STATE OF VERMONT

S.115 - Prescription Drugs, regulation

April 10, 2007

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PROCEEDINGS
CD 126/TRACK 1:
MS. BRILL: In the anti-epileptic area, which I know a tremendous amount because of this litigation that I did, which resulted in the grant to UBV and Dartmouth, you know, and some of them are prescribed 80 percent off label.
Do you guys know what "off label" is?
So that means that you've got a tremendous amount of prescribing going on which are not for indications approved by the FDA. May be effective, just what -- it's not approved by the FDA. Doesn't mean that it's wrong or bad, but when you have a drug that's about 80 percent off label, it does, you know, make one want to look at it.
And when we examined, some of the anti-epileptics we found that -- some of the uses for which the company was marketing the product, actually, the product was no more effective than a placebo.
UNIDENTIFIED ATTENDEE: (Inaudible.)
MS. BRILL: Yeah. Yeah. And this was --
UNIDENTIFIED ATTENDEE: (Inaudible.)

MS. BRILL: And the real problem, you know, placebos really aren't a bad thing, especially in the neurological area like -- in the mental health area, but one of the indications it was being marketed for -- this is Neurontin -- was bipolar disorders, and if they're a placebo, it is really dangerous.
I mean, you're talking about people who really need to have effective meds, if there's anything out there. So that's where we got really concerned, and that's why the case became such a big case because we found marketing for indications for which the product was no better than a placebo, and the indications themselves were very dangerous for consumers. So, evidence --
UNIDENTIFIED ATTENDEE: (Inaudible). Just one (Inaudible) the name of the drug that had a lot of off-label use, that's been in (inaudible) for a bunch of uses.
MS. BRILL: Zyprexa. It is a -- is it atypical -- yup, we announced which was unusual for us, but we did announce, and it appeared in the New York Times that we are in part of an investigation involving Zyprexa. The atypical

antipsychotics is another class of drugs.
Again, I think you need -- we look at this as class by class, but I think typical antipsychotics, Zyprexa, Risperdal and Seroquel are the three major brand-name drugs. They are designed for schizophrenia, but they also use a tremendous amount off label for everything from dementia, you know, senior citizens who -- Alzheimer's, those kinds of -- and also there's --
UNIDENTIFIED ATTENDEE: (Inaudible) hospital, too.
MS. BRILL: Exactly. That would be what bought it, would be used for off label. We are -- as we announced, we are looking at that issue. But I didn't have anything more than I can say about that, or than I --
UNIDENTIFIED ATTENDEE: You're looking at it?
MS. BRILL: Yeah, we're looking at -- that's what you're referring to. But the whole point of evidence-based medicine is to try to inform doctors about what do the studies actually show. So, you know, they may have an individual experience with one patient who may

do really well on Neurontin, just to use the example of our case a couple of years ago.
But it is also important that the doctor understands that may be atypical of how most patients do react who have that condition. So evidence-based medicine is trying to inform them of what do the studies actually show, and it's in the Neurontin area.
We -- part of the settlement was allowing us to hire some researchers to try to translate some of these huge studies for practicing doctors. I mean, Harry probably knows, you know, the atypical area -- not the atypical, sorry, in the anti-epileptic area, there was like a 300-page study done to demonstrate what they were effective for, and what they weren't, you know a guy who's in the emergency room or -- they're not going to sit and read a 300-page study, so how do you translate that information to your average prescriber? That is a huge challenge.
And we're working on that in this one little area, and it's taking a long time, and it's actually pretty expensive. We're using the settlement money to do it, so think about

doing that in all of these different areas, it's really a huge, huge challenge.

Okay. That was all we're going to say about evidence-based medicine. I thought I'd move on to advertising to consumers.

There is provision in here that would allow us to use an FDA warning letter that goes to the pharmaceutical manufacturer as prima facie evidence of a consumer fraud violation. I think you all heard about it. Perhaps there was a question raised in your minds as to, well gee, why doesn't the FDA enforce those, why does the State have to do it?

The FDA doesn't really enforce those. They issue the warning letter, and they don't really, typically speaking, do much with them.

UNIDENTIFIED ATTENDEE: Warning letter for what again?

MS. BRILL: Usually for false advertising. For sometimes it could be more off label marketing, but usually falsification of some kind or another; overstating the benefits of a drug; understating the risks; overstating the typicality, those kinds of things, are what the FDA warning letters are often issued for.

We think we like that provision. We would like to be able to use those letters as prima facie evidence. The pharmaceutical manufacturers would still be able to come in and say no, no, you know, here's the answer to that, but it would just allow us to move the case forward.

There's also a provision in here that would disallow the use of new technologies for ads to doctors like on their P. D.A.'s and their computers, things like that. This is based on a Florida law.

We also really like this. It's sort of forward looking in terms of where the industry may be going in its advertising. So we think that that's very important too.

PBM's, this is a big section, and you're probably going to hear a lot about it, if you haven't already. We support this provision. On this provision, doesn't really require that much of the PBM; it's mostly requiring disclosure to their clients, which again are the plans, serve employer plans and insurance companies, et cetera. We think that the disclosures that are in there with respect to

where they get their money and where the rebates that they get may be going, is an effective provision.

The industry, we did enter into a settlement, and I think I'll pass this out too with respect to one PBM. This was actually two years ago. This is Medco, which is a -- I'm giving these all to you; do you mind?

UNIDENTIFIED ATTENDEE: Yeah.

MS. BRILL: I could give them to him too. Medco is a pharmaceutical benefit manufacturer, and we entered into a settlement with them because we felt that they were not adequately disclosing information to consumers, to doctors, and to plans.

And one of the ways in which the pharmaceutical benefit manufacturers make money is through the PDL system that they have, which often is not -- it doesn't necessarily have the cheapest drug on their PDL, but they will often have a drug for which they are getting the most amount of money back from a pharmaceutical manufacturer in terms of rebates. So those will be the products that are on their -- their PDL.

So you know, if you look at the average wholesale cost of Lipitor versus Zocor, Zocor became cheap because it's now gone generic. These are again, anticholesterol drugs or statins.

Lipitor is probably a lot more expensive, but if Pfizer, which produces Lipitor, gives a fairly large rebate back to the PBM as a result of moving market share, and bringing in more customers, things like, well, overall Lipitor may end up being cheaper for the PBM, so they put it on their PDL.

UNIDENTIFIED ATTENDEE: Doesn't the insurance companies negotiate that stuff with PBM's.

MS. BRILL: Yes. And I think that this industry has definitely gotten better in terms of the clients. The insurance companies -- not many -- many of the clients of PBM's are not insurance companies. Many, many of them are employers, some of them are huge employers like IBM, I mean.

UNIDENTIFIED ATTENDEE: Self insured.

MS. BRILL: Exactly. Many, many --

UNIDENTIFIED ATTENDEE: (Inaudible) as

many bodies as the insurance companies.
MS. BRILL: Absolutely. Absolutely. No question. And many of the other employers would use PBM's, will go through what's called a third-party administrator, where they have someone who they hire, who's supposed to be an expert in all of this and helping them negotiate these situations.
What the bill requires, though, is that there be clearer disclosures to the plans, maybe through their third party administrators, maybe directly to, if they have like an IBM, if they have like an individual who's actually doing the negotiations, it would require those kind of clear disclosures to them about where the buckets of money are coming from, and where they're going.
UNIDENTIFIED ATTENDEE: Is that something that like the IBM's of the world want? I mean, I guess I don't understand where this language is coming from, because I know that -- I mean, insurance companies do their own negotiations. I would imagine that an IBM who really buys their insurance from somebody else, that company --

MS. BRILL: Well, they're self insured, right, but somebody's doing the negotiating for them. Absolutely.
UNIDENTIFIED ATTENDEE: So I guess I don't understand --
MS. BRILL: But not -- not only in this industry, every client of a PBM or an IBM, we probably would have no problems, but many of them are much smaller players who don't understand the ramifications of what they're agreeing to and -- (inaudible).
Well, the state of Vermont is one, and in fact, a couple years ago, an auditor Elizabeth Reedy -- my book if you want --
UNIDENTIFIED ATTENDEE: No, thank you.
MS. BRILL: -- was very concerned about some of the stuff that was going on with respect to the state's contract, and I think the state's contract has improved, but I think, again you have -- there are sophisticated people in this business, and then there are less sophisticated people. And some of the problems that Elizabeth Reedy talked about back in --
UNIDENTIFIED ATTENDEE: What was the date

of that?
MS. BRILL: It was like '04.
UNIDENTIFIED ATTENDEE: '04.
MS. BRILL: Yeah, had to do with different price lists. There's two I'm passing out. I passed one in each direction to really confuse you. Sorry.
UNIDENTIFIED ATTENDEE: Good job.
MS. BRILL: Sorry. Just wanted to make sure you were still awake.
UNIDENTIFIED ATTENDEE: I'm awake. I knew what you were doing.
MS. BRILL: So, to get to your question, really, Pat, I mean there are definitely clients of PBM's who are very sophisticated and know what they're doing, and they are really pushing the PBM's and driving the contract. And then there are other clients who may not be as sophisticated, and we believe need to have some disclosures.
Now, having said that, I think, since 2004, since our settlement with Medco, since a lot of these practices have come to light with respect to (9inaudible) -- I mean, one of the things that was going on, if you look, the

Medco settlement was consumers were being switched from one drug to another drug, because they were being told that it was a preferable product. They weren't being told -- it was actually not preferable for anyone other than the PBM, and possibly their employer.
But their doctor was being told that it was more cost effective, they were being told that it was preferable. And we were really concerned about the nature of this information that was flowing to consumers. We didn't think the consumers were getting the right picture, and to switch someone who's on a maintenance drug and stabilized on a maintenance drug, to another one, again using statins as an example, you know, sometimes they have to have extra blood tests. Sometimes they have to have, I mean Harry will probably be more articulate at this than me, but blood tests is certainly one of the things that you want to look at to make sure that someone is adequately stabilized on a new drug, and that cost was going to be picked up by a health plan, which would not be the PBM, it might be a different health plan, and employers, we believe, had no idea that this

was going on, that they were actually paying more, potentially, for these switches, they were getting a small savings or a small amount of rebate for the switch. But then they would have to pay for an extra blood test or whatever, to make sure that the patient was stabilized. So that's the nature of what our concern was back in 2004.

Having said that, we do think that the industry has improved. We think that we are in discussions with the other players in the industry, very similar to this issue that you have before you.

With respect to Medco, the practices are different. But some of them are the same, some of them are different. It has improved, there's no question that the industry paid attention to what we did in 2004. No question. But we also think this is an incredibly dynamic industry. The fact that they changed so much from 2004 to today shows us that it is really a dynamic industry.

There's a lot of -- there are a lot of different layers, and there's a lot of different movement in different areas, and so

we think establishing some ground rules about disclosures to the plans again, some of them being unsophisticated, unfortunately, will ensure that there's improvement here. So that is why we would like to see this provision in this bill.

UNIDENTIFIED ATTENDEE: (Inaudible). Could I ask you?

MS. BRILL: Sure. I'm sorry. Am I going too long? I apologize.

UNIDENTIFIED ATTENDEE: Somebody else.

MS. BRILL: So, let me be real quick then. (Inaudible).

MS. BRILL: Let me just think. You haven't heard me say anything about unconscionable pricing. That is a big issue in this bill. We believe that this provision in -- and you've heard it described so I'm not going to go through the description of what it would actually do, other than to say that, as passed by the Senate, there is a whole extra step in what we're proposing that is not in the District of Columbia's law that was stricken.

In other words, we first have to show that there's a serious public health threat before

we ever get to go to court and say this product is too costly. That was never in the District of Columbia's law. We also think --

UNIDENTIFIED ATTENDEE: (Inaudible).

MS. BRILL: It was stricken, yes. It's on appeal, but it was stricken, yes. And in addition to having this additional step to require that there be -- the Commissioner of Health find a serious public health threat, we also narrowed the law greatly to address the constitutional concerns of the district of Columbia so that it would (inaudible) affect commerce in Vermont and was, although there were other issues raised in the District of Columbia case having to do with the Supremacy Clause (ph.) and that kind of stuff, we don't think that those would be affected here either. It was really this issue of the commerce clause that was the big issue and we did try to address that.

And I think that was all. I just had one little handout which I can give as I'm getting up. We recently entered into a settlement with the Bayer Corporation involving Baycol, which was another statin drug. Our state received

600,000 for this settlement, and this had to do with their failure to disclose post marketing -- higher than expected adverse consequences from this product. Again, Harry knows all about this. The product was actually pulled from the market.

UNIDENTIFIED ATTENDEE: (Inaudible).

MS. BRILL: So I am happy to answer any questions, and I'm sorry I went longer than expected.

UNIDENTIFIED ATTENDEE: (Inaudible).

As I understand it, from some of the (inaudible), some of the testing that's done of pharmaceuticals, and I think you or someone touched on the area, is comparing a drug with a competitor's, the lower strength to show that my drug is stronger or more effective, or comparing it to a competitor's higher strength to show that mine is less harmful.

MS. BRILL: Um-hum.

UNIDENTIFIED ATTENDEE: And so forth and so on. And what -- I'm just curious, as to whether (inaudible) shining a light on that kind of stuff, I realize there are a lot of details that's probably before the courts

somehow getting that information out in a digestible form (inaudible) helps to do that.

MS. BRILL: Well, I really think -- that's a great issue. And I'm not sure that's one a state can really address.

I really, you know, you have to sort of think what should be a federal issue, what should be a state issue. You know, a lot of the drug safety and efficacy tests are based upon comparing the drug to a placebo and questions with respect to cost is how effective it is compared to other products, more traditional products that are on the market.

And those kinds of tests, typically speaking, manufacturers are not inclined to fund, because it's not going to help them. Often -- and so researchers have to fund those kinds of tests. This is very expensive. But that is exactly what the evidence-based medicine studies are designed to do. They're designed to show on a head-to-head basis, expensive brand-name drug, is it more effective than this generic, like Celebrex, Bextra, it's a ... I'm sorry, it's Cox-2 inhibitor. I get -- I'm not -- this is all -- I'm not --

it's hard for me to remember all these classifications. I'm not the --

UNIDENTIFIED ATTENDEE: It's Vioxx.

MS. BRILL: It's the Vioxx. Thank you. It's the Vioxx of the world. And you know, there are a lot of people out there who think -- a lot of doctors and people who are doing evidence-based medicine, who think that these products are no more effective than basically fancy aspirin, diclonopine (sic.), that kind of stuff, and when head-to-head studies were actually done, that was demonstrated.

UNIDENTIFIED ATTENDEE: And yet the Cox-2 inhibitors, again the Vioxx/Celebrexes of the world, they're tremendously more expensive. I mean, just tremendously more, but who's incentivised to do those studies? FDA doesn't require them, because FDA's issue is not cost effectiveness. It's safety. Sorry.

MS. BRILL: Sorry, it's safety, sorry. I'm sorry. Yup.

UNIDENTIFIED ATTENDEE: (Inaudible).

Just one question. The unconscionable pricing, if we can't affect any manufacturing

outside of our state, we don't have any manufacturing in our state, we have one wholesale supply outlet, what is that going to do to that wholesale supply outlet?

MS. BRILL: We -- it does affect manufacturing out of state to the extent that the product is sold in the state. It has to be a relationship where the manufacturer sells into the state. It has been alleged that the vast bulk of those sales that are going -- manufactured to wholesaler or manufacturer to anyone in Vermont is through that one wholesaler that you're referring to, which is Burlington Drugs. We are not certain that that is the case in terms of how the market really works.

But if that is the case, if it were the case, that it is that, let's say there are no sales, let's say we remove Burlington Drugs, there are no sales directly from manufacturer into the state of Vermont, then the provision as currently written would not -- would not be effective. I just don't think that that's the case. I think that they're direct, I think the manufacturers sell directly into the state. I

think they do it through prescription assistance plans. I think they do it through the wholesaler that you're referring to.

I think there are probably other relationships, we just -- we just don't know. It's the vast bulk of it that does happen through wholesalers, but I don't think that's the limit of it.

UNIDENTIFIED ATTENDEE: (Inaudible). Patient assistant program.

MS. BRILL: Do you know what a patient assistance program is? I'm happy to -- yes?

UNIDENTIFIED ATTENDEE: This is a big issue. I really would like to discuss it more than (inaudible.)

MS. BRILL: Yeah.

UNIDENTIFIED ATTENDEE: Some of the pharmaceuticals (inaudible).

MS. BRILL: Absolutely, but the question is, are they selling the manufacturer directly to like a depot for a chain? That's the question.

UNIDENTIFIED ATTENDEE: But we could end up in court because of this too, right?

MS. BRILL: I -- yes. I will never say we

could -- we could end up into court on this piece. We have tried to design it in a way that will eliminate what's called a facial challenge, meaning that before you ever apply it in terms of enforcement action, that you'd get to challenge it. That's what happened in D.C., and that is what the problem we're hoping to have a challenge that it is involved when we actually have an enforcement action. I don't think on its face it's unconstitutional at this point. I'd be happy to talk to you. It is my opinion, I mean that it is not, on its face. I'm not the judge. It will be up to the judge to decide that. Thank you.

(End of CD-126, Track 1.)

CD 126/TRACK 2

MR. KIMBELL: The beginning, and I'll introduce everybody and --

MS. OJIBWAY: All right. Just give me --

UNIDENTIFIED ATENDEE: The one that's circled right there.

MS. OJIBWAY: Thank you.

(Pause.)

(Phone ringing.)

MR. FRANKEL: Hello, Randolph Frankel.

MR. KIMBELL: Randy, this is Steve Kimbell, and I'm here with the House Health Committee, and you're on the air.

MR. FRANKEL: Thank you very much.

MR. KIMBELL: And we're just beginning. We called you up first, and I'm hoping that you will be willing to listen for a couple of minutes while I frame this issue, and then I know the committee will have some questions of you about just what IMS does, how it acquires the data you use, and what your business is about.

MR. FRANKEL: Thank you. I'll be glad to listen in.

MR. KIMBELL: Great. Thank you. The

chairman's is Steve Kimbell, and I'm an attorney and lobbyist from Montpelier. With me is Arthur Woolf, who's an economist from the University of Vermont, who is going to be providing part of our testimony. Actually, he's here on behalf of his private firm, not in his role as a professor.

We are interested in ... Section 13 of S.115, which is the so-called data mining section that you've heard quite a bit of discussion about.

My client is IMS Health, Inc., which you've heard other witnesses refer to, and they're one of three major healthcare data companies. I just want to step back briefly and give you a little bit of the history from the other body in this bill. The bill was introduced as it comes to you.

S.115 was introduced by the Finance Committee with this language. It went over to the Health and Welfare Committee, which held more extensive hearings, I think it's fair to say, than the Finance Committee did, and that committee concluded that it would be better to, I think, to use the *Chair's words, go slow

with a proposed ban on the commercial use of this data in light of the New Hampshire litigation and in light of their interest in assuring that this bill was a cost-containment measure, not a cost-expanding measure.

So, that resolution by the Health and Welfare Committee was agreed to by the chair of that committee and the Finance Committee, but the leadership decided to make an issue of this on the floor, and on a 16-to-13 vote, they prevailed in putting the language back in that original ban.

I'm here today to plead with you to keep an open mind. There's a lot of negative conversation about pharmaceutical companies in the building and in society at large. I'd like to tell you, at the outset, that IMS Health is a data collection and management company, not a pharmaceutical company. It serves the entire healthcare industry with collection and sale of data of all kinds, and I would hope that you would bear that distinction in mind. Unlike the defendants in the lawsuit in New Hampshire; we have no prediction about the outcome. Judges are always very unpredictable.

A similar thing happened in New Hampshire last year, it is being litigated in federal court. The judge says he'll decide soon, but as an earlier witness said, judges decide when they want to decide, and we don't know what will happen there.

Whatever the result of that lawsuit is, we think that this ban, this prohibition on the commercial use of this data would be wrong public policy.

I just -- I don't expect you to believe my opinion or IMS's opinion about that because we're in the business of collecting, packaging and selling this data. It's a for-profit company. And so when a legislature decides that a for-profit company in the United States -- when a state legislature says we don't want you to do business in our state anymore, I think it's legitimate for the company to come in and try to defend itself and say, wait a minute, we think we do some good things. Before you tell us we can't sell Dodge trucks anymore because they get ten miles per gallon, would you please listen to us?

And that's -- that's what we're here to

do, and I make that analogy not lightly. I think that's basically the equivalent of what you're doing here. You're saying to this company, you know, that's doing a legal business, you can't do it anymore in Vermont.

I took the liberty of putting this binder together because I anticipated that there was going to be about 500 pieces of paper handed around today from the various witnesses, and I thought that putting all of our presentation in one binder that I could walk through quickly, would be helpful to you.

And this is Vermont-specific information, and ... I apologize, but I have to take my glasses off to read something that's close in front of me. And I'm just going to walk through this quickly and highlight it, if you would bear with me.

The first, tab one, is a letter from the general counsel at IMS health to Representative Maier and this committee, and the key point in this letter, in my view, is at the bottom of the first page. Or I beg your pardon, the ... bottom of the first page, that first bullet that, without a commercial use for this data,

it won't exist.

This is one of the dilemmas of this public private healthcare system we have. There's a huge amount of effort going on in the private side, and a huge amount as you know, goes on in the public side. Why does this data exist for any use for research or for the long list of exceptions in the bill? It's because there's a commercial purpose for it.

Just think about it for a second, and I think common sense will tell you, without the commercial purpose, the government is not going to spend the money to generate this data, and I think our own unified health care database that's been in the statutes for years and has been a dead letter (sic.) basically because the government has never put up the money to put the one unified health care budget and database together, that's an example of the kind of partnership I'm talking about.

I just don't think the data will exist. In fact, the long list of the exemptions in the proposed bill ... if you go down them, from law enforcement agencies to university researchers, I submit there's nobody on that list who's

going to pay for this data. It's tremendously expensive to accumulate.

The second point is, of course, Vermont physicians can opt out of having their data used. I can sympathize with Representative Chen's outrage, but I think there's two different issues.

I can sympathize with his outrage about not knowing that his data was being sold by the AMA. He's not an AMA member. I think that's what you said, Representative Chen, and so where do they get off doing that? That's a separate issue, it seems to me. Once they get that straightened out and they opt out and refuse, that's a separate issue from whether or not this data should be able to be used for commercial purposes.

We believe that, contrary to some of the testimony you've heard, if you make marketing more efficient, which is what this data does, it will reduce the cost of marketing. There will be fewer marketers out there, if they know where to go to talk about the product that they're trying to sell.

Randy will be able to tell us how long

this data sale has been part of their business. IMS is a 50-year-old company, but before we sold the data, pharmaceutical companies figured out a way to market to physicians. They did it with footwork, I suspect, talking to pharmacists, finding out who was prescribing what, and that probably was more expensive. In fact, we know it was more expensive than doing it this way.

This data makes pharmaceutical marketing more efficient, therefore, less costly and (inaudible) takes costs out of the system. We cannot give evidence that there's a direct line between taking that cost out of the system and the cost of prescription drugs, because the chain of events is too attenuated.

You've got IMS selling data to more than 100 pharmaceutical companies, they're marketing their products, and what the price of a retail product is so attenuated from the cost of getting marketers into the field that I can't give you any specific data, but I'm -- common sense, to me, says if it's more efficient to market because you've got this data, you don't need as many marketers and in fact,

pharmaceutical marketing forces have been going down in recent years.

Finally, we think that more data, in general, is better than less data if you're going to have to pay for performance, if we're going to have adequate safety programs, if we're going to have transparency, consumer-driven healthcare initiatives, more information out there is better than less.

I would -- attached to that letter is the AMA announcement or the Vermont Medical Society announcement to its members, looks like this, this past summer, about the opt-out program. So notwithstanding, they're -- well, I would just say, this is what the Vermont Medical Society sent to its members, a very simple -- it's attached to Mr. Ashton's letter, the last thing in tab one.

So you can look at that if you're -- if we could flip over to tab two, this study was just released yesterday -- actually, it's an April 10, 2007 study by a policy think tank in Washington called the Political and Economic Research Council. There's quite a bit of information here about them, and you can go on

the web and find more.

I've attached, as the last two pages of tab two, a description of who they are. But the findings in this study are very interesting. Basically, it's an access to provider identifiable data services of provide (sic.) constraint so that fees to -- my point, this doesn't drive up prices; it lowers prices, provider identifiable data reduces waste and physician time by reducing mismatches.

Another point they make is that banning commercial use of provider-identifiable data will not lower drug costs (sic.). Then they cite a study in Canada to that effect.

And, finally, marketing appears ineffective in promoting the use of more expensive brand-name drugs.

So, the -- one of the arguments here is that this data is used with skilful marketers to get physicians to prescribe brand-name drugs, more expensive brand-name drugs than generics. This study finds that's not true, and if you just flip with me -- flip with me to tab four, please.

This is the data on generic utilization

rates in Vermont and the United States. And where a generic is available, Vermont uses it 96 percent of the time, which is better than the national average. So, I -- this -- this refutes the notion that if that's what the pharmaceutical companies are trying to do, get physicians to prescribe the more expensive brand-name drug, it's not working -- where there's a generic available.

MS. OJIBWAY: So, question quickly. This shows the percentage when generics are available?

MR. KIMBELL: That's what I said. That's right.

MS. OJIBWAY: But what percentage of money spent on drugs goes to generics versus brand names?

MR. KIMBELL: Actually, I've got an article on that -- (inaudible) I'll bring it in. I got the specific numbers of generics rising at a rate -- the amount of money is still less, but it's increasing at a rate about twice of the rate of increase of branded. The generic movement is coming, and everything you can do to encourage it, of course, would be

good, but all I'm saying is, the availability of this data to marketers isn't having the impact that the proponents of this bill claim. It's not driving up prescriptions of brand-name drugs when there's a generic alternative. Of course, that's the question (inaudible).

UNIDENTIFIED ATTENDEE 2: This is -- could be very deceptive, or it could be very true. So I just need to see the backup data for this.

MR. KIMBELL: Be glad to. Knowing you're getting buried in paper, I've been trying to be as tight as I can, but I'd be glad to get that for you.

Underline this chart.

MS. OJIBWAY: Well, my question is going to be, so you said -- so it's not working. So if it's not working, why are pharmaceutical -- why are they paying so much money?

MR. KIMBELL: Because it's far more efficient. They can put fewer bodies on the ground because they can target the best methodology. If I am in the market for a multiple sclerosis drug, I need to go to physicians who have M.S. patients. If I go to physicians who don't have any M.S. patients and

don't prescribe M.S. drugs, I'm wasting my time.

So that's why it's important. I believe it's important that a pharmaceutical industry -- and why it drives down costs. But I don't think the claim of the proponents of this bill, the opposite of it is that it drives up costs is accurate, and that's what this --

MS. OJIBWAY: And again, but if it's okay --

MR. KIMBELL: It's more effective.

MS. OJIBWAY: Yeah, and I don't doubt that, because you make that investment, but if it does drive down the costs and you save money, do you believe the cost is being passed on to the consumers with lower drug costs, or is it going somewhere else?

MR. KIMBELL: That's an excellent question. And what I said earlier, I don't have evidence of that, because the chain of events between the data mining and the sale of the data to more than 100 manufacturers to their manufacturing process, to the competition that they're under from the other drug companies, I don't know. There's no evidence

that I have that whatever savings in marketing there flows through the retail level, because you've got the manufacturers, the wholesalers, and the retailers, maybe a retail chain, and then further distribution.

So, I'm just saying, intuitively, there's less cost in the system because the marketing is more efficient.

MS. OJIBWAY: But intuitively, to me, if I'm not saving money on a drug, since somebody else is making the money, yeah, I can see where it's saving money, you know, running an efficient business, but the cost is not how would the cost decrease; you could just pass that savings on to shareholders in the company. If it's not going on to the consumers, it's going somewhere.

MR. KIMBELL: That's a good question. I don't think anybody's studied it. I mean, you're right to ask.

MS. OJIBWAY: But you're right, it's kind of intuitive where you're going to spend that much money, right?

MR. KIMBELL: I -- I know. Oh, I'm sorry.

MS. OJIBWAY: Just, I don't know if --

MR. KIMBELL: Are you done, Hilde?

MS. OJIBWAY: And I'm not really being sarcastic, so I just -- just wondered how you know following the money.

MR. KIMBELL: (Inaudible).

MS. OJIBWAY: I just wanted to follow along that -- that line and, you know, I understand that having fewer people on the ground can make for -- make things more efficient for the industry. So that they'll save money and the issue of where the money goes is a big question.

