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2	ATTORNEY GENERAL RICHARD BLUMENTHAL
3	PRESCRIPTION DRUG ABUSE HEARING
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8	DECEMBER 11, 2001
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23	Legislative Office Building Room 2-E
24	Hartford, Connecticut
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1 MR. BLUMENTHAL: If I may welcome 2 everyone, these are familiar settings for many of you, 3 and for the commissioner and myself having been in the 4 legislature; but for those of you who are here for the 5 first time, welcome to our Legislative Office Building 6 and to these hearings on prescription drug abuse and 7 measures that we can take against prescription drug 8 abuse.

9 We have a broad cross-section, very
10 impressive group of speakers this morning to address
11 what has been a quiet, but consistently devastating
12 problem over the years; prescription drug abuse has
13 afflicted many of our citizens and communities with
14 results that have been often devastating, debilitating,
15 extremely costly to many of our citizens.
16 There has been a tendency to focus on
17 OxyContin as the prescription drug abuse most
18 fashionable, perhaps most troubling in its results at
19 the moment, but it is indeed only at the moment that it
20 seems to have attracted this kind of attention, and the
21 problem really is a much broader, more far-reaching and

- 22 fundamental one having to do with abuse of powerful
- 23 painkillers and other prescription drugs that
- 24 potentially offer tremendous promise and benefits to
- 25 people who suffer from severe chronic pain, but even as

1 they offer great promise, they also come with

2 tremendous pitfalls and problems: abuse and addiction

3 leading to criminal wrongdoing, doctors, diversion.

4 The question is who should receive these
5 drugs, who benefits from them, and who should not, and
6 what we can do to make sure that those who legitimately
7 need and deserve these drugs continue to have them
8 available, but at the same time stop abuse and
9 addiction and the kind of criminal wrongdoing that all
10 too often has flowed from them.

11 Other states have employed methods such 12 as electronic prescription drug monitoring programs to 13 combat abuse. These systems allow for review by state 14 law enforcement officials of the prescription of 15 controlled substances and would also allow physicians 16 to determine whether their patients or prospective 17 patients already are receiving prescription drugs from 18 another physician. That proposal, along with others, 19 will be reviewed in this hearing, and I hope that this 20 hearing is simply a first step, perhaps only the first 21 of a number of hearings, that will address a number of

22 these issues.

I want to thank Commissioner Fleming,
who has been very interested and involved in this
issue. I will be talking to him and others who are

1 represented from the state of Connecticut here today

2 about those prospective solutions.

3 I also wellcome Cindy Denne and Sam 4 Siegelman: Cindy Denne, who is the bureau chief at the 5 Department of Public Health, and Sam Siegelman at 6 DHMAS, I notice that we have been joined by Senator 7 Edith Prague, and I welcome her. 8 I want to thank my staff, most 9 particularly Richard Kehoe, Justin Kronholm -- Justin 10 Kronholm is here, and many of you who dealt with him in 11 the last few days; and also attorneys on my staff, 12 Arnie Menchel, Michael Cole, and Ted Doolittle, 13 assistant attorney generals who have been instrumental 14 in organizing this hearing and in working on this 15 problem. 16 With that, I would like to ask whether 17 any of the other panelists this morning have any 18 opening remarks. First Commissioner Fleming who has 19 been a very strong and stalwart ally in this effort. 20 Thank you, Commissioner Fleming.

21 COMMISSIONER FLEMING: Thank you, Mr.

- 22 Attorney General. It's also my pleasure being here
- 23 this morning. Having spent a number of years here in
- 24 the legislature, I understand what a public hearing is
- 25 all about, and that is for us to listen to what really

1 an impressive list of experts I expect will have to say

2 in the course of today.

3 I've also asked to sit in from my 4 agency, from the Department of Consumer Protection's 5 drug division, the chief of enforcement, Bill Ward, and 6 Leo Roberge, who is the head of the drug division. 7 They will be taking plenty of notes, looking for any 8 ideas that will come out of this hearing. 9 We have been working as an agency over 10 the last several months with the Attorney General's 11 office and with other agencies that deal with the issue 12 of prescription drugs and how prescriptions are written 13 to prepare a proposal which we will present to the next 14 session of the legislature dealing with electronic 15 monitoring of drugs. That is still in draft form, and 16 so any additional information that we might gather from 17 this hearing today we would find very helpful, and I 18 would hope sometime in the early winter when the 19 legislature reconvenes that I will have an opportunity 20 to be where you are, and that is to sit before a group 21 of legislators and make the case for that proposal.

## 22 Thank you.

## 23 MR. BLUMENTHAL: Thank you,

## 24 commissioner.

25 MS. DENNE: I just would like to thank

1 Attorney General Blumenthal for pulling together this 2 very important hearing, and I expect to hear some 3 expert testimony today that will be very helpful to the 4 department as it formulates its policies in terms of 5 the differentiation between medical need and abuse of 6 prescription drugs. Thank you. 7 MR. SIEGELMAN: On behalf of the 8 Department of Mental Health and Addiction Services, I 9 also would like to thank the Attorney General. 10 Although we work more on the demand reduction side of 11 things, it's not unaffected by supply side issues, and 12 we look forward to learning from the experts at this 13 hearing as well. 14 MR. BLUMENTHAL: Thank you. I know that 15 we've been joined, I've seen Representative Dickman and 16 Representative Sawyer who have since joined us along 17 with Senator Talgri (phon sp), and I thought I saw 18 Deputy Commissioner Starkowski. 19 I apologize to anyone whom I've missed 20 in the course of announcing those who are here.

21 We'd like to move right along and ask

- 22 the chief state's attorney, Jack Bailey, if he would
- 23 please address us.
- 24 MR. BAILEY: Good morning.
- 25 MR. BLUMENTHAL: Good morning, sir.

1 MR. BAILEY: Good morning.

2 For the record, I'm John M. Bailey, 3 Chief State's Attorney for the state of Connecticut. 4 I welcome the opportunity to be here 5 this morning to address the very serious problem of 6 prescription drug abuse. As Chief States Attorney, I 7 serve as the chief law enforcement officer of the state 8 of Connecticut. I'm responsible for the overall 9 administration of the division of criminal justice. 10 As you know, Dick, under the 11 constitution, I'm responsible for the investigation and 12 prosecution of all criminal matters in the state of 13 Connecticut. This includes illegal use of prescription 14 drugs. 15 Let me begin by stressing the importance 16 of keeping this issue in perspective. The misuse of 17 prescription drugs is only one element of the substance 18 abuse crisis that is facing the nation today. It is a 19 crisis that touches all aspects of American life and as 20 such is a crisis that requires a comprehensive 21 approach. Yes, prescription drug abuse is a serious

- 22 problem, but there are those who would argue that
- 23 illegal drugs such as heroin poses a far greater threat
- 24 because of a far greater number involved. Again, my
- 25 point is that we must keep this problem in

perspective. We must resist the temptation to follow
 the headlines and focus the bulk of our attention and
 resources on the drug of the day simply because the
 media chooses to do so.

5 If you could recall last winter, the 6 talk of the town in Washington was the illegal club 7 drug Ecstasy. By summer Washington had shifted its 8 attention to the legal prescription drug OxyContin. 9 Prosecuting cases involved both of these drugs. 10 One problem has not gone away because 11 the media and Congress has chosen to focus on another 12 drug. That is why it's so critical that we develop a 13 comprehensive plan that addresses all components of the 14 substance abuse crisis; a comprehensive plan that 15 brings together all involved to work together towards 16 one goal. If we simply choose to follow the headlines, 17 we are doomed to failure. Yes, we might solve today's 18 problem, but we won't prevent tomorrow's. 19 We also must resist the temptation to

20 look for a simple solution. Some, for example, have

21 suggested the way to stop abuse of a specific drug is

- 22 to ban the manufacture and sale of those drugs. Keep
- 23 in mind those drugs are already strictly regulated.
- 24 They are classified as Schedule II narcotics. And the
- 25 reason they are classified that way is because they are

highly potential for abuse and addiction. A physician
 cannot phone in a prescription for a Schedule II drug,
 nor can he order an automatic refill. Nevertheless,
 despite the existing regulations, these drugs are being
 abused.

6 The question for policy makers becomes 7 what we can do to stop the abuse while keeping these 8 drugs available to those who are in need of them. And 9 we cannot understate the fact that there are many 10 people, as you said, Mr. Attorney General, who do need 11 these medications and who do benefit from them. Many 12 in the health care community consider OxyContin a 13 milestone in the treatment of patients with chronic and 14 extreme pain.

Just as important, though, is the fact
that banning specific prescription drugs will simply
not work. The same can be said for the glue that
children use to make model airplanes or the various
other legal household chemicals that have become the
means of substance abuse. If we ban one prescription
drug today, you can be sure that drug dealers will find

- 22 another prescription drug to peddle tomorrow. The
- 23 criminals who are peddling drugs whether they are legal
- 24 or illegal are making tremendous profits, and they are
- 25 not about to look for a new line of work. That is why

it is so important that we develop a comprehensive plan
 toward dealing with substance abuse, whether the
 substance is legal, prescription drugs obtained through
 illegal means, or illegal drugs smuggled across the
 borders and sold on the streets.

6 So what does this comprehensive plan 7 involve? It involves everyone at every level of 8 government, from the police officer who makes an arrest 9 to the prosecutor who makes the case in court and the 10 legislators who make the laws and the judges who apply 11 them. And they must be involved with the private 12 sector. The drug manufacturer must be prepared to make 13 their products less vulnerable to abuse. The health 14 care community must be more diligent in reporting 15 suspected abuse and doctors who recklessly and 16 unethically prescribe drugs. 17 We have made significant progress in 18 developing comprehensive plans. I commend Governor 19 Rowland and the General Assembly for the actions they 20 have taken in recent years, whether additional 21 resources for drug treatment or tougher penalties for

22 drug dealers. Yet much work still lies before us.

- 23 In terms of today's topic, prescription
- 24 drugs, the division of criminal justice supports the
- 25 concept of a prescription-monitoring program. We

commend the Department of Consumer Protection, the
 Attorney General's Office, the Drug Enforcement Agency,
 and the National Alliance for Model State Drug Laws and
 all those who pursue the concept. A properly
 structured prescription monitoring program will be
 another step forward, but, again, keep in mind that it
 will only be one of many tools, and only one component
 of a very comprehensive plan.

9 We have, as you know, Commissioner
10 Fleming and Attorney General, we have arrested Dr.
11 Dudley Hall, mainly because it was reported that he was
12 prescribing more of OxyContin than anyone else in the
13 state of Connecticut. What we did was we put
14 undercover officers as patients entering his office.
15 We had to pay \$150 for the first time in his office.
16 After that, we had to pay \$50, all cash, 100 percent
17 cash, for him writing other prescriptions. And right
18 now he's facing 300 to 838 years.
19 These are only allegations, but I think

20 they're very important because I think monitoring

21 prescriptions could be real progress for us in the

- 22 state of Connecticut. And we really don't have to
- 23 change the law because 21a-274 -- excuse me.
- 24 Cooperation between law enforcement, that means we can
- 25 exchange information, if you get a call or Commissioner

1 Fleming gets a call, we can share that information with

2 the division, and we can begin the administration.

MR. BLUMENTHAL: I want to thank you for
your testimony, Chief State's Attorney Bailey, and for
your work on this problem which will be excellent,
along with, obviously, the State Police and your entire
office, and I hope that you will be part of developing
that kind of comprehensive plan which I think is so
valuable.

In the Hall case, as I recall, there
were hundreds of thousands of dollars in state money.
MR. BAILEY: Right.
MR. BLUMENTHAL: Which is one of the
reasons for our interest, because state spending on
OxyContin alone now is at the projected level of \$7.4
million for this year alone, which has quadrupled in
the last four years.
MR. BAILEY: I think, Mr. Attorney
General, if we all get together and make a plan, I
think it will work. Thank you.

21 MR. BLUMENTHAL: Thank you. I would

- 22 like to again thank you for being here today.
- 23 Captain Peter Warren, commanding officer
- 24 of the State of Connecticut Statewide Narcotics
- 25 Division.

1 CAPTAIN WARREN: Good morning.

2	MR. BLUMENTHAL: Good morning, captain.
3	CAPTAIN WARREN: My name is Captain
4 Pe	ter Warren, and I appreciate the opportunity to be
5 he	re today. And I applaud all of you for your efforts
6 to	discuss the growing problems that are related to the
7 us	e of OxyContin here in Connecticut.
8	For the past four years, I have served
9 as	the commanding officer of the Statewide Narcotics
10 T	ask Force. From my position as the commanding officer
11 of	this task force, and also from my position as the
12 na	ational president of the National Alliance of State
13 D	rug Enforcement Agencies, an alliance of the nation's
14 50	) state police and highway patrol departments that
15 cc	onduct narcotic enforcement in the United States, I am
16 w	ell aware of the problem that our nation faces from
17 th	e abuse of prescription drugs, primarily these days
18 fr	om the abuse of OxyContin.
19	Today the abuse of OxyContin is one of
20 th	e most significant concerns to law enforcement
21 ag	gencies across the country, especially to those of us

- 22 along the East Coast. Abuses of this legitimate drug
- 23 are often caused by those individuals who are heroin
- 24 addicts who seek out an over-the-counter prescription
- 25 drug that closely mirrors heroin.

1 The OxyContin medication is well-known 2 as a legal and effective painkiller for cancer patients 3 and others. OxyContin should never be denied to those 4 patients who need this powerful medication and who use 5 it lawfully. However, the abuses of OxyContin and the 6 crimes caused by the illegal use of OxyContin needs our 7 immediate attention, especially here in Connecticut 8 before the problem becomes far too significant, as it 9 has in other states.

OxyContin is often obtained illegally by
 those addicts or those who profit from the high returns
 of illegally selling these pills on the street, by
 doctor shopping, from forging prescriptions, and
 through theft of OxyContin shipments that are destined
 for pharmacies here in Connecticut.
 As Mr. Bailey just mentioned, detectives
 of the Statewide Narcotics Task Force and others
 recently arrested a doctor who was engaged in the
 distribution of OxyContin at an alarming rate.
 Patients easily received excessive numbers of

- 22 should show all of us the high demand for this drug
- 23 when a trained medical doctor risks everything to turn
- 24 a profit on illegally distributing this drug.
- 25 In another case, we recently arrested an

1 individual who was responsible for distributing air 2 shipments of OxyContin to pharmacies. This individual 3 was being paid to pilfer portions of OxyContin 4 shipments that were destined to the pharmacies here in 5 Connecticut so that an associate could sell these pills 6 on the street. This also shows that people are willing 7 to risk their jobs to steal this OxyContin for others. 8 It is not uncommon for OxyContin to be 9 sold for as much as sixty-five to eighty-five dollars 10 per pill, depending upon the dosage and the number of 11 pills that are being sold and that have been stolen. 12 This compares to approximately the \$6 cost when the 13 pills are sold legally over the counter. OxyContin is 14 also commonly sold on the streets for roughly \$1 per 15 milligram, meaning that an 80-milligram dose of 16 OxyContin can easily cost \$80 on the street, a 17 significant markup from its six- to eight-dollar over-18 the-counter cost. 19

Oftentimes OxyContin is sold on the
 streets by patients who legally obtain these pills but
 who sell a portion of their prescription on the

- 22 streets, as they are aware of the high demand for these
- 23 pills and the high returns by selling these pills they
- 24 can realize.
- 25 Last week I attended a national HIDTA

1 conference in Washington, D.C. HIDTA stands for high 2 intensity drug trafficking area. In Connecticut we 3 have three counties designated as HIDTA counties. 4 Generally the focus of HIDTA initiatives 5 is cocaine, heroin, and methamphetamines. The same is 6 true in Connecticut for the HIDTA initiatives that I 7 manage for the Connecticut State Police Department. 8 However, when the national HIDTA conference -- as does 9 NASDEA, the alliance I serve as president of -- sets 10 aside portions of our meetings to discuss the growing 11 problems associated with OxyContin abuse, it should 12 make all of us realize that OxyContin is a significant 13 problem that is confronting us both at the national and 14 at the state levels. 15 I strongly support the efforts being 16 made here today to strengthen and enhance the 17 prescription process here in Connecticut. The 18 significant criminal problems that are directly related

19 to OxyContin abuse are well documented from Maine to

20 the Carolinas. This should make all of us realize that

21 we need to closely monitor the prescription process for

- 22 OxyContin here in Connecticut.
- 23 This does not mean that I am
- 24 recommending we monitor or second-guess the
- 25 prescriptions written by doctors and filled by

3 doctors to pharmacists to eliminate abuses of forged 4 prescriptions of OxyContin. 5 I would also support Superior Court 6 legislation that creates a statewide database for 7 health care professionals to access so they can easily 8 identify those individuals who have recently obtained 9 OxyContin from other health care professionals 10 already. This would reduce some of the abuses of 11 OxyContin by those individuals who doctor shop to 12 receive multiple prescriptions of OxyContin for either 13 personal abuse of this drug or for personal profit. 14 I would also support new legislation for 15 both OxyContin as well as for Ecstasy, another illegal 16 drug problem that Connecticut and the nation is facing. 17 I would support new legislation that prohibits the 18 specific illegal possession, sale, use, or distribution 19 of these two drugs. I would also suggest that new 20 legislation aimed at these two drugs set penalties for 21 both the total weight and the number of pills that an

1 pharmacists. What I am suggesting is that we consider

2 having these prescriptions electronically filed by

- 22 individual or illegal drug organization is found in
- 23 possession of. For these two drugs, the number of
- 24 pills one is found in possession of should be the
- 25 standard for the appropriate criminal penalty, not the

1 weight alone.

2 While I support new criminal legislation 3 aimed at those who abuse these drugs, I would also 4 support legislative language that mandates treatment 5 for those abusers of both OxyContin and Ecstasy. 6 Specific legislation aimed at abuses of OxyContin and 7 Ecstasy would show the public that Connecticut has a 8 clear interest in prohibiting the illegal use of these 9 drugs and in protecting our children. 10 Again, I appreciate the invitation to be 11 here today, and any time that I or the State Police or 12 Statewide Narcotics Task Force can be of assistance. 13 please call me. MR. BLUMENTHAL: Thank you for being 14 15 here and for that excellent, very balanced, and 16 insightful testimony and the work that you've been 17 doing over many years on this problem. 18 Could you tell us just the three 19 counties in Connecticut that are designated as high

20 usage or high level?

21 CAPTAIN WARREN: Yes. Those counties

- 22 are Fairfield County, New Haven County, and Hartford
- 23 County.
- 24 MR. BLUMENTHAL: Thank you.
- 25 Commissioner.

1 COMMISSIONER FLEMING: Captain, you 2 mentioned the theft of shipments into Connecticut. 3 CAPTAIN WARREN: Yes. 4 COMMISSIONER FLEMING: Can you give me a 5 little more detail on that, the extent of that problem 6 as it comes into the state? How widespread is it, say, 7 over the last five or six years of controlled 8 substances? 9 CAPTAIN WARREN: It has not been a 10 significant problem, but it has occurred on occasion, 11 and the occasion I'm talking about is just a couple of 12 months old. Excuse me for not getting into 13 particulars, but it is still an active investigation. 14 We have made an arrest on it. And we are working very 15 closely with this freight company because they don't 16 want this to be occurring from their employees or at 17 their terminals. 18 So it's not a widespread problem, but it 19 has occurred, and every time that we've been aware of 20 it, we've made arrests on it. It would be foolish not 21 to think that it's happening more often than we're

- 22 aware of, but we have an excellent working relationship
- 23 based on our HIDTA initiatives with all the airfreight
- 24 companies here in Connecticut. They have been great to
- 25 work with, they've been very supportive of our efforts,

 $1\;$  and I look forward to working with them in the future.

2	COMMISSIONER FLEMING: Thank you.
3	MR. BLUMENTHAL: Thank you, captain.
4	MS. DENNE: May I make one comment?
5	MR. BLUMENTHAL: Sure.
6	MS. DENNE: Captain, I just want to
7	point out the importance, and I know we work closely
8	with the State Police, of keeping the Department of
9	Public Health in the loop when there is an arrest of a
10	health care professional that we license because in
11	turn we can protect the public health
12	CAPTAIN WARREN: Certainly.
13	MS. DENNE: by taking an action
14	against that license.
15	CAPTAIN WARREN: Certainly.
16	MS. DENNE: Thank you.
17	CAPTAIN WARREN: Thank you.
18	MR. BLUMENTHAL: Thank you, captain.
19	Please convey our thanks also to the commissioner
20	Spada.
21	CAPTAIN WARREN: I will.

- 22 MR. BLUMENTHAL: I should mention that
- 23 the Connecticut Chiefs of Police Association will be
- 24 submitting testimony. They could not be here today.
- 25 The same is true of the Pharmaceutical Industrial

1 Association, and the National Alliance for Model State 2 Drug Laws. They will all be participating by 3 submitting testimony. 4 Commissioner Starkowski, Michael 5 Starkowski. 6 COMMISSIONER STARKOWSKI: Good morning, 7 Attorney General Blumenthal. For the record, my name 8 is Michael Starkowski. I'm the Deputy Commissioner of 9 the Department of Social Services. Thank you for 10 inviting me here today at this important public hearing 11 on the use and abuse of prescription drugs. 12 What I would like to do first is try to 13 put some things in perspective, try to go over some of 14 the national growth in expenditures on drugs, some of 15 the expenditures of DSS, and an overview of our present 16 systems and what we feel will have the capability to do 17 in the future to avoid some of this fraud and abuse. 18 We acknowledge whole-heartedly that 19 there is a problem in our pharmaceutical system. 20 Unfortunately, state-funded programs are not exempt 21 from fraud and abuse by either clients or providers.

- 22 We feel we are taking some positive steps in enhancing
- 23 our systems in the future to avoid some of this fraud
- 24 and abuse.
- 25 I have a presentation that I'd like to

1 just go over some of the high points of the

2 presentation. Spending on retail prescription drugs

3 nationally rose over 18.8 percent from 1999 to 2000

4 from \$111 billion to \$131 billion. It's the highest

5 cost factor in the health care industry right now. The

6 increase in prescription drugs accounted for 44 percent

7 of the overall increase in health expenditures.

8 Spending for physician and hospital services accounted

9 for 32 percent and 21 percent respectively.

10 So as you can see, what we have to do,

11 in addition to fighting fraud and abuse, is try to

12 control the expenditures of this program.

13 In Medicaid nationally between 1990 and

14 2000, the cost of prescription drugs and the

15 expenditures on prescription drugs went from \$4.8

16 billion to over \$17 billion. As we go into detail, we

17 can show you in the state of Connecticut, our

18 expenditures followed that trend pretty closely.

19 This year we're expecting to spend over

20 \$300 million on our pharmaceutical programs. In the

21 Medicaid program alone we expect to spend over \$237

- 22 million, and in the ConnPACE program we expect to spend
- 23 somewhere in the neighborhood of \$50 million going up
- 24 to almost \$75 million in the year 2003.
- 25 We do serve a number of Connecticut

1 residents, though. Counting our fee for service

2 program, our managed care program, our ConnPACE 3 program, our SAGA program, we serve well over 300,000 4 individuals in the state of Connecticut and either 5 provide assistance or full coverage for purchase of 6 pharmaceuticals. 7 Let me talk about some of the things 8 that we have in place right now. As everyone knows, we 9 have an automated system in place right now where we 10 have a claims processing system, and our claims 11 processing system, which processes somewhere in the 12 range of 24 million claims per year, has a number of 13 features in it which provide some capabilities to 14 identify fraud and abuse. 15 We have prospective and retrospective 16 drug utilization review. Prospective drug utilization 17 review, for those people who aren't aware of what it

18 is, actually, we look at early refills, we look at drug

19 interaction, and we look at inappropriate dispensing

20 based on the therapies that are provided for that

21 particular diagnosis.

- 22 In retrospective drug utilization
- 23 review, what we do is we look at patterns and abuses
- 24 after the fact based on the claims after they're paid.
- 25 We have a lock-in program for abusers.

1 What we do is when we find a client who is abusing the 2 system, what we do is we restrict that individual's 3 freedom of choice, we provide a lock-in to a specific 4 pharmacy, we agree with that pharmacy that the 5 individual will be locked into that pharmacy, and right 6 now we have about 240 individuals in our programs that 7 are locked in to specific pharmacies for abuse. 8 We provide educational letters to 9 providers and practitioners describing ways to avoid 10 abuse and trying to train them on patterns of abuse by 11 clients that may doctor shop. 12 In addition to that, we do some manual 13 manipulation of information. We have a number of 14 systems in the agency that gather information for us. 15 We have the Medicaid Management Information System, as 16 I said before, which processes about 24 million health-17 care claims a year. 18 We have a pharmacy point-of-sale claims 19 transaction system. That is for people who go into a

20 pharmacy and swipe a card, and that will capture all

21 the information and identify them as eligible for our

24

- 22 programs.
- 23 We have a surveillance utilization
- 24 review system, another independent system where we
- 25 gather information from other systems and try to

manipulate that information, and we have the drug
 utilization review reporting system that reports on
 either the prospective and retrospective drug
 utilization review.

5 All of those systems right now require 6 extensive manual manipulation in order to do 7 comparisons to try to find out other information. 8 The constraints in the system right 9 now. Timeliness. When we try to develop reports right 10 now for those systems, because it requires significant 11 manual manipulation, it requires a significant amount 12 of time, sometimes months to get information. 13 Restraints again or constraints: The 14 data. What we use right now is paid claims data. So 15 when we do an analysis, the analysis is after the 16 fact. When we try to compile the information and put 17 the information together, the information may go back 18 as far as 15 months in order to try to gather the 19 information, put it in one environment that's 20 workable.

21 The system is rigid. Right now it's a

- 22 hard-coded mainframe system, and what happens is DSS
- 23 needs have to be subservient to what's ever coded in
- 24 the software and what we can get out of the system.
- 25 There is a cost factor in the system

1 right now. Each report we try to access from the 2 system has an identified cost for the number of hours 3 it took for a programmer to write that report. And in 4 addition to that, it's a relational database system. 5 So we don't have the ability to cross fields, to cross 6 vendors, and to try to compare usually unrelated data 7 that may produce a trend in a particular -- with a 8 particular provider or a particular client. 9 Having said all that, we have done some 10 extensive reviews on OxyContin. What we have done is 11 we have identified the volume paid by DSS, the volume 12 of claims that have been paid, we have identified the 13 highest prescribing practitioners, we have reviewed 14 their diagnoses and frequency, we shared the findings 15 with appropriate legal and law enforcement officers, we 16 quantified the inappropriate prescribing and actually 17 we focused some investigations.

