STATE OF VERMONT

HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: April 17, 2007

Type of Committee Meeting: Standard

Committee Members:

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

CD No: "04/17/07, #2 c"
(Made from CDs 136, 137 and 138)
Track

- - -

PROCEEDINGS

- - -

(Start of Track 1 from CD labeled 4/17/07 #2 c, made from CDs 136, 137, and 138.)

ATTENDEE: I feel a little bit like a ping-pong ball, and so before I ask where people stand on this section, I know it's an important one for -- I think if people have additional clarifying questions right now about what this does, let's do that, but otherwise, let's not get-- let's not yet get into --

FEMALE ATTENDEE: Other versions.

ATTENDEE: -- do we think this is a good idea or what the other versions are. Is that okay with people?

FEMALE ATTENDEE: Thanks, yes.

ATTENDEE: Then maybe we can get through this because we know this is one we're going to be coming back to over the next several days.

FEMALE ATTENDEE: Well, this is just my notes on this Section on E, and maybe you can answer this.

I have a note that says, "Why did someone from the Senate put this in? Needs to have more

specific information."

ATTENDEE: Yeah, I think, I think that's just a different -- that's another section.

FEMALE ATTENDEE: Okay.

ATTENDEE: A different section, and I think Robin told us that that was sort of a last-minute accident thing in Section 14.

MS. LUNGE: Oh, Section 14, yes.

Section 14 was in the Senate Finance version and was meant to insure that BISHCA could keep the records that they have in the multi-payor database confidential, and it just wasn't done in a way that works for them, so what happened was Senate Finance put it at kind of the last minute, and then BISHCA didn't really comment on it at that point. It went to Senate Health and Welfare.

They took the whole section out, so BISHCA didn't comment on it because it was gone, and then it got put back in on the floor, so I think you've heard testimony from BISHCA that they are okay with keeping the information confidential, but they still need to get the provider numbers, so this is not the way they would like to do it.

FEMALE ATTENDEE: So at some point, they'll give us the wording they want.

MS. LUNGE: Well, one of the things that they are working on with OVHA and the AG's Office is to is that OVHA had requested a public records exception for the Medicaid data to be added to the bill so that they could keep their data confidential for these purposes, and so BISHCA and Medicaid are all working on that right now.

FEMALE ATTENDEE: Okay.

MS. LUNGE: So I should get that language.

ATTENDEE: You mean they're going to put that in this Bill, you mean? They're working on it in that context?

MS. LUNGE: Yes.

ATTENDEE: Okay.

MS. LUNGE: Yep.

ATTENDEE: Okay. Geez.

REPRESENTATIVE MAIER: Well, does anybody -- before we go completely away from the data mining section, Second 13, does anybody have any more clarifying questions at this point?

All right. Let's go on to 15. Turn a bunch of pages.

FEMALE ATTENDEE: Oh, that felt good.

FEMALE ATTENDEE: Sure did.

ATTENDEE: There's another big section there.

MS. LUNGE: Section 15 is the unconscionable pricing section. 4651 is the purpose. 4652 is our definitions.

The definitions I would in particular point out is the most favored purchase price, which you'll see later on, and that means the price offered with all rights and privileges accorded by the seller to the most favored purchaser in Vermont, and that is based on -- my memory is a little faulty. I think it was a Wisconsin law where they -- the Wisconsin law basically says you can't sell prescription drugs for more than the most favored purchase price, and that was sued, and that language was upheld in their circuit.

So I didn't do it the same way that they did it, but I used their definition because it had been litigated and upheld.

So the meat sort of starts in 4653, and this section says that, "A manufacturer or its licensee shall not sell in Vermont for an unconscionable price a prescription drug necessary to treat a serious public health threat provided for in Section -- " that should be "as provided for in Section 4654 of this title."

4654 is the section which charges the

Commissioner of Health with being the person that would declare that a particular disease or condition constitutes a serious public health threat.

"The AG may request a determination from the Commissioner of Health, which the Commissioner of Health will cooperate with."

B. B sets up the factors that the Commissioner of Health would consider, and these are a minimum, so the Commissioner of Health could consider additional factors, and that is the number of Vermonters that suffer from the condition, cost to the state or insurance or private insurance companies, both employer-sponsored or private, for treating the condition with drugs, the cost of the drug or the class of drugs used to treat the condition. And that should be health condition. That's another error in the amendment -- to the extent that information is available, whether the prescription drug or class of drugs is essential for maintaining health or life, whether consumers affected with the health condition are unable to afford the drug at the current price and then other relevant factors.

4655 is the next step in the process and --

ATTENDEE: Go ahead.

ATTENDEE: How about 6, number 6 under this?

MS. LUNGE: Yes, yep.

ATTENDEE: What does that mean?

MS. LUNGE: It means that the Commissioner can consider other factors that are relevant to looking at whether or not the condition or disease is a serious public health threat and what role the prescription drugs play in that, in treating that disease and the cost, so that allows the Commissioner to look at other things if he or she thinks they're relevant.

ATTENDEE: One other question on that section. If the Commissioner doesn't consider it a threat --

MS. LUNGE: Yep.

ATTENDEE: What, what --

MS. LUNGE: Happens?

ATTENDEE: -- authority does the Attorney General's request have then?

MS. LUNGE: None. The AG has the right to ask them to consider it, but that's it.

ATTENDEE: Has the right to ask?

MS. LUNGE: Right, so they can -- the AG can

say to the Commissioner of Health, please look at, name your favorite disease, and because we really think that could be a serious public health threat, could you please look at it under these criteria. And then the Commissioner could look at it, would consider it and would look at it, and they may say, no, I disagree. That's not a public health threat. And that's the end of the matter.

ATTENDEE: But the fact is the Commissioner has to do that if the AG --

MS. LUNGE: Correct.

ATTENDEE: -- has to consider it?

MS. LUNGE: Has to consider it. They don't have to decide it is a serious public health threat, but they just have to consider it.

ATTENDEE: John?

REPRESENTATIVE ZENIE: I'm going back to the prior page.

MS. LUNGE: Sure.

REPRESENTATIVE ZENIE: About most favored purchase price.

MS. LUNGE: Yep.

REPRESENTATIVE ZENIE: To make sure I'm clear about the definitions of seller and purchaser.

MS. LUNGE: Yep.

REPRESENTATIVE ZENIE: So a seller could be a PBM or a manufacturer?

MS. LUNGE: A seller would be somebody who Trades in drugs for resale to purchasers in this state, so I think that could be -- it could definitely be a manufacturer.

FEMALE ATTENDEE: Definitely a wholesaler.

MS. LUNGE: I'm not sure if it may -- if it's a PBM.

ATTENDEE: Or a wholesaler.

MS. LUNGE: Maybe a PBM who operates mail order.

ATTENDEE: Okay.

MS. LUNGE: Because then they would be reselling.

ATTENDEE: And then a wholesaler?

MS. LUNGE: A wholesaler.

ATTENDEE: Then on the purchaser's side --

MS. LUNGE: Yep.

ATTENDEE: -- is that ever a wholesaler or a PBM?

MS. LUNGE: I mean, it could be a manu -- well, let me think. A person who engages primarily in selling -- it's going to be a factual determination because you have to see what their

business is and whether it's primarily in selling drugs directly to the consumer so...
ATTENDEE: I wouldn't think a manufacturer would ever be a purchaser.
MS. LUNGE: Right.
ATTENDEE: I wouldn't think.
MS. LUNGE: Nope. No.
ATTENDEE: It can be a PBM or a wholesaler.
MS. LUNGE: It could be a PBM. It could potentially be a wholesaler. It could be a retail pharmacy.
ATTENDEE: Okay.
MS. LUNGE: But again, this sets up the most favored purchase price.
ATTENDEE: I know.
MS. LUNGE: Yep.
REPRESENTATIVE ZENIE: Well, that leads into my next question is how is that determined?
Is this like, okay, what was the price yesterday, and how do we find out who got the best price yesterday, or is it an average over the past three months?
MS. LUNGE: A court would decide.
REPRESENTATIVE ZENIE: A court would decide?
MS. LUNGE: Because it's not specifically

spelled out. Either that, or I suppose the AG's Office could do rules or regulations, but I think probably the court would decide what would make the most sense.
REPRESENTATIVE ZENIE: So if there was a public health threat, we'd buy it at whatever price we can get it for, and then we'd argue about whether or not we paid too much later on?
MS. LUNGE: You could.
REPRESENTATIVE ZENIE: Well, I don't see any other way, based upon what you just said. We wouldn't know whether or not we got ripped off or not until --
MS. LUNGE: Well, remember, there's also a whole court process, so I think you'd probably have to do that because if you need to use the drugs now --
REPRESENTATIVE ZENIE: Right.
MS. LUNGE: -- you need to use the drugs now.
REPRESENTATIVE ZENIE: Right.
MS. LUNGE: You're not going to like ask the Commissioner, have them go through their whole process file in court and then go through --
REPRESENTATIVE ZENIE: I agree. I agree.
MS. LUNGE: So, yeah, I think you're right.

REPRESENTATIVE ZENIE: I just wanted to make sure I understood in my head.
MS. LUNGE: Yep, yep. Nope, I'm just thinking out loud too so...
ATTENDEE: Thank you.
REPRESENTATIVE MAIER: I think it's Patty, actually.
REPRESENTATIVE O'DONNELL: Haven't we already named a few diseases as a serious public health threat, like high blood pressure, diabetes regarding -- I mean, has --
MS. LUNGE: We may have. We haven't done that under this process though, so this is I think-- I don't think that would count because that was before this lot was passed, and it's not retroactive.
REPRESENTATIVE O'DONNELL: But if this law passes, and we're still talking about these diseases being serious public health threats, then automatically, wouldn't that kick all of this in?
REPRESENTATIVE O'DONNELL: I think wouldn't the Commissioner of Health would have --
MS. LUNGE: I think the Commissioner would have to go through this specific --
REPRESENTATIVE O'DONNELL: The Commissioner

would have to go through that process, right?
ATTENDEE: Yep.
MS. LUNGE: I would think so because it would -- you'd have to be able to show in court in that the Commissioner has, you know, that the whole process has been set up.
So that's something that maybe should be clarified in terms of the Commissioner in doing rules about what -- and maybe they would want to use a different term than that. That was the term that Senate Health and Welfare picked was public health threat. But I think you're right; that could be a little bit confusing if it's not specified.
REPRESENTATIVE O'DONNELL: Well, right, because it says the Commissioner may issue a declaration that a health condition or disease is prevalent in Vermont. We've already done all that.
MS. LUNGE: Well, I don't know if we've issued an official dec --
REPRESENTATIVE O'DONNELL: Well, she's issued a statement.
MS. LUNGE: Right.
REPRESENTATIVE O'DONNELL: So I don't know if

it's --
MS. LUNGE: Right, right.
REPRESENTATIVE O'DONNELL: -- been an official declaration.
MS. LUNGE: Right.
REPRESENTATIVE O'DONNELL: But not only by her, but the past Commissioner.
MS. LUNGE: Uh-huh.
REPRESENTATIVE O'DONNELL: There have been pretty big statements --
MS. LUNGE: Uh-huh.
REPRESENTATIVE O'DONNELL: -- already issued.
MS. LUNGE: Right.
REPRESENTATIVE O'DONNELL: -- saying that these are public health threats.
MS. LUNGE: So it may -- it may be helpful, and they could certainly do this in the rule-making process to set up sort of what an official declaration under this section means, so maybe that means that they do something special, and it's not just a statement but --
ATTENDEE: Sharon indicated that she has an advisory committee to do this; she didn't do it on her own. It's an informal setup, so it's not very-- an arbitrary decision, and that could be

set up in rule making if this section gets that far.
FEMALE ATTENDEE: Patty, are those lists like--the only thing that's familiar to me from just the last few months are the chronic conditions that they ticked off, but it didn't have -- there wasn't -- I didn't see anything besides chronic conditions, but they have other things named in this list you're thinking of.
REPRESENTATIVE O'DONNELL: Well, certainly, high blood pressure, diabetes, those are -- those are over the past many years --
MS. LUNGE: Uh-huh, uh-huh.
REPRESENTATIVE O'DONNELL: -- like I said, even the past Commissioner, those are things that have been talked about as epidemic proportions in the state, obesity.
MS. LUNGE: Uh-huh.
ATTENDEE: Harry?
REPRESENTATIVE CHEN: So again, I just want to clarify what this is doing. So it's -- it's creating a process for determining serious public health threats.
MS. LUNGE: Yep.
REPRESENTATIVE CHEN: By the Commissioner of

Public Health.
MS. LUNGE: Yep.
REPRESENTATIVE CHEN: But it's not defining an unconscionable price.
MS. LUNGE: We're just about to talk about that in 4655.
ATTENDEE: Okay. Why don't you finish, and then I'll follow up with a question.
MS. LUNGE: Okay, so in 4655, it sets out the process for looking at unconscionable price, and this would be done in the court process.
So a prima facie case is the legal terminology for what a plaintiff would have to show initially to establish their case in court, so a prima facie case of unconscionable pricing is established where the manufacturer's price of a drug in Vermont is over 30 percent higher than the federal supply schedule. Prices in Healthy Vermonters are the most favored purchase price.
So the plaintiff in this case, probably the AG since they're the person who's given the. Enforcement, or I think it would have to be the AG, would have to show that in court.
If they don't show that, they lose their case. If they do show that, we go to B, which is

that the burden shifts to the defendant, probably the manufacturer, to show that the drug is not unconscionably priced, and they can show, demonstrate cost of invention, development and production, global sales and profits, consideration of research, money received and the impact of price on access in Vermont.
So then the court would look at that and say we agree. Who do we agree with? Maybe we agree with the manufacturer that this isn't -- you know, given what went into it, this seems like a fair price, or maybe we don't, depending on what the evidence is. So that's how that sort of process is set up.
REPRESENTATIVE CHEN: What kind of bar do we know is as stake?
MS. LUNGE: What kind of bar?
REPRESENTATIVE CHEN: How high is this bar set, or how low is this bar set? I have no idea, and I'm just asking.
FEMALE ATTENDEE: It's pretty low.
MS. LUNGE: Well, I think that your testimony from the wholesaler -- I can't remember her name. I'm sorry.
FEMALE ATTENDEE: Maria.

MS. LUNGE: Maria, was that she thinks that the federal supply schedule makes the 30 percent a very low bar. You could of course change the consideration. You could take that out.

They have -- the Healthy Vermonters program is the Medicaid price, so it depends on how good a price Medicaid is getting compared to what other folks are getting as to whether or not that makes it high or low, and then the most favored purchase price is meant to represent kind of the best commercial price in the state.

So that, you would think would be within -- I mean, I don't know whether that would be within 30 percent or not but...

REPRESENTATIVE CHEN: And that's a publicly-available number, that fee, that price?

MS. LUNGE: The AG would have to -- I don't think it's publicly available in terms of being posted on the Internet, but I think the AG's Office could get at that through their pretrial process, potentially.

REPRESENTATIVE CHEN: I guess it would seem to me that I'd like to have a little more comfort with this bar --

MS. LUNGE: Uh-huh.

ATTENDEE: -- before we are going to do this.

MS. LUNGE: Yep. Yep.

ATTENDEE: And I don't know how to get that, and who do we ask for that? I mean, is it, you know, half the drugs that are sold today?

MS. LUNGE: Right.

ATTENDEE: Is it an occasional drug?

MS. LUNGE: Right, and we have a little bit of that information by looking at that color chart that Steve handed out, but that's national data. It's not state data, so -- and I don't think we have the state data available to us, so that's a little bit hard to figure out.

FEMALE ATTENDEE: And, you know, I had the impression from this somehow that basically everybody who's not insured is paying this higher price right now, so they're all in that -- am I getting that right? I mean, because they tend to charge more because they don't get the (inaudible) lower price.

ATTENDEE: They get the highest price.

FEMALE ATTENDEE: Yeah, so a lot of them fall into that anyway, right?

MS. LUNGE: Right.

ATTENDEE: They may, but we don't know.

FEMALE ATTENDEE: The question is we don't know where that 30 percent -- we really don't know where this 30 hits, you know.

FEMALE ATTENDEE: So how often, how frequently does this occur right now today?

FEMALE ATTENDEE: Right now, that's where we're -- yeah, we just don't know --

FEMALE ATTENDEE: Yeah.

FEMALE ATTENDEE: Like what that relative --

FEMALE ATTENDEE: Yeah.

FEMALE ATTENDEE: -- relationship is.

ATTENDEE: Robin, who would know that?

MS. LUNGE: Who would know that?

ATTENDEE: Yeah.

MS. LUNGE: Oh, presumably, the manufacturers because they know all their deals with everybody else, right?

ATTENDEE: But with Steve Kappel's chart -- I have to go find it, but would that help us with it?

MS. LUNGE: Well, it would help you because it gives you the national comparisons of the different prices, but again, those are national so...

ATTENDEE: Well, but yeah, I mean it's a

start.

MS. LUNGE: Right.

ATTENDEE: I guess I'll have to go find it.

FEMALE ATTENDEE: Well, that would give us a sense.

MS. LUNGE: That would give you a sense.

ATTENDEE: Is was this section at one point or another -- am I remembering what people have told me? Was this written more narrowly at one point or another, that it really only applies to the Katrina-type of situation?

MS. LUNGE: Correct.

ATTENDEE: And where was that?

MS. LUNGE: Senate Health and Welfare. It was in an amendment that didn't pass, so it's not in a Bill, but I also brought that for you.

ATTENDEE: And was that bar that Harry's been talking about, was that set at the same level in that particular amendment?

MS. LUNGE: That section was not changed.

ATTENDEE: And was there any testimony about what happened during this hurricane or that hurricane or this natural disaster in terms of prices, and did we actually get any information that might help us to begin to answer this

question about what the bar, you know, what -- did somebody double a price on a -- I mean, what -- do we know what the stories are?

MS. LUNGE: No. At least, I don't. They didn't -- they didn't have testimony about that.

They had testimony from the Health Department a little bit about if they wanted to make it more of an epidemic-type situation, how they would change that language in B, 4654-B to make it more narrow.

That was most of their testimony on that section that I recall anyway.

REPRESENTATIVE MAIER: Are you raising your hand?

ATTENDEE: Well, I was just going to say the federal supply -- the federal -- according to this, I mean on average, all of the cash drugs would qualify.

FEMALE ATTENDEE: (Inaudible) 30 percent.

ATTENDEE: Right, because the federal supply schedule is 51 percent, is 51 percent of the wholesale price, and the cash customers pay a 100 percent so, you know, 30 percent above 51 percent is 100 percent -- you know, it's about 50 percent above.

FEMALE ATTENDEE: What did you say? What is 51 percent? What is 51 percent of the wholesale price, the what?

ATTENDEE: Is the federal supply schedule.

FEMALE ATTENDEE: Oh.

ATTENDEE: Which is one of these things, so it's the green line versus the blue line.

FEMALE ATTENDEE: Oh, there it is. (inaudible).

FEMALE ATTENDEE: So everything.

FEMALE ATTENDEE: So if we assumed -- well, lots of people don't have --

MS. LUNGE: But again, this is the manufacturer's price compared -- so it's the manufacturer's price compared to --

ATTENDEE: Oh, I see.

MS. LUNGE: -- that price, so it's not the retail uninsured price compared to the federal supply schedule, so it's -- if the manufacturer is making money on the federal supply schedule, it should be something under that. If they're losing money, it should be over that.

ATTENDEE: Okay.

MS. LUNGE: I don't know, you know. I don't know, so you don't have the manufacturer's price,

which is the price that you would compare to those lines.

ATTENDEE: Do we have -- can we get that?

MS. LUNGE: I think -- you can ask the manufacturers. I think probably they're going to tell you it's a trade secret, and it's confidential, so I don't think you're going to get it, but I don't want to put words in anybody's mouth so...

ATTENDEE: (inaudible).

FEMALE ATTENDEE: This is -- I mean, when you don't know how frequently the problem occurs, it's kind of strange to make a law to correct a problem that you have no idea how prevalent it is.

MS. LUNGE: I know. Then again, we can't really get an understanding of how prevalent it is.

FEMALE ATTENDEE: It's a trade secret.

FEMALE ATTENDEE: Yeah. Did the Senate already --

FEMALE ATTENDEE: Yeah.

ATTENDEE: The alert is that the Senate passed 1615, cap on education spending.

FEMALE ATTENDEE: Oh, my.

REPRESENTATIVE O'DONNELL: Did they take any

testimony on that? I don't think they did.

FEMALE ATTENDEE: Probably not.

ATTENDEE: The key question is did they ask you, Patty?

FEMALE ATTENDEE: Somebody from the administration.

MS. LUNGE: I definitely have no clue about that.

FEMALE ATTENDEE: Oh, God.

ATTENDEE: Oh, come on.

MS. LUNGE: I can barely keep track of (inaudible).

REPRESENTATIVE MAIER: I don't believe we have additional witnesses coming to talk to us about this section, at least yet, or is that part of what Julie would want to talk to us about?

Well, let me -- at least let me ask if there's additional information or what do you need in order to make a decision on this section or are you -- you already -- what -- what do we need?

REPRESENTATIVE O'DONNELL: Well, I already made up my mind.

ATTENDEE: We need a vote.

REPRESENTATIVE MAIER: Hopper's (phonetic) really engaged, I can see.

