Public Hearing

before

NEW JERSEY LEGISLATIVE COMMISSION FOR THE STUDY OF PAIN MANAGEMENT POLICY

"Issues related to acute and chronic pain management and treatment, as well as pain in patients with terminal conditions"

LOCATION: New Jersey State Bar Association

New Jersey Law Center New Brunswick, New Jersey **DATE:** June 17, 1998

7:00 p.m.

MEMBERS OF COMMISSION PRESENT:

Assemblywoman Charlotte Vandervalk, Chairperson

Joseph Aisner, M.D.

Douglas Ashendorf, M.D.

Harold Bobrow, R.Ph.

Alan D. Carr, D.O.

Peter D. Corda, D.O.

Caryl A. Distel

Sharon Gibson, R.N.

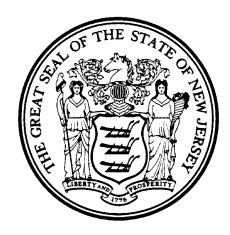
Paula Sue Krauser, M.D.

Michael F. Schaff, Esq.

ALSO PRESENT:

Assemblyman Samuel D. Thompson District 13 Joanne Murad (representing Assemblywoman Joan M. Quigley) Jack Goldberg, M.D.

Eleanor H. Seel David Price, Commission Secretary Office of Legislative Services



Hearing Recorded and Transcribed by
The Office of Legislative Services, Public Information Office,
Hearing Unit, State House Annex, PO 068, Trenton, New Jersey

TABLE OF CONTENTS

	<u>Page</u>
Donald L. Pendley	
President	
New Jersey Hospice and Palliative Care Organization	3
Stephen Brandt, R.Ph.	
Executive Director	
Garden State Pharmacy Owners, Inc., and	
Representing	
New Jersey Pharmacists Association	8
Harry Collins, M.D.	
Representing	
New Jersey Academy of Family Physicians	19
Mary B. Wachter, R.N.	
Director of Legislative Affairs	
New Jersey State Nurses Association	22
Ira M. Klemons, D.D.S., Ph.D.	
Certifying Board President and	
Representing	
American Academy of Head, Neck & Facial Pain and	
American Alliance of TMD Organizations	28
Saul Liss, Ph.D.	
President	
MEDI Consultants, Inc.	34
Gary Stocco	
Vice President	
National Burn Victim Foundation, and	
Member	
American Burn Association Ethics Committee	39

TABLE OF CONTENTS (continued)

Page

Roy C. Grzesiak, Ph.D.	
Clinical Associate Professor of Psychiatry	
Robert Wood Johnson Medical School-	
The University of Medicine and Dentistry of New Jersey, and	
Consulting Psychologist	
New Jersey Pain Institute, and	
Director of Psychology	
Forensic Burn Unit	
National Burn Victim Foundation	42
Joseph P. Valenza, M.D.	
Physiatrist	
Pain Management Program	
Kessler Institute for Rehabilitation, Inc.	47
Bradley Williams, Ph.D.	
Clinical Psychologist and	
Co-Director	
Pain Management Program	
Kessler Institute for Rehabilitation, Inc., and	
Instructor	
Pain Management and Rehabilitation	
New Jersey Medical School-	
The University of Medicine and Dentistry of New Jersey	51
Edward S. Magaziner, M.D.	
Clinical Professor	
Robert Wood Johnson-University Hospital, and	
Assistant Professor	
New York Medical College, and	
Former President	
New Jersey Society of Physical Medicine and Rehabilitation	60
Nancy Pinkin	
Representing	
American Academy of Pediatrics, and	
Advisor	
New Jersey Society of Physical Medicine and Rehabilitation	64

TABLE OF CONTENTS (continued)

<u>Page</u>	
Jack Lavelle Chronic-Pain Victim	65
Loretta Brickman, R.Ph. Regional Director Regulatory Compliance OMNI Care, and Member New Jersey Association of Long Term Care Pharmacy Providers	68
Susan M. Bauman, M.D. Chairperson Biomedical Ethics Committee Medical Society of New Jersey	71
APPENDIX:	
Assembly Concurrent Resolution No. 72 (First Reprint)	1x
Testimony submitted by Donald L. Pendley	4x
Testimony plus attachments submitted by Ira M. Klemons, D.D.S., Ph.D.	7x
Presentation plus attachments submitted by Saul Liss, Ph.D.	27x
Testimony submitted by Roy C. Grzesiak, Ph.D.	166x
Statement submitted by Joseph P. Valenza, M.D.	168x

TABLE OF CONTENTS (continued)

APPENDIX (continued):

Page

Remarks
submitted by
Susan M. Bauman, M.D. 173x

Letter addressed to
Assemblywoman Charlotte Vandervalk
submitted by
New Jersey Pharmacists Association 176x

Letter addressed to
Assemblywoman Charlotte Vandervalk
submitted by
Jeffrey D. Polcer, D.O. 177x

lmb: 1-75

ASSEMBLYWOMAN CHARLOTTE VANDERVALK (Chairperson): Good evening.

Are the mikes working? Can you hear us back there? The silver mikes are for amplification, and the black ones are for the recording unit.

I do welcome everyone here tonight. I thank you for your participation. We have the first hearing for our Pain Management Policy Study Commission. That's a mouthful, but I'm very excited about it because I feel personally there's a real demand for evaluating the whole problem that we have with pain management, and I do feel that we can bring it up a notch in the State of New Jersey.

So what I would like to do is start with the panel members. If they would-- Suppose we start at this end and have them--

If you would just introduce yourself and your affiliation.

DR. GOLDBERG: I'm Jack Goldberg. I'm the head of Hematology and Medical Oncology at Cooper Health System. I am the American Cancer Society Professor of Clinical Oncology and represent the American Cancer Society via the Cancer Pain Initiative.

MR. SCHAFF: I'm Michael Schaff. I'm a partner with Wilentz Goldman and Spitzer, and I head their Health-Care Group. I'm very active in the health and hospital law section. I'm Vice-Chair-- I'm Chair-elect, actually, of the Health and Hospital Committee of the State Bar and some other organizations.

DR. KRAUSER: I'm Paula Krauser. I'm a family physician presently teaching at UMDNJ-Robert Wood Johnson Medical School in family practice, and I do teach the residents about pain management. And I've

lectured at statewide organizations on this and been involved in hospice since its beginnings.

MS. GIBSON: My name is Sharon Gibson. I'm a registered nurse and a certified massage therapist. I'm a member of the American Massage Therapy Association and, also, a member of the Nurse Massage Therapist Association.

MS. MURAD: Joanne Murad, Democratic staff, representing Assemblywoman Joan Quigley.

MS. DISTEL: I'm Caryl Distel. I'm the Director of Patient Representatives at JFK Medical Center in Edison and a member of its Bioethics Committee.

ASSEMBLYMAN THOMPSON: I am not a member of the Task Force but am sitting in on this. I am Assemblyman Sam Thompson. I am on the Assembly Health Committee.

ASSEMBLYWOMAN VANDERVALK: I am Charlotte Vandervalk, Chair of the Assembly Health Committee and Chair of this Commission. I just want to mention that I am very happy to have another member from our Health Committee here because, obviously, we will-- I expect to be dealing with this in the future in our Committee. And I also would like to point out that Dr. Goldberg, who is down on the end, is not officially a member of our Commission yet, but there was a slight mix-up in the appointments, and we do anticipate his being formally appointed in the very near future.

MR. PRICE (Commission Secretary): David Price, Office of Legislative Services, acting as Commission Secretary.

DR. CORDA: Dr. Corda, Director of Professional Pain Management in southern New Jersey.

MR. BOBROW: Harold Bobrow. I'm a pharmacist. I operate a pharmacy in Maplewood, New Jersey.

DR. ASHENDORF: I'm Doug Ashendorf. I'm a rehabilitation physician from Clark, New Jersey, private practice.

DR. AISNER: I'm Joe Aisner. I'm a medical oncologist. I'm Chief of Medical Oncology and the Associate Director for Clinical Services at the Cancer Institute of New Jersey.

ASSEMBLYWOMAN VANDERVALK: Yes. We have a witness list here for people that had called in advance. And, of course, anyone can sign up, and just let us know that you are interested in testifying. We do ask that you, if possible, give us -- I believe it was 20 copies that we had asked for, if that's possible, and, also, if possible, to keep your comments to five minutes. We will have an opportunity to have questions from the panel -- from the Commission members that have questions from the witnesses. What I will do is take the listing--

All right. I'll just start with the order on the list.

Susan Bauman, Dr. Susan Bauman. Is Dr. Bauman here? (no response) All right. We'll come back to her later.

Donald Pendley, President of New Jersey Hospice and Palliative Care Association.

Good evening.

DONALD L. **PENDLEY:** Good evening, Commissioners.

I'm Don Pendley. I represent the New Jersey Hospice and Palliative Care Organization. For those of you who are not familiar with us, our membership is the 46 Medicare-certified hospices throughout New Jersey. You may not be aware that New Jersey is one of the pioneers in hospice care in the nation, and today, about 2000 hospice employees and about 3000 hospice volunteers serve more than 12,000 terminally ill patients in this state every year and their families.

Pain management is an important issue for hospice, of course. Relief of pain and the management of symptoms comes first in the hospice plan of care, for only by alleviating pain can we begin to work with patients and families on the spiritual issues and counseling that make hospice and palliative care so valuable.

Just about a year ago, the membership of my organization, which was founded as the New Jersey Hospice Organization, expanded its name and mission to include palliative care. We recognized that rather than being limited to the needs of the terminally ill, the issues of pain management, symptom control, psychosocial suffering, and spiritual care needed to be incorporated throughout the continuum of care. That recognition prompts our comments to you today.

Stated briefly, we believe that pain management and interdisciplinary palliative care are the right of every patient at every stage in their disease process. We have 12 recommendations to offer the Commission tonight to make that belief a reality. And in the interest of time, I'll cover them but do a little editing from the document that you have there.

Our first recommendation is that patients' right to adequate pain and symptom control must be recognized in the training of all categories of health-care professionals. Curricula in medical schools, nursing schools, pharmacy education, and provider programs should include courses in pain management. Those that presently exist must be improved, as has been documented by many surveys of physicians who have consistently ranked education in pain management as inadequate. We believe these courses should emphasize case studies and illness narratives, which can create an understanding of the broad range of patient needs that might not be achieved by teaching based on conceptual models.

Our second recommendation is that requirements should be placed on all health-care professionals to have a specified number of CME, CEU, or other continuing education credits pertaining to pain management and interdisciplinary care for renewal of their licenses. This education should be designed to build understanding and respect of the priorities, needs, and suffering of patients who are in severe pain and in the advanced and end stages of their diseases. The certification examination in palliative care established two years ago by the American Board of Hospice and Palliative Medicine can identify qualified instructors, and those folks can help develop curricula.

Our third recommendation is that physicians and nurses should be held accountable for relieving a patient's pain. Regular assessment of pain and recording of pain intensity should be included in patient charts as routine practice.

Our fourth recommendation is that education in pain management must extend beyond the use of medications. Many of you are familiar with the effectiveness of cutaneous stimulation -- superficial heat and cold, massage, pressure and vibration -- and that's been well documented, and its use should be increased in practice. But those working with patients in pain should also be aware and educated about psychosocial interventions such as relaxation and imagery, distraction and reframing, hypnosis, etc. These interventions do not replace analgesics, but are used in conjunction with them. Psychosocial interventions should be introduced early in the course of illness, since their early use will allow patients adequate time to learn and practice these strategies while they have sufficient strength and energy to do so.

Our fifth recommendation is that high priority should be placed on patient and family education, and that should be included in treatment plans. Families need to understand that almost all pain can be effectively managed. We need to discourage the misconception among patients and families that pain medication should be saved only for when the pain is severe. Families need to understand that one need not choose between treating the disease and treating the pain. Along those lines, special attention need to be paid to patients who are older, less educated, and who have lower incomes, since concerns about the side effects of medication and addiction are more common for those patients.

Our sixth recommendation is that New Jersey statutes and regulations should be modified to increase availability of medically necessary analysesic medications including opioids. Beyond availability, greater speed of delivery of these opioids should be included, and there are several bills in the State Legislature right now that will encourage that.

Recommendation seven: State policy should encourage the development and revision of reimbursement structures at the Federal level that encourage early treatment of pain and the gradually increasing use of psychosocial and spiritual care as a patient's disease advances.