But the information that we're getting is that prescription spending on prescription drugs is the fastest growing component of healthcare. So, we're not saving money in the system, from what I can gather. It sounds like maybe the industry is saving some money.

MR. KIMBELL: Well, I guess --

MS. OJIBWAY: And --

MR. KIMBELL: -- we're not.

MS. OJIBWAY: -- selling a lot more drugs that -- some of which are the right drugs for right people savings lives and improving quality of life, and others are just ... bogus.

MR. KIMBELL: I think the reasons for the increase in spending broadly on prescription drugs are ones you've heard a lot about, aging population, changing standards for cholesterol, for example, a lot of reasons why, but I don't mean to keep out -- but mindful of your time, if we go -- just step back to tab three, and I'm just going to point this out to you.

This is e-mail traffic between Dr. Elliot Fisher, who's over at Dartmouth, the Center for the Evaluative Clinical Sciences, major variation study think tank at Dartmouth and Chairman Maier and earlier with (inaudible) shortcomings. I'm not going to characterize this, it's only two pages. You can read it for yourself.

Suffice it to say that he expresses concerns about moving too fast with this kind of legislation, and I'll let you read those and draw your own conclusions.

We already talked about tab four. Tab five, just for your information, is the web site about the AMA opt-out program, and I just -- you can read that at your leisure, but I just point out, on the third page, that they

did a survey of physicians before launching this program, and 84 percent of physicians either were not concerned or reported their concerns would be alleviated if they had a chance to opt out of sharing prescribing data.

And I would suggest to you that an opt out in this context with a very sophisticated audience that knows how to use computers and with one click, can opt out, is far different from the discussion about opt-in versus opt-out.

For example, the credit reporting area, it's just a different audience, and I submit to you that physicians have this option, and they can get out. The other option they have, which sometimes you miss the most obvious things, if a pharmaceutical marketer is obnoxious or acts inappropriately, they don't have to see them.

I mean, doctors have the solution to this, if they're being annoyed, in their hands. There's nothing requiring any physician anywhere to see a pharmaceutical marketer. And if they had not behaved properly, then I would hope they won't. So I recommend that to you.

Tab six is very important. The AMA, as

part of the opt-out program, and as part of this overall prescriber identifier program, has launched a program called Therapeutic Insights. January '07, it was launched. It's a way to link clinical practice about chronic diseases to the prescriber identified data so that physicians can, through a disease by disease continuing medical education program, compare their behavior which they have access to through this program, to a regional and national standard and other physicians' behavior.

If you look -- and I'm not going to read this thing to you, but over on the left-hand side of that page, in the gray, down at the bottom of the first paragraph, to review your confidential personalized prescribing data to go to, and it gives a business place to go to his or her data.

The first is this is being piloted, you can see up at the top, it says, in cooperation with the Connecticut State Medical Society, it's being piloted in four states, the first disease, and I was stunned to learn this, that 12 percent of the U.S. population suffers from

migraine, but the first disease that they're piloting this on is migraine. They're going to do one a quarter.

The next disease is diabetes Type II. So this -- we'll use this data base which we believe would be eliminated in Vermont and any other states that use this -- use this data base for any construction clinical purposes, to let the physician see what the practice standards are according to the CME program, how their standards, their practice behavior, compares to it, and what their prescribing habits are like compared to their peers, strikes me as a very useful program that wouldn't exist without this data.

I'd now like to turn over the discussion briefly to Art Woolf who as I said is an economist from Northern Economic Consulting, Inc.

Just so we're real clear, I hired Arthur to give me his opinion, as an economist, about the question of whether this data would exist if we banned the commercial use of it. So he's paid by me, and you can discount his opinion by whatever amount that you think, based on that

fact.
But I can tell you that I didn't edit or change his work. I said, Art, I want your opinion. Do some research. Tell me what it is. And he's entitled to be paid for his time.
So, with that introduction, I'll turn it over to Art.
(End of CD-126, track 2.)

CD 126/TRACK 3
MR. WOOLF: I'll be brief and just reiterate some of the things that Steve said.
I want to make two basic points. The first one is more of a kind of a global point, and that is, more information is almost always better than less information. And I think that's true about physicians, just like everybody else, and doctors are going to make better physicians if they have more information.
Here, we're talking about information about pharmaceuticals, and there's roughly 80 to 100 new pharmaceuticals that are approved by the FDA each year.
I went to the FDA web site this morning, and I downloaded March reports on new drug approvals, and it's nine pages long. They're not all brand new. Some of them are, you know, new labelings, some of them are brand new drugs, some of them have good reason, it's chemistry, new strengths, another one said newer modification, formulation revision, new dosage regimen. There's all sorts of reasons.
But physicians are busy people. And I

don't think they're going to download this every month and read the nine pages of -- of changes in the FDA's approval of new drugs, so how do you get information?
And one way they get information is by pharmaceutical representatives who are trying to sell a product, coming to doctors and talking to them and giving them information.
So, I think that the basic issue is, is this information useful for physicians? And the answer is, yes.
If doctors are making better decisions about which drugs to prescribe, then doctors are going to make better decisions for their patients. And remember, this bill does not -- there's no issue of confidentiality of patients. This is all doctor prescribing information. There's no issue about -- about patient -- patient information is confidential.
So, drugs -- drug spending has been going up as the representative just mentioned. It's been going up faster than the cost of healthcare overall, but that doesn't mean it's contributing to the rise of healthcare costs overall. In fact, according to the economic

analysis, it is doing just the opposite. Drugs actually save money on healthcare costs by taking the place of much more expensive surgical and other interventions. And in addition to that, drugs have also led to an increase in life expectancy.
And the last tab in the document that Steve gave you, I know they copied an article from the Milton Institute of Review, which is written by Frank Lichtenberg who is -- is in the tab --
UNIDENTIFIED ATTENDEE 1: Yeah.
MR. WOOLF: -- who is the health economist at Columbia University. And just read the first paragraph, and that's where he summarizes the article. It's not a technical article. It's written for a lay audience.
But he does give statistics on how the increased use of drugs has saved money in healthcare, and how it's increased longevity, which I think are two admirable goals. So that's the first point.
The second point is that this data is very useful for public policy researchers, not just economists, but public health people,

physicians themselves, and as Steve pointed out, if you prohibit the use of this data for commercial purposes, it will not be collected.

The federal government can't afford to collect it. In fact, the federal government pays groups like IMS for this -- some of this data, the FDA, and the CDC use this data. It's very valuable to them but again, if it is -- if IMS could not sell this data to the pharmaceutical industry for marketing purposes, then it's -- they're not going to collect it and just give it to researchers and academic researchers. I sure cannot afford to pay for what it would cost to collect this data. So, in terms of just some -- I've been reading some economic articles or articles written by economists on healthcare and on pharmaceutical issues, including some articles that have used this IMS data.

And as I was reading, I was just trying to think of some -- or uses for the data maybe that I haven't found in the articles, but maybe they haven't been done, but just kind of information, kind of questions that public policy researchers could use this data, for

example, are doctors in rural areas more likely to prescribe new drugs than doctors in urban areas, or less likely? And does it matter in terms of outcomes? That's a very interesting question for a state like Vermont.

Another very good use for this data, I mentioned that the FDA uses this data. If there is some new study that comes out that finds that two drugs that have a very negative interaction with each other, it would be very useful, or it is very useful for the FDA to know what doctors are prescribing both of these drugs, and the FDA could very -- can very easily, with this data, get the information out to the doctors and say, if you're prescribing drug A and drug B to a patient, stop doing it right now. It would be much more difficult for the FDA to get that information out to the right physician.

It's -- I mean, they could issue a press release, but they usually don't do it. They know right now which doctors are prescribing drug A and drug B, because of this information. So they can -- they can get that information out very targeted to the appropriate doctors.

Other issues in terms of what researchers would be interested in, you know, prescribing patterns for younger doctors and older doctors differ how -- in terms of a specific type of problem that a patient may have? These are just some ideas of things that could be -- that can be answered, some questions that can be answered by use of this data and, again, the big point is that this bill prohibits the commercial use of this data.

And if you prohibit the commercial use of the data, the data will not exist. That's the bottom line.

UNIDENTIFIED ATTENDEE 1: Art, you said that drug -- doctors save money in healthcare costs by avoiding surgery and other more costly things. And I would agree with you for some drugs. However, I think -- I don't watch a lot of T.V., but my favorite commercial, I think it's Sally Fields who says about some osteoporosis drug she -- you know, I -- you're making time once a week, you have to plan time once a week to take this drug. This one you only have to plan time once a month. And there are lots of drugs like that.

I would definitely agree because I have to use inhalers. I'd rather use inhalers once or twice than try to remember, because I don't -- you know, every four hours so, there's some value some of the time, but once a month versus once -- that's not saving money. And I imagine that the other one costs more. But I don't know that for a fact.

MR. WOOLF: May I respond?

UNIDENTIFIED ATTENDEE 1: Let me just give you the rest of the question.

MR. WOOLF: Sure.

UNIDENTIFIED ATTENDEE 1: The rest of the question on that is, how do doctors know that that's what the new drug, that's all it does? And if you have -- have you seen this book, Overdosed America?

MR. WOOLF: I think I've seen a reference to it.

UNIDENTIFIED ATTENDEE 1: I just started reading this. It's not all new to me, but I started reading about the osteoporosis drugs and how it's (naudible) that they work. And when you look at the data, you can come out with some very different conclusions.

And I also know that the Tufts University in partnership with a couple of people, what's her name -- Strong Living, the woman who wrote Strong Living -- Mary-Anne Nelson. Thank you. That program and a similar one called Bundlers, produces the same results or better results than drugs such as Fosamax, and it costs the health care industry nothing.

And according to what I was told in the training program for that, it actually creates new bone rather than binding onto the external bone, and not doing for the -- I don't know all the terms but ... anyway, so there's -- there's a lot of cases like this, and this is what concerns me.

I'm perfectly happy with the drugs that save people's lives and that really do what they're supposed to. But this industry -- and we talked about this earlier -- puts stuff out that is not entirely truthful, based on a selective course of research.

UNIDENTIFIED ATTENDEE: I'd like to give you a chance to bond briefly, if you would like, but given the time of the afternoon and everything, I'd like to focus not so much on

the pharmaceutical industry here right now today, 'cause we could go on a long time, and more on this data mining and IMS, and we have the gentleman here on the telephone, if people have questions about IMS or about this, I'd like that that's --

UNIDENTIFIED ATTENDEE 1: Okay, just responding to some of the statements that he made.

MR. WOOLF: Oh, I know. Just one brief one on the study that I know he copied for you, doesn't deal with specific drugs. It looks at all drugs. It's looking at all prescribing that we have, and his conclusion is that on net, it saves money and saves lives. It doesn't mean that every drug, you know, has tremendously positive cost benefit or benefit cost ratio. Some may have negatives. But on balance, it is a very good thing. And ...

UNIDENTIFIED ATTENDEE 2: I agree with the data that you have is extremely valuable, and I would not want it to be lost. I think the issue of what this bill goes to is how it's being used. I personally don't even like the term, "marketing to doctors," or targeting

doctors, or targeting it to people. We're talking about an essential thing that's in people's lives that should be done through education. And I'd rather see this data being used and put together in educational material that could be given to doctors to help them know what the latest is out there, and so on, not as a marketing tool, and get them weighed to something based upon some marketing criteria and targetability.

Using this data for education, I think, would be extremely valuable, but the marketing side is the part I have a problem with.

MR. WOOLF: And that's what Therapeutic Insights is going to do, use it for education of physicians.

Our point is -- and you know none of us have to like this -- is you're not going to have one without the other, and that's the challenge that you folks are faced with. There's a lot of valuable uses of this data. The fact that you exempt those uses from the ban in this bill doesn't mean the data will be available to do them, and it's our contention that it won't be. So that's the balancing

you're doing here.

UNIDENTIFIED ATTENDEE 1: Valuable, maybe it will be.

I'd like to ask a question or two in that area because I'm concerned about it at a couple of levels.

Have either or both of you been participating with the multi-payer database project that's ongoing right now with BISHKA (ph)?

MR. WOOLF: Only -- only (inaudible) I know about it, but not directly.

UNIDENTIFIED ATTENDEE 1: Because, I mean, I guess I'm concerned about the sort of bold assertions that you're making that the data won't exist if -- I mean, I question whether IMS is going to stop doing this if Vermont does this, in any case, but even -- even if that were the case, we are in the process, and you made statements about this not being funded, and we're -- in fact, in last year's healthcare bill, we funded this to the tune of $400,000. This is an ongoing project in Vermont to produce this sort of database.

And, you know, I guess for the -- and if

you're -- that's not part of the research that you've done, then I would be concerned about that, and we'll certainly -- we're having BISHKA in tomorrow morning. We can ask about the progress of that.

UNIDENTIFIED ATTENDEE 2: Just a brief answer. First of all, if Vermont decided to pass this bill with this provision in it, and it was the only state that did it, there would be 49 other states on IMS (inaudible)

So instead of having 300 million or however many million doctors there are in the U.S., you have everyone but Vermont and New Hampshire, it wouldn't make a big deal in terms of the ability to use this data for all sorts of research purposes nationally, probably. Art?

MR. WOOLF: There would be a little asterisk to say this data excludes Vermont and New Hampshire. In terms of BISHKA's ability to use this data Vermont is so small that I think your sample size for a lot of the pharmaceuticals, and whether the things work and how they work and, you know, what kind of prescribing patterns are valid, you'd be

very -- it would be very hard to tease data out from such a small sample size as -- or even a small population size of Vermont. I just don't think there's that much of a certain drug being prescribed. You really need a national -- a very large -- it's not really a sample. It's every prescription that's been written in the U.S. And you can -- researchers can get lots of valid information out of that. If you just have one state, I don't think they're going to get a statistically valid result.

MR. CHEN: Yeah. I want to clarify two things. One is, if we pass this bill or if there was no IMS marketing data, would marketing still go on to, quote, unquote, busy physicians?

MR. WOOLF: To busy physicians, of course.

MR. CHEN: Yeah, right, and it would --

MR. WOOLF: In fact, there would be more of it.

MR. CHEN: -- be very, very -- (inaudible) that seemed to indicate that it wouldn't go, but it does go, and it will continue to do.

MR. WOOLF: I don't think we said that.

MR. CHEN: And second thing, if we pass

this bill, will Vermont physicians' data still be collected?

MR. WOOLF: I believe it will not, because what you're prohibiting in this bill is the sale of the data by retail pharmacies, to companies like the client that I represent. If you look at the language of the bill, the prohibition is against people in Vermont transferring their prescriber data by drug to anybody else for a commercial purpose.

So I think the answer is, we won't have the data for Vermont because you will have prohibited its -- the collection of it.

MR. CHEN: The collection of it, or is it the use? That's my question.

MR. WOOLF: Well, you're prohibiting transfer. If you take a -- take a look at the language.

MR. CHEN: We need to be clear about that. I think we heard something different earlier, so we need to come back to that.

MS. OJIBWAY: I have a question about this. As an alternative over time and space, so the time is how long has this been a practice? I think I asked that earlier today.

How long has this been a practice to collect data in this way and market it? So, obviously, it hasn't been going on forever, so somehow the world turned without this practice.

And speaking of the world, we don't really do the simpler (sic.) job on healthcare in the United States, so can you tell me about how this information is collected in other countries?

MR. WOOLF: That's for Randy. Frank, you still there?

MR. FRANKEL: Yes, I am.

MR. WOOLF: Did you hear the question?

MR. CHEN: How is this data collected in other countries where it might not be used for commercial purposes? I'm guessing in countries where they have ... more government involvement in the provision of health care that I'm getting that it's not -- it's collected but not for commercial purposes, and I could be wrong, but I'm just curious how this data is collected in other countries.

MR. FRANKEL: Well, what I can tell you is my -- my understanding of the situation. I've never worked in the international side of this

business. The focus of my career had been in the healthcare system in the U.S.A. There are single payer systems, for example, where the data would be checked by the government, and that that's simply all that is available, and there are other systems where it is collected in collaboration of government, and the private sector, not unlike here in the United States.

And so these data are different, based on the construct of the healthcare system in that respective country. There -- I don't know of many that are precisely like our own, so I really don't have a very good analogy.

MR. WOOLF: And could I ask her first question again. How long -- how long have you been doing this, and -- because there's some sense, at least through the doctor that we have on our committee, that this is something that doctors have just recently found out about, as if it were a recent phenomenon.

Is that -- how does that relate to the business that you do, and how long have you been doing it?

MR. FRANKEL: Well, it -- it is not a recent phenomenon. IMS is a company that

started about 50 years ago. And for those of you who have been around as long as I have -- I'm in my fifties -- and in the industry, in the pharmaceutical industry, per se, although I have been at a pharmaceutical company, I spent most of my career on consumer healthcare and managed care, in the information side of the business.

The only data available to the healthcare system in an integrated and comprehensive way during the first 20 to 30 years of that period was prescription data, and it wasn't until the 1980s or early 90s, actually, when the Clinton administration attempted to develop a single payer system, that we, as a legacy, derived an electronic means of conveying prescription data.

And so it was, in the -- probably the early '90s to mid '90s, that prescription data became available, and these kinds of data became possible.

So it's been more than ten years. I can't tell you the exact number, but it -- that has been more than ten years.

MR. WOOLF: And in ten years, you've been

doing the matching that we've been hearing about? In other words, gathering data from pharmaceutical companies and matching it with the AMA, doctors, numbers and names to come up with the specific result that you're now selling to your clients; is that -- has that been going on for that long?

MR. FRANKEL: The ability and products associated at the provider level have been going on about -- ten plus years.

MS. OJIBWAY: Can I ask -- so, specifically, for example, the payments to the American Medical Association as your primary vendor for your data, that has been an agreement for about ten years?

MR. FRANKEL: You know, I'll answer that question as (inaudible) as I can. But I want to clarify something.

The AMA does not sell data. Every physician, when they enter medical school, obtains a medical education number. And the AMA has that. When I am developing or collecting a patient (sic.) to build a comprehensive database, you get it from hundreds, if not thousands of sources. And

that's the case in our -- in our business. And we try to link them all to a common reference number.

Now, we could have picked a number of different types of reference numbers, but the AMA's number was not only a convenient number, but quite frankly, it was a way for us to align ourselves with the medical community, and rather than giving it away to different commercial entities, it seemed an appropriate thing to do.

It's been a long-standing relationship. It gives the AMA a great deal of control and influence over how the data are used. And frankly allows us that arms length in terms of policing some of these things. Because, otherwise, we'd be the fox guarding the chicken -- chicken.

So the AMA relationship has evolved in over -- well over a decade, and yes, we do pay them royalties for the use of the data, and they use it for their own lobbying for positions and CME and things like that, and it's simply been a good symbiotic relationship.

MR. WOOLF: Yeah.

MS. OJIBWAY: Can you please tell me what improvements in health outcomes in this country have been objectively documented to as attributable to data mining?

MR. FRANKEL: Well, you're asking a question that's quite broad because there are many types of data.

There's the outcomes measurement, which is often done with medical claims data. That data doesn't have a patient or a provider identity.

Then there's the prescription data. And in an aggregate form you can look at national trends, and that doesn't need to have provider identity.

Then if you start looking at the (inaudible) utilization and treatment practices, and as you try to develop the capacity to understand how drugs are used and whether they're appropriate there, they start building on individual blocks to build the entire story, and those blocks really are around a prescriber, the provider.

And I can give you a case in point. I -- I was responsible for a disease management capability for quite some time, and we would

look at therapeutic guidelines -- and I'll go back to the '90s because it's convenient, but there's a category of drug called Ace inhibitors. And there were many many studies that showed that these Ace inhibitors for congestive heart failure substantially reduced the rate of deaths and other impairments, and reduced costs quite dramatically if the patient was on it. But it required a certain dosage, and the patient, of course, had to take it every day.

And so provider level data during those days were used to determine that probably for the first ten years that class of drugs was available, less than half the patients with that diagnosis were on those drugs, and fewer than, almost about half of the ones on it were taking it at a high enough dosage, and many of them were dropping off.

And so there was a major health problem in that the message wasn't getting through, and it was only by looking at the treatment variability, meaning, how many doctors are doing it right, versus how many are doing it differently -- I won't say wrong, because I'm

not a physician and don't know -- but they weren't prescribing consistent with the best practices at the time. And it was such a large number, that it required a nationwide educational program. And if we work with averages alone or aggregates alone, we wouldn't have known how big the problem was or how to reach the respective physicians in order to improve the outcome.

That's one of many examples. I can give you others in anti-hypertension and mental health drugs.

MS. OJIBWAY: I guess what I'm trying to get out is the -- is the -- what this bill specifically deals with, which is detailing and where detailing has actually improved health outcomes and meaning that the folks who go around and talk to doctors and convince them to use different drugs or new drugs or whatever it might be, and -- and don't -- don't always give the doctors all the information.

I'd just like -- is there any evidence that that -- that that has improved healthcare outcomes in any measurable way?

MR. FRANKEL: Well, again I will try and

answer that as -- as comprehensively as I can.

There have been studies that showed that treatment variability is raised when there is marketing. Now, treatment variability means that the range around -- the range from the high to the lows, and where there's no marketing the variability seems to be greater. That is indicative of more -- or less consistency in the way care is given. The narrower the treatment variability, the more consistent it is.

So, there is evidence that marketing has that impact but, of course, to be fair, if the marketing is around an inappropriate use, then you'd be improving variability around the wrong outcome. So marketing does have an impact in terms of reducing treatment variability, and the goal of the marketing is mediated by the FDA and the FDA Guidelines and, quite frankly, having come from managed care, I would say the major influence -- and it speaks to another issue about why our drug costs are going up, managed care has a major influence on the utilization of branded drug.

Just to add another point, studies by

Kaiser, studies by a variety of other sources -- and we can get you copies of this, to suggest that between 60 and 70 percent of drug costs are associated with increased swallowing of medication, not one brand versus another, or a brand versus generic, but simply that as people get older, they're on more drugs.

Therapeutic guidelines have evolved in the last dozen years for hypertension, for cholesterol, for diabetes, for mental health, meaning depression, and they've added probably 50 to 60 million people to those who should be treated with drugs.

Then there are acute solutions like HIV, AIDS, that have become chronic conditions, or cancer medications where patients didn't use to live very long, now they become chronic use.

So, you've got that accounting for 60 to 70 percent of the pie. It's the other 30 percent that we're talking about here, and what is the impact on drug costs of the data alone. And I think it's very important to keep in mind, and at least from our point of view, the data we believe provides efficiencies to

the overall system. And that is why it's purchased.

But every company gets to use the same data. So if you think about it, they all deliver a message about the same classes of drugs, given there are four, five, six, seven different messages about the same class, that they have a very rounded view of the options.

And on top of that, managed care has formularies and patients have co-pays and so the actual impact of these data on increasing overall costs is probably negligible and at the same time serves the health care community in many different ways.

So, I know I'm giving you a lot in response to a single question. I'll try and stop now so you can ask another.

MS. OJIBWAY: Well, I think it's getting late and probably my Chair would prefer me not to ask more at this point. So I'll stop.

MR. WOOLF: Now I think Randy wished he could have been here and would be willing to travel, if you want to pursue this. I also know you've got a schedule so --

MR. FRANKEL: Yes, I thank you all very

much. I'm sorry for the inconvenience and short notice. I couldn't rearrange schedules, but I would be very glad to meet with you in person and answer questions. And there's much more to say, obviously, and you know, we just think that the general movement toward transparency is something that would -- that is vital and could be undermined by these kinds of data restrictions.

And we are hoping that you might consider other alternatives, managed appropriate utilization, because we don't think that the data themselves that we are providing them, are causing the impact that you may think they are.

So we thank you very much for, you know, listening to us, and please feel free to call and, I will be there to answer questions.

MS. OJIBWAY: Thank you. And where are you? We're speaking with you today; where are you calling from?

MR. FRANKEL: I'm calling from Connecticut.

MS. OJIBWAY: Oh.

MR. WOOLF: Mr. Chairman, if I could just close with one other thing, the ban in this

bill on page 32.

Starting at line eight, it's a prohibition on Vermont people. Health insurers, self insured employer electronic transmission, a pharmacy or other similar entity shall not transfer or sell regulated records, and that's prescription records, to IMS or anybody else.

So that's what the prohibition is, and that's why Representative Chen said, I thought that this would mean that Vermont data just wouldn't be available for the therapeutic insights program or for other --

MR. FRANKEL: May I just insert one last thing, because I think you'll want to know about it. It's about risk management programs.

These are associated with drugs that have what they call very narrow therapeutic range, meaning on the high side, they can be very toxic, and on the low side, they can be ineffective. And the difference between the two is very narrow.

And some of these drugs have been removed from the marketplace because they've caused significant ill effects, and in some cases deaths. But the beneficial effects were so

great that patient groups basically lobbied the FDA to get them back on the market. And the FDA, in order to manage the risk, has built a system called risk management, and risk management companies where they require pharmaceutical companies to identify the physicians to whom these drugs will be distributed, and the kinds of education they must receive, otherwise the doctor can't prescribe them.

And the pharmaceutical industry leans very heavily on the use of these data to reach these small patient populations who are treated by a small number of physicians. So the orphan drugs, for example, that fall into that category, small companies that may develop drugs or have drugs for Alzheimer's, lean heavily on being able to identify physicians who treat these populations.

And it's a consideration that I think you all should be aware of, so whatever you do, the data are available in some way to assist in this effort, because it's very beneficial to patients.

(Pause.)

MR. WOOLF: Thank you.

UNIDENTIFIED ATTENDEE 2: I got a question after we're done with --

MR. WOOLF: We're done with -- I'm going to leave a full copy of the study that's under tab two, under tab -- you have the executive summary. It's a 50-page study. I didn't think it was good to make 11 of them, but I'm going to leave this with your staff person, and this is the study under tab two right on point. And if you want to, as I know Dr. Chen will want to, read the whole story here, it is -- and if anybody wants -- if anybody wants one, just let me know. But I didn't think it was a good idea --

UNIDENTIFIED ATTENDEE 1: Did the book come out? Did we get a video?

MR. WOOLF: If there are other questions, we'll be glad to come back.

Thank you for working late with us.

Great. Thank you very much.

(End of CD-126, Track 3.)

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CERTIFICATE

STATE OF FLORIDA)
COUNTY OF ORANGE)

I, Richard Castillo, Notary Public, Certified Shorthand Reporter and Registered Professional Reporter, do hereby certify that I was authorized to and did listen to CD126, Tracks One, Two, and Three, S.115 -- Prescription Drugs, regulation, April 10, 2007 proceedings and stenographically transcribed from said CD the foregoing proceedings and that the transcript is a true and accurate record to the best of my ability.

Dated this ___ day of August, 2007.

_____

Richard Castillo, Registered Diplmate Reporter

STATE OF VERMONT

HOUSE COMMITTEE ON HEALTH CARE

STANDARD MEETING

PART ONE

Re: Senate Bill 115

Date: Wednesday, April 11, 2007

Committee Members:

Rep. Steven Maier, Chair

Rep. Harry Chen, Vice-Chair

Rep. Francis McFaun

Rep. Sarah Copeland-Hanzas

Rep. William Keogh

Rep. Lucy Leriche, Clerk

Rep. Virginia Milkey

Rep. Pat O'Donnell

Rep. Hilde Ojibway

Rep. Scott Wheeler

Rep. John Zenie

CD Nos.: 07-127/T3 & T4

07-128/T1 & T2

PROCEEDINGS

CD 127/TRACK 3

COMMISSIONER THABAULT: Paulette Thabault from Banking, Insurance, Securities and Healthcare Administration. What I was gonna do this morning--

ATTENDEE 1: Paulette, one of our speakers is not working, so if you don't mind, speak a little louder.

COMMISSIONER THABAULT: Okay.

CHAIRMAN MAIER: That's as far as it goes?

ATTENDEE 1: Yeah, thank you.

COMMISSIONER THABAULT: What I was gonna do this morning is just address the pieces of this bill that relate to BISHCA and where we have some concerns, point those out to you, and where we feel that we worked through issues when it was in the Senate, I can point those out to you.

So, the first section that I would--will be speaking to is Section 7, and it's under 9472 and--

ATTENDEE 2: Excuse me. What page?

COMMISSIONER THABAULT: I'm afraid I might have a different--

ATTENDEE 2: Okay.

COMMISSIONER THABAULT: I printed it off of

your website, the legislative website. So for me it's page--

CHAIRMAN MAIER: Page 14, where we start, Section 7.

ATTENDEE 3: Sorry I'm late.