ATTENDEE: On this section here?
REPRESENTATIVE MAIER: Yeah. Do you need other information?
ATTENDEE: (Inaudible).
ATTENDEE: Well, I'm just going to throw out, I mean, I think this might be a good place to have a study, to see how many of these are over it, not that -- I mean, because I mean I don't know what we're talking about really price wise, and I don't know that they know what they're talking about price wise. So I mean, I'm just throwing that out.
REPRESENTATIVE MAIER: Right. I'm not going to make-- I'm not going to make a final decision here right now, but I just wanted to know if we wanted -- if anybody needed additional testimony.
FEMALE ATTENDEE: Well, if anyone could testify and give us the information about the prevalence, that would be great, but it sounds like we can't, but if we could get that, it would be helpful, and also, I would like to know if there's any similar law, how it's been challenged, you know, legally, any precedent, legal precedent.
So those are the two things. How prevalent and if there's a precedent to look at around the

country.
ATTENDEE: Well, at least the second, you could tell us more about.
MS. LUNGE: Sure. You've had a bunch of testimony on that by different folks, but I can summarize that, certainly.
ATTENDEE: Okay. Maybe could you do that for us in the morning?
MS. LUNGE: Sure.
ATTENDEE: I think we have you at 9:00.
MS. LUNGE: Yeah.
ATTENDEE: And we have a phone call at 10:00, but we don't have -- so let's do that, and then can you -- can you race us through to the end here?
MS. LUNGE: Sure, I can do that. We're almost done.
ATTENDEE: Wasn't there something that we were going to find out called out-of-state firm shipping? How would this affect out-of-state firm shipping rates directly?
ATTENDEE: Mail order.
ATTENDEE: Manufacturers shipping drugs directly.
MS. LUNGE: I don't think I was going to find

that out but --
ATTENDEE: Yeah, whether, whether a wholesaler or a re -- a wholesaler.
ATTENDEE: They ship it to Massachusetts.
ATTENDEE: A wholesaler in Massachusetts ships it to Vermont.
ATTENDEE: Right.
FEMALE ATTENDEE: Was it that?
ATTENDEE: Well...
FEMALE ATTENDEE: Right, is that -- is that purchase actually -- does that count? Is that a Vermont purchase, or is that a Massachusetts purchase?
MS. LUNGE: I don't think I'm going to be able to find out a definitive answer on that one way or the other.
ATTENDEE: I think Robin was just telling us that that would certainly be -- it would certainly be a commerce (inaudible) question there.
MS. LUNGE: Right.
ATTENDEE: But I think what she was telling us was that the way at least her commerce (inaudible) cases get decided are very fact specific, very situation specific, and so it's sort of hard to predict how any given one is going

to fall.
MS. LUNGE: Right.
ATTENDEE: Is that more or less what you were telling us?
MS. LUNGE: Yeah.
ATTENDEE: So you're not going to be able -- you're not going to corner her into a definite yes or no answer.
ATTENDEE: No, that's okay. That's fine.
But we are going to get a litany of litigation that's already in process on that, right? Isn't that what you were going to do?
MS. LUNGE: I can do -- I can talk about that tomorrow. You have heard testimony about that from Shawn Flynn and also from I think -- I can't remember the woman from PhRMA who was here.
FEMALE ATTENDEE: Judy Corkran, (phonetic)?
MS. LUNGE: Judy Corkran talked about that litigation, so -- but I can summarize that for you tomorrow.
ATTENDEE: Okay. That's all I needed was a summary.
MS. LUNGE: Yep.
REPRESENTATIVE O'DONNELL: I had mentioned this to Steve the other day, and I actually forgot

to mention it to you, but like I want to say in 1999, we paid for an expert on interstate commerce law to do a report about what we could and couldn't do, and it was really kind of a bipartisan effort at the time.

MS. LUNGE: Uh-huh.

REPRESENTATIVE O'DONNELL: A lot of what came out in the report, one Senator who's no longer here didn't like, so that Senator wanted another report to be done, and everybody said no, we paid for one and, you know, you can't -- but it talked a lot about what interstate commerce laws mean in the prescription drug realm.

And I want to say -- and I mean, I can't remember my kids' names from day to day, but I want to say it basically said the only thing we could affect was the one wholesaler, but I think that it would be interesting for --

MS. LUNGE: Yeah, that would be good to know.

REPRESENTATIVE O'DONNELL: -- for the Committee to see that because --

MS. LUNGE: I'll see if I can find it.

REPRESENTATIVE O'DONNELL: Yep, and Bill Russell should know about it. It was --

MS. LUNGE: That doesn't mean he can find it

but...

REPRESENTATIVE O'DONNELL: It was --

MS. LUNGE: We should.

FEMALE ATTENDEE: What a surprise.

ATTENDEE: What a surprise.

MS. LUNGE: So if you could get that to me or Lauren.

(Multiple inaudible conversations).

REPRESENTATIVE O'DONNELL: I threw mine away, but it was -- and --

MS. LUNGE: Great.

REPRESENTATIVE O'DONNELL: What's the heck's his name? Tom Codge (phonetic) I think.

MS. LUNGE: Cool.

REPRESENTATIVE O'DONNELL: Okay.

MS. LUNGE: Great. Well, we'll get that then. So Section 16 is the fee.

REPRESENTATIVE O'DONNELL: And I want everybody to know it was Tom Codge who reminded me about this report and not anybody else outside the building so -- or outside the legislature.

MS. LUNGE: So the fee would be $1,000 per calendar year paid by each pharmaceutical manufacturer of drugs that are paid for through Medicaid, VHAP, Doctor D, V-Pharm or Vermont RX,

so through our public programs, and it's collected by the Agency of Human Services.

It will be used to fund the evidence-based education program and the false advertising provisions.

ATTENDEE: I thought this was already in place. Julie was talking about -- thought maybe we were already collecting (inaudible).

MS. LUNGE: Nope.

ATTENDEE: Maybe she said there were 70, there were 70 --

MS. LUNGE: 71 companies who are marketing in this state.

ATTENDEE: So that would generate $71,000 based on that?

MS. LUNGE: Presumably, unless there are companies marketing who aren't involved in Medicaid, so I don't know how those two things overlap.

ATTENDEE: Okay, yeah.

FEMALE ATTENDEE: Have any of those companies threatened to leave the state or said that it's going to affect their research and development?

MS. LUNGE: I don't recall any testimony either way on this section in the Senate so...

FEMALE ATTENDEE: Sorry. That was tongue and cheek.

FEMALE ATTENDEE: What is -- okay, I have to look through here to see what that -- that fund is going to pay for. The evidence-based education program established --

MS. LUNGE: And the false advertising is the other reference.

ATTENDEE: It's earlier in the Bill.

MS. LUNGE: It's actually the next section.

FEMALE ATTENDEE: Something -- okay.

ATTENDEE: Oh.

MS. LUNGE: Section 17.

ATTENDEE: This doesn't go to --

MS. LUNGE: The evidence-based education is earlier in the Bill.

ATTENDEE: Oh, yeah.

MS. LUNGE: And the reference to 2466-A of 9VSA is Section 17, which is next in the Bill.

FEMALE ATTENDEE: Yes. Okay, great segue. Next.

ATTENDEE: And what's the relationship between the two?

MS. LUNGE: Between those two programs?

ATTENDEE: Yeah.

MS. LUNGE: None.
FEMALE ATTENDEE: They're paying for it.
FEMALE ATTENDEE: But that 71,000 would be used for the false advertising.
MS. LUNGE: For enforcing the false advertising or for the evidence-based education program, and you could certainly narrow it to one or the other and not both, change it to something completely different if you'd like.
FEMALE ATTENDEE: Okay. There's is not a whole lot of money to do that, is there?
MS. LUNGE: Section 17, this -- the A and B are basically cross references. This would go into the consumer fraud section of Title IX, and A and B would just cross reference the other things that were listed as consumer fraud violations, so that if you're looking at consumer fraud, you'd understand that that was part of it too, so it's just meant to help in reading clarity.
C-1 has to do with false advertising, and it would be a violation for a manufacturer to present or cause to be presented in the state a regulated advertisement, which is defined on line 24.
If that advertisement does not comply with the requirements for drugs and devices established

under the federal law and regulations, and that's what those references are to, and state rules, a warning letter and title letter issued by FDA would be prima facie evidence of a violation of federal law and regulations.
ATTENDEE: So this essentially allows for state --
MS. LUNGE: Enforcement.
ATTENDEE: -- enforcement of an FDA violation?
MS. LUNGE: Correct.
FEMALE ATTENDEE: Which they don't enforce.
ATTENDEE: Right.
MS. LUNGE: And then in 2, there's some definitions.
Regulated advertisement is the one that's meant to limit it to Vermont-based stuff.
In D, this is the pop-up ads or electronic prescribing section, and it prohibits the sale, offer for sale or distribution of electronic prescribing software that advertises, uses instant messaging and pop-up ads or uses other means to influence or attempt to influence the prescribing decision of a health care professional. And then there's some more specifics about that.

You can see on the last line of that section, on line 37, it's not meant to apply to -- as you turn over to page 44, information provided to the professional about pharmacy reimbursement, drug formulary compliance and patient care management.
So that line was added. That was the part that was amended in this section because that was added for clarity.
Section 18 has to do --
ATTENDEE: Does this mean what I'm seeing in the living room, that there will be no more ads, like you can buy this particular --
MS. LUNGE: No, no. It means that Harry on his PDA won't get a pop-up ad when he looks to see if there's a drug conflict between two drugs that he's prescribing so it...
ATTENDEE: It has nothing to do with what happens at home.
MS. LUNGE: Exactly, yep.
(inaudible).
ATTENDEE: We would really like to do that, but I don't think we can.
FEMALE ATTENDEE: Would that be -- we'll probably talk about this later. I have no idea how you can enforce that, if that's reasonably

able to be enforced.
MS. LUNGE: You can enforce it through -- the AG could file suit as a consumer fraud violation.
Probably they'd need to get complaints from health care professionals that their prescribing software had that stuff in it, so that's how it would be enforced.
FEMALE ATTENDEE: Does that happen now? You get pop-ups now?
ATTENDEE: Well, see, I don't use prescribing software, so it doesn't happen on my -- the ones I buy, no.
MS. LUNGE: This is based on a Florida law, and I don't know if it's happening in Florida or not.
ATTENDEE: But it's mostly -- some of the electronic prescription software probably does it.
MS. LUNGE: Section 18, this is the section which adds some clarifying language to BISHCA's current authority to add that it's an unfair practice under our -- our current section for a licensee to sell, negotiate or solicit the purchase of health insurance through: A, advertising by making use directly or indirectly of any method of marketing which fails to disclose

that a purpose of the marketing is solicitation of insurance and that contact will be made by an insurance agent or insurance company.

So there has to be notice that the purpose of this ad is to sell you an insurance product.

And B, using an appointment that was made to discuss Medicare products or to solicit the sale of Medicare products or -- I'm sorry.

When you make an appointment to discuss Medicare or ask someone to buy a Medicare product like a Medicare Part D plan, for example, that you have to disclose that you also may -- I'm sorry. I'm getting myself confused here.

You can't use an appointment that you made to discuss a Medicare product to also solicit other insurance products unless the consumer specifically agrees in advance that they're interested in that.

So that was to address a problem that happened early on with Medicare Part D where someone would call up someone and say, We want to come talk to you about our Part D plan, and then they show up the next day, and "Why don't you buy our car insurance and our this insurance and that insurance?"

FEMALE ATTENDEE: Like AARP?

MS. LUNGE: Potentially. I don't know if they're doing it or not, but certainly, they sell Part D insurance.

FEMALE ATTENDEE: And car insurance.

MS. LUNGE: Yep, and that would apply to them.

FEMALE ATTENDEE: And panty hose I guess.

FEMALE ATTENDEE: The support hose.

(inaudible).

MS. LUNGE: So you did also -- oh, I forgot to mention this in the last section. You had some testimony from Sharon Treat (phonetic) about considering C-1 to include not just direct to consumer ads, but also ads marketing to doctors, and then in this section, you got some testimony, (inaudible). In Section 17. Sorry. I just -- I've been trying to also mention like the language issues.

ATTENDEE: I'm committed to being on time for this other meeting, so can you mark there, and we'll come back to that in the morning?

MS. LUNGE: Yep.

ATTENDEE: I had another issue that Robin (inaudible).

ATTENDEE: Steve, is this meeting something I should maybe go to for educational purposes?

REPRESENTATIVE MAIER: Yeah. Yeah. In general, there is a need to go there. Don't feel obliged to stay till whatever hour we're going to, but as long as you can hang in and you got the brains to take it in.

ATTENDEE: Okay. Thank you.

ATTENDEE: All right. 9:00 o'clock for the morning, please, and I promised our Senate colleagues, they have -- they're going to go in on the floor at something like 5:15, Topper (phonetic) and Harry, so I promised them we'd be on time, you know, now that's we're a minute late, so that we could start right on time and get as much done.

ATTENDEE: That's right.

(Seven minutes of multiple conversations on personal issues, and then the rest of the 79:57-minute CD is recorded background noise, no further meeting.

CERTIFICATE

STATE OF FLORIDA
COUNTY OF BROWARD

I, Katherine Milam, Registered Professional Reporter, State of Florida at large, certify that I was authorized to and did stenographically report the foregoing proceedings and that the transcript is a true and complete record of my stenographic notes.

Dated this 26th day of August, 2007.

_____

Katherine Milam, RPR

RE: SENATE BILL 115

DATE: 4/18/07

TYPE OF COMMITTEE MEETING: STANDARD

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 07-139 TRACK 2

WITNESS: DR. JERRY AVORN

MR. MAIER: Dr. Avorn, thank you for agreeing to speak with us. We, as you're well aware, are considering a bill with a number of different pharmaceutical provisions in it, that was passed. It's Senate Bill 115. It was passed by the senate here in Vermont several weeks ago.

DR. AVORN: I have read the bill.

MR. MAIER: We believe, what you want to talk with us primarily about is the data mining section, and we have in front of us a letter from Dr. Kesselheim, and a statement --

DR. AVORN: Right. Dr. Kesselheim is here with me, as well.

MR. MAIER: -- and a statement, but I, for one, haven't read it word for word yet, so I would appreciate it if you could summarize your thoughts for us this morning about the data mining issue, and any other comments you might have about the bill.

DR. AVORN: The static came back, and went away. If it does it again we can talk some more about the connection.

I did review the text of the bill in the last day or two, after it was sent to me, and was actually very excited by it, because it seems like one of the most innovative attempts to deal with a lot of issues of medications, and medication use, and access and costs, that are not getting addressed in Washington. It's clear that if we are going to get anywhere in the next couple of years in making prescription drug use more appropriate for our patients, then it's probably going to be actions like this at the state level that are going to be key.

I'd be happy to talk about this data mining issue real briefly, then maybe respond to questions.

If there's time at the end, the other piece that caught my eye in the bill was the evidence-based prescribing piece, because unrelated to our activities around the data mining issue, for about 25 years we've been engaged in trying to put together programs to teach doctors about medications, that is more appropriate, and less commercially oriented than drug company information, which

unfortunately, is the main way that doctors learn about an awful lot of drugs. So, if you want, at the end we can talk about that.

We're doing work with the State of Pennsylvania, on a non-profit basis, that is helping them to get their doctors to have a non-commercial source of information. It sounds very similar to what is in the bill, to help the state save money, and to help doctors give better care to patients. That website is rxfacts.org.

Why don't I start with the data mining issue? We were drawn into this in relation to the New Hampshire legislation. The question was brought up through IMS and through the course of -- static has returned. You're hearing me, but not static is that true?

MR. MAIER: We're not hearing static.

SPEAKER 3: Once in a while we lose you.

MR. AVORN: Maybe it would be good to call back that 525 number before we really get going on this, because we may be able to do better with another phone call. We'll pick up as soon as you call.

(Pause.)

DR. AVORN: I can hear you like a bell, and you can hear me.

Why don't I just spend a few minutes on the data mining issue, and maybe the best use of time we can use would be to answer questions.

We were drawn to the New Hampshire situation when IMS brought up objections to the New Hampshire statute, including -- and Dr. Kesselheim will join me since he's a lawyer as well, and knows the legal aspect of this better than I do.

IMS was concerned that this would hamper patient care and patient safety, and impede medical research. It seemed very clear to Aaron and me, in reviewing their issues, as well as learning something about other objections to other laws like this around the country that have been proposed, is that clearly they have got a billion dollar business to protect.

I can understand why they don't like these kinds of restrictions. That's their right to complain about it. They, obviously, are not going to come in with a statement saying,

"We're making a ton of money selling this data, so we, therefore, want to keep doing it." They're coming in with objections that are more socially acceptable, like, "This is going to hurt patients. Doctors are not going to be able to learn anything about drugs." That, of course is going to be their rationale.

I, and Dr. Kesselheim, don't agree with any of the contentions that IMS was making, or the objectors to the data mining restrictions have made. Just very briefly, it is not the case that if the statute is well written, as I think the New Hampshire one was, and I believe the Vermont one is, that this would in any way prevent word getting out to doctors about important drug problems.

One objection had been that you couldn't act quickly on a drug recall. That's not a reasonable concern for a couple of reasons. One is, the most important way, if there is a recall like Vioxx, to get the word to patients, is really by the pharmacy, because they're the ones who know which patients are on Vioxx. Doctors in general do not keep

lists of who's on which drugs, sorted by drug. So, if tomorrow it would turn out the Crestor was taken off the market, neither I, nor any doctor I've ever known, has a Crestor file in his office. It's going to be the drug store that knows that. There's nothing about the restrictions that are in the bill that would in any way impede that.

The other objection that got made was that somehow the access of the pharmaceutical industry to doctor identified data is somehow an important piece in the medical education enterprise. In fact, it's quite the opposite.

We spent a lot of years studying how doctors make prescribing decisions and how drug companies market to doctors, and what is very clear is that the data are used to more and more sharply target doctors for marketing efforts, so that somebody might -- if I ever saw sales reps, which I don't, but if I did, somebody might come in, and if I had a big primary care practice, they might know, for example, that I use a lot of generic, statins or generic non-steroidals, and they would be able then to start undercutting the concept of

generics, as opposed to if I favored Lipitor over Crestor as a cholesterol drug, the sales rep, armed with that information, would be able to come in and bad mouth one of the other company's drugs, if they knew that that was what I intended to prescribe.

That's not exactly medical education, and what it clearly does do is force prescribing in a direction that always favors the most costly drugs. No one is out there marketing generic diuretics for hypertension, even though that's the number one recommendation of the National Panel for the Treatment of High Blood Pressure. They're all generic, and there's no margin in them, and it's not worth it for anybody to spend money doing it.

But it's worth a lot for them to market the very high priced drugs like the new receptor blockers, which are not one shred better for a lot of patients than the generic ace inhibitors. But again, no one's spending money on the ace inhibitor marketing for most of those drugs that are generic.

It's not just noise for the doctors. It's sort of systematic noise that always drives

the message in the direction of hyping the expensive product, and there is not a counter effort in talking about the virtues of the, not only more cost-effective, but often safer, and better tested products.

We saw with Vioxx -- one of the reasons 20 million people were exposed to that drug in the first years on the shelves, was the enormous marketing, which we now know took place at a time when we didn't really have the safety data we really needed to have.

It's not just about cost. It's about hyping the ones with the shortest track record, because those are the ones that are still under patent.

I guess the last point I want to just briefly touch on, before seeing if Aaron Kesselheim has anything to add, is the issue of medical research. That's also something we've been doing in my division here at Harvard for about 25 years, is using prescription data which we marry to Medicare, and other Medicaid data, to define patterns of practice, and also to look for drug side effects.

Our group was one of the first ones to have a paper on the connection between Vioxx and heart attacks, that we published a year before the drug was taken off the market. So, we're interested in both learning about drug side effects, and learning about prescribing practices and learning about patient compliance.

There's a number of papers, and we've gotten a lot of literature, and our division drug site and our division here at Harvard and the Brigham, is drugepi.org. All the papers we're talking about are listed. What we found over the years is that, yes, it is true that prescription claims data can be a very important piece of health services research, and I also know and respect the work of Dr. Fischer who has done some important research in the area. But, I don't think it is the case, as some of the drug data vendors have claimed, that if they aren't allowed to mine this data for their own primarily commercial needs that somehow health services, that somehow drug services research, and epidemiology, are going to dry up, because of

the absence of that data.

There are multiple multiple sources of data about prescription claims that research groups can get. We work with state Medicaid programs, with state programs of drugs for the elderly, such as, New Jersey and Pennsylvania have, and with Medicare, which thus far we've gotten clinical claims, like doctor visits and hospitalization. Theres the expectation that Medicare will open up it's prescribing data within the next year or two, and that will be another very important area of prescribing data.

In terms of public health and medical research needs and so forth, a lot of us having been doing quite fine over the last couple of years, decades, in fact, using data about drug use and clinical outcomes to do various important studies about medications, without needing to go to IMS or drug companies to get from them the data they've gotten from their own marketing activities.

So, I don't think it's accurate to say that this would be a real hit on either medical education, patient safety, or medical

research.

Maybe, I should see if Aaron has anything. He's saying he hasn't got anything to add. Maybe I should just quiet down, and see if there are any specific questions or comments about what I have been saying.