Our eighth recommendation is that change be effected within the medical community to bring practice into step with knowledge. We cite one study here by the *American Journal of Public Health*. Eighty-nine percent of medical attending physicians surveyed agreed that it was possible to prevent dying patients from feeling much pain, but 85 percent of them acknowledged that the most common form of narcotics abuse in care of the dying was undertreatment of their pain.

Our ninth recommendation is that State and Federal policy should encourage the use of tested clinical indicators that would trigger consideration of hospice for all potentially terminal diseases. Pain management for terminally ill patients and the quality of both their life and death will improve from earlier referral to hospice. Length of stay of hospice has been decreasing dramatically over the past couple of years, as many of you know.

Item number 10: State policy should encourage expansion of programs in the Department of Health and Senior Services, such as Alternative Family Care, which can provide family-type caregivers for patients in noninstitutional settings who would otherwise be alone. These caregivers can give health-care professionals help and track the frequency and intensity of pain and be trained in effective psychosocial interventions without substantially increasing the cost of care.

Item 11 is that the State should undertake a major public education campaign on pain management, advance directives, and end-of-life decision making.

And finally, Item 12, pain and symptom management would be improved through State policies that encourage continuity of care as patients move from one setting of care to another.

My organization considers the work of this Commission to be vitally important both to our work, to health care throughout the state, and the patients and families that we serve. And we ask that the recommendations of this Commission that are eventually offered reflect an overriding concern for the patient and family and their dignity as human beings.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

Is there anyone on the panel that would like to ask a question? (no response)

All right. Thank you very much.

MR. PENDLEY: Thank you so much.

ASSEMBLYWOMAN VANDERVALK: Stephen Brandt, Executive Director of the Garden State Pharmacy Owners.

STEPHEN BRANDT, R.Ph.: Good evening. Madam Chairperson, Committee (*sic*): I'm honored, indeed, to appear before you. I represent the Garden State Pharmacy Owners, and I was also asked to represent the New Jersey Pharmacists Association in reference to pain management, which by the way, just to get the record straight, we're not opposed to in any form or

manner. However, we have major, major concerns the way this law applies to the so-called retail pharmacy establishment.

We continue to have difficulty with the current law concerning the removal of the limitation on the quantities of Schedule II drugs. The problem is not in the area of cancer or terminally ill patients, but for patients that have other nonmalignant conditions determined to be intractable, or refractory, to lesser treatment.

There is no regulation put forth as to how pharmacists are to know whether or not a prescription received falls under the new law, which is the removal of the 120 dosage units, or the old law, which still applies to all other prescriptions not covered under the new law. No specifics pertaining to identifying patients falling under the new regulations have been issued and will not be issued because of confidentiality reasons. The fact that the physician must properly document the need in his record, unfortunately, is not privy information to the pharmacist. So the question is still open, how does the pharmacist know?

In addition, the so-called nonmalignant conditions, which are determined to be intractable, or refractory, may be due not to the person's pain severity, but rather to a condition known as tolerance buildup toward addictive medications. And I, as a practicing pharmacist for over 35 years, had seen this many times when people had this tolerance. If the patient chooses to go to different physicians and pharmacies, the control of the addictive drug use is compromised to the point of nonexistence. Again it brings me back to the question, how does the pharmacist know of the legitimacy of that prescription?

Our position is and has been that we are not opposed to giving larger quantities to cancer and terminally ill patients, even though they, too, cannot be identified but usually take other medications for the severity of their illnesses. However, we are strenuously opposed to giving larger quantities to chronic-pain patients. There are many more of these patients.

Since New Jersey is part of the metropolitan area, we know that drug abuse abounds. Forged prescriptions are numerous, and I can tell you, from my years of experience, there are many out there. In the past, because of the dosage unit limitation, they were always written for smaller quantities to ward off suspicion. With this new law and the lack of identification in regard to legitimate use, it opens up a Pandora's box with respect to forged prescriptions, which now will be written for larger and larger quantities.

An example was, before when you had 120 rule, they were written for maybe 30 or 40. They would never write for 120 because that would be a red flag. Now, with this thing that you can prescribe 200, 300, or 400 tablets, they could write for 150 and nobody would question it, except the pharmacist, of course.

The American Geriatric Society has just released guidelines in managing chronic pain for people over the age of 50. Even though these guidelines recommend opioid analgesics for moderate to severe pain, Dr. Perry Fine, a professor of anesthesiology, University of Utah, and a national medical director of VistaCare, Scottsdale, Arizona, noted that even though "the use of opioid analgesics for chronic and noncancer-related pain does remain controversial, the health-care provider can use these medications safely when

monitored carefully." Giving large quantities to patients does not encourage careful monitoring.

We believe that the Legislature should revisit and review that part of the law that deals with the chronic and nonmalignant patients. I'm not talking about terminally ill, hospice patients, or anyone else, just patients that may have chronic illness. And I can assure you, pain is bad, but you can have-People have arthritis. That's chronic. It doesn't go away. And they build up this tolerance, and before you know it, they wouldn't have to take more and more Percocets. I think that some control should stay, and I think that in this instance, I think the law should stay at 120 units.

Thank you. If you have any questions, I'd be glad to answer.

ASSEMBLYWOMAN VANDERVALK: Are there any questions from the panel?

Yes, Assemblyman Thompson.

ASSEMBLYMAN THOMPSON: I do have one question. I have to apologize for my lack of knowledge on the particular laws that you're referring to, but you asked a number of times "How does a pharmacist know?" Is the pharmacist held responsible if he fills a prescription that the physician has written, even though the physician should not have written it that way?

MR. BRANDT: Yes. The pharmacist always is responsible not only-- He has a license from the Board of Pharmacy, and there are laws that govern our dispensing habits, not really habits, but performances. We also have a major problem with the fact that as you know, managed care is expanding very rapidly to the point of practically being 100 percent. And they can very well come into a pharmacy and say, "This prescription here was filled

for 200 Percocet or 200 whatever. How do we know this patient has chronic pain?" I don't know. I mean, call the doctor. "Well, I'm not going to call the doctor. We're going to take the money back, and then, you prove it to us that that person is--"

ASSEMBLYMAN THOMPSON: But I'm saying, if a physician has written it for 200--

MR. BRANDT: Yes.

ASSEMBLYMAN THOMPSON: --and you fill it, you are responsible even though the physician should not have written it for 200.

MR. BRANDT: That's correct. We are always responsible, and we don't know the way it -- the law says right now. We don't know whether that is a legitimate prescription in terms of the quantity. That the patient may be legitimate, the doctor is legitimate, but how do we know that his writing and 200 is legitimate because we don't have privy to his information. He may be going into pain management protocols and do the necessary documentation, but we cannot look at that. We don't know. How do we identify these people?

ASSEMBLYMAN THOMPSON: Thank you.

MR. BRANDT: Yes.

DR. CORDA: Does your responsibility lie into notifying the physician if you think that's it an exorbitantly large amount of medication? Is that where your responsibility or your liability lies? In other words, if you do not know this information, this information can be brought to you by calling that physician and delaying maybe giving that prescription. Is that true or not?

MR. BRANDT: That's correct.

DR. CORDA: Okay.

MR. BRANDT: We could call the physician, and we do many times.

DR. CORDA: Right.

MR. BRANDT: The problem is many times the doctor is not around for whatever reason and that creates a problem for us.

DR. CORDA: Right.

MR. BRANDT: The patient is in pain. You can say, "Well, I'm sorry, but I have to get hold of the physician." But again we monitor everything, and pharmacists are notorious for knowing and protecting the public. We are interested in one thing only, the patient. We want to make sure he's treated properly and that drugs like this don't hit the street. And I can tell you, it's out there, and that's a major problem for us. And then we're held liable because we dispensed it.

DR. CORDA: Right. Now does the-- I believe the computer network of controlling-- In other words, do you have access to know if this patient had prescriptions from another pharmacy?

MR. BRANDT: No.

DR. CORDA: You don't have--

MR. BRANDT: No, only if it's a managed care prescription -- a third-party prescription. If it's a cash prescription, the answer is no.

DR. CORDA: So you don't have that access?

MR. BRANDT: No. We don't know that.

DR. CORDA: I understand.

MR. BRANDT: Only in like -- if--

DR. CORDA: The managed care.

MR. BRANDT: Yes.

DR. CORDA: Because I know we get reports from managed care from different providers that have given the same type of medication--

MR. BRANDT: That's correct.

DR. CORDA: --the same class of medication, and if the patient is going from one provider to another provider.

MR. BRANDT: Yes, but remember also they may not go and give their card every time.

DR. CORDA: That's right.

MR. BRANDT: So, I mean, they're doing too many loopholes. So we are fully aware. The cash patient -- that's what I said -- they can jump from one pharmacy to another, and we wouldn't know. So there's a problem.

ASSEMBLYWOMAN VANDERVALK: Yes, Doctor.

DR. GOLDBERG: Can you write an unlimited amount of pills?

MR. BRANDT: Can you write what?

DR. GOLDBERG: An unlimited amount of narcotic pills by this law?

MR. BRANDT: No. Recurrently?

DR. GOLDBERG: Right.

MR. BRANDT: No. It's 30 days or 100 units, whichever is less.

DR. GOLDBERG: So there is a limit?

MR. BRANDT: There's a limit right now, except for this new regulation pertaining to terminally ill and--

DR. GOLDBERG: Which is either 30-- It's a 30 day--

MR. BRANDT: Thirty days, period.

DR. GOLDBERG: Period.

MR. BRANDT: Yes. No limitation. You can go up to 400--

DR. GOLDBERG: So there is a limit. You cannot write--

MR. BRANDT: --500, whatever you want.

DR. GOLDBERG: Right. But whatever that constitutes, as a frequency dose, for the 30 days.

MR. BRANDT: That's correct.

DR. GOLDBERG: You can't write over the 30 days.

MR. BRANDT: That's correct.

DR. GOLDBERG: So that everyone's clear on it.

MR. BRANDT: In other words, if it's 10 a day -- 300. Twelve a day -- whatever.

DR. GOLDBERG: Are there other states in the country that have similar, different--

MR. BRANDT: Well, you have to remember, sir--

ASSEMBLYWOMAN VANDERVALK: Yes, it varies--

Excuse me.

MR. BRANDT: I'm sorry.

ASSEMBLYWOMAN VANDERVALK: It varies from state to state, and when we examined that legislation before it became law, we did look at what other states were doing. The American Cancer Society wanted all limitations off, and we did put some limitations on to the extent that it's a 30-day supply and it has to be documented in the doctor's and physician's

records. But other states do have-- There are some states that have no limitations.

MR. BRANDT: Well, not-- Excuse me, Chairperson. There's a Federal law which does not permit more than 30 days. So the Federal law would apply. The states cannot overrule that -- the more stringent law exists. So in other words, even if the state does not rule, the Federal law supersedes the state, and this can only be a 30-day supply.

ASSEMBLYWOMAN VANDERVALK: Okay.

MR. BRANDT: I'm sorry. I didn't mean to--

ASSEMBLYWOMAN VANDERVALK: No. I was--

MR. BRANDT: It's a Federal law, too.

ASSEMBLYWOMAN VANDERVALK: I have a different memory of it, but if you're sure, then I accept it.

MR. BRANDT: Yes. No. I'm sorry. I didn't mean to--

ASSEMBLYWOMAN VANDERVALK: No. It's quite all right.

ASSEMBLYMAN THOMPSON: So you're saying the state could make it a shorter time period if they wanted, but they cannot make it longer than?

MR. BRANDT: Correct. But that's what New Jersey has done. But the Federal law only says like this -- 30 days. But the states decide whether they want to go over 30 days only or a limit of 120 tablets, and many states did that. Obviously, for obvious reasons, and that is, there are many areas, especially the metropolitan areas such as New York, Philadelphia, and so on -- cities -- where drug abuse is so abundant that they figure that 120 would be a limit.

ASSEMBLYWOMAN VANDERVALK: Yes.

DR. KRAUSER: One comment. I think it's Schedule II drugs--

MR. BRANDT: That's correct.

DR. KRAUSER: --that have the 30 day. But, also, I was going to ask you, I have that patient with the bad arthritis who needs a certain amount of medication to get through the day. Would it help you if I included with that prescription a little note about my rationale that she is functional, as long as she gets her medication?

