Ensures that patients have recourse to a genuinely independent external review when care is denied.

Allows patients to hold their managed care plan accountable when plan decisions to withhold or limit care result in injury or death.

Ensures that women have direct access to ob-gyn services from the participating health care professional of their choice.

Ensures that doctors and nurses can report quality problems without retaliation from HMOs, insurance companies, and hospitals.

Ensures access to specialists, including, when appropriate, specialists outside a plan's network.

Ensures access to clinical trials that may save people's lives.

The House of Representatives faces an historic opportunity to provide patients the protections they need. We look forward to working with you to ensure passage of this important legislation.

Sincerely,

JUDITH L. LICHTMAN,
President.
DEBRA L. NESS,
Executive Vice President.
JOANNE L. HUSTEAD,
Director of Legal and Public Policy.

THE AMERICAN OCCUAPATIONAL THERAPY ASSOCIATION, INC.
Bethesda, MD, September 1, 1999.

Hon. CHARLES NORWOOD,
U.S. House of Representatives,
Washington, DC

DEAR REPRESENTATIVE NORWOOD: On behalf of the 60,000 members of the American Occupational Therapy Association, Inc. (AOTA), I would like to express our endorsement for the Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723. We appreciate your leadership, along with Representative John Dingell, in continuing to puruse strong managed care legislation with real patient protections through bipartisan efforts.

H.R. 2723 contains many critical patient protections that the members of AOTA believe are necessary to ensure patients receive the care that they need. Federal legislation should: guarantee patients' access to all medically necessary specialty care using appropriate utilization review standards; protect patients' right to choose a health care plan allowing out-of-network care; prohibit the restriction of importance medical communications and require information disclosure standards; prohibit discriminatory practices against health care professionals; require timely, independent due process procedures; and hold health plans accountable for their medical decisions.

H.R. 2723 is considerably more comprehensive than legislation passed by he Senate in July. It is important that these protections are available to all Americans enrolled in private health care plans.

Over the August recess we have notified our members, asking them to talk to their legislators. Please let us know how we can continue to assist you in your efforts to have comprehensive managed care legislation addressed on the House floor.

Again, we thank you for your leadership and hard work on this issue. We look forward to continuing to work with you to pursue passage of comprehensive managed care legislation.

Sincerely,

KATHRYN M. PONTZER,
Senior Legislative Counsel,
Federal Affairs Department.

AMERICAN ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY,
Washington, DC, August 23, 1999.

Hon. CHARLES NORWOOD,
House of Representatives,
Washington, DC

RE: Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2823)

DEAR DR. NORWOOD: The American Association for Marriage and Family Therapy is writing to express our strong support for the Bipartisan Consensus Managed Care Improvement Act of 1999 (H.R. 2723). On behalf of the 46,000 marriage and family therapists throughout the United States, we want to applaud you and Rep. Dingell for your effort to provide Americans with comprehensive patient protections.

Your bill offers several safeguards that are integral to our members, as well as the public at large. One provision, the prohibition on discrimination against providers, has particular significance. It expands consumer access to qualified practitioners who are regulated by the states. Without this protection, insurers and plans can continue to discriminate against many licensed health care professionals. Additionally, the provision will foster competition among providers and expand the pool of trained practitioners.

The ability to access speciality care is also a positive component of this legislation. Patients with ongoing healthcare conditions will greatly benefit from the opportunity to access specialists who are trained in the treatment of their special conditions. Moreover, removing the requirement of a primary care referral will reduce costs and delays that burden health care delivery.

Other provisions of significance to our organization include: an independent review process for determination of medical necessity decisions; the ability of people with special health care needs and chronic conditions to continue to access their health care professionals after employers change plans; the ability to hold managed care plans accountable for decisions to deny care; and guaranteed access to emergency care services.

These protections are a superb example of how Members from both sides of the aisle can work together to improve the quality of medical care for all employees. Your leadership in this effort is truly outstanding and appreciated. If there is any role our organization can play in passage of this legislation, please contact our Government Affairs Manager, David Bergman, at (202) 467–5015. Its time to ensure that all American are provided with the security of a comprehensive health care system.

Sincerely,

MICHAEL BOWERS,
Executive Director, American Association for Marriage and Family Therapy.

AMERICAN PUBLIC PLACES EDUCATION AS A TOP PRIORITY

The SPEAKER pro tempore (Mr. TERRY). Under the Speaker's announced policy of January 6, 1999, the gentleman from New York (Mr. OWENS) is recognized for 60 minutes as the designee of the minority leader.

Mr. OWENS. Mr. Speaker, we have just returned from recess and we are about to enter the closing chapters of the first session of the 106th Congress. The end of the first session will only take us halfway. We can continue, and there are probably some things that will continue, but we have a full plate here.

There is a great deal of speculation about exactly what is going to happen with the appropriations bills and the fiscal plan which now is made more exciting by the fact that there is a surplus. After we lock the box and keep the Social Security funds in place, we still have a projection of a 10-year period of a trillion dollar surplus, and that has led to some radical proposals by the Republicans with respect to tax cuts, and that has certainly charged the atmosphere.

I am interested in continuing the dialogue on education. I think that we are in danger of making a great blunder if we do not use this great window of opportunity to do something dramatic to improve education in America. There is a need for a greater commitment from the Federal Government which now only is responsible for about 8 percent of the total expenditure on education. We need more federal support for education.

There are a lot of things that have to happen to improve education in America, but one of the things that has to happen is that we must have more federal support. The Federal Government is where the money is. The Federal Government's money is not made here in Washington; it all came from the local level, so it belongs to the people out there in the States and in the localities. This is no reason why we cannot resolve to use funds from the Federal Government to help solve and resolve some of the overwhelming problems that we are facing in education.

We can still win the war for education support. The status of legislation here at this point does not preclude some major development taking place either before we end this session, or certainly before we end the 106th Congress in the fall of the year 2000.

Let us take a look at where we are at this point. As far as education funding is concerned, we are in bad shape. A number of appropriations bills have been stalled, and we have only passed two; but the education appropriations bill, the Labor-HHS appropriation is further behind than any of the other appropriations in the process. It has not even gotten out of the subcommittee yet. The appropriations bill for education, it seems, is being used as a scapegoat; and it will be the last one out there, and it will have the greatest amount of reductions.

I am not on the Committee on Appropriations, but the rumors are that for the overall Labor, Health and Human Services and Education appropriations, the cut may range as high as 35 or 40 percent. And certainly education is in danger of a 15 to 20 percent cut if we follow the present process whereby there are budget caps. But they are not following budget caps on some appropriations bills. They are leaving the last ones to take most of the burden of the cuts. So education is in deep trouble at this moment in history. But I think we can still win the war.

What I want to talk about tonight is how the American public and public opinion, the common sense of the voters, still is a determining factor here. We need to hear that and know that. All of the polls still continue to show that the American people place education as one of the top priorities, either priority number one or priority number two, in terms of federal assistance, or the use of federal resources to help solve problems. They expect us to do something. They are concerned. And their common sense is correct. Their common sense is on target. But what they need to know is that there are a set of rules being followed and a set of maneuvers underway that will lead to inevitable cuts in education if those rules are followed.

The President is right when he says that not only do we face cuts in this present year, in the present appropriation, but in the bigger scenario that the Republicans have staked out, if they go ahead with a gigantic tax cut of $790 some billion dollars over a 10-year period, then the mechanics of that

Testimony by Russ Newman for the March 30, 2005 NCVHS Subcommittee on Privacy and Con dentiality Hearing

Practice Directorate

March 30, 2005

Mark A. Rothstein, J.D., Chair
Subcommittee on Privacy & Con. dentiality
National Committee on Vital and Health Statistics

Re: Testimony on Privacy and Con dentiality Issues Concerning the National Health Information Network

Dear Chairman Rothstein and Distinguished Subcommittee Members:

I submit this testimony on behalf of the American Psychological Association (APA), the professional organization representing more than 150,000 members and affiliates engaged in the practice, research, and teaching of psychology. We appreciate this opportunity to submit this testimony regarding the development of a National Health Information Network (NHIN).

We understand that the National Committee on Vital and Health Statistics (NCVHS) assists and advises the Secretary of the Department of Health and Human Services in the study and identification of privacy, security, and access measures to protect individually identifiable health information in an environment of electronic networking. We further understand that NCVHS will make recommendations to the Secretary of Health and Human Services in the form of suggested access, security, and privacy measures that should be taken to implement a NHIN. Therefore, the APA offers the following testimony to the Subcommittee regarding our suggestions and concerns in creating and maintaining access, privacy and confidentiality for health records in a NHIN.

The form, scope, uses and control of the NHIN have not been determined. Therefore, our comments can only address potential concerns and suggestions based on directions that we anticipate that the NHIN may take. Accordingly, we would appreciate opportunities to comment again as this dialogue develops.

I. Unique Privacy Concerns Raised by Mental Health Records

Our primary concern regarding the NHIN is the need to balance accessibility of health information with privacy and confidentiality. This testimony will focus on the unique patient privacy concerns of mental health patients.

The NHIN has the laudable goal of improving patient care through greater and more efficient information access. We believe that it has the potential to substantially improve the quality of health care provided in this country by allowing instant access to critical patient information at any point of care. It also has the potential to increase the efficiency of service delivery and, importantly, lower administrative costs. Further, it has the potential to improve patient care specifically by fostering the integration of physical and mental health care as discussed in Section III.A below.

We are concerned, however, about possible unintended consequences to the extent that some of the powerful forces propelling the need for an electronic health record include economic/business concerns about efficiency. In prior instances where broad changes to the health care system were introduced to improve both efficiency and patient care (particularly with the advent of market-driven managed care techniques), many have now concluded that the new systems actually reduced the quality of care because they prioritized economic issues over patient care. The unfortunate reality is that our health care system has become increasingly dominated by corporatized “big business” for which profit making has become an essential part of business. With NHIN, our concern is that too much focus on improving the flow of health information for economic efficiency in the service of profit making and business interests could take priority over various patient care concerns, including privacy. We sincerely hope that this does not happen and that steps can be taken from the beginning to assure a balanced approach to addressing the various interests involved.

In order to develop the NHIN in a manner which will promote quality mental heath care, it is important to consider the unique privacy issues relating to mental health records. Most people understand that mental health records are particularly sensitive because they may contain a patient’s innermost and most embarrassing personal information. Many also are aware that, unfortunately, the stigma attached to mental health disorders and mental health treatment makes the records of that treatment especially sensitive. This is an area of health care where the mere fact that a person has sought treatment, if revealed, can damage careers, reputations and relationships. Any violation of privacy could be devastating to the patient. Thus, patients receiving care for mental health issues may be prone to avoid or discontinue treatment if there is a real or perceived threat to the privacy of their health records.

Mental health care is unique in that successful treatment depends on both the existence of privacy and the *expectation* of privacy. There is no other health field in which the mere threat of loss of privacy can interfere with the success of treatment. As the U.S. Supreme Court recognized in the case of *Jaffee v. Redmond*, 518 U.S. 1, 10 (1996), the psychotherapist-patient relationship is:

> **[R]ooted in the imperative need for con dentiality and trust…Treatment by a physician for physical ailments can often proceed successfully on the basis of a physical examination, objective information supplied by the patient, and the results of diagnostic tests. Effective psychotherapy, by contrast depends upon frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of con dential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the *mere possibility of disclosure* may impede development of the con dential relationship necessary for successful treatment. (Emphasis added).**

Because of these concerns, psychologists and other licensed mental health professionals are trained to exercise great care in protecting their patients' records. The psychologist has typically viewed his or her role as a "gatekeeper" controlling access to those records. We would urge that the establishment of the NHIN preserve mental health professionals' role in being able to control and protect the records so that confidentiality, a trusting relationship and successful treatment may be preserved.

Psychologists have historically served an important role in determining what information in their patients' records to disclose, because they have a great understanding of the heightened sensitivity of mental health records, what records are relevant to other treating professionals, and the special legal and ethical rules concerning the disclosure of psychological records (which are generally considerably more protective than the disclosure rules for medical records). In this role, and working in collaboration with the patients, psychologists have been able, for example, to provide a critical perspective on what is "minimum necessary" information to release to insurers and other third parties, pursuant to the HIPAA Privacy Rule, as discussed in Section III.B below.

The psychologist's role vis-à-vis confidential mental health records is also highlighted by the NHIN's potential benefit of improving patients' access to their own records. The psychologist is in a key position to identify what parts of the patient's mental health record are appropriately viewed by the patient or, alternatively, viewed by the patient with the psychologist's simultaneous explanatory input. In recognition of this role, many state laws actually give the psychologist discretion to withhold portions of that record to prevent physical, emotional or therapeutic harm to the patient. A mental health record may be susceptible to misinterpretation by others, including the patient, or may cause a strong emotional reaction if viewed by the patient. Thus, even when access is appropriate, it is often highly advisable to have the psychologist present while the patient is reviewing his/her record in order to explain aspects of the record and help the patient cope with emotional responses to that information.

II. What mental health records would be included?

Some, but not all, of the concerns outlined above would be reduced by limiting the scope of mental health records to be included in the NHIN. The records that should most logically be included are the basic information that the HIPAA Privacy Rule views as necessary for sharing among health care professionals.

This information, which we call the "clinical record", includes basic items such as diagnosis, symptoms and treatment plan. This basic health information is necessary to assist all health care professionals who are treating patients in providing quality integrated care to them.

There are two types of mental health records that we strongly urge not be included, or only be included with specifically restricted access:

Psychotherapy notes. The HIPAA Privacy Rule recognizes that a mental health professional's private notes concerning therapy sessions contain highly sensitive patient confidences, are primarily for the professional's own use, and are not the type of information that needs to be shared with other health care professionals, insurers, or even patients. Accordingly, these notes are given heightened protection under the Privacy Rule, and can generally only be used by the psychologist who took those notes, absent a specific authorization from the patient. The same considerations call for excluding them from the NHIN, or restricting access so that only the psychotherapist who created them can view them (unless the patient specifically authorizes broader disclosure).

Psychological testing. Similarly, psychological test materials and results should not be included in the NHIN. First, psychological tests are particularly susceptible to misinterpretation by those not trained to interpret these tests. Parts of tests taken out of context by someone not trained to interpret the whole can be harmfully misleading. Second, the test materials themselves are unique (usually copyrighted) and they may lose their value as accurate diagnostic and evaluative instruments if they are too widely shared. This sharing can lead to several problems – from those that are intentional, such as manipulation of the test responses in order to achieve a desired result, such as with malingering, to unintentional invalidation of test results because of prior familiarity with the questions. Third, the raw data of psychological testing is as likely to contain highly personal confidential information as psychotherapy notes. Some of the questions themselves may elicit highly sensitive responses, and also the psychologist doing the testing may write observations and comments on the materials containing the questions and/or answers. Fear of loss of confidentiality may negate the effectiveness of a test in the same manner that fear of loss of privacy can interfere with successful psychotherapy. A patient may not be completely forthcoming with full answers to test questions if he or she thinks that the information may be widely disclosed.

III. Who Would Have Access to Mental Health Records and For What Purposes?

A. Access by Other Treating Professionals/Integration of Mental and Physical Health. We believe that easy accessibility of records by treating health care professionals is one of the most important goals of the NHIN. For example, in the Veterans Administration (VA) system, patients typically see multiple health care professionals during that visit. Prior to the implementation of its electronic system, health care professionals treating a VA patient would not always have access to the patient's medical record when treating the patient because the record was either in the possession of another health care professional or was being held somewhere else in the VA hospital. Now, a health care professional can access the patient's record at any time and can update information and add his or her notes to the record. This is a particularly important feature as mental health care becomes an increasingly integrated part of overall patient

healthcare and interdisciplinary collaboration is improved. This improved access would be possible nationwide in a NHIN.

We believe the NHIN could actually have the beneficial effect of increasing the level of integration of mental health and physical health care. APA believes that such integration is important in light of the growing recognition of the link between behavior, health and illness. It is increasingly recognized that many of the physical ailments that are now the nation's dominant medical concerns, such as diabetes and heart disease, have strong mental and behavioral components. The corollary is, of course, that treatment of diabetes is more effective if a psychologist works with the patient and physician on behavioral and emotional issues, diet, exercise and medication compliance.

Currently, mental and physical health care are all too often provided in separate spheres that have little contact with each other. The integration of these spheres has been shown to greatly improve patient care, particularly in areas such as disease management and with individuals who display "at risk" behaviors such as poor diet, lack of exercise, smoking and alcohol abuse.

Because integration of mental health with physical health information through the NHIN would generally increase access to mental health records, it must be done carefully and selectively. First, there is the potential for differing levels of privacy maintenance in the mental and physical health spheres. With physical health, it is often appropriate to make a patient's record accessible to several physicians of different specialties, nurses and other affiliated staff. By contrast, a psychologist's psychotherapy notes generally cannot be shared with anyone other than the psychologist (without the patient's authorization), and access to the more public clinical record is often not shared with affiliated staff because even basic information, such as the diagnosis, can be highly sensitive. A common problem we have seen is that those on the physical health side are not always familiar with the unique and sensitive aspects of these mental health records and the greater privacy obligations imposed as a result. We are aware of instances in which psychologists have been asked to place their psychotherapy notes and patient files in common databases to which a large number of professionals and affiliated staff have access. For the psychologists to comply would, of course, place them in violation of their privacy obligations under HIPAA, state law and ethics code.

These problems could be expanded on a massive scale if the integration of mental health and physical health information through the NIHN was not carefully orchestrated. We are concerned that if these two very different systems are integrated through the NHIN, the overall level of confidentiality not be lowered to the physical health standard. We strongly urge that the NHIN not take a "lowest common denominator" approach. Perhaps the best alternative, as practiced for many years in Veterans' Administration settings is to have a two-tiered system, with greater privacy control on the mental health portion of the record.

A second concern is the potential unintended impact of the introduction of mental health information into a large number of physical health settings that are not used to having access to this information. Since the stigma attached to mental health disorders is still pervasive, some in the system may react to and treat patients differently if they know about their disorder. Relatedly, there is the concern that health professionals with little experience and training in mental health issues may misinterpret mental health information. For example, a primary care professional would have no training in interpreting psychological test data. If a

health professional were to review the test data alone, he or she might come to erroneous conclusions regarding the patient, and worse, could share this incorrect information with the patient or other treating professionals.

B. Access by Health Insurers. Key questions with the creation of an electronic health record concern the extent to which health insurers and other third party payors will be allowed access to the NHIN, for what purposes, and how would it be limited. We have witnessed a long-standing tension between mental health professionals trying to protect patient privacy and insurers requesting additional information to decide whether the mental health treatment is "medically necessary." Under the HIPAA Privacy Rule, this tension has shifted to disputes over what is the "minimum necessary" information for the insurer to determine medical necessity. Unfortunately, the flexible but vague "minimum necessary" standard leaves considerable room for disagreement. (Fortunately, the Privacy Rule leaves little room for debate when psychotherapy notes are at issue: the insurer cannot demand access.) In some cases, the extent of information requested by the insurer has become a tactic to discourage patients from accessing services, even when these services are necessary. The psychologist's understanding of what information is most sensitive, what is potentially subject to misinterpretation, and what justifies his/her treatment plan, places the psychologist in an optimal position to determine what is the minimum necessary information actually needed by the insurer.

The ability of the health professional to exert control over the record is critical to enable a balance between the need for information disclosure and confidentiality. Any system allowing third party payors unfettered access to mental health information in the NHIN would remove that control and create grave privacy concerns.

C. Access by Law Enforcement. A final concern in this area is whether the NHIN would be made available for law enforcement. Generally, we believe that law enforcement access to patient records should be limited to the absolute minimum disclosure and use necessary in the interest of justice. If the NHIN would be open to such purposes, what type of legal safeguards would protect patients from unreasonable privacy intrusions? We would suggest that the disclosure of mental health records for the purposes of investigations regarding victims of crime or abuse only be permitted based on some form of judicial review – warrant, subpoena, court order, etc. If patients are concerned that their information is subject to government access without due process, they may be discouraged from participating in the NHIN or from seeking necessary treatment.

IV. Questions Regarding Regulatory Scheme and Patient Participation

A number of questions are raised with the prospect of regulating a system based on the NHIN. Would the NHIN be subject to and governed by the HIPAA Privacy Rule? If so, what role would state privacy laws play — assuming that the NHIN would be a national and/or federal network? Given that the Privacy Rule was only meant to set a federal floor, we believe it would be critical that stronger state protections (e.g., on patient consent, authorization and access) still apply to NHIN so that implementing NHIN did not result in substantial lowering of patient protection.

If the Privacy Rule were to govern use and disclosure of patient information in the NHIN, it will be importan to re-assess whether the NHIN creates new privacy risks or issues not contemplated when the Rule was

drafted. For example, if the NHIN shifts control over access to records away from the mental health professional, it would be necessary to reconsider the adequacy and applicability of the Privacy Rule's current mechanisms for controlling disclosure.

Another critical area of uncertainty concerns the threshold question of what choice patients would have as to whether their records would be included in the NHIN. Would their participation in NHIN be voluntary? What, if any, aspects of the NHIN will be mandatory?

In order to make such consent meaningful, patients should be advised of the potential uses of their records, by whom and for what purposes, along with the benefits of participating in the NHIN. This might be provided in a HIPAA-type privacy notice (whether or not the Privacy Rule were to apply to the NHIN).

Finally, once a patient consented to have his/her records in the NHIN, would there be some uses of those records that would require additional authorization from the patient?

For example, while most patients would want their records available to health care professionals who are treating them, they might feel quite different about giving such access to insurance companies. This might be another area where the new privacy concerns posed by the NHIN would justify making certain aspects of the Privacy Rule more stringent as applied to the NHIN. It might make sense to require that the patient gave a HIPAA-type authorization before access to their records was granted to an insurance company (if insurers were to be allowed access at all). Alternatively, patients upon "joining" the NHIN, could select what uses would only be allowed with their authorization.

V. Conclusion and Recommendations

The APA recognizes that this hearing is a beginning point toward developing a NHIN that will balance the ability to access health records with the need for privacy and confidentiality of records. We urge the Subcommittee to adopt the following recommendations relevant to mental health:

- Exclude from the NHIN, or place specific limitations on access to, psychotherapy notes and psychological test materials and raw data.
- Recognize and maintain the important role that the licensed mental health professional plays in determining what is appropriate access to mental health records by insurers, patients and others.
- Promote the integration of physical and mental health information but do so in a cautious manner that preserves the high level of confidentiality of mental health records, for example by creating a two-tier system where mental health records would be subject to more limited access.

We would appreciate the opportunity to work further with NCVHS and the Department of Health and Human Services to give additional input and suggestions on the NHIN as its development progresses.

Respectfully submitted,

/s/

Russ Newman, Ph.D., J.D.,
Executive Director for Professional Practice
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FEDERAL TRADE COMMISSION

JOINT FTC/DEPARTMENT OF JUSTICE HEARING

ON HEALTH CARE AND COMPETITION LAW AND POLICY

Tuesday, June 10, 2003

9:15 a.m.

601 New Jersey Avenue, N.W.

1st Conference Room

Washington, D.C.

For The Record, Inc.
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FEDERAL TRADE COMMISSION

I N D E X

P R O C E E D I N G S

DR. HYMAN: Thank you all for coming to the Joint Hearing sponsored by the Federal Trade Commission and the Department of Justice on Health care and Competition Law and Policy. I'm David Hyman, Special Counsel here at the Federal Trade Commission. This is the latest in a series of hearings that we commenced in February, 2003 totaling approximately 30 days of hearings that are a broad examination of the performance of the health care marketplace.

Today, we take up the subject of market entry, and we have a very distinguished panel to address that subject. We also have a distinguished speaker who is speaking about a subject that's related to, but distinct from, that. We're sort of subject to people's schedules in terms of when we include them. So let me -- we have a bio-book outside that contains the details of everyone who will be speaking today. So our rule is very short introductions. Let me go through those now, and then I'll have a couple of quick remarks about the way the rest of the morning is going to work.

Our first speaker is Professor Robin Wilson, who is an Associate Professor at the University of South Carolina School of Law and a staff member at the South Carolina Center for Bioethics and Humanities. The next

speaker, who will actually be participating by teleconference because of his scheduling problems, is Professor Morris Kleiner, who is a Professor of Public Affairs and Industrial Relations at the University of Minnesota. Those of you who are here in the room can see that we're going from your left to your right in terms of order of the speakers.

The next speaker will be Tom Piper, representing the American Health Planning Association. He has extensive experience in Health Planning Regulation Development. Following him will be Tammi Byrd, who is President-elect of the American Dental Hygienist Association.

The next speaker will be Lynne Loeffler, who is a member of the American College of Nurse Midwives and a practicing midwife for 18 years. Then John Hennessy, Executive Director of Kansas City Cancer Centers. Following him will be Megan Price, who is the Director for Contracts and Communications for Professional Nurses Services in Vermont.

Then batting cleanup, Susan Apold, who is the President of the American College of Nurse Practitioners representing approximately 44,000 Nurse Practitioners nationally. She is also the Dean of Nursing at the College of Mount St. Vincent in New York.

So we'll go through each of those speakers. We'll make presentations from up here, and then, because of the way the Power Point is projected, nobody will be sitting up at the front until the very end. Whereas, time allows, then speakers adhering to their time limits allows, we will have time for a short roundtable discussion involving all of the participants.

With respect to time, Cecile over there on the table will be flashing you notes periodically to let you know how much time you have, so I would appreciate it if you would do that, adhere to your time limits. People will be listening in by telephone. This is also taped, for those of you who want to see yourself memorialized. You can give them as Christmas presents and the like.

Two last comments for those attending, which is, first of all, if you could turn off your cell phones. It's quite disconcerting when you're making a brilliant point and suddenly it starts playing Jingle Bells in the background. And second, simply so everyone knows, the moderated roundtable at the end is limited participation to those who have spoken. It is not an open forum. So although we appreciate your attending and encourage you to submit comments for the record, either based on larger issues or on something you hear today, it's not an open mike.

So with all of that, let me introduce Professor Robin Wilson to speak about unauthorized practice.

MS. WILSON: I want to begin this morning by thanking the Federal Trade Commission and the Department of Justice for holding these hearings. And I wanted to thank, in particular, the Special Counsel for bringing scrutiny and attention to a disturbing practice world wide of using patients for teaching purposes in hospital without their knowledge or consent.

And I want to focus by talk this morning on two such practices; the use of women under anesthesia awaiting surgery to teach pelvic examinations, and the use of deceased patients in the emergency room after their demise to teach resuscitation techniques without the family's or the patient's consent.

I want to start by looking at pelvic exams first. And here we have some good statistical data from earlier this year demonstrating that this practice persists. This is a study published in February by Ubel, Jepson, and Silver-Isenstadt reported in the American Journal of OB-GYN. And what it shows is the result of a small study surveying students at five Philadelphia medical schools in 1995 who had completed OB-GYN rotations. They found that 90 percent, shown in yellow, had done exams on women under anesthesia.

Now in terms of consent it's difficult from the study to know exactly what was told to these women. And this is so because the study did not ask the students specifically within the study precisely what consent was there for the exam. And sometimes it's difficult for students to know what types of consent were given because they may not have been present at the time that it was given.

But the virtue of this study is that it follows on the heals of another study out of Great Britain which was published in the British Medical Journal in January. That study actually linked the practice together with consent. As you see, 53 percent of the students at a single medical school in England reported that they had performed an intimate exam, pelvic or rectal on a patient who was sedated or anesthetized at the time, while they were getting their undergraduate medical degree.

In terms of consent, and that's shown in blue by the way, in terms of consent you'll see that one quarter of the exams the students attested to the fact that there was no verbal or written consent for the exam. Another quarter of the exams there was consent written and then the remaining amount we just don't know. Now by the way, these students did not perform an insubstantial number of exams. The three classes of students that they

surveyed performed more than 700 exams combined and I thought that was significant.

Now we know that the use of women is neither an isolated nor a localized practice. So what I'm going to walk you through is three decades of studies that show that this has happened for a very long time across countries.

We know, for example, this is a study in 1988 by Cohen of medical schools in the United Kingdom. It found that 46 percent of British medical schools, shown in yellow, used unconscious women to teach pelvic exams to medical students for their first time, i.e., the first pelvic they ever did. A 1985 study, which was done by Beckmann in the U.S. and of Canadian schools asked about a variety of teaching techniques. It found that 23 percent, on the lefthand blue bar, of U.S. and Canadian schools reported using anesthetized patients during the initial pelvic exam in 1985. That number by 1992, you'll see, actually rose significantly.

Finally, a study by Cohen which was done, I believe, in 1989, of all U.S. medical schools found a slightly lower amount, ten percent of U.S. medical schools using women to teach first time pelvics. Of course, these studies say nothing about what's happening in the third and fourth years when students are actually

in the wards and getting some hands on training. That's why Ubel studies and Coldicott studies are so significant because they tell us that these practices persist into the third and fourth year.

Many commentators, in fact, note that using anesthetized patients before surgery is something that "has been long practiced." And the American College of OB-GYN acknowledged the practice in a letter to the U.S.C. Center for Bioethics, a colleague that I serve with there. Although they claim that the practice is "becoming less common." And that letter is dated in January of 2002.

Of course, the lingering question, obviously, is exactly what consent was there for these things. Only Coldicott studies of the ones I've showed you definitively answers that question. And yet we have a lot and we know a lot about how students are practicing generally and what is disclosed to patients about general student practice.

For example, one study reported that only 37.5 percent of responding teaching hospitals informed patients that students would be involved in their care. Now, of course, informing someone and asking are two different things. But only a third, roughly a third, were informing patients at that time. But I think what's

really significant is what students and practicing physicians actually tell patients when they go in with a student. And what we see, and I'll show you some data about this, is that they routinely fail to inform patients about the students' status as a student and sometimes Ubel claims that they may even affirmatively deceive patients, and I'll walk you through some of the data that shows that.

Thus, for example, this is a study by Cohen in 1987 that found that only a fraction of internal medicine departments and pediatric departments, 6.1 and 4.9 shown in blue, specifically inform the patient that a student will be performing a particular procedure while 65 to 73 percent of those departments did not, shown in yellow.

Likewise, Ubel found that while 70 percent of OB-GYN departments did inform a patient that a student was on the care team, which isn't shown here, more than half or about half, excuse me, about half shown in the third yellow bar, of U.S. students hid their status or were not forthcoming about it when they actually walked in to do a pelvic.

Now that's not surprising, because 5 percent of OB-GYN chairs actually tell students to walk in, introduce themselves as a doctor and get on with it. But perhaps most revealing is this study by Beatty and Lewis.

There, every medical student had been introduced as a doctor at some point, shown in red, by a member of the medical staff or the hospital staff. Yet only 42 percent of them ever bothered to correct that misimpression shown in white.

Now we have even better studies regarding the linkage between practice and consent in the context of deceased patients and I'll walk you through those now. This is a study that was done by Burns. It's an anonymous survey of directors of U.S. training programs in emergency medical and critical care. He found that 63 percent of emergency medical care units or programs, shown in blue, use newly deceased patients to teach resuscitation techniques.

Fifty-eight percent, shown in red, of neonatal critical care units did the same thing. Ninety percent of those programs obtained no consent, oral or written, which is shown in white.

And then we have the study by Denny, which was done of all teaching hospitals in a medium sized Canadian city. He found that 27 percent of the teachers, shown in blue, had students practice intubation on the recently dead. Thirteen percent had learners practice pericardiocentesis. I'm not a physician, but I'm told that that means passing a needle into the heart sac to

remove fluid. So they were practicing that on deceased patients. And then regarding consent in that study they found that in no case, 100 percent of the cases, there was no consent.

Now Fourre studied directors of accredited emergency medical programs. Forty-seven percent indicated that procedures were performed on the recently dead for teaching purposes as opposed to the patient's purposes or benefit. Seventy-six percent in that study said they "almost never" received consent from family members.

Now this track record has immediate implications for any person who wants to enforce her autonomy rights by bringing an informed consent or even a battery claim. But I'm going to talk about informed consent first. There are several standards that define what has to be told under the informed consent claim. And the majority standard in the United States is the professional standard. In other words, physicians have to disclose what other reasonable physicians would disclose.

And these numbers suggest that it's a common practice not to disclose, not to specifically inform patients and secure their consent before proceeding. And that's going to make it difficult for any person who even

discovers this, that's another big question, but any person who even discovers it to succeed on this sort of claim. This is why I believe that not only has medical practice let down the public, but the law has let down the public too, and I will talk about that more at the end of my talk.

So where are we? Well, we have a widespread practice, over several decades, of doing educational as opposed to medically needed and indicated exams on anesthetized and deceased patients often without consent, often without anything on the general admission form, often without specific consent, anything on the general admission form or surgical form -- I'll come back to that and explain why I believe that's the case -- often without the patient's knowledge.

Now I want to focus the remainder of my talk on anesthetized patients because the same justifications run through why teaching hospitals should be, in their minds, able to do this on women under anesthesia, as run through their discussions of why they should be able to use deceased persons. So I'm just going to focus on anesthetized women.

Now there are two principal ways in which exams under anesthesia or EUA's are actually done. The first is what I'll call the vending machine model. And I

actually take this from a narrative published by a Duke University Professor of a medical student's account. And the medical student described it as this: all these medical students parading in, each to take their turn, you know. Like going to a vending machine and walking by. Only it's not a vending machine, it's a woman's vagina and you're each taking your turn walking by and sticking your hand in. In this situation students claim it is not uncommon for five or six people to do a pelvic on that woman.

Now the second model is, I hope, the more prevalent one. In this model a student is a member of the care team and so it performs a pelvic for learning purposes prior to the patient's surgery. Later in my talk I want to test the intuition that many teaching faculty have that the care team model is defensible and justifiable even if the vending machine model is not. But for the moment, it's important to note that virtually every commentator who writes about these practices believes that they're extremely risky in terms of lawsuits.

For example, Cohen sees clear violations of patient rights under the accreditation standards. He sees battery and he sees a breech in the duty of informed consent. I'm not so sure, as I said a moment ago, that

there are clearly actionable claims of informed consent and battery here, and I'll explain that later. But for the moment, let's assume there are. The hard question, it seems to me then, is how is it that this can continue decade after decade after decade.

And certainly, I think, culture plays a role here. You know, physicians acquire knowledge by experience, hence the phrase, see one, do one, teach one. But there's also a whatever-it-takes ethic because they feel so pressured with so much coming down on them so quickly. It's not surprising then that a spokesman for the Royal College of OB-GYN in Great Britain labeled concerns over this practice as snide, sexual innuendo and academic nitpicking.

But beyond culture, however, teaching faculty articulate several justifications and I want to actually test these today because I think it's important to understand where they're coming from if you want to change minds and ultimately to change behavior.

Now the first is an argument from necessity which essentially holds that we can't ask you because if we ask you, you won't consent. The second is a claim of implied consent. In other words, patients that come to a teaching hospital know what they're getting into and therefore, have signed up to be, as I say, "practice

dummies." Third, there's a belief that teaching pelvics under anesthesia is the best way. In fact, one physician in the literature said, the only way to teach a pelvic.

And then running through all of this is misinformation and fear about the motivations of patients as well as the capacity of medical students to perform. And as the next slide shows, students wildly overestimate their perceived incompetence.

What I'm going to show you is a study by Magrane and you'll see that the scoring on the bottom or around the side is, the best scores are the lowest and the highest scores are the worst. And she asked students to rate their ability to do certain types of things. You'll see that their capacity in their mind of doing physical exams and vaginal exams were not rated very well. But when she asked patients to rate them we see the patients gave these same students much, much more favorable scores.