MR. MAIER: Thank you. I'll see if there are committee members that would like to ask questions.

MR. KEOGH: Doctor, how about the responsibility of the physicians with respect to rejecting some of these proposals on the part of detailers. Would you find it easier for a physician to listen to the detailer, rather than do the research him or herself?

DR. AVORN: That's a really good point. I certainly don't want to take any of the responsibility off the shoulder of the doctors. Ultimately, it's the doctor that writes the prescription and who needs to be responsible.

We've got a situation in which there is not in most states a good source of information for doctors, especially about new drugs. There isn't even any research in the

medical literature that you can go and read, because it's too new, and the doctors are really dependent on the sales reps for those drugs.

My hope is that, yes, of course, we hope the doctors learn what they can, but it's very tough to ferret out a good review of the medical literature. That's one of the things we're trying to do with the rxfacts.org program in Pennsylvania, for the state. To make it available in the same user-friendly engaging way that the sales reps do, but without having a commercial axe to grind.

To answer your question, I don't want to take any of the moral responsibility off the shoulders of the doctors, but I would also like to level the playing field a little bit, and not give this unfair advantage to the sales reps, so that he or she knows my prescribing practices before they walk in the door, and will distort, or tailor their educational message to kind of go after the company's products that I happen to be prescribing. If they've got news to tell me, or an educational message to convey, go for it. That's fine.

There's nothing, as I understand it, about this bill that would prevent them from going out and teaching me whatever they have to teach, or giving me new product news. I just don't want them to do it with this hidden advantage of knowing what the doctor's prescribing, when they're doing that so called educational record. It's really just a sales encounter.

I totally agree with you that we ought to expect more of doctors. It's just very hard to get that information. That's why I'm so pleased that there's another piece of the bill, in which you're also looking at the other side of the coin, and you're trying to figure out how Vermont doctors can actually be given a more evidence-based picture of what's going on.

MR. ZENIE: Doctor, this is John Zenie. I have two questions. My first one is, what role do you think detailers should have if they don't have the doctor identified data? I wrote down, giving out samples, and providing education. Is there some other stuff that you could see as a positive role that detailers

could have in their business?

DR. AVORN: There's the 2007 answer, and then there's the long term answer.

The 2007 answer is that I am not in favor of curbing their free speech. If a company wants to pay somebody a six-figure salary to go out and teach doctors how to prescribe, even if that person didn't have much science in college, and went on to be a used car salesman, that ought to be legal. I don't think we should prevent that. I agree with the gentleman a minute ago who said, "It's too bad we're in a situation that that's a major way for doctors to learn about drugs," but I don't think it's the role of government to say, "You can't do that."

The list I would suggest is very akin to the list you suggested. I don't particularly like drug samples, but I don't think we can make it something that we can forbid them from leaving them. I think there's very good data from which we try to put together, Dr. Kesselheim and I, in our statement, in which people look at the quality and accuracy of the sales information. It really is pretty

distorted, and not a good way to learn. If the doctor as a consenting adult wants to spend his or her time talking to these people, they ought to be able to do that. If they have a message to tell, they ought to be able to tell it without knowing my prescribing history, to be able to give me that message.

For the immediate future, I think we should just level the playing field. If you've got a story to tell, tell it. Leave whatever samples you want to get my patients hooked on, and go.

I think my answer for beyond 2007 would be that I would like it if doctors would have access to a better quality of information, where the sales rep is not on commission to get me to use their product. In fact, the other argument of the data mining issue is that's how the companies decide to reward their sales reps in terms of their bonuses, which can run into the many five-figures per year. Based on the data mining exercise and what other IMS members do, we'll say that," Mr. Smith was able to get Dr. Avorn to use an awful lot more of drug "x". So, Mr. Smith

gets a big bonus at the end of the year."

That, I think, is another way the whole communication gets tainted, and that's also something that would go away, which would be great, if that data mining exercise stops. So, a very limited role -- not so limited. A free speech role will allow them to say whatever they want to say. Then down the road, if there was a program the Vermont bill would also put in place, so the doctor would know that here's somebody that's coming to me supported by the state, to give me nothing but evidence-based, patient-centered, cost-effective, prescribing information, that you would find what we've begun to find in Pennsylvania and four or five other states where we've done this work, which is that doctors really don't want to spend time with a sales rep who may have no clinical or medical training, but is there on commission to push product, when they could get an equally engaging, but balanced presentation, from somebody the state is supporting to come and teach them.

I would hope they would just dissolve and

go away over time, and the state can provide a better alternative. I just wouldn't want to ban them at this point.

MR. ZENIE: My second question was, not counting the doctor identified data, is there anything in the IMS data warehouse that isn't available in any other data warehouse?

DR. AVORN: There are other sources of getting patient specific data, and in fact, better sources than IMS, because, to use the example of our own work that we've been doing a long time here, if one gets data from a Medicaid program, or from an HMO as other groups are doing, not only do you get the drug use data, but you could marry that with the clinical information, again taking great pains to preserve the confidentiality of the patient that we go through to make sure we're not violating anyone's privacy, but for research purposes, like wanting to find out, for example, if people who take Vioxx are more likely to have heart attacks, than people who take Motrin. One can get both clinical data and drug data from HMOs, from Medicaid programs, soon from Medicare, from the

Veterans Administration, and from a lot of other sources. There is nothing that IMS provides through it's commercial marketing that cannot be replicated, to my knowledge, from other sources.

MS. OJIBWAY: I have Two questions. If it can be replicated from other sources, are you able to -- can researchers afford to pay for those other sources?

DR. AVORN: We actually don't pay a thing to get out data from the program in Pennsylvania. They just send out the tapes for free. Medicaid programs charge us nothing, or the cost of copying the tapes, which is trivial. When we get the data for the Medicare program, to look at the clinical data, they just charge us the programming costs to process the data. That is usually a very affordable amount as well. I've not gotten data from IMS in part because colleagues of mine who have tried to get IMS data have told me it's simply unaffordable. I can't speak to IMS data costs, but the other sources are really quite affordable, especially the public sector ones.

MS. OJIBWAY: My other question before that was -- I really appreciate all the time you've taken to go through the bill. You're commenting on what is there. I was wondering if you have any comments -- not that we need more work, but I'm going to ask you anyway. Are there things you would like to see that are not in the bill. Maybe, it wouldn't happen this year, but in the future, related to this area, that's another step up on your wish list?

DR. AVORN: I was so impressed with everything in it, particularly around the evidence-based education, or information services that would be put into place, that I would not want to load it up with anything else, or think about what to do as a follow-up. I would just do everything I could to help you folks get it passed, and take a look a year later, and see how it's working. I think it touches all the bases that ought to reasonably be touched at the state level.

MR. CHEN: This is Harry Chen. I have a couple of questions. I'm reading a letter from Dr. Fischer. He says, "Any effort to

restrict the creation and the use of prescriber identifiable data would be pursued only after the careful consideration of the potential adverse consequences for research and health system performance assessment."

DR. AVORN: What were the words after, "Health system"?

MR. CHEN: "Performance assessment."

DR. AVORN: Okay. Fine.

MR. CHEN: I hear you saying you don't think there would be any major adverse consequences to those.

DR. AVORN: Right. I've looked at how the New Hampshire issue addressed this issue, and they made explicit exclusion for having no impediments whatever on, let's say the access of an HMO, or a multi-physician group practice, or a state public health agency to be able to get that data, and to -- for example, most HMOs that are concerned about quality will, because they are paying the bills for those drugs, they'll know which doctors are prescribing the drugs. If they find that people are using too many anti-depressants, or not enough cholesterol

drugs, they already have all that access without going through IMS, to do whatever quality improvements, targeted education, or interventions that they want.

The same would apply to the state itself to the extent that the Medicaid program wanted to know -- giving out all that OxyContin, or whatever -- the payor of Medicaid had that information, and didn't need it from IMS. So, every quality improvement that I can think of, will actually go forward.

If you turn it around and you say, "What important quality improvement or public health activities really has the IMS or the commercial use of that data led to," it's not a very long list. Although, as I said, I think Dr. Fischer is a wonderful researcher, and does important work, I don't know that we as a health care system need IMS to help us do our quality improvement activities. We can get the data elsewhere.

MR. CHEN: There's one point he made that I actually don't understand. You talked about --

Dr. AVORN: I completely lost you on the

static which has come back.

MR. CHEN: He talked about an atlas of prescribers.

DR. AVORN: I'm still getting mostly static. Are there mute buttons that can be pressed on the different microphones, except for the gentleman speaking, I might be able to hear.

MR. MAIER: Are you back with us?

DR. AVORN: I did not hear the question.

MR. CHEN: I'll try one more time.

Dr. Fischer mentioned an, "atlas of prescribing." That's something he might not be able to do without IMS type data. I have to be honest, I don't know what that is.

DR. AVORN: The group at Dartmouth, including Dr. Fischer and Dr. Weinberg, is really the grandfather of this research, and has done some very important work, mostly on things like, procedures. They have come to put out what has become known as the Dartmouth Atlas, in which they look at the rate of, let's say, coronary artery surgery in different counties around the country, and have done some important work showing

differences in the rates of procedures or operations, or various other things in different regions of the U.S.

That's something that can be done with different data sets, in that one can look at all the state Medicaid programs, if one is interested in Medicaid prescribing. Once Medicare frees up its prescription data, which we are promised it's going to do in the next year or two, it will be possible to get that data from CMS. As I said, there are HMOs that have coverage all over the country, and which could be used for doing that kind of work, and looking at regional differences.

If there was some arrangement that Dr. Fischer has with IMS that I'm not aware of, where IMS was going to give him data on prescribing all over the country, you still don't need doctor identified data to do that. If IMS has got the data, they could make that information available to the Dartmouth group without necessarily having the information on whether Dr. Jones, or Dr. Smith was the prescriber.

MR. CHEN: Thank you.

SPEAKER 5: Doctors, I just had a question about the detailers. I think you just hinted that they don't have a medical background, and we've certainly -- that's sort of been hinted at throughout our testimony, but I'm just wondering if you could just speak a little more on that, and I presume that physicians know they are dealing with people who are sales people with no medical background, if, in fact, that's generally the case.

DR. AVORN: On the latter point, I've been troubled that doctors are not more savvy as we ought to be about the skill level of these people, because most of them don't come in and say, "Hello. I was an art history major in college, and I never took any training except for the four or five weeks the company gave me, and now, I'm going to tell you how to treat your patients."

They do come across very polished, very suave, very articulate, and they've got a canned speech that they are taught in their sales training program by their company. I'm afraid that doctors don't quite pick up on the fact that this person is not an expert in the

field.

Granted there are some companies that will have the occasional pharmacist or nurse go out and do the detailing, but the vast majority of sales reps are people with no particular scientific training, except what they get in the six-week training program from the company.

I don't think doctors are savvy to that, because frankly, and this is a sad thing to admit, the sales reps are likely to know more about the drugs they are selling than the doctor is, because they are given very focused attention on it. They can kind of run circles around the doctor, in part because they have been given training like "If the doctor asks about this problem, here's your response."

There have been a number of court cases in the last couple of months in which we learned what Merck was teaching it's sales reps about what to tell doctors about, "If your doctor raises questions about heart attacks, here's how to change the subject, or here's how to undercut that worry." So, yes, they can come across very polished, but I don't think that

doctors fully understand that they're not experts in this area.

SPEAKER 5: Have any states, to your knowledge, had any requirements that detailers provide information on what their qualifications are, to doctors?

DR. AVORN: We're getting static. I think the question was, "is there any requirement for the certification or education of the sales reps?"

SPEAKER 5: No. I think we've had a little bit of information on whether or not they need to be licensed or registered, but whether they could be required to provide information on what their qualifications are medically, to the doctors.

DR. AVORN: That would be an interesting touch. I think if they had to start every encounter with, "Hello, I'm John, or Susan Smith, from Phizer of Merck, and I have a bachelor's degree with a major in anthropology, and I've not got any degrees in science, and what I know about this drug, I learned in a 6-week training program." I wouldn't want to load up this legislation with

it, just because I would love to see this thing just sail through and become law, but maybe a subsequent step as something that came up earlier in the conversation.

That might have a bracing effect on the doctor to be reminded at the moment of the sales encounter that they're being told how to take care of their patients by somebody that -- my wife's an anthropology major, so I don't have any objections, but I don't want them teaching doctors how to take care of patients. That could be an interesting thing, to make that part of the official announcement at the beginning could be a very good effect.

SPEAKER 5: We'll put that on the list for next year.

DR. AVORN: Sounds good. Just to give a slightly broader answer, I don't think it will be legally or politically possible to do -- I'm not even sure I would be very excited about restrictions on sales reps. In fact, Dr. Kesselheim and I are now writing something about the commercial free speech and the first amendment issues that come up around drug advertising.

Not being a lawyer, although he is, my fear is that attempts to restrict what sales people say, as long as it's not fraudulent, may become difficult to enforce in a political and legal context. Instead it might be better to make sure the doctors have access to a better information source.

Most doctors, as busy, and harried, and overworked as we may be, most doctors know the good stuff from the commercial stuff, and I think would be happy to get the straight scoop from some entity that has no commercial ties, that might be supported in a very modest amount by the state. Then perhaps be able to say, when the person from the drug company comes by, "Thanks. I already know how to treat blood pressure, or I've already read a very good document about cholesterol lowering drugs. I don't really need to hear your speech." That's what we're trying to do in Pennsylvania.

MS. COPELAND-HANZAS: Dr. Avorn, I'm a little concerned about the state sponsoring counter-detailing. It seems to me it would be pretty difficult for a small state like

Vermont to --
DR. AVORN: I lost your voice.
MS. COPELAND-HANZAS: Can you hear me now? How are we doing now?
(End of Disk 139 T2. Continued on Disk 140 T1.)

CERTIFICATE

THE STATE OF FLORIDA,)
COUNTY OF BROWARD.)

I, Michael T. Berkowitz, Shorthand Reporter, do hereby certify that I was authorized to and did listen to CD 07-139 T2, the House Committee on Health Care, Wednesday, April 18, 2007 proceedings, and transcribed the foregoing proceedings, and that the transcript is a true and accurate record to the best of my ability.
Dated this 15th day of August 2007.

_____
Michael T. Berkowitz
Notary Public/ Shorthand Reporter

RE: SENATE BILL 115

DATE: 4/18/07

TYPE OF COMMITTE MEETING: STANDARD

COMMITTE MEMBERS:

REP. STEVEN MAIER, CHAIR	REP. HARRY CHEN. VICE-CHAIR
REP. FRANCIS MCFAUN	REP. SARAH COPELAND-HANZAS
REP. WILLIAM KEOGH	REP. LUCY LERICHE
REP. VIRGINIA MILKEY	REP. PAT O'DONNELL
REP. HILDE OJIBWAY	REP. SCOTT WHEELER
REP. JOHN ZENIE	

CD NO: 07-140 T1

WITNESS: DR. JERRY AVORN
(CONTINUED FROM 07-139 T2)

DR. AVORN: -- one is that we've been putting together -- actually the State of Pennsylvania's been paying the bill, but we've made it available to anybody that wants to use it in any kind of commercial-free sense of the word, the sales materials, if you will, about how to manage cholesterol, or who needs to be on Plavix, or who doesn't need to be on Plavix, we've just been putting that up on the web. That's that rxfacts.org site. So,

MR. MAIER: We lost you.

SPEAKER 3: We lost you.

DR. AVORN: Can you hear me?

SPEAKER 3: Now, you're back. We missed the whole last thing.

DR. AVORN: Are you hearing static, or are you just getting a loss of signal?

SPEAKER 3: A loss of signal.

MR. MAIER: We don't ever get static.

DR. AVORN: I will talk, and tell me if you're losing me.

SPEAKER 3: We lost you right after you mentioned the website.

DR. AVORN: Okay, fine.

SPEAKER 3: We lost you again.

SPEAKER 4: We lost you again.

DR. AVORN: Do you want to try to call the 525 number back?

MR. MAIER: We actually have only about two or three more minutes left for you, or maybe five at the most.

DR. AVORN: Let's continue. These are a couple of important words I'd love to get in. I think it's better now that the static has gone away. I feel like I'm talking to you from Bolivia or something.

SPEAKER 3: If you hear static, we don't hear you.

DR. AVORN: All right. I'll keep talking until I hear static. I take it we're okay, now?

SPEAKER 3: Yes.

DR. AVORN: There's this kind of international conspiracy that many of us are engaged in of non-commercial science based information about prescribing, and there are several Canadian provinces, and there is a continent-wide program in Austrailia. There's

what we're doing in Pennsylvania. A number of other states have expressed interest in it, and some very good work is going on in Western Europe, as well, in which many of us are trying to put together the very best information we can about cost-effective, patient-centered evidence based prescribing.

What we've done at rxfacts.org is put up any of that information for anyone to use it.

SPEAKER 3: We just lost you.

DR. AVORN: Yes. I'm hearing static. Now, I'm not.

SPEAKER 4: We can hear you, now.

DR. AVORN: Could we maybe try a call back, just in case we may get a better line, and we can just get through this?

SPEAKER 3: Sure.

DR. AVORN: I'll hang up. If you could call back the 525 number, maybe we'll get a better line this time.

MR. MAIER: Okay. Thank you.

(Pause.)

DR. AVORN: All right. I'm hearing you okay. Are you hearing me okay?

SPEAKER 3: Yes.

SPEAKER 4: Yes.

DR. AVORN: Fantastic. The question, which is a very good question, and one that comes up a lot is, how can any kind of public health oriented program ever hope to compete against the billions of dollars that the industry spends on their marketing? There are, in brief, two quick pieces to the answer.

One is, the development of the materials, and that has two components to it. One is, reviewing all the literature and making sure you've got coverage of all the important papers. Even the ones, you know, that favor the expensive drugs. The patient needs that, and should be able to get it.

On top of that literature is a big piece of work that is now getting done, not just by our group, but by groups in Canada, and groups in Australia. If anyone wants to send me an e-mail after this, I'd be happy to send you a lot of sources of who is doing this around the world. The e-mail for me, by the way is javorn@partners.org. There is that piece that is already ongoing.

The second component is putting all that

mass of information in an engaging user-friendly format, so the doctor doesn't get a 300 page reviewable literature with 180 references, and be told to, "Look at it in your spare time."

So, what we do is take that and try to make it look like a drug ad, except what it does is say, "You don't need to use this fancy stuff, except for this ten percent of patients who need it. Everyone else can go ahead with the more cost-effective products, here are some safety issues to be concerned about."

To put that into a format that is user-friendly for the doctor -- we also put together, on the web for anybody to use, materials for patients. One of the issues we've gone after is the horrible overuse of the "purple pill" Nexium, for people that don't need it.

So, what we put together at the request of doctors in the field is information they can hand to their patients, and how to get off of the "purple pill" if you don't want to keep taking it, because if you stop it cold turkey,

it can have side effects.

So, there's that materials production piece, and that's kind of done, and we're going to keep doing it. Again, Pennsylvania is paying the bill, as is the Australian government for their program, and the various Canadian provinces for their programs. It's out there, and that large hurdle has been already crossed.

The next piece is having the people in the field. We have found it is real easy to find those people. We only use nurses and pharmacists to go and talk to doctors, and there's tons of them. Some of them are actually refugees from the drug industry who can wake up in the morning any say, "I feel good about what I'm doing for a living." Some of them are clinicians, who doctors can really relate to about managing patients.

Then the question is, who's going to pay for it? Our studies, going back to the '80's, have shown that there is so much waste in the drug budget from the point of view of public sector payors, like Medicaid, and now Medicare, that if you could just reduce the

drug spend by a little bit, you can actually pay for this program. Some of our early studies have actually shown that you can save two dollars for every dollar that you spend.

We are in the course of evaluating this for the people in the State government of Pennsylvania, and finding that, yes indeed, it is saving more than they are spending on the staff salaries, for the people that want to do this, which makes a lot of sense, because if you didn't change a lot of prescribing by having someone go to a doctors office and kind of be an "unsales" rep, as we've done, the drug companies wouldn't be doing it themselves. They know the best way to change prescribing, is to have somebody in the doctor's office, and talk with them about their practice. That's why back in the early '80's I started doing this, saying, "Why don't we use the same kind of evidence, but deliver it to the doctors the same way the drug companies deliver their message, because they're getting through, and those of us who work in the medical schools, are not."

We are finding that it's saving money in

Pennsylvania. The folks in Australia have been doing this for years for the whole country. Various Canadian provinces the same way. So, the amount from the Medicaid program perspective alone, if you could just get doctors not to waste state money, will probably pay for the program. That's a testable hypothesis, but it seems to be working both on the public sector programs -- we know it's working for the drug companies because they keep doing it.

SPEAKER 3: Can I ask a follow-up?