MR. BRANDT: As long as you do your job as far as documenting is concerned and you are willing to let us know, the answer is yes. But you run into -- sometimes into confidentiality problems that nothing could be legislated saying you have to do that.

DR. KRAUSER: No. No. But I can say to the patient--

MR. BRANDT: But if you do it on your own, there's no reason why you can't. Oh, absolutely, yes.

DR. KRAUSER: --you know, I'm going to send a note to the pharmacist to--

MR. BRANDT: Sure. Sure.

DR. KRAUSER: --get him as part of the team so that--

MR. BRANDT: Sure.

DR. KRAUSER: --he understands why you're taking all this medication.

MR. BRANDT: Absolutely.

DR. KRAUSER: Most of the patients don't have any problem with that.

DR. GOLDBERG: Are you aware of any data that suggests that by having more pills being dispensed that there's any more illegal or aberrant use of prescriptions?

MR. BRANDT: Yes. Well, data, no because, thank God, we didn't have that rule in New Jersey, so I can only speak for New Jersey.

DR. GOLDBERG: But there are other states who have--

MR. BRANDT: Yes.

DR. GOLDBERG: --more liberal policies.

MR. BRANDT: Knowing the way the drug abuser works, he's so smart that you don't even know half the time that the prescription is fraudulent. They write so well. They write for quantities. They write like a doctor. And, yes, with this, I feel that the increase of the number of tablets on these so-called forged prescriptions will increase because the pharmacist now has a quandary. What is he going to do? Is this legitimate? Well, you know, there are a lot of people now going to get 200 pills. Well, so it's 100. Well, you're not going to question that.

DR. GOLDBERG: From my understanding, there's no data supporting the fact that there's more illegal use and more diversion of those medications as the pill count increases.

MR. BRANDT: You don't have any data?

DR. GOLDBERG: There isn't any.

MR. BRANDT: Well, I-- Let's put it this way, you don't have any data to prove and I don't to prove differently.

DR. GOLDBERG: Well, we do. We met with the DEA who -- and the CDS who do monitor that. Their contention is there is no evidence for any further diversion as the pill count increases.

MR. BRANDT: I would take that under advisement. I'll check into that.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. MR. BRANDT: Thank you very much.

ASSEMBLYWOMAN VANDERVALK: Dr. Harry Collins, from the New Jersey Academy of Family Physicians.

HARRY COLLINS, M.D.: I'm Dr. Harry Collins, representing the New Jersey Academy of Family Physicians. I'm a family practitioner in Edison. I'm also President of Middlesex County Chapter of the New Jersey Academy of Family Physicians. And as part of my background, I have certification in family practice and a CAQ in geriatrics. And, also, my undergraduate background was in pharmacy. Presently, I'm the Director of JFK's Haven Hospice Program, and I've been the Medical Director for the past eight years since its inception.

And in hospice, we know -- in our hospice program it appears that well over 90 percent of the patients get good pain control. I'm not saying adequate pain control, I'm saying good pain control. However, this cannot be spread to everybody who has pain. This is a limited number of patients. And, unfortunately, patients are living in pain and they're dying in pain, and the patients have a right for pain comfort.

One big problem is where to go, who to see, and what treatments. There are many people out there treating pain. There are many treatments out there, and it appears at the present time a lot of this is inadequate.

I have some personal experience with pain. I had sciatica for a year, and fortunately, I'm recovered, but I know what it's like every morning to get up and expect to be in pain. And fortunately I recovered, but there's many people there who have not.

There's many fears regarding treatment of pain. There's the fear of addiction on the patient's part. There's the fear of cost. The fear of loss of control, and the fear of being labeled as a druggie. Also, there's the same thing on the doctor's part. The doctor's fear of being labeled as a dispenser of medications -- a druggie. Lack of knowledge on the physician's part, and also, the fear of addicting the patient.

Regarding prescriptions, I think it's very important that the patients in pain can get adequate prescriptions, adequate medications, and adequate number of medication. It sometimes is very difficult for a patient in pain to come into the office frequently. And it's very important that -- for them to have enough pain medication at home. Certainly there's room for communication with the pharmacist. We're getting calls from pharmacists every day in our office. We're getting calls from prescription plans every day, and we have no problems talking to pharmacists. We're happy to talk to them. I think working as a team effort we can treat the patients who are seriously in pain and maybe weed out the rare patients who's really abusing medication.

Who is the best person to provide pain management? There's many people out there doing this. I feel one of the best people are the family practitioners. We're trained in a broad-base medicine. We're trained in the psychosocial aspect. We're trained in the pharmacology of drugs. We take care of patients from so-called cradle to grave. We take care of them as babies, we take care of them growing up. We know the family. And it's very helpful for the family practitioner to be involved in this. In fact, we're actually by managed care the so-called gatekeeper or the quarterback. The patients often have to come to our office first to get referrals before going elsewhere.

So to me it seems obvious that the family doctor should be the quarterback, the gatekeeper, the one managing the care. A lot of the care we can't provide. We can write prescriptions, but we can also send people for physical therapy -- different other types of therapy. There's Reiki. There's a whole host of other therapies other than medications, but I think we can be very helpful in this respect.

Patients need access. Patients need education. There's too many patients walking around in pain with a dismal outlook -- the fear of addiction, the patient's fear, the doctor's fear. I think a lot can be done. I think this is a very good opportunity with this Committee (*sic*) to address these issues. In summary, the patients have a right for comfort. Most patients are not seeking drugs. It's a rare patient, I feel, coming into my office seeking drugs. The patients are seeking comfort, and they're entitled to comfort.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. Thank you. You're off the hot seat. (laughter)

Mary Wachter, Director of Legislative Affairs for the New Jersey State Nurses Association.

MARY B. WACHTER, R.N.: Which one of these mikes works? (referring to both microphones)

ASSEMBLYWOMAN VANDERVALK: I think both, just-- It will carry.

MS. WACHTER: Good evening. My name is Mary Wachter, and I am Director of Legislative Affairs of New Jersey State Nurses Association. We represent the interest of the nurses here in the State of New Jersey of which there are 110,000 registered nurses in New Jersey currently. I have a background in nursing. I am a nurse, and I have worked clinically at Cooper Hospital/University Medical Center in the intensive care unit there and continue to practice part-time. However, I am full-time now involved in health policy issues as a lobbyist for the New Jersey State Nurses Association. I wanted to let you know that this past March we passed a resolution -- our membership did -- to help to educate nurses better on pain management and to start to try to address some of the issues and do what we can, as a nurses association.

So I say to you, this Commission, that if there's anything that we can do that you come up with, please, consider us a viable stakeholder that might be able to carry out some of your recommendations. One point that I do want to bring up that is oftentimes considered a turf issue -- and coming from the Nurses Association, of course, where it's going to be taken as a turf issue -- is the issue of advanced-practice nurses here in the State of New Jersey, which are considered nurse-practitioners, clinical nurse specialists, according

to the statute, who are right now unable to prescribe controlled substances. They are, however, able to prescribe controlled substances with a collaborative relationship with a physician, which requires some protocols to be in place. And what we are looking to do with legislation that we have introduced is to expand that to include the controlled substances prescribing for Schedules II through V with the same collaborative relationship with a physician.

Most often, in this state, nurses practice have been in collaborative relationship with physicians in specialty areas. This issue was brought to our attention when the oncology nurse-practitioners in clin specs in the state came to us and said that, you know, frankly, we should be able to prescribe these medications. We have patients that we see in clinics, and so on, and so forth, and we know what medications they probably need. They need to renew whatever pain management drug they're on, and we have to run and find a physician to fill the prescription, and sometimes they're not available.

Now apparently, it's been brought to our attention, as well, that, yes, you can fax prescriptions in; yes, you have emergency doses that you can have for 48 hours; but the fact of the matter is that these are appropriately educated providers of care in the state that has been shown in 19 other states that have this prescriptive authority that it is safe. I have tons and tons of data on this. I would just like to ask this Commission to truly look at the issue of increasing the number of prescribers that are appropriately educated and to ignore the issues of -- or maybe to at least not have in the middle of the discussion the position of organized medicine, which is going to constantly oppose this. Because like any special interest, their point is to protect the special interest of their members. We are certainly to blame for that, as well.

But, anyway, it was our hope from the Nurses Association that this Commission could truly look at this from an objective standpoint. I think that in all of the policy review that I've done in my graduate work on pain management policy, it is certainly a policy alternative that has been considered. And in states that have done it, it has seemed to -- although I don't have any data to support that -- at least help to increase the access to pain management for patients that come to their primary-care providers or their specialist oncologists, and so on, and so forth.

I would certainly entertain any questions that any of you may have. I unfortunately have not submitted written testimony; however, I can get you mounds of it on this issue, if you want it, and would be available for questions.

ASSEMBLYWOMAN VANDERVALK: Is there anyone from the panel?

DR. AISNER: How do you discriminate the background training between clinical specialists and nurse-practitioners because there is a considerable difference in the--

MS. WACHTER: In their role.

DR. AISNER: Well, not only in their role, but in their prescriptive training.

MS. WACHTER: The way the New Jersey Board of Nursing has regulations -- and there are statutes that the New Jersey Legislature passed in 1992 that speak to the issue of minimal education requirements -- they must be board certified in their specialty. They do have to receive-- I believe, it's three credit hours of graduate pharmacology course work, which according to

the University of Medicine and Dentistry's pharmacology hours of didactic pharmacology education, it comes out to be 90 hours, which in the -- compared to the didactic hours of clinical pharmacology for physicians at the medical doctor level are 122 hours. So there are regulations that are in place. I have an entire white paper that speaks to the issues of the educational qualifications of advanced-practice nurses and what is minimally required, according to the State statutes and regulations.

DR. AISNER: No, that doesn't address the question I asked you. In the 19 states or so that have open prescriptive authority to nurses, how many of those have limited the scope in terms of the background training of the nurses?

MS. WACHTER: How many have limited the scope?

DR. AISNER: Sure. Because not all of them have opened it to clinical specialists, and I can rattle off four of the nineteen states, which only the nurse-practitioners would have that authority.

MS. WACHTER: Oh, okay, I see what you're saying. Yes. I don't know that information off the top of my head. Certainly, it is a problem of the nursing profession that we have an umbrella title of advanced-practice nurses, and then under there you have nurse-practitioners, clinical nurse specialists, certified registered nurse anesthetists, nurse midwives. And so, granted, all those different types of providers of advanced-practice nurses. Some clinical nurse specialists are not granted prescriptive privileges in some states and some are. So I see what your point is, which is, not all clinical are specialists. It's the way that we decided to draft our legislation back in the late '80s, early '90s.

Clinical nurse specialists decided they wanted to be part of that advanced-practice legislation, certified registered nurse anesthetists did not want to at that time, and certified nurse midwives had had legislation on the books in the past and decided they wanted to be under the Board of Medical Examiners, where they've been since.

Yes.

ASSEMBLYWOMAN VANDERVALK: Excuse me, if you could get me something in writing on that, I'd appreciate that.

MS. WACHTER: Okay.

ASSEMBLYWOMAN VANDERVALK: Because I won't remember that.

MS. WACHTER: Okay.

ASSEMBLYWOMAN VANDERVALK: Go ahead.

DR. CARR: That was my question, too. Could we get the data from the 19 states--

MS. WACHTER: Yes.

DR. CARR: --to which nurses are allowed to prescribe?

MS. WACHTER: Yes, and actually Florida did a multidisciplinary study at the request of the Florida Legislature because apparently -- I don't remember the reason why this came to light and why the Legislature commissioned this report, but it was made of all pharmacists, medical society representatives, nursing representatives, so on, and so forth, that did a full study that's about this thick (indicating) -- and I will certainly get copies for everybody here -- on the prescribing of controlled substances among advanced-practice nurses in the country.

So that information has already been finished, and I can get you copies of that.

ASSEMBLYWOMAN VANDERVALK: Thank you.

Yes.

DR. KRAUSER: Mary, what has the Nursing Association done to get the protocols going? The 19 states that do have it have some pretty tight protocols, and we haven't established ours from six years.

MS. WACHTER: Some do, right, and some don't. And it was actually in dialogues that I've been in on with physicians who use nurse-practitioners or clin specs. They truly say that they really don't want a whole lot of the Board of Medical Examiners, the Board of Nursing, telling them what their collaborative relationship must be and what their protocols must look like. There is debate about the fact that the Board of Medical Examiners and the Board of Nursing in New Jersey were supposed to come to some agreement on the guidelines of protocols between those two providers. And it was the intention of the statute -- was that they would be just purely administrative protocols.