- 18 I think one of the previous speakers
- 19 talked about Dr. Hall. We were part of that
- 20 investigation. What we discovered in that, though, is
- 21 we also discovered that a number of our clients were

- 22 also purchasing OxyContin on their own. So not only
- 23 were they purchasing pharmaceuticals paid for by the
- 24 Medicaid program, they also had available cash to go
- 25 in, doctor shop, and then purchase the prescription

from either that pharmacy or another pharmacy and pay
 for the entire prescription and not get it entered into
 our system.

4 What we did to try to remedy the problem 5 is, Governor Rowland last year recommended the 6 installation of a decision support system, the 7 legislature approved that through the appropriations 8 act. We have approximately \$2.5 million to go out and 9 develop and implement a decision support system which 10 is actually equivalent to a data warehouse that would 11 give us the automated capability of grabbing data from 12 multiple systems and then compare that data in those 13 systems to try to combat some of this fraud and abuse. As for timeliness, the queries can be 14 15 developed by users once we put up a decision report 16 system and reports can be received literally within 17 hours. The data that we will use in that system will 18 be real-time data, so there will be claims data that is 19 submitted today will be batched at night and downloaded 20 into a decision support system for manipulation through 21 software.

- 22 Flexibility, we'll have ultimate
- 23 flexibility in the system. It will be able to capture,
- 24 it will be able to sort, it will be able to compare and
- 25 report data from multiple fields and multiple systems.

1 The cost, as I said before, the cost in 2 the existing system is we pay by report. In the system 3 that we're designing and that we have going up and are 4 keying on, the design and implementation and all the 5 reporting will be included on the front end of the cost 6 to the system.

And as far as relations, the system
itself will have some built-in algorithms in order to
try to compare some information, and it will have some
funding logic in the system which will be inherent in
the software, compare relations between therapy,
diagnosis, quantity of drug prescribed or actually the
prescription that's prescribed.

We feel that this system will improve detection and recovery of fraud, either be it provider or client fraud, increase overpayment protection, and actually we hope we can get out of the pay and chase since right now all our systems rely on old data and we end up paying the claim and months later we have to go after the provider or client who was fraudulent; we're in that situation where we have to pay and chase. We

- 22 think we will be able to identify abusers much more
- 23 quickly on the front end, we will have prevention
- 24 ability through the use of alerts or thresholds so the
- 25 system will have some inherent logic in it that will

send an alert to either us or the pharmacist or our
 prior authorization advocate to alert us to the
 situation in real time where we think there may be
 fraud or abuse.

5 We think the cost effectiveness of the 6 system will be greatly improved. We are estimating 7 right now that in the first full year of operation we 8 could probably save the state of Connecticut 9 approximately \$10 million in our Medicare program. 10 We will be able to do targeted 11 monitoring and analysis. So in this particular 12 situation, if it's OxyContin, we could target 13 individuals that are receiving OxyContin through the 14 automated system -- I don't mean target those 15 individuals, but target the data that is all that we 16 have on that individual, be it medical services or 17 other services provided. 18 We think what it will provide some 19 overall program integrity. We think we have program 20 integrity now, but having the ability to do some real-

21 time analysis and real-time monitoring really puts us

22 at an advantage.

23 At the end of my presentation, what I

24 did was I included two charts that actually show that

25 since 1998, our expenditures alone in the Department of

1 Social Services, OxyContin have increased over 446 2 percent. So we would appreciate any efforts that this 3 panel or the legislature or Attorney General Blumenthal 4 and Commissioner Fleming would recommend to try to help 5 us. 6 MR. BLUMENTHAL: 446 percent over what 7 time period? 8 COMMISSIONER STARKOWSKI: From June of 9 1998 to January of '01. 10 MR. BLUMENTHAL: And I assume that the 11 system that you've outlined, which we welcome and 12 commend you for instituting, would be easily integrated 13 with an overall prescription drug-monitoring program 14 for private payments as well as the kinds of data that 15 you're collecting? 16 COMMISSIONER STARKOWSKI: Yes. We feel 17 that the data warehouse or the decision support system

- 18 will have the capability to act or interact with a
- 19 number of systems. One of the basic tenets of the RFP
- 20 will make sure that it has open architecture available
- 21 and accessible to other systems to capture data and

22 move data.

23 MR. BLUMENTHAL: Your feeling is the

24 system that you have instituted could save the state

25 \$10 million in either waste or unnecessary prescription

1 drugs?

2 COMMISSIONER STARKOWSKI: Yes. It's our
3 estimate, based on national projections on what we've
4 done with decision support systems, that in the first
5 full year of operation, we would save \$10 million.
6 MR. BLUMENTHAL: Well, we would want to
7 talk to you further, commissioner, about some of the
8 details of what you're doing and what could be done to
9 strengthen overall state efforts in this area. I don't
10 want to take too much of your time now because we have
11 other witnesses. Thank you.
12 COMMISSIONER STARKOWSKI: Thank you.
13 COMMISSIONER FLEMING: Just one quick
14 question, if I may.
15 You mentioned that you have locked in
16 about 240 clients.
17 COMMISSIONER STARKOWSKI: Yes.
18 COMMISSIONER FLEMING: Looking at some
19 of the stats that you gave us, it looks like we have
20 got about 116,000 individuals between various state and
21 federal programs that is the 240 a reflection of the

- 22 degree of abuse or just of the ability to track what's
- 23 going on out there? Because 240 individuals being
- 24 locked in, you feel you have a problem with them,
- 25 versus 116,000 between Medicaid, the state programs,

1 ConnPACE and so forth, is a very small number.

2	My question is: It seems like you're
3 0	doing a good job if you only have 240 people locked
4 i	in. Is that an indication
5	COMMISSIONER STARKOWSKI: I would go out
6 0	on a limb and say it's probably a reflection of the
7 0	constraints on our ability to identify additional
8 8	abusers. And in addition to the 116,000 that is
9 1	represented in the material I provided today, there is
10	another 240,000 that are in a managed care system and
11	Medicaid, so actually there's like 350,000 people who
12	we have pharmaceutical responsibility for.
13	COMMISSIONER FLEMING: The second
14	question: Do the federal regs allow you to lock in
15	those clients that are utilizing federal funds or is
16	that just I know we can do it with the state
17	programs. Would the federal funds, if you find abuse,
18	allow you to lock somebody in?
19	COMMISSIONER STARKOWSKI: Yes.
20	COMMISSIONER FLEMING: Thank you.
21	MR. SIEGELMAN: Just a question, deputy

- 22 commissioner.
- 23 In terms of the people that you do have
- 24 locked in, are any other efforts made around disease
- 25 management or referral for substance abuse treatment in

1 order to deal with the underlying problem in addition

2 to just limiting access to the drugs?

3 COMMISSIONER STARKOWSKI: I wouldn't 4 call it disease management because I think "disease 5 management" is a buzz word that's been around for a 6 while, and most people have a different interpretation 7 of it. 8 MR. SIEGELMAN: Case management pieces 9 for it for attempting to engage people over time in 10 addition to limiting their options, trying to move them 11 in more appropriate treatment. 12 COMMISSIONER STARKOWSKI: We do. We try 13 to not only work with the client, but we also try to 14 work with the prescribing practitioners to make sure 15 that they understand what the issue is with that 16 particular individual so that if we have a particular 17 provider that's been providing services, or multiple 18 providers, we try to get to those providers and make 19 them aware of the situation so they can take some 20 steps.

21 MR. BLUMENTHAL: Commissioner, I would

- 22 like to thank you again for being here and thank you
- 23 for the work that you and your staff are doing with my
- 24 office and others in this area. Thank you very much.
- 25 COMMISSIONER STARKOWSKI: Thank you.

1 MR. BLUMENTHAL: Dr. Russell Portenoy. 2 DR. PORTENOY: Thank you for inviting me 3 to the hearings. My name is Dr. Russell Portenoy. I'm 4 chairman of the Department of Pain Medicine and 5 Palliative Care, Beth Israel Medical Center and 6 Veterans Medical Center in New York City, professor of 7 neurology at Albert Einstein College of Medicine. I'm 8 a past president of the American Pain Society and 9 current secretary of the International Association for 10 the Study of Pain. I also serve on the board of 11 directors of the American Pain Foundation, and I'm vice 12 chairman of the American Board of Hospice and 13 Palliative Medicine. I've been involved in this area 14 for two decades dealing with patients with chronic 15 pain, and I've had a special interest in the four 16 international conferences on pain management and 17 chemical dependency and a fifth conference coming up in 18 June of this year. 19 My testimony today is focused on medical

20 use and abuse of OxyContin. It's based on my

21 experience as a clinician and my knowledge of pain

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- 22 medicine and opioid therapy. As disclosure, I will
- 23 state that I have accepted honoraria for participating
- 24 in educational symposia sponsored by several
- 25 corporations that manufacture opioid drugs, including

1 Purdue Pharma, and my department has received grants

2 from these companies for projects involving

3 professional education and research.

4 There's been intense media attention 5 focused on OxyContin abuse. The published statistics 6 and the poignant stories of people damaged by addiction 7 have justifiably raised concerns about the dangers 8 associated with this drug. In response, there's been a 9 call from some quarters for increased regulation of 10 this drug, or of opioid drugs in general. In some 11 states, actions that increase monitoring or limit 12 access for some patients already have been taken 13 administratively and new laws have been proposed. 14 Specialists in pain management are 15 concerned, however, about the potential -- we are 16 concerned about the potential for abuse, but we are 17 equally concerned about a backlash that could 18 potentially increase the undertreatment of pain. We 19 fear that overregulation, ill-conceived enforcement 20 policies, and worsening social stigma as a result of 21 media attention will reduce the appropriate prescribing

- 22 of these drugs and increase the suffering of patients
- 23 who have unrelieved pain.
- 24 I wanted to frame the issue for you a
- 25 little bit and talk specifically about OxyContin.

1 Since the 1980s, there has been a worldwide clinical 2 consensus that opioid drugs are the first-line approach 3 for treatment of severe pain and chronic pain related 4 to cancer, AIDS, and other serious medical illnesses. 5 Despite this consensus, there have been numerous 6 studies showing undertreatment is persisting. 7 Cancer pain is undertreated to the tune 8 of about 50 percent in a study that I did myself 9 several years ago, showed that 82 percent of patients 10 with severe AIDS-related pain were not receiving opioid 11 drugs. So we have a major problem with under-12 treatment. Undertreatment is a complex problem. In 13 14 part, it's related to physicians' fear of regulation. 15 This is a very real concern. In 1998, for example, I 16 and colleagues collaborated with the Medical Society of 17 New York to do a survey of 1300 New York State 18 physicians, and we found that more than half reported 19 themselves to be moderately to very concerned about 20 regulatory oversight and that one-quarter to one-half 21 admitted to changing the way they prescribe medicines

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- 22 solely because of concern of regulatory scrutiny.
- 23 One-third to one-quarter changed the way they
- 24 prescribed not because of the medical issues, but
- 25 whether they were going to prescribe a certain way that

would yield investigation and potential sanction by the
 state. So fear of regulatory oversight is a very real
 phenomenon.

4 Now, despite persistent undertreatment, 5 it had been improving for use in cancer pain. It 6 followed to some extent the release on the U.S. market 7 of a long-acting morphine formulation called MS Contin 8 which is manufactured by Purdue Pharma. The 9 educational program that followed the launch of this 10 drug sought to dispel deeply-held myths about opioid 11 therapy, reverse misconceptions, and decrease stigma. 12 The later release on the U.S. market of other long-13 acting opioid drugs by other corporations was 14 accompanied by similar educational programs that were 15 pursued by the companies that released these drugs that 16 Purdue Pharma engaged in and was mostly focused on an 17 effort to reduce stigma and reverse some of the myths 18 and misconceptions that were viewed as barriers for 19 appropriate prescribing.

20 Now, as opioid use increased in cancer21 pain, pain specialists began to rethink the traditional

- 22 prohibition about the use of these drugs for chronic
- 23 nonmalignant pain. After more than a decade of debate,
- 24 a 1997 consensus statement jointly issued by the
- 25 American Pain Society and the American Academy of Pain

1 Medicine supported the use of opioid therapy for

- 2 selected patients with chronic nonmalignant pain.
- 3 Similar consensus statements followed from the American
- 4 Society of Addiction Medicine and by the Canadian Pain
- 5 Society. In response to this changing perspective
- 6 about the role of these drugs, those in the regulatory,
- 7 law enforcement communities, and many state
- 8 legislatures had indeed tried to reassure physicians
- 9 that appropriate prescribing for patients with any type
- 10 of severe chronic pain, if done in the normal course of
- 11 medical behavior, would not lead to risk of
- 12 investigation or sanction. The Federation of State
- 13 Boards of Medical Examiners issued model guidelines and
- 14 a variety of states passed intractable pain treatment
- 15 laws in an effort to reassure doctors.
- 16 Now, most pain specialists believe that
- 17 opioids are still greatly underused in the management
- 18 of chronic painful disease, cancer pain, and seriously
- 19 ill patients who are close to death.
- 20 The studies are compelling, but we think
- 21 that undertreatment of pain using opioid drugs in a

- 22 huge population of nonmalignant pain is ongoing. We
- 23 have a huge population of chronic pain patients in this
- 24 country, and most studies show that somewhere between
- 25 10 and 20 percent of the adult population have chronic

pain. At minimum that is 50 or 60 million. There is
 no possible way that pain specialists could take charge
 of that prescribing; the use of opioid therapy in an
 appropriate way has to be brought down to the level of
 primary care provider. Now, at the same time, pain
 specialists are expecting that chronic nonmalignant
 pain is going to increase exponentially during the next
 decade.

9 As the consensus statement begins to
10 have some influence on prescribing practices, we also
11 recognize that abuse is a major issue. In this
12 context, I think it's very important that we understand
13 the difference between abuse and diversion and the
14 problem of addiction, which is a medical problem, which
15 has a strong biologic basis -- studies suggest and most
16 experts believe that no more than about 10 percent of
17 adult patients have the capacity, genetically18 determined capacity, to develop addictive disease.
19 Notwithstanding that, it is clear that abuse is a major
20 problem and efforts have to be made to manage it and
21 prevent diversion.

- 22 Now, pain specialists believe that
- 23 carefully selected patients can receive those drugs and
- 24 have their drug-related behaviors monitored over time,
- 25 and abuse and addiction can be treated. Indeed, people

1 like myself who specialize in this really believe the 2 vast majority of patients who are addicts can be 3 treated with opioids in an appropriately medically 4 supervised way. So opioid therapy clearly has a role 5 to play even in that subpopulation of patients who may 6 be predisposed to addictive disease. 7 So what about oxycodone and OxyContin. 8 The active ingredient in OxyContin is the opioid 9 oxycodone, which has been commercially available for 10 decades. It provides a convenient long-acting delivery 11 system for a drug that is commonly adminstered in many 12 short-acting proprietary and generic formulations, and 13 that is also available in the market in a variety of 14 formulations. There is no scientific evidence that 15 oxycodone is any more addictive than morphine or any 16 other drug. Meaning to say that patients who are 17 biologically predisposed to the disease of addiction 18 are no more likely to select oxycodone than any other 19 other drug. Those biologically predisposed to the 20 disease of addiction are no more likely to be converted 21 to addicts by therapeutic exposure to oxycodone or

- 22 morphine or methadone or to any other neuragnistic drug
- 23 used therapeutically. From the medical perspective, we
- 24 know that patients vary dramatically in the way they
- 25 respond from drug to drug. So we know, for example,

1 some patients therapeutically will do much better on

2 oxycodone than other drugs.

Now, experience with OxyContin by pain
specialists has confirmed what this would lead us to
expect: That some patients do very well with OxyContin
and some don't prefer it as compared to other longacting opioid drugs like MS Contin or Cadian or
Duragesic or methadone. Some prefer OxyContin; some
prefer others.

When Purdue Pharma was developing
OxyContin, it opted to study the drug in populations
with chronic nonmalignant pain, low back pain and
arthritis patients. The studies were positive.
Recently I collaborated in a study of patients with
painful diabetic neuropathy, and the study was again
positive.
After the drug's launch, the company
chose to market it to nonspecialists with a focus on
chronic nonmalignant pain, and they were allowed to do
that by the Food and Drug Administration. The type of

- 22 along with the marketing was very similar with what
- 23 they had done 15 years ago with MS Contin being
- 24 targeted to treatment of patients for cancer pain. It
- 25 was an approach that marketing and education focused on

1 trying to dispel the myths and misconceptions that we

2 know exist out there and are impediments to the

3 appropriate prescribing.

4 Now presumably the combination of 5 marketing and education of the primary care community, 6 combined with the huge, unmet need that exists among 7 the population with unrelieved pain led to a very rapid 8 increase in OxyContin sales, and as sales increased, we 9 had pockets of serious abuse develop in many states, 10 mostly along the East Coast. Among those were people 11 with known histories of substance abuse, but 12 undoubtedly some patients who had not yet declared 13 themselves as having the capacity to develop addiction 14 used OxyContin as a so-called gateway drug; it may have 15 been legitimately and may have been appropriately 16 prescribed by the physician, but the patients lost 17 control of it and developed the disease of addiction. 18 Many of these individuals were 19 highlighted in the press. These were some of the most 20 poignant and troubling stories that we have read about 21 in the last year, patients who were not known to be

- substance abusers. There is no way to know -- there isno evidence that the amount of abuse by known abusersor the use of the drug as a gateway drug is more than
- 25 would be expected with any drug that has the kind of

sales that OxyContin showed. And we also don't know
 the extent to which the media may have been involved in
 generating interest in OxyContin within the community
 of substance abusers.

5 Now, having said that, however, it's a 6 reasonable presumption that the OxyContin problem is 7 greater than it would have been had the company and 8 professional societies linked together and focused more 9 attention on the risks of the drugs, on the risks of 10 all opioid drugs. For 20 years we have received 11 educational programming from the pharmaceutical 12 industry and from professional societies, many of which 13 I've been involved with, that tended to try to minimize 14 risks because we were dealing with the problem of 15 undertreatment as the overriding concern. So our 16 educational programs minimized risk and sought to 17 dispel misconceptions and thereby implicitly encouraged 18 greater and greater use, perhaps increasing the 19 possibility that some patients would develop addiction 20 anew and reports that increased access to the drugs 21 would increase the problem among known addicts.

So the approach to opioid drugs with
legitimate medical purposes should really shift a bit
now, and I can say that the professional societies have
now begun to recognize this. A liaison group, for

example, has been formed among the Pain Society, the
 American Academy of Addiction Medicine, solely because
 of the need to change the approach to the way we've
 been thinking and promoting the use of these drugs in
 the professional community.

Now we know that the approach has to be 6 7 a balanced perspective that recognizes the essential 8 medical nature of these drugs and the fact that they 9 are underused and thereby incorporates the expectation 10 that use will increase, but at the same time recognizes 11 that as use increases and as less-skilled physicians 12 begin to use these drugs in primary care, we may also 13 see an increase in abuse and diversion and addiction. 14 We have to be able to increase appropriate therapeutic 15 use and minimize the risk associated with increased 16 use. 17 The Drug Enforcement Administration 18 recognized the need for that balance and reached out to 19 the medical community, and just several weeks ago,

20 there was a joint release by the DEA with 21

21 professional societies of a consensus statement calling

- 22 for balance in the way that opioid drugs are used by
- 23 both the professional community and also in the law
- 24 enforcement and the regulatory community.
- 25 So we should move forward on this issue

1 of balance, highlighting several critical points. The 2 first is a recognition by everybody that opioid therapy 3 is essential for millions of patients with acute and 4 chronic pain. There is an epidemic of undertreated 5 pain. Driving up here, I heard on the radio about the 6 epidemic of OxyContin abuse. Every time I hear about 7 the epidemic of OxyContin, I think of controlled pain, 8 the enormous cost of human suffering, health care 9 utilization, and lost productivity that occurs as a 10 result of people with chronic pain unable to get access 11 to proper medication. So we have an epidemic of 12 unrelieved pain. 13 Opioid drugs are not a panacea. I 14 myself have considered -- I consider myself rather 15 conservative in who I select for opioid therapy and who 16 I tell doctors to treat. But I think a mainstream view 17 at the present time is that they are clearly 18 appropriate for a subgroup of patients with chronic 19 nonmalignant pain. So that the increase in use of 20 opioid drugs for the treatment of chronic nonmalignant 21 pain means you will see more utilization. You will see

- 22 increased utilization by physicians and, of course,
- 23 increased costs within that huge increase. You would
- 24 expect it to grow, and that would be my view.
- 25 Second, decisions concerning regulation

of opioid drugs should be based on the evidence and not
 based on anecdotes, as poignant as they are in the
 press, some really horrible stories, that touch me as
 much as anybody else; but clearly we can't base policy
 and regulatory oversight on the story of someone who
 unfortunately used OxyContin as a gateway drug and then
 developed the devastation of addiction. We have to go
 by the evidence.

9 Third, we should recognize that there's 10 a lot of complexity in responding to the abuse of 11 legitimate drugs that are now underprescribed for 12 therapeutic purposes. It is very important to 13 recognize that regulatory actions that are intended to 14 reduce abuse might have the unintentional consequence 15 of reducing appropriate prescribing and thereby 16 increase the problem of uncontrolled pain. For 17 example, there are many actions the state could take to 18 reduce OxyContin prescribing, to reduce access to the 19 drug to pain specialists, to not pay for the drug to 20 indigent populations; there are lots of actions that a 21 state or a regulatory agency could do to reduce use of

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- 22 an opioid drug. The question is whether or not reduced
- 23 usage is showing reduced abuse or is actually
- 24 increasing the problem of undertreatment.
- 25 It's very important to have some

evidence that as use is reduced through certain state
 actions, what one is doing is managing the problem of
 abuse and diversion and not contributing to under treatment. This can be done by monitoring programs
 that incorporate some ongoing quality analysis,
 independent studies that can be done in the population,
 end user studies, specific prescriber studies, laws and
 regulations that have evaluated in an empirical way
 over time to determine whether or not what was intended
 actually happened.

Finally, it is also clear now that the professional societies and those in law enforcement and the regulatory communities have to get together and have a dialogue on an ongoing basis. That's why I was so pleased about this hearing, why I was very pleased to be invited to come and testify, why the actions of DEA were met with such a positive feeling on the part of the professional community, because reaching out by the DEA to sit on the same side of the table as the physicians has not happened before.

21 There has to be an ongoing dialogue so

- 22 we can understand what balance is. We have got to
- 23 reduce abuse and diversion but at the same time improve
- 24 pain management so we can design educational programs
- 25 for physicians that are reassuring them that

investigation and sanction won't follow legitimate
 medical use.

3 I have to tell you that given the 4 current climate among physicians, appearing at a 5 hearing like this or reading that the state is not 6 interested in stopping legitimate prescribing won't 7 have any influence. Physicians are already frightened 8 about regulatory oversight. And they need to have 9 systems in place that they feel are protective, and 10 they need to have an ongoing dialogue with the law 11 enforcement and regulatory communities so that they 12 know that the issue of balance is on the front burner. 13 The last comment, of course, relates to 14 the need for treatment. We need much more treatment 15 for patients who have addictive disease. I don't think 16 we're ready to market these drugs directly to the 17 public, as some people have said the trend is moving 18 toward. I think that would be a mistake. We have a 19 big problem with the disease of addiction. This is a 20 highly prevalent disease, it is devastating, it has 21 huge costs to society, and I think we have to be very

- 22 careful as this epidemic of uncontrolled pain is
- 23 addressed with increasing prescribing that we are
- 24 cautious of what we do to potentially increase
- 25 addiction like direct marketing of abusable drugs to

1 the general public, some proportion of whom will have 2 addictive disease even if not yet manifested. 3 Thank you. 4 MR. BLUMENTHAL: Thank you very much, 5 Dr. Portenoy. I want to reassure you that our purpose 6 is not, and I want to stress this point to you and to 7 everyone, not to deny this drug or make it less 8 accessible to people who suffer from severe chronic 9 pain. The drug OxyContin and others like it have been 10 a Godsend to those people, and there are probably many 11 more who are part of a population that are undertreated 12 in terms of pain, but I think that we would be 13 irresponsible if we ignore the risks that you have 14 highlighted so eloquently that there is for abuse and 15 addiction; whether it's 10 percent or 20 percent or 5 16 percent, there is a part of the population that is at 17 risk of addiction and now is addicted, and if we deny 18 that the problem exists, we would be completely 19 irresponsible and ultimately do great damage to the 20 many people who benefit from this drug, because it 21 would be subject to even stronger oversight.

So I agree with you that there is a need
for balance and for concern, as to the people who need
the drug, and I take it from your remarks that more
physicians, primary care physicians, will be presumably

1 prescribing this drug and perhaps need more

2 information, more education, more training in pain3 management.

4 DR. PORTENOY: Right. I think that's a 5 very important point. The educational programming that 6 has been out there for a quarter century really has not 7 focused on those issues that interface between pain and 8 chemical dependency. Now, that's getting redressed 9 now, fortunately, but it is going to take years to get 10 that education out. That's part of the solution, I 11 think.

I think we actually are in extreme
agreement, as somebody might say. We actually agree
with each other, and I think the issue is just to keep
all of those issues, the need for education, the need
for treatment, the need for law enforcement and
regulatory structures that are effective and prompt,
the need for better management of pain with an
expectation of increasing use over time, we have to
keep all those things on the front burner at the same
time and just maintain this dialogue.

Again, I would ask, I would suggest to
you, the state of Connecticut is, talking about EDT
systems and so forth, to think about collecting some
empirical data that builds it into the system up

front. Most states that have EDT systems have no
 empirical data other than what the system provides
 them.

4	MR. BLUMENTHAL: Right.
5	DR. PORTENOY: Since those are sales
6	data, people engaging in illicit acts, one doesn't get
7	the big picture of what's happening in the population
8	of chronic pain, primary care providers. You like to
9	know you have a system that works and doesn't cause
10	more damage in increasing undertreated pain.
11	MR. BLUMENTHAL: One of the purposes of
12	the system, my own purpose in being here today is to
13	increase the amount of data that is available so we can
14	make more informed decisions, quite honestly, an
15	increase in the dialogue between the law enforcement
16	community and the professional community, which I think
17	has been lacking in this area, at least in Connecticut,
18	I think maybe even nationally. You know, when you look
19	at other industries, whether it is securities or
20	utilities, where there is loads of communication
21	between the oversight body and the professionals, and

- 22 in this one there's a lot less. Thank you.
- 23 COMMISSIONER FLEMING: Good morning.
- 24 You raised, I think, probably the most important issue
- 25 for the state as they consider how to deal with this

1 issue, and that is, I'll call it the doctor fear

2 factor, and that fear factor creating undertreatment of

3 pain; and so as a regulator, as we are looking at

4 putting together suggestions to the legislature in the

5 next session, I'm going to need to answer some

6 questions about that.