In fact, which makes us believe that perhaps a lot of people have blown out of proportion the likelihood of being rejected if they ask. In fact, we know that fears of refusal are misplaced because study after study shows that women will consent to pelvic exams by students for the student's education as opposed to their benefit. On the likelihood of consent, for example, we have two

different sets of studies.

I'm going to start first with the studies that look at women who are in out-patient settings. Looking first at the out-patient settings, two studies in the United Kingdom found identical numbers of women willing to have a pelvic exam by a medical student with nearly half, shown in yellow, willing to have the student do a pelvic exam for educational purposes. These were actual women giving actual consent to actual students; not a hypothetical study.

Now we also have hypothetical studies, like this one done by Ubel. He reported in 1990 that 61 percent of students would definitely allow, probably allow, or were unsure, that that's the rust colored bar, whether they would allow a pelvic exam while being cared for as an out-patient. Now Ubel published only the would object statistics, but I've approached him and asked him to help me break down those other data better so we can parse out how many people definitely would allow it and how many people were unsure.

Then we had a second set of studies that deals with women prior to surgery. Again, I want to go back to Lawton. He found that 85 percent of women before surgery said yes to a pelvic, an actual pelvic, for educational purposes by an actual student. And then in a slightly

different approach, we have, Ubel found in a hypothetical study that more than half were willing to consent or were unsure.

In fact, we know that patients will consent even to risky procedures. This is a study by Grasby in Australia. She asked women if they would let people participate in their childbirth and 62 percent said they would. But what's really interesting is how that 62 percent breaks down. Two percent of the patients, shown in blue, would allow a medical student to participate in an instrumental delivery, hold the forceps. Nine percent in a C-section. Twenty-five percent, shown in rust, in a normal delivery.

But what's most significant is that remaining group, the biggest group, would allow students to participate in any way without making any limitation on how they participated. And so we won't see medical education on the OB-GYN wards grind to a halt simply because we ask women.

Why do patients consent? They consent because they see a benefit to themselves. I'm going to show you this very quickly across six studies. The blue bars are the numbers of women who believe that there's a benefit to themselves in having a student involved. And two of those studies saw surprisingly high numbers of women

willing to have students included. Why? Because they thought the students would be more eager, would be more willing to answer their questions, would spend longer time with them.

But not only is that selfish motive there, but there's a significant streak of altruism as well. This was a study of women, pregnant women, who gave consent to the participation in their childbirth. And of those who consented, the study asked what's the single most important reason and you'll see that the wish to contribute to medical education was that, the single most important reason for the women in this study.

Now contrast this again with student perceptions. Only 40 percent of the students, shown in yellow, thought that was what was motivating those women. And again, it's this disconnect that seems to be driving the justification that we can't ask you because if we ask you, you won't consent. And in the end, that's simply inaccurate.

I want to start on my second justification and that is the idea that patients have implicitly consented to being medical guinea pigs by accepting care at a teaching facility. And this again, simply does not stack up factually. What I'm showing you here is a study by King of elderly patients who were actually admitted to a

teaching facility. She found that 60 percent had no idea that they were in a teaching hospital or even what one was.

Now this has, again, immediate implications for a breach of the duty of informed consent claim. One exception to the duty holds that providers need not disclose those risks of which people have common or actual knowledge. In other words, we don't tell people to tell you what you already know. But here, the fact that 60 percent of these patients had no clue that they were in a teaching hospital seems to undercut any claim of a common knowledge or actual knowledge exception by the hospital to that duty, if you could bring this type of claim.

But beyond the factual problem there are other problems with this claim too. First, many patients do not choose to be admitted to a teaching hospital, they're taken there in an emergency. Or they choose that hospital because it's the best reimbursement rate on their plan. Or they're loyal to their physician and they're simply following their doctor to whatever staff that they have medical admitting privileges to, whatever hospital they have their privileges to.

And with the rise of teaching community hospitals, which are not proximate and located next to a

university and do not have university in the logo or the sign, the claim that people would obviously know that something is a teaching hospital, I think, does not have the force that it would have had in 1950. The health care marketplace has changed.

Now more problematic is the fact that we rarely presume consent. And when we presume consent we do it only in those circumstances where we think people will not care. For example, medical examiners routinely remove corneas from deceased persons without the patient or the family's knowledge or consent. Why? Because we think nobody will miss them and we think the cost of asking is simply too high. But here people care, and they care very deeply.

This is a study that shows, these are studies, excuse me, but Magrane and Lawton of pelvic examinations under anesthesia that found that all patients, the first two, all patients wanted to know that a pelvic was going to be done on them. In the next study, which I've shown you, this is a study of first time spinal taps being done on conscious patients. Many of them consented to first time spinal taps, but 85 percent of them, or I'm sorry, 80 percent of them wanted to know that a medical student was doing it for the medical student's first time. So they want to retain the right to know.

And in a slightly different approach, Ubel asked how much importance they placed on being asked. And out of a possible five points with five being the highest score, patients gave an importance rating to being asked about pelvic of a 4.5. In fact, that was the highest importance rating received in that study for any question. Suggesting, as Ubel concluded there, "patients place great importance on being asked permission."

Now the third justification, as I said, is that pelvics done under anesthesia are the most effective or indeed the only way to teach a pelvic. What I'm showing you here is a study by Beckmann showing that there are all these other methods for teaching first time pelvics too. So I'm going to make a distinction first between normal anatomy and then abnormal anatomy. You can see there's AV, Lecture, Teaching Associates; Gynecological Teaching Associates are women who are paid to allow people to do pelvic exams on them for a certain fee. Okay? So we have all of these.

Now it can't be the case that exams done under anesthesia, which are shown in yellow, are the only effective method because teaching faculty have rated these for effectiveness in the same study and you can see that a number of things were rated just as effective as exams under anesthesia.

Now my medical school colleagues say, when I bring this up, that for teaching abnormal anatomy however, exams under anesthesia are essential. And I respond to them that perhaps, you know, you're going to have enough patients in the course of things that will consent that certainly you can do it ever by asking specific permission beforehand. And they respond to me that the supply and demand argument is overly simplistic. Instead they argue that teaching in real time is difficult since they want to expose students to as much as they can in a few weeks.

And there may be some merit to this. For example, we see something of a gray hair phenomenon, meaning that people are more willing to consent to residents who are more established and more experienced physicians than they are to interns, who are first year docs, than they are to students.

So I don't doubt that things may be harder. In fact, we know the willingness to participate drops off as the exam becomes more internal and more invasive. So it is possible that we will have a hardship in certain types of disciplines; internal medicine or OB-GYN, for example. And I'm not trying to minimize that; I recognize that.

Finally, we know that numbers matter a great deal. Magrane asked women who were admitted for

childbirth how the number of students who participated would affect their willingness. She first asked about non-vaginal exams and then she asked about vaginal exams. You can see for the non-vaginal exam 12 percent said that more than two students would be okay, i.e., the vending machine model. But 84 percent would cap it at two students, which looks more like the care team model, shown in yellow. But for the vaginal exam fully 100 percent of the women in that study wanted to limit the participation to a single student suggesting that patients buy into the care team model just as teaching faculty do.

Now, I'm not so convinced that these two models are so different. It seems to me that the key question is whether the student's exam would have been performed but for the fact that the surgeon or the supervising physician is a member of a medical school teaching faculty. With the vending machine model it's probably not the case that a half dozen students would have done that exam without her knowledge or consent if she had been admitted, for example, to a non-teaching hospital or if her physician had not been a member of a teaching faculty.

But this also may be true of the care team model. Consider two scenarios; a woman is admitted for

surgery. The surgeon comes in and reconfirms the pelvic that led him to whatever the surgery is for and then a student repeats that exam. That second exam would not have been done but for the fact that the supervising physician is a member of the teaching faculty. So we have a duplicate that we have to explain and for which, I believe, we have to have consent.

And then similarly if the physician just yielded to the student and let the student do that exam the student then has received a reconfirming diagnosis or pelvic that is of a different character. I don't want to say worse necessarily. Some of the literature thinks that students can actually pick up things that more established physicians can't because the established physicians have been at it so long.

Now this raises an interesting question of whether or not the admission has actually authorized things that are done for the educational benefit of the student as opposed to the medically needed services of the patient. So I give you a typical consent form here and I've collected many of these from hospitals around the country. "I, the undersigned, agree and give consent to teaching hospitals, its employees, agents, the treating physician, his or her partners/consultants, medical residents, house staff and other agents, to

diagnose/treat the patient named on this consent." Now that authorizes first and foremost only those things that are done for the patient's benefit, as opposed to those things that are done for the student's education. Which brings us back to the before test that I just walked you through.

But it's also a real question about whether or not medical student is even contained under any of these categories. Health staff is a term of art. Stedman defines it, which is a medical dictionary, as to mean residents or interns and medical students are neither. Employee is difficult because medical students aren't employees so you can't wedge them under that heading.

And agents is difficult for a variety of technical reasons dealing with the accreditation standards, but the way I read those things is to say agents of the hospital are only those people who have clinical privileges at the hospital, have been through credentialing and area licensed or certified under state law, whichever state law requires. So I have great doubts whether they come under the heading of agent.

In closing, I'm going to spend one moment on informed consent and make a couple of observations that I've already sort of touched upon. The important point about informed consent and battery and other tort claims

is that they're not self-executing. They do you no good unless you know about them and you can't bring them unless you know. And here we're taking people who are in the worst possible position to know; they are dead or they are anesthetized and we are using them without their permission in some instances.

There's another problem too technically with this claim and that's that some jurisdictions limit what gets disclosed only to risks of the procedure and "characteristics of the provider are not encompassed in that disclosure duty." So for example, if your provider's an alcoholic there are courts that say that that doesn't have to be disclosed to you. Conceivably, medical student status may not have to be disclosed either in jurisdictions like that.

And then finally, persons are going to have difficulty showing the causation prong. Causation for an informed consent claim means that you would, if you had known about the pelvic exam for educational purposes you would not have had the surgery. Well, if you're having the surgery to remove a cancer, the likelihood of you making the causation prong is very, very slim. And so for those reasons people will have a great difficulty winning on that claim.

Finally, I want to spend a moment on

accreditation standards because like the claims about torts, accreditation standards, people assume, have been violated here. And what I've found in my research is that there seems to be something falling through the cracks. And I think that's because we have more than one accrediting body that could have weighed in. And frequently when you have more than one person the other assumes the other is doing it.

The LCME, which accredits undergraduate medical education, simply asks that informed consent, for its teaching hospitals, a duty to cover informed consent be placed somewhere in a hospital affiliation agreement. If the hospital takes it on, then they say fine, they are satisfied. When you get to the hospital side that actually looked promising to me when I first looked into this because there are patient rights chapters that give patients the rights to know the qualities and credentials of their providers.

But in dialogs with people at the Joint Commission I discovered it may not yet be an informed consent violation though because the standard or the yardstick for gauging compliance is whether or not the hospital complied with its own policy. If the hospital's own policy doesn't require that it document specific consent, the woman's permission, then they haven't

violated. And that brings you back again, to how would this ever get on the Joint Commission's radar screen because these women don't know and deceased patients and their families don't know.

In closing, my last point is just to say that I think these "paper fixes" that have been used to this point have been done in isolation. I applaud those groups like ACOG(American College of Obstetrics and Gynecology) that have actually issued statements about this, but they're one tiny slice of the health care industry and what we need is a systemic approach that goes across the entire system where we get reasonable people around the table to talk about why this is so difficult to accomplish. I've actually put together a working group to form a task force to look at this question. I hope that we can all come together and talk about how we can have a more effective solution.

And then finally, in the conference immediately following this I can spend a few minutes talking about some things that women can do in the way of self help in terms of avoiding this when they're admitted to a hospital. Thank you very much.

(Applause.)

MR. KLEINER: Hello, this is Morris Kleiner, and I've arrived for my presentation.

DR. HYMAN: Hold on one second, Morris. Let me get your Power Point slides up. Professor Wilson will be holding a press conference immediately next door in Room C and her remarks, just so everybody's clear, are part of our discussion of quality and consumer information issues focusing on physicians. And now, through the miracles of technology, Professor Kleiner is going to speak about occupational licensing and I'll advance the slides.

MR. KLEINER: Well, thank you, David.

DR. HYMAN: You can go ahead, Morris.

MR. KLEINER: Okay. Thank you, first of all, for the opportunity to address the hearing. I'm delighted that the Federal Trade Commission and the Justice Department are now interested again in occupational licensing. It was some 25 years ago when I was working with the Department of Labor that there were many hearings and papers that were written on occupational licensing. And even though the issue has continued to be an important one, there's been relatively little research in comparison to other areas on the role of occupational licensing.

And what I'm going to be discussing is really the growth of occupational licensing and talk about some of the concepts or ways of thinking about who gains and who loses from the process, then providing some empirical

evidence from the academic literature dealing with licensing and health services. And then finally, discussing some of the issues with respect to questions that policy makers, especially at the state and local levels, should ask as occupations come before them in order to increase licensing standards, or in terms of dealing with new occupations that seek to become licensed. So that will be my presentation and I want to thank David for working with me in presenting some of the data that I'm going to be presenting.

So I assume you know what I look like and moving on to slide two on occupational regulation. During the past 60 years there's been a significant increase in the number of occupations that are licensed. Slide number two on occupational regulations shows a typical state, from my home state of Minnesota, really showing the growth of occupational licensing. In the U.S. there's, there are now more than 800 occupations that are licensed in at least one state and about 18 percent of the work force requires a license in order to legally do certain types of work.

To illustrate the importance of the issue a higher percentage of workers are licensed and belong to a union or are directly impacted by the federal minimum wage. In terms of what licensing does, licensing is

defined as a process where entry into an occupation requires the permission of government and the state requires some demonstration of a minimum degree of competency. Generally, members of the occupation dominate the licensing board. The agency is usually self-supporting through the collection of fees and the registration charges from persons in the licensed occupations.

In many states, provisions are established that require a licensed practitioner be present when a service is provided or when a product is dispensed. For example, in some states opticians must be present when contact lenses are dispensed. Other states prohibit, for example, the electronic prescription of certain types of drugs or services.

In contrast, an alternative to licensing is certification. And that permits any person to perform the relevant tasks but the government administers an examination and certifies those who passed and the level of skill or knowledge required. Consumers of the product or service can then choose whether to hire a certified worker. For example, travel agents and mechanics are generally certified by not licensed. In the case of licensing, and this is the important point, is that it's illegal for anyone without a license to perform a task.

Now, what I'd like to do is briefly discuss some of the conceptual issues in terms of licensing. And in the next slide, which is slide number three, entitled Impact of Tougher Licensing Standards, this is a figure developed a number of years ago by a researcher at the Center for Naval Analysis, Arlene Holen. And in this figure she shows the potential benefits of licensing, if licensing serves to preclude less competent individuals from entering the occupation. In this figure, as more individuals are eliminated from entering the occupation, assuming sort of a normal distribution of quality, the quality of those people who are in the occupation goes up. And this assumes sort of a static number of persons in the occupation and that the quality of persons in the occupation follows this normal distribution.

The implications for health care are that if the number of individuals can be limited to the most able then the average quality moves to the right from B to A and the average quality of individuals who provide the service can be increased.

In the next slide, I sort of take this figure, the following figure called The Net Effect of Occupational Licensing. I sort of take slide two and trace through some of the potential benefits and costs of occupational licensing. Now, the argument assumes that

the impact of regulation on the quality of service that's provided to consumers. And this figure provides a way of examining the impact on the demand for and the quality of services.

The figure traces through licensing impact on the demand for regulated services as well as how more intense regulation can have both a positive or a negative effect on the final services to the patient. In the first box at the left of the figure, licensing through state statutes, initial entry requirements and standards for individuals to move from one state to another may serve to restrict the number of individuals in the occupation. These requirements include residency requirements, letters from current practitioners regarding issues such as good moral character, citizenship and the general and specific levels of education of the practitioner.

Beyond statutory requirement, states and local governments also change pass rights to match relative supply and demand conditions for the service. For example, when there's perceived to be an oversupply in the occupation the regulatory board can raise the test scores required to pass the exam.

The second box shows that one of the consequences of regulatory practices is a reduction in

the flow of new persons into the occupation. Now this can have two potential effects. This sort of is the old Harry Truman statement of when he was talking and wanted an economist, he wanted an economist who wouldn't say just on the one hand and on the other, but wanted a one-handed economist who would give him an answer. But I'm sort of going to tell you both the pluses and the minuses.

In the upper box, prices rise as a result of the decline in the number of practitioners as practitioners are able to increase prices. In the lower box, the quality of services provided increases as fewer less competent providers of this service are not allowed to enter the market; this raises the average level of service in the occupation. Therefore, the level of service quality as a consequence of regulation is uncertain, as the last box to the right, where the net effect of, net effects of prices rise, the positive effects of service quality, each may have either a positive or negative effect on the measured quality of service provided.

As with any production relationship, other factors, such as capital, technology may also contribute to the overall quality of service provided. An example of this might be dentistry, an especially highly

regulated occupation that requires varying state requirements. To illustrate, the quality of a dental visit would be negatively related to the pass rate in a state assuming time and effort spent with each patient remains the same. This would occur because either low quality candidates would be rejected by a state or individuals would incur additional occupation specific training in order to pass the exam.

In contrast, increases in the pass rate would enhance access to dental services. Consequently, this outcome would provide greater access as more dentists are available in the state, which would reduce the money price of a dental visit and office waiting time to see a dentist, as well as travel time. Therefore, this would be included in the implicit or full price of a dental visit. Overall dental outputs would be a function of both the quality of a dental visit as well as access to care.

Now, that's sort of the issue of how one might think of the role of regulation on net quality to consumers. Now there's been a fair amount of research examining these conceptual issues. And in the following table entitled table five, or slide five entitled, Studies on Costs and Benefits of Licensing. In this I give information on studies that, first of all, discuss

the costs initially to consumers of different types of occupational licensing requirements.

One that was done a number of years ago at the Federal Trade Commission shows, the upper portion of the table shows the cost of licensing to consumers and practitioners of varying regulatory practices that are associated with licensing.

For example, the average cost of an eye exam and eye glass prescriptions is 35 percent higher in cities with restrictive commercial practices for optometrists. Also, 11 of 12 common dental procedures are more expensive in states with more restrictive licensing procedures. The costs of licensing to practitioners generally involve reductions in the ability to move from one political jurisdiction to another. For example, mobility for persons in health related occupations is significantly reduced in states with tougher standards.

The bottom section of the table shows estimates of the potential benefits, in the next slide, some of the benefits of the potential benefits of occupational regulation to consumers and practitioners. Unfortunately there have been many fewer analyses of the effects of benefits of licensing to patients.

However, some of the earlier studies have found

some positive impacts. One study completed in the 1960s on dentistry shows that tougher restrictions improve the quality of care. In contrast, more recent analysis suggests there are negligible effects on the quality of outcomes to patients as a result of states passing tougher standards.

For practitioners there have been many more studies showing that the impact of licensing on the earnings of licensed individuals is positive. The impact of state regulations of occupations is greater among more educated and higher income occupations. If an occupation like physicians is able to limit the number of competitors, for example, alternative medicine providers, they're able to increase their earnings and presumably prices go up for consumers.

Internationally, there's new evidence that obtaining a license for previously licensed physicians has large earnings effect. The study found that relative to physicians who are granted a license by practical experience, those who had to take a licensing exam with a low pass rate had lower long term earnings.

In occupations like respiratory therapists, there is a greater political or economic power by members of the profession in the state, they were able to obtain licensing provisions for their members and eventually

greater economic benefits for members of the occupation.

In addition, federal regulations dealing with interstate commerce may conflict with state laws. Provisions in state licensing laws may restrict many of the benefits to commerce provided by, for example, the internet. In an earlier FTC hearing, obtaining contact lenses in Connecticut requires the supervision of a licensed optician and a registered optical establishment or store. These state licensing provisions limit the ability of consumers to take advantage of the economic benefits of internet transactions to the extent that other services such as dentistry, medical services, and pharmacy related products have similar occupational licensing restrictions. This may limit the ability to consumers to purchase products which have the lowest cost relative to quality.

In addition, there tend to be conflicts within states between different occupational licensing requirements. For example, dentists are often in conflict with dental hygienists and most states require a dentist to be present. And as a result, dental hygienists are unable to offer, or open offices that deal only with the cleaning of teeth.

In Kansas City, Kansas, for example, there were dentists who were able to get the state to close a dental

hygienist office because no dentist was present when the dental hygienists were offering these services.

Slide seven shows the policy implications of occupational licensing on entry and quality of service. For example, tougher occupational licensing standards, do they have the impact of raising standards and do they have the impact of increasing costs? Generally, in the empirical result, tougher occupational licensing standards tend to raise the costs to consumers relative to alternatives. One, being a relatively lower licensing standard on entry and geographic mobility as well as an alternative of certification, which is item number two. Licensing also raises costs relative to certification and also reduces the choices to consumers.

The way of discussion, especially item number two, is the Mercedes Benz effect, whereas you can either get a high quality service though licensing or no service at all because no other services are legally available.

Item number three is that practitioners on average seem to see economic benefits to tougher licensing but this varies a lot by occupation. Occupations such as dentistry seem to be able to raise their earnings as a result of tougher occupational licensing standards. But other occupations toward the lower end of earnings tend to see relatively small

benefits of occupational licensing. The benefits generally of licensing tend to be fairly difficult to measure. But in the studies of dentistry, especially, the benefits at least of more recent studies suggest that they tend to be fairly small.

Now since occupational licensing is generally imposed at the state level there are a number of questions or issues that state policy makers should ask as occupations seek to become licensed. And this is especially the case in health services where because of third party providers various occupations in the health services are seeking to become licensed or are seeking to increase the current standards that are imposed to enter or to move from one state to another.

So consequently I've provided a number of questions in my conclusions in slide eight which are questions that policy makers should ask. That is, are state licensing laws reducing or increasing the price and/or quality benefits of health care? That is, are the benefits of licensing laws resulting in individuals receiving higher quality care, greater access to services, and will licensing, in fact, increase the quality of practitioners? This includes not only initial entry, but are individuals required to maintain their standards or maintain their ability to stay up with

current changes in technology in their fields?

Do these restrictions also, and the second question, do these restrictions benefit consumers by protecting service quality? And this is also tied to the ability to maintain current standards and current changes in technology relative to the standards that were in place when the individual first entered a particular occupation.

Is the competency of the service enhanced through occupational licensing? That is, are the tests really measuring what individuals are required to do and especially if service quality goes up, if prices go up, how do you handle low income individuals who may lose relative to individuals who have higher incomes and can afford the higher quality care that licensing provides but individuals with lower incomes may now lose relative to higher income individuals? And how do these licensing requirements service low income individuals?

The next slide, conclusions on questions policy makers should ask, slide number nine. Are there unintended consequences to others such as the spread of disease of certification relative to the protections offered by licensing? That is, would certification provide the protections of the spread of disease? Certainly, one can think of a recent disease such as the

spread of SARS. Would having licensed individuals who arguably are of higher quality provide greater protections than would individuals who might be certified and are those benefits sufficient to impose the relative cost imposed through prices and reduced ability of having services through occupational licensing?

Our federal regulations, usurping what states view as the optimal amount of regulation. Traditionally occupational licensing has been established at the state or local level. To the extent that federal government requirements might be imposed to the extent that the federal government might impost universal licensing requirements that apply to all states, what are some of the legal as well as the price and quality benefits of having national licensing requirements which is the case in the European union relative to state by state licensing, which is the case in the U.S.

Now how should different or competing states that impact regulated occupations be handled? Some states have much more difficult licensing requirements than others. States in the Midwest tend to have, it is much easier to pass those licensing exams in many occupations in health services than for example, states like California.

To the extent that individuals move from state

to state, how should that be handled and what level of quality should be imposed on all states. And that is an issue for the federal government to be concerned with as well as the practitioners and the occupations themselves.

And finally, what is the enforcement mechanism to monitor and to impose the appropriate costs to individuals who chose to potentially violate state statutes governing occupational licensing requirements. To what extent do those requirements impinge on the ability of consumers to have a wide variety of choices from the high quality licensed individuals who provide a service to others who may be able to provide lower quality and also lower price of services.

And all those are issues that legislators and state and county governments, who also have been very much involved in regulating occupations, are issues and questions that they should ask as occupations come before them seeking to either become licensed to add to the over 800 occupations that are currently licensed. Or, in the case of many occupations, seeking to impose tougher standards on individuals who wish to enter the occupation.

And I'll be glad to take any questions during, later during the session in which I guess we're going to

be having a round table later on. So thank you very much for the opportunity to address your committee.

DR. HYMAN: Thank you, Morris.

(Applause.)

DR. HYMAN: Next up is Tom Piper to talk about Certificate of Need issues.

MR. PIPER: Good morning. I'd like to thank the Federal Trade Commission and also the Justice Department for allowing me to share some of my observations today and for bringing us to the nation's capital in order to discuss what are some of the most important issues about health care services.

As I speak today, I'll be talking about a variety of topics including the certificate need background, its operations, success and relationship to competition. I'll also be illustrating many of the benefits that the public will have in having assured broad input, access that is being maximized, quality that is being improved and costs that are being contained.

First, let's begin by looking into a few of the milestones of health planning that have affected us over the past century. For almost 100 years medical education has changed dramatically because of a report initially by Abraham Flexner which closed many schools of alternative medicine and changed into what we call today, regular

medicine.

Some would hold that this is one of the first of the 20th century challenges to open competition among health care providers. Now by the mid-1930s, society was moving toward national health insurance and other programs when President Franklin Roosevelt steered legislation into a more conservative Social Security Act. The seeds of public insurance had been planted at this point. Immediately after the second World War the Hospitals Survey and Construction Act of 1946, also known as the Hill Burton Act, was passed. The act authorized federal grants to states to survey the hospitals and public health centers and to plan construction of additional facilities and to assist in their construction. This began to rebuild the foundations of health care infrastructure in America.

After 20 years of infrastructure development publically funded health insurance was passed. Medicare and Medicaid became the new platform for federal and state investment in the health of its citizens. Federally sponsored health planning also came of age and the community demand for public accountability became a national theme with comprehensive health planning.

Less than a decade passed before the Social Administration then connected health care development and

reimbursement and empowered the states to plan and regulate accordingly using Section 1122, the Social Security Act. And with a new authority of the National Health Planning and Resource Development Act, planning and regulation consolidated and solidified into a strong effort to thrive until the early 1980s, when this was moved aside in favor of a new era of competition.

With the move to deregulation, managed care became a popular new tool for competition using diagnostic related groups and other classifications to establish purchasing controls. This became the new initiative to reduce charges, to improve quality and to ensure access. Today, we're struggling to contain the spiraling insurance premiums and find balance between the promoters of regulation and competition.

Well, let's look more closely at the genesis of certification of need. Based on many years of traditional community volunteer efforts, we saw a cooperative, quite public model emerge in the mid-1960s. Business and insurance leaders gathered in Rochester, New York to organize the nation's first community health planning council. Now, this included all the affected groups including consumers, also administrators, physicians, insurers, business, government and others. Within two years the Rochester model was adopted by the

New York state legislature and an era of voluntary health planning was born.

By 1975, 60 percent of the states had voluntarily started health planning and regulation. Much of this ten year effort was encouraged through the Comprehensive Health Planning Act's funding. For the remaining 19 years or 19 states, Louisiana being the last holdout until 1990, federal law leveraged Certificate of Need into place. The chart and map on the next two slides will show how this change happened and what was affected.

On the left, in red, are bars that depict the first 30 states that voluntarily embraced regulations. Hospitals and many others thought that this was an excellent idea and readily adopted that platform. The blue bars on the right then go on to show the 36 states, as well as the District of Columbia, who have continued Certificate of Need through the present time. These colors are maintained on the map on the next slide.

As you can see, this shows how much of the eastern United States initiated Certificate of Need regulation voluntarily, again showing that in dark red. And it also continues to maintain these programs today, those in dark blue as well. Including even some of those in the northwest United States that started early and

then terminated their programs later on. The light blue and the pink are those which terminated their program within the last 15 years.

Now using a very different chart we examine the diverse dimensions of the 37 CON programs that exist today. Down the left column is a list of states ranked by the comprehensiveness of their programs. This rank is calculated based on how many services are reviewed. Now if you look at the list across the top of 30 categories ranging across this matrix. And if you look to the note that where a state and a service intersect, that area is shaded and that means that that state reviews that service.

In addition, the level of the reviewability thresholds; reviewability threshold being a financial point at which certificate need is required. And there are three different kinds. There being that for capital investments such as for buildings, for major medical equipment such as for MRI's and other large equipment, and for new service establishment. These have been converted into a weighted factor on the far right. And when you multiply the weighted factor against the number of services provided you come up with an index or a rank that then shows the comprehensiveness of the program as

you go from Maine at the top to Louisiana at the bottom.

But there's a cautionary note here that this does not relate to the severity of either the CON program or its decisions. But this chart has had many uses. It's on our internet website and many people such as policy makers look at it to see how they can quickly discern the diversity of the CON programs across the country. And some have used it such as in West Virginia in order to streamline their regulatory efforts.

The shades of blue from top to bottom originally divided the states into three categories of regulation with dark blue being the most comprehensive. Over the last ten years a number of states have drifted down the list as review thresholds have raised and the number of services have been reduced.

The map on the next page will easily illustrate the geographic distribution and intensity of CON. Again, the darkest states are those that have the most comprehensive programs. Obviously, CON regulation remains quite popular east of the Mississippi with only a few states like Indiana and Pennsylvania which have terminated their programs in the last seven years.

Now let's move on to the next slide where we begin to talk about the conceptual foundations, some of the criticisms and the benefits of certificate of need.

Let me take a moment just to point out that much of this information seen so far is taken from a national directory that's been produced for the last 14 years in order to track what's going on in certificate of need as well as other kinds of planning, data, and policy programs.

Now, let's talk about conceptual purposes of certificate of need. These can be distilled down into six basic points. First, CON is a fundamental tool to implement community health plans. It provides feedback and support to the development of those plans and it provides support to planning for many health services facilities and systems. It also illustrates an analytical discipline and goal orientation for all planning.

It also intervenes in the phenomenon which is commonly known as the excess supply generating excess demand. And I'll talk about that in a few minutes. And finally it helps preserve precious community and provider capital.

Now what's so unique about some of these purposes? CON is a unique tools that covers a broad range of important features. First a process is based on sound planning theory. It requires extensive analysis and is driven by objective facts. As an open process, this is one of the few venues where the public is not

only welcome but it is invited to be directly involved in the process. Because the market has gaps and excesses like the avoidance of low income populations and concentration of services in an affluent areas, CON often negotiates incentives and supports plans to strengthen services. Quality and effective performance are principles central to the development of standards and criteria and their achievement is often seen through much better applications and fewer denials of projects.

Competition in health care is a very different concept from other types of products and services, in part because planning and reimbursement establishes target capacities and capabilities for specific areas for which providers compete in terms of charges and quality. CON review is very practical in its approaches to health care. It often teaches potential applicants about health service alternatives and business plan effectiveness among other items.

CON's criterion standards and CON's responsiveness to the community based heath planning process often redirects resources into areas of greatest need and helps providers achiever higher and more efficient levels of performance based on what is good for the community rather than what is good for providers.

Now a moment ago I had pointed out that the

market has various gaps and some excesses and here are a few related issues. Like any business capital investment must be passed on to the consumer either through charges or premiums or taxes. Competition in health care is different because providers control the supply of services. Medical practitioners direct the flow of patients and therefore, the demand for services. And consumers don't have enough information. Consumers are not able to shop for most health care, particularly based on price. Where, in fact, are the price lists for them to shop from?

Higher costs create higher charges as aptly demonstrated by the current double digit inflation has health care insurance premiums notably higher than the medical cost inflation state currently seen in our country. Unfortunately, consumers are insulated from the specific costs of care but suffer under the ultimate increased costs in premiums and their taxes. Although reimbursement systems have changed significantly in the last 40 years, the cost of health care continues to escalate and our policy makers continue to look for new answers.

A certificate of need has been criticized since its very inception and the reasons are fairly simple. First, many believe that CON tries to restrain market

entry, lower capital outlays and cap technical innovation all in ways to controls costs. They also believe that CON is more concerned about geography than access rather than social and system questions. Quality is often a factor that critics say is left out of CON reviews. The most prevalent claim is that CON regulators neither understand nor react to health service market forces.

Now these claims deserve some specific responses. The record documents actual CON performance across the country showing that not only are access and quality concerns often considered more than cost, but equity is an important feature in attempts to improve economic and social access for the community in general, and patients and providers specifically. CON uses high standards and best practices to help CON review, elevate quality.

Sound business plans are fundamental to the regulatory process similar to lending principles that are used by community bankers, looking at everything from reasonable cost of facility development to competitor charges for procedures to assure responsibility and efficiency. CON also recognizes the realities of market forces by involving providers, consumers, business, payers, educators and others for the development of criterion standards used to conduct CON reviews thus

ensuring that real live practical experience is reflected in the process. That by using a request for proposals for needs expressed in health plans in some states, applicants are able to compete on many levels and CON tries to ensure that health facility staffing is open to reasonably qualified practitioners.

On the other hand CON discourages the breaking health services into many segments or offering services only to those who can afford to pay or creating practices that exclude other providers or abandoning communities which are depressed or rural or no longer profitable to serve.

Now while we're talking about practical experience, let's talk about practical success. Critics have long used various theories, studies and musings to condemn CON. Over the past two years new evidence from business experience and treatment outcomes has come to light that clearly shows how successful CON has been. The big three auto makers have monitored their costs. Outcomes from Medicare heart patients have been reviewed and ambulatory surgery centers have been tracked. Here are some of the results.

Faced with rising health care costs and the possibility of weakening or eliminating the Michigan CON program the big three auto makers last year undertook

separate systematic analysis of their health care costs in states where they have large numbers of employees and insured dependents. This empirical experience was recorded only in states where they had at least 10,000 employees and comparable health benefit programs.

DaimlerChrysler showed in the year 2000 that their employees in CON states of Delaware, Michigan and New York enjoyed health care costs which were up to 164 percent lower than in non-CON regulated states of Wisconsin and Indiana. DaimlerChrysler also sited and endorsed experience and views of other business organizations including the Leapfrog Group that CON regulation also helps to ensure quality by assuring procedure minimums and promoting higher average program volumes for many health care services.

Now let's look at another auto maker, General Motors. They analyzed health care use and expense data among its employees and dependents in Indiana, Michigan, New York and Ohio; four states where it has a large number of insured from 1996 to 2001. During this time Indiana had been without CON regulations for many years and Ohio had repealed the acute care portion of its CON program a year earlier in 1995.

Comparisons show that GM spent nearly a third less in CON states for health care expenses for employees

than in non-CON states. GM noted that with over a million employees it spends $4.2 million each year on health care benefits for its employees, retirees and dependents. In interpreting its experience GM stated, some argue that deregulating health care expansion will trigger free market forces of supply and demand and lead to lower costs. On the contrary. General Motors has not found that to be true based on our vast experience in states that have varying degrees of CON regulation.

Now let's look at the Ford experience. Ford Motor Company, in its report, included Kentucky, Michigan and Missouri as CON states and Indiana and Ohio as non-CON states. In certain respects the Ford study is broader than the GM study in that it distinguishes between in-patient and out-patient hospital costs as well as service specific costs for Magnetic Resonance Imaging, often known and MRI, and coronary artery bypass graft surgery, often known as CABG. When comparing in-patient and out-patient costs for their hospital Ford found that CON states came in about 20 percent lower than non-CON states. These results, well, the results of their other studies were also equally persuasive. As we look at Ohio and Indiana compared to Michigan for MRI and for CABG services, health care costs were found to be anywhere from 11 to 39 percent lower in CON states.