COMMISSIONER THABAULT: So this is the section where the language, unless the contract provides otherwise, we feel is very important. That was language that was added in the House. And we think it's very helpful because it allows the parties to--it provides a lot of--the whole section provides guidance about what should be in a contract and what should be addressed in a contract, but the language unless the contract provides otherwise, allows the party to negotiate those contract provisions; and as I'm sure you're aware, when there's a contract, terms always come with a price; and if the contract is--to mandate the provisions of the contract, it's likely that those provisions could come at a price, and that those would end up being passed through in a form of higher healthcare costs in the form of premiums. So, we were quite satisfied that the language allowed--allows for the negotiation.

There was concern in the House that perhaps

there would be some unevenness in the negotiating situation between a PBM and the other party, but we really feel strongly that any party that's negotiating with a PBM is equally situated in terms of their bargaining power. There isn't--these are not individual, small businesses that are trying to negotiate with a big PBM by themselves. We're talking about either large companies or self-insured or associations who are self-insured, or health insurance companies who are well-represented, have counsel, and have an equal seat at the bargaining table. So, we think this is a good provision, and we're satisfied with the language.

ATTENDEE 4: I just want to ask a question.

CHAIRMAN MAIER: Yeah.

ATTENDEE 4: You mentioned a couple of times, you referred to language in the House. Do you mean the Senate?

COMMISSIONER THABAULT: I'm sorry. The Senate--I meant the Senate. I apologize.

ATTENDEE 4: Okay. That's what I thought you meant. I just wanted to make sure. I thought maybe this bill went some other place before--

COMMISSIONER THABAULT: I'm so used to it

going the other way. I think I did say that, but I apologize.

CHAIRMAN MAIER: Harry, yeah.

REPRESENTATIVE CHEN: Two questions: So, I hear you to say that there is no--there are no small, self-insured businesses that negotiate directly with PBMs in Vermont?

COMMISSIONER THABAULT: I'm not aware of any, but even if they-- To be self-insured, you have to be of some size. You can't be, you know, a five-person company. You have to have--

REPRESENTATIVE CHEN: Right, but you don't have to be that big, though.

COMMISSIONER THABAULT: No, but you have to have some reasonable size to you. And what I'm saying is that if you were a company where you were in a situation where you could self-insure, you certainly have some counsel and--because you wouldn't be able to set up a self-insurance company without it; and so you have to--so we would expect that that--that that in and of itself would mean that there was adequate representation at the bargaining table around these provisions to be able to negotiate reasonably in a contract.

REPRESENTATIVE CHEN: Okay. Then the second

question is: Do you have a comment on where they ended up in terms of the standard versus where they started? There are two standards apparently. Not being a lawyer, maybe Robin can comment on that, but there are two standards that were discussed in the Senate. One started out and another ended up.

MS. LUNGE: It started out as fiduciary--

COMMISSIONER THABAULT: The fiduciary standard versus the reasonable care and diligence? I think we were--we were supportive of the reasonable care and diligence standard.

REPRESENTATIVE CHEN: Where it ended up?

COMMISSIONER THABAULT: Where it ended up.

The next section is under enforcement, and it's 9473 in that same section, Sec 7. We kind of worked through the language here with the Attorney General's office and are comfortable with the language as it is.

What this section provides is that the commissioner of BISHCA has the exclusive authority when it's the Pharmacy Benefit Manager that is in a contractual relationship with the health insurance company that we regulate, and we think that's important that those health insurance companies have one regulator, but where it's the self-insured

companies, there's dual regulation with the Attorney General's office; and we worked through the language of this provision and we're satisfied with it.

CHAIRMAN MAIER: Thank you.

COMMISSIONER THABAULT: The next is Section 8, and the pharmacy management registration and audit section. Essentially, I would say that we don't object to this provision, but we don't really think it's necessary. We are registering the PBMs through the multi-payer claims project, and so this could be an unnecessary provision. And I guess that's all I would say is that we're already doing what this provision is saying we should do, so you want to-- Sometimes there's an argument not to put in something that's not necessary.

ATTENDEE 5: I have a question about that.

CHAIRMAN MAIER: Okay. Yeah, go ahead.

COMMISSIONER THABAULT: Yes?

ATTENDEE 5: Let's just say we had a different commissioner who didn't want to register PBMs, would that be--would you not register them? Or do you think there's something else in the statute or rules that requires them to be registered?

ATTENDEE 6: It's required in the 9410 to register them.

COMMISSIONER THABAULT: It's required under the multi-payer project. I just needed to double-check with Dian who's really the director of the project.

ATTENDEE 5: That's obviously a different--

COMMISSIONER THABAULT: Maybe this is a good time to interject. Dian Kahn is with me today, and I know that you had some questions. I got the email last night late that you wanted to talk about the multi-payer project, so I did bring Dian, and I hope when it's appropriate, she can testify. I think she'll be able to answer in the detail that you might be interested in.

Let's see. The next piece that I was going to refer to is in Section 13 and I would--wanted to say under D, Section 5.

ATTENDEE 7: What page number? I'm sorry. Which section again?

(Inaudible)

COMMISSIONER THABAULT: Section 7, it's confidential--I'm sorry--Section 13 and it's 4631, and it's Paragraph D, Number 5. I'm sorry I don't have the same pages as you guys. Paragraph 28?

(Inaudible)

COMMISSIONER THABAULT: "D," like in dog and then it's number five. Essentially this is--this is accepting regulatory activity from the prior provisions, which concern the confidentiality, and so we wanted to just support that language. And along that same line under Section 14, which follows, we find this "E" paragraph but problematic.

CHAIRMAN MAIER: You said D-5?

COMMISSIONER THABAULT: D-5.

CHAIRMAN MAIER: Is a concern

COMMISSIONER THABAULT: No, D-5 is fine. We support that.

In the next section, which is Section 14-E, this is the provision that we strongly object to and find it to be quite problematic. This provision will undermine the multi-payer claims project. It will prevent the payers from providing the information in the manner that we need it for that project. So, if the information is filed in a way that's not disclosing the identity of the providers and the patients that will make our project fall apart, and the analysis won't be possible that we need to do. It will make our data

not usable. There are many problems that would result from that. So that was--we did explain that when the bill was in the Senate. It was removed. And I understand this was added back when the bill was on the floor, and so we would strongly urge you to take that back out.

ATTENDEE 8: Which one was that? I'm sorry. Which section?

COMMISSIONER THABAULT: Section 14, Paragraph E.

CHAIRMAN MAIER: It sounds to me like maybe in the rush of this last-minute amendment, they didn't perhaps keep track of this. Does that sound about right?

MS. LUNGE: Yes. The amendment on the floor, no one talked to me about it. It just sort of happened. So--

ATTENDEE 9: Why would you talk to legislative counsel about it?

MS. LUNGE: So I didn't have input on this amendment, so I'm not sure whether it was thought through or not thought through. I think probably they were just putting it back to the original version and such.

CHAIRMAN MAIER: But certainly the policy

committee over there heard your objection and agreed with your concern and took it out?

MS. LUNGE: They didn't entirely discuss this issue because they decided to take the whole section out, and so this necessarily went with 13, so I don't think they actually made a decision on Paulette's issue because they didn't really get to the issue she's raising.

CHAIRMAN MAIER: All right. Well, can we--

COMMISSIONER THABAULT: Although I did testify to that provision.

MS. LUNGE: Yes, you did, but in their discussion, they didn't get that far down in detail.

CHAIRMAN MAIER: I guess before I just lose it completely from any future draft or anything, I want to make sure that I have some conversation with you about it.

MS. LUNGE: Sure.

CHAIRMAN MAIER: So why did someone think it was a good idea to put it in to begin with? And I think I understand--I guess maybe I don't understand exactly what--how Title 12 relates to what we were trying to do in Title 18; is that--So I just need--we need to have that--

MS. LUNGE: And I can speak to that now if you want or we can come back to it.

CHAIRMAN MAIER: Is it a one-minute explanation or is it a longer--more involved issue?

MS. LUNGE: I think it's a one-minute explanation. Basically what this section was--the intent behind this section, and I don't think this section actually does what--I think I drafted it badly. I think we could do it better. But the intent was that BISHCA get the information, but then the information stay confidential with BISHCA under the same terms as the prescription data confidentiality section, generally.

So, this I think Paulette's right is this would prevent them from getting the information which I don't think was the intent. It was that the information stay with them.

CHAIRMAN MAIER: Well, this is-- Thank you. It's part of a bigger conversation that we may need to reschedule some more time on than we have this morning about how the multi-payer database is really gonna work and whether it really--and I don't know if we're about ready to get there, and we can begin that conversation now, but--

COMMISSIONER THABAULT: I just want to say

that we would be supportive of language that would allow us to keep that information out of the public record, because we don't want to have to provide it to anyone that might want it, and that would--that was never our intention, and our rulemaking would hopefully get at that; but if there were a provision in this bill that reinforced that that would be very helpful and we would be supportive of that. We just want to make sure we're able to get the data in the way that we need it.

CHAIRMAN MAIER: I think we need to be careful about how we do this whole area because, you know, the assertion that's made by some as it relates to this section is that this will--is if we do something like Section 13, some version of it or that--what we heard yesterday from some was a concern that the companies that are providing this--this data mining service, you know, if there is no commercial application for what they're doing, then the data would cease to be available to researchers and health policy people and whatever else. And my question was, well, I thought that's what we were doing with the multi-payer database. So I need to under--so that's my general question. Is that what we're doing with the multi-payer

database?
And then drill down a little bit to say, okay, so if once we're successful in getting that going, will the data then be available to researchers, you know, to the kinds of people that are saying that they find some value in what these companies are doing for other than commercial purposes?
Then the language is trying to say, well, you can still do that, but their claim is, well, that's fine, but if there's--if you don't let us make some money on it somewhere, then it's not--we're gonna stop collecting--we're going to stop managing the data and providing it that way. I think we've got that base covered, but that's just sort of my question to you.
COMMISSIONER THABAULT: I mean, I think that if you feel that--I think that as long as BISHCA through the multi-payer project is receiving the data, and we have the capacity to do the analysis, I guess the question for you is whether the analysis that we provide is the only analysis that you want done. And maybe that's a policy question and that may be what the party you were hearing from yesterday was referring to.

For my purposes, the importance is to be able to obtain that data from the payers in the form that we are able to use the data; and that may be similar to what others were saying yesterday--I wasn't here, but that's an important piece. If you're gonna be able to use the data and do the proper analysis and have it be useful, you need to have the identification of the providers. Dan can speak to you about exactly how that works and why it's so important, but that's the point that I'm trying to make. I don't know if that answered your question or addressed your question but--
CHAIRMAN MAIER: So what is--will the data in any--be available in any form to other--to somebody at Dartmouth or UVM to do research on? How would that--how would it be available to them?
COMMISSIONER THABAULT: I don't think that we--
CHAIRMAN MAIER: If they wanted to do their own research project, for example?
COMMISSIONER THABAULT: Can I have Dian or--
CHAIRMAN MAIER: Please, I keep looking at her.
MS. KAHN: Since we're just embarking on the rulemaking process, this is very instructive now to

get the basis or foundation for how we're going to proceed on. The data release is really a huge piece. The submission piece is more technical, but when you get into the whole policy of releasing data, that's really where the action is gonna be. We're working closely with the other two northern New England states, New Hampshire and Maine. Maine is four years out of the gate with their project, and I think they have a very good, robust model. They've been the only state that's been able to get cooperation from CMS to eventually pool Medicare and Medicaid data, which means you're getting close to a population base database on healthcare utilization and cost, except for the uninsured, and they're getting some dummy claims from providers for uninsured populations. New Hampshire's going down the same road.
And basically what you build into your rule are multiple levels of data release that have to do with permission advice from--you know, almost like an institution review board. When you get to a certain level of detail, there is a process for requesting that and either having it approved or denied. So--
CHAIRMAN MAIER: And a researcher would have

to--if they got more data, they'd have to sign confidentiality agreements.
MS. KAHN: And there's a $500,000 penalty in the state of Maine for any misuse or pecuniary use of the data that's released under the conditions. They had a $250,000 fine and their legislature increased it to $500,000 last year for that level of data release.
They now have three basic levels. They have a level of use file which is completely--it's very--in other words, you'd never get a date of birth on a person, but you might know that that record is for somebody between the ages of 40 and 50 years old. Maybe the next level of data release, you'd be able to get single year age. So it's a little bit more granularity in it. The third level might be that you could actually get some very specific geographic information on members and do small area analysis, and stuff like Dr. Lindberg and Elliot Fisher, they do, but you go through three different levels of requesting that data through a very stringent process.
CHAIRMAN MAIER: Harry?
REPRESENTATIVE CHEN: At some point you'll have both patient identified data theoretically

or--
MS. KAHN: I'll tell you how they're--
REPRESENTATIVE CHEN: Will you have also provider?
MS. KAHN: I'll tell you how it's working in the other states which seems to be a good model.
For Maine and New Hampshire, they provide encryption software to the payers and they don't--they don't get direct identifiers. The state doesn't keep patient names and addresses on--they--there's an encryption system so that you're getting a unique identifier for an individual of cross-payers because it's a standard software.
REPRESENTATIVE CHEN: Right. That's what I mean.
MS. KAHN: But for providers there's a whole different challenge. We had a very good explanation the other day when they brought us to speakers at the pavilion auditorium about how you--I'll give you an example. There's probably--I think there's 3,000 licensed physicians in the state of Maine, but they ended up with 440,000 data points for providers in their database because sometimes they're on a claim as a group practice;

sometimes they're using a middle initial; sometimes they're using a different tax ID number. So they have to take all of the identifying information for the providers and they have to unduplicate it so that you can indeed say--you can get it down to the point where you know "Physician A" is "Physician A" no matter where they're practicing or what kind of service they're providing. So the state does have to have access to identifying information for the providers, but that doesn't mean that your rule is going to ever guarantee you're ever going to release that level of detail.
REPRESENTATIVE CHEN: I guess my next question is where are we in the development of this in terms of when would we have this information to you?
MS. KAHN: Right now we're in the initial drafting of the rule. We're kicking off the rulemaking process. We would like to have a rule by the end of this year, by December.
We're also drafting an RFP for the operational part of this simultaneously because that's--we feel like you can do that simultaneously while you generate your rule, because that's more of a technical data submission issue; that has more

to do with the payers and the PBMs and the standards under which they'll submit the claims.
So we're hoping to have a test. To be able to start collecting a test set of this data next January for the prior. And what we've heard from the other two states that are using it now is that when you get your cycle, if you build this right, you can have claims data set within 90 days of when that claim was adjudicated, which is pretty fast--that's pretty timely data if you build it right. It will take us a few years to get there.
REPRESENTATIVE CHEN: So are you suggesting that the three states are going to end up somehow doing this together in some way so somebody can get data across the three states?
MS. KAHN: We're actually working together, and there's an initiative that I've been participating in New Hampshire that Elliot Fisher and his group has been participating in, called the Regional All-Payer Information Initiative. Three states are talking to each other about standards and the fact that we share common geography and sometimes common health systems, so we should actually be collaborating on how we do this to make it fairly harmonized. So it's been very

productive.
We actually--BISHCA, we do have a contract with the Maine Health Data Organization, which is another state agency in Maine, to help us draft the rule, and they also have consulted with New Hampshire. So we're trying to gain efficiencies and try to do it right, and base--we're the third one on to learn from their experience so we don't make the same mistakes they made being the trailblazers. So it's really working to our advantage.
ATTENDEE 10: How do the court cases in these other states effect what you're talking about now?
MS. KAHN: They're very helpful for us because they already had to go face the challenges on ARISA and some of the--you know, what a participant entity will tell you they can or cannot give you. We have some case precedent there that we can use.
ATTENDEE 10: And some of those court cases have not been--they're not finished yet, right?
MS. KAHN: There's a few that are not, but some of the big ones, the ARISA ones have been fairly well-addressed through the Attorney General's office in Maine. Some of them are still

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hanging out there, but they've been pretty active and successful in getting--getting the data they need to really start looking at the population.

CHAIRMAN MAIER: Robin?

MS. LUNGE: So you're talking about court cases where they sued the multi-payer database?

MS. KAHN: Or they've challenged the submission requirement or the requirement to participate and comply.

CHAIRMAN MAIER: The cases she's referring to are different than the ones you're referring to.

MS. KAHN: They have enforcement and penalties in both states. Maine has never--they feel like the threat of the penalty has encouraged the participation of the payers of the mandated entities. They did get to a point where they would get to a level of $160,000 fine and within 30 days of the threat, they received the data. New Hampshire has levied some fines. So they've both emphasized that in order to get everyone to play fairly, you do have to have enforcement and compliance capability.

CHAIRMAN MAIER: Robin, can you just--so those are different cases than the ones we've heard about already?

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MS. LUNGE: Yes.

REPRESENTATIVE CHEN: Can you give us a brief reminder about that?

MS. LUNGE: The case that I talked about yesterday was a recent New Hampshire lawsuit on their prescription drug confidentiality law, so the one that's similar to Section 13 in this bill, which is different than the statute we already have on our (inaudible) for the multi-payer database. So it's a different--different statutes.

CHAIRMAN MAIER: And so Dian is saying there's been some cases in the other states related--different cases related to the submission of data?

MS. LUNGE: Multi-payer.

MS. KAHN: Mostly to do with the self-insured, self-funded, ARISA preemption, those issues.

CHAIRMAN MAIER: Okay.

MS. KAHN: Some of them were--the other two states where they differ from us a little bit, too, especially Maine, is they don't just register the PBMs and TPMs; they license them. So they have a little bit more jurisdiction there, plus they have a little bit more definition on--because a lot of

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the PBMs also act as TPAs and more delegation of care and management of care, pharmaceutical services. So it's a little bit different regulatory environment than we're dealing with.

ATTENDEE 11: Would that be helpful for us to do?

CHAIRMAN MAIER: Well, I think there is a provision here--

ATTENDEE 11: Licensing instead of registering?

CHAIRMAN MAIER: Can you hold on to that and come back to it when we talk more about that section?

ATTENDEE 11: Uh-huh, maybe.

CHAIRMAN MAIER: Did you have a question?

ATTENDEE 12: Yeah. I don't want to go off too far astray on the multi-payer database, but at that presentation at the pavilion auditorium, it sounded like the fines were just--both the representatives from New Hampshire and Maine were feeling like they were a really important piece in getting participation, and I'm wondering--I'm pretty sure we didn't have any fines in our statute with regards to the multi-payer database, and I am assuming you can't impose fines without (inaudible)

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the rulemaking process; isn't that correct or can you?

MS. LUNGE: I would think no. (Inaudible).

MS. KAHN: (Inaudible).

ATTENDEE 12: I'll just throw it out that that might be something we should look at.

MS. KAHN: They said that fine also on improper use is very important.

ATTENDEE 12: Yeah, they were really emphasizing that and it seemed like an important piece that we should be looking into.

CHAIRMAN MAIER: Okay. Can you please hold on to that? Maybe I'll write it up there.

Can you remind some of us that were here last year, and for the benefit of the several that weren't, so why are--what's--what's important from your perspective, from the State's perspective? Why are we doing the multi-payer? Give us a little altitude. Move back a couple steps and say why is this a good thing?

MS. LUNGE: Well, number one, we're always talking about cost and utilization and patterns of care, and we have very sketchy information about how much health care costs because the data that we currently have just has charges. Like, we have a

hospital discharge database, and what it does is it just tells us what was charged and not what was paid, and it's only for hospital based care, so we don't have any data on what occurs in clinics and physician offices, unless the clinics are owned by the hospitals, and some of the discharge aspects come through the discharge database.

We do get some very aggregate information through our expenditure analysis where each major payer will tell us in those broad categories of physicians, dental care, hospitals, how much--how much--how many dollars are spent, but what the claims database tells you is what at the end of the day--it's an adjudicated claim--what was paid for care on a very specific line item basis on a claims basis for services, what was paid for care in--across all settings. So, you're basically getting a lot of intelligence on the use of health care, treatment of populations with chronic disease and the cost of health care for the insured population, which is--you know, it's 90 percent of the state, if you start working towards getting Medicare claims data and Medicaid claims data, which will be a little bit further down the road because you have to deal with CMS on access to that

data and how you use it, but we've essentially not had--we've not had all this detail for the commercial population. We've just had charges for hospital care.

Also, the prescription drug detail, you know, with the PBMs is--you know, you don't get prescription drug detail anywhere else because, of course, that's not hospital; that's out there in the community. And having the TPAs included in the mandate means that you can get information on self-insured plans and use of health care by members of self-funded employer plans which don't come through any commercial data sources, you know, the insurers that don't provide those TPA services. So it gives you a lot more intelligence on how the system is working.

At our presentation the other day from Maine and New Hampshire, there was some very interesting examples of how they're using the data to examine. For the Governor's office in Maine, they're examining the cost shift, getting a little bit more granularity on looking at that and how that works and what it is.

You're also looking at just comparative--New Hampshire just put up the website on pricing, where

a consumer can go in and they can tell you in what radius, you know, geographically they live, who their payer is and who their providers are, and they can get a median price of what's paid for some common procedures. So that the person from the New Hampshire Department of Insurance said that with this growing higher deductibles, higher cost sharing, consumers are--it's more important--if there's a $3,000 difference in a procedure, it can have an impact on your purse, so it's very good information to have access to.

So they're focusing on putting out this transparent price information, using the claims database, because it is what was paid. It's not just the charges, which are more generalized.

CHAIRMAN MAIER: Is it considered to be--how onerous is this on the people submitting the data, either the TPAs or the PBMs?

MS. LUNGE: Well, with the other two states already a couple years into this, we have a lot of payers that are already programming and submitting this data. The only factor for us, which is still an unknown, is what kind of shape the Blue Cross Blue Shield data warehouse will be in to comply with the data submissions, because they're our

largest payer on the insured side, but Cigna is already participating in Maine and New Hampshire. MBP has been very active in the pricing, web-based portal. Joe Hester knows about that particular initiative. So it's really Blue Cross would be the one that we'll have to figure out.

CHAIRMAN MAIER: And, like, are there other than TPAs?

MS. LUNGE: Yeah. Express Scripts, a lot of the same PBMs operate in Maine. So what's very helpful with this is that the person who's running the Maine Health Data Organization and his legal staff that there have been issues that have come up with some of these shared payers and PBMs, they already know what the issues are, or what the technical issues have been that they've fixed or addressed. So, this is nothing new for most of the participants, except, of course, Blue Cross will be a different entity.

ATTENDEE 13: It's not clear to me--and I don't know who can answer this question--is hearing this, then, what's the gap between information assumed to be available through this, if it's not quite there, and what's available right now using the system that we talked about so much yesterday,

the so-called data mining? I mean, where's the gap? Or is there an almost alignment right now?

The only thing it sounds like from here is if a physician saw somebody who is uninsured, and I'm sure they do, and so they're never submitting a claim, so that five or ten percent, or whatever it would be, so they wouldn't be included in the multi-payer database, right?

MS. LUNGE: Right.

ATTENDEE 13: Because it's out-of-pocket. But the commercial, so-called data mining, they would be because they're prescribing no matter who's paying for it, right? So you'd lose that. But other than that, what would you lose? Where would the gap be?

CHAIRMAN MAIER: Do you have an answer for that or--

MS. LUNGE: I don't exactly know what you mean by the data mining. Are you talking about the prescription drug data mining or--

ATTENDEE 13: Yes.

CHAIRMAN MAIER: Yes.

MS. LUNGE: I'm not totally familiar with what-- Does that also include anything that's out-of-pocket that's a point-of-service purchase

that's not covered by insurance? Is that much broader?

ATTENDEE 13: I think so. I think so because it sounds like if the physician prescribes it.

ATTENDEE 14: That's right, if a pharmacist gets it.

ATTENDEE 15: A pharmacist has information and it goes into the--

ATTENDEE 14: Whatever the pharmacist has, so that would include out-of-pocket.

ATTENDEE 13: In fact, isn't that one of the things that we said is in this category of health care, there's more out-of-pocket than in other areas, right?

ATTENDEE 14: Uh-huh.

ATTENDEE 13: So you lose all the out-of-pocket data?

MS. LUNGE: The way the reporting system is set up for the PBMs and the pharmacy providers in the other two states, they do receive the data on the out-of-pocket liability of the member. So that kind of detail does come in through that. You know who the payer is and you know what each payer paid, and you get the drug code. You get all the detail on it, you know, the NBC code (phonetic) and what

type of drug it was. But you don't get--you don't get the data for all of the over-the-counter, out-of-pocket stuff that is not covered, you know, like for the uninsured. Just for the uninsured person off the street, you're not going to get that from the multi-payer.

ATTENDEE 13: You said over-the-counter, but everything that's prescribed, they're getting it now?

MS. LUNGE: If--with this multi-payer, if it's covered by insurance.

ATTENDEE 16: That would be my question.

MS. LUNGE: That's the difference versus if you're paying totally as uninsured.

There is a pilot project both in Maine and New Hampshire with the Kellogg Foundation to receive what they're calling dummy claims from participating providers and hospitals on the uninsured. So they're working toward getting total population database, but that takes a lot more development.

ATTENDEE 17: That's interesting.

CHAIRMAN MAIER: Patty?

REPRESENTATIVE O'DONNELL: I want to make sure we have this straight. So if I have

insurance, all of the information from my doctor's office or the hospital, x-rays, all of that stuff would show up in the database, but if I didn't have a prescription drug part to my policy and went to the pharmacy, that would not show up?

MS. LUNGE: Not if it wasn't covered by an insurance policy, no.

REPRESENTATIVE O'DONNELL: Okay.

MS. LUNGE: This is paid claims. Somebody's paid--some third-party payer has paid them. So I'm thinking that the data mining is probably broader, and it includes everything that occurs at what they call point-of-service transactions in all the drugstores that are hooked up to these data mining. I'm assuming you're talking about an IMS health kind of?

REPRESENTATIVE O'DONNELL: Uh-huh.

MS. LUNGE: Yeah, they collect point-of-service transaction data from probably all retail pharmacies, I would think.

ATTENDEE 18: Can I ask: Do you use any IMS data?

MS. LUNGE: We had conversations a couple years ago related to our expenditure analysis because we knew they had probably a high level of

detail on them. Because the expenditure analysis, it includes all spending on health care, even for people who are uninsured, we were hoping to be able to buy some data from them, which would give us a lot more accuracy, but they are extremely--we couldn't afford them. They wanted $50,000 for just basic aggregate reports, so we could not afford to buy data from them in our particular department. It's very expensive.

ATTENDEE 19: Do you get information from the free clinics around the state? Does that go into your--

MS. LUNGE: We do through a Federal economic survey, but they don't directly report to us.

ATTENDEE 19: So all the services that that pretty significant part--

MS. LUNGE: They would end up probably mostly in the Medicaid database because Medicaid is probably their predominant payer.

ATTENDEE 19: But going to the free clinics, they're not--

MS. LUNGE: Oh, you're talking about--

ATTENDEE 19: I'm talking about the network of free clinics.

MS. LUNGE: Yeah. No, that would be

uninsured, so that--nobody's really paying for that.

ATTENDEE 19: I just wondered because I think that they're keeping records in those places.

MS. LUNGE: They are, yes.

ATTENDEE 19: So there's all that information, but it's not being integrated into the State, even though I believe the State supports it, at least marginally most of the time.

MS. LUNGE: I used to be involved with that coalition, and I know they set up a standard data collection system, so they were collecting like ICD-9 codes and CPT codes so they could tell you the demographics of patients and what they were coming in for. So they do have a standard data system for the participants. That's in Vermont; that's the Coalition for the Under and Uninsured.

ATTENDEE 19: Right now that network is not tied into the BISHCA?

MS. LUNGE: No, they're independent. When we did the H wrap (phonetic) a couple years ago, we did get their summary report of utilization. I mean, I know they're collecting the codes for outpatient care in a standard manner, the ones that participate.

CHAIRMAN MAIER: We just have one more question on this. I had a little note. We're actually not behind schedule. Our next witness--

ATTENDEE 20: Cancelled? Rescheduled?

CHAIRMAN MAIER: Well, isn't available. And Bill's gonna--Bill Smith over here is going to make a few comments for maybe ten minutes. So we're about to be a little bit behind schedule, so if we can have one more question, and then whatever else Paulette needs to tell us.

REPRESENTATIVE MILKEY: Okay. So I just wanted to also make sure I've got this. The IMS type company, if they stop collecting information, you can't afford it anyway, so it will not impact what we're doing, because you can get it for--already for the multi-payer database everything that's available for people with insurance, so it would have no impact on what the State is doing?

MS. LUNGE: Right. They're just picking up all the stuff that the uninsured are paying.

REPRESENTATIVE MILKEY: Yeah. And we can't afford to get it anyway. So we don't have it when they're collecting it; and if they don't collect it, we wouldn't have it either.

ATTENDEE 22: Let me ask a question.