7 I also, as a human being, I'll bet you 8 every person in this room has had a member of their 9 family go through a situation -- I have -- go through a 10 situation where they've been in tremendous pain, and 11 it's an awful thing to watch. So I want to be sure 12 that I'm balancing these things out. 13 In Connecticut, at the present time we 14 do monitor prescription use of controlled substances, 15 and we sort of do it the old-fashioned way, and there 16 is a lot to be said for an old-fashioned way. We go to 17 the pharmacies and we review records and every one of 18 the agents that works for my agency is a trained 19 pharmacist, and they make judgments about the patterns 20 that they see. What we are thinking of proposing to 21 the legislature is what other states have, which is an

- 22 electronic means by which we collect that data, it
- 23 comes into my agency, and those same pharmacists look
- 24 at that data and make those same types of judgments;
- $25\;$  and so what I would like to ask you, and I look at your

resume, it's really fantastic, but can you -- do you
 have any evidence, could you supply us any evidence
 that would compare a state like Connecticut that does
 this the old-fashioned way versus approximately 20
 other states that now use this electronic system where
 that fear factor has increased, where the fact that
 you've put this electronic monitoring system in place,
 it has in fact caused doctors not to properly
 prescribe?
 DR. PORTENOY: Unfortunately, I don't
 think those data exist, and I've asked for them myself,

13 I also think it's complex in other

14 states because of what's happening -- what the

15 individual EDT systems look like. For example, in New

16 York, we have a system that now still requires us to

17 purchase special prescriptions. So that even though

18 the hated triplicate is no longer there, the doctors

19 still have a visible reminder that every time they pick

20 up and write a prescription for a Schedule II drug,

21 somebody is looking. So in New York my expectation

- 22 would be that the EDT system is not going to have the
- 23 relief of the fear factor to the same extent that the
- 24 systems in other states that are invisible to doctors
- 25 do.

1 But the empirical data which people have 2 called for for ten years just isn't there, 3 unfortunately. I think that reflects the reality that 4 the regulatory and the law enforcement community have 5 focused on a problem and they view reducing use as a 6 proxy for better control. Now only as we are coming 7 into this century with this dialogue are people 8 beginning to say maybe reducing use is adding to the 9 clinical burden and is not actually what we want. We 10 want reduced use among abusers and diverters. We don't 11 want reduced use among primary care treaters treating 12 elderly. 13 You are sitting in a position of being a 14 demonstration state for the rest of the country because 15 if you design your program in a smart way that keeps it 16 as invisible to the prescribers as possible, you attach 17 it to education and dialogue and you measure outcome 18 empirically, maybe after a year, you could make a 19 contribution to this whole area of drug regulation that 20 hasn't been there.

21 MR. BLUMENTHAL: For some of the

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- 22 prescribers, the system shouldn't be invisible. For
- 23 some of the prescribers there should be some sense of
- 24 oversight of somebody watching and caring if there is
- 25 overuse or misuse, right?

1 DR. PORTENOY: If -- we're moving to the 2 question of how one judges misuse and overuse. If in 3 fact there is a legitimate concern that a prescriber 4 lacks the skills and is unintentionally misusing or, 5 even worse, is engaging in actions of profit or some 6 other type of diversion, then there is no question that 7 the state has a role to play and it should be there, 8 and I would hope that it would -- it would target its 9 response based on what the true need is and not to 10 eliminate the license from someone who needs training 11 and not to continue somebody's licensure if they're 12 dishonest. 13 MR. BLUMENTHAL: Thank you. 14 COMMISSIONER FLEMING: One thing that we 15 have done over the last year or so, my agency has been 16 meeting with members of the industry, with law 17 enforcement, with the professionals on the medical side 18 to try to come up with a proposal that everybody would 19 buy into. Now, I don't want to water it down to a 20 point where it doesn't work, but I think what you're 21 saying to me is you're a scientist and this is really

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- 22 more of a political science problem. We need to try to
- 23 balance those interests, and your recommendation, which
- 24 I think is a good one, which I've not heard before, is
- 25 that this process that we put together to develop this

1 legislation needs to continue after it goes onto the

2 books.

3	DR. PORTENOY: Right.
4	COMMISSIONER FLEMING: So that all of
5	the different parties, law enforcement, regulators,
6	doctors, pharmacists, are talking on a regular basis so
7	that whatever judgments we're making about
8	prescriptions in the way it's occurring, that we take
9	new technology, thoughts about management of pain into
10	account. It's a hard thing to do, but I think that's
11	sort of our challenge to put this legislation together.
12	DR. PORTENOY: That's right. Thank you.
13	MR. BLUMENTHAL: Thank very much. I
14	hope you don't mind if we call on you again as we
15	design this demonstration program. Thank you.
16	Kathleen Anderson.
17	MS. ANDERSON: Good morning.
18	MR. BLUMENTHAL: Good morning.
19	MS. ANDERSON: My name is Kathleen
20	Anderson, and I'm the director of governmental affairs
21	for the American Society for RSD-CRPS.

- 22 The American Society applauds the
- 23 initiatives of Attorney General Blumenthal in
- 24 addressing the issues of opioid drug abuse as well as
- 25 the crisis in pain management. We appreciate his open-

1 door policy in encouraging those affected by the

2 OxyContin controversy to step forward and voice their3 concerns.

4 The recent debate regarding OxyContin 5 and the future of opioid analgesics is of great concern 6 to the members of the American Society for RSD and the 7 community of patients and caregivers we represent. 8 Reflex sympathetic dystrophy is the worst imaginable 9 pain known to man or women and rates a 42 out of 50 on 10 the McGill Pain Index. Placing additional restrictions 11 on opioid analgesics will prolong the suffering of RSD 12 patients. 13 Presently pain management centers in 14 Connecticut are limited. Treatments revolve around 15 medications, physical, and psychological therapy, and 16 invasive surgical procedures. It takes an average of 17 two years to be diagnosed with RSD, and once diagnosed, 18 most patients must see an average of 4.5 physicians 19 before their pain is treated. How much longer will it 20 take these patients to get relief if tighter 21 restrictions are enforced? Will they live that long?

- 22 Suicide is one of the leading causes of death in RSD
- 23 patients in the United States today. Until more
- 24 facilities are established and HMO's cover their
- 25 treatments, patients will continue to use primary care

physicians and a variety of specialists to obtain pain
 medications for pain relief. Knowing these facts, you
 cannot limit the dispensing of opioids to only pain
 specialists.

5 Research in the area of neuropathic pain 6 and other chronic pain syndromes is just beginning to 7 surface. If tighter restrictions are placed on the 8 distribution of opioids, we will see less interest by 9 pharmaceutical companies in researching pain mechanisms 10 and developing effective drugs. The American Society 11 for RSD supports the implementation of an electronic 12 prescription monitoring program. It would be a more 13 accurate and efficient method of tracking Schedule II, 14 III, IV, and V controlled substances. It is imperative 15 that physicians practicing proper pain management not 16 be targeted as suspicious. 17 We would like to know how balance will 18 be kept. Physicians need to be responsible for

19 diagnosing patients and prescribing opioids

20 conscientiously. Pharmacists must also be accountable

21 for tracking and recognizing suspicious activities.

- 22 Pharmaceutical companies need to improve the structure
- 23 of these medications to reduce abuse. The ability to
- 24 disable a time-released formula by crushing it needs to
- 25 be addressed. It is hazardous and life threatening to

1 both the pain patients and the drug addicts.

2 Ultimately, it is the responsibility of state and
3 federal law enforcement to curtail the illegal
4 dispensing of drugs enforcing stricter consequences for
5 those who abuse opioids.

6 I am a mother of an 18-year-old who has 7 been suffering with RSD for over three years. Do I 8 worry about the effects, the long-term effects of her 9 medication and possible addiction? Yes. Of course I 10 do. But I'll tell you my worries are secondary to 11 the -- to the torture she endures. The pain is 12 debilitating and relentless. It is inhumane. 13 Perhaps a plan to assist those suffering 14 with this debilitating disease and other chronic pain 15 ailments in Connecticut could be initiated and thus 16 prove to be a more effective vehicle in curtailing 17 opiate abuse: 18 One, establish multidisciplinary pain 19 clinics; two, implement the electronic prescription 20 plan; three, introduce legislation requiring

21 certification in pain management for the medical

- 22 community; four, encourage pharmaceutical companies to
- 23 earmark a percentage of their profits for these

24 centers.

25 We feel addressing the issue in this

manner creates a win/win situation. A, patients will
 have the specialized care they need; B, prescriptions
 are monitored more effectively for abuse; C, physicians
 in the medical community are engaged in pain
 management, which will enable them to better identify
 abusers and refer them to drug rehabilitation; and, D,
 pharmaceutical companies would contribute back into a
 system that addresses the needs of the pain patients
 and substance abusers.

## People in pain are a vulnerable population. We need to pursue education, awareness, and research in the area of chronic pain. Until pain is better understood, we need to place the burden on those responsible for drug abuse; not the victims themselves. The American Society for RSD-CRPS asks Attorney General Blumenthal to rethink his position of placing further restrictions on dispensing of opioid analgesics. MR. BLUMENTHAL: Thank you for being

20 here, Mrs. Anderson. As you know, a number of21 proposals you made are ones that I've advocated, and I

- 22 would agree with you that the restrictions should not
- 23 be placed on the recipients, legitimate recipients, of
- 24 these kind of painkillers because this drug OxyContin
- 25 and others like it have been a Godsend for them. So I

1 welcome your being here today so we can develop some of

2 the balance and measure and constructive kinds of

3 proposals that you just suggested. Thank you.

4 MS. ANDERSON: Thank you.
5 MR. BLUMENTHAL: Nicholas Gugliotti.
6 MR. GUGLIOTTI: I'm married. I'm

7 disabled with a liver disease and also chronic migraine8 headaches.

About three years ago, my physician
recommended that I see a pain management specialist
because I was suffering from chronic cluster migraines,
and they were very, very difficult to live with. The
pain management specialist put me on OxyContin, and it
did help the headaches, but after about three or four
months, I began to feel very lethargic and very dull in
my activities, and I didn't like the way I felt, and I
asked the doctor if there was anything more that I
could do or anything different that I could do. The
doctor suggested that I increase the dosage of the
OxyContin, and so I did that.

21 About three more months went by, I tried

- 22 to give it as much time as I could to see what the
- 23 outcome would be. I was in severe pain, so it was a
- 24 help in that regard, but I began to feel depressed, I
- 25 began to feel other side effects that were very

1 uncomfortable. So with my wife, I sought out another 2 pain management specialist. I was referred to someone 3 affiliated with Yale; the doctor there recommended that 4 I continue with OxyContin, increase the dosage, and 5 recommended that I take it morning and evening so that 6 I would have it in my system 24 hours a day. I 7 continued to feel relief from pain, but other side 8 effects that are troubling; went back and saw the 9 doctor a few times and told him I was very concerned 10 about feeling depressed and didn't know if it was the 11 result of the medication or not. He suggested that not 12 alleviating the pain could create depression and could 13 create some of the other symptoms that I was having. 14 So he suggested that I continue to take the OxyContin, 15 which I did.

At this point, it was about nine months
or so I had been taking the medication, and my wife
began to become concerned because I was having
difficulty maintaining my grip, I guess. I was very,
very troubled, I was emotionally upset, and I felt that
I needed, at this point, I needed the medication; if I

- 22 didn't take it, I felt very uncomfortable. So we went
- 23 to the emergency room. I was seen by a physician
- 24 there. He seemed to agree with the other diagnoses
- 25 that I should continue with the medication. They sent

1 me home. I continued to take the medication.

2 Two weeks later I had what I would 3 consider something close to a nervous breakdown. I 4 just couldn't do. I felt very much overwhelmed by the 5 situation that I was in, back to the hospital, I was 6 admitted to the hospital, and put in a psychiatric 7 ward, which was very difficult for me. I was a 8 businessman before I became disabled with illness. I 9 was respected in my community, and it was a difficult 10 thing for me. I stayed there for eight days and went 11 through detox, which was horrible, probably the worst 12 thing that I've ever experienced in my life. 13 I never took OxyContin that wasn't 14 prescribed, I never took a dose more than I was told to 15 take. In fact, I would cut pills in half and try to 16 limit it because I didn't like some of the side 17 effects, but I was continually told by people I thought 18 were professionals and specialists that there was no 19 harm, there was no danger of addiction, that pain 20 medication, when administered where there is genuine 21 pain, very rarely creates addiction. I definitely

- 22 became addicted to the medication.
- 23 I heard some testimony from Dr. Portenoy
- 24 that there is a certain percentage of people that are
- $25\,$  perhaps predisposed. I didn't know that before. I

didn't even know that until today, to tell you the
 truth. No one ever told me that. No physician ever
 told me that. If that was the case, I'm just at this
 point very surprised that no one saw that that could
 have been a possibility for me.

6 After 50 years of living, after getting 7 a Master's degree and being in business, never having a 8 problem with addiction of any kind, having been given 9 pain medicine along the way, my life, various 10 operations, so forth, never had any reason to believe 11 that this kind of problem would occur. I realize as I 12 sit here that I am one of the anecdotal stories that 13 the doctor referred to. And I realize that there is 14 some very eloquent testimony about people in pain. 15 Believe me, when I hear this lady speak about her 16 daughter who is in pain, I would be the first person to 17 say that I would want that young lady to receive the 18 help. I'm not here to say that pain medication is 19 bad. I'm not here to say that I know enough about 20 OxyContin that I should tell you what to do. But I am 21 here to tell you that I believe through no fault of my

- 22 own, I almost lost my marriage, I almost lost my
- 23 family, and were it not for the fact that I had such a
- 24 supportive family, I had a strong faith in God, I think
- 25 I would have taken my life. I felt at a few points in

1 my life that it was not worth going on, and I believe

2 it was directly related to the medication that I was

3 taking.

4 MR. BLUMENTHAL: We want to thank you 5 for being here and for sharing with us that story and 6 sharing with us so eloquently because it adds a 7 perspective, obviously, to the problem --8 MR. GUGLIOTTI: Yes. 9 MR. BLUMENTHAL: -- that we see, and 10 particularly, as I gather from you, the absence of 11 disclosure to you about the potential pitfalls and 12 problems that could accompany use of this drug at the 13 time that you began using it. 14 MR. GUGLIOTTI: Yes, sir. Even when I 15 went and asked for help because of side effects that 16 were troubling, that I believe should have been at 17 least a caution light that someone should have looked 18 further, and all I was told was I should take more, and 19 I feel in hindsight that was a mistake. 20 MR. BLUMENTHAL: Thank you. Thank you

21 very much.

- Is Mr. Joe Andrews here?
- 23 MR. ANDREWS: Good morning.
- 24 MR. BLUMENTHAL: Good morning.
- 25 MR. ANDREWS: My name is Joe Andrews,

1 and this is my father-in-law, Rheinhold Luther. And --

2 MR. BLUMENTHAL: I'm sorry, could you 3 identify him? Could you speak up a little bit? 4 MR. ANDREWS: His name is Rheinhold 5 Luther. 6 MR. BLUMENTHAL: Welcome to both of 7 you. Thank you for being here. 8 MR. ANDREWS: I want to talk about my 9 wife, who was under a doctor's care for OxyContin that 10 she was taking, and living with her and her being a 11 health care professional herself, she knew what the 12 effects of the medication should be, what -- and took 13 great care of herself, and she was a very intelligent 14 person; and this medication, although she took it only 15 under a year, I could see in her that it caused, at the 16 beginning, it caused confusion, which even got worse, 17 which I can't even describe, like the effects of that 18 medication, the side effects -- I can't even begin to 19 describe. But it's -- basically it would cause 20 confusion, disillusionment and like that. 21 Although she was under the care of a

- $22\;$  doctor, we had been to the hospital, we had been to the
- 23 emergency room clinic, and no one -- no one got to the
- 24 bottom of the problem, which was that drug itself, and
- 25 that drug took her life, and it took her life because

no one -- I mean she -- she went -- let me back up a
 little bit.

3 She went from confusion and everything 4 forward to addiction and -- and it took her life, and 5 all that was because -- I believe in my opinion of what 6 the time I shared with my wife and everything, that 7 this medication should only be administered in a 8 hospital setting with adequate hospital personnel who 9 are adequately supervised, and it should not be 10 administered through a physician or anybody else and 11 given to people outside a hospital care setting, 12 because there's no way that I believe -- experience 13 when we went to the walk-in clinic, which I didn't know 14 at the time, but there are people there that they're 15 not even -- they're not physicians, so they don't know 16 what to look for. They don't know what signs, danger 17 signs, are or anything like that. And all these things 18 revolve around the care of a person, and to get that 19 adequate care, with this particular medication, I think 20 should only be done in a hospital setting, and that's 21 all I wanted to say.

## 22 MR. BLUMENTHAL: Thank you very much for

- 23 those comments. Sir.
- 24 MR. LUTHER: My name is Rheinhold
- 25 Luther.

1 COMMISSIONER FLEMING: See the button 2 right in front of you, push that down. Now we will be 3 able to hear you better. 4 MR. LUTHER: Okay. I'll repeat what I 5 just said. 6 My name is Rheinhold Luther. I'm the 7 father of Joe's wife Julie. 8 Julie developed severe migraine 9 headaches as aftereffects of Lyme disease, and she was 10 on various treatments and various doctors until she 11 finally was given OxyContin. In the beginning, it 12 looked like it was a wonder drug. She improved very 13 quickly, she became much more involved in things, and 14 she was becoming her natural self like she used to be. 15 However, after a while, she started to become 16 disoriented, she fell a couple of times, and this all 17 happened -- well, she was treated for eight months 18 totally, approximately, but in the last four weeks, 19 these incidences of disorientation kept increasing, and 20 finally one weekend it got to the point where we 21 insisted that she seek immediate help, and this is

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- 22 when she got the treatment that Joe referred to; they
- 23 took x-rays, and even though she was totally
- 24 incoherent, they sent her home. And she got home and
- 25 later she was dead.

1	So Joe lost a wife; we lost our
2	daughter. Not only that, but Joe was left financially
3	devastated as far as the costs go.
4	MR. BLUMENTHAL: Thank you.
5	Just one question, Mr. Luther or Mr.
6	Andrews. Was the prescription from a primary physician
7	or from a specialist?
8	MR. LUTHER: It was from pain, Salvation
9	Center.
10	MR. BLUMENTHAL: And did your daughter,
11	your wife, go to a hospital? Is that what I heard you
12	say?
13	MR. LUTHER: No. She went to a medical
14	clinic.
15	MR. ANDREWS: I had also taken her to
16	a I had also taken her to Bridgeport Hospital one
17	time, where they had some idea what the problem was.
18	They didn't they were reserved in treating her
19	because they didn't know what they didn't know what
20	the problems were, what the problem had to do with, the
21	medication, and that's the whole problem. If whoever

- 22 is administering that medication needs -- needs to be
- 23 the one taking care of that person. And they need to
- 24 have that, the proper care. If they don't have that,
- 25 then you lose the communication, you lose what the

1 problem is, and you lose a life.

2 MR. BLUMENTHAL: Well, for myself, I 3 think for other members of the panel, we thank you for 4 being here today and for sharing with us your story and 5 your courage. I thank you.

6 We're going to hear from three panelists

7 at once, but I think maybe before we do so, maybe we'll

8 take a break. I don't know how our reporter is doing,

9 but why don't we take a five-minute break and then come

10 back with Dr. Li, Dr. Fallon, and Dr. Herzog.

11 (Recess: 10:40 to 11:02 a.m.)

12 MR. BLUMENTHAL: If I may call you back

13 to order. We're going to hear from Dr. Charlene Li,

14 Dr. Barbara Fallon, and Dr. Alfred Herzog.

15 And if you could just press the buttons

16 in front of you, your mikes will turn on. Thank you

17 all for being here today. Dr. Li.

18 DR. LI: Thank you, Attorney General

19 Blumenthal and panel members. Good morning.

20 My name is Charlene Li, and I am the

21 immediate past president of the Connecticut Academy of

- 22 Family Physicians. I am also an associate clinical
- 23 professor at the University of Connecticut School of
- 24 Medicine and a former member of the Commission on
- 25 Education at the American Academy of Family

1 Physicians. I am currently in private practice in 2 Windham, Connecticut. I would like to take this 3 opportunity to speak to you on behalf of the 4 Connecticut Academy concerning -- regarding their 5 concerns about the abuse of prescription drugs and 6 electronic surveillance of prescriptions. 7 We are all keenly aware of the benefits 8 of controlled drugs, including narcotics for pain and 9 drugs such as Ritalin for attention deficit disorder. 10 However, we are also very aware of and concerned about 11 the dangers of these prescription medications when they 12 are used inappropriately and not in the manner that was 13 originally intended. As family physicians, we are 14 trained to look at the big picture and to approach 15 problems not only looking at the problem itself, but 16 also at all the associated possible contributing 17 factors. Taking this approach, we feel there must be a 18 multifaceted approach to curbing the use of appropriate 19 medications.

20 First, patient education. When patients21 are prescribed medications that have an abusive or

- 22 addictive potential, they must, must be informed
- 23 regarding this fact. All too often patients are not
- 24 aware of the potential dangers of these medications and
- 25 the dangers they can pose to themselves or others who

may use their medications inappropriately. The
 patient's physician should provide this information and
 education with additional information provided by the
 patient's pharmacist.

5 Second, physician education. Physicians 6 should be aware of the addictive potential and abuse 7 potential of all the medications that they prescribe. 8 While all of us are aware of the addictive potential of 9 narcotics, not all physicians may be aware of the modes 10 of abuse of such medication such as Ritilin, OxyContin, 11 or other such drugs. Physicians need to be educated 12 about the current use on the street of legitimately 13 prescribed medications. The state could assist 14 physicians by providing such information. Physicians 15 should also be reminded of the importance of accurately 16 and consistently documenting the amount of controlled 17 medication that they prescribe in a patient's chart. 18 In this way, the physician has direct knowledge of the 19 patient's drug use and can identify patterns of 20 excessive or inappropriate use.

21 Third, the pharmaceutical industry's

- 22 responsibility. The pharmaceutical industry must take
- 23 responsibility to inform physicians of the appropriate
- 24 use of their medications and also potential abuse
- 25 issues, if appropriate. In the case of narcotic

medication, it is critical that the information on the
 use of the medication, when to prescribe it, and for
 what type of patient and patient situation be based on
 appropriate clinical data and not on the desire to
 increase sales of the product.

6 Finally, electronic prescription 7 surveillance. With the use of computers comes the 8 abilities to monitor a patient's prescription drug 9 use. In the case of the larger pharmacy chains, there 10 is an ability to check a patient's prescription drug 11 profile within the entire system. This ability can be 12 helpful in identifying patients who may be receiving 13 multiple prescriptions for the same medication from 14 several different physicians. Certainly, I have had 15 instances where a pharmacist has notified me that one 16 of my patients is receiving a narcotic medication not 17 only from me, but also from another physician in a 18 different part of this state. If there were to be a 19 larger, all-encompassing electronic system, this 20 capability would be more comprehensive. 21 However, I think if we are to consider a

- 22 comprehensive electronic surveillance system for
- 23 prescription medication, we must be sure that such a
- 24 system has safeguards to assure that information
- 25 obtained from the surveillance is used appropriately

1 and in a manner that assures privacy. Additionally, 2 there must be special considerations in view of the 3 upcoming implementation of the Health Insurance 4 Portability and accountability Act, or HIPAA. 5 The concerns of the academy are the 6 following: Number one, if it is found that a patient 7 is receiving multiple controlled medication from 8 different physicians, a method of informing physicians 9 must be developed that does not compromise patient 10 privacy or interfere with the doctor/patient 11 relationship. 12 Two, if a patient is taking controlled 13 medications on a regular basis, but in an appropriate 14 amount for an appropriate reason, it is important that 15 the information be kept confidential. Inappropriate 16 release of this sort of information could negatively 17 impact the patient's job, insurability, et cetera. 18 Even if the use is inappropriate, this information 19 should be used to educate and treat the patient in a 20 manner consistent with patient confidentiality. 21 Three, if the physician is found to be

- 22 prescribing controlled medications in a pattern that is
- 23 judged to be outside the norm, appropriate evaluation
- 24 of the physician's practice type should be undertaken
- 25 before any potentially negative actions are taken. For

1 instance, a physician who provides hospice care as a 2 substantial part of his or her practice may prescribe a 3 drug such as OxyContin frequently, but appropriately, 4 whereas a dermatologist is unlikely to need to 5 prescribe a medication like OxyContin with any 6 frequency. 7 Information regarding individual 8 physicians' prescribing patterns must not be made 9 public in order to prevent inappropriate labeling of 10 physicians. An example of how this type of release of 11 raw information can have a negative impact on physician 12 practices occurred about 12 years ago when Hartford 13 Courant released cesarean section rates of 14 obstetricians of Greater Hartford. One obstetrical 15 group was reported as having cesarean rates 16 significantly higher than that of any other group. The 17 fact was that particular group performed cesarean 18 sections for a group of family physicians and also a 19 group of midwives, thus artificially increasing their 20 numbers. Since the article did not explain this, but 21 published only the raw numbers, their practice suffered

- 22 unwarranted negative publicity.
- 23 The Connecticut Academy of Family
- 24 Physicians urges the state to consider the following:
- 25 One, urge pharmaceutical companies to

1 develop products that have decreased abuse potential 2 and ensure that that marketing is appropriate; two, 3 develop education programs for physicians and the 4 public regarding the abuse potential of prescription 5 medications; three, provide adequate programs and 6 facilities to treat patients who may be abusing 7 medications and also provide support to their families; 8 four, develop safeguards for any electronic 9 surveillance system that may be developed to protect 10 the privacy of patients and physicians and to ensure 11 the sanctity of the doctor-patient relationship. 12 Thank you. 13 MR. BLUMENTHAL: Thank you very much. 14 Dr. Fallon. 15 DR. FALLON: Good morning. Good 16 morning, Attorney General. My name is Barbara Fallon, 17 and I am a physician and founding member of the 18 Connecticut Cancer Pain Initiative, a voluntary, grass 19 roots organization composed of physicians, nurses, 20 pharmacists, internal medicine, medical oncology, pain 21 management, and critical care. I have presented

- 22 written testimony which was presented and discussed
- 23 with Attorney General Blumenthal and his staff in
- 24 October. As a result of that meeting, I would like to
- 25 emphasize the following points:

1 Patients with chronic pain, including 2 patients with cancer, should have access to proper 3 assessment and treatment of their pain. Mandates to 4 curb diversion and use of opioids should be carefully 5 drafted to prevent an adverse impact on patients, 6 doctors, and pharmacists. Opioids are safe and 7 effective in the treatment of pain. When used as 8 prescribed, they rarely result in psychiatric and 9 behavioral disease of addiction. Whereas over-the-10 counter analgesics such as acetaminophen or Tylenol, 11 aspirin, can cause kidney failure, liver disease, and 12 internal bleeding, especially in the elderly. Opioids 13 do not pose such risks. Patients may receive the 14 maximum dosage, mistakenly believing that more will be 15 better -- it is not -- and that drugs must be safe 16 because they're over the counter. 17 Opioids are dosed individually and are 18 titrated to the relief of pain. There is no fixed 19 dose. Thus, many patient's pain is controlled at the 20 lower dosages, while some patients, especially patients 21 with cancer, may need 10 to 15 times that amount.