In summarizing its report Ford stressed the consistent relationship between CON coverage and lower costs across a wide range of different services and settings. Ford's analysts believe that the failure of academic studies to document the cost benefits of CON and regulation is because of the inability of such large imprecise macro echomentric studies to account properly and adequately for the many confounding factors that were otherwise effectively taking into account by Ford.

Low let's look at ambulatory surgery services nationally. A national surgery monitoring organization collected charge data showing that ambulatory surgery center charges in CON states were over a quarter lower than in non-CON states. Now, obviously business and others are concerned about money and about the bottom line. So the illustrations are about lower health care costs.

Now elsewhere the concern we have is for about saving lives. The importance of program service volumes in the connection to CON regulation has been demonstrated recently with the publication of a nationwide study of Medicare patients that document statistically significant lower mortality rates for CABG surgery patients receiving treatment in programs in states that regulate open heart surgery. The University of Iowa research authors note

that most CON studies have focused on whether CON affected capital investment and health care costs and that few have examined direct relationship between CON regulation and quality.

After analyzing experience over 900,000 Medicare patients 65 and older from 1994 to 1999 they concluded, among other things, that CON regulations is associated with better patient outcomes, thus repealing the CON regulations may have negative consequences on patient outcomes.

It also definitively showed that mortality rates were over 20 percent lower in CON states including my own state of Missouri. Critics of CON regulation are reluctant to acknowledge a connection, but there are few mechanisms other than community based planning and CON regulation that systematically promote regional service programs and minimum patient volumes. Obviously, these practices save lives and they save money.

This brings us back to where we started. As I had illustrated before, public input has assured accessibility is maximized, quality is improved and costs are contained. But how does CON relate to the concepts of competition? Quite simply. If you look at Webster's the definition of competition is a business rival competing for consumers or for customers or markets. But

who is the customer? Are they hospitals, physicians or others? Where are the patients? Could they be the ones who are among the trampled masses? They are at the bottom of this old time poster where the business rivals are competing and clashing. Do they have the information needed to measure competing services? The consequences of competition are a great concern.

Because these consequences will splinter the provider delivery network, will threaten safety net facilities, will create high profit niche markets and we will conclude that supply drives demand. Just as the Dartmouth Atlas was briefly reviewed in one of the hospital publications it said that supply generates demand putting traditional economic theory on its head. Areas with more hospitals and doctors spend more on health care services per person.

To compensate, we need balance. We need to balance regulation and competition. And we do this by promoting the development of community oriented health services and facility plans, by providing pricing and quality information on consumers so they have an educated choice, and by providing a public forum to ensure the community has a voice in health care. This, I believe, will protect the consumer's interest.

I thank you very much for this opportunity to

discuss certificate of need and competition. For follow-up you can contact the American Health Planning Association or you can contact me with this information.

This has been an excellent forum. I feel privileged to have been included, and I thank you.

(Applause.)

DR. HYMAN: Thank you, Tom. Next up is Tammi Byrd, representing the American Dental Hygienist Association. And for those of you who are wondering, we will probably take a break either after Tammi or after Ms. Loeffler and then continue on from there. But the door is out there if you can't wait.

MS. BYRD: Good morning. I'd like to thank you also for the opportunity to present the comments from the American Dental Hygienist's Association. I am President-elect for the American Dental Hygienist Association.

I'm here to answer some very pointed questions that have been raised. Number one, what does the empirical evidence say about the cost, the quality and the availability of dental hygiene services? I'd like to address each of these issues. When we look at costs the empirical evidence states that it will lower costs to have independent practice of dental hygienists. There's a comparative study of independent practice along with traditional practices. When we look at these studies the

independent practices were always significantly lower than private practice dental practices.

Other indirect studies show when you take the dental hygiene work in a traditional practice, that when you look at that, that you have the probability of lowering costs to patients of approximately 20 to 40 percent.

What about quality? Independent practice versus traditional practice; in a study that studies independent practice versus traditional dental practices it was proven that dental hygiene practices were as good and we actually safer in several areas. Number one, in infection control and sterilization, in medical alerts and in the determination of whether treatment should be rendered to a patient.

In a study of diagnoses, it looked at the different between the diagnosis of dentists and dental hygienists. There was very little difference, and dental hygienists tended to err on the safer side.

As far as education, dental hygienists are far more educated than dentists are in the overlapping scope of practice that pertains to dental hygiene. Dental hygienists are educated by dental hygienists. They are supervised by dental hygienists and they're competency is evaluated by dental hygienists. In many dental schools

when you get to the periodontal section of this dental hygienists are actually the ones who teach dentists these areas of practice.

When you look at professional liability insurance for dental hygienists it is the exact same whether the hygienist has supervision, no supervision, whether they are performing expanded functions such as local anesthesia, replaning and curettage and several other expanded functions. The supervision or lack of has nothing to do with the price of professional liability insurance when it regards to the practice of dental hygiene.

The ADA accreditation standards assure a competent education. This is from the American Dental Association Commission on Dental Accreditation. If you look at the accreditation standards and the American Dental Educator's Association core competencies for entry into the dental hygiene profession, you will note that hygienists must be competent in providing care for the child, adolescent, adult, geriatric and medically compromised patients.

They must be responsible for the assimilation of knowledge requiring judgement, decision making and critical analysis. They must be competent in diagnosis, treatment planning, provision of the treatment,

subsequent needs, evaluation of the services rendered and making referrals for problems that fall outside the scope of practice for dental hygiene. They are also competent in treating all types of periodontal disease. Dental hygienists must also be competent in evaluating and communicating with diverse populations. They must be competent in life support measures and medical emergencies. They must be competent in comprehensive patient care and management of patients.

When you look at the accreditation standards and these core competencies nowhere in these does it state that the competency is diminished if a dentist is not physically present or supervising a dental hygienist.

The availability and employment forecast. According to the U.S. Department of Labor and Statistics there's going to be a 37 percent increase between 2000 and 2010 of the available positions for dental hygienists. Conversely, dentistry is expected to increase only by 5.7 percent. According to information from the American Dental Association, we graduate between 36 and 3800 dentists a year in the United States. We have 6000 dentists a year that retire or die.

We are not keeping up with the population, so we must look at ways to treat the population and prevention has got to be one of the keys. Dental

hygienists are the prevention specialists of the dental team. Prevention will help save money and save lives.

What regulatory and non-regulatory strategies have been employed to restrict the independent practice or to broaden the clinical autonomy of registered dental hygienists? Number one, efforts have been made to stop or limit the self regulation of dental hygienists. When we look at this we have, dental hygiene is one of the only professions that is regulated by their employers. When we have a board that regulates dental hygiene we also have the ability for the board to impose emergency regulations.

I can speak from experience in South Carolina. I am a practicing dental hygienist. I run a school based oral health program. Statutory change was made in 2000 to allow dental hygienists to work in nursing homes and schools, clinics and various other settings. We practiced from January of 2001 until the end of the school year, the beginning of June that year, with no problems, nothing arose. But once the legislature recessed that year the Board of Dentistry put in an emergency regulation that tied the legislature. This emergency regulation was able to stand for six months.

What it did was it put back in a requirement that had been removed in statute requiring a pre-

examination by dentists. The basis of this emergency regulations was that lives were being endangered and that subsequent claims had been filed that may or may not be proven to cause harm. It is almost two years since that regulation went into place. No substantiated claims of harm have ever been founded. It has never come to fruition.

Also, the actions of the Board of Dentistry at that time in this regulation capacity, they were not working as a regulatory capacity, in my opinion. They were acting as a commercial participant in a given market and limiting access to individuals.

We delivered care to 15,000 children from January until June when we started with no complaints. When this emergency regulation went into place we had to hire dentists to do exams on children before they were able to have services. The emergency regulation listed that there would be no fiscal impact with this regulation. It cost our Department of Health and Human Services over a quarter of a million dollars in this six month period while the regulation was in place and this was only having approximately six hygienists at a time. When we had to hire dentists we had to implement the cost of that exam. Then when the children were referred they had another exam at an office when they were referred to

us, so there ended up being double expenditures also with the Department of Health and Human Services.

On a board of dentistry that has very little input from dental hygiene there are usually one to two dental hygienists serving on the board and one to two consumer members, but the overwhelming majority of individuals are dentists on the boards. Recently, our dental hygiene member on the board in South Caroline has not even been informed of the last two board meetings. She has been left off of the mailing list and not been told there were even board meetings. So we have some conflict here when you're regulated by your employing professional.

It has been documented by the legislative audit council in South Carolina that dental hygiene members on our board of dentistry in South Carolina did not even receive seconds on motions that they made to even open them for discussion. So there is somewhat of a conflict.

Another area that has been used is to maintain gatekeeper privileges for dentists. This includes supervision, orders, examinations and direction. Supervision levels. We have general supervision, indirect supervision, public health supervision. Dentistry works really hard to make sure there is still some tie to dentistry there that they still have some

control over it. In eight states in the United States there is a number of dental hygienists that a dentist can actually supervise in outside settings. Why? I don't know, but there is.

Direction and public health settings, even if there is only direction by a dentist it is still required that it is a dentist giving direction whether they see the patients or not or evaluate any of the work.

The pre-examination, which I just talked about in the emergency regulation, it ties the dental hygiene services to dentistry. There's no evidence to support the need for this.

In private practice this is often required if there's general supervision but yet in a public health setting an exam is not required.

This is setting up a double standard of care. We have individuals that are served in public health settings that do not have to have an exam, which evidence supports. But yet, in a private practice they do have to have an exam. I asked what the reasoning behind this is?

Non-regulatory strategies that have been implemented. We have a quote from the Institute of Medicine. "Rhetoric and political power frequently substitute for evidence and rational decision making." One of the clearest examples of this problem is the case

of dental hygiene services. One thing that has happened is political power has had a very, very high cost to the consumers. Great respect has been afforded with the title, doctor.

At legislative hearings, information and opinion is given without any evidence basis to back it up. I can give personal example on this, also. At school board meetings when we are discussing, in South Carolina the number one reason children miss school is dental problems. Implementing a public health program into the schools has been recommended by the CDC, a Public Health Sealant Program. When we present this program we actually had presidents of the Board of Dentistry and Dental Association members stand up and state that it was substandard care. It was third world dentistry. Everything that is being offered is based on national standards. And I actually have packets of information for the panelists that has the newspaper articles and the quotes and the emergency regulation and different information in that.

In Spartanberg County we had a school board vote unanimously that they wanted the services in their schools. I got an e-mail at 11:37 saying we have voted unanimously for these services. At 12:02 I got an e-mail that said, whoa, put it on hold. We have had so many

calls from dentists asking for these services not to be delivered that we have decided to hold off. So, in less than 30 minutes.

Donations from dental schools have been withheld by dentists. If dentists speak out in dental schools, they have withheld donations from the dental schools. We have had a dentist that was willing to work with us in South Carolina, had checked with the attorneys with the university that he worked with to make sure it was okay for him to be a consultant. He was given a green light, a clear.

But the Dental Association, upon visiting the school, they were told that they would withdraw legislative funding and support. The dentist could not work with us so we had to look for alternate care.

Dental supply companies, we have dental supply companies that have also been told that they cannot provide service, they should not provide services or supplies to us. Recently I received a call. We have been purchasing supplies since January of 2001 and I just received a call a few weeks ago asking me for the name of a dentist that could be listed in order for them to continue selling us supplies.

What consumer information and protection issues will be raised by a less restrictive environment for

market entry? Number one is the consumer's right to choose. The market system, with competition and the efficiencies it generates, is based on the consumer's freedom to make choices among available options.

The health profession's profession has urged revision of the regulations. One of the key principles they have asked for this is the respect of consumers rights to choose their own health care providers from a wide range of safe options.

One thing that has been brought forward is licensure. All states, with the exception of Alabama, require dental hygienists to pass a National Board Exam to become licensed to practice dental hygiene. In order to do this, this requirement, I feel, should be maintained. This assures that there is a knowledge base that has been established and maintained through the dental hygiene education process.

The accredited education should be maintained. Accreditation serves four purposes. To protect the welfare of the public, to serve as a guide for dental hygiene program development, to serve as a stimulus for improvement of established programs, to, and to provide criteria for the evaluation of new and established programs.

One other method that has been implemented is

to stop reimbursement to dental hygienists from Medicaid and from health insurance. What has happened in the past, in South Carolina in particular, we were given a letter stating that dental hygienists were going to become Medicaid providers. Dentistry came to a meeting and threatened to withhold and withdraw their public members from service Medicaid children if hygienists were allowed to be directly reimbursed.

We have situations like this. In Maine, tomorrow, Maine care is looking at their provision. Dental hygienists have been reimbursed for several years for certain services. They are implementing a change at a hearing tomorrow where the hygienists will no longer be reimbursed, if they are practicing under public health supervision, they must be employed by a dentist in a private office.

So we have numerous issues when it comes down to reimbursement. For, in particular, in our state, we, we are authorized by the Department of Health to provide services. A dentist does not have to see the children before we provide the services and we provide urgent case referral and management of these children to make sure they get into offices and are seen by offices. In order to be paid, we must employ a private practice dentist to receive reimbursement.

The dentist never sees the children, never evaluates the work or has any portion of that. He oversees what our policies are but so does the Department of Health. We have a procedure's manual and we have guidelines that we have to work under.

The dentist never participates in actual delivery of care or evaluation, but we must employ them in order to get reimbursed.

What is the conclusion? From the evidence presented you can see that supervision and/or control of dental hygienists is not necessary. Independent dental hygiene will create greater accessibility and have a significant impact on the general health of the public. Dentistry has a vested economic interest in controlling the profession of dental hygiene without any evidence to justify this control.

The legislative changes that are needed to bring about this will not require public expenditures. Yet, it will increase access to care, it will allow consumer choice and it will ultimately lower expenditures for oral health care services.

Seventeen states now have unsupervised practice of dental hygiene, yet only eight states are directly reimbursed by Medicaid or insurance.

One of the strategies by dentistry is to allow

dental, to train dental assistants in providing dental hygiene services. There is no accredited education for dental assistants. Every state in the United States allows dental assistants to be trained on the job.

If you look at, according to the Department of Labor, the salary, approximate salary, for dental assistants in the United States, it is $26,000. If you look at the approximate average salary for dental hygienist it's $54,000. There's obviously a vested economic interest in lowering the standards, but this does not reflect the claims that dental hygienists, providing these services in other settings, are not safe. We have proven that they are, yet on the other hand, they want to lower services to patients.

I feel that patients need to have the right to know that their providers have graduated from an accredited program, have been properly educated and licensed and have the right to refuse treatment if this is not so.

Boards of Dentistry, an organized dentistry, as private, as private business operators, have acted precipitously to persuade public authorities to adopt statutes and regulations that establish competition suppression mechanisms. As you have seen, from this evidence, nothing supports this. Evans and Williams, in

1978, stated that dentists essentially operate as a cartel limiting the supply of care and creating prices higher than they would under competition.

I ask that you review this evidence from the perspective of the public. It is time for change. The current model of dentistry does not serve the diverse populations that need oral health services the most. And it has also placed a superfluous burden on our society.

Thank you.

(Applause.)

DR. HYMAN: Okay. We'll take about a five minute break and then we'll reconvene.

(A brief recess was taken.)

DR. HYMAN: Our next speaker is Lynn Loeffler.

MS. LOEFFLER: Good morning. Like all the other speakers we're happy to have this opportunity to testify today in front of the Department of Justice and the Federal Trade Commission on some issues that are of great concern of the American College of Nurse Midwives.

I'm at the opposite extreme from Professor Kleiner in terms of technology. I don't have any slides. I will use the microphone because midwives only use technology when it's really necessary.

So, my name is Lynne Loeffler. I'm a Certified Nurse Midwife from Blanco County, Texas, which is famous

for nothing except being the childhood home of LBJ. I'm also a practicing nurse midwife and the chapter chair for the region of the country that includes Texas.

The American College of Nurse Midwives is a professional organization for certified nurse midwives. Nearly 90 percent of practicing nurse midwives are members of the college.

Nurse midwives play a vital role in women's and infants' health. We handle approximately 10 percent of spontaneous vaginal births in the United States and as much as 30 percent in some states in the country. Certified nurse midwives are credentialed and expert in their field. They must pass a rigorous, national certification exam and they are licensed and recognized in all 50 states and the District of Columbia.

Nurse midwives are recognized under all states and under federal law as independent health care practitioners with no requirement of physician supervision. Certified nurse midwives provide care to many medically undeserved populations, but they are also an important competitive choice for women of all income and health insurance categories.

CNM's provide excellent care and value as demonstrated by both clinical and cost measures. Epedemia logical studies have further illustrated the

success of using nurse midwives. While operating as independent and self sufficient professionals, certified nurse midwives also collaborate and work in partnership with family physicians, OBGYN's and other health care providers, as recognized in the joint practiced statements referenced in our written testimony.

But despite licensure, despite regulatory, scientific and professional acceptance of nurse midwives and despite the every growing popularity of nurse midwifery services among patients in the public, nurse midwives face significant challenges in gaining a fair opportunity to practice in many communities. Antitrust enforcement has sometimes been necessary to challenge and breakdown anticompetitive barriers to practice.

Barriers to entry and, and obstruction of nurse midwifery practice still continue in many areas. Frustrating the evolution of more diverse, efficient patient choice and focused forms of health care delivery. Antitrust enforcement, by the Federal Enforcement Agencies, must be an important tool in protecting patients' ability to access nurse midwifery services.

The ACNM asked me to come here today to talk to your two agencies about practice restrictions and other barriers which are intended to, or which do in fact, have the effect of excluding nurse midwives from the women's

health care services market. In addition to outright exclusionary practices, nurse midwives, their collaborating physicians and institutional purchasers of nurse midwife services have been subjected to practices which so increase the cost of providing services that the otherwise cost effective advantages of utilizing nurse midwives are lost.

Most of the time, these exclusionary or predatory practices are the product of collusive action by groups of physicians, usually OBGYN's. And here, I might say, that I could substitute midwives and OBGYN's for dental hygienists and dentists and use her slides.

I am not here as an antitrust expert, which I certainly am not, but rather as an affected nurse midwife whose practice in Austin, Texas was closed about a year ago as a result of actions by a group of OBGYNs who viewed our practice as a competitive threat.

The complex details of my situation are set out in the first of several case studies, which will be submitted later this month as addenda to ACNM's written testimony, which was filed today and is available in the hall.

In short, my two partners and I were recruited by the Chairman of the Board of a health care organization and the CEO of a hospital within that

network to start a CNM practice providing continuity of care to an undeserved population. The faculty OB's of the residency program at that hospital, who each contract individually with the hospital to supervise the residents, were never happy about us being there. And over a three year period they utilized several of the techniques that I'm going to talk about in order to close our practice.

The other case studies in our addenda concern nurse midwife practices in another Texas city, in a large Florida city, in a small town in New Mexico, a city in Oregon, a city in Arizona and a city in Iowa. As you can see, there are problems in all parts of the country. In each case, the actions of OBGYN competitors have forced the closure, or at least seriously threatened the continued financial viability, of a nurse midwife practice which fills an unmet community need.

These case studies are merely representative samples, the proverbial tip of the iceberg. It is fair to say that nurse midwives are under siege in many locations. Obstruction of nurse midwives's practice takes a number of forms.

Brief examples, which are covered more fully in our written testimony, include physicians abusing their control of the hospital staff credentialing process to

exclude nurse midwives altogether. Physicians conspiring to refuse to provide consultative or collaborative services that may be necessary in order for nurse midwives to qualify for or maintain hospital privileges. Physicians conspiring to set arbitrarily high prices to be paid by hospitals, nurse midwives or third party payers as stipends for consulting services for nurse midwives.

This was on one of the techniques used in Austin where each of the eight OB's demanded $60,000 a year to be our consulting physicians, which required no additional time or effort on their part over what they were already required to do as supervisors of the residency program. Physicians insisting that nurse midwives, in independent practice, may not have hospital privileges and that privileges may only be granted to nurse midwives who are employed by a physician or a hospital.

Another technique is physicians causing hospitals to adopt restrictive credentialing, supervision or practice policies that effectively prevent meaningful practice opportunities for nurse midwives.

Again, these were techniques that were used in our situation. A sponsor was required and, not only that, the sponsoring physician had to be in the hospital

during the entire labor and deliver of the CNM's patient.

The big problem in many cases is that hospital Boards of Directors have totally advocated responsibility for credentialing to their medical staffs who may have little incentives to credential non-physicians.

Another technique is physicians manipulating managed care contracting or credentialing practices to deny nurse midwives fair access to health planned patients. There have been instances of imposition of a surcharge on the liability insurance premiums of physicians who collaborate with nurse midwives. Reports of such surcharges indicate that only physician owned or controlled malpractice insurance plans impose these surcharges. The Superintendent of Insurance of the District of Columbia ruled in 1992 that such surcharges are not justified by actuarial evidence and constitute double dipping. Yet, in some areas of the country, they continue.

And finally, there have been instances of obstruction of licensing for free standing birth centers by physicians and/or hospitals.

In all these situations, the restrictions are imposed on nurse midwife practice. But the anticompetitive effects are felt by hospitals, noncommunity clinics, health departments and, of course,

the consumers who are deprived of access to nurse midwife services.

Nurse midwives are actual as well as potential competitors of physicians. Although CNM's scope of practice is not as broad as that of a physician, in the realm of normal and low risk, which is at least 75 percent, 70 percent of all births, CNM services are substitutable, not merely complimentary, to those of OB's or family practice physicians.

Nurse midwives offer competitive alternatives in women's health care services, not just for consumers, but also for the various entities that purchase or provide women's health care services. Although some nurse midwives practice as physician employees, and nearly all nurse midwives practice in some form of collaboration and referral relationship with a physician, nurse midwives can legally practice as separate economic entities from physicians in all jurisdictions in this country.

We have two final points today. Each about antitrust enforcement, focus and commitment. The first concerns quality of care bug-a-boos. The second concerns competitive effects analysis.

As to the first, nurse midwives are rightfully proud of the quality of their services. Study after

study confirms excellent patient outcomes and patient satisfaction. Both federal and state law, and national health care organizations including the American College of Obstetricians and Gynecologists, recognize the important and valuable role that nurse midwives play as independent health care practitioners working within the health care delivery system. However, local physicians will sometimes obstruct opportunities for independent professional practice by nurse midwives trotting out tired and debunked arguments.

Nurse midwives' lack of medical school training or medical licensure will be used to support a broad range of restrictions purportedly based on some type of quality concern, such as insistence that nurse midwives must be employed by physicians to get hospital privileges, that a physician must be physically present for midwives to practice, or that nurse midwives are not trained to perform services that they, in fact, perform every day.

These and other restrictions, while couched in terms of quality of care, are empty of merit, are not evidence-based, are usually adopted without benefit of any inquiry, and serve to forestall practice by nurse midwives and to deny choice to patients.

While the arguments used to support these types

of restrictions may sometimes seem plausible at first glance, these types of restrictions are not justified and can be extremely pernicious. In many cases, the doctors who voted to impose the restriction in question are then collectively unwilling to provide the collaboration that they have insisted upon as a credentialing criterion. In these and other cases, the extra measures demanded are not only wholly unnecessary, but are exclusionary, because the resulting duplicative costs make nurse midwives' services uneconomical for patients and third party payers.

We urge the Department of Justice and the Federal Trade Commission to require the same rigor from those who would defend an otherwise anticompetitive restraint on nurse midwives as you would require from those seeking to defend boycotts, concerted refusals to deal, and other restraints in other industries.

We recognize that quality of care to patients and excellent patient outcomes, in our case healthy moms and healthy babies, is essential. So we reject any suggestion that we are asking you not to consider quality. In fact, we are asking that you concentrate your attention very closely on purported justifications that are raised for restraint on competitive practice by nurse midwives.

This is far preferable than to letting pernicious restraints escape close scrutiny merely because the quality banner is waived.

As ACNM's written comments make very clear today, after all the studies attesting to the excellent results of midwifery care, we are far beyond any real vulnerability to a so called quality of care defense. A review of the literature demonstrates, without question, that no quality of care defense could succeed. No clinical, legal, actuarial or regulatory evidence can be mounted to support a quality of care, or for that matter, even a risk of professional liability defense. The evidence is all the other way, supporting the safety, quality and legal and professional autonomy of nurse midwifery practice. ACNM will provide copies of all relevant articles and studies as follow up comments on the record of these hearings.

As to the last point, competitive effects, while nurse midwives often compete with physicians, that does not mean that elimination of a nurse midwifery practice from a market area has the same competitive effect or lack of competitive effect in a community as does a single physician's loss of medical staff privileges.

From an antitrust standpoint, the situation is quite different. Removal of a nurse midwife from a health care community is not, from a competitive standpoint or from a patient choice standpoint, a mere reduction in the supply of competitors. Such collusion takes away from consumers a distinct type of health care provider, one who will generally offer services different, from a different learning base with a different type of care orientation and often with a different cost. And who, thereby, poses critical competition to the prevalent physician practice style in a community.

Indeed competition from nurse midwives can spark innovation and competitive response in a whole marketplace. In a way that the presence or absence of one single physician practice may not. Boycotts and exclusionary practices that deprive consumer of access to nurse midwives pose a marked threat to the diversity of competitive choices available to consumers. They also drive up costs.

Nurse midwives do not bemoan our situation or decry a lack of support or cooperation from other health professionals. Indeed, we've made great strides in the past 50 years and nurse midwives have excellent relationships with hospitals, physicians and managed care

firms alike. It's a minority here who are causing the problems.

In no small measure, though, the presence of antitrust law, as a deterrent to anticompetitive abuses, has been a friend of our growth. The continued vitality of antitrust is a deterrent to abuses, and as a guard for diversity, is dependent on the active exercise of antitrust muscle.

We appreciate the important work the antitrust agencies do in the health care field and we urge active scrutiny and action against restraints that deprive consumers of choice and deprive nurse midwives of competitive opportunity.

ACNM has been a strong opponent of antitrust exemptions in the health care field. As you well know, the lessons of antitrust must be continually taught. The last federal antitrust action relating to nurse midwives was resolved 15 years ago. The problems, though, are still here.

So what does ACNM want? We would like to see some enforcement actions and investigations so that your staffs can judge for themselves the restrictions that prevent consumer access to CNM's in so many markets. We would like to see the potential deterrent effect of enforcement actions so that fewer CNM's may, in the

future, be confronted with these restrictions. And lastly, we would like to see reinstatement of the former Competition Advocacy Program to provide comments to state legislators and regulators on competitive effect and effects on consumers of proposed regulations or legislation.

Thank you.

(Applause.)

DR. HYMAN: John Hennessy is next.

In regard to Ms. Loeffler's comments, I am pleased to announce that we've taken care of one-third of her requests already, because we have reinstated the Competition Advocacy Project and have been filing comments with a variety of states. My recollection is that none of them have involved nurse midwifery, but that doesn't mean we won't do so.

And, in fact, we filed comments relating to a dental hygienist issue in South Carolina. And, in fact, I believe have offered testimony on that. But I'm running into Mr. Hennessy's time. So let me let him talk instead.

MR. HENNESSY: Thank you very much. Thank you for the invitation to speak here today. I will stick within my time frame.

I'm very interested in hearing from the

American College of Nurse Practitioners. We're a 29-physician practice in Kansas City. In the last year and a half we've integrated seven nurse practitioners to our practice. It's been a tremendous advance for our patients. I'm interested to see where the profession is going so we can merge with you.

I'm going to discuss today certificate of need as a barrier to market entry. I'm from the Kansas City, Missouri market. I'll be taking a very micro-focus on how it impacts us in, in both sides of the state line in our metropolitan area.

To give you some perspective, in my career I've been, spent seven of my health care years as a provider of health care services, either as an administrator in a hospital or in a medical group setting. I spent nine of my years as a purchaser of health care services, primarily on the west coast. And, from firsthand experience, I can tell you that market entry has been one of the single most important forces in helping make huge strides in containing costs, not just for health plans and employers, but for patients who have co-payments and co-insurances, as well.

In my experience, the open health care markets have produced cost containment and quality improvement, both in terms of offering new alternatives and forcing

alternatives to improve against each other. Open markets also promote access to care by, for giving more opportunity for care. And we believe it promotes community economic health, as well.

I'm in the cancer business, so I'll tell you a couple things about cancer today. One in two men, and one in two women, have a lifetime risk of developing cancer. So a lot of us in this room. About 80 percent of cancer care is delivered in physician office settings. It used to be a hospital-based treatment regimen, and in the last 20 years has changed dramatically.

And five year survival rates have changed over the last years from 50 percent to 62 percent in large part because of access to screening and detection, improved technology with new entrance and enhanced access to care.

At the same time, the cancer incidents, which is the number of new people per year diagnosed with cancer, is increasing. And the prevalence is increasing, meaning that people who are living with cancer, that number is growing, as well. We're successful in treating the first cancer, which typically means we'll treat them again.

Access to cancer treatment is artificially limited by Certificate of Need. Limited access keeps

vital therapies and technologies out of reach and, in fact, franchises old technologies.

In our experience, CON is a failure as a cost containment tool. I won't go back through a lot of the work that Mr. Piper did in terms of background, but clearly payment mechanisms over the last 20 years has changed dramatically from a cost based system to a system focused on prospective payment, resource based payment and market based pricing. And, while a lot of states have changed their Certificate of Need program over time, many states still have the same program it was back in the '70s.

I'm going to talk to you a little bit about Kansas City and what I call a Tale of Two Cities. I've got a map here that shows you the big picture of Kansas and Missouri. There's a small picture and that bright green line there, which is my technological sophistication, is the state line. There's no mountain range, there's no river, it's a two lane road.

Missouri is a certificate of need state. Kansas is an open market state, there's no certificate of need whatsoever. Like I said, the state line is a two lane road. But in terms of access to health care, it may as well be the Berlin Wall, or the Berlin Wall 20 years ago.

In Kansas City, CON is not a cost containment tool. And I give you some concrete examples from our market. Go to the CMS website, look at the triple AP, double APCC, which is what Medicare uses to pay Medicare Plus Choice Plans for Medicare Plus Choice enrollees. Jackson County, Missouri; Johnson County, Kansas; the exact same number per capita. That's a reflection of actual health care costs. Look at the Medicare Plus Choice co-premiums in that market. You'll see they're exactly the same on the Kansas and on the Missouri side.

If you were to ask for an individual health insurance premium in Kansas or Missouri, you'd see that they're exactly the same. I'll give you a small exception. The Blue Cross plan in our town, it's a one percent difference. What's interesting is that difference is lower in high deductible plans than low deductible plans. What that says is that it's not the cost of facilities and hospital beds and the surgeries that are causing the price differential, if there is any. So in terms of how this actually impacts consumers, people like you and me, not large organizations, it doesn't help from a cost containment standpoint.

We believe CON does not improve quality of care. I have two projects that I report to the Missouri Certificate of Need Committee on, and the only reporting

I give to them is the cost of the project, never been asked on the quality of care we deliver, on the number of patients we deliver care to, just how much we spend. No one asks us anything in Kansas so I think you've got a, probably a case where neither standard is where we'd like it to be, but in either case no one's asked us about quality of care.

The default assumption of CON, therefore, must be that the incumbent equals quality. Now, everything we know about quality improvement in other industries says that's not the case. If that were the case you'd see a name, instead of Toshiba here, it would say Osbourne. That tells you how many people remember the Osbourne computer. But the original PC was developed by a company named Osbourne.

So what does CON do if it doesn't control costs, if it doesn't improve quality of care? Our, in our experience, CON protects incumbent providers, franchisees, from competition, investment and service and care improvement.

Two examples from our market where market entry was denied by a Certificate of Need process. IMRT is the first radiation technology to limit damage to healthy cells. Radiation kills all human cells, you want to kill cancer cells you don't want to kill healthy cells. You

want to preserve the quality of life for patients and you want to make sure you don't create cancers by, by hitting cells you shouldn't.

Our practice was the first to the Kansas City metropolitan market with IMRT in May, 2002. We take care of the pediatric patients for Children's Mercy of Kansas City who, before our entry in the market, had to go to Saint Louis or Denver for, for this type of radiation care. In June, 2002, we had an application reviewed to be the first to bring this technology to the Missouri side of the state line. Our application was opposed by each and every operator of existing radiation therapy equipment.

We didn't get our application approved. And as we a appeal through the court system today, only two of the ten opponents have actually implemented IMRT as an improvement in patient care.

Second example is PET scanning, positron emission tomography, is a tool used almost exclusively in oncology to detect the effectiveness of our treatments and to see if cancer is growing. We were the first to market in a non-hospital setting in Kansas City. We were actually the second entered into the market entirely. And we were at full capacity within eight months.

During that time, 80 percent of the patients we

saw had a change in treatment plan based on PET results. So this was not a technology that wasn't driving results for patients, it absolutely was. In June of 2002 we applied to put a PET scanner on the Missouri side and we were opposed again. What was interesting here is some were existing players and some were players who had no interest in getting into the market, but were interested in keeping us from getting into the market.

One year later, the only PET scanning resources available for oncology on the Missouri side are two part time PET scanners who spend part of their time in other, in either, in Kansas or in other parts of the Missouri market.

So what does our Tale of Two Cities tell us? Well, we have broad access to health care in Kansas. I'm a Kansas resident, so while I benefit from this as a consumer, as an American I really can't tolerate it. But we have new hospitals. All the new hospitals that have been built in the last 10 or 15 years in the metropolitan area are on the Kansas side. We have free-standing facilities, which are including cancer centers, surgery centers, small hospitals. Children's Mercy, who has a facility in downtown, when they had the opportunity to expand, did it in Kansas because there were fewer barriers to market entry.

If you go to the Missouri side you're going to see old hospital facilities and very few community-based options. And the result we see is patients migrating from Missouri to Kansas to get their health care.

We think the Kansas market has broad benefits to consumers, both patients and employers. Timely and convenient access to care is very important. I've done part of my life in the workers' compensation system. And it's not just getting the care but making sure you get it timely to make sure people don't spend time away from work, away from their families and away from producing income for, for their families and for their employers.

My wife had a kidney stone about a year and a half ago. We waited seven days to get access to a lithotritor, which is reviewable under the state law. Those were not a pleasant seven days, and I didn't have the kidney stone.

But what also happens in Kansas is better jobs, high- paying jobs; nurses, physicians, nurse practitioners, laboratory technicians, radiology technicians have all migrated to Kansas as the new technology's been developed over there. That develops a broader tax base. And for those of us on the Kansas side, better roads, better schools, and more public safety.

The health care free market really is an economic engine for the State of Kansas. It is 14 percent of the gross national product and keeping people employed in that industry is good for everyone in the economy.

So today I will give, I have an invitation for the FTC and the Department of Justice. Today we filed two Letters of Intent for Missouri Certificate of Need. We're filing for a linear accelerator with IMRT technology and a PET CT scanner, which would be the first in the Kansas City area. And my invitation is to watch these applications go through the process and to see if this process benefits consumers.

This is not to say there's not a role for government in looking at health care markets. But I don't think it should be as a rationer by limiting supply, but should be in an oversight role in health care markets, as they do in other markets. And some things the, the government does in other markets is that they provide information to consumers that help them make better decisions. So rather than limiting choice, give people tools to make that choice better.