The Board of Nursing drafted proposed guidelines, sent them to the Board of Medical Examiners, who has yet to do anything with them. This topic was brought up, specifically, at either the last Board of Medical Examiners meeting or the one prior to that. And it's my understanding, although I was not present, I haven't reviewed minutes -- is that a lot of the membership has changed and a lot of the people who were on there didn't even remember getting those guidelines. So it was like, okay, we'll go back in the minutes, we'll try to get what they had, and then we'll review them again.

Certainly, I'm sure that issue was brought to light because of this legislation and the issue of where are the protocols and what do the guidelines look like, and so on, and so forth.

To our knowledge, there has not been any problem with the prescribing of drugs that are in the noncontrolled category in the State of New Jersey since this has been enacted and it really-- Although the legislation passed in '92, the regs weren't completed until '94. So this has been about a four-year process.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

Dr. Ira Klemons, President of the American Board of Head, Neck and Facial Pain.

IRA M. KLEMONS, D.D.S., Ph.D.: Good evening. My name is Dr. Ira Klemons. I'm President of the Board of the American Academy of Head, Neck and Facial Pain and represent not only our organization, but in addition, the American Alliance of TMD Organizations, which there are approximately 12,000 members throughout the United States and around the world. The vast majority of the members of our Academy are dentists who treat head and facial pain and temporomandibular joint, or jaw joint, disfunctions.

Over the past 26 years, I've evaluated approximately 16,000 patients most of whom suffered trauma, which was the source of their pain and disfunction. In some case, they remained in pain from 10 to 40 or more years before being referred to us for treatment. In other cases, their pain resulted from a more recent accident. Our success rate is documented at approximately 90 percent regardless of the complexity or chronicity of their problems.

I'm here this evening to express our great concerns regarding the negative impact which managed care has already had and automobile insurance is likely to have in the future with respect to our ability to alleviate extraordinary pain and suffering of thousands of New Jersey citizens. Our patients commonly suffer from a wide array of severe and often debilitating pain syndromes including excruciating headaches, face pain, eye pain, ear pain, dizziness, difficulty swallowing, ringing in the ears, and in many cases, difficulty eating.

These conditions are known to affect a significant proportion of our population and, to a much higher degree, the majority of individuals who have been involved in motor vehicle accidents and suffered neck injuries, even without direct impact to the face or jaw.

Our great concern relates to the fact that at this time in the history of medicine and dentistry, the vast majority of individuals who suffer from these conditions can be treated and have their pain alleviated using devices and techniques which are virtually without side effects. We are terribly concerned, however, that while to date managed care has already managed to eliminate care for a major proportion of individuals whose suffering could otherwise be stopped, auto carriers may soon have the legal leverage to strangle our ability to help those whose conditions result from motor vehicle accidents.

For years in the past and as we speak, certain insurance carriers have been so arrogant that they delayed payment for years at a time or refused payment altogether for treatment which successfully reduces or eliminates pain.

It is common practice to use so-called "independent medical examiners," or IMEs, many of whom have minimal knowledge and little or no experience in treating these conditions. Yet, the carriers use these examiners on a regular basis to obtain denial reports. Attached to your copy of this testimony is a judicial decision in a PIP lawsuit -- that is a lawsuit against an auto insurance carrier -- brought on behalf of a woman who suffered multiple facial fractures in an automobile accident. These fractures resulted in a separation of her nose and upper jaw from her skull, cheekbones, and eye sockets. Her face was reasonably repaired with steel plates and screws, which she will wear for the rest of her life. Yet, the insurance company's "independent examiner," who has at least 30 years of experience writing reports denying the need for treatment, told the carrier not to pay on the grounds that her condition somehow preexisted the accident.

The judge in the subsequent PIP suit was clearly furious, as you can see from the attachment that I've given you, but the insurance carrier well knew that the worst outcome for them was that they would ultimately have to pay the cost of treatment, which they should have properly paid years before. When confronted with this decision and numerous other complaints, to the best of our knowledge, our State agencies have not responded in any meaningful way.

One IME who works for insurance companies both in New York and in New Jersey has admitted under oath to denying treatment for 4000 patients in a row. Just across the Hudson River, the Office of Professional Discipline in New York instituted proceedings to revoke his license to practice because of the fraudulent reports which they believe that he has provided and

for their lack of scientific basis. I know because I was asked to be the expert witness for the prosecution. At his hearing, he boasted -- and I underline the word <u>boasted</u> -- that every one of the complaints filed by injury victims in New Jersey was dropped; and thus, he continues to earn many thousands of dollars for his reports, which uniformly deny treatment to New Jersey injury victims.

The *New York Post* printed an exposé revealing a small part of the outrageous activities which abound in the virtually unregulated IME industry. A copy of the exposé is attached to your handout. We sincerely hope that this Commission will help resolve the IME problem.

We are also concerned that the protocols established by the new PIP insurance law will make it far easier to deny necessary and useful diagnostic and treatment procedures. We suggest that this Commission should have direct input into the decisions being made by the Commissioner of Insurance on the testing, treatment, and services, which will be covered under the new PIP regulations. Please keep in mind that trauma patients with complex chronic pain are not similar to patients seen on a daily basis by most physicians and dentists. Decisions regarding the most appropriate protocols for treating pain patients should be made by those who treat patients with trauma-induced pain, especially complex pain patterns every day. I myself am ready to assist this Commission in this area.

While the field of pain management is growing and improving every day, especially in the field of head and facial pain and TM joint disfunctions, it is probably that without input from practitioners with experience treating chronic pain, the citizens of New Jersey will not have access to the current level of quality care and, even worse, will not have access to the advancements which we looked forward to in the future.

We respectfully ask that the New Jersey Legislative Commission for the Study of Pain Management Policy do everything in its power to allow New Jersey citizens to obtain proper pain management treatment without the encumbrances which now exist for pain management practitioners.

Thank you very much for the opportunity to speak, and I would be pleased to answer any questions.

ASSEMBLYWOMAN VANDERVALK: Thank you.

Dr. Ashendorf, I don't know if you have any questions, but I know you had raised the issue that we really should be talking to the Department of Banking and Insurance to see if we can have some input as they formulate their regs.

DR. ASHENDORF: Yes. Dr. Klemons, perhaps you might want to add what the state of development of diagnostic and treatment protocols is in your field at the moment -- at what stage of development.

DR. KLEMONS: Well, I believe that the stage of development that we're at, at this point is truly-- We're truly at the point where the vast majority of those who suffer from head or facial pain where it's not due to a true neurological cause, that is, a brain tumor, a direct injury to the brain, infection in the brain, in the spine, and so forth -- which amounts to a very tiny proportion of people who suffer from headaches and facial pain-- The vast majority of those who do not fit into that 1 percent to 3 percent category can be relieved of pain and almost always without risking side effects from extensive medication or surgical procedures that have known side effects.

Some of the procedures which we perform are similar to those used in medicine in general, but they have some nuances which are a little bit different and while— Just for example, surface EMGs have obtained or caused a great deal of discomfort in the insurance industry for their use in certain parts of the body. We have no alternative but for using surface EMGs. We don't use needle EMGs for our purposes. And so we're concerned that because the insurance industry dislikes that procedure so much that we will lose the ability to make use of it for head and facial pain, even though we have no other alternative.

ASSEMBLYWOMAN VANDERVALK: Would you elaborate on the EMGs?

DR. KLEMONS: There are two basic types of EMGs. There are those which are -- involve the use of needles which are placed into the neck and down into the arms or down the legs or in the back, and commonly, specialists in physical medicine and rehabilitation, such as Dr. Ashendorf, or neurologists are the experts on that. I am not an expert on-- And certainly he would be able to give you all of the appropriate details on those types of tests.

Surface EMGs do not involve insertion of needles into the body. What's used is an electrode which is connected to the skin in various areas to measure electrical activity in the muscles. These are used in some cases by certain practitioners evaluating neck and back and extremity pain, I understand, but we use it specifically to measure the amount of electrical activity in muscles of the head, face, and neck, and especially head and face, so that we can objectively evaluate the probability that spasm is a factor, since bioelectrical activity does relate to the amount of spasm in a muscle, and also,

allows us to measure the relationship between the electrical activity in different muscles to evaluate disfunction in those muscles.

This is enormously helpful in, number one, objectively confirming that a person who claims to have a pain problem truly does, and secondly, helps us direct our attention to the specific muscles that are likely to be the primary sources of the pain very early on. Because the brain and when the body is involved in referral of pain, that is, pain is actually coming from one place and felt in another— Just for example, most all of you— probably everyone is familiar with the concept of people having heart attacks and the pain is all felt in the left arm. It's never felt in the right knee, for example. And so every muscle in the body can refer pain to other areas.

When we're evaluating a patient for a pain problem, one of the things that we do is look for which muscles and ligaments and tendons and joints are the probable source of the pain that the patient is feeling. EMGs give us an objective basis for doing that.

ASSEMBLYWOMAN VANDERVALK: Thank you.

Anyone else on the Commission? (no response)

Thank you very much.

DR. KLEMONS: Thank you.

ASSEMBLYWOMAN VANDERVALK: Saul Liss, President of MEDI Consultants.

SAUL LISS, Ph.D.: Thank you, Madame Chairperson, for inviting me here, and I'd like to introduce myself. I'm here to talk about energy medicine. I'd like to just introduce my credentials. I'm a Ph.D. in biomedical engineering, and the work that my brother and I have done over the last 24

years includes getting 26 patents in areas from arthritic pain control to multiple sclerosis, cerebral palsy, and dental applications. We have five authorizations to market product from the FDA on chronic, acute, and postoperative pain, as well as depression, anxiety, insomnia, as well as dental applications of restorative procedures without the use of novocaine -- TMJ pain control, as well as muscle relaxation.

We also have 23 peer-reviewed published studies on topics from body pain, headaches, depression, cerebral palsy, spasticity reduction, learning disabilities, dental applications, closed head injuries, and other scientific topics like biochemical effects. We have developed and distributed products over the last 24 years that have helped over 50,000 people.

The uniqueness of our technology as a form of energy medicine lies in the fact that we have learned how to do something that can have an impact on altering the level of serotonin, beta-endorphin, cortisol, ACTH, GABA, and DHEA. We have CSF measurements on serotonin and beta-endorphin, having them rise, and there's also a rise in serotonin in the blood plasma, beta-endorphin, ACTH, GABA, DHEA, and a decrease in cortisol. I don't have to tell this august body what the purpose of all those biochemicals are. So I'll just pass that part by.

I urge you to look at the area of senior care in your pursuit of the pain management problems that you're assessing because I think we have an opportunity to look at the seniors and reduce their pain, reduce their depression, and have a chance to reduce the need for their entering the nursing home. And with the techniques that we are using with the electrical techniques to enhance the levels of these biochemicals, you can, in many cases, reduce the

need for medication or enhance the body's response to the medication. It's as if we can now have the body respond better to the medication and, therefore, reduce the dosage and reduce the side effects. Reduce the side effects and it's win/win for everybody all the way home. And this is based on the fact that it takes anywhere from five millivolts to ninety millivolts to have a signal cross the synapse. And when you don't have that level of voltage to cross the synapse, a signal will not go part way, it will not go at lower intensity. It just won't go.

What we have learned how to do is how to use our particular wave form to utilize the bulk capacitance of the body that will now facilitate the generation of an internal current that increases the triggering energy to make the body respond more readily to these biochemical changes.

So I urge you to give consideration to the last gentleman, Dr. Ira Klemons, who was talking very seriously and very directly about the response of the insurance companies to reimbursement and that it is also an issue with energy medicine because there is a complete lack of understanding in the insurance company, as a whole, as to what does energy medicine mean and how can it help to reduce the cost and improve the quality of life of these people. And I urge you to please make that a strong topic of your consideration because we're all here to help reduce the pain of people.

I've pointed out a particular area, and there are some other areas like diabetic neuropathy where Dr. Everett Coop indicated that in this country, 98,000 legs are amputated a year at a cost -- an average of \$23,000 per leg. Over \$2 billion is spent there. We have already with some of our equipment saved 7 legs from amputation. I urge the Commission to consider looking into

this area both for saving money, helping improve the quality of life for the people, as well as the families surrounding those people with a diabetic condition.