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MS Contin, long-acting medication such
as those in pill form, provide patient dosages that are
potent and can be given every 12 hours. If you needed
360 milligrams of long-acting oxycodone, would you

1 prefer to take two tablets or nine tablets at each

2 dose?

3 Restricting the dosage amount could in 4 fact have an adverse impact on patients because of the 5 numbers of pills they would need to take, and pain 6 medication is not the only medication that they take. 7 Many are on complex regimens for bowel symptoms, 8 sometimes nausea and vomiting, respiratory problems, a 9 variety of things. So this is one thing we need to 10 take into account if we are thinking about adjusting 11 the dosages. 12 The only alternatives to these 13 medications is invasive therapy, placing an intra-14 catheter device or catheter placement into the spine. 15 These are much more restrictive to patients, more 16 expensive, and more risky. 17 Along with measures to curb opioid 18 abuse, CCPI strongly encourages the Attorney General to 19 work with professional societies to establish minimum 20 proficiency standards in treating pain. Education in 21 pain is all but absent in medical schools and residency

- 22 training and continuing education is poorly attended
- 23 because it is not required.
- 24 Education of health care providers about
- 25 pain should be paired with a curriculum in chemical

1 dependency, as many doctors do not recognize substance 2 abuse until very late in a patient's course, making 3 treatment less successful. Providing information about 4 proper prescribing for pain should reduce the vast 5 number of patients needlessly in pain and provide 6 earlier recognition and referral for treatment of 7 substance abuse cases. 8 I would like to make a comment referable 9 to the previous patients who provided testimony that 10 depression and chronic pain certainly can coexist. The 11 affect of acute pain is anxiety, but the affect of 12 chronic pain is depression. Depression needs to be 13 recognized and treated, as do any side effects of any 14 medication that cause changes in a patient's mental 15 status, and clearly that was not appropriately done, 16 from what we've heard this morning. 17 I would also like to say that any 18 competent prescriber would inform patients that they 19 should never cut long-acting medications in order to

20 reduce the dosage, as that would certainly allow an

21 increased release of medication and possibly could

- 22 contribute to chemical dependency along the way.
- 23 That's not my specialty. I would not want to testify
- 24 to that as fact.
- 25 Finally, along with my colleagues from a

1 variety of disciplines here today, I would urge caution 2 against overreaction and remind us that when college 3 students overdose after binge drinking, we do not ban 4 alcohol. OxyContin has a legitimate medical use, while 5 alcohol does not. More medical expenditures, more 6 suffering, more death occur from alcohol abuse than 7 properly prescribed opioids. Don't get me started on 8 tobacco. Thank you very much. 9 MR. BLUMENTHAL: I wish you would get 10 started on tobacco. Dr. Herzog. 11 DR. HERZOG: Good morning, Attorney 12 General Blumenthal, and members of the hearing panel. 13 I am thankful to you all for having this hearing 14 today. 15 I'm obviously here with my hat as 16 president of the state medical society, also want you 17 to know my real job, also, I still see patients in my 18 practice, small as it, and a lot of them are pain 19 patients. Again, thank you for giving me the

20 opportunity to speak with you about this important

21 problem.

- 22 Given the rapidly increasing number,
- 23 strength and complexity of today's pharmaceuticals, the
- 24 CSMS recognizes that the time has come to institute an
- 25 appropriate system to monitor medical prescriptions,

1 though there is a need for strong pain medication for 2 all kinds of patients, and we must put together an 3 appropriate pain management program. We welcome the 4 opportunity to really talk with you and develop such a 5 program; one that does not inhibit the appropriate use 6 of these medications, however strong they may be. All 7 of these issues are important ones. 8 Physicians should not be limited to 9 prescribing particular kinds of medications by the 10 specialty they have. We should all be given access to 11 prescribing these medications. My type of cases have 12 been mentioned, depression, chronic pain often go 13 together. Yes, anxiety too, sometimes all of the above 14 in an individual. While certain specialties, such as 15 oncology and pain management, may treat patients with 16 larger needs for pain medication, may prescribe more 17 frequently in higher amounts because of patient needs, 18 all of us, whether we be internists, we should have 19 available to us the ability to prescribe these 20 medications appropriately for people who need them. 21 Now, having said that, we must

- 22 acknowledge there is a tremendous need for appropriate
- 23 pain relief and acknowledge that there is a need to do
- 24 it sensibly. However, limiting physician's abilities
- 25 could have a negative impact for very good work done

today in Connecticut in providing adequate, good pain
 relief for our patients. While programs and coverage
 should certainly exist to cover issues like pain
 addiction, as we know, it is a possible side effect of
 these medications, we would suggest that companies,
 that is, pharmaceutical companies, should not be
 required to pay for such programs. Instead, what we
 would like is to have these pharmaceutical companies
 help develop an information program for physicians and
 education programs for patients who need the
 medications.
 It takes time as a physician to treat

patients like this, and that's something often that you
can't do in seven minutes. You know the problems we
have these days, managed care companies -- don't get me
going on that -- don't like to pay for that. It's too
much time. However, we need to do it right. We do
feel and think that instead the companies should really
help with these kinds of programs and pay for them.
Now, the other piece of the mix is
addiction services; quite frankly, we need to make sure

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- 22 our health insurance companies fund those addiction
- 23 programs. It is rather difficult. So there is a need
- 24 to deal with this problem.
- 25 Yes, an ongoing need exists to improve

1 education for both physicians and patients. They need 2 to have their medications. Physicians must 3 aggressively educate patients, given the appropriate 4 time, given the appropriate information to educate them 5 about the potential for addiction and potential for 6 abuse. It is small, but it's real, but it can happen. 7 It reminds me of a particular patient of 8 mine, not on OxyContin, but something like that, for 9 the past ten years, never increased the dose. We have 10 talked a lot about why that hasn't happened and what 11 else we can do to make that not happen. So these are 12 the type of issues that take time. 13 Now, there is no doubt that the 14 physicians need to be educated more on this. We are 15 hoping for that. We want that to happen. Hopefully we 16 can develop that in the overall system. We need to 17 work with one another to make it possible. 18 Existing and developing technology 19 offers a great opportunity to assist in our efforts to 20 prevent the inappropriate use of prescription drugs, 21 really makes monitoring of this quite readily

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- 22 available. Electronic monitoring is certainly a very
- 23 sensible way to approach this problem, and we want to
- 24 work with you in setting that up. However, we want you
- 25 to consider at least three caveats that have been

voiced by my colleagues here, but I would like to
 emphasize them, setting up an appropriate electronic
 monitoring system, the right way to go, but also some
 caution in how you do that:

One, safeguards must be developed to
ensure confidentiality. I can't emphasize that
enough. It is so crucial for both the patients,
physicians, pharmacists; and it can be done. I always
tell my patients, look, there is a very simple way for
us, there should only be one physician prescribing your
medication. Pick your favorite pharmacy. Your choice,
but pick a pharmacy. Even before setting it up,
certainly can be done more appropriately once you set
up the program. Accountability problem, we need to
ensure the confidentiality; otherwise, the program
doesn't fly.
Number two, appropriate people, such as

18 treating physicians and pharmacists, should have

19 accurate and rapid access to information. Methods to

20 inform physicians without compromising privacy or the

21 doctor-patient relationship must be part of the

- 22 program. It can be done. We know it can.
- 23 Number three, finally, the program
- 24 should not interfere with the legitimate prescribing of
- 25 controlled substances. You have previously, Dr.

Portenoy was asked is there evidence of decreased
 prescribing, I don't know about electronic monitoring,
 but I can tell you when New York instituted its
 triplicate form program, there was evidence that
 prescribing medications decreased; the more onerous the
 task becomes, the physicians give up. They will send
 the patients elsewhere. They won't say, "You don't
 need it." They will say, "I'm not into this anymore.
 See somebody else."

In fact, there was a decrease in
prescribing. Please help us with that. We would like
to work with you to make that happen. And it certainly
has potential to decreasing misuse. You have a
tremendous opportunity to benefit more of our citizens,
and we're looking forward to helping you set that up.
Thank you very much.
MR. BLUMENTHAL: Thank you. I would say
that I am very sympathetic. I support the safeguards
that you, Dr. Herzog, and Dr. Li both have mentioned,
and I want to thank, really, all three of you for

21 helping to educate me and my office. We've met before

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- 22 and spoken, as I have with so many others who appeared
- 23 today, and you have really performed an enormous
- 24 service in providing us your insight and information.
- 25 I thank you for being here today. Thank you.

1 Keith Macdonald. Good morning, and 2 thank you very much for being here. I know you made 3 probably the longest trip of anyone to join us, and I 4 want to express my gratitude to you. 5 MR. MACDONALD: Thank you, Chairman 6 Blumenthal. It's a project that the state of Nevada 7 has been willing to travel to many states about. Our 8 prescription monitoring programs, we think has been 9 effective, and, in fact, the preceding witnesses were a 10 good segue to essentially what Nevada does. 11 We sat through many hearings such as 12 you're doing relative to what we should do in the state 13 of Nevada. The information about prescription drug 14 abuse, misuse, and correct use of was anecdotal at 15 best. We kept hearing many concerns, we had reports 16 from the medical examiner's offices and other 17 information, but we did not know exactly what was 18 happening. So approximately in 1995, we set about with 19 our legislature to promulgate a project called the 20 Controlled Substance Abuse Prevention Task Force, and 21 that task force was made up of a group of people who

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- 22 would include district attorneys, law enforcement
- 23 officers, doctors, both on the regulatory side as far
- 24 as association goes and other individuals to actually
- 25 advise and set the policies of the program. The

1 legislative intent was, to be legal, which we believe 2 it has under the HIPAA act as well as Whalen v. Roe, a 3 Supreme Court ruling; we believed that it had to be 4 confidential, and that was utmost in our mind because 5 this information must be held in that respect for both 6 patients and doctors. We wanted the program to be 7 transparent so that it didn't affect doctors' practices 8 or pharmacy practices. It has been alluded to here, 9 indeed, that information is being collected, but it's 10 being collected by drugstore chains and organizations 11 for some commercial purposes, but it is not being 12 collected between the chains. So the information we 13 want to gather is for our entire state. And most 14 importantly, we did not want to infringe upon the 15 practice of medicine and particularly pain management 16 because, as has been alluded to, there were some real 17 concerns about people getting appropriate treatment, 18 and that is absolutely the case. 19 We had some secondary concerns. We

20 wanted it to be a prevention and intervention process 21 rather than a law enforcement process. The reason

- 22 being it costs about five times the amount of money to
- 23 place a person in the criminal justice system than it
- 24 does to put them in drug treatment. So to arrest all
- 25 the people -- I'll give you another figure here in a

1 minute -- was just not a possibility for our state. We 2 do allow referral to the criminal justice system when 3 we see a patient getting too many prescriptions in a 4 month, we knew that they had been to Kinko's and had 5 copied a good prescription and went all over the state 6 with it. So there is referrals to the criminal justice 7 system. Importantly, we did not want a chilling effect 8 upon the industry of prescriptions in the state of 9 Nevada because all of the issues occurred here, if you 10 intervene in certain manners, it may cause the 11 inability to give people appropriate treatment. And 12 then, most of all, we want to involve all the stake-13 holders so there wasn't any contest. There was a lot 14 of turf battles occurred on who should run a program, 15 and so on, and I, with the Board of Pharmacy, am just 16 one of the administrators of the program. There are 17 other administrators, and, in fact, a task force made 18 up of people I mentioned previously do set the policies 19 for this organization and project.

We looked at being on line, rather thanbeing retrospective. We are retrospective. We collect

- 22 the data, it's a month late; however, I can tell you
- 23 that most drug abuse doesn't change within a month. It
- 24 continues unabated. So the retrospective concept is
- 25 all right. However, the online process would be much,

much more helpful to practitioners, except the cost
 goes up about five times. The processing of a POS, or
 point-of-sale prescription, is around 25 cents. We are
 operating our program at about four and a half cents
 per prescription. The project was to inform doctors
 about patients who were getting drugs.

7 The most common illegal act is doctor 8 shopping or doctor hopping; the patient goes to this 9 doctor, that doctor, and to 40 or 50. Our best patient 10 had gone to 212 in a year's time. So our task force 11 set up a threshold that when patients saw more than 12 five practitioners or more than five pharmacies or more 13 than 300 oral dosage units in 60 days, or two months, 14 it would generate a document, a drug utilization 15 review, which we euphemistically have called profiles, 16 and we don't like to use that name because a drug 17 profile connotes something bad today in terms of 18 profiling, but we sent a drug utilization review 19 document to the doctors. 20 Well, when we first -- before I talk

21 about numbers, when we first identified the number of

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- 22 people in our state that were going to more than five
- 23 doctors and five pharmacies, it was 1700 people.
- 24 Again, if you put those in the criminal justice system,
- 25 that doubled the prison population in our state.

1 COMMISSIONER FLEMING: How many are 2 there?

3 MR. MACDONALD: A million point seven 4 when we started the program. It is now over 2 million 5 people. So we raised the threshold to ten 6 practitioners, ten pharmacies, and 500 oral dosage 7 units in 60 days. When we raised that threshold, we 8 had 4200 people, and a document that's been presented 9 to you, although not titled, I guess I didn't want to 10 claim ownership, does show that in the first year in 11 1997, legislation was '95, the first year we got the 12 project under way was in 1997, and you'll see the 13 patient profile activity, that the patients who 14 exceeded the drug threshold were 4,179 people. That 15 were individuals that had seen ten doctors, ten 16 pharmacies, or over 500 oral dosage units in 60 days. 17 What we do then is send to the doctor 18 with a cover letter saying this is information for the 19 purposes of better treatment of the patient. It's not 20 a threatening letter at all. It is just a document 21 that suggests that this will help them better utilize

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- 22 information for the care of their patient. They
- 23 receive that document, and they can do a number of
- 24 things. They can do something about the patient.
- 25 Quite honestly, where insurance programs and HMO's and

others that limit doctor's time, they most often start
 from their practice. They often get the patient, the
 profile, and say, "I see what you're doing. You better
 do something about this, but you aren't going to do it
 here."

We would hope that they would refer to
pain management doctors. Often the people call us, the
controlled substances task force, and ask what to do.
And we recommend, number one, that they see a doctor
about pain management because invariably that's the
most common concern that exists out there, they have
unmitigated pain. Secondly, we talk to them if they
don't have pain, but they've gotten into the use of
drugs inappropriately, we talk to them about seeing an
addictionalologist. Also, we have a list of drug
treatment programs that we will provide them if they
have a concern that they would like to get off the drug
and so on. So we work this project through pharmacies
and doctors.

20 We've had in four, actually five years21 now, because the year 2001 is almost over, we've had

- 22 one case of confidentiality destruction, and that was
- 23 through a pharmacist that had given an employer the
- 24 list of the drugs the patient was taking in the
- 25 interests, in his thinking, of public safety. The

1 officer -- the person was an officer in the local law 2 enforcement agency. He was charged by the state board 3 of pharmacy and fined to the tune of around \$2,000, and 4 charged for the destruction of confidentiality. We 5 hold this information to be absolutely confidential, 6 and we don't like it to be disbursed anywhere. 7 We wondered what the outcomes of the 8 program would be, and these are outcomes that we had 9 looked for; that we would be able to advise pharmacists 10 and patients -- excuse me -- pharmacists and 11 practitioners, and that we would be able to counsel 12 patients to pain management, appropriate pain 13 management or addictionalologists or a drug treatment 14 program. Also, as has been mentioned, if you see an 15 outlier on a scale of people who are prescribing drugs, 16 refer them to their licensing boards and let the 17 licensing boards decide whether the treatment is 18 appropriate or not. For the most part, people writing 19 the program will not know. When we have a patient 20 getting, we don't care if it's three wheelbarrows full

21 of drugs if it is going to one doctor and one pharmacy

- 22 and that doctor is an oncologist or pain management
- 23 doctor, they are wavered from our concerns, we don't
- 24 care because that's probably in the best interest of
- 25 the patient.

In the worst of cases we've referred to
 law enforcement. And occasionally we run across the
 case, but I can tell you in our state, as it is across
 the country, law enforcement has varied, and, frankly,
 our district attorneys and law enforcement people don't
 have a large interest in prescription drug law
 violations. So our referral system is quite small in
 total numbers.

Some of the concerns have been expressed
here. People would like to have empirical analytical
knowledge about what happens to patients after they've
been identified. Well, that's very hard. You would
have to almost have one-on-one interviews to get that,
but it would be important if a state could afford
that. Were they referred to drug treatment, did they
drop off the program because they changed their name
and address and are back somewhere else as another
person, or did they leave the state. We don't have
that information.

20 One of the features of the program, if 21 you set it up, will be the fact that you will have much

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- 22 more knowledge than you ever wanted, and it does become
- 23 concerning because you will see how large this problem
- 24 is, you will see what the cause of the problem is, and
- 25 if I may be very offhanded, it isn't OxyContin, it's

hydrocodone. You're going to see there are other drugs
 that are much more involved in the abuse of
 prescription drugs than the drug du jour that you are
 looking at currently. The outcomes are listed on the
 document.

6 The people that we profiled, the average 7 number of medical practitioner visits has dropped --8 now, these are the people we sent out drug utilization 9 reports on -- has dropped from 22 to 12, nearly a 50 10 percent increase; the average number of pharmacies that 11 people are seeing have gone from 16 to 12; the average 12 number of prescriptions has gone from 159 to 56; and 13 average number of dosages, which was astronomical, has 14 gone from 9,000, people who we first identified as 15 exceeding the threshold, were getting 9,700 doses a 16 year, and we have reduced that to around 3,300 doses. 17 So we have been able to measure the outcomes. 18 Now, this is not empirical analysis 19 because we didn't go out and interview the patients and 20 find out where they may have ended up, and we do have 21 some knowledge that they ended up in the coroner's

- 22 office and they overdosed and passed away, making their
- 23 utilization suddenly drop to zero.
- 24 The doctors really like this program.
- 25 We have a stack of letters, and we invite you or any

1 other state to contact the state medical association in

- 2 Nevada, if you will, the State Board of Medical
- 3 Examiners, or their counterparts in any licensing

4 capacity, the dental board, the dental association, or

5 any of the groups because they have found this has been

6 an extremely helpful program for reaching those

7 individuals.

8 This has been a very short review of

9 what the Nevada program does. I'm trying to limit it

10 because you have a number of speakers, but I would be

11 happy to answer any questions at this time.

12 MR. BLUMENTHAL: Well, we hope that we

13 can call on you in other settings by phone --

14 MR. MACDONALD: You may.

15 MR. BLUMENTHAL: -- for the benefit of

16 your wisdom and experience, because it would be

17 enormously helpful.

18 MR. MACDONALD: We would be happy to

19 entertain your officers here, if you don't send them

20 with too much gambling money.

21 COMMISSIONER FLEMING: They have it

22 here.

## 23 MR. BLUMENTHAL: We have an abundance of

24 it here. Let me ask one quick question.

25 MR. MACDONALD: Sure.

1 MR. BLUMENTHAL: The four-and-a-half 2 cent versus twenty-five-cent figures you mentioned, are 3 those current or are they from 1997? 4 MR. MACDONALD: No. They are current. 5 Our cost is approximately four and a half cents, I 6 think it's about 4.6 cents is what we're operating 7 under today. The point of sales, operating one, but 8 the point of sales system cost around 25 cents a script 9 to get the information transferred. Many of those are 10 in operation for insurance companies, but they are 11 online; online time is costly to monitor. That might 12 be a different cost. It would be very effective if the 13 persons who could access the information were limited, 14 however, and there is a danger there because if you 15 have any person can access this information, there are 16 some that attempt to use it for inappropriate purposes. 17 I can give you examples. Law 18 enforcement officers having, of course, a dispute with 19 a spouse and he shows up in the office and attempts to 20 give us a subpoena, and we don't allow subpoenas to

21 obtain information, only court orders. He shows up

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- 22 with a subpoena, he's actually trying to get
- 23 information that the spouse used too many drugs so he
- 24 could enhance his obtaining the children, keep her from
- 25 having the child, that type of thing.

1 MR. BLUMENTHAL: But in many instances, 2 that point-of-sale information has already been formed 3 that it could be accessed, is it not? 4 MR. MACDONALD: That is true with a 5 variety of companies, probably 150 companies that are 6 doing that. How you would gather them together is --7 is a question. 8 MR. BLUMENTHAL: But that could reduce 9 the cost, couldn't it? 10 MR. MACDONALD: Yes, it could. Another 11 thing is that -- each pharmacy, once a day, rather than 12 having a point of sale, once a day could submit 13 information. The chain stores usually do theirs in the 14 middle of the night, they drop their information which 15 they get to a marketing company called IMS --16 MR. BLUMENTHAL: Right. 17 MR. MACDONALD: -- and/or have available 18 for their own computers. 19 MR. BLUMENTHAL: A lot of that 20 information is already submitted in almost immediately 21 to IMS right now, is it not?

- 22 MR. MACDONALD: That's correct.
- 23 MR. BLUMENTHAL: Thank you very much.
- 24 MR. MACDONALD: All right. Thank you.
- 25 MR. BLUMENTHAL: I'm sorry.

1 MR. MACDONALD: Sure.

2 COMMISSIONER FLEMING: It is an old 3 legislative habit. I would like to ask you a few 4 questions in the hearing. MR. MACDONALD: Yes. 5 6 COMMISSIONER FLEMING: The method by 7 which Nevada pays for this, when this program was set 8 up and you started in '95, it's been running since '97, 9 how does the state pay for that? What does it cost 10 you? 11 MR. MACDONALD: The first year we 12 obtained grants and our legislation authorized that, 13 the obtaining of grants and gifts, and we solicited two 14 drug firms, and they were kind enough to provide us 15 with substantial grants, and the State Board of Medical 16 Examiners provided us with a sizable grant to start the 17 program. We also raised in Nevada, we licensed the 18 practitioners who have controlled substance authority

19 with the controlled substance registration. That fee

20 was \$30 a buy number, which we equate to \$10 a year.

21 It helped run the program. Approximately now the

- 22 program runs \$120,000 a year to operate. That's one
- 23 and three-quarters person. Those persons also do some
- 24 other things, but primarily they do the work of the
- 25 task force.

1 COMMISSIONER FLEMING: So it's self-2 funded. The statistics that you've submitted between 3 '97 and 2000, I don't need to know this now, but when 4 you go back to Nevada, if you could tell me out of the 5 types that you profile and found possible over-6 utilization, can you break that out by type of drug, 7 say your top ten? 8 MR. MACDONALD: Yes. I have that 9 information statistically in my briefcase. I would be 10 happy to provide it to you. The top drug is 11 hydrocodone; the second drug is Alprazolam. OxyContin 12 is the fourth or fifth drug. The only other drug in 13 Schedule II in the top ten is Methylphenidate. So 14 there are only two Schedule II drugs in the top ten. 15 The majority are the "pam" family, or diazepams. 16 COMMISSIONER FLEMING: The pharmacists 17 that worked in my agency, they thought that would be 18 the pattern, but if you have got some statistics on 19 that, that would be very helpful. 20 One other stat, it's probably not under 21 your jurisdiction, but we've had testimony here this

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- 22 morning from our Department of Social Services about
- 23 the amount of money that the state spends using state
- 24 dollars and federal dollars to pay for these types of
- 25 drugs. If you have any statistics from your, whatever

1 you call your Department of Social Services in Nevada 2 that would show the costs before and after this program 3 was implemented, that would be very helpful to us as 4 well when we go before the legislature and they ask us 5 questions about it may cost a little more to set 6 something up and there may be a large savings down the 7 road as well. That would be helpful if you have it 8 now. 9 MR. MACDONALD: I am embarrassed to say 10 it, but I like honesty. Nevada is the last state in 11 the United States to obtain medical management 12 information system in the Medicaid program. They don't 13 have it operational yet. They are the 50th state, and 14 it's not operational, so they have collected no data 15 regarding the reduction of cost to Medicaid patients. 16 Any other practices have not collected it either, to my 17 knowledge, so we don't have a cost reduction knowledge 18 that is accurate. 19

19 COMMISSIONER FLEMING: If you would like20 some help setting that up, you can talk to our people21 here.

- 22 MR. MACDONALD: Send some money.
- 23 COMMISSIONER FLEMING: Thank you very

24 much.