In conclusion, Certificate of Need, in our experience, is an impediment to market entry. It's an impediment to innovation. It's an impediment to quality

improvement. And it, lastly, it's an impediment to the war against disease and disability in America.

Thank you for the opportunity.

(Applause.)

DR. HYMAN: John is actually our last user of Power Point this morning. And so, in order to expedite things, if I can ask all of the panelists to come up and Megan Price, and see where their names are.

And Megan Price will be our next speaker. We'll do Ms. Price and Ms. Apold, and then we'll go directly into the moderated discussion.

MS. PRICE: Does that mean you don't make me bigger than I really am even in real life?

DR. HYMAN: I'm not sure how the cameras would work.

MS. PRICE: Okay. Well, I guess I'll stand over here.

MR. KLEINER: David, do you know that I've got a project? We'll be glad to answer questions. This is Morris Kleiner.

DR. HYMAN: Okay. We're -- we actually have two more presentations, which will take us until probably just after noon, and then we'll start the moderated discussion with Professor Kleiner.

Okay. Ms. Price?

MS. PRICE: Thank you very much. My name is Megan Price, whose background -- I am not a nurse. My background is as a reporter and then as a state legislator in Vermont.

I might explain a little bit about Professional Nurses Service and explain our experience in trying to create consumer choice and competition in home health care services in Vermont.

It's been a 23 year episode. Professional Nurses was incorporated in 1980 as a home care provider. We were the first organization in Vermont to apply for and complete what was then the newly enacted Certificate of Need process. So, we were the first to go through this process.

Our request to become Medicare certified as a home health care agency was opposed then and is today still by the Vermont Assembly of Home Health Agencies, which calls itself VAHA. Subsequent requests have been made over 23 years. Subsequent requests have been opposed by VAHA. VAHA is always the only opponent of our becoming Medicare certified and they have prevailed. There is no choice in Vermont in home health care.

Professional Nurses Service is prohibited from providing physical, speech and occupational therapies, medical social work services, Medicaid services for

adults and some children and maternal child health care services. The way they do this is restricting our licensed nursing assistance to their full skill level. Each time the company's has applied for CON change or for a change in state statute, we have been denied. And with that denial becomes more power, more money flowing to the oligopoly and more brazenness in the way they behave in the marketplace.

In 1980, VAHA was estimated to be a 20 million dollar annual industry in Vermont. Today, that annual revenue for VAHA is approaching $85 million a year. VAHA continues to grow and expand its corporate overhead while increasing the numbers of Vermonters either go without services, or find the services that are offered to them by the one provider available to their Medicare of Medicaid insurance and most private insurance, not to their liking. They have no choice of anyone else to call unless they want to pay out of pocket and then they can call Professional Nurses Service.

It's our estimate that approximately $1 billion has flowed through VAHA, which controls more than 95 percent of all home care services in Vermont in the past 23 years.

You asked us to address the cost and quality and availability of services. The following quote's

taken for the March, 1999 Certificate of Need guidelines. Again, it is a Certificate of Need process in Vermont that keeps the oligopoly in place. These are published and the CON law is enforced by the Vermont Department of Banking Insurance Securities and Health Care Administration, known as BISHCA. These guidelines were written 19 years after Professional Nurses Service's inception. Quote, "Due to the lack of objective data and information concerning the quality and access to home health care services, the Division of Health Care Administration is currently collecting data on complaints, waiting lists, et cetera," end quote.

This data collection process has literally been going on for 23 years without resolution. It began most seriously in January, 1998, after we went to the legislature seeking relief and, and asking and bringing people who wanted a choice in home health care services. We have recently asked for information from BISHCA saying where is the data? Where are the reports that you yourselves said you've been collecting and disseminating? And we were told in the last two months that, in fact, they do collect the information and we provide, you know, data on services provided by ourselves. But the response was, quote, "Nothing is ever done with it."

Now, with yet another application under way

from us with a new administration in Vermont, we've retained an attorney to ask for this information, finally, through the public documents statute. And we hope to have some information to determine ourselves the need that we believe and know deeply exists.

As it's clear from the above, the state has no objective data that would create standards by which an applicant, such as Professional Nurses Service, could prove the need for new Medicare Certified Home Health Agency. The issue becomes one for clients who call us in desperation, as there's a nursing shortage in Vermont and nationwide. I literally speak to young people who have been lying in their own waste for three days with no one to come take care of them.

In speaking with private insurance, we have come to believe the Professional Nurses Service costs are lower, our quality is comparable and the timeliness and the delivery of our services often exceeds that of the existing oligopoly members. By example, I can tell you that a contract representative from a Colorado based infusion company called me last winter. I handle contracts for the company. Excuse me. And they had just signed a contract with VAHA, which also represents itself to private payers as VNA Health Systems, and sets one price for private insurance statewide.

But then the oligopoly members, through Medicare, accept. This happened after our last CON application and they decided that the plan we have, as one corporate office and then services statewide, was a good one and they would adopt that. And so, for private insurers coming to Vermont, they called the VAHA central office through VNA Health Systems and get the set rate statewide for private insurance.

This insurer was nice enough to tell me what they had just signed the contract with for VAHA. And the rates for a home needs assessment was $125 through VAHA/VNA Health Systems. Our rate is $70 for the same service. That would be a savings of $55 per home care assessment for that insurer.

The contractor told me that the same time for a nursing visit, the fee would be $95 for the contract they just signed. What did we charge? And, again, it's $70 for that visit. This, again, affects the private market tremendously as well as state and federal tax dollars in terms of revenue coming in with no competition.

In -- excuse me just a second. From a quality perspective, the combined monopoly power of these 13 agencies, and their corporate status, creates the worst possible of all monopoly markets. The current agencies

are not only insulated from the need to improve and to innovate services, but management is also insulated from its mistakes. And, as with most monopolies, their management is prone to overinvest in capital and administrative overhead.

In the mid-1990s, just one oligopoly member purchased the former headquarters of the largest private insurer in Vermont. And this serves -- understand, Vermont's entire population is 600,000 people. So when one small, regional agency buys the multi-million dollar corporate offices of a former insurance company, people gasp. Even legislators gasp.

They came back a year and a half ago to build again and add on to that building. So the corporate overhead, multiplied by 13, we consider is quite substantial and these costs, again, go to private insurance, Medicaid and Medicare.

In an effort to survive in the Vermont market, excluded as we are from most Medicaid reimbursement and even private insurance reimbursement, Professional Nurses has a system, the development of Vermont's high-tech program and traumatic brain injury programs. We were the first home care provider in Vermont to receive JCAHO accreditation. And we're the only provider to guarantee statewide services. We were the first company to offer

services 24 hours a day, seven days a week. We're the only home care provider to offer a State Board of Nursing an approved, nursing assistant course. And upon completion of these courses, nurse graduates can sit for the state licensing exam, these, again, nursing assistants.

The availability of home care services in Vermont is diminished because of the monopoly. There was unquestionably an unmet need for services and innovation. In Vermont, in fact, the Vermont Agency of Human Services contracts with a number of home care providers who have no sealant at all. But they're allowed to provide services through the Agency of Human Services to Medicaid insured populations. While we have brought this to the attention of BISHCA, they have told us simply we don't have the staff to enforce the law and thank you for complying with it.

We have a letter we'd love to show you. The following is a brief excerpt from a newly issued report by the Vermont Agency of Human Services that says, quote, "Vermont's fastest growing age group is those 85 years old and older. And Vermont has been unable to adequately address its need for community based services. Demand out strips capacity. By the end of this decade the number of people needing assistance will climb 52

percent." Despite one agency within state government making these kinds of statements, BISHCA will tell you, you have to prove need. There's no evidence of need. You cannot get a CON. You cannot operate.

What reasons have been advanced to justify restrictions on the entry? Well, people have said it so well. Competition's not applicable to health care. Not-for-profit providers have greater integrity than for-profit providers. I want to make clear here that we are for-profit company, up to 60 percent of our income has been Medicaid. Currently, it's about 45 percent. I don't consider that cherry picking, which is one of the other allegations.

Competition would further fragment the system and weaken the existing providers. VAHA, by the way, opposes both not-for-profit entries into the market as well as for-profit. They don't discriminate, as to corporate status, entering their market.

Competition would result in less efficient, duplicative system with decreased capacity to subsidize uninsured individuals. Competition will erode volume, reduce the economy's scale for the existing oligopoly, et cetera, et cetera.

They also point to other states, which they say have been ruined by competition. Tennessee is among

them. If someone's here from Tennessee, I'd like to know if Tennessee's in ruins. But I'm not sure. And universal access will be lost. Clients will be turned away by some providers.

The goal of the CON laws that was adopted in Vermont was to control the cost of health care. In terms of home health care services, when you apply, not one penny has to be attached to that certificate. If you simply apply and want to offer services, you must get a CON. So there's no dollar cost. All practitioners, the healing arts, exempted themselves while VAHA made sure that nurses, if they want to do home health care, must get a CON. So if you're a physician and you want to open a physician practice you can spend millions of dollars without getting a CON at all.

The CON process, in our opinion, is not the least restrictive process. And, in fact, increases barriers to consumer access. We believe Maine, which was, I think, was mentioned earlier, which has a licensing law for home health care, is an excellent idea. And a bill was introduced this year in the legislature but it got not one minute of testimony, while the CON Law was again rewritten, and again home health care was kept exactly the same. The goal was to go after Vermont's hospitals to reign in their costs, but at the same time,

the power of the oligopoly made sure that home health care was not changed again.

We believe consumer information protection would be enhanced through a less restrictive environment. Consumers can call a number of providers once they have a choice. In Maine, all of them are listed on a home, a home health site on the web page and they make, you know, a consumer informed, excellent decisions. I believe consumers have the capacity to decide what's the best service and if they don't like it, pick up the phone, call someone else.

For 23 years we've experience what we believe to be a tremendous misuse of power by the State of Vermont. As a former legislator and reporter, I cannot name them here, but I can tell you there are appalling conflicts of interest. And the only thing that's going to change is this federal intervention. We have tried every legal avenue including, recently, standing on street corners with a banner saying please change the CON Law in Vermont and free the nurses. And nothing is getting through.

It will take federal intervention. We ask you, beg you to come because I'm telling the truth when consumers call me, they're, when they complain, the complaints are turned right back to the agency for

fixing. And they are then told, have you considered a group home or a nursing home? I don't think that's appropriate in 2003.

Thank you.

(Applause.)

DR. APOLD: Good morning. My name is Dr. Susan Apold, and I am here today on behalf of the American College of Nurse Practitioners, or ACNP.

ACNP represents thousands of nurse practitioners, or NPs, across the nation, and is dedicated to improving access to quality health care across the life span.

As President of ACNP, together with our state and national affiliates, I would like to join with my colleagues in thanking the Federal Trade Commission and the Department of Justice for holding these hearings this morning. I know putting a national dialog to the many barriers to practice experienced by nurse practitioners and other qualified health care professionals.

Today, an individual who chooses a career as a nurse practitioner must be a registered nurse with a bachelor's degree and a master's degree who has successfully passed a national certification examination. These standardized tests are administered by such organizations as the American Nurse Credentialing Center

and the National Certification Board of Pediatric Nurse Practitioners and Nurses, which are recognized by the nursing and medical communities, as well as, by the Medicare program as a measure of an NP's competence.

Graduate NP programs require students to complete advanced didactic study, as well as, clinical clerkships, conduct research and defend a thesis. Further, some nurse practitioners, like myself, complete doctoral study and, in addition to maintaining a practice, serve as professors in collegic schools of nursing and medical schools across the nation.

NP's are prepared to provide primary health care and a range of specialty care services to individuals of all ages. Specialty practice areas include geriatrics, pediatrics and family medicine. NP's practice in every site of service, including office and clinic settings, hospitals, long term care facilities, hospitals, ambulatory surgery centers, school based clinics and prisons and across all socio-economic classifications.

For decades, many NP's have been the central, if not the only, health care providers willing to serve many areas in rural and frontier American and in some of the most disadvantaged urban communities in the country.

NP's derive their legal authority to practice

through state practice acts and licensure. These laws and regulations set forth NP's scope of practice and prescriptive authority.

NP's hold an independent license. This means that we do not derive our authority to practice through a delegation of duties from a physician. This reality differentiates us from our physician assistant colleagues who practice under the supervision of a physician and derive their authority to practice from their supervising physician's license.

This independent license means that if NP's practice, outside their scope of authority, we are at risk of both administrative and legal action. We are at risk, not the physician.

Currently, 25 states permit NP's to diagnose and treat independently. Meaning without any physician collaboration, direction or supervision. In 13 of the 25 states, NP's also prescribe, including controlled substances, independent of physician involvement.

Another one third of the states require that NP's maintain a collaborative relationship with a physician. Collaboration means that the physician be available for consultation, not that the NP must be employed or supervised by the physician.

Frequently, physicians provide these services

through independent, contractor arrangements with nurse practitioners. The remainder of the states require some level of physician involvement, or involvement by the State Board of Medicine, in the regulation of NP practice. There are currently approximately 100,000 nurse practitioners in the United States.

And, from here on in, I can join my comments with my nurse midwife and dental hygiene colleagues.

Growing competition from nurse practitioners does without doubt, put pressure on physicians to be more cost conscious and to respond to consumer's desire for a more holistic model of health care. Empiric evidence reveals that NP's provide high quality, cost effective care that results in patient outcomes that equal, and sometimes exceed, those reported for physicians.

Horrocks, Anderson and Salisbury, in the British Medical Journal, found that, I quote, "Patients were more satisfied with care by a nurse practitioner," unquote. And that, quote, "No differences in health status were found."

Furthermore, NP care and management of patients with certain chronic illnesses have been shown to lead to fewer hospitalizations and the need for less costly acute intervention. In 2000, Mundinger et al, reported in the Journal of the American Medical Association that outcomes

for diabetic and asthmatic patients were equal for physicians and nurse practitioners, while hypertensive patients, managed by a nurse practitioner, had statistically significantly lower diastolic blood pressure readings. Lower diastolic blood pressures are linked to reductions in heart attacks, heart failure and strokes.

Additionally, the literature reflects that nurse practitioners have improved outcomes, maintained quality and decreased costs in patients with heart failure, in geriatric populations, in emergency rooms and in infants in neonatal intensive care units throughout this nation.

Nurse practitioners have been studied for 35 years. Our quality has not been questioned by the data. I present these facts not to challenge the need for physicians and physician services, but to compel us all to rethink whether preconceived notions and the opinion of physician organizations that only physicians may direct care leads to mis-allocated resources and waste in a system bleeding our economy.

In 1993 alone, it was estimated that annual lost cost savings to the health care system, from the failure to use NP's to their full potential, was between $6.4 billion and $8.75 billion. Can or should our system

continue to lose an opportunity to invest these lost dollars in other, much needed health services over what amounts to arbitrary barriers to practice? The ACNP believes we are all dis-served by allowing the current state of affairs to continue.

In preparation for this testimony, in addition to looking at the literature, we spoke to our membership. Over 500 nurse practitioners responded to a call for discussion of barriers to practice for nurse practitioners. Our members reported three predominant barriers. First, restrictions on reimbursement and impanelment on NP's by private, third party payers, limiting laws and regulations and narrow privileges in a hospital setting.

Lack of direct, third party reimbursement for NP services and refusal by managed care organizations, or MCO's to impanel NP's, is one of the most frequently sighted barriers to independent NP practice. Our members report that it is a matter of routine for many MCO's to encourage patients to visit physicians rather than NP's. To limit payment for particular services considered to be within the scope of NP training. Or to limit all access to NP's completely by refusing to credential or reimburse for NP services.

For example, members have detailed instances

where MCO's have advised NP's to apply for provider status or to send credentialing information, but never respond to those applications. Others report that MCO's have told them, just go ahead and bill for your services under a physician's name. In other instances, MCO's refused to pay for durable medical equipment, clinical laboratory tests or prescriptions arising from an NP order, even when those orders are within the NP's legal scope of practice and the NP serves as the primary care provider for a patient.

I had an interesting experience with this when my orders for radiology exams were denied by a radiology service because they required my collaborating physician to have his name on the order. My collaborating physician contacted the agency and said he understood perfectly why my name needed to be on there. But in the future, he would not utilize the services of that agency. Within two hours, the agency's requirement that his name appear on the orders was dropped.

Third party payers require the NP to submit the claim under the name of the physician or require the order to be signed by a doctor. This places enormous hardship on these NP's and for the patients who have chosen them to be their health care provider.

Furthermore, such a system can lead to delays

and mis-communications when results are reported back to the physician rather than to the NP who was treating the patient and who needs the information.

When candid, third party payers have sighted a number of reasons for not recognizing NP's fully. I list four this morning. First, lack of understanding of NP educational requirements for entry into practice. Next, increased administrative effort to discern variation in state laws governing practice and prescriptive authority. Third, failure to take the time to develop a program for credentialing NP's. And finally, concern that physicians may boycott their panels if they include NP's.

ACNP finds the first three without any particular persuasiveness, given that the Medicare program and some third party payers, have managed to develop systems for including access to NP's within their plans, as well as, direct reimbursement to NP's for their services.

Furthermore, we have had members offer to assist insurers in developing credentialing guidelines and policies regarding scope of practice or to serve on their credentialing or quality committees. Yet, insurers generally disregard these offers. Our membership does not believe that it is a coincidence that physicians are major players on Boards of Directors of many of the

managed care companies.

Inequitable or unwarranted laws and regulations at both the state and federal levels, serve as immense barriers to NP entry into the market. At the state level, variation in state practice acts and prescriptive authority interfere significantly with the ability of NP's to contribute to our health care system to the extent for which we are trained and prepared. It is frustrating that these differences and laws and regulations are not based on science or patient outcomes, but rather are the byproducts of political maneuvering, often by the organized medical community.

It is not surprising to learn the barriers to NP practice generally are more oppressive in states with the strongest state medical associations. The American Medical Association has, unfortunately, made it clear to the physician community at large that every effort must be made to block or interfere with NP autonomy and reimbursement parity. These anticompetitive efforts include lobbying to defeat legislation granting NP's independence and instilling the public sector with misleading information regarding non-physicians.

In an article appearing on the AMA website, the organization sets forth its two pronged strategy for dealing with legislation which is favorable to physician,

to non-physician practitioners. First, and I quote, "Spend money. Lobby hard. And work with national medical associations and take the approach of: See the bill? Kill the bill." End of quote.

The second option is to, quote, "Negotiate with the opposition to get the best possible deal." End of quote.

Although the AMA generally cloaks its arguments in concern for the public. Statements, such as that issued after the AMA House of Delegates meeting in January of 2001, reveal the true motivation. Quote, "We are faced with non-physicians extending their practice to where they should not be." End of quote.

Organized medicine also attempts to drive a negative public opinion about the capability of NP's through misleading public comments and policy statements that state incorrectly that physicians delegate duties to NP's and that physicians must supervise NP's. Both fly in the face of the state of the law across the majority of the country today. Yet the unknowing reader, or recipient of this information, including law makers and private payers, are influenced by these statements.

I know that you will be considering the Noerr-Pennington Doctrine and its exceptions tomorrow. I urge you to consider the very negative and manipulative

efforts, such orchestrated campaigns of deception have on consumers. I question why such propaganda should be tolerated.

By way of illustration, in February the American Academy of Pediatrics issued a policy statement called Scope of Practice Issues in the Delivery of Pediatric Health Care in which the AAP asserts that the pediatrician must oversee the pediatric health care team and delegate patient care responsibilities to NP's and supervise the NP. AAP goes on to state that the care provided by NP's is second tier and compromises the quality of health care that should be available to all pediatric patients.

The AMA issued an equally troubling and deceptive policy statement in April. These and other similar statements seem to be calculated to dissuade patients and third party payers from relying on NP's unless, of course, the NP is under a physician's control and the physician is permitted to be reimbursed for the NP services.

Although ACNP acknowledges the leadership of the federal governments in recognizing NP services, there is room for improvement. There are existing federal laws and regulations that impede NP practice, as well. One of the most common frustrations that we hear from our

members is the inability of NP's to certify and recertify for home health care services. Under the Social Security Act, in order for a home health agency to receive payment for services by Medicare a physician must certify or initiate those services on behalf of the beneficiary. In some cases, the certifying physician, who does not have a relationship with the patient, relies upon the input of the nurse practitioner in certifying a Medicare beneficiary for home health.

The Balanced Budget Act of 1997 authorized NP's to develop a plan of care for home care patients but overlooked initiation of this care. ACNP finds this inconsistence and encourages legislative action to correct this problem.

A major concern stemming from federal legislation in Medicares and some private payers, an equitable reimbursement system of paying NP's 85 percent of the reimbursement rate, paid to physicians. In the Medicare context the Balanced Budget Act of 1997 authorized NP's to bill directly to the program regardless of geographic location. Since then, increasing numbers of NP's have obtained their own provider numbers and have billed directly rather than incident to a physician. These NP's, however, are being asked to provide the same level of service, which they

should and do, but get paid less for identical services even though NP's incur the same practice expense costs for delivering these services.

Given that physicians are arguing that they are having difficulty maintaining a practice when receiving 100 percent of the fee schedule payment, you can understand that it is even that much more difficult for NP's to enter and continue in the market. As a result, the many benefits of NP's, including increasing provider access for patients, are being jeopardized without legitimate reason.

Finally, our members have expressed their repeated concern with narrow privileges in the hospital setting. As in the case of MCO's, hospitals also claim to be confused as to how to credential NP's and the NP's scope of practice and concern as a medical staff reaction. Yet, even after NP's make the effort to respond to such concerns, institutions still refuse to grant privileges or grant very narrow privileges.

Our feedback indicates that some hospitals refuse to schedule patients for testing or for outpatient laboratories unless a physician's name is on the order. One NP reported that, quote, "On several occasions I have had abnormal mammogram results sent to my collaborating physician's office and his staff sends them back not

knowing who the patient belongs to. I have had the experience of my patient receiving the results before I do."

Another NP stated that her involvement with a hospital affiliated, urgent care clinic nearly doubled the number of patients the clinic was able to accommodate per day. In addition, a survey of clinic patients revealed increased satisfaction with the clinic services that were directly attributable to her.

In spite of these positive changes for the hospital and the dramatic improvement in access to care for patients have requests to be listed on the referral page for the clinic and in the provider director were denied.

In closing, NP's face many barriers to practice. All of which do a disservice to the health care system and the patients that we serve. Nurse practitioners deliver quality, cost effective health care within our prescribed scope of practice as determined by law. We endeavor to be accepted as equal members of the health care team, bringing to health care the unique perspective of a nursing background.

Nurse practitioners have earned the right to professional autonomy in the form of independent practice and direct reimbursement for the vital service that we

render.

ACNP is hopeful that as greater attention is given to these issues, many of the arbitrary barriers will be removed and an equitable balance will be found to achieve the goal of improving access to quality, cost efficient care to patients across the United States.

Thank you.

(Applause.)

DR. HYMAN: Okay. We've got about 20 minutes for discussion. Our general practice is to ask earlier speakers whether they wanted to dispute or comment on anything they heard subsequently since the subsequent speakers heard the initial speakers first.

So, Tom, did you want to say anything? I mean, or, I'm sorry, Professor Kleiner, first in order but not in presence.

MR. KLEINER: I, I have nothing other than if there are questions for me, would be glad to address them in terms of the overall effects of licensing on both practitioners and/or consumers. We'd be glad to answer any questions along those lines.

DR. HYMAN: Okay. Tom, do you have anything you'd like to add to what you said already?

MR. PIPER: I think probably the only things that I would add to what I said earlier was that when we

look at government oversight of health care services, I think it's important that when we talk about competition and differentiate it from other kinds of competition, you have to keep in mind that over half of the revenue that goes into health care services comes from public sources. Whether we're talking about Medicare, Medicaid, cash grants, other kinds of, of revenue that government really has a responsibility, whether it's state or federal, in order to monitor those to try to assure that the money is being used efficiently, effectively, and toward is higher quality service as possible.

And I certainly compliment Mr. Hennessy in his presentation in, in pointing out the quest for, for quality. And, but I think first and foremost, Certificate of Need agencies represent the interest of the consumers. And we are very concerned about providers' positions, but first we want to see what the impact is on consumers.

But I'd also like to compliment the presentations on dental hygiene and on nurse practitioners because, having employed both in prior lives and in Iowa, I found that it was some of the highest quality services and most responsive to patient needs that we were able to provide.

Thank you.

DR. HYMAN: Do you want to add anything or?

MS. BYRD: I'd, I'd just like to add that in dentistry is not mostly publicly funded. Dentistry, at this point in time, is mainly privately funded and very little public funding does go toward dentistry. So that's part of the problem is because dentistry has become unaccessible to individuals who cannot afford to pay out of pocket or have private insurance. So that affects it.

And as far as licensing goes, dental hygiene has reciprocity in most states and can move from state to state after national licensure. Whereas, dentistry does not. It's restricted and in most states is not allowed.

MS. LOEFFLER: Actually, I had a question for Mr. Piper.

MR. PIPER: Yes.

MS. LOEFFLER: I was interest in seeing the results of the studies from the auto makers concerning Certificate of Need but I didn't really see what the theory of causation was so I wondered what variables were controlled for in, in coming to the conclusion that whether or not a state had Certificate of Need had any impact on the cost of health care in that state?

MR. PIPER: Not having conducted those studies, I don't know all the causal factors went into it either.

What I do know is that they took actual cost in, in health benefits' programs that were very equalized between the states and looked at their bottom line, which is what business tends to do the most. They feel, and I, I believe that in speaking of Ford, in particular, that they spoke to the causal factors, were somewhat critical of other studies in saying that they had not taken them all into effect. But I would tell you that I do not have that information.

On the other hand, looking at other studies such as those done by the University of Iowa, in looking at lower mortality rates and, and the affect of cost. But particularly mortality rates, what they had looked at there, in it was an, an excellent study of all states, of over 900,000 people in order to look at the factors that really had to do with volume. And more than any other item, volume had to do with proficiency. It often is said the more you do the better you do is an ultra-simplification but it is, is a, is a well-held principle in medicine that proficiency is based upon the quantity with which you do. So higher quantity leads to higher quality.

MR. HENNESSY: Two thoughts, one I was going to actually take Tom's comment and, although, we may disagree about whether government should be rationed or,

or act as an oversight, government does have a very strong interest in health care even beyond Medicare and Medicaid. Remember, that most premiums in this country are pre-taxed. So, it essentially is subsidized by tax dollars and even a lot of dental premium is, is subsidized in that fashion.

The other thought I'd share is on, regarding the nurse practitioners. We have found managed care to be a tremendous obstacle for, for nurse practitioners. We had one plan that actually said we, you, your nurse practitioners can't see our patients. And we said, well, nurse practitioners can see all of our patients and if you want the same level of care the rest of our patients have you will allow them to see nurse practitioners.

And, to one of your points, we actually looked at the effect of nurse practitioners in the first year of our practice and we looked at increase in urgent care visits. And while the cost of the visits was $900,000 more than it had been the prior year, we saved $1.8 million in unnecessary hospitalizations. So, very good data suggesting that, that works and we're challenged, like you are, to expand the role of the nurse practitioners in our office.

MS. APOLD: And that's important data to keep in mind because prevention is what saves the dollars

ultimately.

MS. PRICE: Well, I wonder if Mr. Piper has any, you know, from our perspective in Vermont, and we're talking again home nursing, when there's no dollar cost, it's a service, and if it's Medicare or Medicaid, it's a fixed price repayment from your state or federal tax dollars. What would the CON reason be to restrict competition in the industry, which merely serves consumers and keeps them out of a hospital?

MR. PIPER: Home health is, is a broadly debated service as to whether it should or should not be regulated under Certificate of Need at all. In Missouri, we have never regulated home health. Yet, in our Arkansas, directly south of us, they have done it for a very long time. That's one of the few services it regulates.

What we have found was that in looking at home health it is often a balance, and you pointed this out in your presentation, between home health residential, assisted living, nursing home care or even higher levels of acute care as various alternatives. And I think that as you look at that, what I would call a continuum of care, that that is, is a under, a valued principle. That is something that I hoped that the FTC and the Department of Justice and, and any state that looks at this, needs

to take into account a balancing of all of the possible alternatives for care for that particular population, whether is a disabled population or an elderly population or otherwise, it could be eligible for that kind of care.

As in looking at payment mechanisms for Medicare and Medicaid, yes it is a fixed rate, but even the fixed rate is based upon cost. And, and I think it is unfortunate, although I'm not specifically familiar with the Vermont situation, you do need to have multiple practitioners in, in order to make comparative studies. And if you only have one, it doesn't sound right. But --

MS. PRICE: Tom, do you know of any state in the country that limits physicians by CON, that would require physicians to get a CON anywhere in the country?

MR. PIPER: I am familiar that in West Virginia, as an example, which a largely rural state, that yes, they do require getting the Certificate of Need to establish many of their practices. I believe there are a handful of other states. It is not a, a broad precept, though.

MS. PRICE: Thank you.

MS. APOLD: I just have an additional comment. I think it bears repeating that my dental hygiene and certified nurse midwifery colleagues identify the reality that the battle cry for anticompetitive behavior is

always one of quality. And yet there are no data to support that dental hygienists, nurse midwives or nurse practitioners provide a lower level of care or substandard care. In fact, as mentioned by my nurse midwife colleague, the data fly in the fact of that. And, in fact, indicate that our care is good and, in many instances, provides a type of care that is missing from the health care system that we have today.

And I think that it's important that that be heard by the public because of the carefully orchestrated campaign to limit public access to the types of care that we provide.

DR. HYMAN: Okay. Let me start with just a quick question for Professor Wilson and then I have a bunch of questions for other people as we have time to cover them.

The, the data that you showed suggested that if you ask women, a substantial majority, depending upon the context, will consent, and I guess you can run the question two different ways. If they're going to consent anyway, why bother? Would be the sort of pragmatic, liberty ignoring approach to the issue.

Or alternatively, if you asked them and they don't consent then what happens to medical education? So I guess I'd just like to ask you to address both prongs

of that inquiry.

MS. WILSON: Well, I think with respect to the first prong, that the idea of discarding consent in this context flies in the face, and to use another colleague's term, 30 years of biomedical ethics where we have, we have cast aside paternalism and we have returned to patients that autonomy to decide what would happen with their bodies. And so, I just think it just fundamentally doesn't fit with what, what else we've done in, in medicine.

With respect to the ability to train though, I think that you have to look very carefully at both the raw numbers of people who are willing to consent. And I think you also have to look at the absolute need in the medical school years to teach certain things.

There certainly is a possibility to shift things that we might otherwise want to expose people to in the medical school years, to training in the internship in residency years where people have already become committed to a path to become a certain type of physician. It may be that some medical students who are being exposed to things, because we want to give as much exposure as we can, even in a context where we ask, could still be exposed to those things, but later, after they've committed to a path, to actually become an OBGYN.

So, I think it's a, a richer, more complex question than just raw numbers.

So, I think we also have to be more willing. If those numbers decrease, perhaps to move things out of the MD years into the internship for the residency years.

DR. HYMAN: Okay. The next question is for the various provider representatives on the panel. And we've heard a variety of elements, if you will, that seem to be driving difficulties. And in no particular order, licensure/CON seems to be on of them. But there's also credentialing at a local institution. There's also liability, in terms of the availability of insurance. And the risk of liability independent of that. And there's also reimbursement, the ability to get into panels, the ability to get compensated on a level commensurate with services that you're providing.

So just in terms of comparative magnitude of those things. And if I'm missing something, please feel free to add it. I'm just trying to get a sense of prioritization. Which are the bigger problems, which are the problems that are there but are less significant. What's the low hanging fruit is probably the sort of management speak version of this.

So, Tammi, let me start with you.

MS. BYRD: I think, for dental hygiene, direct

reimbursement is a crucial factor. One thing dentistry tends to practice in private practices across the United States. And what has happened, because of the shortage of dentists in the United States, the people that are suffering the most are our elderly and our underprivileged and our school children who don't have access to offices on Monday through Thursday from eight to five.

If dental hygienists, and if you look at the criteria, most dental hygienists who are practicing independently in the United States are practicing in areas of home health and assisted living areas in school based program. They're practicing in areas that are undeserved yet we have no ability to be reimbursed. And so it makes it really hard for a practitioner to be in these areas. And it limits the access.

So, I would have to say from a dental hygiene prospective, direct reimbursement has to be one of the number things.

MS. LOEFFLER: I would say for nurse midwives that credentialing is the number one problem because if you aren't credentialed and can't practice then you don't need to bill anybody.

Billing and reimbursement are certainly secondary issues. But 99 percent of the women in this

culture choose to have their babies in the hospital. So, if we cannot practice in the hospitals, then we can't serve those women.

The problems with reimbursement, partially have to do with the 65 percent Medicare issue because many private insurers also tend to follow that. And also getting listed, as my nurse practitioner colleague was saying, on provider panels so that you have some visibility in the marketplace. If you're not in the directory you don't exist. No one's going to call your office.

MR. HENNESSY: For us it's entirely a CON issue. We, where there's no CON in Kansas, we build facilities and get them up and running fairly quickly. On the Missouri side we, we can't do it.

From a liability standpoint, that's a business decision. We can buy liability insurance. It maybe more expensive but it's a business decision. Reimbursement, we're fortunate, even though we have, we have physicians, we have nurse practitioners and other folks, you know, it's a business decision whether we can get reimbursed or not.

Credentialing, again, is a business decision. So, CON is, is the sole barrier for us in terms of, you know, enhancing the cancer care we provide on the

Missouri side of the state line.

MS. PRICE: Speaking for Professional Nurses Service in Vermont, it is again solely a CON issue. We could, we at one point had JCAHO accreditation with deemed status which is the equivalent of Medicare certification. And yet even with that in place and training nursing assistants for other providers including VAHA statewide, once those nursing assistants want to work for Professional Nurses Service, they cannot activate their skill level.

So, while you can get your blood pressure taken at any pharmacy or order the machine through the QVC channel, or whatever, our nursing assistants cannot do that. And the barrier for us is strictly legislative and really regulatory at this point.

MS. APOLD: It's very hard to pick the low hanging fruit because all of those issues are intertwined for us in the nurse practitioner community. But if I had to pick the most important I would say reimbursement because it's sort of the umbrella issue. And it's important to note that reimbursement, certainly, is fundamental to our existence but it's not just about getting paid for our services. It's also about visibility. It's also about our contribution to the health care system. As long as I am told, just go ahead

and bill it under Dr. Smith's number, I don't appear anywhere. I do not exist. And it is very difficult to advance your profession to let consumers know who you are, not the consumers, let me take that back. They do know who we are. They're very clear about who we are.

But about the health care community in general. It's difficult for them to know what we do and the services that we can provide because we're hidden behind this invisible cloak. And the excellence that we provide completely becomes subsumed under another provider's number because of the inconvenience, the concern, the concern for boycotts from other professional communities that the managed care companies have.

MS. BYRD: I'd just like to add our case in South Carolina, what has happened is legislation has passed the Dental Association and the Board put in legislation that says that the individual that is billing for services actually is the clinical provider of the services. And the dental hygienist is the clinical provider of the services. We actually are licensed and regulated and therefore should be considered the clinical provider for those services but we are having to utilize a dentist to bill for the services.

This is put in as a measure to try to inhibit dentists from participating with us because of some

liability. Yet there are -- our law requires us to have professional liability insurance and there are no changes in liability no matter whether we are supervised or not supervised. So it's been put in as a barrier, this particular issue.

DR. HYMAN: This is a questions for Professor Kleiner and it builds off of a comment Ms. Byrd made, which you identified some of the difficulties you are having in South Carolina with the licensing board. And the suggestion that I had heard was we need a separate board made up of dental hygienists in order to regulate and not be subject to the difficulties by having dental domination on that board.