So, as a conclusion, I just want to offer our own experience and our own support for your important work. And if you will give me the opportunity of giving you that support from our experience, it would be our pleasure to do so. I thank you very much for your kind attention.

ASSEMBLYWOMAN VANDERVALK: I was just wondering, you mentioned diabetes. What else do you feel that your machine is effective on?

DR. LISS: Well, I'd like to say that anywhere that those biochemicals of serotonin, beta-endorphin, cortisol, ACTH, GABA, and DHEA are important would be benefitted. The aspect of serotonin is such an important one that includes everything from migraine headache, depression, anxiety, insomnia, bulimia, anorexia, as well as certain multiple sclerosis and cerebral palsy aspects. We are actually facilitating -- creating a window of opportunity. You can, in fact, use our equipment for 20 minutes and then wait 20 minutes while the biochemicals rise to their full extent and then have a four-hour period during which secondary therapy can have maximal benefit. So that the physical therapy that would be added after the use of our equipment could then have more of an effect.

In learning disabilities, which is nothing related to pain, but just as an example, 12 weeks of treatment with this device in conjunction with a computer-aided learning facilities was able to improve reading comprehension and math comprehension for 22 months in a 12-week period, and that's rather extraordinary.

We have helped people die in peace without the use of morphine at the end. For the good people who are working in the hospice area, which I commend, obviously, this is an area of keeping people more functional and not doped up so that they're just zonked out. You can actually have them more lucid along the way and have a higher quality of life for whatever time they have, and that's what happens.

ASSEMBLYWOMAN VANDERVALK: What are the side effects? DR. LISS: The side effects are a slight irritation on the skin on those people with fairer skin and very little else. You can, in fact, have, if you use our device transcranially -- can have an effect on reducing blood pressure so that the physician in charge must always know whether the patient has blood pressure problems and adjust the -- titrate the blood pressure medication appropriately. And if a person is on Coumadin, we have a monopolar device that increases blood flow, and therefore, a physician would have to know to be careful about the use of that when you're increasing blood flow on somebody with a blood thinner in them. But that's about it. These are very benign side effects compared to what the heavy-duty drugs are giving.

I would need to just put it on the table and say my understanding of what the general response on drugs is that they do a very good job. If the drugs do a very good job, then by all means use it. It's easy to do. For I suspect that it doesn't work on 100 percent of the people, and the people for whom the drugs don't work, and the people for whom there are interaction among several drugs, as you would have in a fibromyalgia case, where you have the multiple symptoms of the depression, the insomnia, the malaise, the pain sensitivity in 11 out of 18 positions, frequently those poor patients will get a

handful of drugs like Prozac and Ativan and Naprosyn and Darvocet, and the interaction of those drugs in that particular patient zonks them out and puts them to sleep for seven hours a day. So I offer that there is absolutely a place for drugs -- no question about it. And if that's the easy way to deal with the patients, by all means do it. But the rest of the people for whom the drugs don't work or the rest of the people for whom there is an interaction among the drugs, they deserve a chance, too.

And I pose to you that energy medicine is, in fact, backed up by the peer-reviewed studies that everybody's looking for, and you'll have a little sample in the little blue folder that I volunteered to put at everyone's place. Next week we're going to have a test on that, so I'll hope you'll read them. (laughter)

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

ASSEMBLYWOMAN VANDERVALK: Gary Stocco, Vice President, National Burn Victim Foundation.

G A R Y S T O C C O: Good evening. Just some background on myself. I'm a former State Police Officer in New Jersey here and a pain patient, as well. I'm retired due to my injuries in a MVA. I'm actively involved in research into pain -- in burn pain. I'm the Vice President of the National Burn Victim Foundation, and I'm the first nonphysician appointed to the American Burn Association Ethics Committee.

I see burn every day -- burn injuries every day in hospitals throughout New Jersey in children and adults. For most people that are unaware, the majority of burns that are treated in New Jersey are treated in local hospitals and not at a burn unit. I certainly have some research

documents that back that up. And that is, across the United States, when I see these patients in the hospital, most, probably 90 percent of them, complain, in reviewing of the medical records and talking to the practitioners, of discomfort, pain, anxiety, and it seems that it is continually not managed appropriately and there is not enough education of the physicians at the community hospitals or the other settings to manage burn pain, which is unique within itself.

And I'm sure that the folks on the Commission here certainly understand that that burn pain is unique and it is very difficult to manage. And I think that should be looked at and there should be representation on the Commission possibly by a burn-care practitioner or someone who is very involved in burn pain management.

Additionally, as being a chronic-pain sufferer for a number of years and going through a cross amount of disciplines from chiropractic to acupuncture to you-name-it and not seeking relief, I think that the Commission might also look at guidelines for primary-care practitioners in setting some type of time frame in which these practitioners should make a referral to a qualified expert in the management of chronic pain.

I, speaking for myself as well as a lot of other individuals in groups that I've been in, recommend that. By being bounced around, it certainly only makes things worse. I think there certainly needs to be more education and possibly guidelines for primary-care practitioners to refer to the appropriate people and not just have these people suffer because of lack of knowledge and education in the management of pain.

I conclude with my comments and certainly would like to answer any questions.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

MR. STOCCO: Thank you.

DR. AISNER: I have a question.

ASSEMBLYWOMAN VANDERVALK: Oh, I'm sorry.

DR. AISNER: Do you think the biggest barrier to refer-- Do you have any other catalog of barriers to referral to appropriate management? Is it just education, or do you have something else that you'd like to catalog in that regard?

MR. STOCCO: Well, I think that for primary-care practitioners that are seeing patients in their practices every day, whether it be someone is suffering from a MVA or orthopedic injuries or whatever the origin, that they need to know of the resources that they can refer a patient to. Now with managed care, I know that it is quite difficult to have pain management covered, as a referral base, and I see that specifically with burn patients every day. People suffering with this awful burn pain continually are not managed appropriately due to lack of knowledge, lack of education, lack of the appropriate resources and support mechanism in team approach to managing the pain. And certainly, I think that the majority, if not all, of the Commission members would agree that the team approach to the management of pain is the optimum goal to conquer that and to relieve the consequences of the original injuries and let someone get back to if not their previous functioning abilities, at least to a manageable, functional state so they can get through their daily living activities.

Additionally, if I may, maybe it should be the Commission's -- or in the review process of potentially appointing to the Commission a pain patient, whoever that may be, so that they can relate from the other side, not from the medical end, of what actually someone has gone through, what obstacles they have gone through, and I think that that would be a beneficial asset to the Commission.

ASSEMBLYWOMAN VANDERVALK: Doctor, did you have a follow-up?

DR. AISNER: No. Thank you.

ASSEMBLYWOMAN VANDERVALK: Well, thank you very much.

MR. STOCCO: Thank you.

Shams Qureshi, Dr. Qureshi? (wrong witness approaches to testify)

ROY C. GRZESIAK, Ph.D.: Hello.

ASSEMBLYWOMAN VANDERVALK: Hello.

DR. GRZESIAK: I've gotten to an age where I can't see a thing without these. (indicating reading glasses)

ASSEMBLYWOMAN VANDERVALK: I know the feeling.

DR. GRZESIAK: I know.

I'm a clinical psychologist with 25 years of pain management experience under my belt at this point. Currently, I am Clinical Associate Professor of Psychiatry at UMDNJ-New Jersey Medical School. I'm Consulting Psychologist to the New Jersey Pain Institute, which is

UMDNJ-Robert Wood Johnson, and I'm Director of Psychology for the Forensic Burn Unit of the National Burn Victim Foundation.

There are three areas that I would like to address: the first two mesh with each other; the third is separate. In contemporary pain management these days, debate continues over the appropriateness of prescribing narcotic medications, narcotic analgesics for nonmalignant pain. Actually, my oncology friends tell me that cancer pain is also undermedicated.

The issues appear to be addiction and function. Let me use a brief example of a man I evaluated perhaps six weeks ago -- in his 50s, multiple orthopedic problems, been tried on many medications. His primary physician decided to put him on MS Contin, which is morphine sulfate continuous release. For two solid years, this man functioned on two pills a day. He went to work, he raised his kids, acted as a parent, as a husband -- a good deal for him, he could function. Then his primary physician got scared. I'm not sure if he was afraid of addiction or if he was afraid of the regulatory agencies. So he did what any outstanding physician would, he turfed the patient to a tertiary center, let our group prescribe for him.

I think the important point here is this man functioned, and he was on a two-year, nonaccelerating dose. He was not addicted. There is a growing sense in the pain management community that we need better parameters and more latitude in the use of opioids in the management of noncancer pain. There is also a growing body of evidence that psychosocial, not biologic, factors are what determine who becomes a chronic-pain syndrome patient. How can we improve this? I think through more appropriate psychological or psychiatric screening of patients.

It has been demonstrated that many patients, just like this man, can be on a stable dose, nonaccelerating, no build of tolerance. When I lecture more informally, I like to say that doctors physicians don't make addicts, parents make addicts, but that's another story.

The second, and related, issue involves the composition of this Commission. While it's generally said in the literature that multidisciplinary pain management grew out of Bonica's thinking during World War II, point of fact is the first two comprehensive multidisciplinary pain centers were started in 1972, the same year I wrote my first book chapter on the psychology of pain. Multidisciplinary pain management has always had three key components: the physician, a psychologist or psychiatrist, and a physical therapist. Now, just looking at the composition of the Commission, I can't be sure there isn't a psychiatrist among you. I know there is-

DR. KRAUSER: I'm a psychologist.

DR. GRZESIAK: Good. Psychologist or a psychiatrist?

DR. KRAUSER: Psychologist.

DR. GRZESIAK: Psychologist. Good. I didn't know that. That's very important; otherwise, you're going to miss many issues that need to be addressed, and working with, Dr. Klemons calls it, the complex patient because all pain patients are not the same--

Well, that kind of takes that point away from me. (laughter) That's fine.

Finally, it's just recently come to my attention that some place in the Legislature new PIP reform stuff snuck through, and it's very, very deadly. It has put a burden on all of the boards -- all of the professional provider

boards to provide a packaged set of diagnostic and treatment parameters, criteria, whatever you want to call them, in a very, very short time. Well, most professional societies have struggled with this for years, and to think that it can be done in seven weeks is only going to lead to shoddy and inappropriate practice guidelines. I think the patient will suffer. I'm not that concerned about the provider suffering, but it seems to me that that should be one of the mandates to this Commission -- to sort of rein in the insurance industry in their attempt to simply run over health care in New Jersey.

Thank you. Any questions?

ASSEMBLYWOMAN VANDERVALK: No, but I would simply like to -- my own comments-- I'm not speaking on behalf of the Commission, but my own comments are that, as one legislator out of many, we were trying to come up with a solution to the auto insurance crisis. And what was decided and put into legislation needs regulations to be implemented. pressure to have this done rather quickly. However, it does not -- and the point I'm getting to -- prevent us, even after the fact, from making recommendations for certain changes, and maybe it's possible that we can have input before those regulations are published and become effective. But even if it's after the fact, if we determine there's a right thing to do, I would think we would make those recommendations and they could be considered after the fact.

DR. GRZESIAK: Okay.

ASSEMBLYWOMAN VANDERVALK: Thank you.

DR. ASHENDORF: Dr. Grzesiak?

DR. GRZESIAK: Yes.

DR. ASHENDORF: Perhaps you-- I, for one, am in agreement of the vital nature of psychologic intervention. Perhaps you can give this Commission some idea of the obstacles and meaningful reimbursement, which you may have encountered, in attempting to cotreat pain patients with other providers in the community.

DR. GRZESIAK: Oh, brother. Managed care is a nightmare. You know, the people who joke about it as being mangled care are absolutely correct. The days of the equity policy that had good mental health coverage are pretty much gone. And even though I'm a consultant to the New Jersey Pain Institute, a medical facility, my bills are always looked at as mental health, as opposed to being part of a medical multidisciplinary team.

On those few occasions when they squeak through as medical, I don't have a problem. But when they go through and they get kicked over to the mental health HMO part of whatever, like Green Spring for Blue Cross/Blue Shield, it's a nightmare. The patient ends up with the bill. And I try to make that clear up front, but it really is very, very chaotic and hard to manage.

DR. ASHENDORF: So what you're saying is that patients are significantly restricted from meaningful access--

DR. GRZESIAK: Absolutely.