DR. AVORN: The last point, sorry to ramble on, but it's a subject dear to my heart. The last point is that doctors can tell the difference. We've had experiences where all people in the field will be sitting in the waiting room with a bunch of patients and a bunch of sales reps, from retail drug companies, and the doctor will come out and see our people first, because they know they're getting from them a useful, no ulterior motive presentation, that's put together my some docs that think hard about these issues, and the person delivering it is

a nurse or pharmacist.
They will want to talk to our people more than they will want to the people from Merck or Phizer, who they know are basically just salesmen or saleswomen. So, yes. It can work.
MR. MAIER: One last question. We have someone else we're waiting to call here.
SPEAKER 3: Tell me why limiting or eliminating this data mining is critical to leveling the playing field, as far as detailing and counter-detailing.
DR. AVRON: The educational message ought to be able to stand on its own merits, and it shouldn't give the salesperson an unfair advantage to be able to tailor that message to one's own person prescribing practice, also without the doctor even knowing it.
Let them go out there and give it their best shot, but not with any secret knowledge. They've already got such an incredible advantage as it is with the tons of dollars that are spent on both marketing to patients and to doctors.
I guess that's the main reason why it

doesn't serve any useful purpose in medical education. They have an unfair advantage, especially if that's used to incentivize them to just push their own product, so they can get a bigger commission.
The consequence, as I said, and the reason I care about it as a problem, is that all it does is push prescribing to the expensive new products, and it undercuts all the folks throughout the medical world who are saying, "Use the tried and true drugs. Use the generics. Worry about the patient's pocketbook." The shift to prescribing more and more expensive products is hurting both state Medicaid programs, and also individual payors in the state who are having to shell out more than they need to get their treatments.
SPEAKER 3: Thank you.
MR. MAIER: Okay. Thank you so very much Dr. Avorn. We never heard Dr. Kesselheim's voice, but thank you for being there.
DR. AVORN: He has been nodding. If any of you want to follow up, just drop me a

note, and I'll be happy to send you -- you know, we don't do this as a business, we just do this because we believe in it. If we can be of any help in this courageous legislation, we'd be happy to do whatever we can.
MR. MAIER: Thanks very much. Bye. We're just going to keep moving here, because we had David Balto, who we're now about ten minutes late for. If you need to take a little break, do it on your own.
SPEAKER 3: David Balto is the next person. He's a former federal trade commissioner here. I just got a copy of his testimony. I will pass that out while I'm setting up the new Pod Phone.
(Pause.)
(Phone Rings.)
MR. BALTO: David Balto.
SPEAKER 3: Good morning, David Balto. The is the House Health Care Committee. I will pass you over to the chairman of the committee, Representative Steven Maier.
MR. MAIER: Good morning. How are you?
MR. BALTO: Good morning Representative

Maier.
MR. MAIER: Mr. Balto, I'd like to thank you for sending us some testimony. It's just been handed around. We haven't had much of a chance to -- we're just starting to glance at it. Perhaps if you could give us a quick summary of what you sent here, I --

(End of CD 140 T1, Track 1).

CERTIFICATE.

THE STATE OF FLORIDA,)
COUNTY OF BROWARD.)

I, Michael T. Berkowitz, Shorthand Reporter, do hereby certify that I was authorized to do and did listen to CD 07-140 Track 1, the House Committee on Health Care, Wednesday April 18, 2007 proceedings, and transcribed the foregoing proceedings, and that the transcript is a true and accurate record to the best of my ability.

Dated this 15th day of August 2007.

Michael T. Berkowitz
Notary public/Shorthand Reporter.

RE: SENATE BILL 115

DATE: 4/18/07

TYPE OF COMMITTEE MEETING: STANDARD

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 07-140 T2

WITNESS: DAVID BALTO, FORMER DIRECTOR OF POLICY, FEDERAL TRADE COMMISSION

(Continued from CD 07-140 T1)
MR. MAIER: -- have some background on PBMs and want to talk to us about those portions of the bill that's in front of us.
MR. BALTO: Exactly. First, my own background. I'm the former Policy Director of the Federal Trade Commission. I held that job for three years in the 1990's, and also was the attorney advisor to the chairman. I currently am in private practice and I do a lot of work in PBMs on all sides of the issue. I actually represent some PBMs that have adopted a transparency model. I represent employers and unions who negotiate with PBMs, and I represent other participants in the PBM marketplace.
My testimony delivers a simple message. When I was the policy director at the FTC, I often testified before state legislators about whether legislation was necessary, and I almost inevitably said legislation was not necessary. I think this is one of those circumstances where the market does not function well, and state legislation is necessary.

The reason why is that the key element of a competitive market -- in order for a market to function competitively, two factors are crucial, choice and information. If either of these are lacking, then government enforcement or regulation may be necessary. I think, if you look at the PBM marketplace, and you've probably heard this from other people that have testified before you, probably in no market are consumer protection and competition problems as rampid.
We know that because of the tremendous number of state and federal enforcement actions and the tremendous amount of private litigation. On page two of my testimony you'll see I quote the National Legislative Alliance on Prescription Drugs where they observe that, "In no other market," that they know of, "has there been such a significant number of prominent enforcement actions and investigations with such a significant impact on taxpayers. Simply put, throughout the United States numerous states are devoting considerable resources to try to cure these problems."

One of the problems they have described on page three -- first of all, rebates given to PBMs and manufacturers. Basically, buyers don't necessarily know about them. Because buyers lack information, they can't effectively bargain to go and make that sure those rebates are being passed on to them.
Second, PBMs engage in different types of conduct, such as, price trends, where they charge one price, and reimburse another. There are switching programs, and then finally there are conflicts of interest in mail-order.
The litigation that's going on shows you how significant these problems are. The First Circuit Court of Appeals looked at this market and they said the lack of transparency also has a tendency to undermine a benefit providers ability to determine which is the best proposal among competing proposals among PBMs. The First Circuit Court of Appeals recognized the importance of transparency.
Now, I know there's two questions that are on your mind. First, can we rely on the market to correct itself? Second, if there's all this litigation going on, won't that solve

the problem? The answers to these two questions are, "no."
Market forces aren't a complete solution, in part because we should realize that this is a market that's not going to correct easily. It's a market in which three firms basically control the market place in which there are high barriers to entry. You're not going to see some self-correction happen naturally.
Now, I'm sure there are people that have said, "oh, but the large employers." The largest employers are able to secure the information necessary to actively police PBMs.
Let me make a couple of points about that. First of all, a lot of the private suits that have been brought, have been brought by the large employers. Whether or not that's a complete solution, I'm quite uncertain of, because they really haven't found it to be a complete solution for themselves.
Second, and this is the most important point I'm going to make today, just because large employers are able to secure information, doesn't protect small employers.

You know, just because GM is able to successfully negotiate a contract where they get adequate transparency, doesn't mean that Cabot's Creamery can get that. Because of that smaller and mid-sized -- and by the way transparency goes to really only a handful of large employers. What that means is that there is a competitive imbalance. The largest employers, large national employers in Vermont, may have that level of transparency, but smaller Vermont based employers will not have that degree of transparency.

In addition, whereas a large employer can devote the resources to actively police these contracts, the smaller employers won't.

The next question might be, well, what are all these going on, including cases by the Justice Department and State Attorney General? There's been over three hundred million dollars recovered in these cases. Why isn't that enough?

The answer to that question is that the litigation is episodic, it's retrospective, and it only cures a single problem. It will not cure things perspectively. And again, to

repeat a point that I made before, legislation of this kind is necessary to create a level playing field between larger and smaller employers.

I mention in my testimony around page six, that there's a huge bargaining alliance, called the HR Policy Association, that has effectively negotiated the model contract with regard to transparency. That's great for the Fortune 50 kind of employes who belong to HR Policy Association. A small handful of those Fortune 50 employers have taken advantage of this model contrat. That's not going to do a thing for the smaller employers. The Vermont based employers who can't avail themselves of that arrangement.

I hope the committee is aware that this type of legislation has been upheld by the courts. Both the main legislation, and last month, the D.C. legislation, has been upheld by the courts. It seems that those decisions provide a pretty good green light for states to legislate some of these areas.

One last point. I'm sure the opponents of the legislation have sort of waived some

letters that the FTC has sent in other states, saying this legislation is unnecessary. I used to be at the FTC, and I used to write those letters. I realize those letters were only meaningful, and I want to emphasize this, only meaningful when they had a strong empirical basis behind them. My testimony criticizes the empirical basis behind the FTC's comments. I mean they're nice theoretical arguments that in some context might work, but they're totally oblivious to the significant fraud problems in this market, and they haven't looked at the nature of competition in Vermont. The legislation they commented on was very different than the legislation that's being proposed in Vermont. The Vermont legislation, unlike the legislation proposed in other states, is a very narrow, refined, balanced approach to trying to regulate in this area.

That's a quick summary of my comments, and I'd welcome any questions you have.

MS. MILKEY: Hi. Thanks for being available to testify. Just following up on what you were saying about large businesses

being able to deal with this, Fortune 500's, and that small businesses aren't, the rest of what we're being told is that we don't need to worry about the small businesses, because they all just let their insurance companies contract this out to administrative managers, or whatever they're called, and that the insurance companies are very sophisticated, and they know how to negotiate and all that stuff. So, could you --

MR. BALTO: Let me make a couple of points about that. I don't think that is a complete answer. First of all, let me make it clear, we're talking about Fortune 50 corporations, not Fortune 500 corporations.

Second, some small businesses self-insure. Some small business contract without individually --

Third, insurance companies are honest brokers, insurance companies should be saying that transparency helps in their effective negotiations of these contracts.

SPEAKER 1: I just want to say your written testimony was excellent. That's probably why we don't have a lot of questions.

We've been trying to read it as quickly as we can while you're speaking. I just want to say it's very clear and helpful, what you provided to us in writing, and of course, your comments backing it up.

MR. BALTO: The one point I really want to leave you with is this level playing field point. Well, two points I want to leave you with. The first is, I've reviewed legislation in numerous states, and your legislation is really really refined, and very narrow. I have to go and advise my PBM clients on how to comply with legislation like yours, and I think your legislation does not impose a very significant burden on the PBMs themselves.

Second, I know you have concerns about small businesses, and rightfully so. The purpose of your legislation, in part, is to create a level playing field between those larger employers who can negotiate and do secure transparency -- transparency must be important, because the large employers do negotiate for it, and the importance of the legislation is to create a level playing field between the large employers which are able to

get the benefit of transparency, and mid-size and smaller employers who are not.

MR. CHEN: David, I want to make sure that you've seen Senate Bill 115 as it's passed the senate, and that we're looking at the same bill. I'm wondering if you have any comments about how to make it better in any way.

MR. BALTO: Why don't I think about that a little bit further. I did see -- I went on the web and pulled down a copy of Senate Bill 115. The one thought that immediately comes to mind is that I really like the main legislation. I like the idea of an explicit fiduciary duty. That's probably the most immediate thing that comes to mind. Let me think about that and e-mail something back to you with more specific comments.

MR. MAIER: Thank you. Following along with that, the main thing that distinguishes us from M-A-I-N-E is, in addition to this somewhat different fiduciary responsibility, is this clause that sort of introduces that whole section of the bill which provides that all this stuff must happen unless the contract provides otherwise, and there's a notice

provision. There's the transparency that you referred to, but the specific language of the statute can be not followed, I suppose would be the right way of saying it, as long as there's an open discussion about it, and they agree via contract not to do those sorts of things. That's different than what Maine did. So, as you commented about ours being narrow and specific, do you actually like that part of it, or is that a concern of yours?

MR. BALTO: What I'm concerned about is -- let me just sort of be precise about the concern, and I know this from a lot of experience. As you probably know, in the mid 1990's the FTC brought enforcement actions against Lily's acquisition of PCS and Merck's acquisition of Med Co. They said, "you have to have an open formulary. You have to give buyers the choice. You have to give plan sponsors the choice of being able to purchase on open formulary."

What happened was, PCS and Med Co engaged in a bit of a charade. They would sort of say, "Oh, if you want an open formulary it will cost you $400 per subscriber, but if you

want a closed formulary it will cost you $50 per subscriber." So, it's like if you want to look under the tent and figure out what's really going on, it's going to cost you a lot.

So, I would prefer something that didn't provide that option, because I think it provides the opportunity for PBMs to offer a false alternative, but if that's the best the legislature can do in terms of enacting something, certainly this statute will go part of the way in terms of curing the problem.

MR. MAIER: Okay. I don't see any other questions. This has been very helpful.

MR. BALTO: If anybody has any additional questions, send me an e-mail, and I will try to write you a short e-mail with some additional thoughts.

If somebody criticizes your legislation as being broad, compared to the bills in the other 20 states, your legislation is fairly narrow. Your legislation is narrow, refined, and not particularly burdensome.

MR. MAIER: Thank you very much.

(End of testimony of David Balto)

CERTIFICATE

STATE OF FLORIDA,)
COUNTY OF MIAMI-DADE.)

I, Michael T. Berkowitz, Shorthand Reporter, do hereby certify that I was authorized to, and did listen to CD 07-140/T1, the House Committee on Health Care, Wednesday April 18, 2007 proceedings, and transcribed the foregoing proceedings, and that the transcript is a true and accurate record to the best of my ability.

Dated this 15th of August 2007.

_____
Michael T. Berkowitz
Notary Public/ Shorthand Reporter

STATE OF VERMONT

RE: SENATE BILL 115

DATE: 4/18/07

TYPE OF COMMITTEE MEETING: STANDARD

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 07-140 T3

WITNESS: John Holler, attorney for GlaxoSmithKline.

MR. HOLLER: I am John Holler, here on behalf of GlaxoSmithKline. I wanted to talk about the unconscionable pricing provision of the bill. The senate finance committees version included a much broader unconscionable pricing provision which regulated, and purported to regulate, any transaction between the manufacturer and wholesaler, whether that wholesaler is in Vermont or not, and would allow for private rights of action against those manufacturers for selling at an unconscionable price.

In response to concerns about the unconstitutionality of that provision, it was narrowed to deal on with, or relate only to transactions that occur in Vermont. The assertion was made that addressed the constitutionality concerns about that bill.

So, what I want to testify about this morning about is our concern that it didn't. We don't think that it does, and I'm going to talk in some detail about that.

First, I want to just mention that aside from the constitutionality issues, is the practical issue about whether, in fact, it

will work. Can the state regulate transactions that occur only in Vermont? There was a significant amount of discussion about that seven or eight years ago when the legislature considered this. There was a bill in the legislature to regulate prices of pharmaceuticals, not unlike the discussion that's going on now, and the legislature hired a consultant, who was here for a pretty extended period of time, as you can tell from this transcript.

There was considerable amount of discussion as to whether as a practical matter the state can regulate the transactions of sales of products by manufacturers who are located out of state. The answer was, "No," for the simple reason that a manufacturer may choose to avoid Vermont itself, to wholesalers who are located outside of the state. That was the conclusion of the consultant that was hired by the legislature.

SPEAKER 2: I didn't understand what you just said. Could you -- you went back and forth. I thought I got it, but I missed it.

MR. HOLLER: I'm sorry. I'm probably

speaking too fast. The simple reason is the conclusion from the legislatures consultant seven years ago was that a manufacturer may simply avoid Vermont's attempt to regulate prices in the state, by engaging in wholesale transactions outside of the state. I don't know how a manufacturer is going to respond, but that's certainly an option for them, to avoid the attempt by Vermont to regulate that wholesale transaction, by relocating that transaction to a neighboring state.

SPEAKER 2: Right before that, I thought you said the consultant also said that we couldn't regulate.

MR. HOLLER: Well, for that reason. The practical reason that the state -- and there are constitutional issues as well, that I will discuss. What I'm referring to in this transcript was the consultants conclusion that the State of Vermont simply can't regulate wholesale transactions because they'll simply go elsewhere.

What I want to focus on is the constitutionality issues, because I don't agree with the Attorney General's conclusion

that by focusing on Vermont's transactions, you address those constitutional questions.

I encourage you to look at, if you decide to pursue this further, the District of Columbia Federal Court decision on their unconscionable pricing statute. They passed a similar, not exact, but similar statute that was challenged in the Federal Court in D.C. and it was ruled unconstitutional, and I think the arguments discussed here are directly relevant to the issues you're considering.

So, two issues. One is the Commerce Clause which says essentially that the state can't regulate interstate commerce. The other is the Supremacy Clause, which says the federal law is supreme and the state law can't supercede it, and that relates to the issues of federal patent laws.

The Commerce Clause issue admittedly is a little more complicated now that the bill passed by the senate was narrowed to deal only with Vermont transactions. When it purported to address transactions that occurred outside of the state, I think it's very clear that that's unconstitutional, because it would

create a burden on interstate commerce. That is sales that occur outside of the state, and the courts have been clear that one state, Vermont, can't take action that's going to result in an impact on transactions that occur outside of Vermont.

So, the question is, if you're only regulating transactions between an out of state manufacturer and an in-state wholesaler, does that satisfy that concern? Is that permissible? And I think that's a very questionable area, because I think the sales would continue to be between an out-of-state manufacturer and in-state wholesaler, and there's a state court case in Vermont from a few years ago which said that a transaction between an out-of-state manufacturer that terminates in Vermont with a Vermont company is, according to the court, the definition of an in-state sale.

You're clearly going to have an impact on interstate commerce, because you're involving an out-of-state manufacturer. There are no manufacturers in Vermont, and a transaction with a Vermont entity. So, you're clearly

going to have a burden on interstate commerce.

In the D.C. decision the court said, "Not only do you look at whether or not you're actually regulating out-of-state transactions, but you look at what is the likely impact of the regulation going to be, and the impact on other states." And the court said, "One effect that would arise, if not one, (inaudible) but every state adopted similar legislation." So, think about the circumstances in which other states adopted a bill similar to what passed the senate, and I think you will see what the D.C. court found was not permissible. That as more and more states adopt these pricing regulations, it forces manufacturers to choose different venues, and poses a significant burden on interstate commerce, which is clearly not allowed under the constitution.

The D.C. court did conclude that similar legislation throughout the country would undoubtedly result in an artificial race between legislatures to set the lowest price as the base for a prima facie case. That is that a sale is unconscionably priced. So, the

district court concluded that similar legislation passed there would be unconstitutional because of it's impact on other states, or if similar states pass similar legislation.

So, as that's not as clear, I think there are certainly substantial questions relating to the issue of the burden on interstate commerce. We think it would likely be found unconstitutional on those grounds.

The more relevant issue, I think, is the Supremacy Clause, which relates to federal patent law. The Supremacy Clause, which I mentioned before, means the federal law is supreme and states can't take action that's pre-empted, either expressly, or by federal law, or implied in preemption. That is if federal law purports to occupy the field, to say this is the way we want transactions to be governed throughout the country to be uniform, states can't enact legislation that undermines that federal construct.

In applying that general principle to patent law, the D.C. court found that that attempt by the state to regulate

pharmaceutical prices was inconsistent with federal patent law.

The purpose of federal patent law is to create incentives for manufacturers to invest in new innovations, to create new products, and this is, of course, true not only for pharmaceuticals products, but for any invention. In exchange, the developer of that patent has market exclusivity for a period of years, and after that point faces market competition, in the case of pharmaceutical manufacturers, generic drugs. That balance of market exclusivity and the incentive to creat new products, underlies the purpose of federal patent law.

The district court here found very clearly that the state's attempt to regulate the price of pharmaceutical products contravenes that express purpose of federal law, of congress to create those incentives for manufacturers to invest in new products, in exchange for that market exclusivity. I would encourage you to read this case. It's not terribly long. I haven't copied it. It's 30 pages, or so. I'd be happy to do that for anybody who's

interested.
The court says, "using the litigation process to determine on a drug to drug basis the application of a given drugs pricing, directly interferes with, and second guesses the balance set by congress in the current system of patents for market exclusivity of pharmaceutical products."
It's a relatively brief discussion because the court found that given the intention of congress in passing patent laws, it intended to preempt the ability of states to make, on a case by case basis, a determination about what the appropriate prices are prior to the expiration of it's patent.
There was an argument made in the senate. I heard the attorney general's office make the argument that the Vermont law is different from the D.C. act, in that the D.C. act said explicitly that it was intending to regulate patent drugs. The bill that's before you talks about pharmaceuticals, but doesn't distinguish between patent and non patent drugs. In my view, that simply will not make a difference to the extent that the Attorney

General believes that they would regulate the generics. Then the patent argument wouldn't apply. I don't think that's the intent to the extent that is was applied to regulate the price of patented pharmaceuticals. It would seem to corollate to run afoul this decision in the Supremacy Clause.
You might say, "Well let's try it and see what happens." There is a significant risk to impose unconstitutional limits on the sale of the products, or any unconstitutional legislation, because the plaintiff in the case, or defendant, whatever the case may be, can recover attorney's fees under federal law, and you may have seen recently the parties in the campaign contribution case were seeking 1.5 million dollars in attorney's fees from that litigation.
So, I don't know what the costs of litigation would be here, but there is very clear precedent under federal law under an entitlement of a prevailing party is a case where a party claims they've been deprived of a constitutional right to recover attorney's fees, and those can become very significant.