And so, I guess Professor Kleiner, given your skepticism about all licensure, I'd be interested in your comments on that proposal and how you might balance the procompetitive consequences from a dental-hygienist-only board without dentists, but limit the potential risks from a dental-hygienist-dominated board.

MR. KLEINER: Well, I think you raised an important point. And let me just briefly comment on the issue of which of these issues are important.

Certainly, from the employee's prospective, the fact that licensing has grown so dramatically over the last 50 years suggests that licensing, in general, is an

area that a lot of occupations see as a way to provide professionalism on the one hand. But also to restrict entry and increase earnings and status within the occupation. And, certainly, if you follow the trends over the last 50 years it is in the area of the greatest labor market regulation.

To answer your question regarding having only members of the occupation as, as members or as determining who can be licensed and who can get in and who can't, there's been a movement in a number of states including California, my own State of Minnesota and Virginia to have public members on these boards.

And, one additional issue is that that the occupations have, have gone to the legislature and said, look, this is a cheap way for you to regulate an occupation and the occupation itself will pay for it through additional fees. Another question to ask the State is if it's so important for public interest, that public funds should be used to support these regulatory boards, which would suggest not only members of the occupation, it can provide professional expertise on what it takes to do the work. But also members of the public who can provide a public consumer patient perspective on what are the benefits and costs of either becoming regulated or additional standards that might be imposed

by the boards.

DR. HYMAN: Does anybody want to comment on that proposal.

MS. BYRD: I will. Dental hygiene does not necessarily want strictly a dental hygiene board. We welcome consumer members on board. However, what happened in South Carolina by being dominated by a dental board that employs dental hygienists, that is what set an emergency regulation up with a loophole, I guess you would say. I guess it's there for emergency purposes. But for a board to wait for the Legislature to recess and a few days later implement an emergency regulation claiming that lives were being endangered by cleaning a child's teeth without an exam by a dentist is something that if dental hygiene was not regulated by our employers, that type of emergency regulation could not have been put in place. Thereby keeping children from receiving services for six months, costing an astronomical amount of money and costing the state an extra quarter million dollars.

DR. HYMAN: Tom.

MR. PIPER: David, I think one of the overriding principles and all the things we're talking about is a difficulty in regulation of being able to talk about what should be because too often a regulation has

to do with what should not be. And one of the great criticisms I would have of many regulatory systems, and certificates aren't even included, is that too often the state plans, if they exist at all, are insufficient to talk about where we ought to be going let alone how we ought to get there. We should be able to anticipate innovation. We should be able to anticipate broader use of health care manpower and woman power and the kinds of disciplines that we could have.

We're not helping customers shop. We're not even helping consumers get the right kind of information. And I think until we're able to put into the hands of the common consumer a price list, a way of rating quality for practitioners and providers, to have standards of access, to be able to have a community planning model, we're going to be continually frustrated. And we will always criticize regulation because it's still about what you can't do instead of what you can do.

DR. HYMAN: Well, on that note I would encourage the panel and anyone else who wishes to submit recommendations as to how we should tailor our efforts as well as how regulations should be tailored in this area. Just take full advantage of the opportunity to submit those comments. And we will carefully consider them.

I'd like to thank the panel for their

thoughtful comments this morning --

AUDIENCE: I'd like to make a comment.

DR. HYMAN: I'm sorry, we don't accept comments from the audience.

AUDIENCE: I've got a question.

DR. HYMAN: We don't accept questions from the audience, either, as I said at the outset.

So, I wish the audience to join me in a round of applause for the panelists, and thank you very much.

(Applause.)

(Whereupon, at 12:35 p.m., a lunch recess was taken.)

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

DR. HYMAN: Welcome back to the afternoon session of the joint hearings held by the Federal Trade Commission and the Department of Justice on Health Care and Competition, Law and Policy. This is part of a multi-month process of holding hearings on a variety of issues relating to the performance of the health care markets, including testimony from a wide array of distinguished panelists and commentators.

We are lucky to have a very distinguished panel this afternoon with us. We've actually copied and bound short bios for each of the speakers today in a document that's outside. We could easily use up all of our time simply recounting the exploits of everyone who's going to be speaking today. And rather than do that, our rule is everybody gets a one sentence introduction and you can read about them.

So, the order in which people are going to speak is sort of left to right. As you see at the table, there's no one there. That's not because there are no speakers here. It's because we have some Power Point presentations and it's easier for people to see it if they're seated out in the audience. After everybody's had a chance to speak, we will then convene the panel and in the time remaining, which will hopefully be about 25

minutes or so, we'll have a roundtable discussion of the issues that we'll be discussing this afternoon.

I can please ask everybody to turn off your cell phones. And I think that was all of the preliminary introductions. Our first speaker today is Professor Michael Morrisey, who's a professor of Health Care Organization and Policy at the University of Alabama. I'm just going to introduce everybody at once to make things easier.

The second speaker is Professor Gregg Bloche, who's a professor at Georgetown University School of Law. He has the record for the shortest commute for the discussion today because it's right across the street. Francis Mallon is the Chief Executive Officer for the American Physical Therapy Association. Steven Lomazow is here representing -- Dr. Steven Lomazow, excuse me, is here representing the American Academy of Neurology. He is a practicing neurologist from New Jersey. Dr. Russ Newman is a psychologist and the Executive Director for Professional Practice for the American Psychological Association. Dr. Jerome Modell is here representing the American Society of Anesthesiologists and he's a Professor Ameritus at the University of Florida, College of Medicine. And then batting clean up, Jeffrey Bauer, who's a futurist and a medical economist studying the

evolution of the health care system.

So, first, Professor Morrisey.

MR. MORRISEY: Thank you, David. I'm delighted to be here. I am a health economist in the School of Public Health at the University of Alabama at Birmingham, and I'm the Director of the -- Center for Health Policy. I'm here speaking in my private capacity.

What I'd like to do is spend a little bit of time talking about certificate of need with respect mostly to hospitals because that's where the research literature lies, tell you a little bit about some new work that's been done looking at the certificate of need in nursing home markets. And then spend the remainder of my time looking at any willing provider and freedom of choice laws all in the context of various entry.

As was discussed this morning, certificate of need programs were established in the '70s to help control health care costs. Hospitals, nursing homes and other providers were required to obtain state approval to open or to expand a facility. At its peak, all states, except Louisiana, had a CON Program. And according to the American Health Planning Association, in 2002 some 36 states plus the District of Columbia still had some form of certificate of need.

The rationale for CON is that health care

providers typically in the early days were paid on a cost based basis and any new facility was essentially paid for, essentially received the cost that it incurred under cost based reimbursement from Medicare, Medicaid and, indeed, private payers. Non-priced competition in the form of services, amenities, quality led providers to expand services and arguably led to duplication of services. So as a consequence, certificate of need would control costs by preventing this duplication of services.

In a standard economic model, CON would be viewed as a barrier to entry. It artificially restricts the supply of a particular health care service and would allow current providers to charge higher prices. Providers would be expected to devote resources to obtain a CON franchise and to do all they could to keep their competitors from offering similar services.

The proponents of CON tend to argue that health care markets are not price competitive. And as a consequence, this regulation of supply is necessary to control cost. CON opponents argue the health care markets are priced competitively, that CON franchise allows the providers to charge higher prices and that an increase in price competition would lead to greater demand for CON franchises or indeed for a greater barriers to entry.

So the question becomes did CON result in lower hospital costs. Amongst the health economics community that has examined this from an academic perspective, the issue is, in my view, largely resolved. There are a series of rigorous multi-state econometric studies from the '70s, the '80s and the '90s that looked at the effects of CON on hospital costs and concluded that CON didn't lower costs. In the most recent work, Conover and Sloan from Duke, concluded that CON repeal had no effect on hospital cost.

And, indeed, there's some evidence that CON, in fact, raised hospital costs. In some work that we did in the late '80s, early '90s, trying to control not only for the other factors going on in the hospital markets, but also to try to take into consideration why laws were enacted or kept in place in the states that they were, we concluded that hospital costs were in the neighborhood of 20 percent higher as a result of Certificate of Need.

Did CON advantage existing hospitals? There have been a series of studies, again, somewhat dated as of today. But in the academic literature resolving much of the issue, Monica Noether in the late '80s showed that hospital costs, and prices were higher the longer CON had been in effect. McCarthy and Kass argue the greater CON toughness resulted in smaller investor owned market

shares in hospital markets. And some work that I did with Jeff Alexander concluded that hospitals were less likely to join multi-hospital systems, less likely to be contract managed the longer Certificate of Need had been in effect. In some sense that's a characterization of having monopoly power, allowing one to live the good life, at least from the point of view of hospital administrator.

Did CON affect quality? There's two dimensions of that side of the question that's been examined. There's some mixed, there will be old evidence on technology diffusion. Most of those studies have found no effect of CON on diffusion of technology. It appears that the market, either by providing services by unconstrained providers or otherwise have been able to provide the services.

More recent evidence has tried to look at the effects of CON on mortality. Some early work by Shortell and Hughes found that CON increased Medicare in hospital mortality. More recently, Robinson and colleagues found that the substantial growth in coronary artery bypass graph programs in Pennsylvania after the repeal of CON but no effect of that increase on fatalities in the CABG area. And much more recently in a 2002 paper in the New England Journal of Medicine, Vaughan-Sarrazin and

colleagues found that Medicare CABG mortality rates were higher in states without CON.

The issue, at least amongst economists, with the mortality literature and the effect of CON is that the causation can run in two directions. On the one hand there's the argument that repeated efforts at a particular procedure makes one better at it. So volume improves quality. But the causation can run in the other direction as well in the sense that because I'm an excellent provider, volume finds its way to me because I'm known for doing good procedures. And so the direction of causation isn't all together clear in this literature.

As I say, most of the literature to date has focused on the hospital market. There has been some limited work looking at the nursing home market. The standard model used by economists in looking at nursing homes is that nursing homes face both a private, relatively inelastic demand and a perfectly elastic Medicaid demand. So, they face two markets. Providers are alleged to price discriminate, charging what the market will bear in each market. And that Certificate of Need serves to limit Medicaid expenditures while allowing private residents to be cared for at market prices.

The argument has been that the, one of the, at

least, major purposes of Certificate of Need in the nursing home market is to try to control state Medicaid nursing home expenditures. So the argument is that private patients can find placements in nursing homes paying the market price. And the rest of the home is filled with residents who are covered under Medicaid. That there's, at least as this theory is put forward, a relatively large cohort of folks Medicaid eligible who could be in a nursing home if there were sufficient beds. The Certificate of Need Program limits those number of beds, limiting the expenditures for Medicaid patients and thereby limiting state Medicaid expenditures.

To date there's been no direct evidence linking Certificate of Need to Medicaid nursing home expenditures. There have been a series of studies that have looked at parts of the story. Charlotte Harrington and colleagues looked at the presence of Certificate of Need or construction moratorium in the nursing home market and found that, indeed, CON and the moratoriums appear to reduce nursing home debt growth. Miller and colleagues, in a couple of studies, concluded that CON redirect its spending out of nursing homes into home and community based services. And that CON had resulted in higher per capita long term care expenditures.

In some undated work, Conover and Sloan,

actually in the late '90s, concluded that CON repeal had no statistically significant effect on Medicaid plus private nursing home expenditures per capita. So a suggestion there that CON was not controlling nursing home costs.

In some work that my colleagues and I have forthcoming inquiry this summer, we look at the effects of the repeal of Certificate of Need in the nursing home market focusing on Medicaid nursing home expenditures. Analyze the data in 1981 through '98, looking exclusively at Medicaid nursing home expenditures and then at Medicaid expenditures for nursing homes and long term care. And we find no statistically significant effects of CON repeal on Medicaid expenditures.

CON may not be binding in the case of nursing homes and/or it may be that there are now many more substitutes available in the long term care market. And to the extent that older adults can now be placed in assisted living facilities, in foster care and those sorts of programs. The pressure on the nursing home market may have changed such that that CON has no longer the bite that it arguably may have had earlier.

So, with respect to CON, what the research literature tends to conclude is that CON has been ineffective in controlling hospital costs. It may have

raised costs and restricted entry. There have been no studies, at least to my knowledge, that have examined the effects of CON on prices paid by managed care plans, although the presumption would be that those prices would be higher as a result of CON's presence.

If anything, managed care and increased competition would benefit from having additional providers being willing to negotiate lower prices and if Certificate of Need is constraining in the hospital market, one would expect that managed care plans wouldn't be able to get as low a price as they otherwise would have. It's also the case that CON has probably delayed entry and reduced competition in those hospital markets.

On the nursing home side, CON is, in our judgment, ineffective in controlling Medicaid nursing home costs. It may have restricted the supply of beds but we can't find evidence that the elimination of CON led to a statistically significant increase in Medicaid expenditures probably because of the many new substitutes in nursing homes.

I wanted to also look at any willing provider and freedom of choice laws as barriers to entry into managed care markets. Any willing provider and freedom of choice laws essentially require an HMO or a PPO to accept in its panel any provider willing to accept the

terms and conditions of the contract. By the mid 1990s, by our count, 11 states had any willing provider laws that covered physicians, nine had them applicable to hospitals and 25 states had any willing provider laws applicable to pharmacies.

With respect to freedom of choice laws, they require that an HMO and/or PPO allow a subscriber to use a non-panel provider and to obtain partial payment from the managed care plan. Again, by the mid-'90s, that is, let's say, 1995, our count identified some six states that had freedom of choice laws covering physicians, five covering hospitals and 18 states had freedom of choice laws covering pharmacies.

Now, arguably what happens with freedom of choice and any willing provider laws is that they get in the way of the one thing that, in my judgment, managed care does well: selective contracting. Over the, at least the first half of the '90s, it's clear that managed care was successful in reducing the rate of increase in health insurance premiums during the '90s by selectively contracting, essentially trading volume for lower prices.

Any willing provider in freedom of choice laws reduces or eliminates the ability of a managed care plan to effectively selectively contract.

Let's look first at any willing provider laws,

then the freedom of choice laws and then at what the empirical literature says about what effects it had. With respect to any willing provider law, an HMO or a PPO exchanges the promise of volume for a lower price from a provider. So, I'm willing to direct my patients to your hospital or to your pharmacy network if you're able to give me sufficient quality and a good price.

The any willing provider law eliminates the exclusivity of the contract. So the effect is that as a hospital, you're now less willing to offer me a low price because I can't assure you the volume that you otherwise would have. In essence, because of the any willing provider law, you agree to a low price but now your competition down the road agrees to accept that same contract at the same price. Some of the volume that I would have directed to you now gets directed to the provider down the road. And as a consequence, none of the providers can get the volume that they otherwise would have. And as a consequence they aren't willing to offer the price that they otherwise would have, at least in theory.

With respect to freedom of choice laws, under the freedom of choice laws subscribers face lower out of pocket prices if they use a non-panel provider. Essentially, a managed care plan may have a small panel

of providers for which one, as a subscriber, one pays maybe a ten or a $20 co-pay.

Under the freedom of choice law, the managed care plan has to allow other providers, allow their subscribers to go to other providers who aren't part of the panel and the managed care plan will pay not the ten or will not require the $10 or the $20 co-pay but may require a $30 or a $50 co-pay. So, one can step outside of the narrow network to get care from other providers.

This gives some providers sufficient, some subscribers sufficient incentive to use the non-panel providers. This reduces the volume that the managed care plan could assure and as a consequence, the panel of providers, the smaller panel of providers doesn't get the volume that it otherwise would have and isn't willing to quote as low a price.

Well, what sort of empirical evidence do we have on the effects of any willing provider and freedom of choice laws? Well, there are really a couple of issues. The first is that these laws aren't randomly distributed across the states but result as a consequence of the political process. Evidence from work that Marsteller and colleagues at the Urban Institute and my colleagues and I at UAB have tried to look at which states have enacted any willing provider and freedom of

choice laws. And essentially conclude that those laws tend to be enacted in states where managed care has not yet been prevalent. Essentially, the take from both of these studies is that the laws appear to be preemptive efforts to keep out managed care.

Well, given that what effect does any willing provider and freedom of choice laws have on health care spending? There's been one study that looked at that by Michael Vita published in 2001. And what he does is look at those any willing provider and freedom of choice laws and create an intensity of regulation variable and controlling for other factors tries to look at the effects of that regulation on health care spending per capita. Finds that those states with intense freedom of choice, any willing provider laws have spending on physicians that are 2.7 percent higher, spending on hospitals that are 2.1 percent higher, and overall health care spending that's 1.8 percent higher. The suggestion here is that managed care plans were inhibited from negotiating lower prices with providers and as a consequence the cost they had to incur for providing care was higher.

In some work that we currently have underway, we have looked at the effects of these laws on HMO market share. One would argue that if these laws are

successful, what they would do is make managed care less attractive relative to more traditional insurance plans. And so as a consequence the managed care plans would have a smaller market share.

So we look at metropolitan areas using that measure of high intensity, any willing provider, freedom of choice laws in the same way that Vita does. And what we conclude is that HMO market shares were six to seven percentage points lower in areas where any willing provider, intense any willing provider and freedom of choice laws existed.

We also found that freedom of choice laws tended to reduce market share more than any willing provider laws and that laws affecting physicians tended to reduce market share while hospital and physician laws were not nearly as effective in that regard.

So, in summary, the any willing provider, freedom of choice laws tend to work as barriers to entry to managed care. The laws appear to be preemptive in that they have been implemented in states where managed care is less prevalent. The laws appear to increase health care cost and to reduce at least HMO market share. The findings are consistent with the view, with limiting the ability of HMO's and PPO's to selectively contract. And that while our study and the earlier ones have looked

at the first half of the '90s, my suspicion is that some of this effect has been attenuated in the late '90s because of the managed care backlash that we've seen. And had that not emerged we would see, you know, a much greater concern about the effects that these laws have had.

So with that, I will relinquish my remaining time and look forward to the discussion.

(Applause.)

DR. HYMAN: Thank you, Mike. Next up is Professor Gregg Bloche, who is going to talk about a slightly different element of the regulation of health care and that is self imposed regulation or maybe not so much self imposed. Speaking about the market for medical ethics.

DR. BLOCHE: Thank you, David. I do not have a power point presentation. As some of you may know, law professors in law classes tend not to use power point. We law professors know that a picture is worth a thousand words. We just prefer the thousand words.

I am also not an antitrust scholar. I should fess up at the outset, although apparently I do play one on T.V. And what I'm going to talk about today is seen by some to be a topic at the irregular and unseemly margins of antitrust law. It's certainly a topic that is

bitterly controversial, I gather amongst the antitrust scholars. I'm not going to address the topic as an antitrust scholar. But I am going to address the topic from a perspective of, I think, of knowing perhaps a bit and thinking at least a little bit about the role of various medical ethics norms and other mechanisms of self covenants in the medical marketplace.

And I want to begin with where virtually all such discussions, I think, need to begin. An article published just about exactly 40 years ago by the Nobel Winner in economics, Kenneth Arrow, an article published in the American Economic Review called "Uncertainty in the Welfare Economic of Medical Care."

And Arrow offered up a claim, a central claim in this article which is rather peculiar as a claim, certainly peculiar as a claim to come from an economist. The claim was and is that physician adherence to an anticompetitive ethic of fidelity to patients and suppression of pecuniary or financial influences when clinical judgment pushes medical markets towards social optimality. That being anticompetitive in the literal sense of the word would move markets not away from optimality but toward optimality.

And this, of course, stands conventional economics wisdom on its head. It did then and the

conventional wisdom amongst healthy economists today is that this claim is either naive or outdated. Arrow's story was essentially this. That anticompetitive, professional norms can compensate for information asymmetry, for uncertainty in medicine and for moral hazard.

Now, I'm going to pretty much assume that you all know what those things are about. I do have an article called the "Market for Medical Ethics" that sets forth some of these arguments in more detail. It ran in the Journal of Health Policy, Politics and Law. And also a related piece that ran in Stanford Law Review last December called "Trust and Betrayal" in the medical marketplace.

Okay. So this notion was at odds with health economists' more typical treatment of professional norms and any self governing norms within an industry as monopolistic constraints on contractual possibility. And Arrow acknowledged that all industry wide norms of conduct limit the options for economic exchange. If there's a norm that you're following as a member of any industry, it means you can't deviate from that norm and offer buyers another alternative. And that reduces competition amongst sellers, of course.

And for some commentators, the very fact of

such limits is proof enough of the perniciousness of professional norms from an efficiency perspective and I'm aware that there are some in academic antitrust law who are of that view. Judge Richard Posner treats the common ideology, as he puts it, of guild members, of members of any professional group, the common ideology concerning matters of quality and craftsmanship as tools for making production into a cartel in order to serve the interest of members whenever there is common norms about how a craft should be conducted.

And in this view, so called guild ideology, deceives both its adherence and the public concerning guild members furtherance of their own interests at society's expense. And guild norms or professional norms that express this ideology in this view, in this classic view, do not deserve the laws deference. To the contrary, the suppression of the competition is brought about by these kinds of norms within a profession or guild ought to be the object of legal attack if we're going to achieve a more competitive economy within that professional sphere and something closer to this optimality. That at least is the classic story, which I'll call the proposed Narain story, but there are lots of other who adhere to this view.

Now, Kenneth Arrow did not deny that physician

adherence to an ethic of fidelity to patient and an ethic of suppression of pecuniary influences at the bed side serves the medical professions of self interest. In fact, built into Arrow's story is a long term versus short term trade off. The core idea is that physicians resist bed side financial temptation, supposedly. Notice I'm not claiming myself that this is all true but this was a kind of an abstract model that was valued by many, back in the early '60s, at least.

The notion here again is that physicians resist bed side financial temptation. On a case by case basis, in order to reap the longer term, reputational, and therefore financial rewards of proceed adherence to this ethic. You might be able to get a short term gain by cheating on your patient at the bedside today providing them more expense tests when you can get away with it. But if you do that over the long haul, so the logic goes, you'll get a bad rep. Patients will trust you less. Perhaps other colleagues who might refer you patients will trust you less and you'll do less well. So it makes sense to adhere to this ethic of short term suppression of pecuniary interest. So at least went the story.

Arrow and critics who view this and other professional norms as pernicious from a social welfare perspective, differ not over whether these norms protect

and reflect professional self interest, but over whether they yield welfare gains or welfare loses. By comparison with a hypothetical absence of such, self constraint. And the question of how law, especially antitrust law, should treat professional ethics is closely linked to how you answer this underlying controversy.

But the question of laws, treatment of professional ethics shows up in other ongoing legal controversies as well outside the antitrust sphere. It's an issue in the context of conflicts over the lawfulness of financial rewards to physicians for futile practice, conflicts over the authority of treating physicians versus health plan managers when medical need is at issue. And it's at issue in conflict over the supervisory powers of health plan managers over clinical practitioners. Tension in all these contexts between professional norms and more immediate market pressures.

Back to antitrust law where this tension is most visibly an issue. Over the past quarter century or so, an antitrust doctrine has come to view professional norms with skepticism as so called naked restraints on trade. But courts have allowed ethics norms, some ethics norms, to survive antitrust's scrutiny through a variety of doctrines that enable these norms defenders to argue that they advance consumer welfare or other public

purposes.

And the three principal doctrines that have been evoked, all doctrines that are bitterly controversial amongst antitrust scholars and lawyers are the worthy purpose exception, the market failure defense and the rule of reason. And most famously, four years ago, in the case California Dental Association versus FTC, the U.S. Supreme Court signaled an increased willingness to entertain exactly these kinds of arguments.

The Supreme Court, as probably most of you know, offered a market failure rationale in defense of ethical rules, professional ethical rules that govern claims about low or discounted fees. And there are a lot of folks, especially free market, pure oriented antitrust folks who are really unhappy with the Cal Dental decision.

Now, if the goal of health care policy and law is to maximize the social welfare yield from medical spending, and I leave open the question of whether that's the goal but I'll assume for the rest of my remarks that it is, if that is the goal then consideration of the place of professional ethics in health policy requires that we pose three questions.

First of all, how can we distinguish between

professional norms that enhance social welfare even if anticompetitive in some sense and the norms that therefore merit our deference and perhaps even some legal protection. And norms that reduce welfare, how can we distinguish between norms that enhance welfare and ones that reduce welfare?

Second, when we conclude that a professional norm is, in fact, socially undesirable, how should we go about choosing among regulatory and legal strategies and deference to markets as means for dissolving the norm? Just because we decide, just because we believe that a norm is socially undesirable doesn't mean that we should therefore intervene in a regulatory or a legal fashion to push the norm back, to dissolve the norm. Maybe the market will attend to that.

And third, when we conclude that a professional norm is socially desirable, how do we go about, how should we go about preserving it? Should we defer to market outcomes and perhaps shield select forms of professional collusion in support of norms from antitrust intervention? Or should we defend the norm actively through regulatory and legal intervention?

Now, my focus today is on the first of these three questions, since time is short. From a public policy perspective, though, the second and third are

equally important. It's hardly obvious that a socially undesirable norm should be targeted by judges or regulators rather than left just to wither in the marketplace. And nor is it clear that a norm, which is socially desirable, needs legal or regulatory support to survive.

Going back to Arrow for a moment, Arrow's story about norms of fidelity to patients and suppression of case by case self interest was not a story about what regulation did. It's a story about a norm that emerged as a result of market pressure.

Now, let's go back to Arrow again. Arrow's explanation for the ethic of suppression of self interest, it's important to put information problems front and center. And here's the core of Arrow's argument. Arrow argued in brief that patient's uncertainty about the effectiveness of medical care is a barrier to the marketability of medical services because people don't know what they're going to get when the doctor prescribes something. They're uncertain about its value and that will discourage people from buying medical services, assuming for a moment that medical care is about as reliable as any other commercial product sold by somebody who can cut and run.

The classic market response to uncertainty and

risk, Arrow pointed out, is the offering of insurance. Here insurance against the undesired outcomes of medical care. Notice we're not talking about medical malpractice insurance only for medical negligence. Nor, of course, are we talking about insurance that covers the cost of getting medical care. We're talking about insurance against getting a negative outcome. Insurance against not getting cured or made better as a result of going to your doctor and saying yes to what your doctor recommends that you do.

For technical reasons, though, which we could get into if there were more time, for technical reasons a market for insurance for the outcomes of medical treatment has not developed and is unlikely to emerge at any time in the near future. And without this kind of insurance, Arrow pointed out, consumers who might benefit from medical care but are disinclined to bear the risk of poor results, are going to demand less medical service than they, quote, unquote, should from a socially optimal perspective.

And here's where the professional ethic of fidelity to patients and suppression of self interest comes in. By making medical advice more trustworthy, Arrow suggested, these ethics compensate to some degree for consumers' uncertainty about clinical outcomes and

consumers' inability to purchase insurance against disappointing results. Now, notice something else that's assumed in the Arrow story, which people believed back then to a greater extent than they do today about medical treatment.

Back in the early '60s, it was a kind of cultural high point that people trust their physicians. People thought that physicians knew what was right and what was wrong. The average lay person was probably utterly convinced that when a doctor recommended a treatment that that doctor had solid empirical data to support it.

Now, our little dirty secret in the medical world has kind of leaked out through the help of the Health Service Research community. And that is that the majority of decisions that doctors make every day don't have solid empirical evidence behind them. Many of you know about the research that John Winberg and others did, pioneering research back in the '70s and '80s on clinical practice variations. And that research led to a whole generation of additional health services research that documented in extraordinary detail the broad range of practice variations in medicine and the lack of empirical basis for a lot of practices. So, to some extent this is additional clinical data and empirical data that

undermines part of the Arrow story.

In any event, so long as you believe that patients know less than their doctors do about the outcomes of medical treatment, there's still something left to the Arrow story. And Arrow characterized professional commitment to the ethic of fidelity to patients and the ethic of suppression of financial self interest as, in essence, a long term marketing strategy. Physicians made this commitment in order to win their patients' confidence. Therefore, this ethic is, as Arrow put it famously, quote, part of the commodity the physician sells. And I emphasize sells, unquote.

This market based account casts physicians' commitments to professional standards of care, suppression of self interest and avoidance of what Arrow called, quote, the obvious stigmata of profit maximizing as signals of physicians' intentions to act on buyers behalf as thoroughly as possible. And because prospective buyers -- that is, patients -- respond to these signals by purchasing medical care at increased levels, the story goes, professional norms that reinforce this kind of conduct and commitment are in physicians' long-term collective self-interest.

And then Arrow makes the next, the next move Arrow makes, he holds that because consumer reliance on

medical advice yields net benefit, something you can still believe even in the face of this new evidence I mentioned about the uncertainty that physicians have about what they do, if you believe that the advice that the doctor gives is less than randomly likely to be useful, you can still buy this part of Arrow's story because consumer reliance on medical advice yields net benefits. Physicians' anticompetitive professional norms also enhance social welfare.

Now, notice something about how I'm using the term anticompetitive. I am not using the term in its perhaps almost euphemistic way, and the almost euphemistic way that it is used by some in the antitrust sphere. Sometimes the word anticompetitive in antitrust cases seems to mean literally restraints on competition between actors. Other times one gets the impression, and Peter Hemmer from the University of Michigan amongst others has written about this, other times one gets the impression that the term is used as euphemism for socially suboptimal so that ironically certain moves by competitors that might be anticompetitive in the literal sense of that word get treated in the case law as procompetitive.

Now, as a non-antitrust scholar, I am in no position to plunge into the morals around the use of that

term. I'm merely saying that when I use the term anticompetitive I mean it in its literal sense, restrictions on the alternative actions that actors in competition with each other are permitted to engage in. And I don't mean it, therefore, as necessarily either a pejorative term or a positive term.

Okay. Since the 1970s, a growing number of commentors from across the ideological spectrum have cast the ethics of the medical profession as a program for self interested restraint trade. And they've cast doubt on the Arrow story. Some commentaries seem to presume that the mere discovery that an ethical norm limits buyers and sellers freedom and benefits sellers is enough to establish the norms social on desirability.

More sophisticated critics of professional ethics offer powerful arguments for the inefficiency of particular anticompetitive norms, especially prohibitions against advertising and price competition. And more controversially contractual lowering of clinical standards of care. And Jim Blumstein and Clark Havighurst are two of the senior figures advocating that view.

These critics tie the norms they target to lost opportunities for consumers to learn more about the quality and prices of alternative providers to obtain

equivalent services more cheaply and to act on their own. It is cost benefit trade off preferences, by choosing lower levels of care at lower cost.

Consideration of the social welfare implications of professional norms can now draw on a new body of research and scholarship that aspires to explain the origins and the persistence of informal, non-legal norms in all sorts of settings, in lots of different settings outside the professional ethics sphere as well as within professions.

And I would point to Robert Elickson's theory of welfare maximizing norms as an especially influential example of this body of work. Robert Elickson's hypothesis is that members of a close knit group develop and maintain informal social norms whose content serves to maximize the aggregate welfare that members obtain in their work a day affairs with one another.

And this is a story that's consistent with portrayals of physician's ethical norms as a self serving restraints on trade. Elickson and his followers have studied various close knit groups from Shasta County cattlemen in California to diamond traders in New York. And they've identified governing non-legal norms. And they've offered persuasive arguments for these norms efficiency within these communities.

The medical profession to some degree resembles these close knit groups which sustain their non-legal norms through peer feedback, gossip and reputational sanctions. And I underscore that the message of Elickson and his followers is very much one of needing those kinds of mechanisms and needing this culture, this close knit culture in order to support these informal norms.

But there are problems with applying this story to the medical professional. Divisions among physicians that arise from specialization, geography, status and institutional arrangements make the sustenance of self serving norms through informal feedback and gossip a lot more problematic. And there's good reason to suspect that the medical profession has become even less cohesive since the publication of Arrow's article forty years ago.

Doctors practice today within very diverse institutional and financial context. Multi-specialty group practices, all sorts of arrangements with health plans and provider networks and highly variable financial incentives exist along side the old solo and small group fee for service practice model that was the norm in 1963 and is still found in many places today.

A more tangible sign, I think, of the profession's diminished cohesiveness is the increased willingness of physicians to testify against their peers

on plaintiff's behalf in medical malpractice suits. This was quite rare up into and through the early 1960s in large part because of physicians' distaste for turning against each other.

The medical profession's internal cleavages also cast doubt on the notion that any one set of norms can maximize the welfare of all or even most physicians. The profession has become a complicated mix of overlapping subgroups who both share a competing interest. And it's therefore hardly clear that traditional physician ethics, including even the norm of fidelity to patients and the suppression of financial self interest maximize the medical profession's aggregate welfare let alone society's welfare.

There have been some recent efforts to explain the persistence of non-legal norms in a different way in terms of their expressive function. And these norms arguably apply to a large extent to the debate about professional ethics in the antitrust sphere. And these recent efforts, I think, cast further doubt when the idea that physician norms maximize the profession's or society's welfare.

It's been suggested that people often abide by social norms not because the norms are efficient within a community but rather because the norms have taken on

meaning as signals of ones cooperative nature. And therefore, signals of one's desirability as a potential partner in collaborative effort and signals of one's reliability.

And there's a notion here that holds that once a norm is fixed in place by common understanding, such as signal, it's difficult to dislodge that norm even if it's wasteful in the aggregate for the group that abides by this particular norm as a signal. And even if it adheres to an alternative norm as a signal could, in theory, perform this signaling function at a lower cost.

Now, to the extent that physician norms perform this signaling function, their persistence can not be taken as evidence that they've maximized the profession's welfare. The norms may merely reflect an equilibrium and a difficulty of shifting to an alternative agreed upon symbol. And this may well apply to what Arrow calls, quote, obvious stigmata of profit maximizing, unquote.

The opthomologist who you hear on the radio selling laser surgery or lots of other examples that date back to the ruckus commercialism of physicians that George Bernard Shaw
-- a hundred years ago.

Okay, the upshot of all this is that recent thinking about the social welfare impact of physicians

anticompetitive norms is deeply skeptical of Arrow's assertion that these norms have desirable welfare effects. And indeed, current law and economics models for the creation and sustenance of social norms invite doubt about whether physicians' anticompetitive norms further the medical profession's aggregate welfare, let alone society's.

On the other hand, these economic models so prevalent in the law in economics field of scholarship, these economic models do not support the sweeping conclusion that physicians' anticompetitive norms, including the ethic of fidelity to patients, are socially wasteful per se. There's a mess here that needs to be sorted out.

I submit this mess needs to be sorted out ultimately on a case by case basis. And simply saying, as some are inclined to in the antitrust field, that we should treat all professional norms including shared commitment to the ethic of undivided loyalty to patients, simply saying that we should treat all professional norms as kin to price fixing doesn't do the analytical work. It avoids the analytic work.

I want to conclude with some thoughts about how we might try to sort out this confusing picture. And I'll start with Arrow's account of ethical commitment as

something for which there's a market, ethical commitment as a response to consumer uncertainly about medical outcomes and a response to consumer demand for professional trustworthiness.

Indeed, I want to suggest Arrow arguably underestimated consumer demand for professional commitment to an ethic of devotion to patients and suppression of self in looking exclusively to medical uncertainty, that is to consumer uncertainty, about medicines biological ethicasy as the source of consumers demand for trustworthiness. Arrow neglected the emotional dimension of patients' experience of illness, their yearnings for support and comfort, reassurance and credible explanation of frightening developments.

And to the extent that sick patients value trusting relationships with their doctors as a way to cope with these emotional needs, Arrow's exclusive focus and law and economic scholars today exclude focus on consumer information deficits, undervalues consumer desire for the ethics of commitment that we are seeking to explain.