25 MR. BLUMENTHAL: Thank you very much.

1 MR. MACDONALD: All right.

2 MR. BLUMENTHAL: Dr. David Haddox.
3 DR. HADDOX: Thank you very much for the
4 opportunity to appear. For the record, I'm Dr. J.
5 David Haddox, Senior Medical Director for Health Policy
6 at Purdue Pharma, LP, in Stamford. I am past president
7 of the American Academy of Pain Medicine. In my
8 capacity as president of the American Academy of Pain
9 Medicine before I worked for Purdue Pharma, I worked in
10 the pain management that Dr. Portenoy referred to in
11 his testimony, to study the interface of pain and
12 addiction, to provide better education, clear
13 definitions for physicians in both the field of
14 addiction and pain. Incidentally, that initial meeting
15 was funded by a grant from Purdue.
16 I'm a physician, I'm board certified in
17 pain medicine, general psychiatry, addiction
18 psychiatry; I also have completed a residency in
19 anesthesiology, and I have a dental degree. My
20 complete CV is attached to my testimony.
21 With me today is Howard R. Udell,

- 22 executive vice president and general counsel of Purdue
- 23 Pharma. I have provided additional information about
- 24 Purdue Pharma in my file testimony.
- 25 For now let me state Purdue Pharma was

1 founded by and is managed by physicians. We are a 2 research-oriented pharmaceutical company which seeks to 3 provide a benefit to patients through new and improved 4 treatments for disases and for people in pain. 5 Purdue Pharma is a Connecticut company. 6 We moved our headquarters from Yonkers, New York, in 7 1973, bringing 150 jobs to Norwalk. For 27 years we 8 expanded in Norwalk, and when we outgrew our facility 9 there, we stayed in Connecticut and established new 10 headquarters in Stamford. Since moving to Connecticut, 11 we have added 817 jobs to the state's economy. We now 12 employ 967 people in Connecticut, a total of 3,071 13 nationwide. Purdue Pharma has been a success story and 14 at the very core a Connecticut success story. We 15 obviously had a special interest in being here. 16 The availability of OxyContin is 17 critical for millions of patients who are suffering 18 from moderate to severe pain where a continuous around-19 the-clock analgesic is needed for an extended period of 20 time. Unfortunately for those people, many of whom I 21 have personally treated, concern generated by the

- 22 criminal use of OxyContin has significantly increased
- 23 in some locations, with the result that some patients
- 24 are asking for their doctors to switch them to less
- 25 effective medications, and some pharmacies are no

1 longer willing to carry OxyContin. Purdue Pharma

2 receives alarming reports like this every day.

3 At the same time, naive teenagers and 4 others are abusing OxyContin and other prescription 5 drugs. For some, the consequences are tragic. They do 6 not understand that the abuse of prescription 7 medication can be as lethal as the abuse of illicit 8 drugs. Abuse of prescription medication is a public 9 health problem for this country that we must all join 10 together to address. This hearing is therefore both 11 important and timely. 12 I appear today because we want to 13 continue our collaborative relationship with you, Mr. 14 Attorney General, to stop the abuse and diversion of 15 our product by criminals and, as you do, we also want 16 to make sure it remains available to meet the needs of 17 persons in pain.

I also have a deep and personal reason
for appearing here today. Before joining Purdue
Pharma, I practiced and taught medicine for 20 years.
For 11 of those years I specialized in the relatively

- 22 new field of pain medicine. When I attended medical
- 23 school, I received less classroom instruction in the
- 24 assessment and management of pain than it takes me to
- 25 drive from Stamford to Hartford and back, even on a

good traffic day. In this regard, however, my medical
 school is not unique. We were no different than other
 medical schools even today. It is fair to say most
 doctors are trained to treat a patient's disease, not
 to treat their pain.

6 I grew up among on the mining 7 communities of West Virginia. I did not have to go to 8 medical school to learn about pain. I've seen the 9 effects of pain on injured miners and their families 10 since I was a young boy. Because I spent a lifetime 11 seeing and treating pain, I welcome the chance to 12 address the critical comment of use and abuse. 13 While all the voices in this debate are 14 important, we must be especially careful to listen to 15 patients who, without medicines like OxyContin, would 16 be left in pain. We urge you to talk directly to some 17 of those patients. They are not addicts. They are not 18 criminals. They are people who, because of cancer, 19 sickle cell anemia, nerve injuries, low back pain, or 20 some other physical insult or disease that had the 21 quality of their lives taken away from them by

- 22 unrelieved pain.
- 23 Today's testimony bears on a significant
- 24 question of health policy: How to address the problems
- 25 of abuse and diversion which accompany the sale of a

controlled drug like OxyContin without restricting its
 availability to meet the needs of doctors and patients
 to the effective management of pain. It's a question
 of balance.

5 This question, however, is neither new 6 nor unique to OxyContin, as you heard. It has existed 7 as long as controlled substances have been available. 8 It is a critical question. We are confident that 9 Purdue has devoted more resources and efforts than has 10 any pharmaceutical company to seeking the answers. 11 Amidst all the publicity and controversy 12 you heard this morning, a few facts stand out. First, 13 the problem of chronic pain in this country is enormous 14 and expensive. According to organizations like the 15 American Pain Foundation, an estimated 50 million 16 Americans suffer from chronic pain, with a cost 17 approximating \$100 billion a year in lost work days, 18 excessive or unnecessary hospitalizations, unnecessary 19 surgical procedures, and inappropriate medications and 20 the patient-incurred expenses of self-treatment. 21 But even that staggering number fails to

- 22 capture the essence of chronic pain in America.
- 23 Moderate to severe pain cannot be adequately expressed
- 24 merely by numbers. It is individual and it is
- 25 personal. It is intense. It is debilitating. It

1 destroys the capacity to perform life's simplest

2 functions, and could even destroy the will to live. I 3 have certainly seen this in my practice. Anyone who 4 has cared for a loved one in pain knows more about the 5 impact of pain than I could ever hope to describe. For 6 those fortunate not to have experienced significant 7 pain for themselves or to have cared for someone, let 8 me ask you to imagine a life where you can't get out of 9 bed, you can't go to work, you can't take a walk, you 10 can't hug your child, you can't hug your spouse, or 11 even kneel in prayer. That can be and often is the 12 life of a patient with chronic pain. 13 Second, chronic pain has been 14 historically undertreated. Only in the past decade has 15 public and medical opinion swung decisively in the 16 other direction, based on the proven effectiveness of 17 individualized therapy, including opioids, in treating 18 pain and the startling improvement in quality of life 19 such therapy offers to patients. 20 The United States Drug Enforcement

21 Administration itself acknowledges that for many

22 patients opioid analgesics are the most appropriate way

23 to treat pain.

24 Third, OxyContin is widely recognized as

25 a highly effective treatment for pain. When used under

1 the supervision of a physician, it's also an extremely 2 safe medication. Its 12-hour controlled release 3 mechanism affords an extended dose of pain medication, 4 allowing patients to sleep through the night or to go 5 to work, and avoiding wide fluctuations or changes in 6 blood levels which can cause side effects. Many 7 patients have told their doctors, have told our 8 company, and have told me personally that OxyContin 9 gave them their life back. I can't tell you the number 10 of times in my practice I heard that almost exact 11 phrase from patients. 12 Purdue shares all of your commitments, 13 Mr. Attorney General and commissioners, to fighting 14 abuse and diversion of controlled medicines. Abuse and 15 diversion harms patients with pain, it harms the 16 abusers, and it harms the cause of pain sufferers and 17 those who treat them, and it harms Purdue and its 18 products. Importantly, abuse and diversion threatens 19 sound health policy, whose course should be driven by 20 the health needs of millions of patients, not by the 21 actions of relatively few criminal diverters.

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- 22 Purdue has taken a leadership role and
- 23 has provided and continues to provide assistance to law
- 24 enforcement communities in preventing the illegal
- 25 importation of OxyContin from Mexico and Canada.

1 Purdue has also changed the tablet markings on

2 OxyContin exported for sale to Mexico and Canada to 3 assist law enforcement in determining country of origin 4 in drug seizures to frustrate smugglers and make it 5 easier for law enforcement to identify illegally 6 imported medications. 7 To more than 7,000 officers nationwide, 8 we have provided placebos to law enforcement for use in 9 reverse sting or controlled buy undercover operations, 10 we voluntarily worked with the FDA to change the 11 warnings in our package inserts, and we're educating 12 youngsters about the dangers of prescription drug 13 abuse, a program that is not replicated anywhere in the 14 United States presently, even including the Bayer 15 curriculum. 16 In our view, prescription monitoring 17 programs, or PMP's, can be a good tool. The PMP's in 18 Kentucky, the one you heard about in Nevada can serve 19 as very useful models. PMP's can reduce doctor

20 shopping and diversion from good medical practices to

21 identify persons who are receiving controlled

- 22 substances from other doctors. Purdue supports the
- 23 adoption by all states of well designed PMP's and urges
- 24 that care be taken to provide uniform standards for
- 25 collection, storage, and retrieval of data.

1 Purdue has also worked with Congress to 2 develop legislation to provide states with incentives 3 to adopt PMP's that meet minimum federal requirements. 4 We are here today to support your 5 efforts in Connecticut to develop your own PMP. We are 6 eager to work with groups represented here to design 7 and support such legislation. In addition, we are 8 prepared to utilize our resources to explain the 9 benefits of an appropriately designed system to 10 physicians and other members of the health care 11 community to gain support for such legislation. 12 We have also seen a draft proposal made 13 by the Department of Consumer Protection. The draft in 14 our view contains many of what we consider to be the 15 most important attributes of the ideal prescription 16 monitoring program, and laudable attributes of an ideal 17 prescription monitoring program in that this maximizes 18 the benefit to the public health; it provides useful 19 information to clinical management to authorized health 20 care professionals; it assists in the detection of 21 prescription fraud and doctor shopping; it allows for

- 22 case management interventions, based on pharmaceutical
- 23 usage and, while fulfilling these objectives, will
- 24 protect patient privacy and create little or no
- 25 intrusion burden into or additional burden on the

1 practices of prescribers and dispensers.

2 Our largest area of concern, however, is 3 that any PMP be designed primarily to benefit 4 physicians and pharmacists in patient medical care. 5 Purdue Pharma hopes to be able to work with your 6 office, Mr. Attorney General, with the commissioners 7 and their staffs, with Connecticut's law enforcement 8 authorities to draft additional bill provisions to 9 protect patient needs, to prevent abuse, and to save 10 the state valuable health care dollars lost to fraud. 11 Ultimately solving the problem of prescription drug 12 abuse requires the cooperation of many elements in our 13 communities, law enforcement, schools, religious 14 leaders, parents, family, the courts, the medical 15 community, the press, and federal and state 16 legislatures, government agencies, social service 17 providers, and the pharmaceutical industry. Purdue is 18 helping through our specific programs and our 19 cooperation with the other elements in the community. 20 As noted, we think appropriately 21 designed PMP's would also be a step in the right

- 22 direction. What is needed, above, beyond, and in
- 23 conjunction with all of these measures is cooperation
- 24 and common purpose among all parties essential to
- 25 solving the problem of prescription drug abuse. This

is a long-standing societal problem that requires a
 reasoned solution. We are committed to partnering with

3 all involved.

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Management of pain is critical in this
country. OxyContin has proved itself an effective
weapon in the fight against pain, returning many
patients to their families, to their work, and to their
enjoyment of life. This advance should not be stunted
or reversed because of the illegal activities of a
small percentage of people who divert and abuse the
drug. The answer to the problem of prescription drug
abuse lies in education, information, enforcement, and
cooperation, not restrictions that would deny patients
effective treatment or therapy.
Thank you very much.

MR. BLUMENTHAL: Thank you. And I might

17 just say we welcome your cooperation being here today,

18 and I know my office and I have met with

19 representatives of Purdue Pharma on a number of

20 occasions, three or more, as have my colleagues around

21 the country from other states in working with them, as

- 22 you know, in a multi-state task force, and we had an
- 23 opportunity as recently as last Thursday to talk about
- 24 this problem and some of the steps that Purdue Pharma
- 25 has taken and hopefully will take.

I noted in your description of those
 steps, unless I missed it, you didn't mention the
 changes in marketing, promotion, advertising. I wonder
 if you could discuss some of those and maybe some of
 the others that you have planned.

6 DR. HADDOX: Well, one thing that we're 7 doing as far as educational activities is we are 8 spending a great deal of time now, in cooperation with 9 law enforcement, educating physicians and pharmacists, 10 nurses on how to spot drug abuse, because that's an 11 area that is typically poorly taught in medical school 12 as well and also how to do things to prevent diversion, 13 because a lot of physicians don't realize they are 14 being taken by the criminal element from time to time. 15 We are also developing an entire line of 16 abuse-resistant analgesic medications. This is a very 17 significant technical challenge, as you are aware from 18 your meetings with us; but we do believe we can 19 overcome some of these challenges. In fact, we have 20 been working on this since before OxyContin was 21 marketed. The technical obstacles are substantial, but

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- 22 we do think we can bring gradually to the market a line
- 23 of drugs that will be less desirable to abusers and yet
- 24 fully effective for patients with legitimate need.
- 25 MR. BLUMENTHAL: I wonder, without

asking you to divulge any confidential information,
 whether you could elaborate a little bit more on what
 the timing may be on some of those disabling resistant
 kind of drugs using alexon or naloxone, which I

5 understand actually have been reported publicly, so I

6 don't know that it's even confidential.

7 DR. HADDOX: That's correct. Yes. One 8 of the theories involves different ways of compounding 9 narcotic antagonists, the drugs that will neutralize or 10 reverse the effect of the medication in a way such that 11 the patient will get the full effect of the medication 12 but that an abuser would neutralize that and not get 13 any effect of it; therefore, it would not be desirable 14 to them. We hope to be submitting clinical trials 15 evidence on the first of those compounds to the FDA 16 next year.

17 MR. BLUMENTHAL: Thank you. Thank you18 very much.

19DR. HADDOX: Thank you, sir.

20 MR. BLUMENTHAL: We hope to continue to

21 be in consultation with you in the future, and thank

- 22 you and Mr. Udell for being here.
- 23 DR. HADDOX: I will look forward to it.
- 24 Thank you.
- 25 MR. BLUMENTHAL: Karen Weingrod and Dr.

1 James Duffy.

MS. WEINGROD: Good morning, and thank you for the opportunity to speak today. My name is Karen Weingrod. I'm director of the Connecticut Coalition to Improve End-of-Life Care, a statewide organization comprised of providers, government and community agencies, and individuals committed to improving end-of-life care across the continuum of health care services.

10 My testimony today does not reflect the
11 coalition's official position as our bylaws and
12 operating procedures prohibit lobbying and advocacy and
13 policy provisions. However, based on my experience
14 with end-of-life care issues, I would like to make
15 several comments regarding the critical importance of
16 treatment of pain for dying patients.
17 Pain control is the integral component
18 of passionate quality end-of-life care. A study by the
19 American Health Decisions, a national coalition of
20 citizen groups concerned about ethical issues and
21 health care, many Americans are more fearful of how

- 22 they will die rather than of death itself. They want
- 23 their pain to be managed, regardless of the possible
- 24 risks of addiction or hastening death, and they prefer
- 25 to die as naturally as possible in familiar

1 surroundings with loved ones.

2 Pain management is one of the most 3 important things the health care system can do for 4 those who are terminally ill. As one man in Idaho 5 stated, "I think that pain is one of the worst things. 6 A person needs whatever is available to stop the pain. 7 You have got to help them stop the pain." 8 One of the greatest fears voiced by 9 participants in these focus groups is that they or 10 their loved ones will die in extreme pain. This 11 tremendous concern was also evident in focus groups 12 convened over the past two years across the state of 13 Connecticut to discuss end-of-life issues. Recognizing 14 that we must work to end the abuse of narcotic 15 analgesics by individuals misusing these medications, 16 it is essential to appropriate treatment for pain. 17 Consideration of the following two 18 points is key to the delicate balancing approach: 19 Patients must be able to freely express their degree of 20 pain with the expectation that it will be treated 21 appropriately and in confidence and that there will be

- 22 no stigma attached to their need for and receipt of a
- 23 narcotic pain medication prescribed for their
- 24 condition.
- 25 Recent studies indicate that under-

1 treatment of pain is a serious problem in the United 2 States, even for critically or terminally ill patients, 3 given the insurance companies' insurance practices. 4 Narcotic abuse should not further restrict access to 5 care by imposing an unintended chilling effect on level 6 of treatment necessary to effectively manage severe 7 pain. 8 Thank you for the opportunity to address 9 these issues. 10 We must pursue a balanced approach that 11 focuses on protecting and serving patients in need of 12 pain control medication with safeguards to prevent 13 abuse. It would be an immeasurable disservice to enact 14 policies that compromise patient care at the end of 15 life. 16 MR. BLUMENTHAL: Thank you. 17 DR. DUFFY: Good morning, Chairman 18 Blumenthal, members of the committee. My name is James 19 Duffy. I'm an associate professor of psychiatry at the

20 University of Connecticut. I'm board certified in

21 psychiatry, palliative care and hospice medicine. I am

- 22 also the chairman of the steering committee of the
- 23 Connecticut Coalition to Improve End-of-Life Care, and
- 24 I thank you for this opportunity.
- 25 My comments on the issue of the use and

1 abuse of prescription medications, particularly opiate

2 medications, are as follows:

First, and most importantly, we must
distinguish between the goal of assuring effective pain
treatment versus the goal of enforcing the law.
Effective, compassionate pain relief of those of us who
are suffering should not be contaminated with the goal
of apprehending criminals.

9 Opiate medications are an effective, 10 vital, and irreplaceable part of our therapeutic 11 armamentarium. Furthermore, recent advances in 12 medications such as OxyContin offer significant 13 clinical advantages that enable us to more effectively 14 manage the pain of our patients. The fact that some 15 individuals choose to abuse these drugs should not 16 impinge upon what I believe are the civil rights, the 17 civil rights of law abiding citizens, to receive the 18 most effective pain relief available to them. Indeed, 19 as you will hear shortly, an objective review of the 20 research indicates that the problem is not that opiates 21 are being abused, rather, they're being underprescribed

- 22 by people like us to those who need them.
- 23 So I believe the goal of any legislation
- 24 addressing issues of prescription drug use and abuse
- 25 should first focus on assuring that Connecticut

residents receive optimum pain relief. In this regard,
 I believe modern medicine has been remarkably effective
 with these pain treatments; however, the American and
 Connecticut public continues to experience unnecessary
 pain.

6 To this end, I would like to share with 7 you some of the results of the recent study funded by 8 the Hartford-based Donaghue Foundation and carried out 9 by the American Society of Law, Medicine and Ethics 10 published in December of 2000. The findings of the 11 study are disturbing and are an indictment of our 12 health care community. These findings include, first: 13 Less than one-third of the patients in 14 the state with chronic pain consider their pain to be 15 under adequate control. 16 Despite the fact that 70 percent of 17 patients with chronic pain described their physicians 18 as understanding and supportive, only 22 percent of 19 these patients said their physicians had actually 20 helped them a lot or controlled the pain. 21 It's disturbing that 43 percent of

- 22 cancer patients continue to experience significant pain
- 23 relief and only 22 percent of patients with RSD
- 24 experienced significant pain relief.
- 25 It's also concerning that patients who

are referred by their physicians to experts in pain
 control in the state typically receive no additional

3 extra relief from their symptoms.

4 The study also reports that physicians
5 and nurses attending our two medical schools are
6 currently receiving inadequate training in pain
7 management.

8 Connecticut physicians, the study 9 reports, are ignorant about the federal and state laws 10 concerning these drugs and are therefore paranoid and 11 concerned about being prosecuted. It seems to me that 12 we have another crisis of not only OxyContin and 13 prescription, but also a crisis in health care. 14 The Connecticut Coalition to Improve 15 End-of-Life Care, Robert Wood Johnson, has recently 16 completed a number of focus groups trying to understand 17 what Connecticut residents experience and feel about 18 end-of-life care in our state. As always, they provide 19 us with wisdom and insight as to what actually is going 20 on. Some of the findings of these focus groups are as 21 follows:

- 22 Connecticut health care providers,
- 23 according to our focus groups, lack sufficient
- 24 knowledge of pain and palliative care.
- 25 Connecticut health care providers,

1 according to their patients, are often ignorant about

2 the resources available to them and their patients who

3 are experiencing terminal painful illness.

Connecticut families and patients do not 4 5 feel educated about their options when it comes to pain 6 and symptom control, and they feel that their health 7 care institutions have not developed effective 8 mechanisms for treating pain in end-of-life issues. 9 Finally, they all feel that the 10 reimbursement through the experience of palliative care 11 and pain control by third-party payers, excluding 12 Medicare, is totally inadequate. 13 So based on these research findings, it 14 must be concluded that we as a society are failing to 15 respond to the needs of our fellow citizens when it 16 comes to their pain and their symptoms at the end of 17 their lives. 18 I do believe, however, something can be 19 done to improve this state of affairs, and I would 20 suggest consideration of the following measures:

21 I think first we need to educate

- 22 physicians and health care providers on pain management
- 23 and also on palliative care issues. Pain management
- 24 should be a core skill set of all physicians who care
- 25 for patients, not just experts. Despite the fact that

1 these skills are quite simple to acquire, physicians 2 continue to display ignorance in this area. So in this 3 regard, I must begrudgingly support a mandatory 4 educational requirement in pain management as part of 5 physician licensing. This training should include not 6 just medical, but also legal aspects of pain 7 management. I believe these educational initiatives 8 should be funded by the state and funded by cooperation 9 between the state medical society, our two medical 10 schools, and our Connecticut Department of Public 11 Health. 12 I would suggest that we need to educate 13 our public about their options and rights when it comes 14 to pain management and end-of-life care. All of our 15 residents should be informed that they have a right to 16 expect that their pain be managed at the end of their 17 life. This should be, a great belief, a matter of 18 civil rights and not just health care.

I would urge you to consider acquiring
 health care reimbursement for palliative care of all
 third-party payers, which is not currently the case in

- 22 this state. I would suggest instituting laws,
- 23 regulations, or guidelines that protect physicians from
- 24 sanctions for providing what is actually an adequate
- 25 pain relief in certain groups of patients.

Finally, we need to assure that patients
 with pain continue to have access to the most effective
 analgesics available today. In this regard, OxyContin
 should not be singled out for particular mandatory
 regulatory restriction. As we have heard, this is
 actually just one of many drugs that have the capacity
 to be abused. OxyContin is an effective medication.
 It has brought relief to so many patients suffering
 from severe pain.

10 Finally, just the thought that although 11 in recent years we have witnessed a remarkable, almost 12 tidal wave of technological advances in medicine, it is 13 regrettable that we have managed to transplant the 14 human heart, but we cannot respond compassionately to 15 the suffering of those not in need of one. Thank you. 16 COMMISSIONER FLEMING: Thank you very 17 much. Any questions? 18 MS. DENNE: No. 19 COMMISSIONER FLEMING: Thank you. Mark 20 Cooney and John Parisi. 21 MR. COONEY: Good morning. I'm here to

22 talk a little bit about --

## 23 COMMISSIONER FLEMING: Just for the

- 24 record, state your name.
- 25 MR. COONEY: My name is Mark Cooney. I

represent the Chain Association, it is a Connecticut
 association of drugstore chains. I'm here to talk a
 little bit about the monitoring of the drug
 substances.

5 Currently we have stores that we 6 represent in New York and Massachusetts for our 7 company, and they currently are monitoring 8 prescriptions that are Schedule II, and the idea of 9 monitoring in all the classes to us just seems to be a 10 large amount of information, and these classes were 11 designed based off the addiction rates, and having the 12 Schedule II's monitored seems to be the best route to 13 go to try to look more along the classes for addiction 14 rates.

15 One thing we try to do is, as a company 16 and as an association, is to decrease the workloads for 17 our pharmacists. In today's day and age, to try to 18 decrease prescription errors and the amount of work 19 pharmacists have to do, concentrate on filling 20 prescriptions correctly and getting information to the 21 customers, the counseling to our patients, is becoming

- 22 our major focus, and creating any more work to our
- 23 pharmacists in these situations just seems to be going
- 24 the opposite direction of what we're looking for.
- 25 We are in favor, obviously, of

1 controlling prescriptions that have a high potential 2 for abuse and everything else. One thing we've looked 3 at in the other two states is the amount of 4 prescriptions that are sent in for the amount of 5 controls --MR. BLUMENTHAL: The other two states 6 7 being? 8 MR. COONEY: New York and Massachusetts. 9 MR. BLUMENTHAL: I'm sorry? 10 MR. COONEY: New York and Massachusetts. 11 The information is sent in to these 12 states, and once it does, a fair amount of it is coming 13 back rejected for missing parts of information from the 14 prescription. At that point, this information has to 15 be taken back down, broken up, given back to the 16 stores, pharmacists have to go back through, research 17 the information, add in whatever information is 18 missing, that has to be sent back in to the corporate 19 level, and that information is again sent back to the 20 states. So, in other words, we're creating more work, 21 you know, at the store levels, you know, for our

- 22 pharmacy, and we're trying to go the other way. We're
- 23 trying to decrease the workloads of our pharmacists.
- 24 MR. BLUMENTHAL: Run through that
- 25 again. What happens?

1 MR. COONEY: What happens is when 2 prescriptions are filled, the information is 3 electronically sent to these states once a month, and 4 that information is processed by the states for 5 monitoring controls, any prescriptions filled in the 6 Schedule II classification. Of those prescriptions, 7 there are a large amount that are being rejected for 8 either missing information, bad data, something along 9 that line, and what they're doing at that point is 10 sending it back to the companies, they are breaking 11 down that information, taking that information, sending 12 it to the store level, and they have to again research 13 what's missing, whether it's a serial number, whatever 14 it may be, reprocess the information, and send it back. 15 We are, of course, in favor of 16 monitoring Schedule II prescriptions. Again, those 17 were designed for the degree of abuse. Now, spreading 18 that out to drugs that are in classes, you know, III's, 19 IV's, and V's just seems to be a lot of excess 20 information. If there are prescriptions that are in 21 those classes that are, you know, being abused, maybe

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- 22 we should look at those medications and move those to a
- 23 Schedule II classification.
- 24 MR. BLUMENTHAL: Let me just ask you,
- 25 you're with Stop & Shop?

1 MR. COONEY: Yes.

2 MR. BLUMENTHAL: And where are you 3 based? 4 MR. COONEY: I cover -- I'm the regional 5 pharmacy manager. I cover our stores in Connecticut 6 and New York. 7 MR. BLUMENTHAL: You don't cover 8 Massachusetts? MR. COONEY: I have in the past. But I 9 10 am licensed in both Massachusetts and New York. 11 MR. BLUMENTHAL: And don't you now keep 12 and compile information about prescriptions that are 13 filled? 14 MR. COONEY: Yes. 15 MR. BLUMENTHAL: And don't you in fact 16 transmit that information to IMS? 17 MR. COONEY: Yes. For Schedule II's in 18 those two states. 19 MR. BLUMENTHAL: All right. And when 20 IMS gets that information, does it send it back to you 21 and create all the work that you referred to?

- 22 MR. COONEY: Right.
- 23 MR. BLUMENTHAL: IMS does?
- 24 MR. COONEY: Yes.
- 25 MR. BLUMENTHAL: But you do that

1 voluntarily?