DR. ASHENDORF: --to psychiatric and psychologic services--

DR. GRZESIAK: Absolutely.

DR. ASHENDORF: --in conjunction with pain management.

DR. GRZESIAK: I've reached a point where I've considered Medicare the best reimbursement system going, and now they just changed

that last month and made it twice as hard and twice as long in paying their bills. And they don't answer questions anymore.

Anything else?

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

DR. GRZESIAK: Where can I leave these? (referring to written statements)

ASSEMBLYWOMAN VANDERVALK: They're for the panel members?

DR. GRZESIAK: Yes.

ASSEMBLYWOMAN VANDERVALK: We'll make sure they're distributed. Right.

Dr. Joseph Valenza, from Kessler Institute for Rehab, and I also see Bradley Williams, also from Kessler. Did you want to come up together? **JOSEPH P. VALENZA, M.D.:** I'm Dr. Joseph Valenza. I'm a physiatrist from Kessler Institute, and I run their pain management. I'm in Chester, New Jersey, and in East Orange. I'm also on the faculty of UMDNJ in Newark.

Today I wanted to talk about chronic nonmalignant pain syndromes. I think that whenever we see a person in pain we have to differentiate between malignant pain, which luckily if you talk to my patients are going to kill you because then they can get the medicines they need, or nonmalignant pain syndromes such as reflex sympathetic dystrophy, which is now called chronic regional pain syndrome, fibromyalgia, the different arthritides. Being a physiatrist, I get to see disabled people. They can be spinal cord injured, traumatic brain injury, and these people have a lot of pain.

Therefore, we want to come up with an approach so that we can manage their pain so we can make them more functional. And again where somebody has a malignant pain give them whatever they need to make them comfortable.

When it's a chronic nonmalignant pain, our goals are a little different. We work on function. The whole point is to-- A lot of the patients that come to me -- they're laying in bed, they're crying all day -- I never tell them I'm going to relieve their pain. They actually hate me the first day because they tell me I don't care about their pain, I care only about their function. And the reason is, you can always put someone on a general anesthesia and take away their pain, but they're not going to be functional. So they're going to get bedsores. I'm not doing them a benefit.

What I want to do is take away their pain or reduce their pain so that they can go back to work, they can take care of their families. To do this, we believe in a multidiscipline approach. I don't think that if you just give someone a medication they're going to get better, even though I'm a doctor and I can do that. I think that you need, and it's very important -- I think you need a psychologist involved. There's a lot of psychological issues. No matter if I gave them enough medicine, I injected them, they feel better, they're not going to perceive benefit unless I have a full team. And I think that team would consist of psychological intervention, the different therapies. You should have an anesthesiologist look at the patient to see if there's anything that can be injected.

The thing that we have to be careful about is getting frustrated. Some of our patients just will not report that they are getting better for whatever reason. Some we just didn't treat them appropriately and sometimes because there's secondary gains. They had a car accident, and they're going to be making money by being disabled. What we wind up doing to them is we send for surgery because we get frustrated. We'll go, "Go to the surgeon, he can fix you." A lot of the times they come back even worse. So we want to do everything possible conservative first and then, only in the last resort, if they can find something that they can surgically can fix, okay, but if not, we should try to refrain from that.

One of the things we do at Kessler Institute is we do a thing called a functional restoration program where sometimes we turn to the patients and say, "Your pain is not going to kill you. Your nervous system is lying to you. You've perceived pain, but really it's just your nerves firing inappropriately. And, therefore, yes, you can walk on that foot. It's not going to cause any more damage." And what we do is we do different exercise programs. We get them to use proper body mechanics. We get them to ambulate distances, and a lot of times they'll realize, yes, the pain, it will always be there, but I can go back and do work, even though I didn't change their pain complaints at all.

Opioids -- that's always the hot subject on should we or shouldn't we. Well, again, it's 120 tablets. It's a problem because you say tablets. What's in tablet? With Percocet, there's five milligrams of a thing called oxycodone and Tylenol. Well, if I can only give 120, I can give a medicine, which is a long-acting medicine, called oxycontin where I can give 20 times the amount, and that's only the one pill, too. Well, how come we're only counting pills? It's a real problem for the patients.

Now when we give opioids, we make them sign a contract. We make them understand the differences between addiction, withdrawal,

dependency. When you look at the literature, not many people get addicted from these medicines in pain programs. Addiction means you're going to do something bad with the medicine or you're going to do something bad -- you're going to go out and you're going to steal. That's really is what society is concerned about.

People get dependent to their high blood pressure medicines. If you take them off, they're physically dependent. If you take them off, their blood pressure is going to shoot up, but yet we still give it to people. So why the concern about the opioids? Well, we're worried that again they're going to do bad things with them. When we give opioids, we try to give the long-acting medicines, like the oxycontins, the MS Contins, the fentanyl patch -- why the patient doesn't get the high from them. But again, when you give these long-acting medicines, you want to give what's called rescues. Rescues are when they're doing something more active. They're going out and they're cutting their grass, whatever, and they're going to have more pain. You give them a rescue-- When you're figuring out how much of a rescue dose you should give, it's usually 10 percent to 20 percent of their total dose in a day. Well, that's what gets you in trouble because then a lot of times you're above that 120 limit. So you're medically doing what's best for the patient, but then if you're counting the tablets, you're violating the law or you're violating the old law.

So that's why to me it's very important that I can write whatever number of tablets I want to write, and then if the pharmacist has a question, call me. One of the parts of our contract is we discuss with the patient that they can only use one pharmacy. If we find that they're using other pharmacies, we'll stop prescribing from them. We'll taper them off the medicine. We check their urine. If we find out that they have pot in their urine or any other substance that we're not prescribing, we taper them off. Whenever you're giving medicines to a patient, only one physician should be giving the medicines. It shouldn't be-- You could have an internist giving the hypertensive medicines and the physiatrist or whoever is acting as their pain management physician can give the opioids, but only one physician. Because if not, nobody knows what anybody else is doing.

Dr. Williams is our pain management psychologist at our facilities. And I can tell you that I think it's dangerous for physicians to prescribe these medicines without someone to screen them first. Because there are some patients that are going to come in and, yes, they're just looking for the medicines because they're addicted or they have other reasons for wanting the medicines. And it's very helpful to have someone that's going to try to get at those issues.

BRADLEY WILLIAMS, Ph.D.: I'm Bradley Williams, and I'm the Co-Director of the Pain Management Program at Kessler Institute. I'm a clinical psychologist. I'm an instructor on the faculty of PM and R at UMDNJ-New Jersey Medical School.

With regard to the issue of treating chronic nonmalignant pain, I just want to make a few comments to stress the value of multidisciplinary treatment. Multidisciplinary treatment that addresses the whole pain problem rather than just the pain symptom has been shown to be more effective in reducing suffering and is more cost effective that any single modality that

treats the sensation of pain alone in the absence of addressing the broader pain problem.

Use of treatment plans that focus on the development and independent implementation of multiple strategies by the patient for coping with the larger pain problem have been shown to have the highest success rates in reducing suffering and the least reliance on expensive and endless treatments. The use of opioid analgesics in isolation, without the context of a multidisciplinary treatment plan that addresses issues of the broader pain problem, increases the risks that the patient will suffer from developing problems associated with the use of opioids including psychological dependence or engaging in aberrant drug behavior, such as addictive behavior—notably, psychosocial and societal consequences such as addictive behavior. There's a reason that in the past regulations have restricted patients from medications, such as opioid analgesics, that could have significantly reduced their suffering. In summary, treating the whole problem decreases suffering, increasing functioning, and decreases cost.

I'd be happy to take questions.

Yes, Dr. Ashendorf.

DR. ASHENDORF: I think the same question I asked Dr. Grzesiak. What are the greatest obstacles that patients are encountering in getting access to your facility and your program?

DR. WILLIAMS: We treat patients who are covered by several types of insurance, worker's compensation insurance, personal injury, and health-care insurance, such as HMOs, managed care. At this juncture, we have a great deal of difficulty getting coverage from managed care.

As Dr. Grzesiak mentioned, it's not seen as necessary. It's seen as mental health, not as in a medical model. Oftentimes, they'll tell us that they'll let our physicians see the patient, but they require the patient to go to someone else in their program for psychological treatment. Someone who doesn't specialize in pain management does not understand the complex psychological issues and behavioral issues involved in the suffering that goes along with chronic pain.

DR. CORDA: You stated that you go through several steps to try to prevent your patients from abusing the medications you give and your examples, and such. What would you say your percentage of patients that you treat you find out that you have to stop medication because of abuse?

DR. WILLIAMS: The same percentage as occurs -- aberrant drug behavior in our population is essentially the same percentage as occurs in the general population.

DR. CORDA: So you don't see any difference because you're giving strong pain medication or Schedule II medications?

DR. WILLIAMS: No, we don't. We focus-- Initially, we screen patients in people who are at high risk of drug abuse. We provide treatment but not always treatment with medications. The use of opioid medications is one of the many strategies that we teach patients for coping with chronic pain. And, in fact, for the last 30 years, mainstream chronic-pain management has focused on nonpharmacological strategies, so we include those, as well.

All patients, as Dr. Valenza mentioned, are contracted. They understand in an official manner the definitions of dependence, physical dependence, emotional dependence, and addictive behavior. They understand

our requirements and what they have to do to continue getting the pain relief provided by these analgesics. And quite frankly, we believe in tough love. If they don't behave in a manner that's consistent with the safe use of the medications, we don't give it to them.

DR. VALENZA: We also see tolerance. We don't have-- Patients will come back and say their pain got worse. If you go further into the history, it's because when we first saw them, they were just laying in bed. Now they're out playing football with their kids and stuff. So with the increased activity, they require increased medication, but we don't want-- Once we get the person steady, very rarely do they ever come back and say, "I need more medication because my pain got worse." They will come back and say, "I'm having an operation. The doctors that are operating on me don't understand pain medicine. Could you call them up or could you give me a prescription because I know that I have a contract with you and I can't get any pain medicines." That works well.

We drive it into them that they have to follow the contract. They're not allowed to go to emergency rooms. If they go to emergency rooms to get medicine, it's a violation of the contract and right away they'll be discharged from us. And every time they see me, and it's a real pain, we count every medicine they have and we write down the number. We make sure it corresponds on what they told me they were taking or what I told them they were taking. They can't tell me, "Well, they had extra pain, so they went up by one pill." That's against the rules. And if they run out before they saw me, they're going to just wait and they're going to suffer because they didn't follow the rules. And when I see them the next time -- well, I might not be treating

them again because, if they were really having a crisis, they should have called me. We would discuss it. You come in.

The other problem with this limitation of pills -- if you limit to me so that I can only do 120 pills, a lot of these patients I would have to see once a week or once every two weeks. Now, I guess from -- well, I'm a member of Kessler, so it doesn't matter how many patients I see, but it would be a very costly thing to have these patients coming back once a week just for medications. We don't believe in mailing the prescriptions because, when you start mailing prescriptions, they didn't get them. We don't fax prescriptions. We need to know-- If I'm going on vacation, they need to know because it's their problem if they run out.

And again this is this tough love of they have to follow the rules because we're afraid. We don't want them to do something bad because it will affect us.

DR. CORDA: If you have a patient that's controlled -- a chronic-pain patient that's controlled on the medication, how often do you feel is necessary to resee that patient?

DR. VALENZA: I like to see them -- initially, I want to see them every two weeks until the medicine is stable. Then, I usually go to once a month, then, every two months. I don't like to see them less than that.

DR. CORDA: So you would like to be able to give two months medication after they're controlled?

DR. VALENZA: Yes, I would like to, or it could be two prescriptions where they come in and they just pick up the prescription, but we don't have to go through a formal reevaluation and stuff.

DR. CORDA: Right.

DR. VALENZA: That's what most-- At this moment, I see every patient once a month. Again, it just becomes real time consuming, and it's really not necessary.

DR. WILLIAMS: It's costly not only in terms of financial costs, but it's costly to the patient, too. Ideally, we want to get the patients to the point where they are independently managing their pain problem and engaging in all of the aspects of their life that lead to quality of life. And if you have to go see the doctor every week to get your pain medication, that's really going to interfere with your functioning, your quality of life. With patients who need close monitoring, we're happy to do that. But ideally, we want to get people to where they need the least amount of intervention and are managing their pain problem essentially on their own with our guidance.