Arrow's characterization of this ethical commitment in static terms as part of a market equilibrium missed dynamic features of the market for medical ethics that play a large role in ongoing health

systems change. Over the past hundred or so years, physician commitment to the ethic of suppression of self interest for the sake of patients hasn't stayed the same. It's, in fact, very widely, it's fluctuated greatly up and down almost certainly in response to changing demand side pressures.

At the dawn of the last century competing clinicians were hardly bashful about their entrepreneurial pursuits and claims for remedies. We still have the metaphors of the times snake oil and the like. And as I mentioned before the ruckus of commercialism, the snake oil sales and the like, the George Bernard Shaw parody in his play, The Doctor's Dilemma, just about a century ago, this sort of thing made doctors' commercialism the butt of jokes. It undermined consumers' belief in the value of what healing professions had to offer.

And by the second decade of the 20th Century, doctors in this country got this. They understood that their credibility, their trust in society and ultimately their incomes were at stake, were at risk and that something within the profession needed to be done simply in terms of the profession's own economic and social welfare.

And medical schools and the medical profession

began to respond aggressively to this image problem. They began to close proprietary medical schools. Some of you may be familiar with the Flexnor Report, which basically reflected a large, broad based effort of self regulation aimed at cracking down on medical commercialism.

Proprietary medical schools were closed in droves. Clinical commercialism was cracked down on with new ethics, with more vigorous enforcement of ethic norms. And the medical profession presented its ethical commitment to suppression of self and to loyalty to patients as evidence of its superiority over other kinds of clinical practitioners, non-physician clinical practitioners.

By the time Arrow published his article in 1963, patient confidence in the medical profession had surged in response to this effort and in response to the development of scientific medicine. And patient confidence in medicine had risen from an abysmal low to a historic high. Physicians had identified and met over a period of 30 or 40 years a previously unfulfilled consumer demand for trustworthiness.

Yet having won consumer's confidence, American physicians were by the early and mid-'60s under less market pressure to prove their trustworthiness and many

took opportunistic advantage, especially after the Medicare statute was passed in '65. Opportunistic advantage of this trust, of this climate of trust.

Okay. By acquiring ownership interest in hospitals and clinical laboratories and other health care businesses and the anti-commercial norms that Arrow had treated as part of a larger equilibrium fell by the wayside as physicians advertised aggressively and stopped providing free and discounted care to the poor. In other words, the profession began to drift back to its late 19th Century commercialism.

Consumer awareness of this drift back, I suggest, and consumer cynicism about claims that doctors are little motivated by money opened the way for managed health plans to be explicit in the last few decades about financial incentives to physicians to limit care. And the managed care revolution itself has transformed the market for medical ethics by introducing a demand side perspective, sharply different from that of sick patients, the demand side perspective accompanied by explicit use of financial incentives to pull physicians' loyalties away from the interest of physicians at the bedside.

And yet we have the managed care backlash of the last several years and a conflict not yet resolved

over which way medicine will go. Will we go towards more commercialism or will we go towards, will we go back towards a kind of reaffirmation of the norms that Arrow was talking about? What is clear though, I think, and something that we need to keep in mind, is that the norms that Arrow's article treated as an equilibrium arose, in fact, through a dynamic process in which consumers' concerns about the doctor's trustworthiness and the physician's willingness to suppress self interest changed over time.

And I'm going to cut things short because of time and David's signaling. But I do try in the conclusion of this article, the Market for Medical Ethics, to offer what I hope is a more nuanced story about different context in which we should be more versus less protective of some of these norms. There are aspects of medical care, typically when you go to see a doctor on an out patient basis for something that's relatively minor, there are aspects of medical care that are much like other consumer transactions and for which various kinds of complicity, including complicity with respect to professional norms is therefore more problematic from the antitrust perspective.

But there are aspects of medical care; the desperation of a dying patient and his or her family, the

fear of the uncertainly at a time of disability and time of great emotional need in which the elements of medical practice that impart faith and confidence by virtue of notions of suppression of self interest are important to cherish. And from the antitrust perspective, one can't make, I mean, my core bottom line message here is one can't make antitrust policy in the health sphere without shirking from the task of a, without focusing on the task of detailed assessment of how health care has performed, what consumers and patients experience is.

One can't treat this whole thing as a black box and say, well, these constraints are, per se, problematic. They are naked restraints on trade and therefore should be rejected. Antitrust policy needs to become even more than it is today, explicitly a health policy.

Thanks a lot. Sorry for going so long.

(Applause.)

DR. HYMAN: Okay, next up is Francis Mallon, from the American Physical Therapy Association.

Those of you who are wondering, we will take a break, but we're going to get through at least Francis, certainly, and I expect Dr. Lomazow as well.

MR. MALLON: Thank you, David. I appreciate the opportunity to make a statement to the Commission and

to the Department and to all of you here present. I am going to be a little less philosophical than the well-informed presentation that you just received. So I hope you bear with me on that.

What I'd like to do is say a little bit about physical therapists, give you some background on that. And then address an issue which is a major obstacle for patients in achieving access to physical therapists. And then I'd like to talk a little bit about a very problematic situation that is fueled by the problem created in the access area.

The American Physical Therapy Association represents more than 63,000 physical therapists, physical therapists assistants and students of physical therapy. Physical therapists are licensed health care professionals who diagnose and manage movement disfunction and enhance physical and functional status. Following an examination of a patient with an impairment or a functional limitation or a disability, the physical therapist will outline a plan of care and then begin treatment and intervention.

Physical therapists treat across the broad spectrum of populations. And they will be treating problems resulting from such things as back and neck injuries, sprains, strains and fractures, arthritis,

burns, amputations, stroke and heart attack, multiple sclerosis, birth defects such as cerebral palsy and spineabifida and injuries related to work and sports.

The practice settings for the physical therapists are also quite diverse ranging from the private practitioner's office to the hospital to the skilled nursing facility, the rehab facility, to schools, fitness and training centers and industrial and work settings. In the written statement that I provided, there's a break down of the percentages that work in these particular areas. And you'll note from that that approximately 35 percent of physical therapists work in some hospital related setting, whether it be in patient, acute care, rehab, in patient, out patient or extended facility. And 35 percent of physical therapists are in private practice. About seven percent work in a home health care and about six percent in skilled nursing facilities.

The current educational minimum for a physical therapist is a graduation with a post baccalaureate degree from an educational program accredited by the Commission on a Accreditation of Physical Therapy Education, CAPI. And CAPI is recognized by the U.S. Department of Education as well as by the Council for Higher Education Accreditation, CHEA.

Currently there are 204 accredited physical therapist programs throughout the United States. Of these, 75 grant a Doctor of Physical Therapy degree, a clinical doctorate. And another 75 are in the process of transitioning from a Master's Degree to a DPT.

A typical physical therapist curriculum includes education and foundational sciences, such as anatomy, histology, physiology as well as in the clinical sciences that touch on systems that physical therapists deal with, be they cardiovascular pulmonary, integumentary, musculoskeletal and neuromuscular. Each curriculum involves a very extensive clinical education preparation.

As for physical therapist regulation, physical therapists are licensed in all 50 states as well as the District of Columbia and Puerto Rico. And this has been true since the early 1970s with the license removement beginning some time back or the regulation movement beginning some time back in the 1940s. The core requirements for licensor are graduation from a CAPI accredited program and successful completion of a national licensor examination. States will vary in terms of additional requirements, testing in jurisprudence, testing in ethics and so forth.

As for payment for their services, physical

therapists receive payment from three primary sources; private pay, government programs the largest of which is obviously Medicare but also through Medicaid, through the Veterans Administration, through various workman's comp programs and through the individuals with Disability Educational Assistance Act. And then through private insurance; Blue Cross Blue Shield, Aetna, United Health Care and others.

Coverage for physical therapist services is fairly comprehensive in both managed care and fee for service programs. As with other health care services, PT services are subject to visit limitations under managed care plans and to payment limitations as, for example, under the physician fee schedule that is employed under Medicare. Most physical therapist service in out patient settings are billed using the CPT coding system and primarily through the 97000 series including such things as physical therapy evaluation, therapeutic procedures, manual therapy, -- and so forth.

There is one major obstacle for patients seeking access to physical therapists. And that is the requirement that the patient must first go to a physician before that patient can see a physical therapist. This requirement is still written into 13 state laws. It does have, however, a much more expansive impact relative to

insurance and payment.

Slowly this very anachronistic requirement is changing relative to state law. 37 states currently have some kind and permit some type of direct access to physical therapist services. Of those 37, 14 have no limitation, 23 have some form of limitation. For example, there is one state that requires a pre-existing medical diagnosis. There are others that have time limitations on how long a patient can be treated under a direct access mode. There are also 47 states that allow a patient to come directly to a physical therapist for an evaluation.

Although the legal obstacle to securing direct access to physical therapists is slowly being removed, the payment barrier looms quite large. Insurers find it very difficult to remove themselves from the belief in the concept of the gate keeper and the physician as gate keeper. And that, despite the fact that there has been evidence produced that under a direct access mode there can be less utilization and there can be less cost with no harm whatsoever to quality.

In a study published in Physical Therapy in 1997, researchers found that relative to physician referral episodes, direct access episodes encompassed fewer numbers of service; 7.6 versus 12.2, and

substantially less cost, $1,004 versus $2,236. The study involved paid claims data for the period of 1989 to 1993 from Blue Cross and Blue Shield of Maryland.

Although legalizing direct access practice for physical therapist must be the first step in the process, very few patients will be able to take advantage of these legislative reforms unless and until insurance policies accept these changes in state law. You've all heard the maxim that payment shades practice. And I would say that there is probably few examples better than the example of the requirement for physician referral to get to a physical therapist that evidence the truth of this maxim.

Not all insurance programs, however, have remained blind to the benefits of direct access. Insurers in Maryland have paid for direct access for many years. And likewise, in recent years, Arizona and Montana and North Dakota and North Carolina and others have also had insurance programs that have paid for physical therapist services without a referral. And currently there's legislation pending in Congress that would permit Medicare coverage for direct access to physical therapist services.

As a result of this obstacle to patient access to physical therapists, a condition has been fueled that did not arise directly out of this need for a referral

but certainly has grown and expanded before it, because of it. Traditionally when a physician's patient needs physical therapy, the physician sends the patient to an independent entity that provides the physical therapist service. In the out patient setting, that entity might be an independent physical therapist, a physical therapist clinic, a rehabilitation agency or an out patient hospital department. The patient receives the needed physical therapy and close communication with the physician is maintained. There is no financial connection between the physician and the setting in which the physical therapy is provided.

This traditional relationship sometimes changes when the reign on the health care dollar is drawn tighter. And practitioners look for ways to make up for revenue shortfalls. For some physicians and medical practice management consultants, physical therapy is seen as a readily available means of negating some of the revenue loses. What frequently follows then is an offer or option rendered by the physician to the physical therapist or by a group of physicians that the physical therapist must either join the physician practice as an employee or contractor or be content to know that no more referrals will be coming his or her way.

The major change in the traditional pattern is

that the physician will not just be the referrer but will also benefit financially from the services provided as a result of that referral. Whether it is mandated by law or by insurance policies, the requirement that patients obtain a physician referral for a patient to receive services from a physical therapist clearly creates an unfair and an un-level playing field between physician owned physical therapist practices and practices owned by physical therapists.

Under these arrangements the physician has financial incentives to refer the patient to his or her own practice rather than a practice in which the physician has no such interest. Because the physician controls the referral it makes it difficult for physical therapists who own and operate their own practices to compete for patients whose access to these physical therapists is controlled by the physician.

Studies have demonstrated that this phenomenon, frequently known as POPTS, Physician Owned PT Services, may have a significant, this phenomenon may have a significant adverse economic impact on consumers, third party payers and physical therapists. Specifically a well publicized study appeared in the Journal of the American Medical Association in 1992. Co-authored by Gene Mitchell and Elton Scott, the study documented the

higher utilization and higher costs associated with services provided in POPTS situations in the State of Florida.

In summary, among other things, the study revealed that visits per patient were 39 percent to 45 percent higher in joint venture facilities, both gross and net revenue per patient were 30 to 40 percent higher in facilities owned by referring physicians. Percent operating income and percent markup were significantly higher in joint venture physical therapy and rehabilitation facilities. And joint ventures also generate more of the revenues from patients with well paying insurance.

At about the same time in other study that was published in the New England Journal of Medicine, there was documentation of higher costs associated with physical therapy care under the California Worker's Compensation Program when the services were provided in POPTS situations. Although the mean cost per case was about ten percent lower in the POPTS situation, the significant increase in utilization created a substantial sizable cost to the program. In the study the authors stated that because of the reduced cost, $143,672 were saved.

And in a subsequent article, the authors

referred to the fact that this phenomenal of self referral or POPTS generates approximately $233 million in services delivered for economic rather than clinical reasons. As I have noted, studies have found that physicians who had ownership or invested interest in entities to which they referred ordered more services including physical therapy services than physicians without those financial relationships.

This correlation between financial ties and increased utilization was the impetus for Congress to enact the two Stark laws, Stark 1 in 1989 and Stark 2 in 1993. Stark 1 applied to services in clinical laboratories and Stark 2 extended that to other services, including physical therapy.

Specifically this law states that if a physician or a member of the physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services including physical therapy under the Medicare program unless an exception applies. After this law was enacted, many physicians divested themselves of their physical therapy practices. Center for Medicare and Medicaid Services, formally HCFA, had issued final regulations implementing the law on January 4, 2001.

For the period, for most of the 1990s, there was really a chill on the establishment and spread of physician- owned physical therapy services. But that chill greatly thawed as we approached the end of the century due to the regulations that were published. And the tendency of those regulations to take what were loopholes in the Stark legislation and basically turn them into chasms. And those regulations were implemented and began to be used or followed, we can see at this present time the reemergence of the issue of physician owned physical therapy services.

So in conclusion, I would say the removal of the referral requirement from state laws will allow patients direct access to physical therapists. And the removal of the referral requirement from insurance policies will make these access complete and permit physical therapists to compete with physicians on a level playing field. Thank you.

(Applause.)

DR. HYMAN: Dr. Lomazow?

DR. LOMAZOW: Good afternoon. My name is Dr. Steven Lomazow. I'd like to thank the Federal Trade Commission and the Department of Justice for soliciting the advice of the American Academy of Neurology with respect to the issue of increasing unsupervised access of

non-physicians to patients. There are things here which are on my CV so I'll skip over that portion.

Neurologists and other physicians across the country are confronted by a growing number of states that allow non-physicians direct access to patients. To my knowledge, and I will trust Mr. Mallon's numbers, 14 states allow unrestricted direct access by physical therapists. And others permit direct access to patients for a finite period of time under special circumstances.

The American Academy of Neurology and its 18,000 members has a strong desire to educate law makers about the potential of increasing adverse outcomes as more non-plenary licensed groups seek to do what has been within the traditional purview of highly trained physicians. We firmly believe that direct access in these circumstances could negatively impact patient safety by eroding the quality and increasing the cost of patient care.

It is essential that a skilled physician evaluates and diagnose a patient's condition at the earliest possible juncture. Lacking adequate medical training, therapists are not properly equipped to make informed and often critical decisions about referral and treatment of patients. Patient care will be seriously compromised.

Allow me to state more specifically our concerns with non-physician direct access. First of all, direct access could lead to delayed treatment of serious medical conditions. Initial evaluation by a skilled physician is necessary to screen patients for serious problems that are beyond the scope and training of physical therapists. Triage by physicians significantly increases the likelihood that patients see highly trained professionals as early as possible. Compromising this authority means that patients will wait much longer for accurate diagnosis, at times incurring expensive, avoidable and unacceptable risk.

The national crisis in medical liability insurance is already strangling health care resources. Access to patient care by lesser trained individuals will do no more than greatly compound the problem. The liability problem we have at the present time isn't the entire problem. But it is the straw that is breaking a very large camel's back.

Direct access would also decrease prevention of serious medical conditions, lacking early sound medical diagnosis by trained physicians, conditions that might otherwise be prevented. Things such as stroke that depend on early diagnosis for good outcomes or cancer may be delayed in diagnosis. This could put patients at

grave risk and lead to greatly increased costs for later, more intensive health care intervention.

Direct access would undermine coordination of care, which is essential for good patient outcomes. Appropriate coordination of care leads to better patient outcomes. The health care of patients require a thorough initial evaluation by physicians in order to properly coordinate the best program of care. Patients who need physical therapy often require treatment from other rehabilitation specialists such as occupational therapists, speech therapists, nurses and vocational counselors to manage the different aspects of their disability. Physicians are clearly best equipped to direct this care.

Unrestricted access to non-physicians could significantly drive up, not drive down, health care costs. To employ an old maxim, an ounce of prevention is worth a pound of cure. Without physician referral, patients receiving physical therapy services are more likely to receive unnecessary treatments, leading to increased health care costs to third party payers. Costs will be increased and there will undoubtedly be cases where patients will receive needless and excessive therapy based on improper diagnosis and inadequate examination.

I take issue with Mr. Mallon's assumption that POPTS and physicians' access to patients will increase care. Our issue is quality. He mentioned Stark. Well, we have Stark, and that's as far as it should go. Enforce Stark, but going in the other direction is clearly deleterious.

In many states, direct access to physical therapist is coupled with an expansion of a scope of practice even farther than just direct access allowing performance of complex diagnostic tests of nervous system function. Electromyography, known as EMG, and nerve conduction velocity studies, which are part and parcel to EMG, are essential tools employed by highly trained specialists to diagnose and direct proper treatment of a wide variety of muscle and nervous system disorders. A complete examination involves the insertion of needle electrodes into muscles to assess their function.

Unlike an X-ray, for example, which is routinely and safely performed by a technologist for the later interpretation by a licensed physician, EMG and nerve conduction studies are a dynamic and variable procedures that requires sophisticated medical decision making throughout their performance. The performance and interpretation of these tests are generally taught within a curriculum of years of post graduate, specialty medical

training in the field of neurology and rehabilitation medicine or -- In fact, one or two year post residency fellowships are also available for even more detailed study of their performance and uses of these examinations.

Only physicians have the training to diagnose diseases. Tests like EMG and nerve conduction studies depend upon visual tactile and audio observations of the examiner as well as information gained prior to the test by a thorough and complete neurological examination. There is no way for physicians to independently verify the accuracy and quality of reports of physical therapists.

Accurate diagnosis means better patient care. Complex diagnostic tests such as EMG and nerve conduction studies allow physicians to distinguish symptoms from a wide range of conditions, including carpal tunnel syndrome, diabetes melitis, radiculopathy from herniated disc, motor neuron disease or Lou Gehrig's disease and Myasthemia Gravis to mention only a few.

These are many conditions that masquerade as others and require years of clinical training and advanced knowledge to make a sound medical diagnosis. Misdiagnosis leads to delayed or inappropriate treatment, including surgery at times, and a diminished quality of

life. It is not unusual for neurologists to find referrals for diagnostic testing to be inappropriate and not performed at all.

Unwarranted scope expansion could lead to unnecessary or excessive testing and an increase cost to third party payers. In states where non-physicians performed diagnostic EMG, there are numerous examples where a test performed by non-MD's must be repeated by specialists to properly diagnose potentially life threatening conditions.

Physical therapists are trained in therapy, not diagnosis. They're not physical diagnosticians. They're physical therapists. Needle and EMG and nerve conduction studies are diagnostic procedures. They have no therapeutic benefit.

Neurologists often defer decisions about the intricacies of physical therapy to professionals specifically trained in this discipline. We believe that we should be afforded the same consideration and respect for our professional training. Physical therapists are essential cogs in the wheel of health care. But they should not be the hub.

Physicians receive years, not hours, of training in diagnosis. Physicians complete four years of medical school and at least four years of post graduate

training. Specialists in neurology and rehabilitation medicine are highly trained in the skill of diagnosing neuromuscular conditions. The physical therapy curriculum in related areas is measured in hours, not years.

The issue surrounding direct access in the expansion of scope of practice for non-physicians are much more than turf battles for physicians. Our goals first and foremost include ensuring patient safety, protecting quality care and controlling the rising cost of health care. The practice of medicine is dependent on skilled physicians guiding and directing patient care and incorporating the skills of non-physicians in a coordinated program to the benefit of the patient.

Compromising the leadership and supervision of the highly trained physician leaves patients confronted with a maze of health care providers, many of them, although extremely important to the overall care of the patient, are not equipped to guide the patient through the system. And as Dr. Bloche testified, patients don't know what they're getting and they have to be guided by the most competent professionals.

The American Academy of Neurology is extremely concerned about the future of health care if physicians are not properly and expeditiously directed to physicians

to diagnose their illnesses and manage their treatments. We strongly urge you to consider the ramifications on patient safety, quality of care and health care cost if physicians are taken out of the driver's seat.

We welcome any opportunity to further assist federal decision makers in more systematically evaluating the potential adverse impacts on health care from non-physician direct access and scope expansion. We share the Federal Trade Commission's and the Department of Justice's concern about the escalating costs of medical care.

The American public deserves the highest quality and most efficient care for their health care dollar. Increasing open access to and scope of practice of non-physicians is a step backwards. Would you really want someone who is not a trained physician looking up at you from an Emergency Room from a diagnostic test or from an operating room? I thank you for your indulgence.

(Applause.)

MR. HYMAN: I think we'll take about a ten-minute break, and then we'll continue with the remaining three speakers and then go directly into the moderated round table.

(A brief recess was taken.)

MR. HYMAN: If everyone will take their seats

again, I think we'll get started. Our next speaker is Dr. Russ Newman, from the American Psychological Association.

DR. NEWMAN: Thanks, David. I'd first like to thank David, the Commission, and the Department for an opportunity to come and talk to the Commission and Department about barriers to market entry.

I am a licensed psychologist. I am also an attorney licensed in the District of Columbia and Maryland. I am neither a scholar on antitrust nor an expert in the area. And I'm here today to talk on behalf of the American Psychological Association's 155,000 members and affiliates.

The American Psychological Association is quite familiar with the barriers to market entry. It's an issue with which we've had quite a bit of experience over the relatively young history of psychology. Psychology established its status as a licensed, independent, health care profession, independently licensed to do diagnosis and treatment in the late '60s and early '70s. No sooner had that independent status been established than did psychiatrists in Virginia work in concert with the Blue Shield plans of Virginia in order to require that psychologists be supervised by and billed through psychiatrists in order to receive any reimbursement from

the Virginia Blue Shield plans.

In response to a challenge by the psychologists, the Fourth Circuit Court of Appeals in the Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia found that practice to be anticompetitive and opined, "We are not inclined to condone anticompetitive conduct upon the incantation of good medical practice." With that decision from the Fourth Circuit, the independent practice in an outpatient setting pretty well was laid to rest for psychology. Any challenges to that seemed to fall by the wayside.

With one exception, attention from that point on turned to the practice of psychology in an inpatient setting. And that one exception is represented in a case that was filed in the Southern District of New York, Welsh v. The American Psychoanalytic Association in which psychologists challenged the American Psychoanalytic Association's policy of preventing psychologists from being trained to provide psychoanalysis. That case was settled successfully with barriers to entry to that training open for psychologists.

That one exception notwithstanding, the action for psychologists and barriers to market entry have really been in the area of hospital practice. Hospital practice was an issue where psychologists' existing scope

of practice enabled them to provide those same services in hospitals, but for the existence of some early hospital licensing laws that didn't include psychologists, and but for the opposition of organized psychiatry.

17 states now plus the District of Columbia now have statutes that recognize psychologists' authorization to provide independent services within hospitals. But to really get a picture of the barriers that have been erected in the hospital arena, an example of the facts in California, I think, help provide both the history of the challenge to access in hospitals as well as the tale of current, existing conflict with respect to gaining access to hospital access.

California was among the early of the jurisdictions to enact hospital practice statute by amending their existing hospital licensing law, Health and Safety Code Section 1316.5, back in 1978. But the real critical provision of law was enacted through amendment to that law in 1980 in which the law now contained language that prevented discrimination against psychologists. In fact, the law said that if a hospital offered services that both physicians and psychologists could provide, such services may be performed by either without discrimination.

Despite that amended statute, in 1983, the California Department of Health issued a regulation prohibiting hospitals from permitting psychologists to carry primary responsibility for the diagnosis and treatment of patients in hospitals. In response to this regulation, the psychologists sued in a case now known as the California Association of Psychology Providers v. Peter Rank, who was the Director of the Department of Health Services at the time. The trial court in that case declared the regulation to be invalid and in conflict with the existing statute. An appeals court, however, reversed that decision, and the case went on to the California Supreme Court.

In 1990, the California Supreme Court struck down the regulation in conflict with the original hospital practice statute and interpreted that statute to be clear in authorizing that psychologists could take primary responsibility for the admission, diagnosis and treatment of their patients in hospital. Additionally, that court interpreted the existing statute and its non-discrimination provision as meaning just that. Non-discrimination means non-discrimination, that when psychologists and psychiatrists are both able to perform a service by virtue of the scope of their practice, "Neither is subject to constraints from which the other

is free."

Implementation post CAPP v. Rank has hardly been easy or smooth. In particular, implementation in the State Hospital System for psychologists has remained quite a challenge. In 1996 and 1998, the psychologists in the state hospital setting went back to the legislature and amended that original hospital practice statute to explicitly indicate that it applied to the state hospital setting.

Despite those amended provisions to the statute, in December of 2002, the Department of Mental Health issued a special order which allowed only psychiatrists to serve as attending clinicians, the role that is actually what allows a provider to provide primary responsibility. And it also required psychologists to practice under the supervision of psychiatrists. Psychologists in California are anticipating legal action against that rule which they believe to be in conflict with the existing statute, but in the meantime, some activity in the legislature has resulted in some interesting activity.

In some discussion of the legislative intent from the original amendments to the hospital practice statute, the legislature then sent a message to the Department of Mental Health Services urging them to

become compliant with the existing law. In response to that, the Deputy Director of the Department of Mental Health Services sent a memo to all the medical staff of state hospital facilities in California urging them, without any specificity, but urging them to make their facilities compliant with the existing statute 1316.5. In response to the memo from the Deputy Director, one particular chief of medical staff of one of the state hospitals responded in a way that is very much exemplary of the response by psychiatry to the implementation of this law.

According to the chief of medical staff of Patton State Hospital, he says, and I quote, "It is my opinion as chief of medical staff at Patton State Hospital that our medical staff has complied with Health and Safety Code 1316.5. While the medical staff has been willing to examine the current utilization of psychologists within Patton State Hospital, it has been with the idea of improving patient care in a safe and legal environment. The evolving political link made by the psychologists' lobby is that Health and Safety Code 1316.5 compliance requires state hospitals to allow psychologists to become attending clinicians. Within this law, there is no mention in plain language of medical staffs being required to grant psychologists the

position of attending.

"There has been no objective outside opinion of what the law Health and Safety 1316.5 requires. Until such time, the Patton State Hospital medical staff will rely on the plain language reading of the law. It is not out of disrespect, but rather out of deference to the carefully constructed laws produced by the legislature that we reach this conclusion. The medical staff of Patton State Hospital is in compliance with Health and Safety Code 1316.5."

The psychologists, as you might imagine, disagree.

I would also note and call the Commission's and Department's attention to a recent article that appeared in the June 1st issue of the San Francisco Chronicle, which looked at the salaries of state employees in California. And of the top ten highest paid state employees, approximately five were psychiatrists employed in the state system. And interestingly, the reason the salaries of psychiatrists tend to be high is there is thought to be a shortage of psychiatrists and of that service in the system so that recruitment and retention bonuses are paid to psychiatrists.

In addition, psychiatrists serve the role as being on call in the facility, a role that's enabled by

being an attending clinician. And as a result of the salary received from those bonuses and on-call experience, the end salary is boosted from 30 to 270 percent over the original salary of those individuals according to the San Francisco Chronicle article. In one instance, one particular psychiatrist in addition to his salary was receiving well over $100,000 in recruitment and retention bonuses as well as on-call pay.

While California may be the best example of barriers to hospital practice for psychologists, it's far from the only example. Another instance which currently has been in dispute is in Nebraska where fairly recently, 1998, by relative standards, psychologists in Nebraska persuaded the legislature to amend the hospital practice statute in Nebraska so that any hospital was prohibited from denying clinical privileges to psychologists as a result of their license. Psychologists were added to a list of a number of other professions that were already included in the hospital licensing law.

Despite the change in statute, however, many psychologists in the State Hospital System were being refused medical staff standing in those hospitals. And 15 psychologists in November of 2002 sued the individual psychiatrists who were responsible for the medical staff's decision to refuse medical staff standing to

those psychologists. The suit was brought in federal court based on an alleged violation of a provision of the Civil Rights Act in which a property interest was being denied without due process. The case survived the motion to dismiss and was fast proceeding to trial, although on the eve of trial, the case settled and the psychologists within the Nebraska State System have now been authorized to be part of the medical staff as a part of the settlement to that case.

The scope of practice issue for psychologists in hospitals is, as I mentioned earlier, one of actually doing the things that psychologists were already able to do in an outpatient basis, but now in a different setting. That, of course, doesn't mean an expansion of practice. Another issue now beginning to develop within the health care community and for psychology is with respect to statutory authorization of prescription privileges for appropriately trained psychologists, which of course is an issue of expanding psychologists' scope of practice and an issue which of course requires legislation leading to an acted statute to do that. Of course, then there is opposition to that which is considered part of healthy legislative debate on the topic.

We are, however, beginning to see some activity

that falls outside of the healthy legislative debate of the topic. As one case in point, a psychologist in Tennessee, among the states that are currently pursuing legislation to authorize appropriately trained psychologists to prescribe. This psychologist in Tennessee had a long history of being invited to do presentations and workshops on behalf of a number of pharmaceutical companies because of his areas of expertise in depression and panic disorder and cardiovascular disease; the psychologist found that all of his invitations were being rescinded and no new invitations to speak at any of the pharmaceutical company events were forthcoming.

He also was understanding that he was believed to be part of the prescription privileges movement in Tennessee. He believes and it is alleged in a pending lawsuit that at least one psychiatrist threatened the pharmaceutical companies with a refusal to prescribe their medication if those companies continued to use this psychologist as a speaker on their behalf in workshops and presentations. As I mentioned, this is collateral to the issue of scope of practice, but when I think of interest then perhaps relevance nonetheless. The real issue, of course, will be in the implementation phase of any existing prescription privileges statutes.

We now have one statute in the State of New Mexico where psychologists are now authorized to prescribe. That statute went into effect July 1, 2002 and has been in a regulatory proceeding since in order to promulgate regulations to implement that statute. We at the American Psychological Association believe that the implementation phase of that statute will bear close watching in order to assure that in fact the law was being implemented as the law was originally enacted. But I would argue to you that in my profession, we're inclined to say the best predictor of future behavior is past behavior. And if that's the case, I would suggest that all of the implementation of the new prescription privileges statute that we'll see bear close watching.

In conclusion, I again want to thank the Commission and the Department for this opportunity to talk about barriers and to say that from our perspective, we see this as an ongoing dialogue and stand ready to offer whatever help we can at any point in time. Thank you.

(Applause.)

MR. HYMAN: Next up is Dr. Jerome Modell, and I would note that we have, since the beginning of this session, learned how to spell anesthesiologist on his name tag.

DR. MODELL: Thank you very much. I appreciate the opportunity to be here this afternoon to talk with you about a subject that I've been involved with now for over four decades. I am Jerome H. Modell, M.D. and I'm a, at present, I am Professor Emeritus in the Department of Anesthesiology at the University Florida College of Medicine.

From 1969 to 2000, I was a professor of anesthesiology in that department. And I chaired the department for 23 years from 1969 until 1992. In 1990, I was asked to become the senior associate dean for clinical affairs in the College of Medicine. And since that time until my retirement from these positions into the Professor Emeritus position in January of 2001, I have been in that position as well as the Executive Associate Dean of the College of Medicine, the Interim Dean of the College of Medicine, and the Associate Vice President for Health Affairs at the University of Florida.

I also, by way of interest and background, have been a consultant to over 50 academic health sciences centers in this country. I have delivered over 200 invited lectures around the country and overseas and published over 200 scientific papers and book chapters in the fields of clinical care anesthesiology and patient

safety. Over the past four decades, I have been extensively involved as an academician and a clinician in the training of anesthesiology residents. And for approximately 15 years of that time, also training student nurse anesthetists.

I'm here today as a representative of the American Society of Anesthesiologists (or ASA), a national organization comprised of approximately 38,000 persons most of whom are physician anesthesiologists. Anesthesiologists either provide or approximately medically direct the anesthetic care for about nine out of every ten of the 30,000,000 cases of surgical procedures performed per year in this country. The most common format for anesthesia practice is the anesthesia care team mode where the anesthesiologist will medically direct two or at most three nurse anesthetists simultaneously in caring for patients.

Next most common is the delivery of anesthesia by the anesthesiologist on a one to one relationship with the patient. And current data suggests that that occurs approximately 30 to 45 percent of all cases are performed in that manner. Least common, about ten percent, are cases in which nurse anesthetists deliver anesthesia under the supervision of the surgeon or other operating practitioner. The bulk of these cases are performed in

their own hospitals and physician offices.

The national scope of practice conflict or debate, if you will, between the ASA and the American Association of Nurse Anesthetists (or AANA for short) has been well publicized. It stems fundamentally from the AANA's position that nurse anesthetists are qualified by their training and experience to engage independently in the practice of medicine as it relates to anesthesia care. And ASA's position is they are not. ASA believes that nurse anesthetists should be directly supervised by a physician, preferably by the medical direction of an anesthesiologist.

Over the past three decades, this conflict has played itself out principally in the state legislatures and health related state regulatory bodies. It has also surfaced in the Congress mainly because the medicare rules for hospitals and ambulatory surgical facilities have, since the inception of that program, required that a nurse anesthetist be medically supervised. Beginning over a decade ago, the AANA embarked upon an effort to dismantle this quality oriented federal requirement. But the AANA effort was derailed two years ago when the current administration reversed the prior administration's proposal to repeal the medicare supervision rule.

Under current medicare regulations, physician supervision of nurse anesthetists is sill required. A state governor, however, is permitted to "opt out" of the medicare supervision rule if after seeking advice from his or her boards of medicine and nursing, the governor determined that an opt out is in the best interest of the state citizens. A nationwide survey and over a dozen statewide surveys uniformly disclosed that medicare beneficiaries support the supervision requirement by a margin of nearly three to one. Most governors who have opted out have essentially opted in, if you will, to state laws or regulations requiring physician involvement. Several other governors have been known to consider the opt out mechanism and elected to take no action.

Today, aside from the medicare rule, about 45 states require as a matter of state law that nurse anesthetists be supervised by or collaborate with a physician. This pattern of required physician involvement exists because legislatures and regulators have determined that the delivery of anesthetics is sufficiently dangerous that the involvement of a physician is necessary to protect the patient medically. We must realize that we're talking here about the application of chemical agents which, when administered

in sufficient doses in the wrong combinations or given to a particularly sensitive patient, can kill, permanently incapacitate or mutilate the patient.

A qualified anesthesia provider must also properly diagnose and treat life-threatening medical conditions in the operating room. In many cases, he or she is providing complex procedures and therapies to maintain and improve a patient's medical condition while concurrently administering an anesthetic. Almost no patient is qualified in this highly dangerous environment to assess either the skills of the proposed anesthesia provider or to assess the risks expected or unexpected inherent to the administration of today's anesthetics.