2 MR. COONEY: It is a requirement in 3 those two states. 4 MR. BLUMENTHAL: Sorry? 5 MR. COONEY: It is a requirement in 6 those states. 7 MR. BLUMENTHAL: I'm talking about IMS, 8 marketing services. 9 MR. COONEY: Yes. 10 MR. BLUMENTHAL: They don't send it back 11 to you and say, "Give us all this additional 12 information," do they, or do they? 13 MR. COONEY: That I don't know. 14 MR. BLUMENTHAL: But if this information 15 were compiled correctly and completely in the first 16 instance, it won't be sent back to you? 17 MR. COONEY: Correct. 18 MR. BLUMENTHAL: Mr. Parisi. 19 MR. PARISI: My name is John Parisi. 20 I'm a pharmacist and owner of Ivery & Dudley Pharmacy 21 and Health Education Center in Winsted. I am also

- 22 president of the Connecticut Pharmacists Association.
- 23 My desire today is to bring you the point of view of
- 24 the health professional that patients see most
- 25 frequently and the professional with five to six years

of drug therapy education: a pharmacist. The
 pharmacist is also the gatekeeper of all prescription
 medications, and this point is one of significance.

4 The pharmacist shares the concerns of 5 law enforcement regarding using the prescription 6 medication. Our main goal is to make certain that 7 every patient gets the proper medication for his or her 8 medical condition and takes his or her medications 9 properly. If any drug gets into the wrong hands or is 10 abused, this is abuse. Every day, pharmacists across 11 the state monitor thousands of prescriptions for proper 12 drug, proper dosage, side effect profiles, and, most 13 importantly, communicate with the patient about any 14 concerns that they have about their drug therapy. Part 15 of this monitoring is being sure the patients are not 16 overusing or abusing medications. Routinely 17 pharmacists call other pharmacists about possible 18 pharmacy shopping by patients. Routinely pharmacists 19 refuse to fill prescriptions from patients who are 20 either unfamiliar to them or in situations where the 21 prescription itself cannot be verified.

- OxyContin is the new darling of thepress, spotlighted in every Sunday edition early in
- 24 2001. Actually, you may notice that this has already
- 25 been relegated to the back page. The question we are

facing is should we add another layer of regulation on
 top of what is already in place just because of press
 coverage? Is OxyContin being abused more than any
 other controlled substance or is it in vogue due to the
 publicity? Is OxyContin being abused more than other
 forms of oxycodone, the active ingredient in

7 OxyContin?

8 As a community pharmacist involved with 9 home-based hospice programs in our area, we dispense 10 many different medications to patients faced with 11 terminal illnesses. Pain medications are just part of 12 hospice care, but a key part. One of the first things 13 we tell our hospice patients is that we tell them we 14 should be able to keep them pain free, carrying on 15 normal life. This knowledge allows the patient to move 16 on to other important areas of life without the fear of 17 writhing in pain or being heavily sedated during their 18 final days. A misconception is that hospice is only 19 provided in hospitals. Actually, the majority of 20 hospice patients are cared for in their homes with the 21 support of hospice teams made up of nurses, physicians,

- 22 pharmacists, clergy, and others.
- 23 In our pharmacy practice, pain
- 24 management is one of our specialties. We need all pain
- 25 medications available to our patients when they need

1 them. This means if a physician needs to order a

2 medication at 4:00 a.m., it happens many times, that

3 medication must be available at 4:00 a.m., not five or

4 six hours later. Any restrictions on where the

5 medications can be obtained are unacceptable. Every

6 licensed pharmacy must be able to dispense every

7 medication that is needed by the public. Safeguards

8 are already in place.

9 I did an analysis of all OxyContin

10 prescriptions dispensed in my pharmacy in 2001 and have

11 brought many interesting things into focus.

12 Oncologists do not write most pain prescriptions

13 because the most common form of chronic pain seems to

14 be back pain. Limiting prescribing of OxyContin to

15 oncologists would be a detriment to the majority of

16 pain sufferers.

17 OxyContin prescriptions were a small

18 percentage of all oxycodone prescriptions written.

19 Actually about 6 percent were OxyContin 80-milligram.

20 The majority of oxycodone prescriptions were for

21 oxycodone and acetaminophen combinations (Percocet,

- 22 Tylox) or aspirin combinations such as Percodan. When
- 23 looking at abuse, do not assume all oxycodone
- 24 prescriptions are OxyContin. These other products have
- 25 been on the market since the early 1960s. The cost of

OxyContin, however, was the highest of all oxycodone
 formulations. If the cost of OxyContin to the state of
 Connecticut is the issue, this should be addressed
 separately.

5 The Drug Control Division is 6 recommending electronic monitoring of controlled 7 substance prescriptions. The Connecticut Pharmacists 8 Association is in support of this regulation as long as 9 the individual pharmacies do not bear any additional 10 cost. Computer programming is expensive and a 11 pharmacy's margin is very small. There is no way that 12 the increased cost, including even a  $4 \frac{1}{2}$  cent 13 transmission fee, can be passed on, as pharmacies have 14 no control over drug retail prices in up to 90 percent 15 of the prescriptions dispensed. 16 Getting the right drug to the patient 17 when the patient needs the drug is the foundation 18 therapy is built upon. When a loved one is in pain, 19 making a caregiver feel like a criminal to obtain the 20 pain relieving medication is in itself a crime. 21 Pharmacy has led the battle to get proper pain

- 22 medication prescribed to patients so that issues such
- 23 as assisted suicide do not have to be discussed.
- 24 Finally, physicians are more likely to order adequate
- 25 doses of pain medications so patients can have quality

1 of life in their final months. Any talk about

2 increased surveillance, increased paperwork, or

3 increased certification will only decrease physicians'

4 desire to prescribe proper dosages of pain medications

5 to the terminally ill.

6	MR. BLUMENTHAL: Thank you, Mr. Parisi.
7	MR. PARISI: You're welcome.
8	MR. BLUMENTHAL: And thank you for being
9 here today.	

10 MR. PARISI: Thank you.

11 MR. BLUMENTHAL: Both of you, Mr. -- I

12 understand if your main concern, if I may put it most

13 simply, is that there shouldn't be a cost to the

14 pharmacy of this monitoring program?

15 MR. PARISI: That is our main concern of

16 the management program. I don't think we have any

17 trouble. That certainly can be done, and we support

18 anything that cuts down on abuse of medication. We

19 have no trouble with that.

20 MR. BLUMENTHAL: So long as there were 21 no restriction on the number or kind of pharmacies,

- 22 which is not part of this proposal, I want to assure
- 23 you, you wouldn't have any objection to it?
- 24 MR. PARISI: No. We certainly want to
- 25 see free access. We feel that's really important to

1 the patient.

MR. BLUMENTHAL: Thank you very much.
 Thank you.
 Sherry Green of the National Alliance

5 for Model State Drug Laws is not going to be with us as
6 we announced earlier. So I'm going to ask Pat Good to
7 please join us now.
8 MS. GOOD: Good afternoon.
9 MR. BLUMENTHAL: Thank you for being so

10 patient.

11 MS. GOOD: Sure. No problem. My name

12 is Pat Good, and I'm with the Drug Enforcement

13 Administration. I'm in the Office of Diversion

14 Control. That's an area that specializes in illicit

15 drug and chemical activities, and I'm the chief of the

16 liaison and policy section.

17 In that section, we have had a lot of

18 involvement with prescription monitoring issues over

19 the last 30 years, and we are sort of a federal

20 ombudsman for the programs. I appreciate the

21 opportunity to speak to you today regarding the abuse

- 22 of controlled substances and the role that electronic
- 23 prescription monitoring programs can play in dealing
- 24 with this problem. Certainly the recent problems with
- 25 OxyContin have focused more attention on this issue,

1 but as we have heard many others say, this is obviously

2 not the only issue.

3 As a little bit of background,
4 legitimately manufactured controlled substances play an
5 important role in our life. We all heard many people
6 state that they're essential to the well-being of those
7 in pain. DEA does not dispute that, in fact, has come
8 out in favor of acknowledging that. However, the
9 diversion of legitimately manufactured controlled
10 substances is a major cause of drug-related
11 dependencies, medical emergencies, and fatalities. The
12 Substance Abuse and Mental Health Services
13 Administration, or SAMHSA, which conducts the annual
14 National Household Survey on Drug Abuse, estimated that
15 in 1999, the last year for which it had a full report,
16 2.6 million people reported nonmedical use of
17 prescription pain relievers. That's 2.6 million
18 people. The DAWN network, Drug Abuse Early Warning
19 network, also administered by SAMHSA, reported in 2000
20 that mentions for oxycodone were 108 percent higher
21 than was reported in 1998. Again, that's the generic

- 22 oxycodone, encompassing all products with that
- 23 ingredient. Also in the year 2000, 2 percent of all
- 24 emergency room mentions were for oxycodone products.
- 25 This doesn't make it the highest by any stretch, but it

1 certainly is a change from years past.

2 A little background in the federal law. 3 The Controlled Substances Act was enacted in 1970, and 4 it set up a closed distribution system for controlled 5 substances. And this is important here because many 6 drugs are abused by drug abusers, many of them licit, 7 but the illicit drugs are set up in a framework where 8 they all originate from some licit source. All of 9 those sources have certain legal requirements and 10 recordkeeping requirements, registrants deal with 11 registrants, and sales must be made only to other 12 people that are properly licensed, unless they're being 13 delivered to a patient by a legitimate doctor. All the 14 parties to the transaction have to keep records, so 15 ostensibly we should be able to go back and track 16 everything from the time it's manufactured to the time 17 it's delivered to a patient. 18 As a supplement to this, DEA has a 19 system called ARCOS which captures reports of drugs

20 distributed to the wholesale level and down to the

21 retail level of all opioids or all Schedule II drugs

- 22 and all opioids and Schedule III. That system called
- 23 ARCOS is given to the states periodically at least once
- 24 a year, and it can report consumption levels for any
- 25 given class of drugs or particular drug product. It

1 can tell where your state ranks per capita on the

2 consumption levels compared to the national averages.

3 It can be imported down to the mid-purchaser. Those

4 purchasers are generally pharmacies or hospitals. So

5 with any given state, let's say Connecticut, we can

6 tell you that X amount of a particular drug was

7 supplied to the pharmacies in your state, and we can

8 tell you which pharmacies bought the most, which ones

9 bought the least, we can tell you how you stack up

10 nationally, whether you're first, middle, low in

11 consumption.

12 These figures don't mean a whole lot.

13 Somebody's always going to be highest, and it could all14 be legitimate. Somebody is going to be lowest. The15 variance between the highest and the lowest may be very16 small.

17 The curious part, though, is it stops at
18 the retail level. We can tell you that 20 pharmacies
19 bought 80 percent of your OxyContin. We can't tell you
20 what the 20 pharmacies did with it. That's where
21 prescription monitoring systems come into play. When

- 22 there is a problem, the prescription monitoring systems
- 23 can backtrack and see just what is going on. They can
- 24 serve as a warning system; when complaints are
- 25 generated, they can allow complaints to be resolved

1 more expeditiously than what would happen if we had to 2 send teams of investigators running around to every 3 pharmacy in town trying to backtrack specific doctor's 4 prescriptions or specific patients' prescriptions. 5 When we have to go on site and do this 6 tracking, we're creating an aura that perhaps we are 7 investigating or checking on people. It becomes public 8 knowledge because the pharmacist looks over our 9 shoulders and knows who we are looking at. The 10 monitoring system allows you to do this in the privacy 11 of your office without infringing on anybody's freedoms 12 or rights. It also is an aid to prescribers who may 13 14 suspect their patients are doctor shopping because in 15 many states the doctors can contact the state agency 16 and obtain from them information on any patients they

17 suspect might be seeing multiple doctors.

## 18 This is all done within a strict 19 framework of privacy. The data is never authorized to 20 be given to anyone who does not already have the legal 21 authority to see it. By that I mean agencies like DEA,

- 22 agencies like state boards of pharmacy, already have
- 23 the legal authority to go into a pharmacy and review
- 24 prescription records. So those same kinds of agencys
- 25 would be granted legal authority through whatever

1 statutes enact a monitoring system to do just that with

2 the proper limits on service.

3 They also, as we've seen from states 4 like Nevada and many others, they've served as a way to 5 deal with public health issues. They have helped 6 people get into treatment, they have helped uncover 7 outmoded practice standards or people that may be using 8 drug therapies that are no longer in favor. So this is 9 not only looked at a law enforcement measure. In fact, 10 many states look at them as a public health measure. 11 DEA has long supported states in their efforts to 12 prevent and detect abuse and diversion of 13 pharmaceutical controlled substances through the 14 implementation of such programs. They consider these 15 our primary ways of clamping down on doctor shopping 16 and prescription mills because they raise the level of 17 awareness and they enable investigations to be 18 conducted swiftly and unobtrusively. 19 Some of the states that have problems 20 with OxyContin make an interesting comparison, if you 21 look at the states with monitoring versus those that do

- 22 not have it. OxyContin, as you know, was introduced
- 23 back in '95 by Purdue Pharma. You have heard about the
- 24 product itself, and you've heard also about the abuse
- 25 issues that face us today. We looked at a number of

1 data sources, including medical examiner data, and as 2 of November 1st, that data showed that there were 117 3 deaths verified as being OxyContin specific and another 4 179 nationwide possibly related to OxyContin. 5 We have also looked at data -- we have 6 heard IMS mentioned. We have to purchase that data. 7 It's restricted what we can do with it. We cannot 8 access patient names, doctor names; we only can get 9 aggregate data. But in getting that, we found that 10 five states with the highest per capita rates of 11 prescriptions for OxyContin were also five states that 12 did not have a prescription monitoring portion, and 13 they were the five states reporting the most abuse of 14 the product. Those states were Alaska, West Virginia, 15 Delaware, New Hampshire, and Florida. 16 Conversely, the states at the bottom of 17 the lowest per capita rate of abuse all had long-18 standing prescription monitoring programs, and they 19 report very few problems. Those states being New 20 Mexico, which has since lost its monitoring program, 21 Illinois, Texas, New York, and California.

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- 22 Curiously, a sixth state does have a
- 23 monitoring program. That state is Kentucky, and two
- 24 things play here that I think are important to note.
- 25 Having the system is only the beginning. What you do

1 with the information is very, very critical.

2 Kentucky's system is outstanding, it 3 captures Schedule II, III, and IV drugs. It has a 4 small staff of people monitoring it, and their 5 resources are dedicated to responding to requests from 6 physicians to make sure their patients are not doctor 7 shopping. It was not particularly proactive in 8 identifying potential problems. Once the problem is 9 noted, however, it is a great resource to try to track 10 down possible violators. 11 Also, a state like Kentucky has 12 bordering states of Virginia, West Virginia, Ohio, all 13 without monitoring programs, that did not have 14 monitoring programs, so that abusers can avoid being 15 monitored themselves. 16 The states with monitoring programs now 17 number 15, and there are about 7 or 8 more that are 18 like you trying to get legislation rolling. The 19 start-up costs vary, and some good news I do have about 20 costs that may spark some interest, the Congress of the 21 United States was so impressed with the ability of

- 22 monitoring programs to deal with issues that have
- 23 emerged before the publicity of OxyContin that the
- 24 Senate Appropriations Committee put \$2 million in a DEA
- 25 budget for Byrne grants for states to start up

prescription monitoring programs. We shortly expect to
 have with BJA, the Bureau of Justice Assistance, some
 of the criteria established. So we expect to -- the
 states to use this as seed money to start programs of
 this type. Again, we offer whatever support we can
 provide.
 We believe that the monitoring programs

8 provide an excellent tool in monitoring diversion

9 issues, and we also believe very strongly in the

10 balanced approach to preventing diversion while

11 assuring access to the patients who truly need

12 controlled substances, whether they're opioids or other

13 types.

14 I appreciate the opportunity to speak to

15 you and would be happy to answer any questions.

16 MR. BLUMENTHAL: Thank you very much for

17 being with us and making the trip.

18 I wasn't sure whether you made reference

19 to it just now, but my understanding is that there is

20 some grant money available to states who are seeking to

21 establish this kind of program?

MS. GOOD: Yes. The budget that was recently signed has \$2 million in it to be allocated to the states through the Bureau of Justice Assistance in the form of Byrne grants.

1 MR. BLUMENTHAL: Is that in the 2 Department of Justice? 3 MS. GOOD: It's in the Department of 4 Justice, and we will shortly have parameters and 5 criteria, and we will make sure that state agencies 6 engaged in this process are made aware of it. 7 MR. BLUMENTHAL: How soon do you think 8 that money will be available? 9 MS. GOOD: I would say in the next 10 couple of months. 11 MR. BLUMENTHAL: Thank you. 12 One other question. If you were -- and 13 I don't mean to ask you an unfair question. If you 14 were to pick a state or a couple of states whom you 15 would recommend Connecticut should follow, in other 16 words, the states that have the best so far of those 17 monitoring programs, could you suggest one or two? MS. GOOD: Well, there are some 18 19 parameters that differ from one state to another. 20 No one likes the paper forms, I'll say 21 that right up front, because they are not invisible to

- 22 the prescriber and they're somewhat of a pain in the
- 23 neck. But they're really the only mechanism right now
- 24 that can take away the possibility of someone issuing
- 25 fraudulent prescriptions because you can have a fistful

of fake prescriptions and the pharmacist can dutifully
 submit them to the monitoring program and nobody will
 be the wiser. So there is a benefit with having the
 forms.

5 The states with the forms are New York, 6 Texas, and I'm running out of -- I forget who. But 7 those are -- I have one coming on. 8 Some other attributes that are very 9 effective, Nevada is extremely effective in the way 10 they use their data. They also capture all schedules, 11 like Kentucky, which is a definite benefit in the sense 12 that it is true that if you create a, quote, stigma, or 13 reporting requirement around one group of drugs, that 14 someone's going to be diverting that type of drug, they 15 can move to another schedule. So there is a benefit to 16 doing all schedules, especially in opioids, because so 17 many combinations are in Schedule III. So for those I 18 would recommend Nevada and Kentucky. There are 19 similarities and differences.

20 DEA has a publication that will run 21 through the way each state is set up. We would be 22 happy to provide that to you.

23 MR. BLUMENTHAL: That would be very

24 useful if you could. Maybe my office could contact

25 you.

1 MS. GOOD: Sure.

2 MR. BLUMENTHAL: Thank you.	
3 COMMISSIONER FLEMING: Thank you again	
4 for being here now this afternoon. I would just like	
5 to thank you and the DEA for all the past help that you	
6 have been to my agency. I know we had had two very	
7 high-profile cases this year with diversion of	
8 controlled substances, but on a regular basis, what a	
9 lot of people don't see is the amount of interaction	
10 that goes on between DEA and the agents in the	
11 Department of Consumer Protection's drug abuse as well	
12 as the other law enforcement, and it seems to work very	
13 well.	
14 MS. GOOD: I think you can thank one of	
15 the gentlemen in the back of the room for that, then.	
16 MR. BLUMENTHAL: Who is that?	
17 MS. GOOD: Steve Simes (phon sp) is our	
18 local supervisor, and he should be he was back	
19 there.	
20 MR. BLUMENTHAL: Is he still? Thank you	

21 for your help.

## 22 COMMISSIONER FLEMING: I have spent a

- 23 little bit of time in a surveillance van. It is not
- 24 terribly comfortable. I know those guys have a tough
- 25 job. But it's the day-to-day stuff that's extremely

1 helpful to us.

2 You did mention, I was aware that there 3 was federal -- there is federal money available that my 4 agency would qualify for. The only question I did 5 have, for \$2 million, in the scheme of things, is not a 6 great deal of money, and the amount of grants would be 7 how much, and for when you say start-up, how long would 8 it be for? 9 MS. GOOD: I'm not sure we have the 10 answers to that yet. We met with the senate 11 appropriations staff last week to iron out what they 12 envision the money to be for and what we thought would 13 be realistic. I think we were somewhat apart. 14 They were looking to give small amounts 15 to as many states as possible to get them off the 16 ground, and we wanted to make sure the amounts given 17 were meaningful enough to make sense. So we were 18 looking at the fewer states, high amounts; they were 19 looking at more states, lower amounts. 20 But in talking to some of the folks

21 about how much it actually cost to get the technology

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- 22 rolling, if the grants were 150 to 200,000, that seems
- 23 to cover the technology piece. We were looking at up
- 24 to 500,000 needed for the entire intrastructure set-
- 25 up. So I don't think there has been a restriction set

1 yet. We are in the early stages of meeting with DJA to 2 develop realistic cost assessment and standards. 3 We also right now only have the budget 4 for one year. We have no guarantees it will be in next 5 year's budget. 6 COMMISSIONER FLEMING: I understand 7 that. Thank you. Thank you very much. 8 MR. BLUMENTHAL: Thank you very much. 9 COMMISSIONER FLEMING: Before you set 10 those standards, if you want to give us about a quarter 11 of that, fine. 12 MS. GOOD: I will put you on the list. 13 No problem. 14 MR. BLUMENTHAL: Diana Norris. 15 MS. NORRIS: Good afternoon, Attorney 16 General Blumenthal, Special Counsel Kehoe, and invited 17 panel witnesses. Thank you for the opportunity to 18 provide testimony on behalf of Connecticut Nurses' 19 Association. 20 I am Diana Norris, an advanced practices

21 nurse, and a member of the Connecticut Nurses'

- 22 Association Professional Practice Committee. I'm also
- $23\,$  assistant director for the Eastern Health System
- 24 Network Hospitalist Program.
- 25 We would like to commend the Attorney

1 General for bringing together professionals with a 2 variety of perspectives and expertise related to drug 3 control, law enforcement, and health care before 4 drafting legislation. Any successful prescription 5 monitoring legislation must be designed and implemented 6 with a balanced perspective containing appropriate 7 checks and balances. 8 Prescription drug abuse affects millions 9 of Americans. This number itself is not important. 10 What is important is that a large number of people 11 suffer from addiction to prescription drugs, resulting 12 in families that are torn apart, lives that are 13 destroyed, and people who die. A prescription 14 monitoring system with a clear mission created by a 15 group with a balanced perspective could assist in 16 efforts to bring prescription drug abusers into 17 treatment and recovery. This kind of system could also 18 provide a mechanism for identifying illegal activity 19 and ensure that the prescribing of legitimate, helpful 20 medications continues for patients who need them.

21 This issue must be addressed with a

- 22 balanced approach because patients must receive
- 23 medications that are needed, prescribers must not be
- 24 reluctant to provide medications that will help their
- 25 patients, especially now, when there is a threat of

1 malpractice if pain is not well managed, and non-2 punitive systems for treatment must be in place for 3 individuals suffering from the disease of addiction. 4 The focus of any board developing a 5 prescription monitoring system must include 6 establishing a committee consisting of individuals who 7 have a broad base of knowledge and perspectives of 8 Connecticut issues and who would be affected by this 9 kind of legislation. This committee should be 10 empowered to determine the needs before any legislation 11 is developed; determining the flow of prescription 12 medications from production through dispensing and 13 identifying gaps in accountability for the drugs 14 produced; determining through a systematic process what 15 monitoring systems are already in place and where gaps 16 exist; establishing the extent of problems related to 17 prescription abuse in Connecticut; identification of 18 current drug treatment confidentiality issues and 19 rights and developing legislation that would be 20 consistent; determining what is the necessity of a 21 prescription monitoring system, what needs to be

- 22 accomplished. Would we improve the system of
- 23 identification of drug abusers in order to intervene in
- 24 obtaining treatment, if this is a major problem, or
- 25 would this be a system to catch individuals in criminal

behavior, which may not be a major problem? Would we
 add another layer of reporting and monitoring which
 would make it more difficult for prescribers and more
 costly? Would we design a program based on best
 practices?

6 Legislation for a prescription 7 monitoring system needs to take into account the 8 following: Defining the mission or missions for the 9 program based on the identified needs; reflecting the 10 latest research and trends about treatment (alternative 11 programs versus a punitive system); considering the 12 costs, given the extent of current competing interests; 13 ensuring confidentiality for any data that is developed 14 and that access to the data is based on a very 15 selective need to know; ensuring that systems for 16 identification and referrals for health care workers 17 who have as an occupational hazard prescription drug 18 abuse, and that the systems are used to intervene 19 rather than using the criminal justice system. 20 Legislation of that nature is complex

21 and should be based on a thorough review of needs.

- 22 Language needs to be carefully crafted by individuals
- 23 without political agendas who have the knowledge and
- 24 skills to determine Connecticut's needs.
- 25 In the 2001 legislative session, it was

1 clear during hearings before the Public Health 2 Committee related to mental health issues that 3 alternative programs for drug abuse and impairment are 4 needed, not punitive systems and incarceration. 5 The Connecticut Nurses' Assciation's 6 interest in developing legislation for prescription 7 monitoring is multileveled and includes its interest 8 and expertise in patient care, prescribing for any 9 advanced practice nurses, impaired nurses and health 10 care workers in their recovery and return to safe 11 practice, confidentiality issues and the safety of the 12 public health. We want to be included in developing 13 any legislation that concerns prescription monitoring, 14 and I thank you for the opportunity to address this 15 important issue; and the Connecticut Nurses' 16 Association looks forward to continued work together 17 for a healthier Connecticut. MR. BLUMENTHAL: Thank you very much. 18 19 We have a panel now involving Susan 20 Richter, Dr. Ed Hargas, Jeffrey Mendenhall.