CHAIRMAN MAIER: Yeah.

ATTENDEE 22: What you just said, Ginny, what it left me with is we don't need this company to do any of the data collecting. Is that what you wanted me to--

REPRESENTATIVE MILKEY: No.

ATTENDEE 22: No?

REPRESENTATIVE MILKEY: I only wanted to know what I asked. There's a whole lot more that they do and who gets it that I don't know, and I'm not making conclusions about that. But what I wanted to know was for our purposes in the State; that's all. There's no more to my question than what I asked because I don't know who else--I don't know everybody that's buying it and what they're using it for, and I don't know whether I think that's important enough that we ought to make sure these--

ATTENDEE 22: But for our purposes in the State, by that you mean for us to analyze what the prescribing patterns are of doctors?

REPRESENTATIVE MILKEY: For the multi-payer database and all the things that we're trying to do with that.

And I'm also concerned that we don't have

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that information and wondering how we might get it if we can't afford to buy it from INS.
ATTENDEE 22: That was going to be my next question.
REPRESENTATIVE MILKEY: Whether there's something we can do to get that information that would be affordable.
ATTENDEE 22: How could we?
REPRESENTATIVE MILKEY: We may not want to get into that now.
ATTENDEE 23: And I think that's a key issue, too, because the prescribing pattern of doctors is one of the biggest things we need to know if we're going to cut down the costs. So, you know, figuring out how we could get that information is very important.
CHAIRMAN MAIER: We'll know a lot. We'll know 90 percent of their prescribing--
REPRESENTATIVE MILKEY: 90 percent of people are insured. So--
CHAIRMAN MAIER: Maybe even 96.
ATTENDEE 24: But, right, but there's a difference between being insured and having a pharmacy benefit.
CHAIRMAN MAIER: That's true.

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ATTENDEE 24: I mean, I know a lot of people who have insurance, but they don't have a pharmacy benefit.
CHAIRMAN MAIER: It's probably not 90 percent.
ATTENDEE 24: I'd be interested to know what that number is.
MS. LUNGE: It's pretty high.
ATTENDEE 24: Is it high?
CHAIRMAN MAIER: It's probably not 90 percent. It's higher now with Part B.
MS. LUNGE: I'll go back and look at our survey and some of the stuff I have from it. It's pretty high. Most people with major comprehensive medical have a pharmacy benefit. It's over 95 percent, I believe.
ATTENDEE 24: That surprises me.
MS. LUNGE: It could also be different cost-sharing tiers depending on what you buy.
ATTENDEE 24: Medicare would make a huge difference, but I'm thinking like, you know--obviously, we think where we are. I'm thinking families and I do know families that don't have that it.
CHAIRMAN MAIER: Yeah. Okay. Let's--

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MS. LUNGE: With multi-payer, you'll get the cost-sharing information for that pharmacy benefit. You'll know how much the person's deductible is, what's the general out-of-pocket.
ATTENDEE 25: So even if someone has a high deductible, that still generates a claim and that will come through.
(Inaudible).
MS. LUNGE: Something you might want to ask Elliot Fisher about, something I talked to him a couple years about: In Michigan a couple of years ago, they did a multi-payer project. It was in the late '90s with Blue Cross Blue Shield Michigan, which was probably--which is probably their--it was their hugest payer, plus they had the Medicare, Medicaid, and they did--they did everything--and he said that the most--and I talked to David Winberg about this, too, who is Jack Winberg's son--and one of the most compelling findings they had from that project had to do with prescribing patterns; and they actually got very engaged with their state medical society and local docs, and it had to do with prescribing for children with attention deficit disorders. They found these enormous variations and they found out it had to do with

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socioeconomic census tracks and expectations of behavior, and it ended up being one of the biggest benefits they got from doing that study is understanding that and how the medical community and the education system all interacted, and they said it was very productive. And Blue Cross followed up on that. They did do a lot of work on that. And Elliot Fisher would probably tell you about that. It was very powerful.
ATTENDEE 26: That's very interesting, but you do have documentation on what people have for--how many people have pharmacy insurance?
ATTENDEE 27: Right, and we can get back to you with it.
CHAIRMAN MAIER: That's through the survey.
MS. LUNGE: That and we have--
CHAIRMAN MAIER: We took testimony back in February about the big survey.
ATTENDEE 28: You guys did this nice slideshow.
ATTENDEE 29: Can I just follow-up? Okay. I just want to make sure I understand. When you talked about that particular study in Michigan that was very helpful, where was that data coming from? Was that a private source or was that a government

project that funded that?
MS. LUNGE: That was the Center for the Evaluative Clinical Sciences, you know, Winberg's shop.
(Inaudible).
MS. LUNGE: Somehow he got into--he got into some kind of an arrangement with the Blue Cross Blue Shield of Michigan and the large unions because of the auto makers out there. There was this big push on the employers and purchasers to try to figure out what's going on in health care in our state. So it was--I think it was a public-private partnership that funded that. I actually have that whole Atlas sitting in my desk because it was a real classic. It was one of the first times anybody tried to put all the claims, all the data together and try to figure out what was going on in their state at a pretty fine geographic level.
CHAIRMAN MAIER: Let's see if we cannot--
COMMISSIONER THABAULT: I just wanted to get back to the fines issue, and I'll go back and check with Herb, but the provision here does allow that the commissioner can investigate same and otherwise enforce a violation of a subchapter. And I

certainly have authority when regulating health insurers to impose fines. So I'm not sure if there's additional, you know, specific fine levels--
CHAIRMAN MAIER: Yeah, if you could get back with us on that.
COMMISSIONER THABAULT: That you would want, but I'll get back to you on that particular point.
CHAIRMAN MAIER: It might be a different answer for nonsubmission.
ATTENDEE 30: Versus improper use.
CHAIRMAN MAIER: Because that would clearly be--
ATTENDEE 30: A less serious.
CHAIRMAN MAIER: Under the statute they have to--we said they have to submit, but there might be a different answer for that than for improper use.
COMMISSIONER THABAULT: I'll double-check, but I have pretty broad authority in terms of the investigation and enforcement of our laws with respect to health insurers. And in this law here, this bill, the benefit manager is to be treated as a health insurer, so I think there's a lot of flexibility. But I will get back to you specifically about whether defined levels of fines

should be incorporated. We'll get to that.
CHAIRMAN MAIER: Great. Thank you.
COMMISSIONER THABAULT: And then just the very last piece that I wanted to just support in this bill is the piece about marketing, and just that we would certainly support that, particularly in a situation where you have potentially--
CHAIRMAN MAIER: What section is this?
COMMISSIONER THABAULT: I'm sorry. Section 18 under Insurance Marketing. This section is really just saying if in the process of insurance marketing, you're advertising and you are going to advertise, you know, a bingo game, for instance, to learn about your Medicare options, and really what I'm gonna do is sell you some insurance when you're there, too, I need to disclose that upfront; and we, of course, think that's really important and support that. We want you to keep it in.
ATTENDEE 31: So AARP has to disclose if they have, like, 37 different companies that are selling prescription drugs to elderly people; is that what's going to happen?
COMMISSIONER THABAULT: No. It's just when you make an appointment to meet an individual or you solicit a group to come and hear about Medicare

advantage, you know, options with the pharmacy, and you're also going to try to solicit insurance sales while you're there, you tell them the purpose of this engagement is to tell you about your options but also to--it's to sell you some insurance. So they're on notice that this is a sales call.
CHAIRMAN MAIER: Okay.
COMMISSIONER THABAULT: Okay?
CHAIRMAN MAIER: Thanks very much. Thanks for come in, Dian, on such short notice.
(End of CD 127/TRACK 3)
CD 127/Track 4
MR. SMITH: (Inaudible) Miller & Smith in Northfield, a contract lobbyist for CVS Caremark, a newly merged company, which we used to represent just Caremark. CVS, a large retail pharmacy, has merged with Caremark as of March--the middle of March, with SEC approval that has already happened. So I'm not quite sure how this plays out in this committee. I just wanted to let you know that. These big companies are changing and moving and trying to find ways to maintain their competitive edge in the marketplace.
And if I could, first of all, let me also apologize for Lauren Baldwin not being here. My

understanding is she's somewhere in Iowa. I did try her by phone today without success. Maybe if something's come out of this committee, and this committee needs to hear from her, perhaps by telephone either Friday or next week, I'm sure she'd be happy to get on the line and give you her expertise.

So, maybe if I could give you five or ten minutes from 25,000 feet as not an expert in this area, but what I've seen representing Caremark for a couple years now.

First of all, the business model for PBMs has changed in the last ten years. It used to be that they were linked to the manufacturers, perhaps a subsidiary of a manufacturer out there, and now at least the bigger ones, such as CVS Caremark, MEDCO, Express Scripts, are not. Why has the business model changed and what does that mean for Vermonters?

I think ten, 15 years ago with the link to the manufacturers and with the lack of sophistication of clients and new things, like using technology to track pharmacy benefits, so that you could make sure that someone got the best price drug or the drug that really works for them

or they can do some substitutions. Those didn't even exist 15 years ago, and now they do largely because--in my client's view because of the competition amongest PBMs and the willingness of them to bring technology to bear in this competitive marketplace.

So why did it change? First of all, litigation. I don't think you can underestimate what the Julie Brills of the world do, and I certainly wouldn't want to say that that's not useful in its place. As an attorney, I'm less litigation adverse than your average bear. I think that sometimes large businesses have differences of opinion and then what happens is litigation. So I don't necessarily view it as a black mark on an industry if there's litigation involved which ultimately benefits consumers.

These big companies are doing what they do, and they're trying to make money for their shareholders, while still maintaining the client base that they have and the customer base that they have. If they go outside that too far, litigation is the final step to bring them back in line. I guess what I'd say regarding litigation is that has been effective in that realm, and they probably

don't need any added help there.

In other areas that you have clients that are increased in sophistication, there's been a lot of question about client size of a PBM. I can tell you from former Caremark, now CVS Caremark's point of view, they deal with businesses to about down to 700 employees. That's--I haven't seen a number below 800, but I want to go to 700 just in case someone comes back and says, oh, 716 out in, you know, Ohio, Smith. So let's call them dealing with a pretty large company. I don't know how many 700 employee businesses we have in Vermont. It's not too many. And that's the kind of business that probably doesn't need specific protection. And if they do, you know, they can afford to pay the better lawyers than me to litigate those things.

So we have litigation. We have increased sophistication and size of clients. We have independence from the manufacturers. These have all developed in the last ten years. Another thing is the competition between PBMs, and who decides what benefits you're bidding on. Well, that's the hope for a client, the health insurer, the large employer, the State of Vermont puts out an RFP and says, "Here's what I want. What's it going to cost

me to get it from you?" I'm sure you'll hear with much more skill about that at your eleven o'clock discussion with, I think, Brian Quigley and maybe Andy Pridell, also a couple of folks from Express Scripts and MEDCO, about the competition and how that all flows from the need of the client. So that's--those are the kind of the four big changes that have happened in the last ten or 15 years in this marketplace.

One of the things that I know is of concern is making sure we have a purchasing pool to make sure we--you know, sort of like a buyers club for medicine, and at its simplest--and I know I'm oversimplifying here--that's what a PBM is. Caremark with 60 million covered lives, one of those terms, has a lot more leverage power, buying power with both ends, both from the manufacturer, and in telling, saying to retailers, if you want to sell, you know, pharmacy over the counter to Blue Cross Blue Shield's people, your price is going to be "X," not "X," plus five percent. So you have--that's the opportunity of PBMs is that they can bring prices down as a large purchasing pool. They can move people towards generics where it's appropriate for them, where their docs tell them

it's appropriate to use, and in those two areas now, as opposed to ten years ago, PBM's role is aligned with those of the client. And the cost containment because the contracts are typically two-year contracts. You might see a three-year contract occasionally. They know that two years from now they got to bid that again, and they better have done a good job or they can just go to the next company. That's kind of the 25,000 foot version of what I'm seeing in this marketplace.

There's another area that I think is adding to savings where it's appropriate is mail order pharmacy. It may not always be appropriate. It may not always be comfortable for that insured person to do it that way. There may be some issues with safety and reliability of certain kinds of drugs sent to cold climates. I know there's some you can't send. I mean, doctors certainly know there's certain treatments you can't get through the mail, because if it sits in your mailbox in February, it's not gonna be any good.

ATTENDEE 32: Or July.

MR. SMITH: That too. That might even be worse. So what I can get you, also, is I'd like to give you by electronically, if you'd like it, Price

Waterhouse Coopers has done kind of a look at this last month for the Pharmacy Benefit Managers Association, and I can get that to you electronically if the committee would like that.

The one final thing is that PBMs nationally average save 29 percent of what you can go into the pharmacy and buy on your own. And how much could PBMs save Vermonters? Well, if which know some 90 percent of our people have a pharmacy benefit, then 90 percent of the people can save, you know, a good chunk of money that that would help us in the long run. Maybe--I know Kathy Callahan is coming in this afternoon. I think she might be a person that would have the information on what Vermont has saved by using a PBM in its most recent contract. You might want to ask her about that, see if there's some savings there that have, in fact, happened by using a PBM. I guess I'd say in closing, remember it's optional coverage. I mean, this is not--some health insurers or some employers can't afford this as a benefit. So anywhere we can save money we should, but it is an optional benefit. And I guess I just would having thrown all that at you, and you've listened very nicely, are there any questions that I can answer; or if I

can't, I'm sure the folks from the PBMs at 11:00 can. Any questions for me or any discussion about CVS and Caremark?

ATTENDEE 33: And maybe you could do some research. Do you have any sense of what the administrative cost related to a PBM is?

MR. SMITH: An administrative cost related to a PBM? What's it cost to have them save the 29 percent?

ATTENDEE 33: Yeah, yeah.

MR. SMITH: Okay. We can get you that this week.

CHAIRMAN MAIER: Were you suggesting--I mean, almost no one would have a drug benefit plan that wasn't using a PBM already; would they?

MR. SMITH: Right, right, very true.

CHAIRMAN MAIER: So that whatever savings there is is already going on.

ATTENDEE 34: It's happening now.

MR. SMITH: As the Chair knows, it's a very fluid marketplace both for specific drugs and for what clients demand, but it's driven by the client. Maybe fifteen years ago, it wasn't. So--what's--I know the other PBMs certainly want to, you know, be helpful here, and this S.115 address those concerns

or not, I leave that to the experts at 11:00.

ATTENDEE 35: I'm trying to make sure I understand. For example, the 29 percent average savings on prescriptions, when that--if I'm insured, say, by Charlie's Company and Charlie's insurance, and I'm insured through you, who gets the 29 percent savings? Do I, the patient, see the 29 percent or does Charlie see the 29 percent savings?

MR. SMITH: Well, that's going to depend on what your insurance has set up. If you have a $5 co-pay, it's five bucks to you. Instead of it being ten dollars, it was $7.10, that's a savings for your health insurer, and you would still pay your $5, as long as you're less than the overall amount. Did I answer that sort of?

ATTENDEE 36: What about if it's 20 percent?

ATTENDEE 35: What's that?

ATTENDEE 36: 20 percent, not a $5 co-pay, who gets the savings?

MR. SMITH: Then everyone would save. You're saying if a $10 item is $7.10, because you used the PBM, you pay 20 percent of what?

ATTENDEE 36: I wasn't so much worried about the $10 items, but the $150 items.

MR. SMITH: I know. I'm just sorta kinda making the math easy for me. You can make it $1000 if you like.
ATTENDEE 36: Make it 100.
CHAIRMAN MAIER: Robin, you want to help here?
MS. LUNGE: I think there are a couple things I would respond to for that question. One is it depends on whether the savings is from the price that you paid the pharmacy or whether it's a rebate, because if it's the price you pay in the pharmacy, then you're paying 20 percent of that, and then the rebate would go back to the client. But, also, if your insurance saves money, at least in theory, that should be reflected in your premium also. So there's that relationship.
MR. SMITH: I'm getting the raised eyebrows from the experts over here, so I think they have some good answers for that either now or when they're in the chair.
CHAIRMAN MAIER: Let's come back to it when they're in the chair. Did you have a question, John?
REPRESENTATIVE ZENIE: I can bring it back. Thank you.

MR. SMITH: Thank you. Again, my apologies for Lauren not being here. Thank you.
(End CD 127/Track 4)
CD 128/TRACK 1
MS. CORCORAN: As I indicated, there's a couple things I kind of want to talk about. The first being the interactions that the industry has with health care providers, the interplay between the industry and the FDA in regard to interaction with health care providers, as well as ensuring the safe and effective use of prescription drugs.
I'm going to touch a little bit on the AMA opt-out which I believe you heard some testimony about yesterday. That's a program that we support, too, and we believe also addresses concerns that we hear about physicians. And then finally wrap up a little bit on some of our concerns with the unconscionable pricing piece of this legislation and our experience in DC that passed a similar provision about a year ago.
As I said, as an initial matter, you have before you the PhRMA code on interactions with health care professionals, and this is a code that was passed originally in 2002, updated in 2004, and it deals with what PhRMA and our member companies,

who have all kind of signed on to adhering to this, believes are the appropriate type of communications and behaviors and interactions with health care professionals. And by "health care professionals," we're talking about physicians, nurses, nurse practitioners, all those who are engaged in the delivery of health care. And again, it's done in a "Q" and "A" form, which was found to be an effective way to get at some of the common questions we hear about. Is it appropriate to pay for the gas of an individual? And the answer will be no. Now, is it appropriate to work with a certain practice and help them or provide them with services or information that's specific to the type of health care that they deliver to patients? Yes, as long as there's that connection.
Again, our companies, most if not all of the members of PhRMA have pledged to adhere to this. In addition to--and I think this is an area, too, that a lot of people aren't familiar with is that again, most if not all, of our companies have very rigorous compliance programs internally, and those compliance programs are not just after you hire somebody to work as a representative of the industry. It happens beforehand. I was recently

at a seminar in which an individual from Glaxco talked about kind of the riggers individuals go through before they even are employed by Glaxco to represent the industry and their products, and then they talked a lot about what happens afterwards and the accountability within the company. And if individuals do not adhere to the compliance programs, when they go back and question them, there are steps that occur, such as being fired or being on probation.
So I think it's important to know that in addition to the PhRMA code, the individual companies have these great compliance programs. And again, too, we often encourage if a doctor has a concern about the behavior of a representative from the industry in their office, they should notify the company and/or say something to the representative or refuse to see them. I mean, we believe that doctors can and should take appropriate steps, too. Also, it helps us as a trade association to interact with our companies and let them know some of the stuff we're hearing about.
The other thing that's important to know is not just the trade association, the company, but

the FDA also plays an important role in the interactions that our companies have with health care providers.

As you all know, a lot of information is distributed by this industry specific to products. Again, most, if not all, of that information is first run through the FDA. Some of it is required under law. If you have, you know, drug labels, information about how a drug should be taken, it's all approved by the FDA. You'll have electronic. You'll have email. You could have the stuff that's even on TV, the direct to consumer advertising, those ads on TV. While legally companies aren't required to have all that approved, they do as a practical matter because of that relationship, and the commitment to working to the FDA and making sure that the kind of information that they distribute is consistent with the FDA's approval of that drug and that drug for that usage. So I think when you think about the industry and the interaction, there are a lot of different levels. There are a lot of different levels of accountability, and it is stuff that the industry is committed to.

Along the lines of the relationship with the

FDA, there's another component, too, and this is an area of--actually, I have two more handouts. I'll rotate these around because--and I realize they're little paper, so I'll try to--

One of the areas where the FDA basically holds the pharmaceutical industry responsible for is ensuring the safe and effective use of medicines. As you know, the FDA approves the drugs, works with the companies. There is a lot of once a drug's approved for marketing, there's a lot of postmarketing update to make sure that there's an efficient way for issues with drug interactions to be reported to the FDA. You also have in many instances, before a drug is approved for marketing, especially in areas where smaller populations, there could be a higher kind of risk benefit analysis done at the FDA, where the FDA wants to ensure that for these drugs, for these patient populations there is a very fast and effective way for the pharmaceutical manufacturers to reach into those doctors and those patients, to notify them as fast as possible of any sort of concerns with the use of that so that they can then engage with their patients. This is an area where I think you heard a little bit yesterday from IMS, the term risk

maps. This is a tool that's being used more and more often with the FDA and the pharmaceutical industry and these drugs, because the FDA, as well as the industry, is finding that with a lot of medications, the implementation of the risk maps takes away some of the concerns of the risks with the drug, while ensuring that patients have the benefit of that drug.

The first document you have in front of you is a two-pager document. You'll see that it was prepared by Hogan and Hartz, a firm in DC, that specializes a lot in the FDA. This talks about the key role that pharmaceutical companies play with the FDA to ensure the effective use. And what we tried to do is give an idea on the second page about the categories of diseases--I think there are about ten of them--the estimated number of patients that fall in those categories, as well as how prescriber data is used to make sure that when it comes to a product for one of these classes, any information, or to the extent that the risk map requires a physician registry, which sometimes they do, the industry has the data and information to get to those doctors very quickly, very fast.

I think one of the things that's important to

understand is manufacturers largely sell to wholesalers. They don't sell to physicians. They're not doing a direct sale to a physician that might occur in some other manufacturing. So the way that the industry gets access to the information about what doctors, what practices and who's prescribing specific drugs is through the purchase of this data from IMS; and that's why, as you see in this chart here, it's important for a number of patients that this data is available so that you can have targeted, educational campaigns.

The other letter you have before you, you'll see it's written to Amlyn, and I--I brought this because I think it really solidifies the fact that it's not just the industry. The FDA also sees how important this information is because built into this letter is the assumption that the industry, the company Amlyn specifically, is going to have access to prescriber data information to then target these physicians. And if you look on page three, where it starts talking about--you'll see a whole bunch of bullet points, where it says these agreements include the following: The fourth bullet point, the fourth, fifth and sixth, really get at the assumption that Amlyn is going to have

the data to go in and target the physicians that they need to target to provide them with the appropriate information about these drugs.

So I just think when you talk about this issue, and you talk about the use of this data, it's important to note that it is a commercial use. I mean, that is what this industry does. It uses it for it. It has become much, much more a fabric in which the industry, working with the FDA, ensures targeted, educational material to physicians. So I just wanted to provide you with at least those two documents. There is a litany of other documents I could provide you if you wanted some follow-up that really lays out just how important it is.

That leads me into kind of the final thing--Actually, I'm sorry, two more. The AMA opt-out just briefly. I believe you heard a little bit about the AMA opt-out yesterday. We believe that that is the appropriate program to address concerns that we know physicians have with at times inappropriate behavior of representatives. I believe you also heard the statistics. The AMA spent a lot of time working on this program, designing the program, polling physicians to find

out, you know, those that have concerns with certain practices or behaviors, and whether this program addresses their concerns; and my understanding in seeing that is most doctors overwhelmingly said that with this program, our concerns are met because we understand that the value that this data also has on the patients' safety side. So, again, we believe it's a great program. We support the AMA. We're working with them. And, again, to the extent we can educate doctors about that, so they understand a program exists, and then also why it's important that the data still is out there.

CHAIRMAN MAIER: Ginny, then Harry, then Sarah.

REPRESENTATIVE MILKEY: I'm just curious how much of the use of this data goes towards patient safety and how much of it goes towards marketing?

MS. CORCORAN: It would be hard for me to say, you know, "X".

REPRESENTATIVE MILKEY: Ballpark is fine.

MS. CORCORAN: Pardon me?

REPRESENTATIVE MILKEY: Ballpark is fine. Is it, like, 90/10, 50/50? I mean, is it primarily used for marketing or is it primarily used for

patient safety?

MS. CORCORAN: When you talk about marketing, this falls in that category of marketing. I mean, that's how they view follow-up, post-marketing education of physicians.

REPRESENTATIVE MILKEY: I don't think that's how we view it.

MS. CORCORAN: Pardon me?

REPRESENTATIVE MILKEY: I don't think that's how we view it, or at least I'll speak for myself; that when you're trying to sell drugs, that's one thing, and when you're trying to make sure that they're used properly once they're sold, I'm just curious how much of your effort goes into those two kinds of things.

MS. CORCORAN: Each company is going to be different. If you're a company that has a lot of products subject to risk maps, it might be higher. Then again, this data is also used for "Dear Health Care Provider" letters. Anytime there is a change in or a concern about interactions with other drug products, this is the data that's used for that. So, this synergy is such that it's difficult to say a certain percentage is just for sales and certain marketing. It does fall--it's all part of kind of

one large system.

REPRESENTATIVE MILKEY: Okay. So if you were--if you were unable to use the information for detailing, for going around and promoting new drugs, would you still buy it? Would the company still buy it?

MS. CORCORAN: Well, the AMA opt-out is the program that exists to address that question, which is, you know, why I raised it before. Because the AMA opt-out allows doctors to opt out of having that information used for that specific reason, yet the companies can still use it for the safety reasons. So there is a program out there.

REPRESENTATIVE MILKEY: So you opt-out through AMA so no detailers come to your office?

MS. CORCORAN: The way the AMA opt-out works is you go on to their website or I think they might have cards and stuff, and a doctor can opt-out for a period of three years, and that opt-out requires the companies to basically--think about it as a firewall; so that while the marketing divisions had the data for their safety protocol from the things that the FDA required, the individual sales rep or detailer, who's going into the physician's office, does not have access to that data.

REPRESENTATIVE MILKEY: In theory?
MS. CORCORAN: In practice.
REPRESENTATIVE MILKEY: Doesn't have access to that data from the AMA, but they can still get all of the information through I--what is it?
ATTENDEE 1: IMS.
REPRESENTATIVE MILKEY: IMS and if they can get information from other source and put it together, can they still--
MS. CORCORAN: Actually, the way the program works is the--the data is opted out, so the detailer does not get it. There is no way. I mean, our companies contract with the AMA and they contract with IMS. It's built in that if a doctor opts out of having the data in the detailers, the companies are required to honor that. So, yes, the companies get the data, but the detailers do not have access. There's no run around--
REPRESENTATIVE MILKEY: They don't have access to the IMS data?
MS. CORCORAN: IMS AMA data, correct.
REPRESENTATIVE MILKEY: But there's one body of data that comes from the IMS, and then there's code numbers, physician code numbers that come from the AMA.

MS. CORCORAN: That data is aggregated by IMS. It's not to--
REPRESENTATIVE MILKEY: Okay. So then can IMS get information somewhere else that would replace what the AMA data does and come up with the same information and avoid using the AMA data?
MS. CORCORAN: I think--
REPRESENTATIVE MILKEY: We've been told they can.
MS. CORCORAN: They might, you know, unless IMS is here. The way the opt-out works is the data is still available from IMS. This is more about the onus being on the companies.
REPRESENTATIVE MILKEY: I hear what you're saying, but what we've been told is that there are other ways that IMS can get data from other sources that isn't AMA data and end up with the same information for detailing that doesn't violate their agreement not to use the AMA stuff; and so therefore, my question is: Is this true and effective if we want to protect the physicians from being marketed using the stuff?
MS. CORCORAN: That's new information to me. I'm not familiar with it. I do know that the AMA opt-out is a program that was designed to help all

physicians, not just AMA members. So I'm not aware of how a company, if a doctor opts out, any doctor, not just an AMA, through the AMA, how that is negated through any other collection by IMS. I'm not aware of that. And that's not something I'm familiar with.
CHAIRMAN MAIER: Harry?
REPRESENTATIVE CHEN: I'd just like to know what the--your viewpoint would be on an opt-in program rather than opt-out program?
MS. CORCORAN: I think our viewpoint is consistent with the AMA. When the AMA went out and looked at this, they believed, much like we do, that it's much better to give the doctors the choice. If they're aware--the safety reasons for the information and then they choose to opt out, versus blanket, you know, opt-in program. If you looked at the polling that was done by the physicians, I think 85 to 90 percent of the doctors said, You know, if you had the opt-out that gives us the choice, we're happy.
REPRESENTATIVE CHEN: So as a follow-up, if you were in a state where only five percent of the physicians were AMA members, would you consider that a valid sample of physicians in that state?