ASA is proud of the fact that a major part because of its multi-faceted, $20,000,000 patient safety program, anesthesia-related mortality rates have dropped radically over the past three decades. When I was a resident physician in the late 1950s, the anesthesia-related mortality rate was approximately one in 500 to one in 2,000 patients. Today, depending upon the relative health of the study population, anesthesia care is up to 400-fold safer in terms of mortality than it was when I was a resident from 1957 to 1960.

I take particular pride in this because we at the University of Florida were amongst the first in the

country to advocate the continuous monitoring of things like pulse oximetry and end tidal carbon monoxide tension in all patients under anesthesia. And actually submitted this for publication five or six years before it became a standard for the country. It has made a difference.

Even the most recent anesthesia outcomes data, however, show that much remains to be learned and done. Our goal is that no one dies or is harmed from the administration of anesthesia. Here again, our department has been a leader and that one of our faculty members, Dr. Monk, has just completed a study showing the decline in cognitive skills in the elderly population after anesthetics to be a real thing and not a myth.

In this context, our goal is that no one should die or no one should be harmed from anesthesia. I am well aware that this form is organized by an antitrust enforcement agency. I ask, who is better qualified in the state legislatures and health-related regulatory bodies to determine on the basis of expert advice for physicians and other health care experts the appropriate minimum standards of anesthesia and other medical care necessary to protect the citizens of that state? Has ASA exercised its Noerr-Pennington rights under the Constitution to persuade these governmental bodies to closely regulate nurse anesthetists scope of practice?

You bet it has, again and again.

We frankly cringe at the suggestion implicit in the description of this hearing that there's something sinister or wrong about that activity. ASA has pursued this course of activity not because it enjoys their constitutional right to do so, but because it feels obligated to assume and assure that patients across the country are provided with the best possible anesthesia care consistent with the current state of medical knowledge. ASA feels well-justified in this pursuit principally because of the differences and qualifications of anesthesiologists and nurse anesthetists, and because anesthesia outcome studies have consistently underscored the importance of anesthesiologists' participation in every possible case.

Under current standards, anesthesiologists must obtain a Bachelor's degree after four years of undergraduate pre-med studies emphasizing the sciences. Then, four years of medical school resulting in an M.D. or a D.O. degree, and a four-year anesthesiology residency program for a total of 12 years. By contrast, nurse anesthetists under today's standards obtain a Bachelor's degree in nursing to become a registered licensed nurse, and then complete a two to three-year nurse anesthesia training program for a total of six or

seven years. That's the difference between the two disciplines of five to six years of formal training.

There are many grandfathered nurse anesthetists in practice today who have had as little as only four years of total nursing and anesthesia formal training in the past to prepare them to administer anesthesia. Although the specific differences in training and clinical experience for the two disciplines are numerous both as to depth and subject area, what nurse anesthetists fundamentally lack is the comprehensive medical knowledge acquired by anesthesiologists in medical school prior to undertaking their anesthesia specific training and applying that knowledge in an extended residency program.

The AANA speaks proudly on its web site about the fact that it costs eight times as much to train an anesthesiologist as a nurse anesthetist. To me, this fact, if true, speaks absolute volumes about the relative qualifications of the two provider types to give the safest and most comprehensive medical anesthesia care. At the core of quality anesthesia practice is an understanding of the complex physiologic mechanisms of the human body in health and disease and how various chemical agents affect the -- systems, the cardiovascular, respiratory and neuro-systems, to name

the most significant.

Anesthesia providers must know how to deal successfully in a matter of seconds or minutes with changes in the patient's physiologic condition. That is not the practice of nursing. It is the practice of medicine, made possible by education of a physician prior to receiving training in the specialty of anesthesiology and then building on that education during residency. Not surprisingly, various anesthesia outcome studies over the past two decades have demonstrated lower morbidity and mortality rates when anesthesiologists are involved in the patient's care. A University of Pennsylvania study in 2000, showed that adjustment for patient acuity and hospital characteristics, after that, there were 25 excess deaths per 10,000 medicare surgical patients when an anesthesiologist did not provide or direct the anesthesia care. And these results were very recently essentially replicated in an outcome study financed in part by the AANA.

There is a current shortage of anesthesia providers in this country, both anesthesiologists and nurse anesthetists. In response to a national survey conducted last year, one-half of the responding hospital administrators complained about a lack of anesthesia providers so that they had to either close operating

rooms early or extend cases until the following day. Contrary to popular belief, the ASA has consistently advocated the current shortage be solved by the training not only of more anesthesiologists but of nurse anesthetists as well.

ASA has repeatedly taken the position that nurse anesthetists are valuable members of the anesthesia care team, and rather than erecting barriers to their entry into the marketplace, has welcomed the training of more of them. Nurse anesthesia basic education is financed in a significant measure by federal funds. ASA has never called into question the wisdom of these appropriations. The ASA board of directors has recently recommended to its house of delegates, that ASA educational membership be opened to nurse anesthetists; thereby providing more ready access for those individuals to ASA's comprehensive, continuing education programs and ensuring that they will become even more valuable members of the anesthesia care team.

In addition to supporting the training of more nurse anesthetists, ASA in recent years have supported the training and licensure of anesthesiology assistants (or AA's). AA's are health professionals qualified by advanced education and clinical training to work under the medical direction of an anesthesiologist. AA

training requires a two-year course of anesthesia study following completion of a science-based undergraduate curriculum, and of -- and clinical training in anesthesia. Student AA's spend over 2,000 hours in clinical rotations involving more than 500 cases, about the same as student nurse anesthetists.

The two current master's degree programs offered by Emery University and Case Western Reserve University are accredited by the Commission in Education of the Allied Health Administration Programs. In recent years, AA's have begun to seek licensure as a category of health care professional under state law. The ASA has supported this effort. AA's are currently licensed in Alabama, Georgia, New Mexico, Ohio, South Carolina, Vermont, and legislation was recently passed in Missouri.

Professional liability insurance rates charged the AA's and nurse anesthetists are the same, except that AA's must be medically directed by an anesthesiologist as distinct from any other type of physician. ASA advocates that the scope of practice to the two types of providers be identical. This is the case in a large hospital in Atlanta which has the largest case load east of the Mississippi, and approximately half of their 67 anesthesia care team providers that work under the direction of an anesthesiologist are AA's and the other

half are nurse anesthetists. Both do the same types of things and receive the same type of renumeration.

Given the nature of these hearings, it's of interest that the AANA and its members have undertaken a virulent lobbying and public relations campaign against further recognition of AA's by the states and federal agencies. This has included the procuring of congressional letters to the Department of Defense, denigrating AA qualifications to participate as proposed by DOD in the tri-care program for members of the military and their dependents. It has further included the sending of at least 400 letters to the Department of Veteran Affairs, objecting to the mere mention of AA's in its anesthesia manual that is currently under revision.

Two weeks ago, an AANA advertisement appeared in Stars and Stripes warning our service men and women about the unqualified AA's about to be forced upon by the Department of Defense. Perhaps of greatest interest are reports from a number of anesthesiologists in my own state of Florida including the University of Florida. They have received boycott threats from nurse anesthetists in the event that these physicians support legislation authorizing licensure of AA's or participate in the organization of ASA training programs at either of the two universities, Miami or Florida.

I, personally, find it startling and disappointing that nurse anesthetists would pursue this reckless course, especially in the fact of the severe shortage of anesthesia providers in my state.

In conclusion, I am not a lawyer, and I certainly am not schooled in antitrust laws nor am I a health economist. But I do understand after over 40 years of practice, teaching and research to improve safety are the fundamental ingredients of sound, safe anesthesia care. If the Congress and state legislators are persuaded that the public good is better served by dismantling the system that currently requires medical direction of every case involving anesthesia care, it will represent a tragic development for the nation's health care system.

Until that time, however, both I and my society will vigorously advocate in favor of physician supervision and continue our efforts to make nurse anesthesia care safer than ever. Thank you.

(Applause.)

MR. HYMAN: Finally, Jeffrey Bauer, speaking on behalf of the American Association of Nurse Anesthetists.

MR. BAUER: Thank you, David, and thank you to the Federal Trade Commission for giving me the opportunity to participate in this very important debate

which I truly believe is part of the bigger picture of health care reform.

I was a kid who grew up in the '50s and the '60s, I can readily validate Dr. Bloche's characterization of the Kenneth Arrow view of doctors, namely, that doctors and only doctors know how to diagnose and treat illness and the doctors all know the same thing. So, you might ask what happened since then that makes me firmly convinced today that doctors are not unique and they're not deserving of any right to restrict the consumer choice to other equally qualified practitioners.

Now, I want to give you a quick overview of some rather bizarre experiences in my life that lead me firmly to this conviction. It all began back in the late '60s, a little after my 21st birthday with an overindulgence one night in Paris when I managed to consume both a bottle of champagne in its entirety and a large bar of Belgian chocolate. I felt like I was going to die the next day, much worse than a hangover.

And so, I asked the mother of the family that I was living with for that year if she would get me an appointment with a doctor. And she shot back, well, what kind of doctor would you like? And I just go, a doctor, there's only one kind of doctor, the ones that know it

all. And so, no, no, no, you know. We have different kinds of doctors here in France, and she went down the differences. They had allopaths and homeopaths and naturopaths, all recognized by the insurance system. I thought, boy, these crazy French, they realized something other than an MD could possibly have some understanding of human health.

I then went on several years later to become the director of educational support services for several residencies in a 400-bed teaching hospital. And I came down with a hospital staff infection that flattened me about as much as the champagne and the chocolate. And nicely, seven of the residency directors came to my bedside at my apartment. They were so concerned to get me back in action. And they poked and prodded and all asked me things, and I thought, seven doctors, you know, I'd get the same opinion.

And they took a vote on whether to give me antibiotics, and it was four to three against. And boy, did that begin to challenge my assumption that all doctors saw things the same way. Then I ended up getting a Ph.D. in medical economics not too long thereafter. In, 1973, joined the faculty at the University of Colorado Health Sciences Center with full tenure track appointments in both the Schools of Medicine and

Dentistry. And spent seven years publishing rather than perishing.

And ultimately, after I became tenured after seven years of teaching statistics and research at these medical and dental schools, I became the assistant chancellor for planning and program development. And my principal responsibility for the four years as assistant chancellor was to integrate the undergraduate curricula of medicine, dentistry, nursing and pharmacy.

And so I had this unique opportunity beginning with the champagne and chocolate going through four years where my job was to make it possible for a nursing student to take bio-chemistry alongside a medical student. And actually, we discovered there was no difference in the health sciences that these students were learning. So I became intimately aware of the curricula that were used to train physicians, nurses, dentists, and pharmacists.

And because I was originally trained as an economist, I found that I could look at all of this from the perspective not only of my years as a professor, being a statistician and research professor, but also looking at the economics harms that were associated here. I realize that many of the people who would be digesting this testimony are themselves Ph.D. economists or lawyers

well-versed in antitrust. But it is no doubt in my mind that I've tried to defend in many of my writings that there are entry barriers, undeserved entry barriers against other qualified practitioners, usually deriving from state practice acts.

There's clearly, as a monopoly, harm under this old practice, the pricing arrangement where there are unnecessary health care costs giving this opportunity and revenue to doctors to supervise people that quite frankly have equal or even better skills. There's also the ability on the part of the doctors claiming the right to protect solely the direct access to patients for unjustified income disparities. And there is the imposition of unnecessary and unearned supervisory fees which have been nicely mentioned by two of the preceding speakers.

But at the bottom of the line, there is the captain of the ship authority, the very strong assertion that only the doctor is qualified to take care of the SS Health care or whatever it might be, and it is the ship that fails to recognize that other people could meet the same criteria.

So toward the end of my four years as the assistant chancellor, I began to go back to my physician colleagues and many friends outside of academia who are

doctors, what is it that makes the doctors special? You tell me because you've been to medical school, that you are the only ones who are qualified to supervise patient care. And after many interviews with physicians and four years of immersing myself in the curricula of a lot of the non-physician professional schools, I developed and presented in my book, "Not What The Doctor Ordered," what I thought were the seven criteria that medicine stood on to claim its right to control the patient enterprise. I even had a cartoonist in my book, Not What The Doctor Ordered, put the captain of the ship up there. You had to step up these seven steps to prove that you deserve to be in charge of a health care delivery team.

And very quickly, there is our advanced education, namely, a six-year minimum, all involved in clinical sciences at a publicly accredited academic health center. Ongoing certification where you had current knowledge, you're required once you completed your training to stay current, not the years of training because the half-life of medical knowledge, I argue, is now less than two years. Competency-based testing on a regular, periodic basis showing that you knew what you were still doing. Again, unrelated to years of training, but to keeping up with fast-based change.

The scientific base, something that I strongly

believe in, using randomized and controlled trials reported ultimately in a peer review literature a coherent, clinical model. And indeed, allopathic medicine and osteopathic medicine are very clear and somewhat different clinical models. But so, too, did nursing and pharmacy in the various advanced therapies. And definitely a philosophy of patient care. Professional liability was clear. I don't think anyone should have the right to see a patient without someone else overlooking their shoulder unless they can get insurance coverage and have meaningful sanctions for violating the professional responsibilities.

Then, there's a professional ethic, namely, commitment to the general welfare and an accountability to the clientele, that again were part of what my physician friends told me made them the unique captains of the ship. But last but not least was the quality assurance. And I think that if the research enterprise in the last few years has done one thing more than the other, it's this concept of evidence-based practice and outcome measurement. And I included that in a book written back in '98 as one of the seven pillars of independent practice.

So, when I began to apply this based on my knowledge of what people knew, I discovered that there

were actually several substitutes within defined scopes of practice who merited independence defined by the same criteria that physicians had used to be the captain of the ship. Not only were physicians qualified to be the captain of their ship, but advanced practice nurses, clinical pharmacists, advanced practice therapists and psychologists, very amply and ably described by several preceding speakers, met the same criteria. And I'll be delighted to debate those with my physician friends in the panel in just a moment.

But I think there are clearly factors which would negate this right to independent practice if any one of these seven, be it the physicians or the advanced practice nurses or therapists, were to fail to maintain the integrity of these foundations to allow the model to get muddy or to somehow avoid liability. If they were to be subject to randomized and controlled research trials, in other words, defensible research that showed inferior outcomes or if we were to discover discrepancies between expected and actual practice, we could challenge that independence. But absolutely no evidence of any of those have been submitted so far today.

What we have heard and what we see in considerable evidence provided in documents I'll share with you in just a moment are some very false arguments

against the independent practice for certified registered nurse anesthetists. For example, there's the ample argument, part of ASA's litany, that physician supervision ensures quality. And yet the concept of supervision is poorly defined and inconsistently practiced. Supervision can mean many different things to many different people. And it's also backed by unfounded assertions, not by research.

Indeed, I would love to refer you, and, in fact, do refer you to the March newsletter of the American Society for Anesthesiologists where the editor of that particular journal says, and I quote, "For the safety of our patients, we realize that physicians must remain in charge of all aspects of medicine including the delivery of anesthesia care." We've already heard that today. "Although most nurse anesthetists," and I love this, "like most anesthesiologists," why not all anesthesiologists, "have as their preeminent goal the provision of good, clinical care for their patients, the nurse anesthetists state and national organizations all too often appear to be fixated on the single issue of independent practice."

I'm absolutely amazed then that the ASA can argue that they're going to be guaranteed good quality care when the editor of their own journal and the

official publication of the ASA just two months ago admitted that not all anesthesiologists are dedicated to high quality care. There's an assertion by extension that the anesthesiologists prevents independent practice. There's certainly the reference to the well-known scarcity of anesthesiologists in rural areas, and I live in rural America so I'm well familiar with this. And then of course, there's the declining quantity of new anesthesiologists.

And, again, I refer to one month later, to last month's issue, April, excuse, now that it's June, two months ago, from the Secretary of the American Society of Anesthesiologists. And she said, I'm relating to this argument that anesthesiologists will ensure necessary coverage in quality, this is a direct quote:

"In summary, because of low number of trainees and low written pass rates which bottomed out at 46 percent of the people that took the exam in 2000, the number of newly board certified anesthesiologists who became available to enter the national workforce pool went from an annual high of 1,536 in '97 to only 705 in 2001. This represents only half the number of new ABA diplomat anesthesiologists available annually five years earlier."

This is not invective from the AANA, this is

from the official publication of the American Society of Anesthesiologists.

Another false argument is that the independent authority eliminates collaborative practice. And we've already heard the evidence or the concern that nurse anesthetists or psychologists or physical therapists who are allowed independent authority would not continue to be part of the team. Yet, in doing my research, I found many areas, many of the states where independent practice is allowed, in anesthesia, in physical therapy, et cetera, where collaborative practice is still very, very important. And indeed, what I have also found is that many anesthesiologists support independence for CRNA's. Any assertion that all anesthesiologists feel the same way as what we've heard today would be totally wrong.

Then there's this idea of the quality imperative compelling us to keep nurses in ICU's. And again, from April issue, and again, written by the editor of the ASA's own journal, I find this patronizing quote:

"In order to increase the ranks of the student nurse anesthetists, recruiters must draw from a critically short supply of nurses in general, and ICU nurses specifically. This requirement is counter-productive in a time when patient's safety in the ICU is being emphasized by major corporations such as Leapfrog."

I'm very familiar with the Leapfrog assertions. I've read that literature extensively, and it deals with the physicians, not with the nurses. And again, I find it an example of anticompetitive behavior to suggest that nurses should stay in the ICU rather than move to critical care and advanced practice nursing by delivering anesthesia.

Another false argument is that the captain of the ship tradition saves money, and yet there's ample evidence that there's a wasteful duplication. I have four people, in other words, an anesthesiologist supervising three anesthesia assistants or three nurse anesthetists, why not have them all delivering the anesthesia? At least the certified nurse anesthetists and the anesthesiologists?

And indeed, there are many cases where the captains are less knowledgeable than the crew in this issue of delegation or supervision. And I discovered, and I think it's a clear lesson of the health reform debates of roughly ten years ago, that the public cares much more about choice than cost and health reform.

So efforts to suggest that we need to maintain cost here are second to what I think is clearly the public's focus on having choice between qualified providers. There's also the assertion made in several

ASA tomes that the dependent practitioners will remain loyal to the care team. One of the reasons that I do not include physician assistants in my book, "Not What The Doctor Ordered," is as I began to interview physician assistants, I found many of them demanding independence even though they by statute were required to be reporting to physicians. And so PA's, when they first formed their training programs, argued very strenuously that they would stay within the fold. I think it might be safe to say that as many as the majority would now like out.

The issue of anesthesiologists being the solution to the problem also strikes me as inappropriate in context to debating whether nurse anesthetists and physical therapists and the like ought to have independence because in reality, I think it is an anticompetitive act to replace CRNA's. And there's absolutely no way by my criteria that anesthesiology assistants are substitutes for CRNA's. They don't even come close in that seven-step ladder that I mentioned a moment ago. And there are certainly no models or valid studies demonstrating actual advantages to anesthesiology assistants.

And I certainly as a former medical school professor and academic administrator don't see how any new program could grow in the state that medical centers

find themselves in today. Nobody has any money for program expansion. So, if you say what problem the anesthesiology assistants solve, the answer would be none. I can only see control as the issue.

There are several protections that can be used to support independent practice. First of all, surgical privileges are awarded by hospitals, not by state legislatures, not by state boards. And indeed, the privileges are commonly tied to competencies, and you can go to any hospital meeting aimed at trustees or medical or even senior executive leaders and discover that making sure you've maintained the competency of your people is an obligation of the hospital. There is no evidence, anything that I'm aware of, that hospitals would credential AA's. States may pass laws but it doesn't mean the hospitals will accept them given their considerably lesser degree of training. And I think it's very clear that the American Hospital Association and the State Hospital Association support the CRNA's in their position and do not favor continuing the mandatory supervision requirement.

The next, and it's a very important point, is that the surgeons ultimately get to accept the anesthesia practitioner. And so, if indeed the surgeons are quite willing to accept anesthesiologists with nursing

background or anesthesia administered by nurse, then I think it's perfectly safe to say that the people who are on the ultimately responsible side of the table have no problem with this. And then, there is the formalized expectations of individual and organization accountability. Nobody practices unsupervised today. One of the biggest significant changes taking place in health care today is requiring everyone to be very much operating out in the open and accountable.

So the conclusion that I draw after many years of being involved in this with a bizarre background is that the CRNA's are at least as good as anesthesiologists by any of the criteria that merit the right to independent practice. There is no valid research showing that unsupervised CRNA's provide inferior care. I repeat, no valid research challenging that assertion. And the fact that professional liability claims have dropped dramatically over the last decade for CRNA's I think proves the fact that they have an excellent record.

And I also think there's ample evidence that anesthesia services will be worsened by mandatory supervision because then nurse anesthetists cannot practice, for example, when the doctor takes a well-deserved day or two off. If one would argue that we should leave physicians in control of the system, then

why do we have so many problems after a century of physician-controlled medicine that we're trying to reform? First of all, there's the argument, well, we're going to see continued quality if we have the anesthesiologist in charge. That I'm very disturbed by the fact that so many, an increasing number of anesthesiologists themselves are incapable of being certified by their profession's criteria.

I also, as an economist, am concerned that something greater than the income differential, something greater than a factor of two, somewhere between two and three, of the money that can be earned by an anesthesiologist and a nurse anesthetist for effectively doing the same thing. And since there's no difference in outcomes, I absolutely can't understand why there's this difference in incomes. Then there's also the issue of access where supervision unnecessarily reduces the availability of services.

The argument, I think, that the bottom line is that the arguments against unsupervised CRNA practice are simply wrong. They're not backed by science and fact. And I think it's based effectively on inconsistency in the arguments, and I've shown you examples from the recent literature and the self-interest. I think the real concern is that the doctors believe that CRNA's are

not what the doctor ordered. And what it really should boil down to in the 21st century policy of this country, and that's why I'm so happy the Federal Trade Commission is looking at this, is the consumers deserve the choice.

It's not an issue as one of the previous doctor said of the doctors having the right to the patients, it should be the right of the patients having the choice of equally qualified providers. And in the case of anesthesia and several other professions recognized in this room today, there is simply no justification for the medical monopoly. I submit that ending this monopoly is an important key to health reform. Thank you very much.

(Applause.)

MR. HYMAN: If I can have all of the panel come up and take their seats? We've got just a little over 20 minutes, because we always end on time. Cheers from the panel and the audience. And we've covered a lot of territory. Our general practice is to allow the earlier speakers to comment on the later speakers because the later speakers had the benefit of hearing the earlier speakers before the remarks.

I think I'm going to modify that slightly because as you've figured out by now, we've sort of paired the physical therapist and the neurologist, and the anesthesiologist and the nurse anesthetist. And so,

I'd like to ask first Mr. Mallon and then Dr. Modell whether they wish to comment on the remarks of respectively the representatives of the American Academy of Neurology and the representative of the CRNA's. And then we can throw it open more broadly for comments. And I have a whole series of questions.

But let me start with Dr. Modell first. I'm sorry, Mr. Mallon then Dr. Modell.

MR. MALLON: Surprisingly enough, I would like to offer some comments.

MR. HYMAN: I'm shocked. Shocked. Please.

MR. MALLON: I think, Dr. Modell, the concerns that you raised on their face are plausible. The problem is there is no evidence to say that they exist in reality. There's no evidence to say that direct access to physical therapy is going to cost more. In fact, what evidence exists says that it will be cheaper. There is no evidence that says that direct access to physical therapy will create harm.

And in fact, the testimony of liability insurers would be just to the opposite, that direct access has no effect on premiums. Nor could you search any of the 50 state licensure boards to find any evidence of professional action taken against physical therapists because of harm in this area. The same could be said, I

think, about lack of quality and lack of coordination. That's with regard to direct access.

Secondly, with regard to EMG, EMG constitutes no expansion of PT practice. PT's have been doing EMG since at least the early '70s. Medicare recognizes and pays for EMG provided by physical therapists. I doubt that medicare would pay for something that is going to create harm or is being provided by incompetent people. The states, by and large, in fact there is only one state that we know of that directly prohibits physical therapists from performing EMG, and even before that provision, that state had no physical therapists performing EMG. It happens to be Hawaii.

Thirdly, EMG's do not produce a medical diagnosis. They produce findings which are used by physicians to make a medical diagnosis. And I should clarify here, physical therapists are not claiming to make a medical diagnosis. We do not diagnose pathologies. We, I'm not a physical therapist. Physical therapists do not diagnose pathologies. And there is no time that we've ever claimed that. Physicians on a daily basis use the findings supplied by physical therapists, and many neurologists do this, supplied by physical therapists in order to make the EMG finding, in order to make a medical diagnosis.

Fourthly, we have great respect for neurologists and all other physicians and we are certainly not wanna-be physicians. We are physical therapists. And I take a, I hate to be old fashioned, I take a little umbrage at the position that only physicians care about quality and patients. Quality and patients are the utmost concern of the physical therapists, and I suspect to many others. And physicians have no hold on that market. Thank you.

MR. HYMAN: Dr. Modell, briefly?

DR. MODELL: Yes. I'd like to have an hour and have his slides so that I could have his talk but with a different perspective. But I know that's not possible.

With all due respect, I think many of the things that you pointed out are your opinions. You talked about basing them on fact. I didn't see the facts. You talk about there's no definition of supervision, the Toepfer regulations in the mid-1980s of Medicare clearly outlined what is necessary for appropriate medical supervision of nurse anesthetists and nothing has changed. And those regulations came from the Ethical Practice Guidelines of the American Society of Anesthesiologists. I know that because I gave them to the Senate Committee that put that bill forward at that time.

As far as the education of the two groups, sure, you can take pharmacists and nurses and doctors and give them some of the basic science material together. We've done that. But I have had a program that I was responsible for, for training anesthesiology residents and a program for a school for nurse anesthesia at exactly the same time in my institution.

The people that came in to the nurse program were all A students. They were the cream of the crop. It was extremely competitive. We took about four or five students a year out of a pool of several hundred. Nevertheless, these individuals had to have supplemental tutoring or educational courses in addition to the general courses that we gave in order to make up for the lack of the background of medical school. There's just no question about it.

Another thing that I have done over my past 45 years as a physician has been to review alleged medical malpractice cases. And I know under HIPAA regulations, I can't disclose any particulars, if I did some of you would absolutely cringe. But I probably looked at about 400 at least, roughly one-third for the plaintiff and two-thirds for the defense. Some of the errors of omission because of the lack of medical school education and medical knowledge in making prompt diagnosis of

adverse things that occurred under anesthesia have accounted for the majority of the problems in causing death or brain damage in those patients.

I'm a little different than the rest of you. I'm a practicing physician. I've never in my life gotten paid on the basis of how many patients I've taken care of or what I did to them because I practiced in the US Navy, the University of Miami and University of Florida. I've always been salaried. I've never looked to see what I get paid or don't get paid for them. I think I can be objective.

And now, for the past two years, I donate my time to the University of Florida and I take care of patients and I teach students and residents without getting a paycheck. I do it because I love it. And I've had a lot of experience doing it and I don't see how anyone who is an economist can take a couple of little excerpts from a couple of newsletters, particularly one, David Matthew is not the editor of that journal, by the way. David Matthew is not an editor of that journal. He lives in Gainesville.

I know David, I talked to him two days ago, he's not an editor of the ASA newsletter. But you can't take a couple of excerpts like that. What you can take are the studies like the Pennsylvania study. And that

study is very, very impressive in that there were 25 more deaths in 10,000 medical patients when anesthesiologists don't medically direct nurse anesthetists.

The other thing you need to look at is the fact that the majority of the unsupervised "nurse anesthetist cases" are in rural hospitals and doctor's offices. They are short cases, they're not complex cases. The people who are really sick, they don't take care of them in those hospitals. They ship them to us at the university. So, you need to correct those things for patient population.

As far as office safety is concerned, I was appointed by Governor Bush in the State of Florida to the Commission on Safety in Office Surgery a couple of years ago. When you remember nationwide, they blew up all of the deaths that we had in offices, in plastic surgeon's offices, cosmetic surgeon's offices and so on. I had the opportunity as a member of that Commission to review every one of those cases and to participate. I was the only anesthesiologist on that Commission of 12 people. The others were nurse anesthetists, surgeons, lawyers, consumers, et cetera.

But that Commission recommended to the Board of Medicine that nurse anesthetists not do independent general anesthesia in doctor's offices on the basis of

safety. We did make the opportunity available for surgeons who are qualified to medically direct the nurse anesthetists in their office. And the surgeons then had to apply to the Board of Medicine to become certified to be qualified. To date, I think there is only a small handful of surgeons who have done that and been credentialed to do that on the basis of training and experience.

So, let's look at the facts. And the fact is you can't take away a medical school education and an extra two years of residency from me in order to say that a nurse anesthetist is at least as good if not better than I am in being a doctor. Now, I'm not anti-nurse anesthetists. I work with them all my life. I think they're terrific people. They're well trained for what they do under appropriate medical direction. And if I'm going to sleep, Lord help you, if you don't give me a medical direction of that nurse anesthetist, for I can promise you my family will be after you with my son who is a lawyer.

MR. HYMAN: Let me open this up to anyone who hasn't spoken yet.

DR. LOMAZOW: First of all, I don't want to get into a one-on-one with Mr. Mallon, but it's more than Hawaii. My home state in New Jersey does not endorse and

does not permit physical therapists to perform electromyography. So it's clearly not just Hawaii.

Number two, the basic issue of this whole thing here is do you want to run the system on high octane or regular? Do you want to use factory parts or do you want to use knock-offs or rebuilts? The American public deserves the best. They pay for the best. America rewards excellence. So, you can run the system, but then all you're going to wind up with is an execrable reduction in quality and accessibility of health care if the people who are most qualified -- now, we have survived in that, as much as you like it or whether you don't like it, doctors have survived the natural selection process it takes to become a doctor.

There's a limited amount of physicians in medical schools. We sacrificed 12 years of our lives over 60 hours a week, and that's minimum, to get where we are. We're survivors. We've been naturally selected to get there. And we deserve what we get. I don't apologize. I don't apologize for physicians.

And then, I'm also not talking about economics. You guys are talking about economics, I'm the one that's talking about quality. And I concur with the other doctor over here. And as far as the captain of the ship thing is concerned, as much as you may like Fletcher

Christian, there's no doubt that Captain Bligh was a better and more qualified sailor. Thank you.

MR. HYMAN: Let me first ask whether Dr. Newman wanted to get involved. And then I'll go back over to this side.

DR. NEWMAN: Certainly. No question. Please.

MR. HYMAN: You can say no.

DR. NEWMAN: No, I do. I do want to get involved. Loaded otherwise. I think one of the basic questions here is, and it applies across the board, is there only one way to train for the purposes of providing good quality service, whatever that service might be? And I can only look at it from the perspective of those issues that we're involved with, and I would argue there is more than one way to train for that. Both in terms of the training that goes into the practice of psychology in hospitals.

The California Supreme Court in CAT v. Rank very explicitly said either the psychologist or the physician could be captain of the ship. There was nothing about either that foreclosed them from being the captain of that treatment team. But I would take it beyond that and say that we have seen very clearly from a Department of Defense demonstration project, the psycho-pharmacology demonstration project sponsored by the

military and the Department of Defense in an attempt to answer the question: Can already licensed clinical psychologists be trained with enough medicine and pharmacology to be able to prescribe safely and effectively without having to go to medical school?

And in fact, the conclusion of that program by every study that's been undertaken is a clear yes. Clinical psychologists can be trained without going to medical school, with enough medicine and pharmacology to provide safe and effective prescribing. In fact, the most comprehensive study done by the American College of Neuro Pscyho-pharmacology found that those psychologists who were trained in the program "filled critical needs and performed with excellence wherever they served." So, I would argue to you that there is in fact more than one way to train to provide qualified services.

MR. HYMAN: Professor Bloche?

DR. BLOCHE: I'd like to build on what Dr., is Lozamow?

DR. LOMAZOW: Lomazow.

DR. BLOCHE: Lomazow said. I also, myself, went to a residency training program. I know that feeling of being exhausted, being on call, getting up the next day, somehow trying to make it through the day, feeling that you're at the end a survivor, and feeling

somehow that the system owes you something for what you endured. That's a very profound and natural kind of feeling.

At the same time, from a public policy question, the issue is not what way of doing things provides the absolute best, the Cadillac of health care. The issue is one, of course, of benefit tradeoffs. And the data simply hasn't been here, frankly, in any of these presentations for a rational assessment of what the cost benefit tradeoffs are for the series of cheaper versus more costly ways of doing things.

There needs to be data both about quality and outcomes and about the cost that an incremental difference in quality, incremental difference in intensity of training, et cetera, entails. And medical malpractice suits or judgments or settlements are not good data. There's ample evidence to indicate that medical malpractice outcomes are neither sensitive nor specific as indicators of quality.

And a final observation, if I may. The cacophony of what plainly are of turf claims, here after all there is

-- it would be quite a coincidence if out of randomness the positions taken aligned with the interest of those who took them. The cacophony of turf claims here

undermines the credibility of all health professionals before the American public when it comes to quality issues. And the transparency of professional self-interest behind these professional organizations' claims also erodes the ability of professional organizations to argue credibly for those professional norms that may serve the larger welfare.

You're burning the seed stock here and I think that there needs to be more of an understanding of the common self-interest of American patients and health care providers and how that is eroded by doing Jerry Springer.

MR. HYMAN: Professor Morrisey?

MR. MORRISEY: Yes. Let me briefly just concur with Professor Bloche. It seems to me that the issue here is really a lack of evidence on one side or the other. And at minimum, it would be nice to see the Commission and the Department come forward with a call for additional rigorous analysis trying to look at whether or not the differences in licensure provisions, differences in scope of practice, differences in direct access, differences in payment issues affect cost, affect utilization, affect quality. At minimum, that would be a good outcome in my judgment.

MR. HYMAN: Let me follow up on that point and ask a specific question, and then let some more people

speak. The specific question is actually to Mr. Bauer. Dr. Modell referenced two studies, one done by it sounded like Penn, and the other he mentioned done by the American Association of Nurse Anesthetists which he suggested gave consistent results in a direction that he liked and presumably you wouldn't. So, I guess I'd just like to ask you to comment on those studies and then expand.

MR. BAUER: I strenuously disagree with Dr. Modell's interpretation of the statistics of those studies. I am familiar with them. And I would assume he might have the power to get us a little debate in the ASA journal because I as a former medical school statistics and research professor would be happy to explain why those studies absolutely do not support the assertions that he made.

I'm probably the only person sitting at this table or testifying in this hearing today that is the author of a statistics and research used in medical schools. So, the integrity of research and the like is something I love to debate. And simply the claims that he made relating those deaths, I won't get into the methodology right now unless you would like me to, but I'm prepared to. I think that's a little bit --

MR. HYMAN: I would encourage both of you to

submit written statements on that, if you see fit.

MR. BAUER: I would be happy to do that.

MR. HYMAN: But I think given our time, it's probably not the most efficient use. Actually, I think we would do it in writing, and let me, you had your hand up otherwise, Mr. Bauer, as did you, Dr. Modell. But Mr. Bauer was first.

MR. BAUER: I just want to make sure that the Federal Trade Commission does not lose an issue that I haven't heard from the physicians on the panel, and that's the right of the consumers to choose.

Let's go back to the Arrow study, and one of Professor Arrow's points was the inequality of information. And that is simply no longer true. It's now possible for people with the right kind of background to get the same information. There's absolutely no uniqueness to the information base available to a physician or a nurse or a pharmacist. That has changed dramatically.