DR. VALENZA: And hopefully, most of these patients are working so they have to take off work and interfere with the life that we try to send them back to, to come and see us. So we're against that.

DR. ASHENDORF: Dr. Valenza, does the Kessler Institute presently utilize physician extenders, such as nurse-practitioners, in the pain program?

DR. VALENZA: No. I have a coordinator who is a nurse.

DR. ASHENDORF: I'm sorry.

DR. VALENZA: I have a coordinator who's a nurse who the patients will call if they have questions, but when it comes to like writing medicines-- I just made a contract with the patient that they can only get medicines from me. I don't let them get medicines from other doctors I work

with. And if I'm working with you and you're an anesthesiologist and stuff, I'll call you up and say, "I have a patient," but you're not allowed to get medicines from them.

DR. ASHENDORF: So, if I'm correct, you use nurses in the capacity of education of patients?

DR. VALENZA: Education, they'll field questions.

DR. WILLIAMS: Case management.

DR. VALENZA: They'll case manage them, right.

DR. ASHENDORF: And case management, but to facilitate communication between the various treaters and insurance entities?

DR. VALENZA: Yes.

DR. ASHENDORF: Do you have any opinion on a greater utilization of such extenders in the prescription of controlled substances?

DR. VALENZA: I would be against -- or I think it's risky for anybody that doesn't write pain medications every day to be writing them. I think that-- Again I'm a physician, so I'm biased because I think only a physician should write it. I think it's -- even in medical school, we were trained not to give pain medicines. So it's a big jump for me to be giving pain medications. I'm doing it for my patients. But, no, I think it should be a physician that's a psychiatrist, a physiatrist, maybe a primary-care physician. I don't think it should just even be any physician that's writing higher doses of medicines, especially if you're not comfortable and especially if you're not going to go through all the rules and steps that we go through. I think you're going to land up getting in trouble.

DR. ASHENDORF: Thank you.

DR. AISNER: Well, I didn't want to argue that point with you, but we can do that later after the -- if you want to--

DR. VALENZA: I don't know what discipline you are, but I'm sure it's okay.

DR. AISNER: There's a lot of data that suggests that well-trained nurses can handle this, and it's been well defined in other states. So I'm not sure that I would rest on that point, and we can argue it later.

DR. VALENZA: Yes.

DR. AISNER: I have a different question.

DR. VALENZA: Okay. Do you want me to respond to your--

DR. AISNER: I'm wondering if you could clarify for us this issue of the number. If you're using 60 to 90 long-acting dosing units, explain to me why you need more than 120 breakthrough dosing units at a time?

DR. VALENZA: Because if you try to get oxycodone, okay, which is the active ingredient in Percocet, it comes in five milligram tablets. If they came in twenty milligram tablets, okay, but it doesn't. It comes in five milligram tablets. So the problem is, if you do -- if you're giving, say, oxycontin, which is the long-acting medicine, and you're giving two hundred milligrams of it, well then, your rescue is 10 percent of that -- twenty milligrams. If you're giving a breakthrough medicine, say, every three hours or every four hours, you're going to come out with a lot more than four tablets a day.

DR. AISNER: But I would suggest to you that if someone is using breakthrough every three to four hours, their dosing level at the long-acting is suboptimal. And there's a lot of data that indicate that that's the correct

mechanism and algorithms for doing that. One modifies the long-acting drugs on a scale that's determined by how much of the short-acting breakthrough is used.

DR. VALENZA: And I agree with you 100 percent. The problem is it always doesn't-- You're not always able to have that happen. We try to titrate up. Sometimes they'll get stomach upset. They'll get nauseous from the higher amount of medicines. They become so constipated, but with the rescues they don't. And that's why you use the rescue. In a perfect world, I would never use a rescue. Unfortunately, with the patients I've seen, it doesn't always happen.

DR. AISNER: Am I also hearing you right that you're going over 200 milligrams per day on the long-acting drugs for nonmalignant pain?

DR. VALENZA: Yes.

DR. AISNER: You see that constantly?

DR. VALENZA: Do I see it constantly?

DR. AISNER: Do you see that consistently because that -- at the upper end of dosing even for malignant pain?

DR. VALENZA: Do I see it constantly?

DR. AISNER: Do you see that as a consistent dosing level in patients with chronic nonmalignant pain?

DR. VALENZA: I have a spinal cord patient who has horrible neurogenic pain and she is-- Well, actually, she's on the fentanyl patch. If you convert it, she's at about 400 milligrams of -- if you convert it to oxycontin, she would be at 400. I had another spinal cord, who's a para, who would probably be about 300 milligrams a day. I think that a lot of patients -- I'm giving you

my worst patients -- you would have at 120. Do I think that the upper limit of dosing is 400? No. I've seen -- not my patients, but I've seen patients at 4000 milligrams, and that's -- they're comfortable. So I don't know if that's the upper limit. That's not what I've seen. Again, if you keep titrating up with your rescues, you're going to be well above that in some of this population.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. Dr. Edward Magaziner.

EDWARD S. MAGAZINER, M.D.: How do you do?

I'm Dr. Magaziner. I'm the immediate past-president of the New Jersey Society of Physical Medicine and Rehabilitation, Rehabilitation Specialist, a medical subspecialty. Nancy Pinkin is one of our advisors, and she's also going to speak tonight. I'm also a Clinical Professor at Robert Wood Johnson-University Hospital and Assistant Professor at New York Medical College. And I'm board certified in pain management, as well as in rehabilitation medicine.

In the field of physical medicine rehabilitation, I deal with patients afflicted with a wide variety of disabling conditions. These diverse patient populations might include patients with stroke, amputation, birth defects, cardiac conditions, or even fractures. Now, I'm sure that none of you would dispute the need for rehabilitation for any of these conditions that I mentioned, but let us consider for a moment precisely why you would not dispute such care. Most likely, it is because each of these medical conditions I listed is either self-evident or can be proven with existing so-called objective medical tests.

We are after all a society enthralled with high technology. As we read about unprecedented scientific breakthroughs in cancer therapy, genetic cloning, and organ transplantation, many of us experience a sense of invincibility with this technology, a conviction that present science can certainly detect, if not treat, most medical conditions. And, of course, if a condition cannot be detected, some would say proven, with a test, then what concern should it be to us as a society.

I submit to you that if modern science were truly able to detect most medical conditions that we would not be sitting here tonight talking about something called Pain Management Policy. As I see it, we are here tonight precisely because the single most common human condition since the beginning of time -- the only one that affects virtually every man, woman, and child at some point in their lives -- cannot be proven by technology, yet, that condition -- pain -- remains, as Albert Schweitzer once said, "a more terrible Lord over mankind than even death itself."

Why do we need pain policy? Because of the following harsh realities: The sheer number of patients affected -- virtually tens of millions across the nation. The enormous cost of treatment for these patients in the hundreds of billions of dollars. The cost of pain-related conditions to the nation's industries including their productivity, reductions in disability payment costs. An increasing awareness amongst patients of existing treatments which are available for pain management and the consequent demand for those services which may not be available. The shrinking availability of precious health-care resources. The fact that pain management is still an emerging science in which investigational and off-label prescribing

and procedures are sometimes necessary. The fact that no reliable diagnostic tests yet exist confirm the diagnosis of many painful conditions. The fact that optimum diagnostic and treatment protocols are still in development. Also, burgeoning litigation on pain-related issues and the increasing median age of the U.S. population.

There's also the increasing reluctance of third-party payers to cover quality-of-life issues including pain. There's a general bias often held by payers and even some physicians that conditions which lack objective diagnostic testing are somehow fraudulent or otherwise unworthy of treatment. Increasing numbers of pain patients are denied adequate treatment and who are choosing to end their own lives out of desperation. There's an increased vigilance of the regulatory agencies and professional licensing boards regarding the use of controlled substances. There's inadequate instruction and continuing education of medical students, resident physicians, and even practicing doctors about modern contemporary pain medicine developments. And there's also financial disincentives including the threat of contract nonrenewal to primary-care physicians and specialists and some managed care companies for utilizing pain management services.

Now we are here tonight presumably because the Governor and the Legislature are aware of this looming health-care crisis. They are concerned about the medical needs of New Jersey physicians and citizens and that they wish to intervene in a positive and humane fashion. There are, unfortunately, some recent adverse trends in the health-care system which threaten to undermine these goals and the efforts of the Commission here.

The first of these is the Automobile Insurance Reform Act of May of 1998. It is our understanding that under this Act the Division of Consumer Affairs has created an ad hoc committee with the licensing boards of medicine, chiropractic, dentistry, physical therapy, and psychology for the purpose of advising the insurance commissioners to so-called appropriately and allowable diagnostic and treatment protocols. I understand that this ad hoc committee has only six weeks to develop these guidelines. Our national societies, orthopedics, physical medicine and rehabilitation, and others, have been working on protocols for years and have been unable to come up with good guidelines yet.

When we think that faced with such a daunting assignment that this ad hoc committee might at least reach out to the State's best to societies for assistance-- And I can tell you, as of yet, our Society has not been contacted. We are concerned that the protocols which may be created may limit the treatment of pain in an effort to save costs and might be contrary to some of the conclusions that would be put forward by this Committee (*sic*). We think that this Committee should work together in some fashion.

Another item is that this new law may subject responsible physicians to monetary, civil, and even criminal sanctions because of legitimate disagreement on treatment protocols and permanency issues. It also may create malpractice exposure due to conflicts in other professional standards in the community.

Some other trends along the payer side which are having a chilling effect on pain management include the continuing and drastic reductions in allowable physical therapy visits, unfair claims and practices by the insurance industry, and bundling and discounting or even disallowing pain-relieving procedures. I mean, there are treatments that I do that I try to go and beg the insurance company to allow us to do, and they just totally refuse even though we present them with literature. And the patient is left either to not have treatment or pay this out of their own pockets at a cost that might be prohibitive. Often we have to give treatment for free to be able to help people who are in severe pain.

This also-- Insurance company utilization of third-party claims specialists. They're not held to any professional or certification standards that audit and improve reimbursement, and possibly, they deny things perhaps on a commission basis. The insurance company utilization of so-called independent medical examiners who may be receiving hundreds of thousands of dollars of compensation a year for their independent opinions concerning their clients. Also, the inexcusably long, repeated, and systemic insurance company delays in the payment to providers after the treatment has been provided and without sanction by any of the government agencies on that behalf.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you.

NANCY PINKIN: I just wanted to add, if I could, I also represent the Academy of Pediatrics. And both the physiatrists and the pediatricians feel that as far as the physician extender, such as the nurse-practitioners, that really the -- as Dr. Valenza said, the complexity of pain management and handling of narcotics belongs with the physician who has training to do that.

ASSEMBLYWOMAN VANDERVALK: Thank you. Thank you very much.

MS. PINKIN: Thank you.

DR. MAGAZINER: Thank you.

ASSEMBLYWOMAN VANDERVALK: Jack Lavelle.

JACK LAVELLE: Hi. Thank you for having me here tonight. My name is Jack Lavelle. I'm a retired police officer and a chronic-pain victim.

What I want to state about is the Kessler Institute. I had an opportunity to go there, and thank God I was able to go there. I stayed 30 days there, and the doctors there were wonderful. They met my needs. They understood my needs finally. It was like a blessing in disguise. It was like I died and went to heaven. Prior to that, even as a police officer, I did different things that really weren't the right things to do -- pseudo addiction, mixed different medications to take care of the monster that used to strike at me every night, neuropathic pain. I had a spinal fusion, a laminectomy.

It happened in the line of duty. I was injured. I was dragged out of a car. What I am trying to say is that I was titrated up to high dosage of oxycontin, approximately 840 milligrams in the a.m. and 7 in the p.m. so that comes approximately -- over 500 milligrams a day, something like that (*sic*). But it didn't impair me whatsoever because, matter of fact, the department, I think, was trying to put me out on disability. That's why they sent me there knowing it was a -- be put on the pharmaceutical way of taking care of pain management.

Plus, under management, they wouldn't have to pay any further under workmen's comp. But under the Federal Disability Act, they have to

prove that if you're impaired, you're not capable of doing your job. So with counselors' assistance, I had to go through every type of -- everything I did in my occupation. I had to fire the weapon. I scored the highest in the department. There was a blood test taken before and after. I had to drive a car at high rates of speed, simulated and actual car -- high rates of speed. Again blood was taken before and after. I scored highest in the department. Physical testings and every other thing -- scored the highest in the department.