MS. CORCORAN: Well, my understanding--and I haven't--is that that sample came from more than just AMA physicians. And also, again, the program is designed for all physicians. It's not just AMA members. So I think it's more educating to the extent that you reach more physicians so that you let them know about the option, versus necessarily a fact that they're a member of the AMA or not.
REPRESENTATIVE CHEN: And do you happen to know about just of a sample of physicians how many of them actually know about this program?
MS. CORCORAN: I don't know. That would depend on the state. Again, you know, part of this is kind of educating physicians, and I know the AMA is working very hard. This is a new program. It just started in July. So it's less than a year, and it takes some time. But I know the AMA is committed and we're committed to doing what we can to help educate physicians.
CHAIRMAN MAIER: Sarah?
REPRESENTATIVE COPELAND: Are you required by the FDA to do this postmarketing studies?
MS. CORCORAN: Yes, yes.
REPRESENTATIVE COPELAND: And the information that you base the studies on is minus the opt-out

folks or it includes them?
MS. CORCORAN: It includes--the data is still available to the companies for those kind of postmarketing surveillances and follow-up because, you know, there are times where you're gonna have a product that is more widely used in a company and there's an issue where they need to get out letters fast. They need to get those out to the doctors. What, say, you have in, you know, this one drug where they're sending out all these letters, and ten percent of those doctors have opted out of the program, what that means is that the individual representatives in the company won't have that data to go in and sit in front of the doctor and discuss it with them.
REPRESENTATIVE COPELAND: Okay. So for those purposes of safety studies--
REPRESENTATIVE CHEN: They'll still get the letter, right?
MS. CORCORAN: The doctors get the letter, right. The doctors get the information. It's just that they're not gonna have when the sales rep comes to call on them, the sales rep isn't going to have that physician's prescribing patterns.
REPRESENTATIVE COPELAND: Okay.

CHAIRMAN MAIER: Lucy?
REPRESENTATIVE LERICHE: I guess I'm just trying to reconcile in my mind this new--when you say program that began in July, my memory might be off, but I thought we heard testimony from people who said that this has been going on much longer than since July. So I guess I'm looking for a little clarification about what exactly the program is that you're referring to when you said the "program" began in July.
MS. CORCORAN: The AMA opt-out program.
REPRESENTATIVE LERICHE: Oh, just the opt-out part because the AMA has been collecting data. They've been doing in for about ten years, right?
MS. CORCORAN: Yes, yes.
REPRESENTATIVE LERICHE: But only recently have they began with the opt-out?
MS. CORCORAN: Yes.
REPRESENTATIVE LERICHE: Okay.
MS. CORCORAN: Yes, that is the program. They probably spent a year, maybe two years leading up to when the program became functional, I guess is a way to look at it, discussing, polling, trying to figure out what was the best way to address doctors' concerns, but it became operational in

July.
CHAIRMAN MAIER: Hilde?
REPRESENTATIVE OJIBWAY: Following up on what Lucy said, it's been about ten years since this information has been available. So 11 years ago if a drug was dangerous, how did they get the information out before?
MS. CORCORAN: Actually, I believe prescribing data has been available a little bit longer than that, but I think IMS is probably best able to answer that question. To the extent that the AMA became part of the system, that probably is the case, ten years.
Before you had this aggregate data--and, you know, I can only speak off kind of my understanding how the industry would work, I would suspect that they'd have to just blanket letters out to physicians. So, you know, now instead of a company saying--sending out letters to every physician in the United States regardless of their practice, now they have the capability through this data and the collection to target the physicians that they know are prescribing or more likely to prescribe. So I see it as a much more efficient way to do what they probably had to do in a more blanket way before.

What's also happened, too, is you have more and more drugs coming to market in the last couple years, like that charted indicates, where when the FDA is making a decision on the credit of risk benefit analysis, and now that they know that this data is out there, they're more likely to look at it and say, okay, drug "X" might have a little bit more risk than we might be comfortable with historically, but we also know that the benefits for an MS patients, especially certain patients, is just too great for us not to give that patient doctor's access. And now that we know that the companies have this data to get at physicians in a very fast way if something happens, and they want to make sure that they have additional information, we're gonna allow the company to market it. And, again, you have a letter that talks about really specific things that those companies need to do.
So I think it's two things: Improvement in the kind of data, and also the ability of the companies to really get at and target physicians.
REPRESENTATIVE OJIBWAY: Just to follow-up a little bit with that, so say, I'm a doctor and I've written prescriptions, but then Patty comes in and you don't even know about the future, so that warns

them about the ones that have written, but it doesn't really--if it's only targeted to the physicians who prescribed it so far, and if it's dangerous, then it sounds like you're not--by not alerting all the doctors, there's doctors who may prescribe that in the future who won't get the warning because they're not being targeted.

MS. CORCORAN: No, I wouldn't say that. I mean, you know, if you have some products out there--I'll just, you know, Vioxx. I mean, it will get a lot of attention, and that company because of the wide usage of it, they're more apt to send it out to all physicians.

What I'm talking about are drugs, like the diabetes drug or MS, where the patient populations are much smaller. You know--you're gonna have a better idea of the physician practice that's going to be prescribing that drug versus a statin, which is probably going to have a wider practice. So it's not that physicians aren't going to be notified. It's just that on more drugs for smaller populations, it's a lot easier to reach into those physicians, too.

REPRESENTATIVE OJIBWAY: And this isn't your job, but I'm just curious, who alerts the patient?

MS. CORCORAN: The physician. That's the physician--we don't have access to patient information. I mean, this is all identified as prescriber information. So it is the physician.

REPRESENTATIVE OJIBWAY: So the way the system works is if your physician doesn't let you know that you're taking it, there's no other kind of warning system?

MS. CORCORAN: There are other warning systems out there. I can speak just as a patient and an individual, I'll turn on CNN or MSNBC and hear about information about a new warning from a drug product. I mean, the networks that we have outside of just what the companies are required to do are pretty expansive. I mean, we're a 24-hour news cycle, so information can get out pretty quickly.

CHAIRMAN MAIER: I'm trying to move us along here.

REPRESENTATIVE MILKEY: Just a quick clarification on something that you said before regarding the firewall regarding using information from companies such as IMS. You said that the detailers are not allowed to use that information in terms of marketing new products to physicians,

and is the firewall that they don't get to see the information or that they get to see it, but they can't use it?

MS. CORCORAN: They don't see the information.

REPRESENTATIVE MILKEY: They don't see it. Thank you.

MS. CORCORAN: There is protections in place that they don't have access to that.

If I just have two more minutes and stuff, there is another provision in here I just wanted to highlight, and that deals with the unconscionable pricing provision. I'm sure you've seen a lot about it.

CHAIRMAN MAIER: You like that one.

MS. CORCORAN: We do have a lot of concerns. In case you aren't familiar, DC passed a similar provision, and it was overturned by the district court on three grounds. Two of them are applicable here, one being a commerce clause, because this bill is designed very much like the DC bill.

It is written to be directed at manufacturers and the price at which they would sell in the state of Vermont. And much like DC, while regulating the sale of a product in Vermont is, you know, clearly

within your authority, going outside to regulate activity that occurs wholly in another state does infringe upon the commerce clause, and the DC court was very clear on that. And, so, again, we believe that there are real issues with the commerce clause on that. This could also be read, too, in addition to kind of impacting manufacturers and reaching outside the state, there are some concerns about the kind of impact this might have on in-state entities, too. So I just want to raise those concerns so that you are aware of not just the reaching outside the state in commerce issues, but also potential issues with businesses within the state of Vermont.

CHAIRMAN MAIER: Such as?

MS. CORCORAN: Well, if you're looking at this and talking about sales of a product in Vermont, and you're going to say that no product can be sold in the state of Vermont, it is written saying no manufacturer can sell in the state of Vermont, but as a practical matter, manufacturers largely sell outside the state of Vermont. So, you know, you could reasonably read this one or two ways. You could read this as reaching to transactions out of the state or reaching

transactions in the state; and to the extent it's transactions in the state, then it's those entities in the state that are purchasing or selling from a manufacturer that would also it be impacted, whether it could be a wholesaler, it could be a pharmacy. It just depends on the chain from the manufacturer down.

And again, the DC court did overturn a similar provision. It found it to be a violation of the commerce--a per se violation of the commerce clause on its face. In DC, the government has chosen not to appeal that aspect of the decision. So in DC, while there are some other reasons why the statute was overturned dealing with the supremacy clause and foreign commerce clause, the aspect dealing with US commerce clause, the government is not appealing.

ATTENDEE 1: But they are on the supremacy and the foreign commerce.

MS. CORCORAN: They are on those two other issues.

ATTENDEE 1: Which rather--for another day.

CHAIRMAN MAIER: Right, just for the--

MS. CORCORAN: I'll be happy to discuss the supremacy clause.

ATTENDEE 2: There are other experts on that, not me.

MS. CORCORAN: But it is--it just suggests, too, when you're thinking about decisions and why you would appeal a case, you largely would appeal if you thought you had a chance of succeeding, and DC government clearly does not think they have a chance of succeeding on that element. So--

CHAIRMAN MAIER: Obviously we're coming back. It's already on our list of things to come back to. I just remind the committee that Robin's earlier testimony is that our provisions are written more narrowly than the DC ones. And so, anyway, we'll come back to that. We need to come back to that. I would thank you for your time and--

MS. CORCORAN: Oh, thank you; sure.

(End of CD 128/Track 1)

CD 128/Track 2

CHAIRMAN MAIER: Sharon Treat, who was on our schedule at 2:00 this afternoon, had a medical emergency. We learned about that about a half an hour ago, and Joshua is going to be in and around town anyway, so he was happy to come back at 2:00. And that will give him a little more time.

(Inaudible).

But he had something else in Waterbury, so he wasn't far away. So, anyways, they'll be back at 2:00, which brings us right to our eleven o'clock with John and then your people and the folks from Medco.

ATTENDEE 1: I never changed the name on the schedule. I wasn't sure who was coming, but Peter Harty from Medco is here to testify on our behalf, and Andy Fradell (phonetic) is also from Medco and--

CHAIRMAN MAIER: And do you want to join him?

ATTENDEE 2: H-A-R-D-Y? Please, H-A-R-D-Y?

MR. HARTY: "T."

CHAIRMAN MAIER: Welcome.

MR. HARTY: Thank you. Mr. Chairman, members of the committee: My name is Peter Harty, and I am vice-president for state government affairs at Medco which is a PBM. I appreciate the opportunity to join you here today. I do not have a prepared handout or formal testimony. I'd be happy to provide some information after the discussion today. And frankly, I do hope it is a discussion. Many of the faces around the table are familiar to me from years past. Some of you are not so familiar, so I suspect that there's a little bit of

a difference in terms of depth of knowledge. So what I thought I would do for starters--and I encourage questions at any point in the process. I don't know what your formal system is, but I take questions as they come to you.

So I thought I'd talk a little bit about what we do as an industry and as a company and how the marketplace works, and then talk a little bit about the bill in the forum which you have it in front of you.

There's another witness from one of our competitors, Brian Quigley, who will talk about some of the different aspects in a little more detail. So if you excuse me, I do get a little dry mouth as I talk, so I'm going to take a break every now and then for some water.

I want to talk about the marketplace first. Medco is one of the admittedly three largest PBMs in the marketplace. But the Federal Trade Commission, when they've looked at this marketplace, they've done a couple different studies, and their view of the marketplace is that there's somewhere between 40 and 60 PBMs in this space. There are three of us who are national in scope, ourselves, Express Scripts and Caremark, but

then you have, you know, the fourth largest PBM is actually Anthem slash Wellport. It's a health plan, and they have their own internal PBM capabilities. They do the same things that we do everyday in terms of managing the benefit. They just do it, you know, for their captive lodge; those who are with them for the medical benefit. They also compete outside that space for just the drug benefit. And what the FTC has found is in every regional marketplace, the smaller local and regional players who are capable of competing with us for the business, so every now and then we get something that we lost a piece of business to a PBM I've never heard of. CatalystRx is somebody we never heard of until a couple years ago, and they took the State of Nevada contract from us.

So, what the FTC has determined is when they looked at this marketplace is the competition among PBMs is in their words vigorous. That's their word. In the year 2004, they looked at the marketplace in order to decide whether Caremark could acquire one of their competitors, Advance PCS. At the time that would have been the merger of two of the four largest PBMs, and the FTC let that merger go through because of that vigorous

competition in the marketplace. Their view was that allowing these two players to merge would not substantially reduce competition and have a negative impact on payers and consumers.

We deal, frankly, with large, sophisticated employers and health plans as our clients. I know that there's a legitimate concern in some places about sort of the smaller employer. What about the 50 employee business? What about the 100 employee business? They don't contract with us for PBM services. We contract with the likes of and the folks that we have who have employees in the state of the likes of General Electric, General Motors; United Health Group doesn't have employees but it has members. Those are the types of folks that we contract with. To the extent that you're concerned about the smaller employers, they contract, to the extent they even provide a drug benefit for their employees, they will purchase an insurance contract with MVP, with United Health Group, with Blue Cross Blue Shield, and then that health plan contracts with the PBM. All right? So that Joe's Garage or Phil's CPA Shop, you know, you don't have to worry about whether they're sophisticated enough to get the right deal because

they're getting that benefit through a sophisticated purchaser which is the health plan. So we call that an aggregator. All right?

The marketplace sort of works by we don't go out and sell and people buy our services. What happens is these folks put out their request for proposals, much like the State of Vermont does for its employee plan. And they decide that the purchaser, in this case the health plan and the employer, decides what the benefit is that they're going to offer to their members. So if you think about their employees, think about the drug benefit that you may have. Certain drugs are covered; certain drugs are not covered. There may be an incentive to use mail service; there may not an incentive to use mail service. There's a copay for generic drugs for brand named drugs for preferred drugs. All that is set by the employer. They make all those decisions. They put all that plan design together, and they put out request for proposals, an RFP that says here's the benefit we want to provide, and we want to contract with the PBM to administer this benefit that we've decided to offer, which is a key point, because at that point the plan has made all of the discretionary

decisions. They've decided what the drugs are. They've decided how much you're going to pay for them. They've decided whether they want to do interchange programs. They've decided whether they're going to incentivize the use of certain drugs over other ones and they've made those decisions.

It is oftentimes done with the use of a consultant. There are national benefits consultants, groups such as Mercer. Seagull is another one, and I understand that Seagull is a consultant for the state employees and its plan. And these consultants not only help them design the plan but also help them through the contracting process. These are folks that have experience negotiating with PBMs, so that even those clients who may be somewhat less sophisticated have the benefit of someone with the breadth of experience, who can sit down and help them both design a plan and negotiate with folks like us.

So the RFP comes out. Sometimes you bring them along, you know, copies of a couple of them, but it's not unusual for these things to run 50, 60, 70 pages. Anything that's important to the client in terms of their relationship with their

PBM, they put in that RFP. And it includes questions like, you know, what revenue you have from pharmaceutical manufacturers. That's important to the client. And it's not just what rebates do you get? It's what revenue do you get, regardless of what you call it, and tell us about that. Then it's also questions like, okay, so you get that revenue, are you willing to pass 100 percent of that revenue on to us? Or would you prefer to do it under some other sort of circumstances? We oftentimes get RFPs that ask us to bid the business on two different ways. One involves full pass through of all the rebates, and the other involves a more traditional model. The client will then sort of look at it and decide which one makes the most financial sense for them, which one actually is the most cost effective way to provide that benefit.

So, we get multiple PBMs, who will then bid on that business, if we're interested in doing business on those terms, and the client, usually with the help of the consultant that we talked about, will then decide this is the one that makes the most sense to me. They will then set off to negotiate a contract with that client.

Sometimes there are clients who actually put the contract right as part of the RFP. So, as part of your response, you have to agree to their contract already. Sometimes you negotiate the terms. Sometimes they frankly say, okay, we got two or three best and final, you know, participants. We had eight PBMs, for instance, who bid. We're narrowing the field down to two or three, so now you give me your best and final pricing. All right? Now you give me a better deal because you know you're one of the finalists. And sometimes, frankly, it's like labor negotiations. They'll take us to a hotel, and Caremark will sit in one room and we'll sit in the other room, and the benefits folks who are contracting with for the client, will go back and forth from room to room and say, can you beat this? Can you beat that? And it's a very intense, competitive environment. And frankly, the clients have, despite what you may have heard about the unlevel playing field, frankly, they have the advantage because we want their business. We hate to lose business. We love to win it. That's what drives our executive team, you know, because that's what's good for the company. The more business we win, the better off

we are; and the less business we lose, the better off we are. It's a very competitive marketplace.

And what's happened to prescription drug expenditures over the last decade or so? When we were first here years ago, the year over year growth in terms of prescription drug expenditures was in the double digits. There's no question about that. We were looking in the year 1999, 2000, we were talking about 16, 17, 18 percent growth on a national level.

In the year 2005, according to data that CMS, the Centers for Medicare and Medicaid Services put out earlier this year, 2005 is the most recent full calendar year of data, growth year over year from 2004 to 2005 in prescription drug expenditures was less than six percent on a national level. It was 5.8 percent, and it's been coming in that downward curve over the last couple of years. And their view is that the--you know, the reduction in that trend number is attributable to largely the tools that we bring to the marketplace. It's the increase in use of mass service pharmacy, which is a more cost efficient way to deliver drugs than most retail environments, and it's the increase in use of generic drugs, which is one of the, you

know, great tools that we use in order to reduce expenditures for our clients.

Now, I'm not saying that we're the only factors involved in that. I mean, everybody in the health care system plays a role. You need the doctor to prescribe a drug that can be generically substituted. You know, obviously the retail pharmacies have a role to play in terms of generic substitution, but what we're finding is that growth used to be prescription drug expenditures were the single fastest growing component of our health care expenditures and they no longer are. Through the tools that we've brought to the table, we've succeeded in reducing that peripheral. Sure it's still going up. And you ask the question of why is it going up? As we look around the table, I can ask the rhetorical question, you know, how many of us are using more prescription drugs today than we were ten years ago? I can always raise my hand and my wife's hand in response to that. As the population ages, we're using more drugs than we used to for longer periods of time, for more chronic conditions, such as heart disease, diabetes, high blood pressure, the types of things that we're going to have to take prescription drugs

for, you know, for quite some period of time going forward and if not for our entire lives.

So we're spending more, but the question is: Is that a bad thing? And if you keep people on their diabetes meds, for instance, and you keep them out of an emergency room, yes, your drug line item may be more, but the overall health care costs are less because you're not sending people to the emergency room to deal with complications that result from not taking their medicines. It also helps them avoid some of the comorbidities of diabetes, as just an example. I think that's something that is very important for folks to keep in mind. The trend is coming down largely attributable to the tools that we're using.

To talk about some of the other issues that I'm sure are kind of front and center, the whole concept of transparency. As I talked about in the beginning as I was describing the process, you know, these are sophisticated purchasers. They read the newspapers. They understand the issues that have been out there for a number of years, and if it's important to them, they ask the questions in their RFP.

There are some for whom it's not important,

including some of our clients. They really don't care what our relationship with manufacturers is because it doesn't make any difference to them. What they're focused on is the competitive process. Do they get the best price? Did they get the best possible deal? And if we make money on something, they don't really care.

There are some folks who want full transparency and they want full pass through of every dollar we get from every manufacturer. If they want that, they ask for it in their RFP, and we compete with other PBMs to do business with these folks on those terms.

There are some in the middle who say, okay, I don't want 100 percent, but I want something so I'm going to guarantee an amount per claim or per prescription, or something along those lines, so you get that certainty. Different models suit different peoples objectives from a business point of view. The folks who get all the rebates, you might think that's the best possible deal that you can get, but there are risks that are associated with that. If you contract with us on the assumption that you're gonna pick a number out of the air, that you're going to get 50 million

dollars in rebates based on your business with us, our ability to earn those rebates is determined by our ability to meet certain performance obligations that we have with the pharmaceutical manufacturers. If we don't meet those targets, maybe we only get 47 million dollars in rebates-- Did I say 50 million? I'm not even sure of the number. So, 50 million dollars, we only get 47. So you were counting on 50, you now get 47. What do you do? You got a three million dollar gap in funding with a prescription program that you're gonna provide for your members or for your employees. So some clients say we don't want to run that risk. We'd rather have you, Medco, run that risk. So you guarantee us a certain amount of rebates, and if you happen to make more money than that on rebates, great, make money. If you make less than that, then you take the loss and we don't have to worry about it. That's just one example of why there's different models in terms of how you share rebates with different clients because it meets their objectives.

At Medco, you know, we talk about this publicly, but more than--or roughly 80 percent of the rebate dollars that we get from manufacturers

are passed back to our clients. The other 20 percent, you know, is because we have other arrangements with other clients, and they firmly believe that it's better for us to take the risk and keep those dollars and use those dollars, frankly, sometimes to subsidize other aspects of our pricing relationship with our clients.

So the marketplace really does deal with the issues that have been talked about here. The Federal Trade Commission was mandated by the Congress in 2004 with the passage of the Medicare Modernization Act to do an analysis or do a study in connection with these issues of a perceived conflict of interest. You know, PBMs drive up drug costs. Are we focused more on earning rebates than helping our clients save money, et cetera, et cetera? And the report came out in August of 2005. They looked at some very specific questions and they issued a report. It was 100 pages of text, 100 page of attachments, so 200 pages. You can boil their conclusions down to two words: Is that the allegations of conflict of interest and self-dealing are, quote, without merit, end quote.

I tell people all the time I get mad they didn't use three words, like, totally without merit

or completely without merit, but at the end of the day the conclusion is when they looked at 160-some-odd million claims, they looked at our contracts with health plans, they looked at our contracts with manufacturers, and they determined that our interests are aligned with the payers. We make money when we make good decisions in connection with our clients by offering a cost effective benefit to their members and their employees.

And, yes, we make money. I feel compelled to sort of put on the table, we are a for-profit company. We're traded on the New York Stock Exchange. We have shareholders who expect a return on their investment. Our net income in the year 2006 was 1.6 percent after all of our expenses, all of our taxes, and so on and so forth was 1.6 percent. The only problem with that is if you talk to our CEO--

CHAIRMAN MAIER: Of what?

MR. HARTY: I'm sorry?

CHAIRMAN MAIER: 1.6 percent of what?

MR. HARTY: Off of 42 billion, something on that order of magnitude.

CHAIRMAN MAIER: In terms of your sales or

revenues?

MR. HARTY: Total revenues. You know, the only problem if you talked to our CEO is he wished it was higher than that. 1.6 percent is not--you know, on a percentage basis, it's pretty low. On an absolute basis, which I assume is where your question is coming from, yes, it's a fair amount of money in the order of 600 million dollars or something like that. That's the business we're in.

We are, frankly, despite what you might hear from people, we actually make more money off of generic drugs than we do off of brand name drugs and rebates. If you look at our earnings reports, if you look at all the filings we have with the SEC, you'll see that that's really what does drive much of our profitability or the greatest part of our profitability which is a win-win for everybody.

Yes, we make money off of dispensing generic drugs. The plans save because it's cheaper for them for the generic drugs, and the members and employees save because the copay is almost always--I can't think of any instances where it wouldn't be cheaper for them to get a generic, as opposed to a brand name drug.

CHAIRMAN MAIER: So how do you--I guess the

simplest way to ask it is how is it that you're making money when the decision is made about generics, as opposed to brand?

MR. HARTY: When we're dispensing, the same would hold true for the retail pharmacy, as well as for us. Most of it comes, frankly, on our mail service capability. And perhaps I should just back up for a second and talk about it.

We do operate mail service pharmacies. We dispense drugs for chronic conditions, like high blood pressure and, you know, cholesterol, exactly, all those types of things. So in that case, we're a pharmacy. We're selling the drugs we buy. You know, as a major purchaser of prescription drugs, we're one of the largest purchasers of generic drugs in the country, because you have 60 million lives that are involved in our book of business. We have a lot of patients. So we buy at a price and we sell at a price, and we make money on the markup just like any other private sector entity out there.

CHAIRMAN MAIER: So it's not in your role as a PBM then in that case? That's a separate part of what you do?

MR. HARTY: As with any pharmacy, buy low and

sell high. I mean, I use that as sort of a relative term here, but I mean, our objective is to get reimbursed for more than we pay for the drugs and the cost of the services that we provide to our associates.

CHAIRMAN MAIER: BUT that's a separate--does that come into play in part of these--what we have in front of us here are things related to contracts that you let with companies in your functioning--in your role as this middle man, this middle--this middle entity between manufacturers and the rest of us, but this generic pharmacy business that you run, does that plug into that somehow or--

MR. HARTY: It's part of our contract with the payers. I mean, it's--the price points, you know, here's how they're going to reimburse us for brand names at mail. Here's how they're going to reimburse us for generics at mail. Here's how they're going to reimburse us for generics at retail and for brand name at retail. It's all part of sort of that one deal.

In the one case we're the pharmacy dispensing the meds is the mail service pharmacies. Why we take it into inventory and we dispense it in accordance with pharmacy laws. In the other, we're

a vehicle for reimbursing the pharmacy which is taking possession of the dispensing. It's all part of the contract with the payer.

CHAIRMAN MAIER: And maybe--I guess I'd just like to suggest, we have about ten minutes left with you, and if we could orient this to the legislation we have in front of us and what your particular comments or concerns are about that, I think that's--we need to head that way soon. Is that where you're going, Hilde, or do you have a question?

REPRESENTATIVE OJIBWAY: I do have a question, but I'll wait and see if there's time at the end.

CHAIRMAN MAIER: Okay.

MR. HARTY: I think that our basic policy approach is marketplace is addressed the issues that this committee has been discussing for a number of years. What you won't see is you won't see our clients coming in and saying we need legislation to accomplish these objectives. In fact, I understand folks like MBP, have basically said, perhaps not in this committee but in other committees, they don't feel that this type of legislation is necessary.

There are some--so I guess our basic pitch would be, do we really need any legislation to address this issue, because despite what some folks might say, I've debated Sharon Treat a number of times in different forums, when you look at the marketplace, when you look at the FTC report and look at the data, there's no issue that the marketplace hasn't already taken care of. You may wish the people did it differently, but this is what meets their objective. So that would be our first pitch is that this is a section of the bill that you don't need.

Brian will talk in a little bit more detail about some of the specific issues that we have as an industry, in connection with enforcement, for instance.

But is the bill better than some of the things that we've debated in the past? Yes, it is. One of the things that I think is particularly appropriate is at the beginning of the first of the two sections dealing with PBMs, you have a provision in there that says unless the contract otherwise provides, here's the way you will do business. What we would never want to see is a bill that says there's only one way to contract

with PBMs and it's within the four corners of this document. Because as the head of our client contracting group used to say all the time to me, you've seen one client contract, you've seen one client contract. And just think about--I talked about the three different ways to deal with rebates: Take them all, take none or take some guaranteed amount in the middle. Why should we dictate there's only one way for somebody to deal when these folks have determined that there are different ways to do it?

So, in terms of specifics, I think that there are some. For instance, the registration provision: We already have to register under some law that was enacted in the last session or two sessions ago. BISHCA is finalizing the appropriate requirements for registration. To have another one in here, which would seem to be duplicative, is another example. So those are a couple of the general comments that I have, Mr. Chairman, and again, Brian, will address some of the industry issues in more detail.

REPRESENTATIVE MILKEY: Just one topic that came up in an earlier discussion was that Maine requires PBMs to be licensed. Do you operate in

Maine?

MR. HARTY: We do.

REPRESENTATIVE MILKEY: Any issues there?

MR. HARTY: Is your question limited just to the licensure question or is it--because, frankly, since Maine passed the law that I'm sure Sharon Treat will talk about with you, if she hasn't already, we have not written any new business in the state of Maine because the law that they passed up there, while it's withstood legal challenge, frankly, creates what we view as being an artificial marketplace. It's not a marketplace in which we want to do business because it contains things that the market isn't really looking for.

REPRESENTATIVE MILKEY: My question is on licensure.

MR. HARTY: Andy, do you know if we have a licensing?

ATTENDEE 3: I was talking to Brian about it. Brian can speak to it.

MR. QUIGLEY: It's been a few years since we've testified--

CHAIRMAN MAIER: I'm sorry. Can you--

MR. QUIGLEY: I'm sorry. Brian Quigley representing Express Scripts. It's been a few

years since we testified in Maine, but I do not believe that the Maine law specifically requires PBMs to be licensed. It has very specific requirements as to PBMs acting as fiduciaries and disclosure and turning over rebates, but my recollection--I was trying to see if I had the Maine law here--is that they do not require the PBM to be licensed in the sense of an insurer being licensed with solvency requirements and market conduct requirements.

Express Scripts is no longer doing business in Maine because of the passage of that law, so my personal information is a little out of date, but I was there when the law was enacted and I don't believe--I've read my testimony there many times because I've introduced similar bills. I don't believe they require licensure in the sense of an insurance company being licensed.

REPRESENTATIVE MILKEY: I don't think we were told as in an insurance company, but I thought we were told-- Am I wrong about that?

CHAIRMAN MAIER: No, no. I'm just--

MR. HARTY: Mr. Chairman, I think we confirm--we can confirm--I don't recall in that PBM bill that there was a licensure provision. Maybe

some other provision in the law where it's required, I just don't know, but we'll confirm that and get back to the committee.