That is really all I had to comment about. I would encourage you to look at this, and I can give you citations from the transcript. If you are interested in the history of it, this is the transcript of the consultants the legislature hired a while back. Their arguments are still relevant and really apply equally with the bill that's before you. But certainly to look at the D.C., because I think it is squarely on point in terms of the issues that are before you.
SPEAKER 2: Just to re-emphasize, this is all related to the unconscionable pricing issue?
MR. HOLLER: It's focusing on the unconscionable pricing section. That's right.
SPEAKER 2: Thank you.
SPEAKER 3: Do insurance companies have a position on the (inaudible) confidentiality of the data records?
MR. HOLLER: Of the data records? No.
SPEAKER 4: Educate me more on the patent law stuff. It makes sense to me saying we have this agreement saying we will protect the researcher by giving exclusivity for marketing

the product, and so on, but is there a certain level of reasonableness in terms of profits and the cost a manufacturer may incur? In other words, can they basically have unlimited profits, or profits up to a certain cap, or is there a limit on how much they can spend on marketing the drug that can then be recouped as part of the cost or the profit scheme?
MR. HOLLER: I think it's a very good question, and it relates to congress's role in determining the appropriateness of those patents. Congress regularly revisits this and other areas of patent law, both as it applies to pharmaceuticals and other drugs to look at the exclusivity period. I don't know if they've looked in terms of that balance of profitability, marketing expenditures, and so on.
The issue really is, what is the term of their exclusivity? Within that, I think the presumption is that the manufacturer of that product can charge whatever the market will bear within the period of that exclusivity. That's just the nature of the patent system.
SPEAKER 3: It all makes sense that there

has to be this handshake and understanding of this, but it gets into the realm of, okay, then what the patent law is actually doing in the sense of pharmaceuticals is legalizing a monopoly on a particular patent. Because research has been done, they have the right to have exclusivity, and be able to recoup the cost of profit, but profit based upon how much price they can get out of the market. I guess I have a lot to learn. Thank you very much.

(End of testimony of John Holler.)
(CD07-140/T3).

MR. STORROW: Thank you for taking me on such short notice. My name is Chuck Storrow. I represent Express Scripts.

What I would like to do is talk about the enforcement provision in the PBM sections, which is on page 21 of the bill passed by the Senate. Basically, this follows-up on the testimony from Mr. Quigley, from Express Scripts, concerning the enforcement provision.

I've just passed out some language for an amendment that Express Scripts is proposing to

the committee, and in essence what this language does is put the enforcement authority over PBMs exclusively with BSHCA's (phonetic) (inaudible), and also de-couples the linkage to the Consumer Fraud Statute. The problem from Express Scripts point of view is that by linking enforcement of the provisions in this bill to the Consumer Fraud Statute, it creates a high degree of legal risk for the company, because among other things, people who have standing to sue under the Consumer Fraud Statute can seek (audio) damages, and that puts the company at risk, and has the potential of raising drug prices.

That's the concern. The reason why we think it's appropriate to do this -- I'd like to sort of step back and think about the players in the market. When Ms. Brill was testifying she was asked to give an example of an unsophisticated purchaser of PBMs in the State of Vermont, and her response was, "The state itself with it's medical services product for state employees."

I would contrast what Ms. Brill offered as an example of an unsophisticated purchaser

with Ms. Callahan's testimony of how the state's gone about lining up prescription drug benefit services for state employees, and the satisfactory experience they've had with negotiating contracts with Express Scripts, and the fact that they are very sophisticated in how they approach this.

I would submit that there is not a need to provide additional protections to entities -- the State of Vermont is a little bit of a bad example in that the Attorney General's office would represent the State of Vermont as the state's attorney in connection with any dispute with a PBM that has a deal with it.

There is a high degree of sophistication with the (inaudible) of PBM services. They do not, as a result of that, need the benefit of the Consumer Fraud Statute, and the problem with the applicability of the Consumer Fraud Statute is that is elevates the legal risk for the companies, and therefore, would have the tendency to increase the amount that they're going to charge in relation to these contracts.

A related point that I would like to make

is that under the Consumer Fraud Statute right now, in order for the statute to be applicable, there must be a consumer involved. The activity has to involve a consumer. The statute defines a consumer as being "a person or a business who purchases goods or services for their own use and not for the purposes of resale."

I think that is a policy philosophy that if you're buying goods and services for the purpose of reselling, you're operating in a manner that is different than when you're purchasing for your own internal use. Basically, I think the distinction of the definition of consumer in the Consumer Fraud Statute basically is saying, "Look, if you're buying goods and services for resale, you're operating in a manner where you don't need the protection of the Consumer Fraud Statute."

You folks are the legislature, and you can change that policy approach in connection with enacting this statute. I think it speaks to the notion that in this case the purchasers of PBM services are doing it as a package of goods and services that are assembled by them,

that are then essentially resold, whether to employers, if they are self insured, or to health insurance companies in connection with helping them manage a prescription drug program. That's then provided to people who buy that.

So, that shows that in this situation we're not talking about unsophisticated purchasers who are buying something for their own use internally, but you're talking about sophisticated purchasers who are buying these services in connection with assembling a package of essentially an insurance product that is then resold.

That's essentially our pitch in a nutshell. Again, that these are sophisticated purchasers. The example that was given of the unsophisticated purchaser that's out there, I think, contradicts the assertion that they are, in fact, unsophisticated, because the State of Vermont is able to negotiate these contracts in a satisfactory manner, and given the potential downside of the imposition of the Consumer Fraud Statute in these situations, we would respectfully submit that

the committee favorably consider the proposed amendment.

SPEAKER 4: So, the language is basically in there, you're just taking out all references to consumer products.

MR. STORROW: And we are putting in there that it would be that BSHCA would have the exclusive authority of enforcement. It makes sense to us if you're going to require PBMs to be registered with BSHCA, that BSHCA be the enforcement authority.

Another way you could slice this is that you could keep the Attorney General as the enforcement authority with respect to PBMs interacting with non-health insurer entities. That's the way the bill is currently structured. Our preference would be that it all fall within BSHCA.

SPEAKER 5: I notice there's a change in the first paragraph of your amendment (inaudible)

MR. STORROW: That's right, and that goes to -- maybe the way to respond would be to direct your attention to beginning at the bottom of page 14, "The definition of health

insurer." That's 9471 Sub 2. In the bill, as passed the Senate, the entities that are referenced in Sub A at the top of page 15 are the health insurers that are currently regulated by BSHCA. Where "B" and "C", for the purposes of this bill, are considered health insurers, but not health insurers in the traditional sense of being an insurance company. They are like self employed insurance groups.

So, the bill as currently worded makes the distinction that companies that fall within "A" are subject to the exclusive authority of the BSHCA commissioner in terms of regulating PBMs, and "B" and "C" can be both of them. So, we just took out any references to the subdivisions below subsection 2 -- I don't know if I'm making sense here.

SPEAKER 5: Yes. Putting them all under BSHCA.

MR. STORROW: Right.

SPEAKER 5: And now, they are under other places?

MR. STORROW: Well, they are -- the "A" ones are BSHCA, and "B" and "C" are BSHCA and

Attorney General, either, or.

SPEAKER 5: And that's according to the way the bill is written? "B" and "C" are BSHCA or Attorney General?

MR. STORROW: Right. I have to go back to --

SPEAKER 6: The compromise language between BSHCA and the A.G. that they brought forward and sent to Health and Welfare, was that BSHCA would have exclusive jurisdiction over the entities they currently have jurisdiction over, and those are the entities in 2A.

SPEAKER 5: Yes.

MR. STORROW: One clarification point that hasn't been raised. There's been discussion of (inaudible) and the Department of Labor. That would all relate to a situation where an individual insured or beneficiary of a health plan, if they had standing under the Consumer Fraud Act to bring an action, at least in the case of say an employee of a self insured employer, that individuals remedies...

(End of 07-140/ T3)

CERTIFICATE

STATE OF FLORIDA,)
COUNTY OF MIAMI-DADE.)

I, Michael T. Berkowitz, Shorthand Reporter, do hereby certify that I was authorized to, and did listen to CD 07-140/T3, the House Committee on Health Care, Wednesday April 18, 2007 proceedings, and transcribed the foregoing proceedings, and that the transcript is a true and accurate record to the best of my ability.

Dated this 21st of August 2007.

_____
Michael T. Berkowitz
Notary Public/ Shorthand Reporter

STATE OF VERMONT

HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: April 19, 2007

Type of Committee Meeting:
Standard

Committee Members:

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

CD No. 07-143/T1, T2, T3

CD No. 07-144/T1

PROCEEDINGS

REPRESENTATIVE MAIER: Good morning, Julie. Thank you for taking the time to be with us. I guess you have some testimony that we'll see in a couple of minutes, and we also have a few questions for you. Do you want to start by summarizing your testimony or would you like to start with our question?

MS. BRILL: Whichever way you'd like. I'd be more than happy to run through my testimony with you. It might be easier if you actually have it in front of you.

Because what I've done, I knew the committee when I was there last time, and particularly you, Steve, had a question about, well, what data is there to demonstrate either the problems with respect to marketing to physicians or the problems relating to using doctors prescribing data.

And what we have done is we've pulled data for you and we've looked for the most conservative sources. So we've tried wherever possible to use for instance GOA information, General Accounting Office, information, so that

is the information I wanted to run through with you. And also, I have responses to Art Wolf's, the major points in his letter in my testimony. I mean the written documents.

REPRESENTATIVE MAIER: So let's wait until we have that in front of us. And maybe I'll start with the question or two that had come up since we saw you last and/or things that we or others have asked, we're considering or others have asked us to consider that we want -- we'd like here an opinion on.

We received testimony yesterday on the enforcement section of the PBM regulation section from Chuck Sturrow (phonetic) and Express Scripts essentially asking us to remove all reference to the consumer fraud section -- consumer fraud statutes in that section.

And I was hoping that you could just review the history of that with us, why you think it's important in these consumer fraud sections. I know there were some negotiations that went on between you and Bishka (phonetic) about that, but if you could maybe take a couple minutes to respond to that request that was made of us.

MS. BRILL: Sure. My understanding, and I

have received some e-mail that has gone back and forth from a person who I believe maybe Chuck Sturrow's (phonetic) client, a Brian Quiggley (phonetic). Did you hear from him?

REPRESENTATIVE MAIER: Yes, right.

MS. BRILL: He was the person, great. So I believe I understand what his concern is. But let's take a step back. Enforcement under the banking laws do not give any private right of action whatsoever.

There is no ability of a consumer or a plan to vindicate rights under Title -- under those portions of Title 8. The Consumer Fraud Act allows not only our office to do enforcement, but also plans and consumers to bring enforcement actions that they want to do.

That's generally speaking. So that's, one, a very large difference. My understanding of -- I'm just trying to pull up the Bill as it was enacted. But, well, okay, here we go.

But my understanding of Mr. Quiggley's concern is that the ability of consumers, in this case beneficiaries, to bring an action under this section of the Bill if it's enacted

would be preempted under ERISA. That's my understanding of his concerns.

And I don't believe that's the case. I have actually spoken with David Balto (phonetic), who I know you also have heard from, who's probably the nation's leading expert on PBM issues, who is independent of the three big ones that make up the vast bulk of this market, 80 percent of the market.

And he spent a lot of time thinking about PBM. I specifically ran by him Mr. Quiggley's argument and he said that's just not going to happen. David and I are still talking about that issue and I'm trying to get more specifics from him on that.

I also don't believe it to be the case. But at the very, very least, you know, if there is an ERISA problem, I think we should narrowly focus in on what that ERISA problem is.

And there's no reason to get rid of the entire enforcement section and our office's ability to enforce and a plan's ability to enforce simply because Mr. Quiggley has the notion that if a beneficiary were to do enforcement, that might be preempted under

ERISA.
So that's my current view on that. I don't think he's right, David Balto doesn't think he's right. And that's probably the most important point. But if he does happen to be right, one ought to more particularly focus on his issue rather than simply saying there should be no enforcement under the Consumer Fraud Act. Is that responsive to your question?
REPRESENTATIVE MAIER: Yes, I guess so. Maybe you could just explain a little bit about -- give a little example of what you might envision, you know, the type of enforcement action that this would allow your office to take that might not be allowed in another without this language.
MS. BRILL: What was just the very last word you said? Without this, what was that?
REPRESENTATIVE MAIER: Without this language.
MS. BRILL: Oh, okay. Sorry. I apologize again, but the connection is not so great. Well, we would still be able to do our general enforcement work with respect to PBMs.
As you heard from David Balto, There are

some significant investigations that are underway currently.
Because although I have told you all that the industry has improved since 2004, there are still quite a number of problems in this industry that we are looking at quite actively. But what we would be unable to do would be to enforce this section of the law so that if -- in other words, this section, what you currently have in front of you, is creating new obligations on the part of PBS.
They will have to give notices to plans about certain kinds of options that are available to employers in the instance of the Attorney General's office, or in the instance of Bishka to insurers.
And they will also have to act with due diligence, you know, that language that we have with respect to their duty of care. In the event that they fail to do so, our office would be unable to enforce those provisions with respect to plans that are sold or marketed to employers and consumers. That is, the plans themselves, the businesses who are harmed by either that failure to live up to that duty or

the failure to give the appropriate disclosures would also be unable to enforce their rights.
Essentially you'd be enacting an empty shell because there would be no enforcement whatsoever. That's certainly by the plans themselves.
REPRESENTATIVE MAIER: I'm about to move to a different area. Does anybody have a question?
UNIDENTIFIED FEMALE: But that doesn't mean that's an individual, right? Not an individual? Just a company who's in contract with a PBM, right? Not an individual?
MS. BRILL: If you were to eliminate any enforcement under the Consumer Fraud Act, then plans would not be able to enforce their rights, and beneficiaries would not be able to enforce whatever rights they might have under this section that you're enacting.
UNIDENTIFIED FEMALE: Okay. Thank you.
REPRESENTATIVE MAIER: Patty O'Donnell has a question.
MS. O'DONNELL: Aren't the plans right now presently able to enforce their rights because it's a contract, and they can take the PBM to Court if they don't fulfill their end of the

contract?
MS. BRILL: There's always a contractual right. But the section that you're enacting creates obligations on the part of the PBM that are not contractual obligations; they are statutory obligations.
And, yes, a plan can bring a PBM in theory to Court over contract violations, but that's something different than what you have in front of you.
REPRESENTATIVE O'DONNELL: But the testimony that we're hearing is there's no small businesses that contract with PBMs. It's the insurance companies or the larger businesses, including the State, that are self-insured.
We've heard a lot of testimonies about how these entities hire a negotiating firm that is a very big, powerful firm to negotiate for them.
So we really don't need this language because -- any of the PBM language -- because nobody is negotiating their own contracts out there or needs to be protected from the State.
MS. BRILL: I'm really glad you asked that question because I spent some time thinking about that. That was also a question that you

had asked when I was there, gosh, whenever it was, a week ago.

And I've actually talked with David Balto about that question. And what the current system has built into it is a requirement that anyone who isn't very sophisticated, you know, one of the Fortune 50 or Fortune 100 companies, has to hire a third party administrator or -- that's what they're called, these PPA's -- has to hire someone to negotiate for them because they just can't do it themselves.

So what you're doing for those small entities is you're building in costs for them to provide these benefits to their employees.

What this Legislation is designed to do is to allow small businesses to get the information on their own so that they would be able to, if they wanted to, to negotiate on their own without having to have the additional cost of going through a third-party administrator.

The system as it is now, let's assume you're right, you know. What you just said, Patty, is a data-driven issue. Are there any small businesses or medium-sized businesses, or for that matter what we would consider very

large businesses, but still, you know, from a PBM's perspective might be considered a, quote, unquote, small business, are any of them negotiating directly with the PBM.

Let's assume for a minute empirically that what you heard is correct and that they are all using these third-party administrators. That seems to be a problem with the system, that all of these businesses have to hire someone in order to figure out how to do their benefits. It shouldn't be so complicated. It ought to be much more transparent.

And what you're doing by the lack of transparency, you're building in additional costs for these businesses that just shouldn't be there.

But it is a data-driven issue, and I don't have data on that. And I don't know if they actually provided data to you about their customer base. I think that would certainly be interesting to see to verify.

REPRESENTATIVE MAIER: Okay. Another question that's come up, Julie, still in the PBM section, back at the very beginning of the section or more or less at the beginning, the

beginning of the substantive part in any case.

Section 94.72, sub A, right where it starts, and with the language that "unless the contract provides otherwise," and then it lists the various duties and responsibilities after that, the question has come up about the first due diligence duty under that and whether it makes sense to have that be one of the things that can be waived as a result of the negotiations in the contract. And Harry Chen, maybe he'd like to give you his thought about that.

MS. BRILL: Sure.

REPRESENTATIVE MAIER: He keeps raising it. But the question is that perhaps that ought to be pulled out to remain an obligation regardless of whether or not -- of what else may happen in the contract. Did you want to add to that, Harry?

REPRESENTATIVE CHEN: It just seemed to me that if we believe that people should have a certain standard of responsibility in a contract or in a relationship, that it shouldn't be something that you can waive by a contract.

MS. BRILL: I think that makes a lot of

sense. I agree with you on that. The contracting issues really have to do with the notices that come later, which is I think the point that you're making.

And it would seem that the standard by which PBMs have to operate with respect to entities that cover beneficiaries in Vermont, you know, ought to be just a statutory standard. And certainly that is the way it is in the District of Columbia and the Maine laws, both of which have been (inaudible). It's just a statutory obligation that this is the duty under which the PBMs have to operate.

REPRESENTATIVE MAIER: Any other committee comments or questions on that?

REPRESENTATIVE CHEN: Actually, I have a question, Julie. This is Harry Chen again. The Maine and D.C. standard is a higher standard than ours, is that not correct?

MS. BRILL: It is certainly worded differently. They use the word -- if I recall correctly, they actually use the word fiduciary duty.

What we've done is we've taken language from case law in Vermont that relates to how an

insurance agent needs to treat an insured.
And, you know, certainly we think that this is, you know, a fairly high standard, reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a PBM acting in like capacity, etcetera, etcetera, you know, -- but it does not actually use the term "fiduciary duty."
REPRESENTATIVE MAIER: Thank you. And then there were a couple of maybe smaller questions that Robin had been tracking. And I might just ask Robin Lunge (phonetic) to maybe just jump in the chair there, Robin, and maybe you can remind me what -- I know there were a couple things you were pointing to that you thought at least Julie should at least know about.
MS. LUNGE: Yeah. Okay. On -- actually, one is just a question, Julie. Can you hear me okay?
MS. BRILL: Yes, I can hear you great. Can you guys still hear me all right?
MS. LUNGE: Yeah. In the Medicaid disclosure statement, the price disclosure and certification, Section 5, which is on -- the language is on page 11 that I'm going to refer

to, the question came up about the certification of the prices that stem by the president, CEO or designated employee and what -- if there was a false report what the penalty for that false report would be, if you know.
MS. BRILL: Okay. I am now -- I may not be working with the same --
MS. LUNGE: It's in D.
MS. BRILL: It's Section 5. I'm there now, sorry. The document I'm working from is the Bill that's passed by the Senate.
MS. LUNGE: Right. So the pagination is different.
MS. BRILL: Yeah. So D says that they have to enforce. What Title are we in?
MS. LUNGE: We're in title 33, so this is under Medicaid.
MS. BRILL: Right. And there is currently no enforcement provision here?
MS. LUNGE: No. Oh, wait.
MS. BRILL: Excuse me. I'm sorry. Go ahead.
MS. LUNGE: There's Consumer Fraud Act enforcement.
MS. BRILL: Oh, okay. There it is. The

penalty is $10,000 per violation, up to $10,000 per violation.
MS. LUNGE: So because the enforcement is through the Consumer Fraud Act, it would be a civil violation?
MS. BRILL: Yes, it would be a civil violation, correct.
MS. LUNGE: Okay. Okay. So that was just a question I wanted to get your thoughts on. The other issue I just wanted I think more to tell you about is in the Section 17.
MS. BRILL: Okay. It might take me a minute to get there. About what page is it on?
MS. LUNGE: It's the second-to-the-last or third-to-the-last page.
MS. BRILL: Okay. Almost there.
MS. LUNGE: This is the provision that allows enforcement through Consumer Fraud Act of violations of the federal advertising.
MS. BRILL: I'm there, yeah.
MS. LUNGE: So there was some testimony that the way the language is written right now it's directed at direct-to-consumer ads.
And there was some testimony that the committee should consider adding in the

direct-to-doctor advertising.
MS. BRILL: I completely agree with that. I'm not sure which language -- if that is the case --
MS. LUNGE: I think the language would be added under "regulated advertisement."
MS. BRILL: Okay. I'm just getting there. "To the general public of a commercial message." I think it's definitely, if people might interpret that in the way that you've just described, that is, only covering direct-to-consumer advertising, then absolutely it should be changed.
Because, as I mentioned when I was there last week, the vast bulk of advertising really is focused on what's called direct-to-doctor or doctor/physician advertising.
And that certainly is in our view the more important -- I mean, both are very important. But certainly the doctor advertising is very important.
MS. LUNGE: That's all I've got to mention.
REPRESENTATIVE MAIER: So why don't we now have your written testimony, so why don't you walk us through that.

MS. BRILL: Sure. That's great. I'm glad. Of course, I'm not sure what the Committee's timetable is on this entire Bill.

I will be back in the state tomorrow and all next week. And, of course, if other questions arrive either today or tomorrow when I'm back in the state, I'm more than happy to be in there.

But as I mentioned, I got a very strong sense when I was there last week that what you were looking for was data. You wanted to know, you know, how is it that some of these practices are driving up drug costs.

And, Steve, I thought you in particular had asked me that question, and it might have been that others did as well.

And just to begin with, as I said, I did not want to pull data for you except from the most conservative sources that I could find.

So I was really focused on, you know, either peer-reviewed articles or publications by the industry or government publications.