21 Thank, you Ms. Norris.

- 22 MS. NORRIS: Thank you.
- 23 MS. RICHTER: Good afternoon.
- 24 MR. BLUMENTHAL: Good afternoon.
- 25 MS. RICHTER: I appreciate the

1 opportunity to make some comments this afternoon. My 2 name is Susan Richter, and I'm the vice president of 3 Patient Support for the New England division of the 4 American Cancer Society. My background is nursing, and 5 I'm a charter member of the Connecticut Cancer Pain 6 Initiative also. 7 As you have heard many times so far 8 today, pain and its undertreatment is a major public 9 health problem in this country. Today over 8 1/210 million persons in the United States have had cancer, 11 and more than 70 percent of them experienced pain from 12 the disease. Unrelieved pain causes needless suffering 13 and destroys the quality of life at a time when nearly 14 all cancer pain can be relieved. 15 There are many barriers to the 16 management of pain that include inadequate training of 17 health care professionals, poor communication between 18 patient and health care professional, fear of 19 regulatory scrutiny by the health care professional,

20 and perhaps the top reason the cancer pain patients

21 refuse treatment and health care providers undertreat

- 22 pain is the fear of addiction.
- 23 Recent news reports have focused
- 24 primarily on addiction and abuse of pain relievers.
- 25 These reports unfortunately contribute to the under-

1 treatment of pain by reinforcing myths and 2 misconceptions and may harm the quality of life of 3 cancer patients. Since addiction is such a common fear 4 that patients hold, such fear may prevent them from 5 taking their medications. It also encourages family 6 members to urge them to hold off as long as possible. 7 The American Cancer Society has set 8 ambitious goals for 50 percent reduction in cancer 9 mortality, a 25 percent reduction in cancer incidents 10 and measurable improvement in the quality of life by 11 the year 2015. Pain is the most feared complication of 12 cancer, and it is a major quality-of-life issue 13 affecting those with cancer. Meeting these goals will 14 require us to have new partnerships and will require a 15 commitment from both the private and public sectors. 16 In the year 2000, Congress has 17 designated this decade as the decade of pain. This is 18 an opportune time for everyone concerned about this 19 critical issue to step forward and offer to spread the 20 facts about pain relief. We need survivors, family 21 members, health care professionals, legislators,

- 22 educators, employers, researchers, and media
- 23 professionals to continue to provide the dialogue that
- 24 will help dispel the myths and misconceptions that
- 25 currently limit the existing opportunity to have good

1 treatment. The American Cancer Society strongly 2 supports statewide educational initiatives that address 3 patient and provider fear of regulatory action in order 4 to reduce barriers to appropriate pain medication. 5 Public and provider education is greatly 6 needed to correct these widely held and false beliefs 7 that create barriers for patients attempting to access 8 the pain control that they needed. Cancer patients 9 have the right to know that their pain can be relieved 10 and that proper cancer pain management does not result 11 in addiction. Physicians and other medical 12 practitioners have the right to know that they will not 13 be prosecuted for appropriately treating their 14 patients. 15 And the American Cancer Society 16 recognizes that there is an urgent need to improve the 17 quality and availability of cancer pain treatment. The 18 society also recognizes that there are strong societal 19 interests in assuring the appropriate use of controlled

20 substances. We believe that attention to the misuse of

21 controlled substance has overshadowed and impeded

- 22 attempts to manage pain. Currently we have not found a
- 23 proper balance between these two issues, and that has
- 24 been a great cost at the expense of those who need to
- 25 have their pain controlled. The society believes that

concern for pain management should receive equal
 footing and funding with other health initiatives from
 federal and state government and/or private agencies.
 On a personal note, a little over a year
 ago, my brother, dying from advanced melanoma in a
 Connecticut hospital, faced his own struggle for pain
 relief. As his advocate, I attempted to overcome the
 huge obstacles that were before us without success. In
 the process, I was actually asked, "Are you trying to
 kill your brother?" I was so disappointed to learn
 that all our educational efforts had yet to change many
 attitudes, behaviors, and beliefs about cancer pain

14 The American Cancer Society stands ready 15 to work together with federal, state, and local 16 officials to ensure that policies intended to curb 17 abuse and diversion of pain medications have minimal 18 impact on legitimate pain management for cancer 19 patients and to ensure that consumers and providers 20 receive the education needed to dispel misconceptions 21 and relieve unnecessary suffering. Please help me in

- 22 creating a real sense of urgency for this critical
- 23 issue. Let's help people with cancer understand their
- 24 right to request and receive effective pain management.
- 25 We do not believe that cancer care can be complete

1 until pain is under control. Thank you.

MR. BLUMENTHAL: Thank you. Which of 2 3 you would like to go? 4 MR. MENDENHALL: Okay. My name is 5 Jeffrey Mendenhall. I have several hats to wear. I am 6 clinical supervisor of the Branford Home Care Office of 7 The Connecticut Hospice, Inc., where as the chairman of 8 the Pain Care Committee, I am also chairman of the 9 Connecticut Cancer Initiative for this year and up 10 through next year. I'm going to read some excerpts 11 from my written testimony today. 12 MR. BLUMENTHAL: We will have your 13 written testimony. 14 MR. MENDENHALL: I understand that. 15 MR. BLUMENTHAL: I can assure you that 16 we will read it or have read it in most cases. So you 17 can feel free to summarize. 18 MR. MENDENHALL: Yes, indeed. 19 During the past year local media and 20 some politicians have tended to exaggerate and distort 21 the nature and scope of drug-related criminal behavior

- 22 in our communities, even to warn of an impending
- 23 epidemic of abuse. But the only real documented
- 24 epidemic is the public health crisis caused by chronic
- 25 pain. Based on 2000 census data, approximately 600 to

1 700,000 adults living in Connecticut are living in

2 daily routine pain.

3 For many patients, families, and their
4 physicians, their reasonable and proper caution has
5 been turned into irrational fear; fear of the only
6 class of drugs proven safe and effective in the
7 treatment of moderate to severe pain. Opiophobia is a
8 sadly common occurrence, both in the general and
9 professional communities, and it is the single greatest
10 barrier to effective pain management, here and
11 throughout the world.
12 Clinical research and experience have
13 shown roughly 90 percent of this pain can be
14 substantially, if not completely, relieved using simple
15 interventions, including the use of carefully managed
16 opioid medications. I believe the failure to treat
17 pain when we have the knowledge and resources to do so
18 is morally and ethically equivalent to torture.
19 I also believe it is crucial to
20 understand that pain is not just pain. Pain impacts
21 all aspects of a person's life, and it can become soul

- 22 destroying. It can also be life-threatening,
- 23 decreasing immune function; and when chronic pain
- 24 persists, it can become a progressive crippling,
- 25 disease; RSD referred to earlier.

1 While I am actively involved in pain 2 management at the end of life, today I am more 3 concerned about the vast majority of persons who suffer 4 pain. Those with chronic nonmalignant pain. Chronic 5 noncancer pain in adults who are not terminally ill is 6 often viewed as malingering, as an annoyance, and, 7 worst of all, drug seeking. Hospice patients 8 mistakenly believe that it is, quote, foolish to worry 9 about addiction in patients who are dying. Incorrect. 10 To be correct, it is foolish and dangerous to worry 11 about addiction as a precondition for treating pain. 12 We know that diversion and abuse of 13 prescription drugs is an historic problem, as is the 14 rate of substance abuse and addiction in our 15 population. I don't know of any reliable evidence that 16 the rate of abuse has increased. It's also well to 17 remember that prescription drug abusers typically use 18 several drugs together and cocktail often with 19 alcohol. To blame one drug is not only unfair, it is 20 inaccurate and inflammatory.

21 MR. BLUMENTHAL: You don't mean to

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- 22 suggest that alcohol is prescribed?
- 23 MR. MENDENHALL: No, no, I do not. Of
- 24 course not. But it is legal, of course. I'm only
- 25 attempting to get across the point that people who

use -- misuse prescription drugs typically are misusing
 a number of drugs, and they often are using alcohol at
 the same time.

4 MR. BLUMENTHAL: I see. Okay. Maybe I5 misunderstood you.

6 You know, just to state the obvious,

7 this hearing is not about whether there should be pain

8 relief for people who suffer from -- I think I speak

9 for this panel and for most people I know, to say that

10 there should be increased availability and

11 accessibility of these drugs for people who

12 legitimately need and deserve them. I think I've

13 referred to these drug as a Godsend.

14 MR. MENDENHALL: Yes.

15 MR. BLUMENTHAL: Our concern is not with

16 trying to restrict the flow of any drug that can be

17 useful in treating pain. I hope you haven't

18 misunderstood our purpose here today.

19 MR. MENDENHALL: No. But as I said, we

20 have seen great reluctance, we have seen people go from

21 being normally cautious to being almost irrationally

- 22 afraid of using drugs, not only drugs that would be
- 23 effective in controlling pain. It is the chilling
- 24 effect that I think a lot of us are worried about. I
- 25 was really heartened to hear about that joint statement

1 that came out of Washington, D.C., with the DEA 2 administrator, Mr. Hutchinson; Dr. Portenoy was 3 involved in the press conference. One of the things 4 that I'm recommending is that we look at that statement 5 here in Connecticut as something of a mission statement 6 for a coalition that would help to guide us toward a 7 more balanced and rational public policy. 8 My concern as I walked across the 9 pedestrian bridge this morning and somebody said, "Oh, 10 are you here for the OxyContin hearing?" I didn't know 11 that it was about OxyContin. I knew it was about 12 public health, public safety, and ultimately public 13 policy. Obviously OxyContin has been the big drug news 14 this year. But I've worked, you know, in oncology and 15 hospice, and over the years, other opioid medications 16 have been the drug of choice, the flavor of the month, 17 as people have sometimes said. It's unfortunate that 18 diversion and substance abuse occurs, but that's 19 criminal behavior. We need to trust both the public 20 health and the pain management issues in addition to 21 the public safety on the criminal side of the question.

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22 MR. BLUMENTHAL: Can you comment on the

- 23 monitoring program? Would anyone like to comment on
- 24 the monitoring program that's been suggested? Which,
- 25 by the way, would not only cover OxyContin.

1 MR. MENDENHALL: I understand that. We 2 had a presentation from Mr. Roberge at our most recent 3 meeting last week. I think many of us were impressed 4 with, were in accord with that sort of thing. 5 MR. BLUMENTHAL: Right. 6 MR. MENDENHALL: I moved from California 7 a little over two years ago, so I am familiar with 8 living in a state where there is monitoring and a 9 triplicate program. 10 MR. BLUMENTHAL: Did that program have a 11 chilling effect as one of the things you mentioned as 12 one of your apprehensions? 13 MR. MENDENHALL: Well, what I would say, 14 what they finally did in California in triplicates in 15 treating people with terminal illness is to get an 16 exemption for triplicate prescriptions for patients who 17 are terminally ill. Doctors treating the terminally 18 ill were able to write C2, Schedule II prescriptions, 19 without prescriptions, they only had to write on the 20 bottom of the prescription pad the number of the law, 21 which I can't remember at the moment, it was a senate

- 22 bill, they would write the number and exempt, and they
- 23 were able to write those kind of prescriptions.
- 24 But it did have a chilling effect in the
- 25 sense that only about 30 percent of the doctors in

1 California had triplicate writing privileges. Which,

2 depending upon how you look at it, is a good thing or a3 bad thing.

4 What tended to happen, and you may have 5 heard about the Bergman case in California, where a man 6 was seriously undertreated for his pain in part because 7 his doctor did not have triplicate writing privileges. 8 There were many other factors, the hospital that was 9 involved should have gotten involved and been much more 10 proactive. Hydrocodone is a C3 drug, this is 11 California, the triplicate program, you don't have to 12 have a triplicate to write for Vicodin. So many people 13 write for Vicodin. And that is what -- one of the 14 reasons this poor man got into so much trouble, his 15 doctor kept writing more and more Vicodin prescriptions 16 and not -- he wasn't able -- he should have referred 17 him to somebody who could have written him triplicate 18 for morphine.

DR. HARGUS: Can I just comment, just
about that one point? I believe Dr. Portenoy commented
about it. When they established the reporting format

- 22 in New York, which was triplicate, they -- there was a
- 23 rapid decrease in the amount of those -- those narcotic
- 24 drugs, and not just a decrease in these drugs, but a
- 25 switch to other less, you know, effective medicines.

1 MR. BLUMENTHAL: Was that -- was that a 2 temporary switch? 3 DR. HARGUS: Which? I will just make a 4 little point about this in Connecticut. You seem to --5 when we got this report justifying the electronic 6 monitoring of controlled substances, everybody seemed 7 to be proud to state that, oh, it hasn't affected, 8 Massachusetts has gone up, Rhode Island is going up, 9 New York is going up. Well, it's not cause and effect 10 there. What has happened is I think docs are beginning 11 to realize that patients are grossly being under-12 treated. It's not the fact that this provided them a 13 safety network or some great assurance that they 14 wouldn't be prosecuted. It's the fact that people are 15 beginning to wake up, you know, Massachusetts, a lot of 16 bright people, but they wake up late too. 17 MR. BLUMENTHAL: Let's turn to you, if 18 you have --19 DR. HARGUS: I didn't want to --20 MR. BLUMENTHAL: Did you want to finish?

21 MR. MENDENHALL: If I could, just with a

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- 22 couple of brief presentations.
- 23 MR. BLUMENTHAL: Sure.
- 24 MR. MENDENHALL: I won't say much more.
- 25 I believe that all parties involved in

1 this hearing should endorse the joint statement by the

2 DEA administrator and pain management coalition that

3 was part of that press release on October 23rd, and

4 that is part of my statement.

5 Connecticut insurance companies should 6 cover consultations at Association for the Society of 7 Pain Management-approved comprehensive pain management 8 centers in contiguous states because we do not have a 9 comprehensive pain management center that meets the 10 standards of this group in Connecticut. We had one at 11 Yale. It has since been closed. So we are a state 12 without that full multidisciplinary pain management 13 center. We don't have that. 14 I personally took my wife to see Dr. 15 Portenoy in New York City because we couldn't find a 16 pain management specialist that was able to treat the 17 problems that she has. We were fortunate that our 18 insurance paid for that, but most people are not that 19 fortunate. I strongly suggest that we look at 20 requiring that kind of coverage until such time as we 21 have a full-service facility.

I also think it's important that we
consider the Medicaid side of the equation when it
comes to hospice. Connecticut is one of very few
states, I think less than ten now, that does not

1 provide a Medicaid hospice benefit. This adversely 2 effects poor and disadvantaged persons at the end of 3 life. We must implement this benefit which would 4 provide the sort of comprehensive pain and inter-5 disciplinary pain management which I believe all 6 parties agree is effective and the most cost 7 effective. It is also simply an outrage, I think, 8 since Connecticut is the home of the first hospice in 9 America, that we do not provide that kind of care for 10 all of our patients, all the people who live in the 11 state. 12 And, finally, I think that all primary 13 care providers, ranging from physicians, nurses, 14 pharmacists, physician assistants, I've talked with 15 physician assistant classes at a couple of universities 16 in the southern part of the state, and they are not 17 getting pain management training, I can tell you that. 18 We need to require that all of these primary care 19 providers have some continuing education, continuing 20 medical education a minimum amount of time before their 21 relicensure, and also that all of the clinical training

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- 22 programs in the state provide education and pain
- 23 management and end-of-life care that would also include
- 24 substance abuse and addiction.
- 25 MR. BLUMENTHAL: Well, I thank you for

1 those very well-taken points. I agree with you,

2 certainly, on the last point; and on the other two,

3 which are a little bit beyond the purview of this

4 hearing --

5 MR. MENDENHALL: I understand. I was 6 trying to make a more systemic look at how we could 7 work with some of these other issues. 8 MR. BLUMENTHAL: I would like to work 9 with you on those points either as part of this process 10 or separately. 11 MR. MENDENHALL: Yes. 12 MR. BLUMENTHAL: Certainly, you may know 13 I have taken some fairly strong stands about insurance 14 coverage and HMO coverage on some of these issues; and 15 also with respect to Medicaid funding and hospice, I 16 have also publicly been an advocate, but I would like 17 to work with you on it. Thank you.

18 DR. HARGUS: I'm Dr. Ed Hargus. I am

19 certified in hospice and palliative care medicine, pain

20 management, through the American Board of Anesthesia,

21 and pain management through the American Academy of

- 22 Pain Medicine, the board of pain medicine. I have been
- 23 a practitioner in pain since about 1985, and I may be
- 24 the oldest, oldest continuing care pain provider in the
- 25 state of Connecticut. There may be a couple of guys

1 still alive. We've been doing this for quite a while,

2 and I established a pain clinic at our local hospital

3 in Southeastern Connecticut many years ago.

4 I submitted written testimony which can 5 stand, but I would just like to make a few other points 6 here that need to be stressed: One, Dr. Portenoy said 7 the fear factor cut down the prescription usage or 8 prescribers, a fourth to a half of prescribers changed 9 their pattern of writing prescriptions. I think that 10 is absolutely true in the state of Connecticut. I have 11 seen patients almost on a daily basis who were referred 12 because of what I perceive as the fear of the primary 13 care practitioner to take care of the narcotic 14 prescriptions of that patient. I have seen patients, you know, the last 15 16 few months when I was in practice, we had a couple of 17 patients back to back, young people who suffered severe 18 crush injuries to their legs and had ample reason to 19 have lots of pain, and they both came in and they both 20 had pain control, and I scratched my head, saying, 21 "Well, that's great. What are you here to see me

- 22 for?" And they were here to see me because their
- 23 regular doctors would not continue writing narcotic
- 24 prescriptions for them. They had established pain
- 25 control, but their primary doctors would not prescribe

1 narcotic medications for them.

2 And I don't think the doctors are bad 3 people. I think, you know, there is a real fear, these 4 are very difficult patients to take care of. They 5 consume a lot of time, and a lot of paperwork, too, by 6 the way, but they consume a lot of time, and you don't 7 get reimbursed for patients who have terrible 8 problems. You get reimbursed for patients who have 9 five-minute problems. So reimbursement is a big issue 10 regarding some of these things. 11 So it's a very real, real thing, and I 12 think people don't really realize it. You think you're 13 doing a great thing and a good thing. Well, you may be 14 doing way more harm than good; to save \$10 million or 15 so, you may be causing a great deal of harm to people 16 in the state of Connecticut who already can't get pain 17 relief and pain care.

18 Whether you know it or not, Dr. Duffy
19 mentioned the Donohue study, Connecticut statewide pain
20 study. It took about two years to do. So this is no
21 little ditzel study. This took quite a bit of time.

- 22 And it showed these patients, like you said, are
- 23 grossly undertreated in the state of Connecticut. But
- 24 it also showed, a point you should be very aware of,
- 25 that there are few people certified in the state of

1 Connecticut, pain care, few are certified in hospice

2 and palliative care medicine.

We are looked upon as the experts, yet there are very few of us, and the other docs would maybe like us to be taking care of lots and lots and lots of tons of patients; but you know what? There is only so many hours in a day that we have. So that's a key issue here.

9 You heard that Yale closed its pain
10 clinic, UConn closed its pain clinic, the University of
11 Massachusetts closed its pain clinic. They are not
12 evil places, but it is tough to do this stuff.
13 And for the Attorney General, I think
14 there are some legal aspects that no one has even
15 broached here. There are contractual issues between
16 hospitals and pain practitioners. For instance, most
17 of the pain practitioners in the state of Connecticut
18 are certified, I believe, through the American Board of
19 Anesthesiology. Most hospitals you will find, I think,
20 have contractual relationships, exclusive contracts
21 which bar other practitioners from providing pain

- 22 services to patients in their communities and their
- 23 areas. That is not a 100 percent number, but it is --
- 24 but it is a reality. And I think that it may be time
- 25 that those kind of laws and that kind of contractual

relationship should not be allowed to exist in a state
 or in a part of the country where services are under represented.

4 Well, the other thing that -- I don't 5 want to say disturbs me, but the devil is always in the 6 detail, always in the detail. When I read paragraph 5 7 here, the commissioner shall adopt regulations, blah, 8 blah, blah, electronic monitoring, et cetera, the 9 adoption of these regulations pursuant to the statutes 10 may be initiated upon the passage of this bill, I got 11 terribly worried because this was all great, and then 12 all of a sudden the real details of this and how you --13 if this is adopted, it will be the details that will 14 destroy, harm patients, harm pain care or not. So there was no apparent mention here of 15 16 oversight, outcomes, who is going to -- who is going to 17 do this, what groups are going to be represented, who 18 aren't going to be represented, who is going to look 19 over this whole process. I think that there is the 20 real, real rub here.

21 If you establish this, you know, you

- 22 think that this will help pain practitioners, and I
- 23 have to tell you that in the most idealistic world it
- 24 would help me as a pain practitioner because I would
- 25 have access to information that I sometimes can't get.

1 You know, I'll throw out at least one example of a 2 patient I had come in that, you know, that I had a call 3 on, it was a patient of mine for many years with a 4 chronic pain problem on methadone, who seemed to me to 5 be a model patient, and I got a call from someone 6 outside, said, "Oh, he's selling these drugs." Click. 7 I sort of have to worry about that, and I called up, I 8 forget which office, and in the state of Connecticut 9 you have about three offices I can get on the phone and 10 say, hey -- maybe four, if I call the Attorney General. 11 COMMISSIONER FLEMING: That is almost as 12 hard as trying to get through to a doctor. 13 DR. HARGUS: I got through that. 14 COMMISSIONER FLEMING: Because I've had 15 trouble getting through to doctors, but I don't know 16 what it is that you're referring to there. But my 17 agency has not released any draft of any legislation. 18 You're correct, the devil is in the details. 19 MR. BLUMENTHAL: What do you have 20 there? I'm sorry. 21 DR. HARGUS: I have an act concerning --

## 22 COMMISSIONER FLEMING: I have no idea

- 23 what that document is. There is an old expression in
- 24 politics about sausage making and law making. It
- 25 appears there always is a lot of work to be done, and

1 the devil is in the details, as you say. Oftentimes 2 what the legislature will do is they'll ask a 3 commissioner to adopt regulations so that individuals 4 such as you will have an opportunity to come before the 5 administrative agency to make sure that we get it 6 right. I can assure you, if we go forward with this, 7 that you will have input into that process. 8 But I think the other point that needs 9 to be made here is that no one sitting up here is 10 interested in trying to prevent somebody who is in need 11 of this type of medication from being relieved of pain, 12 and we can all tell a story about someone close to us 13 that has experienced pain. I watched my sister die 14 from cancer, so I can assure you, she received an award 15 in this room from a previous governor for her courage 16 from the Connecticut Cancer Association. So don't 17 misinterpret some of the motives. But if you had an 18 opportunity to see some of the things I've seen on the 19 streets in the community where abuse of these 20 substances can destroy a community, then you would 21 understand why we're trying to balance these two needs.

- 22 My agency has responsibility to
- 23 legitimately regulate the use of these drugs, and I've
- 24 seen what good they can do in the case of my sister and
- 25 I have also seen the terrible harm they can do in a

community in some of our urban areas when somebody does
 abuse it, in some case a doctor who has sworn to do no
 harm abuses. What we're trying to do is find that
 common ground and want to work with you to do that. So
 try to keep that in mind.

6 It's not an easy process. It won't be
7 easy for the legislators that sit up here and will have
8 to decide how best to do that and to the extent to give
9 the commissioner the authority to adopt regulations to
10 make it work.

11 DR. HARGUS: Well, I may be unduly

12 paranoid, but I think with good cause. I had a

13 complaint filed against me years ago by a patient

14 stating I addicted that patient to narcotic

15 medications. This is a patient with RSD, severe RSD.

16 Eventually totally cured, eventually back to work,

17 everything, who saw a psychiatrist, truly got a multi-

18 disciplinary approach, who refused to go into a

19 substance abuse counseling session. It took the

20 Department of Consumer Protection, it took them 14

21 months to get an answer to me as a physician.

- 22 How do you think I felt for 13 months?
- 23 How do you think other doctors, you know, we're human
- 24 beings too, our profession depends upon our license,
- 25 and if there's any -- any problem with our license,

1 whether it's true or not, you risk your livelihood. I

2 think that's a very real threat to people. So you have

3 to be extremely careful with your legislation.

4 MR. BLUMENTHAL: We want to thank you 5 for being here today. We have other people who have 6 waited for a while to talk to us, and we appreciate 7 your talking to us. Thank you very much. 8 I'm going to go a little bit out of 9 order. If James Giglio is here. Since you've come all 10 the way from New York and we're running a little bit 11 late, I'm going to go to your point on the schedule. 12 Thank you for joining us. 13 MR. GIGLIO: Thank you for inviting me. 14 My name is James Giglio. I'm director of the New York 15 State Bureau of Controlled Substances. Thank you for 16 the opportunity to present New York State's experience 17 in curtailing the trafficking and abuse of illicit and 18 controlled substances. We are flattered that you would 19 consider New York to share our program with you while 20 you develop your own.

21 New York has found no problem, no

- 22 activity as effective dealing with this problem as our
- 23 own prescription monitoring program. Our program
- 24 currently exists of an official form and electronic
- 25 monitoring. In New York State, regulation of illicit

1 controlled substances is the responsibility of the

2 Bureau of Controlled Substances.

3 The bureau is located within the 4 Department of Health and is charged with the 5 administration and enforcement of the New York State 6 Controlled Substances Act, those substances which are 7 prescribed, administered, dispensed and are valuable in 8 the treatment of illness and disease. As such, these 9 medications must be accessible to those who need them. 10 However, when abused or used improperly, the same 11 medications also have a potential to cause drug 12 dependency, personal injury, impairment, and even 13 death. It is the bureau's responsibility to assure 14 that these drugs are accessible for legitimate medical 15 purposes while at the same time preventing diversion 16 and abuse. 17 This is accomplished by monitoring and

18 regulating illicit and controlled substances from the
19 point of their manufacture and distribution, through
20 prescribing and dispensing and ultimately patient use.
21 The major focus about the bureau's activities and the

- 22 ones I've been invited to give testimony before this
- 23 panel today is New York's official prescription
- 24 program.
- 25 Since 1972 there's been required

prescription for Schedule II controlled substances in
 New York, be prescribed on an official New York State
 prescription form, and substances such as Valium,
 Librium, also be prescribed on the official forms. The
 prescription forms are issued to licensed practitioners
 in multiples of 25, imprinted with the practitioner's
 name, address, phone number, and a sequential serial
 number. With each prescription order, practitioners
 must indicate their specialty. This specialty is taken
 into consideration when evaluating an order.
 Before issuing the forms, which cost
 practitioners \$12.50 for a book of 25, the bureau
 verifies that the practitioner is currently licensed by

14 the state and appropriately registered with the Drug

15 Enforcement Administration, the DEA registered

16 address. Registration information is updated quarterly

17 with data supplied by DEA and the New York State

18 Department of Health.

19 From 1972 to April of 2001, the bureau

20 issued a three-part prescription consisting of an

21 original and two carbon copies, commonly referred to as

- 22 a triplicate. The way that system would operate is
- 23 this: The prescribing practitioner would complete the
- 24 prescription and retain one copy for his or her
- 25 records. The patient would then take the original and

1 one copy to the pharmacy to be filled. The pharmacy 2 would mail the remaining paper copy to the department, 3 where the prescription information would be stored and 4 made accessible for monitoring and analysis. 5 On May 1st this year, pursuant to 6 landmark controlled substances legislation which, 7 significantly, addressed pain management needs, 8 legislation went into effect in New York State for 9 prescriptions on a single-part form. The new form has 10 security features to deter scanning and photocopying. 11 It has a heat-sensitive ink component. If an attempt 12 is made to alter the prescription with water or 13 chemical solvents, the word "void" appears in three 14 different languages. It also has a rub-off feature on 15 the front which the word "void" appears. Instead of 16 the dispensing pharmacy having to mail in paper copies 17 every month, the required prescription data can now be 18 submitted to us electronically.