CHAIRMAN MAIER: We can come back to that. We already have that on our list of things to come back to, I think; yep. (Inaudible).

ATTENDEE 4: This really doesn't have anything to do with this bill. This is kind of a general health care question. So you do 40 billion dollars in business?

MR. HARTY: Something like that.

ATTENDEE 4: How much of that is actually spent on drugs for people for patients?

MR. HARTY: The great majority of it. I mean, certainly--and I would--I can probably confirm the number. My guess would be we're talking 90 percent or something goes towards reimbursement for prescription drugs, so it's directly related to that.

ATTENDEE 4: And then another ten percent goes to administrative costs?

MR. HARTY: Administrative tax and so on and so forth, but I can confirm that.

ATTENDEE 4: I'd like if you could, thanks.

ATTENDEE 5: That's what I think my question

was going to get at because on the one hand, you said several times that the market addresses the issue that you're talking about, and what we're really talking about in this sector is reducing cost, but if this business didn't exist ten years ago, and I'm not saying--you know, the pharmacy management benefit, but they didn't exist so there wasn't that cost to health care. It wasn't there. And now there's that cost and it's going up. And so the price of prescriptions has gone down, but I don't know how much it just leveled off and it just switched from paying one to the other, and for the overall cost of health care, it didn't help reduce the cost.

MR. HARTY: When you think about what the market was like, let's go back ten, 15 years ago. If you had a drug benefit, and ten, 15 years ago, most people didn't have a drug benefit. If you had one, you went to the doctor; the doctor wrote a script; you went to the pharmacy; the pharmacist filled it; you paid out-of-pocket; you took the receipt home; you put it in the shoebox; and at some point at the end of the--you know, some period of time, you took all those receipts out and you sent them to the insurer when you had 80 percent of

whatever it was that you paid, because that was sort of defined as the usual and customary. That was the fee for service market the way it existed at the time. There was no competition between manufacturers in terms of price because it was whatever the doctor happened to write was what got filled.

What we brought to the marketplace--and George Posse (phonetic)--or not George Posse, whoever used to be the president of Express Scripts, said all the time, if PBMs didn't exist today, somebody would have to invent them because what we did is we brought competition among manufacturers. Let's say there's five manufacturers of a cholesterol reducing agent. We have 60 million lives. You either want to be on our formularies or you don't. We're only going to put three on. We're not going to cover all five because we want to reduce that competition, so manufacturers for the first time had to give price discounts. It's just an after-the-fact, as opposed to the beginning.

What's it worth to them in terms of reducing their price to have access to 60 million lives? So we brought that price competition in. We

established networks of retail pharmacies. Where instead of the pharmacist charging you whatever it was that suited their needs, there's now a negotiated rate which is generally cheaper than what they would have sold it to you if you just walked up and paid cash for the product. So, we've brought savings and efficiencies to the marketplace by inducing that type of competition.

And, again, we end up with 1.6 percent. Where does the rest of it go? It goes back to the plans. When you look at what the GAO, it's now called the Government Accountability Office, when they looked at the use of PBMs by the Federal Employees Health plans, back in 2003 they issued a report, they found that the savings that were generated by virtue of the tools that we brought to the table reduced premiums for their members by one percent across the board. Whether you were a member who was using the benefit or not, your premium was one percent lower because of the savings the plans achieved by virtue of what we deducted. So the data and the experience is that we actually do save money, a considerable amount of money, and, yes, we make a profit by virtue of doing that, but take us out of the loop and you

don't get that competition, and you don't get those savings.

ATTENDEE 6: But there's a cost to the savings.

MR. HARTY: There's a cost, but it's up to the plans to decide. If we don't save them money, if we don't do what it is they wanted us to do, they fire us and they put out another RFP and they get a different contract with someone who will get the results that they're looking for.

CHAIRMAN MAIER: Patty and then John.

REPRESENTATIVE O'DONNELL: I can speak for Medicaid and some of the history here. Eight years ago, seven years ago in the Medicaid budget, people were paying a co-payment and they could go and get any kind of drug they wanted no matter what the cost of the drug was. The first year we went to PDLs through a benefit management company, we booked ten million dollars worth of savings that first year, and that was just we had to estimate because we didn't know. We had no idea where this was gonna bring us, but we knew we had to do something about the cost of prescription drugs because it was, as you said, growing at a rate of 16 percent at that time.

Going through a benefit management, when we have a population of 600,000 people in this state, we don't have a lot of buying power. Going through a PBM, we're not only the 600,000 people in our state, they're the 60 million patients. That's huge buying power from the pharmaceutical companies.

So even though it cost us money to go to PBM, it has saved us--and nobody's even kept track in the following years of what that number would be, but it has to be astronomical. Because if we were still paying the way we were, full cost for every drug and not doing a PDL and not buying in the kind of volume we're buying, it would be well in the range of millions and millions and millions of dollars. So that--I mean, from the Medicaid budget, I know for a fact. I can't talk about individual insurances because I don't--I never worked in that arena, but as far as the Medicaid budget, it did save millions of dollars. And, you know, the legislature that made the decision on that at the time made a good decision.

CHAIRMAN MAIER: John?

REPRESENTATIVE ZENIE: Using your example of five companies you helped get those prices down,

and I assume that's true, who does the work to look at competition based upon the merits of the drug itself? In other words, price isn't everything relative to one drug is better than another one, and the one that's least beneficial has lower prices, so we make that the one you put on your list as the one to buy.

MR. HARTY: It's a good question. The first step in any formulary development is the clinical one. And that's where you have a pharmacy and therapeutics committee, P&T committee. Hospitals have them; health plans have them; we have them. It's made up of clinical folks, doctors and pharmacists, who will review the literature. They're independent. They're not Medco employees. They're independent folks. They're from universities, academic centers, practice centers. And they're reviewing the drugs in the category, this and all the available literature, including studies about use and all that sort of stuff, and they're making a determination about whether--in our case there's three buckets they can any given medication in, and this is without regard to cost. This is just safety and efficacy. You must have it on the formulary because it offers such a clinical

advantage over any other drug that's in that category, you have to have it available. Must not have it because in their view there's safety issues that outweigh the benefits of that drug; and then the ones in the middle that may have. And those may haves, then the second step is that's where you begin to work with some of the competitiveness. At the gross level, the drugs are roughly equivalent from a clinical point of view, is there any reason for our clients to cover all of them? And that's for some may be yes. We want a completely open formulary. And for some of them it may be no. That's where you get into that, okay, they're roughly comparable, so we'll take three out of the five.

The doctor, though, always has the final say. The doctor can either agree to write the prescription for one of the preferred ones or not. If in the doctor's judgment that would not be appropriate for the patient, then the doctor writes the prescription. If it's not covered, you know, by the plan, then the patient is gonna pay for it out-of-pocket. Most plans, though, will have some sort of an appeals process. For medical necessity, this is the only drug that's really appropriate for

this member; and so therefore, you go through this appeals process, and the plan will decide whether to cover the drug for that individual or not.

So the clinical decision always comes first. Financial decision comes second, but it's always between the doctor and the patient as to what's the right drug. The question, then, is just what level of coverage, if any, is there for the drug?

Does that answer your question?

REPRESENTATIVE ZENIE: I think so. Addressing and talking about competition, I'm more interested in the competition relative to the benefits of the drugs, rather than the cost, because most physicians and a lot of--would pay more for a better drug if it is a better drug.

MR. HARTY: And that's way the benefit will usually be structured. They'll prefer one drug over another if the other drug happens to be appropriate. Again, it's a voluntary benefit people are providing, and if you have to pay more for the drug because it cost more, but it's the right one for you, then that's sort of where you are. You can always make that appeal, if appropriate.

REPRESENTATIVE ZENIE: Thank you.

CHAIRMAN MAIER: We need to try to wrap this up.

REPRESENTATIVE MILKEY: Okay. You mentioned a couple of reasons for the price of pharmaceuticals going down: Mail order pharmacies, generic drugs, and it seems like formularies, all these things converged about the time that PBMs started to become more commonly used, and I just wonder, do most of your plans that you--most of the employers or health plans that you work with allow the use of local pharmacies for filling prescriptions at the same benefit? In other words, I, as the consumer, would pay the same amount of money whether I get it from the mail order or the local pharmacy?

MR. HARTY: I would say that most of them provide financial incentive to the member to actually go to mail service, the drug appropriately filled with mail service.

REPRESENTATIVE MILKEY: And if I go to my local pharmacy, have they agreed to provide the drugs at the same price as mail order?

MR. HARTY: Usually not. And I mean, you passed a law here maybe a year or two ago, I forget, sort of required--not sort of but

definitely required that retail pharmacies would participate in our network, you know, for maintenance drugs. There's two different kinds of drugs. There's the acute stuff that you need today: An antibiotic, your kid has an ear infection; you need amoxicillin. You don't want to send a prescription to us and wait for it to come in the mail. You want to go to the retail pharmacy. And what we dispense, I think I mentioned before, the sort of the maintenance meds, diabetes, so on and so forth. So the question, then, sort of boils down to for the plan, which is deciding how to allocate the dollars that they have. Do they want to incentivize the use of mail service, which is cheaper for them, so that they give the member a financial incentive or some of them make it a requirement to go to mail service because that's the best way for them to use the limited bucket of dollars they have. If they can get a prescription filled for 80 bucks at mail service that would cost $100 at retail, they're going to incentivize the use of the mail service pharmacy.

Some of them don't see it that way. Some of them say, okay, we want you to be able to go

wherever you want to go, we'll pay the 100 bucks regardless, but it's up to the plan how they want to do that.

When the law went into effect here, my understanding is the way BISHCA's looked at it, is they have to--they can participate in our maintenance network, but they have to do it at the same rate as mail service, and they have to fill the prescription for 80 bucks, as my example, as opposed to 100 bucks. I don't think any pharmacy has taken that offer up because, frankly, they just can't do business on those terms across the board the way we can because of our volume.

REPRESENTATIVE MILKEY: Even the chain pharmacies?

MR. HARTY: I don't think any chains were. The last word we got, we didn't have anybody participating.

REPRESENTATIVE MILKEY: So we're really moving to big companies supplying all of our medicines, except for the critical.

MR. HARTY: I mean, 80 percent of the prescriptions that are filled in this country are filled at retail pharmacies. We're--

REPRESENTATIVE MILKEY: There are good

reasons for that. Anyway, thank you for answering my question.

ATTENDEE 7: I don't know whether you're the right person to ask this question to or not.

MR. HARTY: I bet you I'll have an answer for you.

ATTENDEE 7: As I look at this scenario, the company that you represent is supposed to offer savings, efficiency, competition. Maine developed--puts this law into effect. I know of two pharmacy benefit managers that have left the state just because of today and there may be more. I'm wondering what the impact now is because of what your company is supposed to do in terms of savings, what's the impact on the state of Maine? Do you have any idea?

MR. HARTY: It's a good question and it's one that I ask all the time. That law was passed in 2003. South Dakota passed a different law in the year 2004, I believe, and the question that I always have is where's the data that shows that this approach that they've enacted in the law has saved anybody any money? The usual cycle for PBM contracts is about three years. Maine was a little bit different because it was tied up in litigation

until final resolution was sometime the tail end of last year. South Dakota, if this statutory approach was going to save money, don't you think somebody would have data that would show that South Dakota is spending less money on prescription drugs than the other 49 states? I mean, where are the data in Maine? It's anecdotely I will tell you there's a stock analyst who talked to some employers in the state of Maine, and their view of the world was because they couldn't get current contracts with PBMs, they were actually spending more on their prescription drugs than they would otherwise, because they kept these older agreements in place that didn't have the newest schools and the newest pricing available in the marketplace outside of Maine, but that's anecdotal. There are no data that I'm aware of.

Now, Sharon Treat may have a different point of view. I know that she talks a lot of time about the State of South Dakota, when they let out their employees' contract, right about the time the law there went into effect, the State saved money. Well, that's why you switch PBMs is to save money, and they didn't need the law. In fact, the State put out the bid before the law went into effect

there. So, if they took tools and approach that saved them money, great for them, but they didn't need a law to do it. So I told you I'd have an answer to your question but--

CHAIRMAN MAIER: I want to move along to Brian, but I know this will come up and while you're in the chair, since you're from Medco, Medco's had a couple of--or several lawsuits over the years, another settlement this last fall, 155 million dollar settlement, and I just wanted to--we can hear more about the particulars of that, but I just wanted to give you an opportunity to respond to--respond to that from your standpoint.

MR. HARTY: Sure. 155 million was paid to the US in connection with a contract that we had in--for administering benefits for Federal employers under the Federal Employers Health Benefits program.

The bulk of that--that lawsuit or that investigation, you know, started back in 1999. So, the activity that was the subject of that investigation for the most part was literally in the last millennium.

And then we had the AG investigation, which I'm sure Julie Brill has talked to you about, and

the 20 multi-state AG. In terms of business practices, both the Federal and the State issues were resolved in 2004 in terms of how we deal with things from a business point of view. What was left with the Feds was just the financial component that was associated with that, and we paid 20-some-odd million at the time to the different state AGs--or to the different states, including the State of Vermont. So we resolved the financial aspects of that, but we also resolved the Feds at the same time, frankly, the issues that were related to the Federal False Claims Act, which what happened, frankly, was, we had a supervisor in our pharmacy down in Florida that was filling prescriptions for Federal employees; and this supervisor thought that the best thing for Medco was to make sure that we met our performance targets. You know, a certain number of prescriptions had to be filled within a certain amount of time. Her view was if we didn't meet those, we'd suffer a financial penalty; so what she did, with some people that worked for her, she went in and she backdated prescriptions. So that when it came in Tuesday and it couldn't get filled by Wednesday, she would then sort of backdate it to

make it look like it came in on Wednesday. We discovered that internally. We brought it to the attention of our client, the Blue Cross Blue Shield folks. We brought it to the attention of OPN. We fired the employees who were involved in it. We came clean. We lost the business, but what the net result of that was, by virtue of what these folks did is, there were false claims submitted to the government. They were reported falsely based on the information we got from her. So we dealt with that and we settled the lawsuit. It was one of those things where it had been going on, as I said, since 1999. So the best thing for us as a company, as a business was to settle it, as opposed to continue to deal with this litigation that was already, you know, seven years old at the time we settled it. Bring it to an end, it's the best thing for our company. It's the best thing for our shareholders, and we're hoping to win the business back. We have--we have bids in on the RFP at this point, cycling back round again. It was unfortunate it happened, but we put it behind us.

CHAIRMAN MAIER: Thank you. Thanks for being here today.

MR. HARTY: Sure.

(End of CD 128/Track 2)

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CERTIFICATE

THE STATE OF FLORIDA
COUNTY OF VOLUSIA

I, Heidi L. Hutson, RPR, Notary Public, Registered Professional Reporter, do hereby certify that I was authorized to and did listen to CD 127/Track 3 and 4, the House Committee on Health Care, Wednesday, April 11, 2007, proceedings and stenographically transcribed from said CDs the foregoing proceedings and that the transcript is a true and accurate record to the best of my ability.

Dated this 10th day of August, 2007.

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Heidi L. Hutson, RPR

STATE OF VERMONT
HOUSE COMMITTEE ON HEALTH CARE
PART 2

Re: Senate Bill 115
Date: 4/11/2007
Type: RX Drug Regulation

Committee Members:

Rep. Steven Maier, Chair
Rep. Harry Chen, Vice-Chair
Rep. Francis McFaun
Rep. Sarah Copeland-Hanzas
Rep. William Keogh
Rep. Lucy Leriche, Clerk
Rep. Virginia Milkey
Rep. Pat O'Donnell
Rep. Hilde Ojibway
Rep. Scott Wheeler
Rep. John Zenie

CD No: 07-129/T4

Reported By:
Christina Gerola
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Esquire Deposition Services
Orlando Office
Phone - 407.426.7676
Esquire Job No: 887539

PROCEEDINGS

- - -

CD129/TRACK 4

MR. SLEN: I'm Joshua Slen. I'm the director of the Office of Vermont Health Access. I have Ann Rugg, who is deputy director with the office with me today, and has had jurisdiction over the pharmacy program since we began the pharmacy benefit administrator a number of years ago.

We have prepared testimony for you today, and we're going to walk through -- with your indulgence through a number of sections of the legislation that we believe could be improved from the Medicaid perspective, and in some areas could avoid conflicts with some language changes. In other areas we have some policy recommendations which we'd like to talk with you about. So I'm going to provide the 10,000 foot view, and Ann is here to talk in detail about any of the specific proposals that we have.

ATTENDEE: Now, when we had an initial walk-through of the bill, the very first question that we wrote on the board here --

maybe if you could do that along the way here, it was pointed out that a lot of the language about the statewide PDL was being stricken, so the question came up as to so why didn't it work. We were told we should ask you.

MR. SLEN: Do you want us to start with that or --

ATTENDEE: Whatever is easier for you. If that fits into your presentation, that's fine.

MR. SLEN: That's a large -- that's a potentially large discussion topic.

ATTENDEE: Well, if it takes too much of what we were planning to do, we have you until -- we have a scheduled conference call at 3:00. So that's what we have. If you would rather come back and talk about that, that's also fine.

MR. SLEN: Well, why don't we -- why don't we start with what we have here, and I think we'll probably get through this and to that.

ATTENDEE: Okay. Thanks.

MR. SLEN: The first piece here, the current language, the way this memo is designed, the current language, what's in the bill currently is on the left-hand side, and

then our explanations, information and then recommended language is on the right side in each contiguous section. And then there's a break, and then current language --

ATTENDEE: Current language of the bill?

MR. SLEN: Of the bill, yes.

ATTENDEE: You don't have the page here, Josh.

MR. SLEN: Yeah, I apologize.

ATTENDEE: That's all right.

MR. SLEN: We have the section numbers --

ATTENDEE: Section numbers through --

ATTENDEE: I understand. I'm looking for section 7.

MR. SLEN: So the first is section 1.

ATTENDEE: Oh, yeah, right.

MR. SLEN: It's 1998 A7.

The section requires us to have a plan to inform Vermonters about drug pricing and to focus on -- on Medicaid and state employees information that FUHC pricing is better. In fact, that runs counter to our actual studies and analysis which show that the Medicaid program net of rebate actually does receive better pricing than the 340B programs in the

state of Vermont. So we're not certain that it's the best public policy decision to instruct us to tell people something that, in fact, is not necessarily -- is certainly not universally true.

ATTENDEE: That runs kind of to what we were told.

ATTENDEE: Yeah, we were.

MR. SLEN: We have a study that we did in 2006 which we'd be happy to share with the committee.

MS. RUGG: The biggest distinctions would be in terms of Medicaid rebate. And in terms of general pricing, pricing to the general public, certainly 340B pricing is -- is far better than would normally be available in a retail setting. But the difference is that, when we build into it the rebate, that 340B products are not eligible for Medicaid rebate, because the manufacturers have made them available to the federal 340B program at a discount, thus they can't be discounted again under that, under the Medicaid rebate program, and that's where our difference lies.

ATTENDEE: I guess we'd like -- I'd like

to see the study.
MR. SLEN: Sure. I'm happy to provide that. So our recommendation --
ATTENDEE: We're still -- we're still learning about a lot of this stuff. So who, and -- is it -- so it's your responsibility to develop the plan, or would be, I'm sorry, under this language? Who's developing the plan here?
MR. SLEN: The agency for human services, which would be us.
ATTENDEE: And is it -- is it only focused on Medicaid, or is it meant to be broader than just Medicaid?
MS. RUGG: The latter.
ATTENDEE: So the point you're making, though, is -- but Medicaid would still be the one putting together the plan, even though it was meant for more than just Medicaid?
MR. SLEN: That's the way it's written.
ATTENDEE: I think if you take Medicaid out of it, it might make sense to give the plan to somebody else, because it doesn't make sense to me to ask Medicaid to develop a plan that they're not going to be involved in. You could decide who you thought to (inaudible) --

ATTENDEE: Well, I guess we'll come back to that, one of our --
ATTENDEE: (Inaudible.) He's not here.
ATTENDEE: We could pretty much know what the plan is (inaudible) if we gave it to him.
MR. SLEN: The second comment we'd like to make is in the same section, it's C of that section. And the language that may be the easiest way to cut to the chase on this one is on the third page of our document. The language that we're asking for would be language that says purchases funded by Medicaid shall be included only to the extent authorized by the federal centers for Medicare and Medicaid services.
And we want to make sure to provide our manufacturers with assurances, for example, that we're not going to do anything outside of what or that would run counter to what CMS requires.
MS. RUGG: And this might be a good place to comment on the state PDL issue. The Vermont health access pharmacy benefit management program's preferred drug list features drug classes where there are clinical concerns

for -- there are high utilization issues or high cost issues.
If you looked at a peer PDL from -- solely from what prices were available in the community and what the clinical issues are, then you could apply a preferred drug list across all insurance companies in all employment plans. The difference is that in our preferred drug list we have negotiated these supplemental rebates for the Medicaid program, and the federal approval at this moment distinctly says that we cannot require manufacturers to participate in a rebate program and condition it on their providing rebates for state only programs. That's a federal requirement under the current approval schematic that they've used for the three pools that have been approved in the country to date.
ATTENDEE: I don't understand what you're saying.
ATTENDEE: Can you say that again?
MS. RUGG: Sure.
ATTENDEE: I suggest you take it back.
MS. RUGG: Let me take it back a tad.
As a condition of drugs being covered

under the Medicaid program, the federal law says that manufacturers have to pay a rebate. Now, that "has to pay a rebate" is called -- is called over rebate. They were authorized under the Omnibus Reconciliation Act, federal act, in 1990. And that means that no drug can be covered by any Medicaid program anywhere in the country unless a manufacturer has agreed to rebate. Some states, and Vermont being one of them, have negotiated for additional Medicaid rebates.
ATTENDEE: Before you get to the supplemental rebates, we heard -- a few weeks ago we heard a little bit about this, or maybe it was only a week ago. But am I right in saying that that has to do with the initial rebate program to making sure that the Medicaid price is the lowest price offered?
MS. RUGG: Yes.
ATTENDEE: And does the committee member, I think maybe it was Robin or Steve that told us about how all that stuff gets sent to a central place, and then the rebates get sent out to the states, but we don't necessarily know who paid what in, we just get a certain

amount out?
MS. RUGG: That's right.
ATTENDEE: Does the committee remember? John wasn't here for that, but the rest of us had a little background. So that's the -- that's the first -- that's the more traditional rebate.
MS. RUGG: What's called a federal rebate or an over 90 rebate or what's traditionally referred to as the Medicaid rebates.
Now, and then the next step is, as I say, Vermont does -- has secured supplemental rebates since 2002. And by -- supplemental rebates are allowed under the federal Medicaid program. And what states individually do or collectively do with other states through pooling arrangements are go to the manufacturers and ask for additional rebates. And in the asking for the additional rebates, the states are making commitments to the manufacturers as well. The states are effectively saying, if you can make your prices competitive or comparative to less expensive alternatives, older drugs, generics, then we will promote your drug, we will prefer your

drug on a preferred drug list.
And as I say, Vermont has had supplemental rebates since 2002. Initially we did it on our own, just Vermont negotiating with the individual manufacturers. Subsequently, through our PBA, who was then First Health, we negotiated rebates with -- at partnering with nine other states. And under our current PBA arrangement, rather than negotiating it through our PBA, it's a partnership at the moment between Maine, Iowa and Vermont, and we ourselves are administering this pool so that the pool is owned by the states and is always available to the state. And we have been able to negotiate rebates that are comparative to the pool that we were in previously.
And in this state fiscal year, we're anticipating about $3.9 million in supplemental rebates. And that's after much of our population or a lot of our population are now covered by Part B. So we're still getting nearly $4 million in supplemental rebates.
ATTENDEE: I guess, again, a little context for the committee, this is the sort of thing or it's the primary sort of thing that

the PBMs that we were learning about this morning are doing with their private customers as well. And in fact originally I think we did this through our PBM, and now we're broken off from it a little bit in this different way.
But these supplemental rebates, it sounds like -- it sounds strange because it is a little strange. But it's -- you know, in 2002, around that time frame is when states started to get into the game that had been going on for a little while with the PBMs and their -- and their clients. So -- and it was all a little bit unusual.
MS. RUGG: But you're a hundred percent correct. It's the normal way of doing business in the insurance company, and I candidly don't understand why other states (inaudible). It's a little work, but it's well worth it for that kind of money.
ATTENDEE: What did you call -- did you call them TBAs? You have another name for them --
MS. RUGG: PBAs. Pharmacy benefit -- in our case we have a pharmacy benefit administrator.

MR. SLEN: PBA, PBM, there's some slight distinctions in the industry, but they're both pharmacy benefit managers, pharmacy benefit administrators.
ATTENDEE: We had this discussion this morning about the contract language between a PBM and the client and whether -- one of the biggest points of negotiation in those contracts is whether or not these rebates are given to the client or not, or whether they -- the PBM keeps it internal to its business and reflects that. Then they would say -- and, you know, validly, for the most part at least, they would say that gets then reflected in the price that they charge for the administration contract.
But some of the problems that were raised at the time is there wasn't a lot of transparency about that. It wasn't clear what the rebates were, where they were going, how much they were. That's why there are now -- it's now a little more common to have these PBA arrangements where the client gets the rebates, but they're -- but they're perhaps paying a little bit more in terms of the administration

fees.
Is that at all helpful?
ATTENDEE: Okay. So that's the main distinction, of the administrator, the client gets the rebate directly but pays a little bit higher fee, where the PBM is the client or the -- well, the other way around.
Never mind. I barely got through the first one.
ATTENDEE: Right. That's one of the --
ATTENDEE: Do you know what I mean?
ATTENDEE: That's one of the --
ATTENDEE: Does anybody know what I mean?
ATTENDEE: That's one of the big points of difference. There are probably at least a dozen others, but --
MR. SLEN: So what Anna's been pointing out is one piece of the complexity for a statewide PDL. There's several other pieces, which is where we started this sort of -- we've kind of gone on --
ATTENDEE: A little bit diverted.
ATTENDEE: Could you repeat what --
ATTENDEE: I'm still not clear.
ATTENDEE: You lost me with that. I want

you to repeat that one thing you said, which is -- I never did hear it again. Did I miss it?
ATTENDEE: It was when we said, wait a second, can you repeat what you said?
ATTENDEE: You said you can't do something.
MR. SLEN: So we can't draw the -- let me try for the third one -- round on this one. You can't use Medicaid lives to leverage supplemental rebates for the Vermont population.
MS. RUGG: And then our PDL, though, has --
(Unreportable exchange ensued.)
MS. RUGG: But then our PDL has products on it preferred, because they've been made available by the supplemental rebate arrangements. So if another insurer attempted to use our PDL, they wouldn't --
ATTENDEE: They wouldn't see savings (inaudible) --
MS. RUGG: They wouldn't see the same savings on those same products.
MR. SLEN: So the broader context here, if you think about having three states or nine

states or ten states in Medicaid lives, Vermont's a very small state. So the number of covered lives matters when you're negotiating rebates. So you could say, well, let's pool all 600,000 Vermont lives. That's a big pool. Right?
Well, in our previous rebate arrangement, I don't know how many millions of lives we had. We had a lot. We had Michigan. We had some big states. We had millions of lives. And Vermont can't create a pool inside our walls as big as the Medicaid supplemental rebate pools that we can pool together through these multi-state agreements.
Now, whether or not that actually results in a better or worse price over the long term in negotiating supplemental rebates is up for debate. There's no way to know unless you go down that road. But we would have some complicated negotiations, because we would have to, if we had a state PDL, make some compromises across commercial lines and Medicaid lines of business that would mean that we would narrow the scope of what we could negotiate for on the Medicaid side as far as

rebates. So there would be some cost implications for certain as far as reducing our rebates. There's no doubt about that.
ATTENDEE: Okay. Thank you.
MR. SLEN: Sure. Okay. So the third issue, which is on page 3, is the Healthy Vermonters program. And the simple change we put in here is we changed it to -- we put a may in, underlined "may" on the right-hand side most of the way down on page 3. And I'm going to let Ann explain the reasons for this, but we're going to start with an explanation of what the Healthy Vermonters program is, which is --
MS. RUGG: Now, the Healthy Vermonters program is the equivalent of a discount card at this point. This is to cover a population from 225 percent to 300 percent of the federal poverty level for those people who are not aged or disabled and up to 400 percent of the federal poverty level for those who are aged and disabled.
MR. SLEN: So these are folks that do not receive a Medicaid payment for their drugs. So we're not paying -- they're not signing up for

our program and then we're paying for their drugs, they're just getting the Medicaid price at the counter because they have a card.