So that's what you have in front of you. So let's Begin. Just to walk you through this, I thought, you know, IMS perhaps when it's in

its more honest moments it, you know, does tell the industry that what it is about influencing prescriber perceptions, attitudes and behaviors, and in order to do that it provides data that's critical to help to make sure that the message is delivered are the right one given the brand strategy. It really is a marketing effort that they're involved in.

So that's what that first quote is designed to remind everyone of. But focusing on the cost impact of marketing to doctors, you know, what the data shows is that the industry is very smart in the vast amount of money that it is spending on marketing to doctors; that the reason it does it is because it's effective and it does increase sales.

In a very recent publication, November of 2006, found that for every dollar spent on marketing a specific drug, sales go up by up to six dollars.

Now, that study was focused on direct-to-consumer advertising, but it did have some data on other types of marketing. The GAO did say that $11.2 billion was spent on drug marketing which does not include free samples.

That also doesn't include the actual salaries of the detailers, so that's why some of the estimates that I had given you last week were much, much higher.

An industry study showed that of over 100,000 doctor visits, the study found that each doctor spent on detailing produced what they call an RIO, or return on investment, of between $2.28 and $5.18.

GAO reports that the increased cost of heavily advertised drugs is driven primarily by increased numbers of prescriptions written, not increased price.

Between '99 and 2000, for example, the number of prescriptions for the most heavily advertised drugs increased 25 percent, while prescriptions for drugs that were not heavily advertised only rose four percent.

Prices for the most heavily advertised drug rose six percent compared to nine percent for the others. So this is not a price-driven issue; it is a marketing issue if you understand the distinction.

In other words, the industry is not necessarily raising the prices of its most

expensive drugs.

What it is relying on is increased prescriptions switching from lower cost drugs to more to higher cost drugs through their marketing effort. That's what that fact points out quite clearly.

And then, you know, we had lots of examples of particular classes of drugs. You might remember the last time I was there I said it's often difficult to generalize about drugs and you really do need to look class by class to see what's happening.

And just as one example, we looked at the diuretics. And Harry can tell you guys lots more about diuretics and how many people need them and how many people are on hypertensives.

But it is one of the most popularly prescribed drugs for people with high blood pressure. And so low-cost diuretics are actually very inexpensive. Higher cost hypertensives are obviously higher cost and they are quite heavily marketed.

Pennsylvania's Pharmaceutical Assistance Program, which is known as PACE, found that in 2004 31 percent of all prescriptions for

hypertensives -- excuse me, for antihypertensives were for a high-cost drug, even though the diuretics would have been the appropriate choice.

Had the diuretics been prescribed, the State of Pennsylvania would have saved $11.6 million, $8.7 million per 100,000 persons treated for hypertension or 24 percent of their total antihypertensive budget. That's a lot of money.

So I just thought again you might want to see some of that data. And there's a lot more out there, but we were just trying, as I said, to be somewhat conservative.

The next section of my testimony is really designed to respond to some of the points that were made by the economist, Art Wolf. And what I've done is I got quotes from his letter to you, and then our response to those points. Should I continue running through this?

REPRESENTATIVE MAIER: Well, why don't you take it up a notch or two and not literally read us through the letter. But can you just maybe summarize the main points here? We have about -- maybe about ten more minutes with you

before we need to move on.

MS. BRILL: Okay. Well, they basically -- you know, Art is an economist and he makes lots of assumptions in his analysis.

The biggest assumption, well, one of the biggest assumptions he makes is that information being provided by the industry to doctors is accurate, and actually studies have found that much of the information is not accurate.

So to the extent that it's important to get doctors accurate information, the question is whether this entire marketing scheme is the best way to get accurate information to doctors or is it really more skewed and not as accurate as it could be. That's what the first bullet there is about.

He also assumes that the drugs that are being marketed are cost-effective. He makes this point, that providing this information to them will actually help reduce health care costs. In some way that's probably the biggest assumption.

As I just pointed out, actually what's being marketed are the most expensive drugs, not the less expensive drugs. And the whole point

is to get physicians to prescribe more costly products in the vast majority of cases.

And I give you another example of a couple of drugs that were being heavily marketed and now actually have been either pulled from the market or there are very heavy warnings about how they should be used.

So again assumption is that it's actually cost effective, the marketing that's going on, but in fact it's not. The next point is a further one in that area.

He says, for instance, that lowering blood pressure or medications that lower blood pressure are a good example to show how potentially surgeries later on that might be necessary could be avoided.

And generally speaking it is true that there are many pharmaceutical classifications that if taken on a regular regime might avoid more costly surgeries. But high blood pressure is again a great example.

And that's the example I mentioned before about how diuretics for the vast majority of people are really completely appropriate which cost about nine dollars a month, whereas if you

are convinced that the channel blockers and the other more fancy drugs for this, the ace inhibitors are better than what you are putting a patient on is a $27 to $60 dollar cost regime.

Then he posits that certain information would be really helpful to know, but really it wouldn't be helpful to know for anyone other than an economist or a drug company. I won't really spend a lot of time on that.

But one of the bigger assumptions that he as well as his client, IMS, and others are making is that if this law is passed this data will go away.

And the assumption that's built into that is IMS and Verispan would stop producing the data if Vermont were to enact this law. Or maybe the assumption is that if Vermont were to enact it, then everyone would enact it. And, you know, that is a big, big assumption. And it's not data driven.

There's no empirical evidence whatsoever that the companies, IMS, and Verispan, would be economically induced to stop gathering the data if one or even a handful of states were to enact this law. It's something they're telling us,

but they are not giving us any data to show that it is necessarily true or that we should think that that prediction will come about.

The final point I want to make, and it's just sort of an interesting point, and maybe one more for Harry than anybody else. But the manner in which IMS actually gathers the data, and Verispan, the way they gather the data would never be approved by an IRB, an Institutional Review Board, for the protection of human subjects, because they do not get informed consent from the physician when they're collecting this data.

So here they are talking about health care, health outcomes, the need to provide this information for researchers.

And it's interesting to note what they're doing, which would not pass muster. So that's probably what I wanted to let you know in terms of running through my response to Art Wolf's letter.

REPRESENTATIVE MAIER: Okay, thank you.

MS. BRILL: I'm sorry if that went on longer than --

REPRESENTATIVE MAIER: No, that's fine. We

have a last couple of points here. You want to touch on those or?

MS. BRILL: I'd be more than happy to if you'd like. I just thought that -- there's some data there about free samples and to what extent free samples are actually leading to higher costs.

It was a point that I had made when I testified previously. But here is actually some data for you. Some of this data is repetitive of what I've just said; for instance, diuretics. But there's also some information there, (inaudible), prescriptions and some other data.

And then just the final point is that actually, you know, this heavy marketing to doctors has been one of the areas that has led to some of the safety problems that we've seen.

And, as I just mentioned a moment ago, Vioxx, which is one of the Cox 2 inhibitors was very heavily marketed. There was actually quite a bit of competition between Vioxx and Celebrex, both of which were very heavily marketed.

Vioxx ultimately was pulled from the market because of the greater risks of cardiovascular events, and there's a lot litigation now over

whether or not Merck knew about that. And then there's some other examples there.

So this heavy marketing to doctors, you know, in areas where there's a lot of competition among brands in certain classes of drugs is certainly one of the areas that has led to higher health risks. So that's what that last point is about.

REPRESENTATIVE MAIER: Question from Hilde.

REPRESENTATIVE OJIBWAY: I have a question about free samples. If a physician gave free samples every time that drug might be called for, so he's giving it to every single patient who comes through, I don't know if that happens, but I was wondering if the doctor is giving free samples where he might think that the patient -- he might know they don't have insurance or know something about their personal situation to think that they really need it because they're low income; if that's happening -- well, first of all, it would be interesting to know if that's happening; and, secondly, if it is happening, then it would seem to me that the practice of the free samples and the negative aspects would fall more on low income people

than folks with insurance or higher income.

MS. BRILL: You know, there really isn't in my view anything in the Bill that deals with -- that would stop marketers from giving free samples. You know, and the only reason I put this in the written document that you have in front of you was because I had mentioned it before and I wanted to give you some data about the effect of free samples that you may remember I mentioned before and I'll reiterate again.

The free sample area is certainly one that is subject to very hot debate. And on one side are exactly the points that you're making; that is, that the free sampling really assists people who don't have coverage who aren't low income enough to qualify for state programs and yet need some very expensive drugs. But built into that are exactly the kind of assumptions that you just talked about.

The patient would have to go to the doctor each and every time she needed that drug. The doctor would have to have a free sample available when the patient needed it and then, you know, be in a position where the doctor could give it to the patient.

And there's a lot built into those assumptions. I mean, typically speaking, what really happens here is the doctor starts the patient off with a couple of free samples, and then the patient goes on and has to start paying for the drug once the patient finds, you know, that the patient likes it.

I mean, these typically speaking are maintenance drugs, drugs that the consumer is going to need for a very long time typically speaking.

So but I don't want to discourage the point that you've made, because again there are a lot of people who've spent a lot of time thinking about this and have that concern.

And my -- the real answer to that is that there's nothing in this Bill that's going to directly impact free samples and the distribution of free samples.

REPRESENTATIVE MAIER: John Zenie?

REPRESENTATIVE ZENIE: Hi, Julie. It's kind of a related question about the value of free samples. And I'm talking my own personal experience where I'm not low income, I do have health insurance and my physician has given me

free samples to see if they help me with whatever my issue is, which I found very valuable so I don't have to buy a whole 30 days worth and find out after taking it twice that I have bad side effects and then try something else. So there seems to be some value there and a cost savings with having free samples. Would you agree with that or can --

MS. BRILL: As I just said, I do think that there is value to patients with respect to getting free samples. I don't think there's anything in the Bill that's going to stop that from happening.

Has someone testified that free samples will no longer be given out if some provision is enacted? Because I just don't see that. You know, free samples you don't -- if maybe what they're saying --

REPRESENTATIVE MAIER: Nobody has testified to that.

MS. BRILL: Okay. Maybe the argument is somehow that if the companies don't have the prescription data they won't be able to specifically target the free samples to the right doctors, that would just be a silly

argument.

Because they know who needs what free samples by the type of doctor you are. Are you are a family practitioner, are you a heart specialist. You know, that will really inform as to what kind of medications you might be prescribing. You don't need to have prescription history to know that.

So the first answer is really I don't think anything is going to affect the distribution of free samples if this Bill is enacted.

But having said that, absolutely, I mean, there are some times when it might be helpful. But this is not a charitable activity that the pharmaceutical manufacturers are engaged in.

They give out free samples because overall for the vast majority of patients it puts them on a drug, perhaps as you're saying, for a short period of time to see if they like it or don't have side effects, at least immediately visible side effects. And then they -- then the consumer starts to pay for it and the plan starts to pay for it.

As you know, many side effects aren't going to be visible or known for potentially years.

So having taken a drug for 30 days certainly is helpful to figure out whether it's something that's going to work well for you, but it's not determinative.

REPRESENTATIVE MAIER: Thank you. Last question maybe from Virginia Milkey.

MS. BRILL: I have time. If you guys need to move on, no problem.

REPRESENTATIVE MAIER: No. We have another witness here in a couple minutes.

MS. MILKEY: Julie, is there anything that prevents, if the situation calls for it, if somebody is getting a new prescription and there's a question as to whether it's going to have side effects or work or whatever, and it's agreeable to the physician and the patient that the person could get, you know, a couple of days or free from the pharmacist. Because they fill up the bottle when you call and say here's the prescription. You know, with an inhaler it's a different matter. But there are many things they just fill up the bottle based on what's prescribed.

And it wouldn't be the same as a free sample, but rather than somebody having to spend

the money for a whole month's supply, is there anything that prohibits that from happening under then maybe insurance company policy?

MS. BRILL: So you're basically saying that the pharmacist would give a couple of extra days over and above the 30?

MS. MILKEY: No. That the person could say I've got a 30-day prescription but can I just get two or three days to make sure that I don't have rashes or, you know, nausea or something before I commit to the 30 days?

MS. BRILL: I'm not aware of anything that prohibits that. Harry may have a different view.

MS. MILKEY: I know there's some cases where it wouldn't work.

MS. BRILL: Yeah. I mean, the problem is typically speaking again what we're talking about in the vast majority of cases here are maintenance drugs that the consumer will need and does need every day.

And I might have mentioned to you last time, so the other issue that is triggered by your question is there are health effects to switching consumers back and forth from one

product to another product even within a class.

So, for instance, I mentioned the statins, which are cholesterol-lowering drugs. There are many people who develop best-practice guidelines who say that when you go from one statin to another, like Lipitor to Zocor, even though they're in the same class, the doctors should be doing blood tests to make sure that the patient is adequately maintained on the new products. They're not identical compounds, and that's the whole point.

They're in the same class, but their brand of drugs -- they're different because they actually are different chemical compounds.

So in some instances what you would be talking about, Ginny, would result in having to do additional lab work on this patient to make sure that they are being adequately maintained in this kind of experiment that they want to run.

So sometimes it might be ill-advised. At other times with other classes of drugs maybe it wouldn't be so problematic.

REPRESENTATIVE MILKEY: I was thinking not of necessarily a -- obviously, there's

circumstances where you wouldn't want to do that.

But, you know, when you're getting an antibiotic for something and they give you the cheap one that makes you nauseated, and that's less money because it's a generic. But it seems like maybe there would be some issues on brand names too.

MS. BRILL: I actually found the more expensive ones, they're the ones that make me nauseated.

REPRESENTATIVE MILKEY: Thanks, Julie.

REPRESENTATIVE MAIER: Thank you very much, Julie. And we're -- I guess my current goal for voting on the Bill is on Tuesday. We'll be working this morning and some tomorrow, so if we need to be in touch with you we know where to find you.

MS. BRILL: That's fine. And because again I'll be back in town, maybe I'll just come to the committee room and that will make it easier for you if questions arise as you're discussing it. So thank you very much by letting me talk by phone today. Thanks very much, everybody.

REPRESENTATIVE MAIER: Bye. We're going to

move on.

UNIDENTIFIED MALE: We have Mr. Frankel here. I would just introduce him to the committee since he's not from Vermont.

This is Randy Frankel, vice president AS IMS Health. And I asked him to come today because as I've listened to all your testimony I realized THAT this Bill purports to add regulation to PBMs and to pharmaceutical companies in various ways.

But it actually puts Randy's company out of business in Vermont. So it's an additional regulation but it's an outright ban. So I thought it would be helpful for somebody in the company to come up and say what they do in light of somewhat extreme measures you are considering about their company, banning what is now a legal business. So with that, I'll leave you Randy Frankel and he will answer your questions, I think. Welcome.

REPRESENTATIVE MAIER: Welcome. Welcome to Vermont.

MR. FRANKEL: Good morning. Thank you.

REPRESENTATIVE MAIER: We spoke with you on the phone, is that right?

MR. FRANKEL: Yes, you did.
REPRESENTATIVE MAIER: So you are from Connecticut?
MR. FRANKEL: Yes, I am. And I come here for the maple syrup.
REPRESENTATIVE MAIER: I am from Connecticut. Whereabouts in Connecticut?
MR. FRANKEL: I am in Fairfield County, Westin. I've been a resident of Fairfield, now Westin. Very nice, but we don't have the mountains. It's nice to visit.
REPRESENTATIVE MAIER: Well, if you have kids in the Fairfield schools they may have had my brother. He teaches middle school science.
MR. FRANKEL: Great.
REPRESENTATIVE MAIER: Welcome.
MR. FRANKEL: I do appreciate you allowing me to come here and speak with you. I'm always struck when I listen to the issues about how complex an issue it is and how many different perspectives there are.
Steven actually suggested that I give you a sense as to some of my background; I'll do it very briefly because I'm not a lifer in IMS.
I've been here a year and a half. I did

spend over a decade in the pharmaceutical industry so I know it inside and out.
But I spent even more time than that in the managed care world and did have some experience in the pharmacy benefit management world and was responsible for the development and managed the departments that built drug interchange programs and formularies and disease management programs and outcomes research.
And we even hired Jerry Avorn to do counter-deselling in the state of Massachusetts in the early '90s. I was essentially responsible for managing drug costs for our clients. And we had 30, 40 million members that we represented.
So I've been on the other side. I then went to the consumer world in the sense where I went to consumer health care and tried to build decision support tools for patients through Web M.D. And I was a senior vice president there and I was responsible for that.
And then, frankly, having been through all of those areas, noting that information seemed to be a common denominator in a real -- a loss, a real gap in the system for consumers, for

payors, for physicians, for virtually everyone, I moved to IMS.
And because of their interest in expanding the business from the pharmaceutical industry into a managed care, into outcomes research, into the payor market, the government market and the consumer market. So having been on both sides, it seemed like this was my next step in my career.
I have a few more left so I'm not sure where they will all go. So that said, that's my background. I've known IMS internally for a year and a half, but certainly over the last 30 years I've worked with the data. I've known about the company.
I can tell you that inside the company there is a bit of a state of shock. We've been in business for 50 years. I would say that 45 of the 50 we were considered very good corporate citizens.
Went through the '70's and '80's where the data helped to identify underutilization and how to gain optimal usage for hypertension, for cholesterol, for depression in males and females, the data helping with HIV, identifying

doctors who are treating it. In helping with Risk Management programs to reduce -- to bring difficult and high-risk drugs to the market.
All of these things have been going on for a while and our data have been very useful. Now we find that the world is evolving, as it should.
The population demographics are shifting and drug costs are going through the ceiling. And now our data, somehow we are entangled in it as though we're doing something wrong.
I can tell you that as a company we don't feel that way, although we will be the first to say I think we're late to the table in terms of helping people understand that these data are neutral. We provide them throughout the health care system to stakeholders.
And it had -- probably not enough -- have not put enough effort behind trying to make it useful in government, certainly that's one place. And I can tell you in the consumer world where we're struggling now to see how we can make the data available to patients so they can use the data as well to select appropriate care or appropriate physicians and so forth.

But as you move into new markets, and particularly in government, what you find is a great deal of difficulty finding out how to present the data.

First of all, in every state you have to find a person you can talk to, and then when you do you need to develop a view or a product in such a way that can be sold to other states; otherwise, it becomes a custom project and it's too expensive for you to buy.

And we have that with academia and researchers, we have it in the government arena. Although the federal government is a client of ours. The FDA, the CDC, DEA, CMS, a number of agencies, federal agencies, buy data from us.

So this raises a number of issues -- and certainly may help to address some of the questions you had. Why are we so expensive for government agencies, for example.

Can another database take our place. Well, I'll explain in some detail why I don't think that's the case now or in the foreseeable future. And it would also -- I would also suggest that the government wouldn't buy the data if they had their own.

So we do serve a function that cannot be served elsewhere. I am told and have been told many times that we have for what we do the most elegant database in the world.

And we are a worldwide company and we help companies look at other -- countries, that is -- other countries look at other countries and compare the data utilization and how well they do. So we are a worldwide firm and dedicated to health information wherever it takes us.

And it's available and will be made available to more and more markets, more and more clients, more and more customers like yourselves.

So I want to start by saying it's been a difficult road to try and reach a decisionmaker at a state level, and I'm not saying Vermont specifically.

But we do want to work at the state level. And this is not a sales pitch I hope. I hope it doesn't sound that way. But it's just been a difficult thing to do. And I think that our data can be very useful.

So that's kind of our company and what we do. Now states are -- and it's not just

Vermont. You all know that in New Hampshire a law was passed; we're all expecting a ruling in the next week or two. And I don't want to make this a matter of law. I'm not a lawyer.

So First Amendment and physician privacy, the legal issues of that will be made known to us in the next week or two. But I can tell you that the overriding themes tend to be more about pharmaceutical marketing than our data.

We are getting entangled in it and teasing apart what our data actually do from what marketing does, from what the pharmaceutical industry does is really a very difficult task from our perspective.

We don't have a sales force and we don't call on doctors. We provide data. The data, as I said, are neutral; and they are reported in a format that a client asks of us.

And what I've heard around the table, what I've heard from witnesses have to do with safety issues that are FDA mediated, not us. They have to do with marketing issues which are not being addressed in this Bill.

Pharmaceutical representatives will continue to go into doctors' offices. They have

a financial and a legal imperative that if they spend a billion dollars developing a drug they must sell it.

And so I'd like to address what I think I'm hearing as the issues here. I'm hoping you'll ask questions. I don't mean to just talk at you.

But the issue of the data driving health care costs is, one; the issue of patient privacy I'm hearing as a second; the fact that another database could be put together like Legos and our database isn't necessary is a third.

And then the last one would be physician privacy. And I think I'd like to address that on a number of levels, you know. And I'd like to say right up front.

There's no one in my company who works to be able to provide the data so that representatives could abuse doctors.

I have best friends who are physicians. I've worked with thousands over my career. There's nothing about us that is intended to be inappropriate or abuse doctors. So I'll try and get to that to the end.

So the issue on cost: Fundamentally, I'm a

scientist at heart. And if you don't change any other dynamics I don't see how you're going to change the outcome. And by that I say, if sales representatives are still going to be calling on doctors, if they conduct any and all of the marketing practices they do now, and they will, because of the imperative I suggested earlier, and if they are not -- and if our data went away I think it what we heard from witnesses, they will simply create their own databases and it will be business as usual in six months' time.

I know for a fact that several companies are already designing what they would do in the event that these data went away. And so from a standpoint of what happens in a doctor's office, eliminating these data in six months time will barely be noticeable and so I would not expect that the outcome would be very different.