To date, over 95 percent of New York
 pharmacies have been certified to submit prescription
 data electronically, either by tape, diskette, or

- 22 encrypted over the Internet to a secure Web site.
- 23 Those pharmacies not submitting electronically are
- 24 required to submit data manually on a form provided by
- 25 the bureau.

1 We are currently nearing the end of a 2 transition period during which both triplicate and 3 single-part forms are valid for use. After December 4 31st, the triplicate will become invalid and all 5 official prescriptions must be written on a single-part 6 form. 7 The new system is already providing 8 advantageous -- I'm sorry -- is already proving 9 advantageous to the bureau in its prescription, 10 dispensing, and diversion concerns. Under the old 11 triplicate prescription system, prescription 12 information from mail copies had to be data entered, 13 which created backlog and put limits on accessibility. 14 Now with the vast majority of prescription information 15 being submitted electronically, prescribing and 16 dispensing data can be accessed virtually on a real-17 time basis. 18 I was going to go through a couple of 19 the programs or couple of reports that we can generate, 20 but for time I'll just skip over that.

21 MR. BLUMENTHAL: Thank you.

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- 22 MR. GIGLIO: It is sometimes argued that
- 23 official prescription monitoring programs interfere
- 24 with or inhibit the legitimate prescribing and
- 25 dispensing of controlled substances to meet patients'

1 medical needs. Several years back, the bureau

2 undertook a review of its official prescription data.

3 We found from 1984 to 1994 that prescribing of Schedule

4 II opioids, hydrocodone increased by 25 percent and

5 morphine by 661 percent. This data led us to conclude

6 that practitioners have prescribed and continue to

7 prescribe controlled substances that are appropriate

8 for their patients.

9 Confirming this is forms the bureau
10 issues annually to practitioners. In 1989 when we
11 placed benzodiazepines on the official form, we were
12 issuing some 3.4 million forms per year. This year we
13 anticipate issuing approximately 7 million. This
14 demonstrates the effectiveness of New York's
15 prescription monitoring program.
16 We recently received a report from the
17 Drug Enforcement Administration regarding the
18 consumption of OxyContin on both a state and national
19 basis. Data reveals that in New York State OxyContin
20 consumption per 100,000 population was below the U.S.
21 average in both 1999 and 2000. Of the 54 U.S. states

- 22 and protectorates for which data was provided, New York
- 23 ranked 50th in consumption for 1999 and 49th in
- 24 consumption for 2000.
- 25 We believe that these facts are not a

coincidence. We believe that oversight afforded by our
 prescription monitoring program curtails the diversion
 not only of OxyContin in New York but also of the other
 drugs required on the official form.

5 Finally, I would like to commend this 6 panel for recognizing the threat to public health and 7 looking into ways by which it can be prevented. As 8 both professionals and private citizens, we are all in 9 this fight together. My hope is my presentation today 10 of the success of New York's prescription monitoring 11 program assisted the state of Connecticut in 12 implementing one of its own. Thank you. 13 MR. BLUMENTHAL: You have definitely 14 assisted us, sir, and thank you for being here. We 15 would like to get back to you to learn more about your 16 program as we move forward. Thank you. 17 MR. GIGLIO: By all means. Thank you. 18 MR. BLUMENTHAL: Lori Zehe.

19 MS. ZEHE: Hi.

20 MR. BLUMENTHAL: Good afternoon.

21 MS. ZEHE: Good afternoon. How are you?

Mr. Blumenthal and Commissioner Fleming
and the other members of the panel: I'm pleased that I
was invited to be here to speak with you today about
the issue of prescription drug abuse.

1 For those of you I don't know, I do not 2 know, my name is Lori Zehe, and I am the executive 3 director of Capitol Area Substance Abuse Council which 4 covers 16 towns west of the Connecticut River. 5 including the city of Hartford. I've been working in 6 the field of substance abuse for the last 12 years; 8 7 here in Connecticut and 5 in Ohio. 8 The issue of prescription drug abuse is 9 not new. It's been a reality for a number of years, 10 for many decades, as a matter of fact. However, the 11 recent rash of deaths due to OxyContin abuse has pushed 12 this issue to the public -- into into the public eye. 13 As with many drugs of abuse, the ability to snort the 14 drug of choice makes it much easier for an individual 15 to use rather than to be selective or take the length 16 of time that it takes to digest the drug. And this has 17 resulted in a number of younger people experimenting 18 with drugs such as OxyContin and other prescription 19 drugs and becoming addicted to many of them. 20 As we move forward looking at public

21 policy, we need to keep in mind that OxyContin is only

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- 22 one of many prescriptions that are abused. We need to
- 23 be measured in our approach to avoid throwing out the
- 24 baby with the bath water. None of us are for that.
- 25 These drugs are effective when used as prescribed.

1 OxyContin is considered a Godsend for many seriously 2 ill individuals, especially end stage cancer patients 3 for whom prescription drugs delivered on a four-hour 4 schedule are not sufficient for pain management. 5 We must balance the need for pain 6 management with the propensity for misuse and abuse. 7 In speaking with my colleagues across the state, we are 8 aware that young people are abuse -- well, young people 9 and older people are abusing OxyContin and other pills 10 and are paying for them in many ways: They are 11 stealing them from parents' or relatives' medicine 12 cabinets, they are buying them on the streets, they are 13 writing prescriptions from a parent's prescription pad 14 if there is a child of a doctor. They're also being 15 prescribed often for teenagers who have had things such 16 as knee surgery. I don't know how appropriate that 17 is.

I also learned in the last few days that
there is another way that young people are obtaining
prescription drugs, and that is many of them are trying
to get jobs as pharmacy technicians, because there is

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- 22 no current regulation of pharmacy technicians, from my
- 23 understanding, and it is very easy, if they are
- 24 counting out drugs, instead of putting 60 in a bottle,
- 25 pocketing a couple in their pocket. I did just learned

this from one of my staff members who works with the
 community and works with young people who are abusing
 drugs.

4 Frequently they divide the pill into 5 quarters and take it with alcohol, creating a 6 synergistic effect. More often the pills are crushed 7 and inhaled, creating a quicker and more intense high. 8 Another source of prescription drug 9 abuse that I don't know if anyone talked about today, 10 it is well-known that many seniors have a tendency to 11 share their prescriptions with others: "This worked 12 for me, so, here, you should try this." In most cases, 13 it's done innocently without malice, but totally 14 unaware of the consequences of taking prescription 15 drugs that have been prescribed for others. 16 What would a reasonable approach be to 17 reduce prescription drug abuse? I brought you a few 18 suggestions that I hope are helpful to this body. 19 First, effective prevention and 20 education. We'll never end the abuse of drugs by 21 eliminating them. The only way we will succeed in

- 22 reducing drug use is by reducing the demand for drugs.
- 23 Effective substance abuse prevention and education
- 24 programs are necessary. They're necessary to target
- 25 specific populations of students, parents, teachers,

1 youth workers, social workers, and others.

2 Substantial research has been done on 3 prevention programs in the last 10 to 15 years. We now 4 know what works and what doesn't work. We also know 5 that we must use multiple strategies and multiple 6 domains with consistent booster sessions: Public 7 awareness, information dissemination, education, 8 capacity building within our communities and 9 individuals, alternate activities, environmental and 10 policy change, which is what you are looking at, and 11 early intervention. 12 Unfortunately, prevention programs have 13 been traditionally underfunded. Just as an example, my 14 own organization, which is one of 13 regional action 15 councils, was cut three times in the fiscal year '02 16 budget. Our core funding was a base funding of 17 \$75,000. That's now down to a little over \$50,000. So 18 we have to continue to look elsewhere for funding. 19 We also in the state of Connecticut have 20 an excellent system of local regional -- whoops, I'm

21 sorry -- local prevention councils in every state --

- 22 excuse me -- in every city and town in the state. And
- 23 so no one else has that kind of infrastructure, but
- 24 those local prevention councils that work in our town,
- 25 town officials, residents, parents, and students are

1 also underfunded. They receive from 1800 to \$10,000.

2 They have not had an increase in ten years.

3 Public policy has to change to provide
4 sufficient resources dedicated to prevention efforts if
5 we're going to impact the issue of prescription drug
6 abuse.

7 Second, we need to look at early warning 8 symptoms -- systems. In Connecticut we need to 9 establish an early warning system that alerts all 10 parties to the latest drugs of abuse. Nationally the 11 Drug Abuse Warning Network utilizes information 12 submitted by hospital emergency rooms across the 13 country. As far as I know, at this time there are no 14 Connecticut hospitals in that network. Connecticut 15 needs to establish some type of warning system for 16 emergency rooms in order to spot trends in drug abuse 17 as they emerge. This is not only true of prescription 18 drug abuse, but it's true across the board. 19 I also do a lot of work with inhaling 20 abuse. Again, the state of Connecticut has no 21 reporting system. So we only find out about the

- 22 emergency room deaths and such through other sources.
- 23 Third, we need to look at regulation and
- 24 enforcement. While we do not want to discourage
- 25 physicians from prescribing drugs for the appropriate

patients or pharmacies from stocking them, there is a
 need for improved regulation. I would recommend five
 steps.

4 The first regulation should be 5 tightening and enforcing what we have, those 6 regulations on prescribing and dispensing prescription 7 drugs that are already in place here in Connecticut. 8 The next step should be developing or 9 enhancing a system of monitoring prescriptions by 10 individuals and physicians. 11 In addition, physicians should be better 12 educated on prescribing these drugs cautiously, as the 13 earlier example I gave you of a young student who 14 received OxyContin for knee surgery. I don't know if 15 that was appropriate or not. Just need to hope that 16 the doctor did do it appropriately. 17 Pharmacists must be thoroughly trained 18 in identifying forged prescriptions, as well as 19 improving the storage of those drugs subject to theft 20 and misuse. With our new, modern technology, maybe the 21 time has come to develop a new method of writing

- 22 prescriptions that make it less likely that they can be
- 23 forged. This would also eliminate the errors in
- 24 dispensing prescriptions that occur due to, not to
- 25 insult any physicians, but the notorious handwriting of

1 physicians.

2 In addition, we should look also to 3 those talking about pharmacies that this whole issue of 4 pharmacy technicians, having kids who are already using 5 drugs trying to get those jobs is a concern, and how 6 can we tighten up that system. 7 The final step, manufacturers should 8 review the composition of these drugs just to determine 9 if there is a way to reformulate them to achieve the 10 same results for the patient while making them less 11 susceptible to abuse. This also includes manufacturers 12 giving clear instructions to the physician, the 13 pharmacist, and the patient. Lastly, the fourth issue that we need to 14 15 look at is treatment. Last, by no means least, is the 16 availability of treatment services on demand. Those 17 unfortunate individuals who succumb to the lure and

18 addiction of drugs must be provided with treatment

19 services at the appropriate level of care for their

20 particular situation. When an addicted individual

21 recognizes the need for treatment, he or she is

- 22 motivaed at that point. Telling somebody they've got
- 23 to wait for two hours, two days, or two weeks, and many
- 24 times more, is unacceptable because at the next
- 25 craving, the addict will overcome his ability to resist

1 and a precious moment of opportunity is lost.

2 Here again, there is a lack of treatment 3 services at all levels. Waiting lists are common. 4 Efforts have been made to improve services in the state 5 and in the Hartford area, but we continue to be unable 6 to place individuals in treatment. 7 On the adolescent level, which really 8 concerns me much, the picture is even bleaker. 9 Adolescent drug abuse is not recognized by parents or 10 teachers. Schools attempt to deal with the behavior 11 problems that result but are hesitant to refer a child 12 for a substance abuse assessment. It's my 13 understanding if the school identifies the problem as 14 substance abuse, they are then responsible for the cost 15 of special education and treatment services. With 16 school budgets as tight as they are, educators are 17 extremely reluctant to incur those expenses. 18 Those are the recommendations that I 19 bring before you that I tried to gather from my own 20 work, my staff, and my colleagues across the state; and 21 in conclusion, I would just like to applaud you, Mr.

- 22 Blumenthal, Commissioner Fleming, for making a priority
- 23 of this issue of prescription drug abuse, and also
- 24 after hearing some of testimonies today, I'm sure that
- 25 you on the panel really need the wisdom of Solomon, and

1 I hope that you come close to achieving the right mix, 2 and that you use every tool available to you to come to 3 a reasoned approach to this issue. 4 MR. BLUMENTHAL: We want to thank you 5 for being here. We will be sure to call on your wisdom 6 again. Thank you. MS. ZEHE: Thank you. 7 8 MR. BLUMENTHAL: Carl Mahler and Steven 9 Levin, please. 10 MR. MAHLER: Hi. 11 MR. BLUMENTHAL: Thank you for being 12 here. 13 MR. MAHLER: Good afternoon. I promise 14 I will be brief. 15 My name is Carl Mahler. I'm a nurse. I 16 am the vice president for the Hospice Council of 17 Connecticut. It is called Hospice and Palliative Care 18 of Connecticut. I represent the 27 Medicare certified 19 programs that provide for over 8,000 patients who died 20 in our hospice programs last year. 21 These terminally ill families and

- 22 patients choose hospice care because these programs
- 23 offer excellent pain and symptom control, education and
- 24 choices. They allow dignity and control over the
- 25 quality of life time. The interdisciplinary team of

1 experts that provides this care includes the patient's 2 primary physician, the nurse, the social workers, the 3 home health aide, the trained volunteers, clergy and 4 bereavement counselors. All these volunteers work 5 together to palliate not only their physical symptoms 6 that arise when a loved one is facing the end of life. 7 Pain can be the most disruptive symptom 8 and yet the most treatable one as we've talked about 9 today. There is an enormous amount of education that 10 happens when patients are placed on a hospice program. 11 There is a lot of education that families are fearful 12 of addiction and of the very large doses of medication 13 that are provided at the end of life to make those 14 patients comfortable. There is a lot of education 15 about the physicians, as you've heard today. Many 16 physicians are very hesitant to order more pain 17 medication because they are unfamiliar with the dosing 18 requirements of the terminally ill patient in pain. 19 Whatever this legislation accomplishes, 20 it must not negatively impact the hospice patients, as

21 you have said. We agree with that. There is a

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- 22 concern, however, that physicians must not become
- 23 hesitant to properly prescribe or paranoid of the
- 24 oversight the legislation may propose. They may be
- 25 afraid to treat the patient appropriately.

1 Additional concerns that we would 2 present for your consideration are: That when the 3 legislation, if it is presented and approved, that the 4 physicians have a lot of education around the details. 5 Some physicians will just hear this new law and 6 cringe. When the legislation is communicated, it 7 should reassure the prescribers that pain management is 8 not being targeted, that the targets of this 9 legislation are the practitioners who sell for their 10 own gain. 11 The other concerns that we have are 12 about patient confidentiality, also about the 13 monitoring, what type of ongoing monitoring will occur 14 to assure that this legislation has no detrimental 15 effects on patients' pain control. Will the monitoring 16 body include experts in pain control to speak to 17 adverse effects if and when they are identified? 18 Finally, we understand that 19 prescriptions will not be monitored in hospitals. Will 20 that in fact then encourage physicians to just admit 21 patients to the hospital because there they won't be

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- 22 afraid to prescribe the larger doses of medications?
- 23 Is this, then, the best place to aggressively treat
- 24 pain? Most hospice patients prefer to be at home and
- 25 to live there until they die.

1	Thank you for this opportunity to voice
2	our concerns. I think we all agree that the patient
3	has to be our first consideration and their comfort and
4	how this legislation may affect them.
5	MR. BLUMENTHAL: Thank you very much.
6	DR. LEVIN: Good afternoon. I admire
7	your fortitude for plowing through all this.
8	MR. BLUMENTHAL: Thank you for your
9	fortitude. I noticed both of you have been here most
10	of the day. Thank you.
11	DR. LEVIN: My name is Dr. Steven
12	Levin. I currently practice in New Haven, Connecticut.
13	I share of the views of the care
14	providers that have testified today.
15	Since arriving in Connecticut in 1997, I
16	have been actively involved in pain education and
17	patient advocacy through my associations with the Yale
18	University School of Medicine, the American Cancer
19	Society, the Connecticut Cancer Pain Initiative, the
20	Connecticut Hospice, and the American Society for Law,
21	Medicine and Ethics as well as numerous national

- 22 societies that focus on improving treatment.
- 23 Despite the increasing awareness of the
- 24 importance of properly evaluating and treating pain,
- 25 efforts to provide sufficient medical resources have

1 been lacking. There are many barriers to the

2 management of pain, including inadequate training of
3 health care professionals, poor communication between
4 patients and providers, the fear of regulatory scrutiny
5 by health care providers. Perhaps the top reason that
6 patients refuse treatment and are fearful of providing
7 treatment is fear of addiction.

8 The medical community is slowly evolving 9 understanding of the nature and magnitude of this 10 epidemiological crisis that has led to incomplete 11 treating of caregivers in general. The American 12 Society for Law, Medicine and Ethics conducted a pain 13 management study in Connecticut which presented the 14 results of a public conference in December of 2000 at 15 the Connecticut Hospital Association. This conference 16 confirmed that most of the physicians feel equipped --17 this survey confirmed that most physicians feel ill-18 equipped to offer pain management control to their 19 patients. Meanwhile, the medical schools in 20 Connecticut have felt compelled to reduce their 21 commitment to clinical pain management services and

- 22 physician training, apparently because of financial
- 23 concerns. Unfortunately, this reduction in academic
- 24 pain management resources comes at a time when
- 25 expansion of these resources is needed.

1 Many physicians report that they are 2 aware of other physicians who have been subjected to 3 disciplinary proceedings for prescribing opioid 4 medications and this has made them more conservative in 5 prescribing medications for their patients. Review 6 from public records from 1980 has shown that only a 7 handful of cases involving disciplinary action have 8 occurred relating to the treatment of pain, contrary to 9 the general perception of physicians. Assuming the 10 public record is reflective of the actual number of 11 proceedings against physicians for prescribing opioid 12 medications to treat pain, we might conclude that the 13 appearance of the regulatory oversight can have a 14 chilling effect on treatment. 15 Recent news reports have focused 16 primarily on addiction and abuse of pain relievers. 17 These reports unfortunately contribute to the under-18 treatment of pain by reinforcing misconceptions and may 19 harm the quality of life for patients. Since addiction 20 is a common fear that patients hold, such a fear may 21 prevent them from taking their prescribed medicine.

22 I've had examples of this within my own family. It may
23 cause family members to encourage people to not seek
24 treatment. Fear of addiction seems unfounded to this
25 magnitude for patients with pain, as numerous studies

1 have shown that less than 1 percent of patients 2 actually suffer addiction. And while we should not 3 ignore the possibility of addiction, we should view 4 these concerns in light of nearly 30 percent of our 5 population that may suffer significant chronic pain 6 symptoms. Evidence in support of appropriate pain 7 treatment details improved quality of life for patients 8 and decreased medical and disability costs for society. 9 As we attempt to resolve concerns over 10 pain medications abuse and diversion, we must be 11 careful to allow and promote access to appropriate 12 medical care for legitimate patients. Basic fairness 13 compels access -- to protect access to medical 14 treatments to the many people who require them and not 15 punish them for inappropriate or illegal misuse of 16 these treatments by others. Our collective actions in 17 this regard must be undertaken with the acknowledgment 18 that chronic pain and cancer pain touch our lives, 19 those of our friends, and those of our family. 20 The proposal for the electronic

21 monitoring of controlled substances has several

- 22 theoretical advantages in helping patients to
- 23 identify -- I'm sorry -- identify patients who may not
- 24 be taking medications appropriately or in identifying
- 25 physicians who require continuing medical education.

1 First, should real-time prescription information be 2 made available to physicians attempting to monitor 3 compliance in patients on opioid medications, and 4 deviations from structured care plans could be detected 5 earlier. Secondly, prescription patterns could be 6 monitored regionally and information about high-risk 7 areas could trigger more intensive surveillance in 8 these high-risk areas. Thirdly, such a system could 9 help to identify knowledge barriers that could trigger 10 CME for care providers. Continuing medical education, 11 that is. 12 However, the proposed electronic 13 monitoring system raises concerns, not the least of 14 which is a possible chilling effect on appropriate 15 patient care if such is seen as a mechanism to promote 16 disciplinary action against care providers. Also the

17 system could create inadvertent barriers to patient

18 care if it is overly burdensome. Therefore, the

19 implementation of the system should come only after

20 testing confirms that reporting is an efficient and

21 economical process. Finally, the system that appears

- 22 to be proposed may not provide the rapid feedback that
- 23 physicians could utilize in improving monitoring of
- 24 compliance of patients.
- 25 I would reiterate that Congress has

designated this as the "Decade of Pain." This is an
 opportune time for everyone concerned about this
 privilege to step forward and offer to help spread the
 facts about pain relief.

5 There is a strong societal interest in 6 assuring appropriate use of controlled substances. I 7 believe that potential misuse of controlled substances 8 has and will continue to overshadow and impede proper 9 pain management if we're not careful. Efforts to 10 improve public safety against misuse and diversion of 11 opioid medications are important, but should not come 12 at the expense of this continued challenge of continued 13 treatment.

It hank the panel for its attention to It his important issue and allowing me to share my thoughts on this issue. And in particular I would like to thank Attorney General Blumenthal for the actions that he has already taken on behalf of a number of my patients. I am happy to report to you that these actions have resulted in favorable outcomes and has in one instance saved a patient at risk of undergoing

- 22 potentially life-threatening treatments.
- 23 I'm happy to share these success stories
- 24 with you. I look forward to working together and in
- 25 ways we can share many other success stories together.

1	MR. BLUMENTHAL: Thank you very much for
2	being here. I hope we will continue to have
3	opportunities to work together and create more success
4	stories. Thank you very much.
5	We are very sensitive to the concerns,
6	as you gathered from sitting here, that both of you
7	have raised so cogently today. Thank you.
8	Our last witness today is Jeffrey
9	Casberg.
10	MR. CASBERG: Good afternoon.
11	MR. BLUMENTHAL: Good afternoon.
12	MR. CASBERG: Again, my name is Jeff
13	Casberg, Director of Pharmacy Services, ConnectiCare.
14	I would like to thank you for allowing
15	us to participate in this forum. Just a couple of
16	brief points.
17	First I'm a licensed pharmacist in the
18	state of Connecticut, practicing in the state of
19	Connecticut for the last seven years. So I have some
20	expertise in this in promoting appropriate use of
21	medications for members.

- I will make three brief points and keep
- 23 it brief here. Number one is ConnectiCare's concerned
- 24 about the appropriate use of controlled substances;
- 25 number two, we're concerned that any legislation passed

would inhibit the access to needed pain medication at
 the point of sale; and, number three, we would like to

3 offer continued assistance in developing any

4 legislation in the future.

5 In the point of appropriate utilization, 6 abuse of controlled substances is not new to health 7 care professionals. It's been going on for years and 8 years. As we have seen from other witnesses in other 9 states, there are controls around the utilization of 10 controlled substances in other states. So I am 11 interested in participating in the development of this 12 for the state of Connecticut. 13 I think the abuse of OxyContin in the 14 last couple years has increased dramatically, which has 15 brought us to this legislation right now. This topic, 16 actually, we have a committee that meets quarterly of 17 about 10 physicians from the state of Connecticut, some 18 of the physicians may serve yourselves. We meet 19 quarterly, we discuss their use of medications for all 20 of our membership. There are 275,000 members in the 21 state of Connecticut.

- 22 We met two months ago on this very
- 23 issue. We discussed OxyContin, and we raised four
- 24 proposals. I will tell you what they actually
- 25 proposed. The first one we proposed was at the point

1 of sale to allow the initial prescription to come

2 forward for 60 tablets or so, which allows them to walk
3 out the door of the pharmacy with a prescription and at
4 a later point request medical necessity criteria for
5 continued use. That was the first.

6 The second one is continue what we have 7 currently done for several years: Retrospectively look 8 at prescriptions for our clients and develop thresholds 9 as so much prescriptions per member per quarter, number 10 of doctors they have seen, type of medication used, and 11 then eliminate unnecessary reporting physicians through 12 looking at other diagnosis criteria such as cancer or 13 other things such as that. Then once we develop that, 14 send that out to practitioners, describing to them 15 which possible patients could be abusing the 16 medications. 17 So we've been doing that on a quarterly 18 basis for several years. That was probably number two, 19 retrospective drug review.

20 Third was a similar non-physician

21 focused education, but towards the member. It would be

- 22 a little softer. Basically running an electronic data,
- 23 looking at members who basically are pharmacy shoppers,
- 24 members who go to several pharmacies, getting different
- 25 types of medications, trying to avoid edits at point of

sale, and sending members who do that educational
 points why it's best to use one pharmacy, why it is
 better to use one pharmacy rather than multiple
 pharmacies.

5 Number four is to do increased education6 to physicians.

7 After presenting these four proposals to 8 our physicians on the committee, the final proposal was 9 to stay with what we had currently been doing. Not to 10 put point-of-sale edits in, but to remain with the 11 retrospective drug utilization review with possible 12 abuse potential with some of their patients. The 13 committee decided they do not want their point-of-sale 14 edits appropriate especially in the realm of pain where 15 it is an acute need where they need the medications at 16 that time. And after reviewing the number of patients 17 on these medications, it was felt it was abuse, but the 18 abuse is the exception rather than the rule, and that 19 in our current situation with retrospective drug review 20 that can address this, rather than putting additional 21 stops at the point of sale or physicians or causing

- 22 increased paper hassle.
- 23 So that is a summary of why we decided
- 24 to stay with what we are currently doing. And
- 25 ConnectiCare is concerned about putting legislation

1 around electronic edits and would be more than willing

2 to work with you on developing and providing our

3 expertise in this area.

4 MR. BLUMENTHAL: Thank you very much. 5 I think we're done with the witnesses 6 that we had scheduled. We may well want to schedule 7 another such informational hearing, and I stress that 8 it has been informational. It's provided a lot of very 9 useful insight and data to us, and I hope to members of 10 the public, and we want to thank everyone who has 11 participated. 12 COMMISSIONER FLEMING: Also, I'd like to 13 thank the Attorney General for organizing this. It's 14 been very helpful to me. If my agency decides to go 15 forward with legislation on this topic, much of what 16 was said here today will help us to develop whatever 17 the legislature decides they want to take up during the 18 short session. So I appreciate everybody coming out 19 and giving us your thoughts.

- 20 MR. BLUMENTHAL: Thank you all.
- 21 (Public Hearing adjourned at 1:53 p.m.)

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