MS. RUGG: Right. And because -- well, again, it's a discount card, not only -- not only a federal payment, there's no state payment on this. What essentially happens is if people are eligible based on these income levels, they present the card in a pharmacy setting, and what they get is pharmaceuticals at the price that we pay as opposed to what they would pay as a private citizen.

Healthy Vermonters has been predominantly a program for the aged and disabled. And with the implementation of Medicare Part D last year, much of that population is no longer accessing Healthy Vermonters, because their Part D coverage is providing them with a pharmacy benefit.

MR. SLEN: So the language that's in the bill would expand.

MS. RUGG: That's right.

MR. SLEN: And require some complexity with the secondary price issue.

MS. RUGG: Right. The proposal -- and

this is language that has been in place that was subject to a federal 1115 waiver, that would have allowed us to essentially negotiate rebates for this population and then share the rebate with them, with the beneficiaries.

This was actually the model that was the first attempt at Healthy Vermonters, which goes back - I don't know - five years ago, thereabouts. We called it the pharmacy discount program, PDP, which is -- adds to the confusion, because that's what Medicare calls their prescription drug plans. But it was a similar discount. And the intention was -- initially we actually implemented it on the assumption that it would be approved by CMS and that we would negotiate rebates. We would effectively fold it into the Medicaid program. We would get that discount, and when we got that discount, we would share that with the beneficiaries, thus reducing what they paid.

That was challenged by PhRMA in the -- in the court system, and we lost. And we had to shut down the program. And we resurrected it as solely a discount program under the Healthy Vermonters. But again, the language was there

subject to the approval of an 1115 waiver.

And then this proposal was to remove that, that language, and then provide, again, this negotiated rebate option that -- that was -- that would be related or comparative to negotiating a rebate separate and apart from Medicaid rebates.

MR. SLEN: And so our position on this is that because of Part D the need for this program at all is much less and will continue to be less over time as more and more, a higher percentage of the population actually avails themselves of that Medicare Part D over time. And we've already been down the path once on the negotiating rebates side of this equation. And it's not -- it's potentially, given all the other things that we have to do, chasing a pretty small tail of benefit with potentially a lot of work. And so we've -- we prefer not to have the language at all, to be clear.

ATTENDEE: If it is there, then it would be this. So this is sort of like choice B. Choice A is --

MS. RUGG: Well, we were also thinking that at this point the majority of the

remaining population, sir, are not aged and disabled, and much of that population may very well benefit from the ESI, Catamount initiatives. So our thought was that if we left the language in with a may in there, that if the ESI, Catamount coverage would not become available or beneficiaries were not taking advantage of that opportunity, then there would still be a backup plan for our pharmacy coverage.

MR. SLEN: And I just wanted to be clear that the may does eviscerate the language. We all know that. A shall requires you to do something, a may leaves it to the discretion of the department, and our initial stance would be that we would not do it, and that we would wait to see if it was necessary, based on whether -- how quickly we're ramping up to 96 percent.

Essentially, if you have everybody insured, fully insured, through all of the other programs that this legislature has required to be implemented, then you don't need this other program which would provide a very limited benefit if everyone has full benefit provided through the other programs.

ATTENDEE: I am not clear. Are you saying you think there's a legal issue, or was that just explanatory?
MR. SLEN: Explanatory.
ATTENDEE: Okay. Thank you.
ATTENDEE: So before, when you tried to do this and you were told you couldn't, I didn't quite understand, the issue was that you were trying to leverage the discount by using the Medicaid people? Is that what the issue was on this, or was it something else?
MS. RUGG: At that time the intention was and would have been -- would be the intention under the language as it previously existed here was to request an 1115 waiver. And in this context, that's asking for a waiver against the Social Security Act to expand coverage under the Medicaid program, under title 19 of the Social Security Act, the Medicaid program, and thus make them, designate them, a Medicaid population, and thus subject to the same rebate.
ATTENDEE: And -- and before you didn't go for the waiver, and did it -- did the program (inaudible) -- is that what happened?

MS. RUGG: We implemented it on the assumption that we would get --
THE ATTENDEE: Would get --
MS. RUGG: -- an 1115 waiver.
ATTENDEE: And you didn't get the waiver and had to shut it down.
MS. RUGG: Had to shut it down. And actually at that time CMS was very -- CMS was very positive about the concept. We were very close to being approved when the courts shut us down. And shortly thereafter, actually, Maine did, in fact, get an approval for a program very similar. And the difference between their program and our program was that there was -- there was a state contribution to the benefit, a small one, but a state contribution. So it still was a -- you know, a state supported program.
ATTENDEE: Okay. And so that's what the new language proposes to do, is to add the state contribution -- no. But we've crossed off the waiver language, because (inaudible) said we didn't need it.
MS. RUGG: Well, our reading the language, and I'll look to my right --

ATTENDEE: (Inaudible). That's what we were told, it was done in the Senate because -- because you no longer needed a section 115 waiver.
MS. RUGG: My understanding, or at least -- maybe I'm misreading this. But I was reading this, there's this general language that talks about negotiating rebates for any publicly funded program or public benefit. So it includes corrections and others, the notion that we would separately, separate and apart from Medicaid, negotiate a rebate in support of state programs.
ATTENDEE: Okay, so that's (inaudible) --
MS. RUGG: And then this would be -- yeah, this particular provision would be under that particular model.
ATTENDEE: Okay. So you wouldn't need the waiver because you'd be negotiating separately. Wouldn't be --
MS. RUGG: Right. Right.
ATTENDEE: Then the last part of my question is, if we were to do what you're recommending and just cancel the whole thing, who gets -- who gets hurt?

MR. SLEN: Well, potentially, if we were able to implement this and additional people signed up who aren't signed up today, those people would not be able to sign up, is what would happen. But what we're asserting is that we're seeing a downward reduction in the total number of people signed up for today's program, and as you do an expansion, we don't anticipate that there's very many people that would actually sign up for it, because there's a full benefit available through Part D.
ATTENDEE: If you're 65?
MR. SLEN: Or disabled.
ATTENDEE: Or disabled. So there's -- so I'm still trying to quantify who, even if they're not getting a benefit right now, could be getting a benefit. I understand that the Part D, if you're disabled or over 65, that that offers benefits to people.
MR. SLEN: And then Vermont offers programs from 0 to 225 percent of poverty.
ATTENDEE: Okay. So we're covered up to 225.
MR. SLEN: Well, up to 150 or 185 for full benefit Medicaid for adults and children, other

than to 300 percent for children. So we -- children aren't on this table really at all.
ATTENDEE: Does the Medicaid up to 150 or 185, does that include VHAP?
MR. SLEN: Yes.
MS. RUGG: Yes.
ATTENDEE: Okay. So we're only talking about people who aren't on Medicaid or VHAP, which is anybody -- and we've got charts, we just haven't got them up here. And then there's the -- whatever it's called, V script something for up to 225?
MR. SLEN: And then remember we're also rolling out Catamount, which covers another big chunk of the population from 150 to 300 in October, leaving -- you know, you just start to have very few people who aren't eligible for a full benefit somewhere.
ATTENDEE: Do you have a sense of what -- you know, what size that little few is? I mean, basically it's people who are still uninsured?
MR. SLEN: It's people who haven't -- yeah.
ATTENDEE: Who don't have that -- who are

underinsured?
MR. SLEN: It could be anyone in our whole program spectrum, theoretically, who haven't chosen to sign up for any of the existing programs because they don't want to pay the premiums for them, or because, if they're in a non-premium area, they just haven't signed up.
ATTENDEE: Okay.
MR. SLEN: So --
ATTENDEE: You know, I kind of want to say the number last year was only, geez, right around 2,000 people, and that was before Medicare Part D, right?
MR. SLEN: I don't recall.
ATTENDEE: I'm trying to remember the numbers, but it's not a lot of people that took part in that program anyway.
MS. RUGG: The current coverage under Healthy Vermonters for the non-aged and disabled is up to 300 percent. So the Healthy Vermonters plus -- well, let me step back a bit.
If someone doesn't take advantage of the assigned Catamount up to 300 percent for some conditional reason, they are currently still

getting Healthy Vermonters. If we are able to execute a pool for -- a rebate pool for state programs, corrections and programs like this, that same population will then get an additional discount based on whatever was collected there.
MR. SLEN: I'm sorry. Can I suggest that if the committee wants to spend the next 10 minutes on this one, I'd like to get an outline of the other ones on the table. This one is one of the smallest issues on the list.
ATTENDEE: Please, sir. Thank you.
MR. SLEN: And we're happy to come back, but I know that you're under a time constraint.
And on page 4 of the PBM section, and the department here refers to BISHCA, regulating the PBMs -- that's correct, Robin, that it refers to BISHCA, the department in this area?
ATTENDEE: Yes.
MR. SLEN: And what we're asking is, as part of that charging of a fee to cover their expenses, that the language be added allowing the Office of Vermont Health Access to declare that our PBM meets the requirements and to not have it pay the fees, which would just be

rolled right into our appropriations, so we'd be paying ourselves. So we're just asking to not have that circular payment mechanism put into place.
ATTENDEE: What is upon declaration from the office? What is that about?
MS. RUGG: The language describes certain conditions that have to be met, and that the -- the BISHCA conditions that have to be met. And these -- the department's -- BISHCA's expenses are what would be being paid for by those fees. So if we declare that the conditions were met, could demonstrate it --
ATTENDEE: I see.
MS. RUGG: -- through the conditions of the contract, could we bypass they're having to share in the cost of administering what we would be providing them.
ATTENDEE: And does BISHCA like this language too?
MR. SLEN: We haven't had any complaint from anyone from BISHCA about this language.
ATTENDEE: No, they want to charge Medicaid.
ATTENDEE: I think they did, actually,

testify against (inaudible) --
MR. SLEN: We would be happy, of course, to work with our BISHCA counterparts on --
ATTENDEE: Teammates.
ATTENDEE: Cousins.
ATTENDEE: Okay. We'll have to hear about that. It seems reasonable to me, but --
MR. SLEN: Okay. The next section 13 at the bottom of page 4, this is the privacy section.
And Ann, do you want to explain?
MS. RUGG: I heard testimony this morning, and this is in regards to the disclosure of Medicaid claims information in relationship to the privacy questions. Right now, under the public records request, if we had that information available, anyone can ask for it. Manufacturers can ask for it. These data compilation companies can ask for it, and if we have it available, we have to make it available.
And for us, it seems to be counterproductive that the bill and other activities were heavily counter-detailing manufacturers' efforts to promote their

products. And yet, in this particular situation, we then have been faced with the need to provide them with information that makes -- information on what prescribers are actually doing, what those physicians are doing. And at least I heard a discussion of -- was it IMS or IHS this morning? But I know that, for example, two companies have been approaching us with significant regularity over the years. One is called Data Niche, and another one is called GHX. And they request and obtain this information. And at least the former is nationally known as using that information, selling that information for marketing purposes to the manufacturers.
ATTENDEE: So they have been getting it?
MS. RUGG: They have been getting it, because if we have the information, we have to provide it. And in this -- in this situation, I mean, I heard testimony this morning about how the information is used. It's used for health and safety reasons.
As an insurer, our position has been on things like health and safety issues. If there's a notification or available information

on a product or a problem with a product or a change in the product being pulled from the market, we take the responsibility for notifying pharmacies of information we've obtained, prescribers, and beneficiaries.
A typical example -- well, not a typical example, but an example was in the last week you may have seen in the press that Zelnorm has been pulled from the market. And we notified prescribers and pharmacies and beneficiaries within three days of that. For the pharmacies, we're notifying them that it would no longer be covered. From a prescriber's point of view, we notify them of everyone in our claims record that they have prescribed the drug for. And for beneficiaries, we notify them and indicate they should contact their primary care provider to seek an alternative.
We did it on VIOXX. We've done it on other products. So we take the responsibility of assuring the health and safety of the beneficiaries covered by our programs under these circumstances.
If the prescriber community wanted us to provide the information for some research

project or they're concerned about something, then we'd be willing to do it. But I know our drug utilization review board has indicated that they are in support of this language. They themselves, as physicians and pharmacists, are contacted with regularity by manufacturers, and the indication is that they are, in fact, using our claims information to identify who to target for -- for contacts.
So in this particular case we not only appreciate the language of the bill but we actually are requesting an additional language on the public records act to assure that we do protect the name of the prescriber as well as the beneficiary. The beneficiary is protected by HIPAA, but the prescriber currently is not. And that information has been provided and has been used.
ATTENDEE: I'm just curious, because, you know, in this case, is there a cost to providing that information? I mean, how -- obviously there's a cost. That's -- I guess I'm saying, what is the cost? Because you're providing using public funds --
ATTENDEE: They can charge. Under that

law, they can charge the cost of reproducing --
ATTENDEE: So you do do that?
MS. RUGG: Yes.
ATTENDEE: Charge to recoup the costs?
MS. RUGG: Under the terms of the -- under the public records act. It is not a great deal. It does -- in some cases it doesn't really cover our costs, but there is prescribed costs in that particular situation.
ATTENDEE: So it doesn't actually cover -- I mean, if it covers just for copying, it doesn't cover staff time or things like that.
MS. RUGG: Right. Only -- only within -- there are prescribed amounts that can be charged.
MR. SLEN: And there are requests that come in on a more broad -- from a more broad perspective that require significant work, and some entities do pay for that work, to do programming and things like that, to get information that's not readily available. So that -- that does happen also.
ATTENDEE: And how long -- you said you get these requests regularly.
About how long has this been, in your

mind, that they've been coming in?
MS. RUGG: All of us.
ATTENDEE: Pardon?
MS. RUGG: All of us. I mean --
ATTENDEE: No --
MS. RUGG: -- it is not unique to this, that these data compilers would contact us and ask for specific information under public records.
ATTENDEE: Right. But what I meant was, is it 15 years, 20 years, 10 years?
MS. RUGG: Oh. Oh. Normally it's -- it's usually within the last year. In some cases it's very specific, the last quarter, the last six months. It's current information that they're seeking.
ATTENDEE: I'm still not being clear.
How long has this been going on, this practice, in your experience? Is it fairly new? Has it been happening for the last five years, ten years?
MS. RUGG: I think there's a greater frequency. I have been affiliated with our pharmacy benefit management program since 2001, there has been increased activity.

I can't say -- I wouldn't know if it's -- well, actually, in one case, in this GHX, they seem to be a relatively new entity. Data Niche has been asking for information for probably the last 10 years. And others, you know, it's sporadic. You know, it just seems to be a greater amount of requests at this point. Now, whether it's because it's become more of a public issue -- and I don't mean related to this bill. But in the last year or two, the high cost of drugs, the greater degree of management, the very fact that in our preferred drug list then ultimately there are non-preferred products, and it would be those manufacturers that would be targeting prescribers to try to promote the use of the non-preferred item over the less expensive preferred items. So we feel it's a direct correlation with, you know, the development of our preferred drug list.
ATTENDEE: Can I --
ATTENDEE: If we can move along.
ATTENDEE: I think we can do that some other time. But I just want to understand what you just said, and whether you think that would

increase the cost of drugs to Medicaid by what you just said.
ATTENDEE: Absolutely.
ATTENDEE: And can you just briefly explain why that is so.
MS. RUGG: If for no other reason than the manufacturers have information so they can target products that are non-preferred, thus they cost the program more money.
ATTENDEE: And the manufacturers get more money because they don't pay the rebates, is that why?
MS. RUGG: They don't -- they don't agree to provide supplemental rebates, but the products then heavily promoted are then costing us more than the alternatives that are available on the preferred side.
ATTENDEE: I've got to ask this one: What about the PDL? I mean, you know, I know we wrote into language that Medicaid patients have to go, you know, buy generic first, then, you know -- so how do they get off the PDL list? I mean, I don't understand where any of this should even make a difference for Medicaid.
MS. RUGG: Well, federal Medicaid law says

that you have to have an open formula. Any product that the manufacturer pays that federal -- that first rebate is available to a Medicaid beneficiary. So effectively, think of it as you have a preferred side and a non-preferred side. The preferred side is less expensive, the generics low cost alternatives are those with rebates. The non-preferred are the more expensive products. But you can't say no one can have the non-preferreds.

And there may be valid, clinical reasons. You know, you work your way through the products that are available, that are less expensive. And then the more expensive product may still be the only one that meets the beneficiary's clinical need.

So -- but it's up to the prescriber to prescribe it, to request a prior authorization, to provide the clinical information that supports the need for that drug. And in that sense, if the manufacturers are targeting the providers, the prescribers that are -- that are not prescribing the non-preferred drugs, promote their use, encourage their using those products, then we'll see a great -- we see a

greater number of calls just trying to access the more expensive product.

ATTENDEE: But I don't understand where a doctor would go through all the paperwork involved to override the PDL, because it's not an easy process. It's not -- he can't just call up and say, this is what I want and that's too bad. There's steps that need to be taken now in Medicaid.

So, I mean, to me it just seems like it's an awful lot of paperwork for him to allow a patient to have the more expensive drug than the generic first. I mean, it's mandated that you have to do those steps.

MS. RUGG: Well, let me give you --

ATTENDEE: I mean, maybe not in insurance companies, but certainly in Medicaid.

ATTENDEE: I'm sorry. I just need to move this along here.

MS. RUGG: Could I give you just one example and that will do it, I promise?

ATTENDEE: Well, do you have other things you want to tell us about here or --

MS. RUGG: Well, I would do one more, if you'd give me just a tiny minute.

But in answer, an example was a manufacturer actually pre-produced a PA form with all the appropriate criteria written on it and the language right out of the criteria, so that all the doctor had to do was sign it.

ATTENDEE: Hmm. Maybe we need to tighten up the Medicaid requirements then.

MS. RUGG: Well, in this particular case the DUR board requested that we send a notice to all prescribers that we would not be accepting that and they would need to provide additional information from the patient record. But there was an example of how (inaudible). And if you want to, I can cover that if you'd like to.

ATTENDEE: If you can finish up quickly, that would be great. Thank you.

MS. RUGG: Sure. There's a proposal in the bill that suggested a thousand dollars per calendar year be charged to each pharmacy, pharmaceutical manufacturer to support the cost of the counter-detailing program that would be administered by the Health Department. And what -- and in a nutshell, what we're suggesting here is that we do it rather on a

percentage basis, because some manufacturers actually do not sell. They do not sell products equal to a thousand dollars in a given year. Some of them are very small. And so the way that we crafted this particular one would generate just about the same amount of revenue, and it's based on a half a percentage point based on the identifier for each manufacturer and the drugs spent -- spend in the previous calendar year.

ATTENDEE: Okay. Thank you. (Inaudible).

Back on the one that you were just talking about, with the public records law, do you know already that -- is this BISHCA okay with this?

MS. RUGG: Yes, they are. There actually was an earlier draft in which we thought they wanted protection from the records requirement, and they specifically said they did not. So we removed -- where it says records held by the agency in human services, at one point we thought they would want that protection as well, and they indicated they did not.

ATTENDEE: But as far as --

ATTENDEE: Paulette indicated this morning that maybe they did. So they might have

changed their mind on that.
ATTENDEE: You mean to add them into this?
ATTENDEE: Maybe. I think Paulette is considering that.
ATTENDEE: Well, but then I'm also -- I want to make sure that we aren't creating a problem as it relates to getting the data, releasing the data to them (inaudible) multi-payer database.
MS. RUGG: No. We thought at the time --
ATTENDEE: That's the reference to title 18?
MS. RUGG: -- that we were fine.
ATTENDEE: Yeah. Well, the chapter 91, subchapter 3 is the prescription drug data confidentiality, which has an exception for the multi-payer database. So they should be fine on that. But I can check with them to make sure they --
ATTENDEE: All right.
MS. RUGG: And the AAG's (sic) office also reviewed that language.
ATTENDEE: Thank you.

COUNTY OF SEMINOLE.)

I, Christina Gerola, Notary Public in and for the State of Florida at Large, do hereby certify that I was authorized to and did listen to CD 07-129/T4, the House Committee on Health Care, Wednesday, April 11, 2007, proceedings and stenographically transcribed from said CD the foregoing proceedings and that the transcript is a true and accurate record to the best of my ability.

Dated this 20th day of August, 2007.

_____

Christina Gerola
Notary Public - State of Florida
My Commission No.: DD617707
My Commission Expires: 12/10/10

STATE OF VERMONT
HOUSE COMMITTEE ON HEALTH CARE
PART 2

Re: Senate Bill 115
Date: 4/11/2007
Type: RX Drug Regulation

Committee Members:

Rep. Steven Maier, Chair
Rep. Harry Chen, Vice-Chair
Rep. Francis McFaun
Rep. Sarah Copeland-Hanzas
Rep. William Keogh
Rep. Lucy Leriche, Clerk
Rep. Virginia Milkey
Rep. Pat O'Donnell
Rep. Hilde Ojibway
Rep. Scott Wheeler
Rep. John Zenie

CD No: 07-130/T1

Reported By:
Christina Gerola
Notary Public, State of Florida
Esquire Deposition Services
Orlando Office
Phone - 407.426.7676
Esquire Job No: 887539

PROCEEDINGS

- - -

CD130/TRACK 1

ATTENDEE: Because of the New Hampshire law and then also the unconscionable pricing cases from the DC area, I'm not sure if you have other things you'd like us to hear about. But if you could maybe just start with a little bit of your background, that would be helpful.

MR. FLYNN: Sure. That's fine. And how many minutes are slotted for this session, including questions?

ATTENDEE: You've got until 4:00. So you've got 50 minutes right now.

MR. FLYNN: Okay. Well, I promise not to take that long. So my name is Sean Flynn. I'm a professor of law at American University. I run a project on -- called the program on information justice and intellectual property. It deals with both intellectual property law itself and also the laws regulating intellectual property protected goods. And that's where our access to medicines project fits in.

I also serve as counsel for the national

legislative association on prescription drug prices, so that's my relation with Sharon Treat's group. And I understand she was scheduled to testify today but has had to go into some emergency dental work, I believe, this morning. So I apologize for that, and I will try to fill in for her as best as I can.

We are -- in my work on behalf of NLARx, we are involved as a meekas (phonetic), as a meekee (phonetic), meeki (phonetic) in the New Hampshire case, so I'm pretty familiar about what's going on in that case.

The data mining provision of the bill that Vermont is looking at is fairly closely modeled on the New Hampshire provision that has been subject to litigation by IMS in New Hampshire Federal District Court.

That case, just to give you the quick update, has been argued and fully briefed and is currently before a judge, but there hasn't been any decision in that case. So I can't really inform you about, you know, any kind of law that's emanating from that case. But I do know generally the kind of arguments that have come up.

Before turning to -- to the legal issues, why don't I just briefly touch on some of the policy issues on the bills and the justifications for it, and then I'd be happy to get into more of any of the legal discussion as a response to questions or some of the things that I know.

As discussed, I'd be most interested in talking about the data mining and the unconscionable pricing parts of the bill. I haven't reviewed closely, although I'm somewhat familiar with, the idea of PBM regulation overall, so if people have questions on that, I may be able to answer them. And I can surely get back to you with answers. So that's helpful.

So let me just talk about the two provisions kind of first together and then separately. As you may know, spending on medicines in this country, since 1990, has increased fivefold. We've had the most -- most rapid increases in medicine prices than any other country in the world. Medicine prices have been increasing at twice the rate of general health spending, which itself has been

increasing at over twice the rate of inflation. We now spend, although this was not always the case, about twice as much as any other OECD country on medicines. Around 1990 the U.S. spent about the same, very similar prices to other OECD countries, and now our prices are about twice as high.

So the big question is, what accounts for this increased spending. About 40 percent of the increases on medicine spending since 1990 can be attributed to price increases in the U.S., predominantly on drugs that are already on the market. So just prices of drugs going up is about 40 percent of the increased cost. Another 30 percent of that increase in spending is attributable to the shifts in doctors' prescribing habits from cheaper, sometimes generic, sometimes not drugs to more expensive, usually newer, almost always brand name prescriptions. So 40 percent is price increases and 30 percent is prescribing habit shifts towards more expensive drugs. So the two aspects of the bill I want to talk about are really trying to address those two problems directly.

The data mining provision is focused mostly on the shifting of prescribing habits to more expensive drugs. And so let me talk a little bit about the links between data mining and the shifting of prescribing habits.

So first of all, about 86 percent of pharmaceutical marketing expenditures is spent directly on marketing to doctors. Now, if you think about that, you know, for a little bit, the reason for that, although we see the direct to consumer kind of television advertisements most in our daily lives, the fact is most marketing is actually done at doctors for the simple reason that doctors prescribe our spending habits on medicines. If there was a person whose job it was to prescribe your next car, you can guarantee that most marketing would be geared towards that person instead of general consumers.

So about 86 percent of all marketing is spent on doctors, and the marketing itself in the pharmaceutical industry is a huge piece of the pie. They spent, in 2004, about $27 billion on drug marketing. 86 percent of that was devoted specifically to doctors. The

pharmaceutical industry spends more money than any other industry in the country on its sales force and on media advertising. So the pharmaceutical industry is spending more on advertising than anybody else, and most of that money is directed specifically towards doctors.

Now to weave in some of the data mining. So in the 1990s, the way pharmaceutical companies targeting their marketing fairly radically changed. And it changed through the process of prescriptions becoming more and more online, more and more computerized, digitized, allowed for companies to access that data by purchasing it from intermediaries, and then sorting it through huge computer programs, what we call data mining programs, to sort that data in various ways. And this became perfected through the 1990s by companies like IMS and other companies.

Then they started purchasing the data set that the American Medical Association has, what they call the physician master file, which is a data set on every physician in the country, whether or not they're an AMA member. And by sorting the prescriptions that the IMS

purchases from either pharmacies or pharmacy benefit managers, intermediaries, et cetera, by purchasing those raw prescriptions and sorting it and comparing it against the AMA master file, these companies can identify every prescription that is written by a specific doctor in the country. Essentially, every prescribing doctor can be tracked. And their data can be tracked on a day-to-day basis.

So today, a pharmaceutical representative that we call a detailer can tell from one week to the next if their sales calls were efficient, if they resulted in shifting doctors' behavior from one drug to another. They can identify what they call, in their own lingo, cowboys, which refers to doctors that are more willing to prescribe untested or new drugs and target their marketing of new drugs towards them. They can identify things as crass as what kind of, you know, meals are more effective than others in marketing and in shifting prescribing habits, what kinds of gifts are more effective than others, whether granting a consultancy or a speaking fee to a certain doctor will motivate their behavior

more than others, and even, according to some studies, you know, the kind of detailers' physical appearances that a doctor may prefer.

The data can also be used to have kind of a subtle disciplining effect. A detailer can enter an office, and when they try to sell something, like any salesperson, they attempt to extract promises from a doctor to, for instance, you know, shift from one statin to another, from a generic to a brand name drug. And then they can actually consult that data to find out if, in fact, the doctor did shift their prescribing behavior. And they can come back into the office and either subtly, implicitly, or sometimes even explicitly discipline the doctor for not having shift -- you know, kept that promise. You know, they can indicate to the doctor that they're aware of the doctor's prescribing habits and encourage them to act upon the information that was given before.

So there's a number of studies that indicated this kind of behavior has a very serious impact on drug prescribing behavior. Some of the most direct evidence we have about

how effective it is is just how much spending has increased on this kind of behavior since data mining has come into fruition.

So, for instance, since 1997, between 1997 and 1990 -- or 2002, the pharmaceutical industry as a whole doubled its sales force to over 90,000 drug representatives, which is about one in every five office based physicians in the U.S. Their spending on direct marketing increased by over 275 percent between 1996 and 2004. And as I mentioned before, there's been about 30 percent of the fivefold increase in drug prices since 1990 has been attributed to shifts of doctor spending towards higher prices.

So all of this story is to say that there's basically three core motivations behind data mining protections. The first is privacy. The bill that's in front of you protects both patient privacy and prescriber privacy. The patient aspect, HIPAA already prohibits the sale and transfer of patient identified data; however, that law is not very well enforced, and so the Vermont law adds a new enforcement mechanism for what's already protected under

federal law. But HIPAA doesn't at all ban the trading or selling of prescriber identified data, so this bill adds a new privacy category that doesn't exist under federal law.

Second justification is cost. As I mentioned, the shifting of prescribing data that's been made very efficient through the data mining based pharmaceutical marketing has lead to -- you know, has helped lead to the skyrocketing of medicine prices.

And the final is just a public health objective, that increased quantity and efficacy of direct marketing to physicians has led to shifts in drug behavior that may not be appropriate. There's been an increase in the amount of inaccurate information that's been discovered coming out, and in general it leads to, you know, kind of the corruption of medicine and the doctor/prescriber relationship in a way that is infringing upon public health. So the three justifications are really privacy, policy and public health.