So what do these data actually do. And I think that's an important issue. First of all, let's contemplate the fact that these data are made available to all companies, big and small, so if one company knows of a higher prescriber, so do all the others.

If there are four or five products in the

anti-cholesterol medication, product one has a representative who says this drug turns blue or yellow, representative two says that's true but yellow isn't a very popular color.

And I don't mean to make light of the subject. But the reality is all five will be giving their perspective on this. And in the end the physician tends to get balance.

I would also say that because they're high prescribers they're knowledgeable. Because they're physicians, they're the most educated decisionmakers in our health care system.

So the fact that all companies have the data, big and small, does several things. It creates -- in some cases it negates one another. In other cases it augments information.

And I'd say as importantly if these data went away, some of the large companies, which are the size of small countries, will build their own databases; smaller companies will not.

So small biotech companies, small pharmaceutical companies -- you may have seen testimony from a company called Asai, and they make a drug Aricept for Alzheimer's disease.

Now, this is a drug that's been proven to

prolong the length of time during which a patient stays at home; it's about two years.

That also happens to reduce costs. But the quality of life issue is probably in my mind the most important. They came into the country and have promoted -- we'll use your words -- promoted the drug with 80 sales reps.

There are over 100,000 general practitioners. 80 sales reps. Now, if they didn't have our data -- and they've testified to this in other states -- they would have had to sell the product to a Pfizer, a Merck, a larger company with a larger sales force.

So the data actually creates a more level playing field and allows the smaller companies to compete against large companies, large companies to compete against other large companies.

It makes it a more competitive situation. And if one company isn't telling the truth, believe me, the others will let them know about it and they'll send a letter to the FDA.

So that enhanced competitivenes maintains some level of control. The second thing the data does has to do with efficiency. Frankly,

sales forces can be smaller because companies know where to allocate their resources. And that's just a reality.

And so people will buy something because it increase -- maintains the costs at the same level but increases sales. But they will also buy when you don't increase sales but you reduce costs.

Our contention -- and you obviously have to apply your own judgment to it -- is that there are efficiencies that come about as a result of these data of knowing who to talk to.

Now, that may sound onerous, but that is how everyone -- including politicians -- figures out who to talk to. We don't have all the time in the world and don't have all the resources.

You wouldn't talk to someone about cholesterol if they treat depression. You don't go to a psychiatrist to treat hypertension. It's just the way you tend to tailor your message.

But these are very educated people. And the appropriateness of the message is what's key. And they make decisions based on what's in the best interest of their patients. We still

believe that's the system that works.
So the overall, what do these data do to drive costs, well, we think that it's more of an efficiency measure, not a cost measure.
And I'll get to the last point on cost, which is will then why is utilization going up. You just heard it isn't about pricing. People are swallowing more tablets, well Kaiser Foundation, Med-Co, Express Scripts, they are a -- California Health Foundation have all done studies. And about 70 percent of the reason that utilization is going up is based on an aging population, new guidelines and better science.
Of the 70 percent, two-thirds of that is based on the fact that our population is getting older. I take three medications, I didn't used to. And that will happen as the population grows.
It doesn't matter what you do in this Bill. Your drug costs will go up because of that in this state. Second is better science.
More acute conditions have become chronic. Diabetes would kill in the first year. People live 30, 40, 50 years with it. And many other

diseases, HIV went from being an acute illness to a chronic illness.
There are guidelines for hypertension. There are new guidelines for cholesterol, for diabetes. All of the new guidelines, not from us, from the NIH, have added 50 to 60 million people to those who should be treated in this country.
So when you add up an aging population, guidelines with earlier treatment, turning acute to chronic illnesses, and you look at all of that, that's two-thirds of what happens in terms of utilization.
So that's why drug utilization is growing. So the question then gets down to what contribution did the data make. Because I hear about marketing, I hear about don't use newer drugs because they are higher risk. These are FDA and marketing issues; our data don't impact that.
Whether samples are distributed or not, our data don't impact that. We are used to allocate their resources and so they save money. You might ask what would happen if they don't save money, they'll build databases, the cost

structures will go up. I wouldn't swear to it, but when costs go up they tend to show up somewhere.
So it might have a perverse effect of actually increasing costs over time. So I'll get on and you can ask questions if you want to.
But patient privacy, I am hoping that you all know by now we have never had a breach in 50 years.
We don't think that truly is an issue here. And I'll be glad to answer questions if you want to. But we don't ever see a patient name. We have created the system so the patient's name is de-identified before it comes in our door.
It's encrypted into pieces and distributed to different groups outside of our walls, so we couldn't put it together if we wanted to.
And as a result we've never had a breach and it's never been an issue for us. And I would say that applies to our industry in general.
So we'll get Ben to -- and I want to say we've covered privacy, the issue of another database. Well, Medicare and Medicaid each have about a 15-percent sample. You add them both up

together and you will not have enough to project to your entire state.
You need a baseline or a certain amount of it to reach a threshold where you have a certainty about what's happening in your entire state. So you will need payors.
And I can tell you in past lives that I've tried to put payors together. I had two companies that we were working with that when we called a meeting we had 60 people. They had vendors all around the country. They all had different formats. They all had different ways of reporting.
When they didn't get data, they all did different things with the empty slots. And it took us two years to put them together. Now, things may be better now. That was ten years ago. But it won't be simple.
And in the end, even if you succeed -- and by the way, in two or three other neighboring states, tens of millions of dollars have been spent, the databases are not finished. They're behind schedule and they're overbudgeted. My point is not that you can't do it. It's not simple.

If you're calling for the troops in the form of a new database, I would not expect it anytime soon.

So it's going to be five years I'd guess before you will have a useful database, and when you do, you won't be able to look outside of your state.

So you won't see what originates here and gets filled in New Hampshire, for example, or what originates in New Hampshire and gets filled here. And if you get all that, that may be a few more years.

If you can link to their database, you will then not have a national norm to compare your data with. So I'm not saying it's impossible. I'm not saying you can't do it. But if you succeed, you will be looking at a robust Vermont database probably won't be linked to many of your neighbors. And you'll still need a national database.

The federal government is not planning to spend that money. I've been to HHS. Nobody has a budget, a budget we estimate is about $85 million a year just to maintain this business.

So it's hard to imagine that you will have

a database to replace us very quickly. That doesn't mean you shouldn't do what you want to do. It's simply a factor here. If that's one of your considerations, that all else being equal, we'll have our own soon, I would say that's something that needs to be considered carefully.

Last point, physician privacy. And I personally have a difficult time with that, I think all of us in the company do. In this system we believe that a patient would not benefit from physicians having a right to privacy.

Because understanding the quality of care, understanding variability of treatment, which is not a small issue in this country, we have established therapeutic guidelines that wait 15 to 20 years before half of the doctors in this country are utilizing it regularly.

That's the diffusion of knowledge and the variability in practice. This is why Dartmouth had a Dartmouth Atlas. This is why they want to deal, one, on the prescription drugs and they're going to use our data.

Because anywhere you look you will find

enormous variability around this country. It will be regional, it will be within your state, it will be within a specialty, it will be within an age group.

And in the end the only way to change and improve outcomes is to first look at it at an aggregate level we have a problem or we have an opportunity; okay, how do we take advantage of it.

It doesn't happen by issuing a document or putting it in JAMA. It happens by connecting to the decisionmaker. So the whole idea of being able to identify where to go and who to talk to is critical from a cost perspective and from an outcomes perspective. And I can give you an example.

We did a disease management program, we did it for diabetes. We did one for asthma, we did it for congestive heart failure. And the latter one is the point I'll make. Congestive heart failure, Ace inhibitors, a plethora of articles saying that for congestive heart failure if you take a certain dose of Ace inhibitors it will reduce death rates, I think it was about 30 percent. Dr. Chen, you probably remember this

better than I.

It was an enormous plethora in favor of using the drug. And we found some eight to ten years after the launch of the drugs no more than 40 percent of the patients were on the drug. And then when we looked at the actual dosage; it was less than half of them were on an inappropriate dose.

We could have gone to every doctor in the country to try and educate them but we didn't have the money.

So we looked at those doctors who were sub-optimally treating and they were the ones we went to. You can't effect change if you don't know who to go to. Aggregate data just tells you what's happening; it doesn't allow you to do anything about it.

There's actually something right in here from the GAO that gets into preliminary findings regarding an approach focusing on physician practice patterns to foster program efficiency.

It basically is saying that all of the information about aggregate data, the criticism about aggregate data is that you can't effect change. I'm happy to leave this. It's not

meant to address us specifically. But why physician identity.

Because if you want to change outcomes in disease management or even generics, three reports right here of our data on generic utilization rates, in Vermont, the rate of generic utilization where there's a generic available is 67.2 percent, in Maine it's 47.2 percent, in Massachusetts it is 87.7 percent.

Now, that tells you there's a difference. What I would do in a situation like this and what I've done when I was managing this, is I'd say I wonder why that is.

Show me the variability. And you will find when you look at this that if you set that 87.7 percent or in Vermont 67.2, you will find and set that as your mean the bell curve right around it, you will find the outliers who are at 96 percent and some who are at 46 percent. You know who you want to talk to, the ones at 46 percent.

The data aren't making a judgment; they're a tool. We've made it available to the pharmaceutical industry, because for the first 40 years of our business there was no data in

the health care system other than RX data.

Medical claims data is ten years old in any form. And guess who has the largest medical claims database in the country, we do.

We have some 40 to 50 million lives in it. We do outcomes research. We've bought eight or nine companies around the world to do comparative effective work and we tie it then to prescribing.

And here's an example how I do that: This we did with California Medical Association and then with the AMA. I'm sure I'm running out of time. But this is called -- they are putting insight -- it is not our program.

What we did is we said, we worked with AMA, these are the best practices for migraines. Next quarter it's diabetes type II, next is hypercholesterolemia.

The AMA chooses. They've got the best experts. They can get to write up what the best practices are. Well, that's fine, and that's been done before.

But this is what's really happening in the world. The guidelines say this, but let me show you on a national level what is really

happening. And how many times -- here's one that -- here are the drugs that are being used to actually treat it.

We found that opiods, addicting drugs, were being used from a very large portion of patients with migraines. That's not indicated. Most doctors would tell you they never do it, but when you look at the national data you will see their prescriptions and the diagnosis.

Then we get down to the actual CME problems. So doctors can get something for their effort, we show them about co-morbidities, tend to cluster with the illness.

Then we get to a point that's showing them about the drugs. This is Connecticut, here's how the drugs are used in Connecticut and here's how they're used nationally.

And by the way, by clicking on a link, the doctor then can see how their prescribing works, what they are doing. That is the difference. Up until now it's always been at the 50,000-foot level.

This is a program that uses our data where we try to move into the medical community, academics, researchers. It's not quick, it's

not easy. And we may be taking too much time. And the perception may be that we're taking our time.

That's not the reality. This started in 2004; that's how long we've been working on this. Now, this is an instrument. What we will be doing is using physician identifier information to prepare them for payor performance. It's coming.

But what people do is they punish you because you're not performing, they don't teach you how to perform better. So we're helping to develop this using individual prescribing information.

And part of this CME credit will be to show doctors how they can change their patterns so that they improve and get paid more. This is like your credit rating. They tell you what it is but they don't tell you how to make it better.

So we will be able to give doctors confidential information. This is not seen by anyone. This is done, goes through the medical societies. We've offered it to people here in Vermont, and doctors will be receiving that.

In fact, it's probably on line right now. But it's just an application of how the data can help physicians. You can only imagine how it could ultimately help.

(CD changed.)

MR. FRANKEL: -- nor am I trying to put things off. We will make our data available to you. We will work with you on this. We haven't had a good interface in the state, and you don't have to wait two to five years before you have a replacement. And my point is it seems logical to see is there something here that we can do together.

And if you don't like what we do, I know you have the ability to bring me right back here next year and you can right to my face tell me this doesn't work.

So before you put us out of business in the state of Vermont, I would suggest that we have what can be a national asset that can be used by you.

And we would ask you to be thoughtful and to give us a chance to work with you on it and show you it and hopefully we'll come to some conclusion that way.

REPRESENTATIVE MAIER: Thank you. Lucy?

REPRESENTATIVE LERICHE: Just a guess. You asked the question why wouldn't we just take advantage of your data, why don't we just use the data.

I think the answer to that question might be because we probably can't afford it from what we've heard from testimony.

It sounds like this is a very -- your market and your customer base tends to be people who have access to really huge resources compared to a very small data from, like Vermont with 600,000.

So one of the things that you mentioned in the beginning of your testimony is that you are going to talk about costs. And I didn't -- I heard you talk about costs.

But I was kind of interested -- I was really more interested in the cost of your data and how that marketing happens. And I'm also interested in, as another unrelated piece, about the relationship that you have with the federal government and how you -- what kind of data the federal government gets from you.

And a third question has to do with your

claims data. You said you also have a lot of claims data. And that was interesting to me because I thought of your company as being primarily a pharmaceutical data company.

And I'm wondering where that claims data comes from and how representative you believe that is nationally.

MR. FRANKEL: I can take the last one first, if you don't mind, because that comes from managed care organizations.

I don't remember the exact number, but somewhere in the order of 60 to 80 different. It is nationally representative.

And it is projectable to the entire nation that involve payors. It does not include Medicaid. It has some in it. Actually, I'll try and correct my thinking here.

If I recall correctly, we have enough to project all payors, and so that would include Medicaid and Medicare.

So I can get you more details on that, but indeed I know that the Blues are putting together a database which might ultimately be larger. But the one we have now I believe is the largest of its kind now, some 40 to 50

million lives.

And we've had many years to develop the software to help understand what's in it. Because when you have that many variables, actually creating reports is very complex. So yes, that's the database side.

The cost side, we have been learning over the last several years that as we go from market to market there have to be different price points. And we do have tiered pricing.

And so I would not say that if you came to us two or three years ago you would have met with that type of reaction because it's really been happening since we've realized there's a demand for it.

In fact, our policies are creating an imbalance and we're trying to correct it. So I think that coming in now, we'd sit down with you and try and figure that out with you. And the price would not be where it was before.

That said, what we would ask in return is to help us a little bit in that if we can create some type of a report that is either purchased on an annual basis or can be used by others, then it just allows us more flexibility to

continue reducing the price.
And this is not rocket science. This is cars, widgets, anything else. The more you produce, the less it costs. So those are factors that we would have to discuss.
But we would not be charging you the same that we do the pharmaceutical industry. Now, the prices we've quoted you in the past have probably been because they were custom work.
If you were to buy a custom car for $400,000 or $500,000 a year, it's because somebody is manually working on every piece. And that's what happens when we do custom work.
And so we would try and develop something with you that could be repeated or useful elsewhere, and that way we'd be able to split the costs and reduce it for you. Did you have another question I should have answered?
REPRESENTATIVE LERICHE: I have actually a lot of questions, but I would like to get maybe if there's time at the end --
MR. FRANKEL: I wish I had time to answer them all.
REPRESENTATIVE MAIER: Sarah and then Harry. Are you all set for now?

REPRESENTATIVE HANZAZ: Yeah, for now.
REPRESENTATIVE CHEN: Just a couple questions. Of your prescription drug database business, what percentage is spent on with pharmaceutical companies? Give me a number and then a percentage.
MR. FRANKEL: I would not say that I got all these numbers perfectly engrained. In order of magnitude, half of our business is probably in the United States or maybe less. And I'm not familiar with overseas.
We're in 100 countries, as you can imagine. So if you're just looking in the U.S., the vast majority is from pharmaceutical manufacturers, and part of that is with academic and researchers, we have actually given away data.
So when that work takes place it doesn't add to sales. And we have hundreds of requests a year that we meet, and I think that's probably an understatement.
REPRESENTATIVE CHEN: Okay. So just to follow up, how many dollars are pharmaceutical companies spending on your data?
MR. FRANKEL: I don't know how to answer that. I don't even know. Because you're

talking about the overall data. We're a $2 billion company, and that's all data. So if you're talking about pieces of it, then I get lost in the weeds. I wouldn't know.
REPRESENTATIVE CHEN: So on a magnitude, drug companies are spending, what, billions of dollars on your data?
MR. FRANKEL: Oh, absolutely, yes.
REPRESENTATIVE CHEN: Probably even tens of millions --
MR. FRANKEL: You have companies spending a billion dollars a year on their sales force. So if they can reduce the number of salespeople and cover the -- in fact, Pfizer has recently reduced their sales force.
There's a very almost amusing interplay between various companies, you know, we'd be willing to drop the sales force if you'd be willing to drop the sales force. That was going on in the press, we don't think we need as many salespeople.
Well, what happened is you had basically a war from 1995 to the early 2000's. Everyone kept adding salespeople and, sure enough, doctors started getting aggravated about it, as they

should.
And everyone was waiting for the first one to step back. Now that's happening. And they can do that because these data allow them to cover the same spectrum.
REPRESENTATIVE CHEN: So just to kind of follow up on the first question which I had, are you basically saying that you have a negligible amount of business with your databases that are with nonpharmaceutical companies?
MR. FRANKEL: I would not say negligible. I'd say small.
REPRESENTATIVE CHEN: Small.
MR. FRANKEL: And we do work with managed care, for example. We provide them reports. And we are now, as I've told you, moving into outcomes research, which is a fairly significant size.
But when you are building that on a two-billion-dollar company, it is slow in terms of being very material. But, you know, that's well beyond the tens of millions of dollars a year.
We have I think seven, eight, maybe even nine companies around the world to do that using

the medical claims database.
REPRESENTATIVE CHEN: And then I guess just kind of a general question. Do you think that -- this is an issue obviously as to the legislature we've been trying to deal with -- that when a physician or a customer makes a transaction, writes a prescription, that they are aware that this data is going away somewhere?
MR. FRANKEL: Well, I don't know about the consumer. I would say most physicians know that the data is going somewhere. They all know it's going to the payors, and so that's definitely the case.
We are certainly a public entity. We've never held any of this a secret. What we do has been open practice for 10 to 15 years in this industry.
I just think that awareness is -- I would say that many doctors have been told; awareness is whether it's fresh in their mind. But I would say based on what I've seen, most doctors are either aware or not bothered greatly by what goes on.
Many are. And PDRP was our solution,

because our problem is that if all 50 states come up with their own PDRP, we don't know how in the world we'll comply with it.
REPRESENTATIVE MAIER: What is that PDRP?
MR. FRANKEL: PDRP is the AMA program so doctors can opt out. Awareness there is at 21 percent of the program. And you might say, well, why is it so low? It was seven percent about, I don't know, four months ago.
Communication experts will tell you that awareness is a function of frequency and time.
REPRESENTATIVE CHEN: I guess the follow-up question is, when doctors sign up with insurance companies and with managed care organizations, we sign something that says you want to have our data.
When patients work with insurance companies, they have policies and notification that this data goes to insurance companies. So my question is, do you think consumers overall and doctors secondarily know that information that they haven't signed an agreement with is going away? I don't know. I can't tell you that. We've worked with every one of the pharmacy boards around the country in terms of

these kinds of rights to privacy, and everyone interprets the laws to mean that it's -- the right to privacy is for the patient, and we certainly comply with that.
I could not tell you whether doctors are aware. I have had no evidence to that effect.
REPRESENTATIVE MAIER: Sarah?
REPRESENTATIVE HANZAZ: So who buys your product? Pharmaceutical manufacturers buy your product?
MR. FRANKEL: They are -- yes, that's one of the customer classes. Government buys it.
REPRESENTATIVE HANZAZ: Okay.
MR. FRANKEL: Academics buy it.
REPRESENTATIVE HANZAZ: What would be the proportion of --
MR. FRANKEL: The vast majority is the pharmaceutical industry. And that's because prescription data, quite frankly, governments weren't interested in prescription data until costs started getting out of control.
We're talking about a phenomenon that's probably just five years old that people are starting to care and want data in the various states.

Trying to sell at the state level before that would have been and was quite useless.
REPRESENTATIVE HANZAZ: So your product is custom-made for the customer or is it a package deal and they massage the data on their side?
MR. FRANKEL: It varies. Every customer is different. It's a hard thing to explain but I'm going to try. I'm not trying to evade the question.
The fundamental machine that generates it, like building a car, is standardized, but it allows a certain amount of customization as to what the interior components are, what the color looks like.
And that is the customer's choice. Sometimes they just buy raw data and they will analyze it themselves. So there are a variety of different uses.
And they put it all into a package and they tell us what they're going to need for the year, and that way we can run it all efficiently. And that's how they get their best prices.
REPRESENTATIVE HANZAZ: And how many of those customers, those vast majority of your customers, are companies based in Vermont?

MR. FRANKEL: I really don't have the answer. It would be very small. I mean, most of these are Nationwide companies.

REPRESENTATIVE HANZAZ: Okay. And tell me why would some of these customers come to IMS as opposed to Verispan? What is the niche that you provide?

MR. FRANKEL: Well, I would -- I speak not just as an insider, but having watched the industry over 30 years. I think as a company it's the quality of the data, the accuracy of the data, the breadth of the data is simply much better than our competitors.

I mean, most people who look at the data, I mean, you heard from Elliot Fisher. I didn't hear what he said, but I think these people would tell you that when they look at our data that it's very elegant. And I'm not a stat person. I wouldn't know one database from another.

REPRESENTATIVE HANZAZ: And that would be for the custom product that had all the bells and whistles?