What I'm saying was, these things do not impair you, and you don't have any euphoria from it. In the beginning, yes, there was a little euphoria. You felt good about yourself, but after that, the pain was just masked. And even several times, occasionally, I'd say to myself, "I don't need this stuff," and I'd stop taking it. And all of a sudden, that monster would come out again, and I said, "Wait, wait a second, I do need it." And thank God for people like Kessler who were able to provide it for me.

And prior to that— The other thing that happened to me was really annoying to me in a way. Different doctors have different opinions and they don't get together with it. My wife would listen to other doctors that say, "That's way too much. No way. He shouldn't even be on that amount," and it caused me a divorce, the God's honest truth. I'm really very angry about that because, if doctors would only get together to understand what's going on out there— I guess you could say years ago, when people had major headaches or went crazy or something like that, they found out that they had tumors in their brain later on when— They ended up with CAT scans and other X-ray

machines and stuff like that. But when they were crazy, just threw them in a crazy bin.

Today when you have pain, you have to be a malignant person to be looked at. The norms are, if it's nonmalignant, "Hey, you shouldn't have to suffer. You shouldn't be taking narcotics, shouldn't be taking that type of stuff." You're a dope addict, and you're looked at as a dope addict. You walk into a pharmacy and they look at you like, "What the hell's wrong with this guy. What's he taking all this shit for? Is he a junkie?" And it's not too respectful.

Prior to going for that, I went through thermocoagulation where they actually burnt most of the nerves in my back so I wouldn't have to take any medications whatsoever, but that didn't work. So I did have to resort to pills. I was totally against it -- totally against it -- but that was the only thing that relieved-- Right now I take 600 milligrams of morphine a day. I function properly, I work normal, I drive, no problems whatsoever. I just felt I owe something towards it. The doctors put themselves on the line, their medical license on the line to treat people like myself, and I feel I have to give something back to it. That's why I'm here to speak in behalf of it.

I want to thank you.

ASSEMBLYWOMAN VANDERVALK: Well, I thank you for sharing that with us. I know that's not the easiest thing to do, but we need that type of input to get the full perspective.

MR. LAVELLE: Thank you very much.

ASSEMBLYWOMAN VANDERVALK: Thank you.

Earlier I had called Dr. Shams Quershi, and I think someone else came up at the time.

So did you want to testify? (Dr. Quershi declines from audience) Oh, all right. Okay. Thank you. I just apologize at the confusion. Okay. Loretta Brickman.

LORETTA BRICKMAN, R.Ph.: Madam Chair and members of the Commission: I would like to thank you for giving me the opportunity to address you this evening. My name is Loretta Brickman. I am a New Jersey registered pharmacist. I am the Regional Director of Regulatory Compliance for OMNI Care. We supply long-term care medications to nursing home patients. I am here this evening as a member of New Jersey Association of Long Term Care Pharmacy Providers.

Before I begin my prepared comments, I would like to note an issue that was discussed earlier this evening concerning confidentiality and the roadblock that it creates in order for pharmacists in the ambulatory community pharmacy setting to supply the larger quantities of medication because they're not privy to some of the information that they should have. May I respectfully make a suggestion that legislation be drafted to recognize the pharmacist as a health-care provider. We all know that pharmacists are integral members of the health-care team. Unfortunately, there is a glitch in that the Federal legislation never actually included pharmacists as part of the health-care provider team. If we were to do this in the State of New Jersey, as Connecticut just did in May of this year, this would help solve the problem of confidentiality.

I would like to limit my remarks to the regulatory obstacles and requirements that very often hamper health-care providers from rendering the most timely and effective pain management to long-term care residents and hospice patients. It is important to note that long-term care facilities function in very much the same manner as hospitals. Patient charts are maintained and physician order sheets are generated. Medication administrative records are also used for documentation. Nursing home regulations with the Department of Health mandate these requirements.

These facilities differ from hospitals because physicians are not present on a daily basis. They normally see their patients every 30 days. Therefore, they must work off of this documentation system. The multidisciplinary team must rely on this system to prevent negative outcomes. It is important to realize that the level of care has increased today in the nursing home setting. We find the entry-level resident to be 80 years old or older and more volatile. More nursing homes have subacute units than ever before. The residents in their 70s or younger and not as ill are now entering the assisted-living setting.

Patient care in this closed system is in jeopardy. By virtue of New Jersey rules and regulations, we are required to provide 24-hour care. Due to current CDS regulations, sometimes this is not possible. CDS regulations require an emergency telephone order for a C-II narcotic to be no more than a 72-hour supply. The hard copy cover for this order must be received by the pharmacy within 72 hours. If more medication is needed, the pharmacy must also receive a written prescription at the same time for the additional quantity. If these requirements are not met, no further medication may be sent.

The Federal DEA regulations recognize the closed-system controlled environment of the nursing home and the direct supervision of the hospice patient. Understanding the needs of the patient within this environment, the Federal Drug Enforcement Agency has developed regulations that should decrease negative outcomes. The new DEA regulations allow the prescribing practitioner to fax the original signed order to the pharmacy provider. This facsimile will then be used as the hard copy original order. If the practitioner is not able to use this method, he or she will then have seven days to provide the hard copy cover to the pharmacy. With the mail service we have today, this regulation is more reasonable. The DEA is even allowing the hard copy cover of the 72-hour emergency prescription in the community ambulatory setting to be received within seven days as well.

I understand that we, as health-care providers, are concerned about fraud and abuse, but I also realize that we have an obligation to our patients. That obligation is not to have them suffer one moment longer than is necessary. I certainly wouldn't want my loved one to suffer needlessly, and I'm sure neither would you.

I would also like to state at this time that when I prepared this testimony, legislation had not yet been introduced into the Assembly. I am very happy to say that Assembly Bill No. 2188, sponsored by Carol Murphy -- Assemblywoman Carol Murphy and Assemblywoman Charlotte Vandervalk, the Commission Chair, have introduced this bill and it has passed the Assembly Health Committee. I also would like to say that there is a proposed Senate bill, companion bill, Senate Bill No. 1214 sponsored by Senator Jack Sinagra. So that, hopefully, this will be addressed in the very short future.

Thank you. Any comments? I'd be happy to answer any questions.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. MS. BRICKMAN: You're welcome.

ASSEMBLYWOMAN VANDERVALK: Dr. Susan Bauman, we called you first and now, I think, you may be last.

SUSAN M. BAUMAN, M.D.: The first shall be last.

Thank you for graciously allowing me to speak. I apologize for not being here at the designated time. I spent 45 minutes going two miles on Route 287, but I think that's a problem of a different part of the State government.

I appreciate this opportunity to speak and I realize the hour is late. I will be, hopefully, within my time limit here. I am a family physician and geriatrician and Associate Professor of Family Medicine at Robert Wood Johnson and teach at Hunterdon Medical Center's Family Practice Residency Program. But I'm here tonight as the Chairperson of the Medical Society of New Jersey's Biomedical Ethics Committee to speak on pain management policy to your Commission.

One advantage of being last rather than first is you get to hear everybody else, and therefore, my comments may be slightly different than what I have passed around, although certainly will not contradict them, I hope.

I think a historical note might be in order here as to why the topic of pain is hot at the moment. Certainly, it is hot. It's in the medical literature, the bioethics literature, and is evidenced in the creation of this Commission. And I think the attention to pain, which is quite appropriate, has really grown

out of the attention to death and dying in this country in general. And that attention really, one can say, started in this state with the *Quinlan* case over 20 years ago. New Jersey has been, through its Supreme Court decisions, in the forefront of ensuring that patients are able to die with dignity. *Quinlan, Jobes, Farrell, Conroy* -- illustrious cases known throughout the country and all New Jersey cases. The Supreme Court followed the lead of New Jersey, shall we say, in the *Cruzan* case in saying that people have a right to die with dignity, a right to refuse medical care.

Well, what does this have to do with pain? As you all know, last year the Supreme Court of this country held a case related to physician-assisted suicide. The Court found that there was not a constitutional right to physician-assisted suicide. That was widely publicized. I think what was not as widely publicized were some of the comments by the Justices related to the management of pain, in particular, Sandra O'Connor's comments, which some legal writers on this topic have said almost articulate a constitutional right to good and appropriate pain management and saying that, if anything, this is what people need and should be guaranteed in this country. And, therefore, I think we have a mandate from above, so to speak, to set the tone and allow for better pain management.

Physicians have known for a long time that pain management in this country is not very good. Certainly, patients have known that pain management is not very good. And another New Jersey institution, the Robert Wood Johnson Foundation, spent \$7 million in the support study over the last couple years and proved just that. One of their major findings was that over one-third of people in this country die in significant pain, pain which could

be treated. This is a horrible fact and it, I think, shook up the medical profession, as it should have, and I think these cases along with the support study are part of the history which shows what is motivating this Commission today.

Well, what does organized medicine have to do with all this? Why are physicians so terrible at treating pain, and what can organized medicine do about it? I think the reasons why physicians do such a bad job is surely complex and multifactorial. And a big part of it is the lack or at least the former lack of appropriate education in palliative care in medical schools and in residency programs. I think that educators, physician educators, and the medical profession is trying to remedy that. There are more and more courses at the medical school level, courses in residencies. Hospice has been an excellent resource. The National Hospice Organization has an educational initiative in that regard and that will help a lot.

I think the second big factor has to do with physicians, not just ignorance of palliative care, but actual misperceptions and misconceptions regarding addicting medicines, what constitutes addiction, how should medicines -- what is the difference between physical dependence and psychological addiction, or drug-seeking behavior. Organized medicine and medical education is trying to remedy this, but this is certainly going to be a slow process. The American Medical Association has started a large initiative in this regard, as far as educating physicians.

Well, what is the third factor? I think this is where you people come in -- is because I think that the third factor in physicians undertreating of pain has to do with either the regulatory burden or even the perception of

a regulatory burden. There was an entire issue last year of the *American Society* of Law, Medicine and Ethics Journal devoted to issues of pain regulation and management. I'm sorry, I do not have that reference in my remarks, but if this group is not familiar with that issue, I can get you the reference because it is most-- There must be 18 articles by national legal experts, physicians, pharmacists about this complex problem. And one of the most poignant things in the whole journal was a story of a physician in New York City, an upstanding physician, well-regarded faculty member, who -- I'll make a long story short because I don't remember the details of the story -- ended up having his license suspended for three months around a question of inappropriate prescribing of narcotics for a chronic-pain patient. There are stories like that that put a chill down every physician's back.

I asked around and tried in a very brief way to see if there were such stories in New Jersey or such history in New Jersey. I have not heard any, and I guess that it's good that I don't have any to report; although, I suspect that there are some out there. But what I would like to say is that even if there is not a long history of the Board of Medical Examiners in this State inappropriately criticizing/disciplining physicians for their appropriate treatment of pain patients, there is the perception that that occurs, and that has a chilling effect on physicians. The State Board of Medical Examiners controls our licenses, and there's certainly nothing worse to a physician than the thought that somebody is investigating whether or not you should lose your license.

So what I would like to plead with you people is that the most important thing that you can do is help set the tone, set the stage in New Jersey, along with the State Board of Medical Examiners to encourage the appropriate treatment of pain. We all realize that there are a few bad apples among physicians who are inappropriately prescribing, and there are certainly a few people in the population who are drug seekers, and regulations and law have to be crafted for those few. But when you are crafting law and regulations for those few, you must think about the side effects of those laws and regulations on the majority of physicians who are well-motivated, well-meaning people who want to serve their patients, who want to treat their pain appropriately, and if anything, need encouragement from the law to do that because physicians, I think everybody knows, all suffer from a certain amount of legal anxiety. So your job as legislators is to appropriately decrease that legal anxiety in how you craft your laws and regulations so that we may encourage physicians to do the right thing for their patients.

Thank you. I'd be glad to answer any questions.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

DR. BAUMAN: You're welcome.

ASSEMBLYWOMAN VANDERVALK: I believe we've completed the agenda.

Is there anyone else that had requested to testify and has not? (no response) I think we covered everyone.

I thank you all for being here. I found it very worthwhile, and I would just ask the members of the Commission if they could stay for, hopefully, just a few minutes where we can discuss what needs to be discussed and set the next meeting.

(HEARING CONCLUDED)