And I also would like not to lose sight of the fact that the knowledge base changes so fast that even though I feel sorry for the years you stayed awake and missed all that sleep as a resident, it's irrelevant now because probably 80 percent of what you learned in your residency program is no longer relevant. And so, there's

a constant need to renew and that's why I developed the seven pillars, if you will, not of wisdom, but at least of moving science forward.

It's very important that the professions have criteria to make sure you stay up with the changes. The number of years that you trained is irrelevant to how competent you are with today's medical sciences.

MR. HYMAN: Dr. Modell?

DR. MODELL: I raised my hand because you asked, we have to look at cost-benefit ratio. According to the Silber study, there's one more dead person per 400 anesthetics given that were unsupervised. Now, my question is which one of us or which one of our relatives is the one person and how much was their life worth?

If you can put, the economist can put to me on paper what one in 400 excess mortality is worth, then I can address that question. As a physician and as someone who has spent hundreds of thousands of our own dollars trying to make anesthesia safer, I can tell you, that number is unacceptable to me and to my colleagues at the University of Florida.

DR. BLOCHE: You just pointed to the challenge, though. You need to put a number on that one and 400. Ultimately, what is involved here is the need to come up with a valuation of a life saved. What is this

particular method, this particular policy costing in terms of, well, the cost of each life saved? Because, yes, we can always say what if it's so and so who we love, who we know? But when we lose those resources because we're taking the more expensive method of doing this, then we don't have those resources for other health care needs.

So, there is that kind of tradeoff that always has to be built in to that part. And so, if you can gather that data, that would be wonderful.

DR. MODELL: To me as a physician, it's totally unethical to say I will let somebody die for money. I've never done that in my life. I've taken care of people who didn't have a dime, all right, that I've actually given them money when they left the hospital to go get something to eat. I can't do that. I can't let people die to prove a point.

The anesthesia death rate is low enough today due to our efforts, not just mine but everybody in the profession, that I am told it will take well over a couple of million cases to get the type of statistical numbers you want and assign the dollars to it. And my feeling is, you know, I guess I'm glad I'm 70 years old. Maybe I won't have to look every time at the results of that and try to put faces to the people that we killed in

order to get those numbers.

I'm not an economist. And I can't put a price on a patient's life, I'm sorry.

MR. HYMAN: Mr. Bauer?

MR. BAUER: I will in my written testimony show why the one in 400 is an absolutely meaningless statistic. And even though I, as an economist, thirst at the opportunity to do this kind of cost benefit study, I will agree on one point with Dr. Modell. It would take a study of millions to come up with a valid point here, and the Pennsylvania study to which he refers is several orders of magnitude short of millions.

DR. MODELL: Oh, yes.

MR. HYMAN: Anyone else? Let me ask whether anyone wants to make any closing remarks. I have many more questions but we're running out of time. So, anyone?

DR. LOMAZOW: I just want to say that this whole issue of lesser trained versus more trained, it just simply flies in the face of logic. I mean, and you can talk about studies and studies and studies, but it's just illogical. You want the best. You want the people that are best trained, the best qualified to do the thing.

Do you want a certified plumber or do you want

some guy next door to come over? And it's the same situation. I mean, there's, we reward excellence. We reward training. The best get as far as they can go and they strive to be the best. And why go to the Mayo Clinic? Why not go to Podunk General Hospital? I mean, they're the same.

I mean, you have to go back, with all the statistics and all the education, just go back to plain logic. And the whole idea of less qualified people simply flies in its face. Thank you.

DR. NEWMAN: Maybe this is more the province of the Department of Health and Human Services than the Federal Trade Commission, but I would just point out that we ought to be a little careful in terms of our preoccupation with getting the best when we have as many people as we have out there who are receiving no health care at all.

MR. HYMAN: Anyone else?

MR. MORRISEY: Don't forget consumer choice, please, Federal Trade Commission.

DR. MODELL: Can you put the word "informed" before that?

MR. MORRISEY: Happily.

DR. MODELL: And then define how a consumer is informed about the risks and the training of the person

giving them anesthesia because even my own relatives, some who have Ph.D.'s in other areas call me to get them this and that and the other where they live in anesthesia because they have no idea how to make a choice.

MR. BAUER: They can just read my book. Sorry about that. I said that with a twinkle in my eye, please.

MR. HYMAN: Well, on that note, I'd like to thank the panel for their provocative presentations.

(Applause.)

(Whereupon, at 5:01 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

Date created: 2004

APA's Russ Newman Testifies on Behalf of New Mexico's Important Step Toward Comprehensive Mental Health Care

WASHINGTON - Russ Newman, the American Psychological Association's (APA) executive director for professional practice, testified before New Mexico's Psychologist Examiner's Board in support of regulations that would implement the state's new law granting prescriptive authority to psychologists.

New Mexico was the first state to enact a law granting psychologists the right to prescribe. Seeing a psychiatrist in New Mexico can take up to six weeks and an hours long commute. HB 170 and the regulations to implement it will expand the pool of mental health care providers by providing additional training in medicine and pharmacology to psychologists who are already experienced clinicians with doctoral level training.

In his remarks Newman thanked the board for its work developing a legal and regulatory "safety net" for prescribing psychologists and their patients. The regulations are a collaboration between the Psychologist Examiner's Board and the state's Medical Board.

"The prescribing psychologist statute and proposed regulations are quite comprehensive, careful, and well thought through in setting up extensive education and training requirements for prescribing psychologists which include numerous check points and safeguards," Newman said .

Under the regulations, psychologists will undergo a rigorous training period. The period includes classroom study, physician supervised clinical and assessment practicums, followed by a standardized national examination. Prescribing psychologists will also undergo a two year conditional prescribing period overseen by a physician. Only at that point will prescribing psychologists work independently, albeit in close collaboration with the patient's physician.

"The collaboration provisions of the regulations codify good clinical practice," Newman said.

This collaboration includes not only having the psychologist initiate contact with the patient's physician when medication is warranted, but also having the physician initiate contact with the patient's psychologist when any changes in the patient's medical condition might affect the treatment being provided by the psychologist.

"This ongoing two-way communication is a model of integrated care," Newman said.

"With the adoption of these regulations, the New Mexico psychologists who have completed, or will complete the required didactic and practicum training will be in a position to provide badly needed psychological and psychopharmacological treatment services, working in collaboration with patients' primary treating health care practitioners," Newman said.

The American Psychological Association (APA), located in Washington, DC, is the largest scientific and professional organization representing psychology in the United States and is the world's largest association of psychologists. APA's membership includes more than 150,000 researchers, educators, clinicians, consultants and students. Through its 53 divisions and its affiliations with 60 state, territorial and Canadian provincial associations, APA works to advance psychology as a science and profession, and as a means of promoting health, education, and human welfare.

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Date created: 2005

APA Raises Privacy Concerns on Mental Health Records:

Proposed nationwide system of electronic records requires managing many patient confidentiality issues

WASHINGTON - Patient privacy of mental health records was the focus yesterday during a hearing in Chicago, Illinois on the proposed National Health Information Network, which is an element of the Health Information Technology initiative put forth by President Bush in April 2004. The hearing was held by the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics whose charge it is to make recommendations to the Secretary of Health and Human Services as to what privacy protections are necessary to implement an effective electronic health record.

Testifying on behalf of the American Psychological Association, Russ Newman, Ph.D., J.D., executive director for professional practice, raised concerns regarding the need to maintain an extraordinarily high level of privacy where mental health records are concerned.

"We believe that a National Health Information Network (NHIN) has the potential to improve the quality of health care provided in this country, allowing instant access to critical health information at any point of care," said Newman. "At the same time, however, we are extremely concerned about issues of privacy and confidentiality, particularly with mental health records, raised by this proposed increase in accessibility of health information."

According to Newman, in order to develop the NHIN in a manner which will promote quality healthcare, it is critical to consider the unique privacy issues relating to mental health records. "Most people understand that mental health records are particularly sensitive because they may contain a patient's innermost personal information. Many also are aware that, unfortunately, the stigma attached to mental illness and mental health treatment makes the records of that treatment especially sensitive. Any breach of privacy could be devastating to the patient. Unlike most other areas of health care, the mere possibility that confidential information might be disclosed prevents successful treatment from occurring by interfering with the development of the necessary trusting psychotherapy relationship and open communication with the therapist."

Additionally, Newman raised concerns about access to mental health records by others in the healthcare system not trained or experienced with mental health issues, health insurers and law enforcement officials. Newman also discussed what choice patients would have in deciding whether to have their records included in NHIN. "If patients consent to electronic records, it would be necessary to inform them of all potential uses of their records and by whom. While most patients may want their records available

to health care professionals who are treating them, they might feel quite different about giving such access to insurance companies."

The American Psychological Association (APA), in Washington, DC, is the largest scientific and professional organization representing psychology in the United States and is the world's largest association of psychologists. APA's membership includes more than 150,000 researchers, educators, clinicians, consultants and students. Through its divisions in 53 subfields of psychology and affiliations with 60 state, territorial and Canadian provincial associations, APA works to advance psychology as a science, as a profession and as a means of promoting health, education and human welfare.

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APA Comments: Proposed Rule Providing Modifications to Standards for Privacy of Individually Identifiable Health Information

by Russ Newman, PhD, JD

April 24, 2002

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Privacy 2
Hubert H. Humphrey Building
Room 425A
200 Independence Avenue, SW
Washington, DC 20201
Re: Proposed Rule Providing Modifications to Standards for Privacy of Individually Identifiable Health Information, as published in 67 Fed. Reg. 14776, March 27, 2002

Dear Department of Health and Human Services Representatives:

I submit these comments on behalf of the American Psychological Association ("APA" or "we"), the largest membership association of psychologists with more than 155,000 members and affiliates engaged in the practice, research, and teaching of psychology, pursuant to the March 27, 2002 request (67 Fed. Reg. 14776) for comments regarding proposed modifications to the final rule regarding standards for the privacy of individually identifiable health information ("privacy rule"). As requested by the Department of the Health and Human Services (the "Department"), we focus our comments on three provisions of the privacy rule for which modifications have been proposed. Our comments concern: the proposed elimination of the patient consent requirement, the psychotherapy notes authorization requirement, and the "minimum necessary" requirement.

On December 17, 2001, the Mental Health Liaison Group ("MHLG"), the primary mental health advocacy coalition for mental health consumers, professionals and providers in Washington, DC, wrote to Secretary Tommy G.Thompson, regarding the patient consent, minimum necessary, psychotherapy notes authorization requirements, and other provisions in the rule. Our comments offered below are similar to those contained in the MHLG letter, which was signed by 38 other leading mental health consumer, professional and provider groups. Given this similarity and that the MHLG letter represents a consensus on the consent and other provisions that the Department now proposes to modify, we attach this letter to our comments for your consideration.

Patient consent should remain in the rule and be refined to address concerns of emergency medical providers, pharmacists and other entities regarding its impact on care.

The APA is disappointed with the proposed removal of the patient consent requirement of the rule at 45 C.F.R. § 164.506. During Congressional consideration of privacy legislation in the 1990's and throughout the privacy rulemaking process, we have consistently argued that patient consent is a cornerstone of assuring medical records privacy.

Patients have a right to their privacy, and therefore the right to protect the privacy of their records. Patients are afforded the opportunity to exercise their privacy right when they give consent for the use and disclosure of their records for payment, treatment, and health care operations purposes. Removing consent as proposed essentially shifts "ownership" of records to the entities that use and disclose them for treatment, payment, and health care operations purposes. Under the proposed modification, the patient is merely given the opportunity to acknowledge that he or she has received notice as to how his or her records will be used and disclosed.

As the Department notes, consent has little value under current practice and in the rule because it is mandatory. If a patient refuses to give consent, for example, he or she could be denied treatment. In practical terms, the distinction between patient consent and notice may appear slight. The patient will either allow his or her records to be used and disclosed for payment, treatment, and health care operations purposes, or be refused care in both instances. The distinction, however, may have legal ramifications for patients and for those entities that use and disclose the patient's records.

Consent represents a signed agreement by the patient regarding the manner in which health care professionals, providers, insurers, and other entities will use and disclose health information in the future. If a patient believes that his or her information has been improperly used or disclosed, evidence of such violation is legally framed by the terms of the consent agreement. Patient notice does not provide this framework, since a written and signed agreement does not exist between the patient and users of the record.

We urge the Department to carefully weigh this distinction, because the proposed consent modification, as mentioned, essentially shifts "ownership" of the record from the patient to the entities that use and disclose the record for treatment and administrative purposes. Under the modification, patients will lose their ability to give permission regarding the use of their records. Entities, but mainly insurers, will gain regulatory recognition of their use and disclosure of patient records. This modification, subtle as it may be in practical effect, appears to undermine the right of patients to the privacy of their records.

Rather than remove the consent provision entirely, the APA suggests that the provision be refined. For example, we believe that the Department makes strong arguments regarding the excess burden that consent places on pharmacists and emergency care providers. These arguments revolve around the difficulty of obtaining patient consent and its intrusion on the provision of patient care and services. The consent provision should be refined to consider such circumstances.

Health plans should be required to obtain patient authorization for treatment, payment, and health care operations purposes for which a patient could not foresee the use and disclosure of individually identifiable information.

In addition to strengthening the patient consent requirement, health plans should be required to obtain patient authorization for those treatment, payment, and health care operations purposes for which a patient could not foresee the use and disclosure of individually identifiable information. We view these certain purposes as administrative functions of the insurer that are not part of the direct treatment of an individual patient. We suggest this change preferably in addition to retention of the consent provision. If the Department ultimately removes consent, such patient authorization would be an important compromise that will help ensure the privacy of patient records.

The Department's statement in commentary to these proposed modifications that many patients "expect that their health information will be used and disclosed as necessary to treat them, bill for treatment, and, to some extent, operate the covered entity's health care business" may be true (1). Many patients, however, accurately believe that their treatment is no longer private. This belief appears to be particularly held by patients in large health plans, which commonly place private health information in easily accessible databases for use and disclosure by many employees for many purposes, identified in the rule as treatment, payment, and health care operations purposes (2).

Patients have lost confidence in the privacy of their records and in the confidentiality of their relationship with their direct treating professionals. In fact, we suggest that many patients loathe the current access of health plans to their private records for administrative purposes that benefit the health plan and have nothing or little to do with their individual treatment. Part of the problem stems from the necessary reality that, as the Department acknowledges, health plans lack direct contact and only have an "indirect treatment relationship" with the patient (3). This lack of direct contact and a treatment relationship with the patient, however, is at the core of the need for a patient privacy law in the first place.

Patients generally are not concerned with the use of their records by their treating professionals. Rather they are worried, and legitimately so, with the use of their records by entities with which they have little or no contact.

The current broad use and disclosure of records by health plans represents an unacceptable status quo. A status quo that the Department exacerbates by providing health plans with great access to patient records through very broad definitions of "payment",

"treatment", and "health care operations".

Health insurance industry advocates have argued that expansive definitions of "payment, treatment, and health care operations" are warranted, since access to identifiable patient information helps them improve patient care in addition to plan administration. Indeed the APA agrees that some health plan activities, such as on-going quality assessment, can improve patient care. However, these activities generally improve patient care in the aggregate and are not related to the direct provision of care to an individual patient. Therefore, an individual patient's privacy is substantially weakened or even lost when his or her individually identifiable information is shared for administrative purposes or for purposes that may benefit patients in general.

While the patient consent requirement would certainly not interfere with the treatment, payment, and health care operations of health plans, patient authorization for use and disclosures that are administrative would take some effort on the part of health plans. However, in our view health plans should not have such access to individually identifiable patient information for these purposes without patient authorization in the first place. Requiring patient authorization would represent an important proactive step toward guarding the privacy of patient records.

Many of these administrative functions that should require patient authorization are embedded in the "health care operations," "treatment," and "payment" definitions. These various administrative functions include: quality assessment and improvement activities, protocol development, clinical guidelines development, student training activities, and fraud abuse and detection programs. We urge the Department to require patient authorization for these and other administrative functions of health plans.

The psychotherapy notes patient authorization should be accompanied by an additional patient authorization for the release of particularly sensitive psychological test data.

The APA is gratified to see the Department's continued support for patient authorization for the release of psychotherapy notes for treatment, payment, health care operations purposes and for other uses and disclosures. By requiring an insurer or other covered entity to obtain patient authorization for psychotherapy notes, 45 C.F.R. § 164.508(a)(2) provides an important privacy protection for patients seeking and receiving psychotherapy and related mental health services. Slight modifications proposed by the Department appear to strengthen the provision and, as the Department notes, to "clarify that this information is not permitted to be used or disclosed without individual authorization for purposes of another entity" (4).

We appreciate the Department's commitment to the understanding that mental health records, such as psychotherapy notes, need heightened protection in the rule. The reasons for such heightened protection are manifold but rooted in societal stigmatization of mental disorders, and more intimately to the individual patient, in the fear that disclosure of a mental disorder and treatment to loved ones, family, friends, business associates, and even acquaintances could harm these relationships, perhaps irreparably.

Patient authorization for release of psychotherapy notes will help secure the privacy of the relationship between the patient and treating psychologist, but more protection is needed. Psychologists and some other mental health professionals typically create and maintain psychological test data, which are in addition and often directly related to psychotherapy notes.

The privacy of test data should also be protected through patient authorization for release to ensure effective psychotherapy and other mental health treatment. Such authorization will help preserve an atmosphere of confidence and trust so that a patient "is willing to make a frank and complete disclosure of facts, emotions, memories, and fears (5)."

To clarify terms, "test data" includes test results, raw test data (generally, the test form itself, the actual answers of the patient on the test form, etc.), reports, and global scores, and "test materials" include protocols, manuals, test items, scoring keys or algorithms, and any other materials considered secure by the test developer or publisher. In this comment, we refer to both test data and test materials under the blanket term, "test data."

Since publication of the proposed rule in November 1999, the APA has repeatedly requested that the Department provide for patient authorization for the release of psychological test data in comments to the proposed and final rule (6). We have since been joined in our request by 38 other leading mental health advocacy organizations of the Mental Health Liaison Group. In a December 17, 2001 letter to

Secretary Thompson (as referenced above and attached), the MHLG requested that the Department amend the rule to provide for patient authorization for the release of testing records.

A primary reason for providing for patient authorization of test data is one of continuity. A patient cannot feel secure in the privacy of his or her relationship with a psychologist, if a realistic perception exists that some records, namely psychotherapy notes, require specific authorization for release, while other records, psychological testing and assessment records, with similar and highly sensitive, often embarrassing, information do not.

In discussing the psychotherapy notes patient authorization requirement in the final rule, the Department clarified the rationale for the requirement:
[T]he rationale for providing special protection for psychotherapy notes is not only that they contain particularly sensitive information, but also that they are the personal notes of the therapist, intended to help him or her recall the therapy discussion and are of little use or no use to others not involved in the therapy. Information in these notes is not intended to communicate to, or even be seen by, persons other than the therapist. Although all psychotherapy information may be considered sensitive, we have limited the definition of psychotherapy notes to only that information that is kept separate by the provider for his or her own purposes. It does not refer to the medical record and other sources of information that would normally be disclosed for treatment, payment, and health care operations (7).

We respectfully submit that psychological test data are exactly the same type of sensitive information as psychotherapy notes to warrant patient authorization for release. Essentially, the Department has determined that heightened protection for psychotherapy notes is needed because such notes: (A) contain particularly sensitive information, and (B) are kept separate by the mental health professional for his or her own purposes. The Department further elucidates on the second requirement by indicating that such notes are of little or no use to others not involved in the therapy, are not intended be communicated to or even be seen by persons other than the therapist, and do not refer to the medical record and other sources that would normally be disclosed for treatment, payment, and health care operations. As with psychotherapy notes, psychologists and other therapists may include portions of test data in patient medical records, but that portion which is generally not shared should similarly fall under a patient authorization requirement for release.

A. Test data in psychological assessment contains particularly sensitive information.

Psychologists typically utilize psychological tests that require patients to divulge highly sensitive personal information, which is typically as sensitive as the information contained in psychotherapy notes. For example, the Minnesota Multiphasic Personality Inventory (MMPI-2), one of the most commonly used clinical tests, contains an item asking the respondent to indicate whether he or she has "indulged in unusual sex practices." For example, MMPI-2 asks a respondent whether he or she "has used alcohol excessively." For example, the Rorschach, again a common testing technique, asks respondents to interpret what a series of inkblots might represent. Common responses include emotional expressions, fantasies, and notations by the psychologist on the respondent's behavior while giving the response.

Obviously, these questions themselves and the answers the patient provides contain particularly sensitive information, far more sensitive than nearly any information related to treatment for physical diagnoses. This information is more sensitive than general mental health information that may be provided to health plans for purposes of payment, treatment, and health care operations. Certainly, test data include patient emanations of highly sensitive information, which may have meaning only to the psychologist giving the test. For these reasons, psychological test data contain sensitive patient information similar to that contained in psychotherapy notes and meets this part of the Department's rationale for requiring patient authorization for release. In addition, these highly sensitive and personal responses are meaningless to persons not trained to interpret them in the aggregate, as elaborated below.

B. Highly sensitive test data are kept separate by the mental health professional for his or her own use.

A psychologist is required by ethical standards, law, and contractual agreements to carefully determine the release of test data, to keep certain test data for his or her own purposes, and to not include such data in the medical record (8). Many of these standards and laws are meant to protect the patient and the privacy of the records, and contractual agreements with the test developer or publisher are primarily meant to protect the tests themselves.

According to the APA Code of Ethics, a psychologist must " . . . make reasonable efforts to maintain the integrity and security of tests and other assessment techniques consistent with law, contractual obligations, and in a manner that permits compliance with the requirements of this Ethics Code (9)." Unless otherwise mandated by law, a psychologist must request patient consent for release of test data in order to obtain payment for services (10). Many states have statutes that require formal consent before records can be released or protect against disclosure of mental health records under the psychotherapist-patient relationship. Even with such consent and consent requirements, however, many psychologists release only certain test data to health plans.

For purposes of disclosing test data to health plans, such as (under this rule) for payment, treatment, and health care operations, many psychologists provide written psychological assessments in place of sensitive test data. A psychological assessment, often a standardized report, contains such information as an overall summary of diagnosis and treatment, diagnostic impressions and interpretations, and treatment recommendations. Psychologists generally keep separate and for their own use test results (other than summary results provided), raw test data, global scores, and test materials, such as protocols, manuals, test items, scoring keys, algorithms, and other related materials.

A psychologist keeps much test data for his or her own use for purposes of psychotherapy and treatment and to protect the privacy of the patient and of their psychotherapeutic relationship. In addition, many psychologists specialize in testing and administer testing for psychologists and other therapists for purposes of patient treatment. Authorization must also apply to psychologists as test givers.

When a patient provides answers during psychological assessment, these are responses of the patient, similar to responses that a patient would provide during psychotherapy. Assessment questions may require the patient to reveal highly sensitive personal information, and the psychologist will protect this information as necessary. Psychological testing then, like psychotherapy, depends upon "an atmosphere of confidence and trust in which the patient is willing to make frank and complete disclosure of facts, emotions, memories, and fears."

Psychologists are particularly careful not to release test data, other than assessment summaries, to individuals who are not qualified to use such data. Regarding assessment techniques, interventions, results, and interpretations, for example, psychologists have an ethical duty to " . . . take reasonable steps to prevent others from misusing the information these techniques provide. This includes refraining from releasing raw test results or raw data to persons, other than to patients or clients as appropriate, who are not qualified to use such information (11)." Psychological testing standards call for responsibility for test use to be assumed by or delegated only to those individuals with the training and experience necessary to handle these responsibilities in a responsible and technically adequate manner (12).

Inappropriate release of test data can harm the health of the patient and the treatment relationship between the psychologist and the patient. In commentary to the proposed and final rule, the Department clearly recognizes this potential harm and has thus included a patient authorization requirement for release of psychotherapy notes. A patient, however, may be harmed in numerous other ways not directly related to treatment when sensitive test data is inappropriately disclosed.

One way that a patient can be harmed by the release of certain test data, such as raw data for example, is by its misinterpretation by individuals not trained in psychological testing, or by its use out of proper context. For example, an item on the MMPI-2 is combined with other items to determine if the respondent is being truthful. In other words, for assessment purposes several items on the MMPI-2, when viewed together can assist a psychologist in determining whether the respondent is attempting to mislead with his or her responses. One of these items asks the question: "I do not always tell the truth." If the person answers "no" to this question, it may then be combined with other answers to indicate that the person is actually attempting to mislead the tester. However, a "yes" answer, to a person not trained in interpreting this test, may be seen as meaning that the person is an untruthful person, when in fact he or she is being truthful in answering the item.

In addition to potential misuse, psychologists must consider release of test materials in relation to test security, potential invalidation, copyright law and contractual obligations. Psychologists' consideration of these issues has been succinctly discussed in psychological publication:
Disclosure of secure testing materials (e.g., test items, test scoring, or test protocols) to unqualified persons may decrease the test's validity. Availability of test items to an unqualified person can not only render the test invalid for any future use with that individual, but also jeopardizes the security and integrity of the test for other persons who may be exposed to test items or responses. Such release

imposes very concrete harm to the general public-loss of effective assessment tools. Because there are a limited number of standardized psychological tests considered appropriate for a given purpose (in some instances only a single instrument), they cannot easily be replaced or substituted if an individual obtains prior knowledge of item content or the security of the test is otherwise compromised (13).

Psychologists must make sure when disclosing records to health plans, for example, that an individual in that plan is able to use the test data appropriately and to ensure that unqualified individuals do not have access to the data. In doing so or in providing assessment summaries in lieu of test data, psychologists protect the interests of the patient and meet their contractual and other obligations to the developer or publisher of the test materials.

Because test data contain particularly sensitive patient information, which psychologists and other professionals, under ethical and legal obligations, keep separate for treatment purposes of the individual patient, the APA urges the Department to require patient authorization for test data. The mental health consumer and professional community is united behind the need for test data authorization as an important means of securing the privacy of the records of persons seeking and receiving psychotherapy and other mental health services. This important authorization should be included in the final rule.

Psychologists and other therapists should not have their participation in health plans predicated on seeking patient authorization for psychotherapy notes.

An important component of the psychotherapy notes authorization requirement is that a covered entity, such as a health plan, "may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization (14)." Obviously, this provision ensures that the psychotherapy notes authorization requirement is meaningful in that a patient may continue to receive treatment and remain enrolled in a health plan, even if he or she chooses not to provide sensitive information contained in psychotherapy notes to a plan.

Likewise, a psychologist or other therapist should not have his or her participation in a health plan predicated on seeking patient authorization for psychotherapy notes. In its December 2001 letter to Secretary Thompson, the MHLG anticipated that health plans could potentially attempt to pressure therapists into seeking patient authorization for psychotherapy notes. The MHLG urged the Secretary to provide guidance to ensure that the psychotherapy notes authorization could not be circumvented in this manner.

Unfortunately, we believe that health plans are now generating HIPAA information, targeted to our member psychologists, which is unclear as to whether they must obtain patient authorization in order to remain in the plan. For example, in a recent publication from Regence BlueCross BlueShield of Oregon ("Regence BCBSO"), participating professionals are informed that:
Non-psychotherapy notes are maintained in the patient's chart. Any items falling into the non-psychotherapy notes category must be disclosed to the health plan and the patient, with only a general consent. With patient authorization (specific disclosure with expiration and/or revocation rights) psychotherapy notes may also be disclosed to the health plan. All Regence BCBSO and affiliated health plan agreements require the creator of the record to release records necessary to facilitate payment and health care operations. In the future, Regence BCBSO will require contracted physicians and other mental health and chemical dependency providers to secure authorizations under HIPAA that permit them to "use and disclose" information to the health plan (15).

After elucidating the privacy rule's definition of items not included in psychotherapy notes, the Regence BCBSO publication states that:
Under some circumstances non-psychotherapy notes may be sufficient to meet health plan needs for documentation. However, the quality of record keeping varies widely and access to psychotherapy notes may be necessary to make payment on some claims (16).

Under the Regence BCBSO description of patient authorization for release of psychotherapy notes, a psychologist or other therapist could reasonably believe that a health plan can require him or her to obtain authorization for purposes of the treatment, payment, or health care operations of the plan. In addition, the therapist may perceive from this health plan instruction that obtaining patient authorization may be required as part of his or her continued participation in the plan or that payment for services is predicated on the obtaining of patient authorization for psychotherapy notes.

While it may be appropriate, in extraordinary circumstances, for a health plan to request that a psychologist or other therapist seek patient authorization for psychotherapy notes, such request should not be coerced, either on the patient or the therapist. Certainly, this

should not be a routine request under "some" circumstances, related to inadequacy of the quality of documentation provided to the plan by a health care professional.

The privacy rule is quite clear that psychotherapy notes are not required for purposes of payment, treatment, or health care operations. The rule clearly indicates those data elements that are excluded from the term "psychotherapy notes" that may be made available to a health plan for treatment, payment, and health care operations purposes. These are: medication prescription and monitoring, counseling session start and stop times, modalities and frequencies of treatment, results of clinical tests, and summaries of diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to dates. Psychotherapy notes are separated from these elements for the use of the therapist in treatment. A plan may ask for clearer or better documentation from a provider regarding that information which is not part of the patient's psychotherapy notes, but a plan may not routinely, or even sometimes, require a therapist to authorize release of information contained in psychotherapy notes for its administrative purposes.

The APA does not know how common this sort of instruction, as provided in the Regence BCBSO materials, is. Unfortunately, we believe that it could be a common instruction, which highlights the need for guidance by the Department on this issue.

The "minimum necessary" requirement should be interpreted most favorably to the patient to preserve the privacy of records when disclosed to health plans and other entities for treatment, payment, and health care operations purposes.

We appreciate the Department's proposed modifications that clarify that oral communications between health care professionals in treatment of a patient are not subject to the minimum necessary requirement. The "incidental" disclosure exception to the minimum necessary requirement for such oral communications appears well designed and narrow to ensure that patient treatment between health care professionals is not impeded. The APA supports the inclusion of this modification in the rule.

More importantly, we appreciate the Department's rejection of the suggestion that disclosures for treatment, payment, and health care operations be exempted from the "minimum necessary requirement (17)." Requiring that health plans request the minimum amount of individually identifiable patient information necessary for health plan administrative purposes lies at the heart of the protection that the rule affords to patients and their records.

The privacy rule provides health plans and other entities great access to patient records for uses and disclosures related to treatment, payment, and health care operations. This broad access is balanced in part by the minimum necessary requirement so that each time a patient's record is accessed by a health plan or other third party, such entity must demonstrate that it is requesting the minimum amount of patient information necessary for the purpose of its use. Removing or weakening the minimum necessary requirement would swing the balance of the rule in favor of health plans and would essentially gut the protections that the rule affords for patients.

The Department appears to recognize this balance in its commentary accompanying these proposed modifications:
With regard to payment and health care operations, the Department remains concerned, as stated in the preamble to the Privacy Rule, that, without the minimum necessary standard, covered entities may be tempted to disclose an entire medical record when only a few items of information are necessary, to avoid the administrative step of extracting or redacting information. The Department also believes that this standard will cause covered entities to assess their privacy practices, give the privacy interests of their patients and enrollees greater attention, and make improvements that might otherwise not be made (18).

The APA appreciates the Department's continued recognition of the primary importance of the minimum necessary requirement for the protection of the patient record. From our standpoint, health plans are most likely to be tempted to request an entire medical record, as has occurred in the past. Throughout our comments, we have mentioned our belief that health plan demands for individual patient information have substantially eroded the privacy of the records. For persons seeking and receiving mental health services, where particularly sensitive health information is involved, the minimum necessary and the psychotherapy notes authorization requirements will improve records privacy, while not denying health plans access to information for their administrative purposes.

The APA welcomes the Department's recent outreach to psychology and other professionals and consumers regarding the minimum necessary requirement. We assume that outreach is part of the Department's intention, as stated in commentary to the proposed

modifications, "to issue further guidance to clarify issues causing confusion and concern in the industry, as well as provide additional technical assistance materials to help covered entities implement the provision (19)."

Regarding any such clarification or interpretation that the Department may provide regarding the minimum necessary standard, we strongly urge that the Department interpret the provision most favorably to the patient and treating professional. This means in practice that if health plans must have concrete definitions of minimum necessary information for treatment, payment, and health care operations purposes, that such information be the absolute minimum necessary for such purposes.

To some extent, this minimum necessary data is already outlined for mental health records in the rule through the "psychotherapy notes" definition. In other words, depending on the purpose of the disclosure, a health plan may have that portion of the patient's record that concerns medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and summaries of diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date (20). A health plan may not have a patient's psychotherapy notes, absent patient authorization.

A health plan should never request, as some health plans currently demand, a patient's entire record without a compelling reason of a need for the entire record. This is an abuse of records disclosure of which the Department is apparently aware and which the minimum necessary requirement is meant to end.

Psychologists, by nature of the patients that they serve and the sensitivity of records associated with treatment, are deeply committed to the preservation of the privacy of mental health records and patient records in general. The APA is currently working to help our members understand and come into compliance with the privacy rule. We hope to continue to tell our members that the privacy rule contains a substantial floor of federal protection for their patients' records. For these reasons, we hope that the Department will retain the consent provision and improve the psychotherapy notes authorization and minimum necessary requirements, as we have requested.

The APA appreciates the Department's consideration of these and our past comments. We hope that the Department will continue to rely on the APA as it implements the rule. Please contact Doug Walter, J.D., Legislative and Regulatory Counsel, Government Relations, at (202) 336-5889, regarding these comments and for any further assistance that we may provide.

Sincerely,

Russ Newman, PhD, JD
Executive Director for Professional Practice

Endnotes

1. 67 Fed. Reg. at 14778.
2. Regarding patient concerns with the privacy of their records, see for example, California HealthCare Foundation, National Survey: Confidentiality of Medical Records (January 1999). Available at http://www.chcf.org (http://www.chcf.org) .
3. 65 Fed. Reg. at 82648.
4. 67 Fed. Reg. 14798.
5. Jaffee v. Redmond, 518 U.S. 1 (1996), at 10.
6. APA comments to the proposed rule may be found at http://www.apa.org/practice/privacycomments.html (http://www.apa.org/practice/privacycomments.html) . APA comments to the final rule may be found at http://www.apa.org/practice/thompson.html (http://www.apa.org/practice/thompson.html) .
7. 65 Fed. Reg. 82623.
8. For purposes of brevity, we generally do not attempt in this comment to discuss the large body of federal and state law that concern the release of psychological test data. Many of these laws are peripheral to but affect the disclosure of test data for purposes of treatment, payment, or health care operations. We reference these laws for purposes of the Secretary's information and would provide more information regarding these laws upon his request.

9. American Psychological Association, Ethical Principles of Psychologists and Code of Conduct, Standard 2.10 (1992).
10. Id. at Standard 5.05.
11. Id. at Standard 2.02.
12. American Educational Research Association, American Psychological Association, National Council on Measurement in Education, Standards for Educational and Psychological Testing, Standard 11.3 (1999).
13. American Psychological Association, "Statement on the Disclosure of Test Data," American Psychologist, 51, no. 6 (June 1996): 646.
14. 45 C.F.R. § 164.508(b)(4).
15. Regence BlueCross BlueShield of Oregon, "The Behavioral Health BluePrint Newsletter," 1, no. 1 (November 2001): 3. (Available on line at: www.or.regence.com/provider/bcbso (http://www.or.regence.com/provider/bcbso) .)
16. Id.
17. 67 Fed. Reg. 14786.
18. 67 Fed. Reg. 14786.
19. 67 Fed. Reg. 14787.
20. 45 C.F.R. § 164.501.

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