Now let me maybe -- let me maybe pause here for a minute and just ask, are there any questions particularly that I can respond to

about this bill, arguments that you've heard against it, et cetera, before I move on to the unconscionable pricing bill?

ATTENDEE: I actually just wanted to ask, you said that -- was it from 1996 to 2004, the number of detailers has doubled? Did you say something like that?

MR. FLYNN: I think it was 2007, but let me just correct that number. Let me just see.

From 1997 to 2002 the pharmaceutical industry doubles its sales force.

ATTENDEE: Okay. Because we were told by somebody yesterday representing some aspect of the industry that they actually are -- that they're saving money because they don't have to send people out to do all this detailing, that -- where they don't really know, they have to do the buckshot approach. My words, not theirs. But -- and it -- they -- I got the impression from what they said that they were telling me that there's less of this going on because they can really target people now. (Inaudible) --

MR. FLYNN: No. No. Quite the opposite.

ATTENDEE: (Inaudible.)

MR. FLYNN: They may be saying that -- that the process, the marketing, is much more efficient with data mining, and that's absolutely true.

ATTENDEE: Um-hmm. They said that too.

MR. FLYNN: But because the process of marketing is more efficient, the dollars spent on marketing have a higher rate of return. So there's an incentive for them, and they have, in fact, spent more on marketing, not less, because of the ability to target their marketing this extremely efficient way.

So it's true that the buckshot approach would be less efficient, but that does not translate into and therefore we spend less on it with this more efficient approach.

ATTENDEE: Okay.

MR. FLYNN: Do you see my point?

ATTENDEE: Yeah, I absolutely see your point.

MR. FLYNN: And I can give you a cite, if you would like a cite for that figure I quoted. It's 5, Yale Journal of Health Policy Law and Ethics, 786. And that's a 2005 article.

ATTENDEE: Can you say it again?

MR. FLYNN: It's 5, so volume 5, Yale Journal of Health Policy Law and Ethics, and then page 786. And that's a 2005 article, Yale Journal of Health Policy Law and Ethics.

ATTENDEE: The other question I had was -- I apologize if you said anything about this, I was out of the room getting an answer to another question. If -- if physicians opt out of the AM -- of having their data used for marketing purposes, the data that the AMA has --

MR. FLYNN: Right.

ATTENDEE: -- can the data mining companies get that information from some other source or as it's passed somewhere else, you know, a different tier of the system and reassemble it and reintegrate it from a different source somehow so that the pharmaceutical companies can meet the law but still get around it?

MR. FLYNN: Oh, I may be confusing two things. Are you talking about the AMA opt-out program?

ATTENDEE: Yes, I am.

MR. FLYNN: Yes. Okay. So under the AMA

opt-out program, when -- if a physician opts out, they do not opt out of AMA selling their prescriber identified information to data mining companies.

ATTENDEE: Right.

MR. FLYNN: They do not opt out of that.

ATTENDEE: I understand.

MR. FLYNN: The only thing they do opt out of is the data mining companies are then supposed to -- I don't know exactly how this works. Are supposed to instruct the pharmaceutical companies that that data should not be used to be given to specific detailers walking into a shop.

ATTENDEE: And the pharmaceutical representative said this morning that they have a firewall, and the detailers don't get to see that integrated information.

MR. FLYNN: That's right. The detailers don't get to see it. The head of the marking office can still see it. You can still instruct your detailers about which doctors they should go to based on the data. The salesperson, the detailers themselves, cannot see the data. But the person in the

pharmaceutical industry can still see the data, the company as a whole can still see the data. So they can still construct their marketing preferences based on the data. They can still reward their detailers based on the data, and they can still use the data to track specific physician performance. But they have to do that at the other side of the firewall. They can do it -- the data miner doesn't see it, as is usually the case --

Data miners literally can sit in their car and pull up their laptop and look at what a doctor's performance is. If the physician opts out, the person with the laptop has to be on the other side of the firewall. But that data is still fully accessible to the pharmaceutical company.

ATTENDEE: Okay. That answers part of my question. But in testimony we had yesterday, I thought we were told that -- and maybe that was it, that there were other ways that the data mining companies could get the information --

MR. FLYNN: They already get it. I think that's a -- it might be a confusion, because the data -- the data mining companies still get

the data from opted-out physicians.

ATTENDEE: I understand that, but --

ATTENDEE: This is the question. I think what she heard was that if the AMA suddenly dropped off the earth --

MR. FLYNN: Okay.

ATTENDEE: -- and their data file was no longer -- master data file was no longer available, I think what was suggested to us was that there would be other ways that IMS could get that data that they could match, then, with the other prescriber files.

MR. FLYNN: Oh, okay.

ATTENDEE: Which led to the rest of my question, which is for those doctors who don't want that information used by detailers, is there -- is there an alternative way for the data mining companies to get the information, even though they have the AMA information, and put the other source's information together with what they get from the pharmacies and come up with the same information so that the detailers can use it when it didn't come from the AMA? That's what I thought (inaudible) --

MR. FLYNN: I think the short answer is

yes.
ATTENDEE: Okay.
MR. FLYNN: The AMA data is not -- it's not the only -- it's not the only way that they match up to patients -- to physician identities. It's one of the ways they do. But the AMA process -- getting the AMA data is -- in some respects, it's cream. I mean, it makes -- it makes the data file that they're using more full. But in many instances the prescriber is identified on the prescription itself. And so they don't even need the AMA data to cross-register it, although the AMA data can, you know, help them by providing the actual physical address and the doctor's specialty. But all that information is publicly accessible in other ways.
So I think -- I think the answer to your data -- I think the answer to your question is yes, even if, for instance, the AMA disappeared, there would still be a need for legislation if what they were trying to accomplish was not have physician identities being bought and sold for pharmaceutical marketing purposes.

ATTENDEE: Thank you very much.
MR. FLYNN: Sure.
ATTENDEE: All right. Lucy and then Hilda and then (inaudible) --
ATTENDEE: Thanks so much for talking with us, Sean. This is really interesting testimony.
This morning we heard from a representative of PhRMA who said that, in fact, if they weren't able to -- if they weren't able to access the information from data -- from the AMA and do this -- this detailing, that, in fact, there would be a lot of research that wouldn't happen and that there would be a real public health -- it would be a step backwards in terms of public health.
I was wondering if you would comment on that.
MR. FLYNN: Yeah. Absolutely. I think that's a large red herring. I don't think it's true. And let me read you a quote from Jerry Avorn, who is the chief of the division of pharmacoepidemiology in the department of medicine at Brigham and Women's Hospital, and he's a professor of medicine at Harvard Law

School, and he's written books on this subject.
He testified on a related bill in Maine that I have in front of me. I don't know if you submitted comments on this bill, but his comments would be the same. Now let me just read this paragraph.
So he says our research unit has published about 200 papers in peer-reviewed medical literature using prescription claim data, the kind of data that we're talking about, for research and public health purposes. Like other groups doing such work around the country, we obtain the detailed medication use data we need from state and federal insurance programs such as Medicaid and Medicare. Other research groups obtain equally detailed medication use data from a variety of HMO data sets, the veteran's affairs medical programs, et cetera. Researchers have numerous opportunities to access such data from sources other than IMS and similar companies. In fact, these other sources are far more useful for research because they contain more detailed data about patients' diagnoses and the use of clinical services.

It is therefore clear to us that the actual not effective legitimate evaluation of prescriber identified prescription information for non-commercial research use (sic). Indeed, this statute specifically excludes (inaudible) from its prohibition.
So that would be my answer. I mean, just to summer (sic) up, Avorn, he's saying the useful data can be received from federal -- from federal and state government programs including Medicaid, Medicare, et cetera. They can also still be received from HMOs or from the Veterans Administration, et cetera. So there doesn't appear to be any real legitimate research impact on this.
ATTENDEE: Okay. Thank you. And one other question is, I'm wondering if you have your -- if you happen to have written down all of the testimony that you just gave us at the beginning here, because you -- you threw out quite a few statistics that I found very interesting, and I would really love a written copy of your testimony.
MR. FLYNN: Sure. I'd be happy to send that along.

ATTENDEE: Thank you.
MR. FLYNN: And should I send it to your staff member who I've been --
ATTENDEE: That would be perfect.
MR. FLYNN: Okay.
ATTENDEE: Just so you know, Sharon Treat e-mailed the committee a packet of material including a letter from Dr. Avorn, and it's ready to hand out to the committee. And I'll pass it out, you know, at the end of the day or something like that.
ATTENDEE: Sean, just a follow-up somewhat on Lucy's, because you said, you know, three reasons, the policy reasons for why this is good legislation.
The public health I was very interested in, because again, from what we've heard so far, first of all, is what Lucy said, if we don't have this available, we won't be able to have good research information. Second argument was that when drugs create a problem, that this allows a fast and easy way to communicate directly with the patients, and if this weren't available, then I suppose the communications would be delayed and they'd be

in danger longer. I think that's the -- that's how it would be a negative public health --
MR. FLYNN: Right.
ATTENDEE: Right. But I'm really interested in -- you said how are other ways. When there's -- when physicians are influenced to use drugs that may not be in the best interest of patients, which is what it makes it sound like here can happen, I'd be more interested in getting information about how this changing prescriptive behavior creates a public health hazard or a danger.
MR. FLYNN: Right. Right. So, I mean, first let me just respond very briefly. I had already hit the first point. But their second point, that you wouldn't be able to notify doctors, you know, if the FDA finds the next VIOXX, and you need to tell all the doctors that -- you know, that they need to stop prescribing some dangerous medicine, that just seems pretty flatly untrue.
The federal government already collects data. This is -- I mean, if you've heard about the DEA numbers that are included on every prescription, and that's required by law, one

of the things that the AMA does is provide DEA numbers and link them up to names and addresses for marketing purposes. But the federal government has at its disposal that information already that it can use for, you know, public health threats, et cetera.
In addition, there's still -- you know, pharmaceutical companies do maintain records of, you know, generally what doctors are prescribing what medicines without getting, you know, down to the details of when everybody prescribes what.
I just don't think that's a valid concern, that it would prohibit anybody from responding to a public health threat once it was released.
Okay. On the other -- the side of the other public health issues on -- basically what the data mining process does is highlight and make more effective the worst parts of our pharmaceutical distribution chain. So we allow in this country -- you know, if you -- if you thought about what's the opposite of data mining and detailing, it would be something that Jerry Avorn calls academic detailing, where you had public interest, public health

professionals that would provide unbiased information to doctors about the relative risks and rewards of different medicines. Right? And those individuals would have no pecuniary interest in you buying one drug or another. Their actual job would be to provide you with the most objective information available. And there are programs like this. Jerry Avorn has designed one. There's one in place in Pennsylvania where you actually pay people who act like detailers, except they provide unbiased information that's backed up through medical science.
Now, what we have in this country is kind of the opposite of that. We rely, to a large degree, on the information from the people selling those drugs themselves to construct, you know, quote, unquote, scientific information to give to doctors with the specific objective of increasing the bottom line of that drug company. Now, they couch their information, you know, with whatever scientific information that they can in order to convince someone to shift their drug purchases, but the drug companies have a very

well-known pecuniary interest to cover up information that is not in the best light of their drug and to highlight information that makes them look good.

That process has negative public health impacts in that it carries a large, market-based incentive to not provide doctors with the full story. So doctors that rely on that more than they rely on the more objective ways to figure out which drugs they should be prescribing will be more likely to fall into the traps of prescribing medicines that won't be in the best interests of clients.

The data mining piece comes into that and makes -- and makes the whole process super charged. It enables the detailers to know exactly what marketing impacts work the best on an individual, doctor-by-doctor level and focus on those impacts on that doctor.

I mean, just to give a small example, I mean, my own doctor, I went in a month ago and talked to him about his detailers. And, you know, he's, there's no way I'm at all influenced by detailing to prescribe one drug over another. Now, of course if there is a

list of drugs that were all similar to me, I might prescribe a different one because I especially liked this one detailer.

Now, that's exactly the wrong way to prescribe drugs, and it has negative health impacts on our country when you're choosing drugs between a list based on which salesman you like best. So removing the data mining helps remove a little bit of the super-charged atmosphere that surrounds, you know, drug sales by detailers. It doesn't remove it entirely, and there's First Amendment problems with being able to deal with this in an entirely public health focused way. But it attempts to decrease the most kind of super charged aspects of it.

So is that clear, or more questions on that?

ATTENDEE: Yeah, that's fine. But I guess if there was any articles or any evidence that shows how it's had a negative -- I completely understand what you're saying. But if there was any evidence showing the negative impact that you could refer us to, that would be helpful.

MR. FLYNN: Sure. And I think -- I don't know that I've seen any specific article expressly linking the data mining. What we have is a large amount of information about the fraudulent marketing practices by pharmaceutical companies, where information that's in the marketing materials that they give to doctors is wrong, like they're giving false information to doctors and promoting their drugs. And the amount of information that flows of that kind is then -- we know is increased under data mining. I don't know if anybody has put the dots together in an empirical way showing that data mining, you know, impacts false advertising by this amount.

ATTENDEE: Okay. Thank you very much.

MR. FLYNN: Sure.

ATTENDEE: (Inaudible) was on my list. And then Patty. Okay.

ATTENDEE: Sean, I wondered if you could contrast for me the privacy issues related to data mining and to the fact that physicians already have their prescriber specific information going out through their -- whether it be the insurance companies or the state

insurance companies?

MR. FLYNN: Right. Well, the issue -- so, I mean, I think that's two different issues. So yes, when they write a prescription, they are, in a sense, writing it to an insurance company and a pharmacy. I mean, that information has to be released to a number of individuals along the chain of custody in order for everybody to be reimbursed for the medicine and the medicine to get in the patient's hands, and none of that do we object to and none of that do farmers (sic) object to. You know, I mean, that's part of -- of how that process works.

Where the privacy concerns come in, and just to, you know, paint this with a broad brush, data privacy concerns come in generally when data that is given to a company for one purpose is then turned around and used usually in a commercial, you know, for-profit way, transaction, for a purpose that was not the original purpose of the data.

And so the question from a legal standpoint is, you know, should our background rule be that companies can do whatever they

want with the data they held no matter if that was the purpose for that data to be released, or should the background rule be a privacy protecting rule that the data that is released by someone should only be used for the purpose for which it was released without an added layer of consent, et cetera.

So when doctors release a prescription which contains their name to a pharmacy and then it's relayed to an insurance agency, all that is within the contemplated chain of custody of that prescriber information. What's not normally contemplated when a doctor signs their name to a prescription is that that data will then be sold to pharmaceutical companies to target marketing to them.

So you'll find, you know, in the materials I'm sure you have in front of you, you know, many statements of exasperated doctors dealing with data miners who had no idea until some data miner tells them why didn't you prescribe my drug last week, that this information was actually getting all the way to pharmaceutical companies, you know, without -- without their knowledge or consent. So that's one issue.

And then of course there's a whole other issue about this isn't just any kind of data. We're not just trading doctors' names and addresses, we're trading part of patients' medical files. You know, there's some small part of the patient's medical file that's being traded without either the doctor or the patient's consent. So nobody tells the patient, when you bring in a prescription, that your doctor is going to sell it or that somebody else is going to sell it to a pharmaceutical company to target marketing either to that doctor, or in some extents we still have stories of individual patients receiving targeted marketing from pharmaceutical companies, even though that was supposed to be outlawed by HIPAA.

So there's a whole -- there's a whole range of uses of that data that were never contemplated in the original prescription, and those uses that go outside of the contemplated use are when the privacy concerns come in. Now, I don't mean they're constitutional privacy concerns. There's (inaudible) unconstitutional about what's going on here.

But it's -- privacy becomes one of the objectives, the valid objectives of the legislature in regulating these transactions.

(Inaudible.)

ATTENDEE: Sean --

ATTENDEE: I think we need to try to leave some time for the unconscionable pricing.

ATTENDEE: Sean, are there any states that license detailers?

MR. FLYNN: I don't -- I'm not sure if there are any states that do. I know for a fact there are several states right now that are contemplating it. And I'm trying to think. There is -- I'm just trying to think of which of these have been released. I know there is a proposal that has been released in West Virginia, and I know that there are several other states that are considering this now.

ATTENDEE: And along with that, does -- in terms of -- and for me, my concern is about misinformation (inaudible) drugs that really don't do anything for people, or do anything more than what's already out there, not -- you know, I want people to get the right stuff.

MR. FLYNN: Of course.

ATTENDEE: And if detailers are distributing misinformation or fraudulent information or just not complete information, are there any current ways that states -- that they can be penalized for that, or would the licensing be the route to take if that was something that we wanted to do?

MR. FLYNN: Yeah. Not having an intimate knowledge with your own law, I'm not sure whether or not there's anything in Vermont's law that would -- that would hit that. There may be. There may be something in your consumer protection act that, you know, deals with fraudulent statements by the seller of goods that's broad enough to cover this information. The licensing routes usually cover, specifically, that information.

So one of the problems, for instance, is that it's already illegal, under FDA rules, to give certain kinds of fraudulent information from pharmaceutical companies to doctors, et cetera. That's not always enforced very regularly. And then there are, you know, certain aspects that are less regulated than we would like them to be.

So I know licensing provisions, one thing the licensing provisions are attempting to do is set up an educational requirement to be a detailer, like actually regulate them as a profession and require that they have a background in science, for instance. Another thing that they do is actually, you know, prohibit certain practices and say that -- set up a complaint process and set up a process for delicensing people who violate the process, regulating gifts.

So there are numbers of steps along this way, and if you're interested in going this route, you should, you know, certainly talk to your staffer, and there are some models and things that you can look at out there that we'd be happy to help you with.

ATTENDEE: Thank you.

MR. FLYNN: Sure. So let me -- let me go briefly over to the unconscionable pricing and just reopen it for questions on the two levels.

So the unconscionable pricing piece is aimed at the other of -- the second leg of why spending on medicines generally is very high in this country, especially over the last two

decades. So about 40 percent of the fivefold price increase since 1990 is due to price increases of existing drugs, and some of those price increases are rather astronomical.

Currently, most of the price restraint that we have in the United States on pharmaceutical pricing is through some kind of pooled purchasing. So you're a state or you're the federal government or you're a huge purchaser in some way or another, you can negotiate lower drug prices with drug companies, you can create formularies that exclude higher priced medications or exclude medications that don't seem to do -- that aren't -- that aren't cost effective when balancing their effectiveness versus their cost, et cetera.

When you are an uninsured person or an individual payer, you're not protected by any of that, and you're completely open to the vagaries of the market, and especially the vagaries of this particular market in which pharmaceutical companies are selling, in many case, an essential good, something that's needed for people to maintain their health and

well being, and often under monopoly conditions created by patents.

This is the only real provider of an essential good and service under monopoly conditions that I can think of off the top of my head that's not subject to some kind of routine price regulation by either states or the federal government. And because of that, there are some, you know, a number of fairly absurd abuses of that practice.

One that comes to mind, for instance, is the drug Norvir, which is an essential AIDS treatment, which, in two days before Christmas in 2003, the company raised the price by five times only in the United States, not in any other countries, pushing the price to well over $40,000 a year for a drug that used to cost $8,000 a year. People that are paying for that drug out of pocket, I mean, many people literally can no longer take their medicines. And there's lots of examples like that.

So the unconscionable pricing piece attempts to put an overall cap on the most needed medicines. Let me just turn to it.

I guess, are there any particular

questions on this that I should focus on?

ATTENDEE: Well, I would be -- I'd be particularly interested, since I know you've been involved in the DC case --

MR. FLYNN: Right.

ATTENDEE: -- have you actually had a chance to review the specific language that we have in front of us, or there's several options of language as to whether our legislative council has -- we haven't been through this in detail yet, but has suggested to us at least that she believes she's going to try to write the language of this more narrowly to address some of the concerns that were raised in the court case. So if you've had a chance to look at that, I'd be interested in your thoughts on that as it relates to what the court decided in the case down there.

MR. FLYNN: Right. Sure. Happy to.

So first of all, there was a DC unconscionable pricing act. It was overturned at the district court level. It is now on appeal. That case was argued last week in front of the federal circuit, and there's not a decision yet. So we don't know exactly what's

going to happen in that case.
ATTENDEE: And your --
MR. FLYNN: I can tell you there's several specific ways that this bill is different that responds to some of the arguments that were accepted by the court below in the DC case.
One major one, which I think is very important, is that the DC act limited itself to the regulation of patented medicines, and that gave rise to a challenge to the DC act, that it was discriminating against patented medicines. By only targeting their regulation towards that was therefore preempted by the federal patent act. So I think the targeting of this bill towards all medicines is a good step forward of kind of avoiding that kind of argument.
We will hear, and there most likely will be some kind of lawsuit. The position of the pharmaceutical industry is that any regulation of pharmaceuticals is preempted by the patent act, because they believe that the patent act gives them an unrestrained monopoly right to price at whatever they want.
I don't believe that argument is tenable. You may hear it, and this act very well may be

sued on that basis. But I think the targeting of patented medicines -- of removing that aspect is a large step.
The other aspect that the DC court was focused on was a commerce clause issue of not permitting DC to regulate sales that take place wholly outside of DC's borders.
So there's several places in the Vermont act where it makes quite clear that what you're regulating is sales that take place in Vermont. And I think that's a good change and just makes it clear what should have been implicit in the DC act was that they were regulating within their police power jurisdiction, they weren't trying to regulate national sales prices. But to the extent that any court needs to be informed of that directly, I think this bill does that.
There's one aspect of this bill that troubles me a little bit, not necessarily from a legal but more from a policy angle, the unconscionable pricing restriction is narrowed to address only conditions that are a serious public health threat, and then it has a subjective mechanism for determining what those

mechanisms are. So the health commissioner is required to issue a declaration and consider various things.
My concern there is I think your -- I don't know what your commissioner of health feels about this, but you're setting up your commissioner of health to get a large number of visits by pharmaceutical lobbyists on a routine basis. I would rather have an objective criteria that has no discretion built into it to cabin that lobbying and just leave it out.
So one suggestion I might make is that the Centers For Disease Control has a list of serious health conditions on their website, and you could just refer to that. So any drug that treats a condition identified by the Center For Disease Control on their website, and I can provide you that website address, should be declared as serious, but, you know, should be equated to a serious public health threat in the (inaudible), something like that. I would be -- I would be trying to find an objective not subjective criterion for determining the trigger for that.
ATTENDEE: A list of what, again?

MR. FLYNN: It's a list of the -- the CDC has a list of -- what they call it, I think, conditions and diseases.
Here it is. Let's see. Yeah. They have a public website that lists diseases and conditions. It's accessible off of CDC.gov, but the address is somewhat longer. I can provide it to your staffer if you would like to look at it.
But I would endeavor to try to use that or a similar kind of preexisting -- Vermont itself, the department of health, you may ask them. They may have some kind of list of, you know, diseases and conditions that they give some weight to as being, you know, health conditions that they've determined for other means. But I think it would be preferable to refer in the act to something existing rather than, you know, set up some kind of administrative route to negotiate these things on a case-by-case basis.
ATTENDEE: A question that I had is when you see this legislation and it comes up, I have no idea when it says, you know, that a drug that is over 30 percent higher than prices

available to federal drug agencies, I have no idea, out of all the drugs that are prescribed, how many might fall into this category.

I mean, you gave an example of something used to treat AIDS, but I don't know how widespread a problem this is.

Do you -- do you -- can you give me information on how widespread it is?

MR. FLYNN: Not really, because really the drug prices in this country really differ state to state. What we're talking about is drug prices to people who have no collective bargaining power, so people who essentially are, you know, paying the raw, retail price of a drug, et cetera. And I don't have any data on, you know, comparing those things to the federal supply schedule, for instance.

Where would that data be? So Families -- Families USA may have something. I mean, the two places that do drug studies -- the two organizations that do drug pricing studies are -- AARP puts out a drug pricing study every year or actually quarterly. And I don't remember whether they have -- I think they do have -- one of these has a section.

So the other one is Families USA. It's an organization based in DC that does a large number of drug pricing studies. And I think the Families USA website contains a pricing section that does have some information comparing prices to the federal supply schedule prices. I don't know what the Healthy Vermonters price or the most favored purchase price would be. But the one thing where you probably could get some data is looking at the federal supply schedule versus, you know, drug companies average wholesale price, something like that.

ATTENDEE: Thank you.

MR. FLYNN: Sure.

ATTENDEE: I have more. Can I keep going? Okay.

Another question I have, getting back to the previous issue, supposing that the data mining supply is dried up on the physicians' side, but an increasing number of prescriptions are written by nurse practitioners and nurses, right? I mean that's a significant number, and it's a number that's increasing, I believe.

MR. FLYNN: Right. Right.

ATTENDEE: So what is happening in that area? Do they need -- does the legislation need to be -- how big a problem is that and what should we do there?

MR. FLYNN: I believe your legislation does define prescriber -- yeah. It would -- your legislation would currently cover those issues. It defines prescriber as an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice. So if a nurse practitioner is allowed by law to prescribe medicines, then my read would be they would be protected as well.

ATTENDEE: Detailers, do they visit the nurses as well?

MR. FLYNN: Oh, yeah, they do. They visit everyone -- they visit everyone in the doctor's office, often buy them all lunch. So yeah, that happens.

ATTENDEE: Thank you.

MR. FLYNN: Sure.

ATTENDEE: Sean, before you go, could you just -- just so we have it clear in the record here, could you talk a little bit again about

what your relationship is with NLARx and what type of an organization that is and how you're compensated by them for your time today or in other ways?

MR. FLYNN: Okay. Yeah. So I serve as counsel for NLARx, which more often than not is a pro bono position. I'm not being compensated at all today, to my knowledge. And I've been serving as counsel for them for a few years now. And they are a 501(c)(4) nonprofit organization that is an association of -- the members are either state legislators, an entire body of the state legislator, or individual legislators who join on an associate basis. So it's an organization of state legislative officials. And it's headed by Sharon Treat, who is the former president of the main Senate and worked there for many years on drug pricing legislation.

Is that enough?

ATTENDEE: Yes. Very helpful, thank you.

MR. FLYNN: Sure.

ATTENDEE: One more question.

ATTENDEE: Sean, this may be a little off base, but in terms of what we've been talking

about, one of the concerns that I have, and this may not be the place to address it, is in -- when pharmaceutical companies fund studies, academic studies, there have been instances, when a study doesn't actually turn out to have a positive result, they've actually -- they've been able to gag the studies being results -- the results being published in scientific journals.

MR. FLYNN: Right.

ATTENDEE: Is there anything we can do as a state to prevent that from occurring in our state?

MR. FLYNN: There are. Yeah. This -- it's not in this chapter, but the main thing the states are looking at to deal with that problem is to set up clinical trial registries. So that would be a requirement, that a pharmaceutical company that does business in your state post on a publicly accessible website somewhere a list of the results and description of every clinical trial that was done, good or bad, positive or negative, as a condition for selling drugs in your state.

And so there are models you can -- I

believe on the NLARx website, or you could contact Sharon Treat directly. And there's also several states that are currently working on. And I believe -- I'm trying to think of -- I believe there's one or more -- there's a couple of states that have actually passed legislation in this area already. So there's some models out there on that area.

So clinical trial registry is the words you're looking for. And there may be some other solutions, but that's the main solution that's being looked at by states right now.

ATTENDEE: All right. Thank you very much.

MR. FLYNN: Sure. Pleasure.

ATTENDEE: And we appreciate the time you've made available for us today.

MR. FLYNN: Okay. Absolutely. My pleasure. Thank you very much.

ATTENDEE: Thank you.

COUNTY OF SEMINOLE.)

I, Christina Gerola, Notary Public in and for the State of Florida at Large, do hereby certify that I was authorized to and did listen to CD 07-130/T1, the House Committee on Health Care, Wednesday, April 11, 2007, proceedings and stenographically transcribed from said CD the foregoing proceedings and that the transcript is a true and accurate record to the best of my ability.

Dated this 20th day of August, 2007.

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Christina Gerola
Notary Public - State of Florida
My Commission No.: DD617707
My Commission Expires: 12/10/10

STATE OF VERMONT
HOUSE COMMITTEE ON HEALTH CARE
PART 2

Re: Senate Bill 115
Date: 4/11/2007
Type: RX Drug Regulation

Committee Members:

Rep. Steven Maier, Chair
Rep. Harry Chen, Vice-Chair
Rep. Francis McFaun
Rep. Sarah Copeland-Hanzas
Rep. William Keogh
Rep. Lucy Leriche, Clerk
Rep. Virginia Milkey
Rep. Pat O'Donnell
Rep. Hilde Ojibway
Rep. Scott Wheeler
Rep. John Zenie

CD No: 07-131/T1

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