MR. FRANKEL: For any product that uses our data. One of the things, for example, when you

use Medicaid or Medicare data, first of all, you can't look at it until it's three years old. It is of no use for you in looking at your situation now.

They are saying it will get better. But Medicare part B is nowhere being delivered and that's already a year and a half old. So anything else would fly in the face of the facts.

And then you find that when you look over the history of the database there were times when there were changes in the way the data were reported.

And rather than going back and making all of it the same, they simply say at this such-and-such a date we changed the way we reported.

So you have to be -- to use their database, you have to have the historical perspective and understand how to make adjustments to normalize it, to even it out.

And there aren't a lot of experts who can do that, and it's fairly expensive to do. We do all that, so it makes it easier to use the data.

And when academics and researchers use it,

we train them on the use of the data. But they don't have to do all that work. So we're told repeatedly that we have the most elegant database in the country.

REPRESENTATIVE HANZAZ: And you insinuated, I think, if I was understanding correctly, that you are now developing a lower-cost product, one that might put you in the reach of some of the academic or research end of things?

MR. FRANKEL: We have already priced it lower in other areas in order to do that.

And so we have already begun that process. The question is of course what you want. We tend to sit down and explain the variables, what are the issues that drive our costs, how can we save you the most money. And then you get to choose based on that what you're willing and wanting to have.

REPRESENTATIVE HANZAZ: And these would be for academic and research things?

MR. FRANKEL: And for government.

REPRESENTATIVE HANZAZ: So there wouldn't be any -- it wouldn't be for consumer use? It would be of an academic nature?

MR. FRANKEL: Well, we will also do the

same thing with the consumer. Right now there really isn't much of a consumer market. You have a few web sites.

We have sold data to Web M.D., for example. I've been to Revolution Health. I've been to a number of places to try and make -- I mean, this kind of data without the actual physician data would be very helpful for patients to know something about.

You'd want to explain it differently, the context would change. But knowing what's happening on a national basis, I mean, I was alarmed when we started diabetes and we did a nationwide survey and found that most patients had no idea what their blood sugars were.

Many had blood sugars that were three or four times the norm and that were told it was perfectly all right. Hemoglobin AonC's, which should have been done every quarter are done in this country on an average once every two years.

And if you tell patients about that, they go to their doctor and they say I think I'd like a hemoglobin AonC. And you know what happens? They get it. So there is a need, there is in the market, we're having to build that and

create it.
REPRESENTATIVE HANZAZ: I'll hold on that.
MR. FRANKEL: By the way, you're all thinking of counterdetailing, which truly is a useful tool. You would need provider-level data to know who to call on.
So how would you target? Using the same word "intentionally," how would you know who to call on? You don't go to a prescriber who is a very efficient prescriber with a counterdetailing effort because it's a waste of money.
REPRESENTATIVE HANZAZ: There's a new market for you.
MR. FRANKEL: Well, it's a new market. But it's the value of the data for everyone. It's not meant to be restricted. Nobody else was interested.
REPRESENTATIVE HANZAZ: Or could afford it.
MR. FRANKEL: Or could afford it, yes. I stand corrected.
UNIDENTIFIED MALE: I guess I'm going to take you back on your questions and kind of ask it in a different fashion. I'm very well aware of how valuable your data is.

Much of your testimony talked to the amount of information that could be gathered on a research basis.
My question, is your two-billion-dollar business gathering data worldwide or?
MR. FRANKEL: Worldwide.
UNIDENTIFIED MALE: Worldwide. And I'd like to, kind of following up on Harry's question, what, of the two-billion-dollar business that you are, what percentage is sold for noncommercial purposes or commercial purposes? It sounded like you were saying, well, it's more than half.
MR. FRANKEL: No. It's very small for the noncommercial purposes.
UNIDENTIFIED MALE: Very small. Ten percent?
MR. FRANKEL: I'd say on the order of magnitude it's probably around there, but I don't know the exact number.
And it's also because we give a way a lot of data, and it's because the prices are lowered to that segment. So, I mean, all those things add up to it being a fairly small component.
We could not afford to give it away at that

price if we didn't have a commercial use for the data. There's no one in this world who has the ability to raise the shareholder money to create something to give it away.
UNIDENTIFIED MALE: Then my follow-up question is, if your data excluded Vermont data, how much revenue would you really lose?
MR. FRANKEL: Very small.
UNIDENTIFIED MALE: So IMS really wouldn't go out of business and be nonfunctional not having Vermont physician-directed data?
MR. FRANKEL: I'm not here because we will go out of business if Vermont disappears. I am here because you're setting a policy that we personally think -- I personally think is just not good for health care.
The issue of transparency, if this is repeated, perceived as a really vital tool or a viable tool, which I don't think it is, in fact I'm sure it is not, would start to fragment the database in a way that it would no longer be useful over time. And would we create other products to try and make up for the loss.
We're in business. We must do that. We have shareholders' responsibilities. So if this

goes away, we will try to build something else, and pharmaceutical companies will build something else.
The point is you have a tool now that you can use that you can't replicate for many years, and we're here trying to say please work with us.
I just don't see how you can lose by working with us to see if we're sincere. Because you -- we will be back here again, we know that. I won't be here because you won't believe a word I have to say, I understand that.
We're here trying to say this is a valuable asset; be thoughtful before you discard it. It's only the state of Vermont that will really lose. Risk management --
UNIDENTIFIED MALE: Help us to get to where we're trying to get to. We're trying to get to the fact that your very valuable data -- which I don't know anybody that can say it's not -- is being used by people who are using it for divisive means. We're trying to stop that practice. How do we stop that practice?
MR. FRANKEL: Well, first of all, I can tell you that when I did it -- and I did do

it -- we used drug interchange programs. We called doctors and said, in essence, I'm paraphrasing if you had known that drug A was 30 percent less than drug B, would you still have prescribed drug B. You know what? They said no.

So they changed. That's the drug interchange program. How did we get to that. We used provider-level data. We had experts tell us algorithm-wise which drugs we thought were comparable.

But mandating that is it dangerous because no two people are alike. In aggregate, these drugs can be equally effective and they can kill someone, so you've got to leave it up to the doctor and the patient to make the decision.

But you can inform. Counterdetailing is just informing. But you can't afford to send someone out to every doctor's office in the state of Vermont.

You will need provider-level data to find out where the outliers are, and they will be the ones you will communicate with.

You can have step care in a formula. You could have three-tiered co-pays, preferred drug

lists. There are a variety of ways of getting to managing costs. I will tell you as someone who really I believe to be an expert in this area, I spent ten years managing drug costs.

No matter what you do, drug costs will go up in the state of Vermont because of the aging population. There is nothing you can do to change it.

What we found is if you had two -- if you had a trend line like this, you would bring it down for a while and then it would follow the same trend. And the reason for that is the underlying issue is an aging population.

And new drugs for conditions that couldn't be treated, multiple sclerosis, cancer, I mean, you start adding them up, these are all new diseases; diabetes, and diabetics are living longer.

That isn't going away. And I'm not hearing any of you saying you don't people having any of these people to have these drugs. You don't want them to have the ones that turn out to be dangerous, but we don't know which ones those are.

The newer ones that do work, like Aricept,

were at one-time a new drug, but today they're being shown to keep people out of nursing homes. It is a very difficult thing to do. And so you develop guidelines, you have people go through a thoughtful process so that you minimize your price, the cost, and you manage that you do no harm.

I think in terms of no harm, I think with respect to these data, there are no empirical data that would tell you -- and I don't want it to sound like an excuse -- that if you limit the data, costs will go down.

It's never been done. They did an experiment in Canada where they tried that and they found that it didn't have a impact. Canada is not the United States, and I know that.

So but I don't know where anyone who could honestly say -- except based upon opinion -- that cost wills go up. And you've heard opinions to say, well, actually, you know, the costs will go down. And you've heard opinions to the contrary.

I do know that risk maps will be impacted, FDA compliance with Risk Management programs fo multiple sclerosis and a variety of diseases

where there's a need for prescriber-level data, FDA-need for prescriber-level data.

These drugs will not be on the market unless they can be targeted to people who will use them and be aware of the delicacy of the situation.

These are drugs where a little too much and you have toxic effects, a little too little and it doesn't work. And people need to be trained. And so they, pharmaceutical companies must have these data to be on the market. That's just a reality.

REPRESENTATIVE MAIER: (Inaudible) And then I'll go back to Sarah.

UNIDENTIFIED FEMALE: Couple things. I would like to challenge your Notion that the drug prices have to go up because of an aging population. And I think that there are a lot of reasons why they probably will.

But there are other approaches to dealing with health conditions that are successful that don't involve drugs that unfortunately don't get marketed in the same way.

And I'd be curious to see if research is done to confirm some of the things that are

common practice and work for many people, whether we could get that information out to doctors as successfully as the pharmaceutical companies get out the information on their new expensive drugs.

One thing as I've listened to you that concerns me, from all the testimony we've had, we understand that detailers don't market generics, they market expensive new brand-name drugs, and that their commissions are based on their sales.

So there's a lot of incentive to get as much of that -- as much usage of these things whether or not they are more effective than the current drugs or generics despite safety concerns.

And we know also from testimony that all the research on new drugs isn't published, it's withheld from the public.

So if detailers are successful in using your data to get more doctors to prescribe more expensive new drugs and that becomes the prescribing norm, then the information could also be used to say to other doctors, well, no you're not doing this right, you should be

prescribing these more expensive new drugs simply because of the success of detailers.

And it will drive costs up. And it may or may not have any affect, better affect on people's health. And, you know, so based on what I've heard from all of our testimony, including (inaudible), I'm more concerned about that.

MR. FRANKEL: And I don't disagree with virtually anything you've said. Number one, one of the things I had in the disease management programs in the '90s was meditation. It's been shown to lower blood pressure and lower the incidence of depression and a variety of other things, and so we actually advocated for having a course in meditation as part of disease management.

So I don't disagree with you. I don't have any comparative data on it. I don't know how to, you know -- other than if I meet someone who's in human resources who believes me. Most people would laugh at me, and a few did. I have to admit, a few did. I've meditated since 1994.

UNIDENTIFIED FEMALE: That laughter was good for them, too.

MR. FRANKEL: Yeah. So I've spread cheer and good health throughout the world. But as for the second question, it's really about comparative effectiveness studies.

Project Hope, I know Gail Wilenski, these are people who are trying to get money to fund comparative studies so that doctors can see whether drug A is actually better than drug B.

But our data don't do that. Our data don't drive that. And taking it away would -- almost assumes that -- if you take the data away from -- we stop collecting it and providing it, it will disappear and the system will adapt. Well, it won't. It will create a void that will be filled by something else that does the same thing.

So I guess what I'm saying is use the data to create an appropriate framework for formularies, for counterdetailing, for other things you might do.

But eliminating it and thinking then it will be gone I believe is incorrect, because I already have information that it will be replaced by something else.

UNIDENTIFIED FEMALE: So I guess I'm

hearing what I heard in the very beginning of our testimony, which was that we really need to let the bad stuff as we perceive it go on in order to have the good stuff? There's no way around it?

MR. FRANKEL: Well, I'm sorry to hear you say it quite that way. I -- and this is now a bias of my own. I don't think all pharmaceutical practices are bad. I do believe some are bad.

UNIDENTIFIED FEMALE: No. I'm talking detailing of the nature that I described and not giving accurate information, giving incomplete and misleading information to doctors.

MR. FRANKEL: But that's not because of the data.

UNIDENTIFIED FEMALE: No. It's use of data that you provide.

MR. FRANKEL: Actually, I don't think that's true. I think that's because of inappropriate or inadequate training.

And you might say that if those representatives were trained better, than our data would actually be very instrumental.

UNIDENTIFIED FEMALE: Except the purpose of

what we're doing is to sell more new expensive drugs to make money for the pharmaceutical companies.
MR. FRANKEL: And if that's Aricept for Alzheimer's disease, you'd be glad.
UNIDENTIFIED FEMALE: I would be glad if what they went out and did was educated doctors fairly and accurately about the alternatives, and that they were not rewarded primarily for selling expensive new drugs, some of which I think should be out there and some of which are useless.
MR. FRANKEL: But our data have nothing to do with that process.
UNIDENTIFIED FEMALE: You facilitate them using the information most effectively to get more doctors to use the stuff, in some cases the good stuff that I would like to see more of those, but in many cases stuff that costs us money and gets no better results.
MR. FRANKEL: You know, I don't know what else to say about it. I think the data are used for good and bad purposes. But the data don't decide what's good and bad; that is the FDA.
UNIDENTIFIED FEMALE: Which doesn't enforce

its own regulations.
MR. FRANKEL: That's another issue.
UNIDENTIFIED FEMALE: But that's another part of our Bill.
UNIDENTIFIED MALE: My question is actually sort of in this area a little bit of questioning. So the data is available to everyone so if I wanted to buy the data, how would that transaction take place?
MR. FRANKEL: We don't sell to a person. We sell to companies, we sell to organizations. I mean, we don't want --
UNIDENTIFIED MALE: You don't sell to any organization that would come to you?
MR. FRANKEL: No. If it's an organization with the mission of identifying doctors and hurting them in some way, we wouldn't sell it to them. We do go through a screening process.
UNIDENTIFIED MALE: That's my question. How do you figure this out?
MR. FRANKEL: Well, first of all, we have hundreds of clients right now, so if you're one of them we've already been through this process.
A corporation that's in the health care business, and they come to us and they want to

buy data; if our data are appropriate for the use, we will quote them on what it costs, and then they will tell us whether they want to buy it.
If our date are not appropriate -- and I can tell you one area where everyone is weak, that's pricing; and the reason for that is the retail price and what is actually paid are very different.
And it differs by every plan in the country. So every plan negotiates its own prices. So if you try and sway or influence or educate -- any of those words -- someone based on retail places, you will invariably and almost every time be inappropriately be educating those individuals. And so it has to be done by the plan. In your Medicaid plan, in your preferred drug lists, you have your own prices.
They're probably not perfectly consistent with retail prices because some discounts may be larger than others. So we might -- if we educated people based on retail, we might be working against our plan and so we don't do that.
UNIDENTIFIED MALE: But there is some

process, if I were a potential new client, there would be a process that I would have to -- forms I'd have to fill out or information I would need to provide to you.
MR. FRANKEL: We now have people who are responsible for government, we have people who are responsible for academic and research. This is relatively new because we've only been doing it for about two years.
As I said, we're late to the table, because our earlier attempts to do it were really flat-out failures. We were rejected or no one knew what they wanted to buy. And we had just walked away and said the market isn't ready yet, it hasn't matured enough for us to --
UNIDENTIFIED MALE: What I'm looking for is this process.
MR. FRANKEL: Okay. I'm not in sales.
UNIDENTIFIED MALE: But I guess what I want to -- I mean, at some level I want to understand whether or not -- part of your testimony is the information is available to everyone and that they use it to compete and those sorts of things.
So if I wanted -- but I'm just trying to

understand who that "everyone" is or could be. And so if I'm a new potential client and I exclusively wanted to use your data for purposes that were destructive to the medical system and it was clear to your process that that was what I wanted to do with it, I'm just trying to explore, how would you find that out and then how would the decision -- that you would choose not to sell your data in some situations?

MR. FRANKEL: Right. In some situations.

UNIDENTIFIED MALE: How would you gather that information?

MR. FRANKEL: If I was selling a gun, and I don't have one and don't use them. If I saw someone come in the door, unfortunately this is a bad time to be saying this, and I apologize, but they didn't look stable; I wouldn't sell them a gun.

There are people thinking they they're going to accomplish something with the data that can't be done or is not the right thing to do with it, the conclusions will not be accurate and we would not be able to endorse the results, and so we would tell them that and we probably would not sell to them.

But that is an extremely small situation. The situation you're describing, as a new client, a new pharmaceutical company, the State of Vermont, you'd be calling us and you would be transferred to someone who handles our state government affairs and they would say we'd like to come in, we'd like to talk with you, find out what you want, what you need.

We would speak to you about the trade-offs and their impact on cost and try and figure out if we can provide something to you. We have states that say we want it but we want it for free.

UNIDENTIFIED MALE: And I'm not talking about me as the state of Vermont. I'm talking about me as a potential -- a hypothetical company that might want to do something that all of us would agree was either wrong or elicit or even illegal.

How would your company determine that and how would that choice be made in that context for you not to sell it in a situation where we would all agree it was inappropriate?

MR. FRANKEL: If we're lied to, we won't know. But we always ask, because you have to

specify what data you need. So we will typically -- we don't just -- it's not like we want to pound the data, I'll send you the data.

What are you trying to accomplish. What are you trying to accomplish, what are the goals of the research, what are the data parameters you're looking for.

And then our people will look at it and say based on what they're asking for, they won't get to where they're going. Because many people start research not realizing that they'll never get to a conclusion, they just don't have enough data or the wrong data.

So we will consult with them and say, well, if you change that to this and if you added these things, these are the kinds of things you'd be able to show. We come to an agreement, we write out specs, you approve them, you sign off on them.

So we now have an agreement. We know what you're trying to do. You know what you're going to get, and you know what the cost is. And we write a contract, and we -- then within a specified period of time we deliver it to you.

Or you could hire us to do the analysis for

you. Then we will endorse the results. We will say this is done by us. But if you do your own analytics, unless you give us some of advanced notice and a chance to review it, we won't endorse the product.

UNIDENTIFIED MALE: So that seems to go against what you said several times, which is the data is neutral.

So you do understand that there's some situations where the data is not really neutral and you would actually choose not to sell your data because of some purpose for which it was being used?

MR. FRANKEL: I think I'm giving you more of an exception than a norm. The issue is that if someone wants to do a study that is inappropriate or -- and we wouldn't often know about it -- but if we did, we simply would say no.

If they wanted to use our pricing data -- and we've that had often. They've come to us and said we want to use your pricing data to show the cost of X, Y and Z, and we say no, we won't sell it to you. We know our data would be inaccurate in that setting, so we just won't

sell it to you.
So is that a lack of neutrality, I don't know. I'm just saying to you we wouldn't want to inappropriately sell something that we know won't work to start. But can they buy data that would work, yes, absolutely.
UNIDENTIFIED MALE: I can understand as a data-providing business you wouldn't want to provide data that wouldn't work for what the potential client wanted it to do because they would be upset with you and, you know, thinking you sold them a bill of goods -- I can understand that.
But clearly -- and I realize I'm talking hypothetical here. But clearly there could be a situation where the data might be perfect for what they wanted to do with it, but that result was something that we might all agree was inappropriate against, you know, bad care, illegal, you know. What would -- the data would be perfect for that purpose.
MR. FRANKEL: I'm afraid it's one of those things I'd have to say you know it when you see it. If you give me an example, I might respond to it, but it's hard to imagine a situation like

that.
UNIDENTIFIED MALE: Maybe ABC Pharmaceutical Industries Destroyer, that's the name of my company, you wouldn't sell data -- would you sell data to someone like that?
MR. FRANKEL: I don't know that we have. I don't know that we have. You know, that's really a very hard question to answer.
I don't know how to answer that. I don't think we would reject you because of what you do. We sell to managed care. We sell to people who are trying to manage formularies.
I'm here telling you we can give you data you could use for counterdetailing. Are you a "Pharma destroyer," I don't know. You may be sounding like one. But the data would be used appropriately and accurately. And so I mean --
UNIDENTIFIED MALE: There are other groups that could use the data. There's a group of -- an individual group that wants to do some research and make the pharmacy industry look bad.
MR. FRANKEL: It happens every day.
UNIDENTIFIED MALE: And would you sell to them?

MR. FRANKEL: I would have to say I don't know that. I really don't know. I don't know. But those articles appear virtually every day.
UNIDENTIFIED MALE: Some information --
MR. FRANKEL: Our information is quoted all the time. I'm sure it's in all of these things. You're all quoting growth rates; they're probably ours.
When the FDA goes over looking at various disease states to see what the need is, they present our data, you know, this is the size of the opportunity, this is an un-met need.
Our medical claims data will show you that when you take various diagnoses and you put them together, you will find that half of that population is not currently being treated even with beta blockers after a post-myocardial infarction.
Today only 80 percent, only 80 percent -- this is as good as it gets -- 80 percent of patients who have had a heart attack are on the Standard of Care, which is a beta blocker.
So if you wanted to find out how to get that to 100, you'd have to look at those data and see which doctors did not prescribe it and

just say, just a reminder, friendly reminder, and you will see the number go up. That's how you use the data to improve outcomes.
I'm sorry. Did I answer your question? I'm not sure I did.
REPRESENTATIVE MAIER: Sarah, I think. Did you have a question?
REPRESENTATIVE HANZAZ: Uh-huh. So you talked a little bit about the idea of good purposes and bad purposes, and there was a little back and forth there about how you define good and bad.
But you talked with Steve about the relationship that you have, that IMS has with its clients in that you kind of -- you have to know what their purpose is. And good or bad might be a judgment call. But you kind of have to know what their purpose is in order to be able to sell them data; is that right?
MR. FRANKEL: Well, for a new client. Think about a situation where you've been working with a company for ten years, and they have a very sophisticated staff of biostaticians and epidemiologists and you know over time that these people know as much about it as you do.

They're no longer asking you whether these data are appropriate. You're just trying to make sure that the specifications that they're asking for are going to be met.

So over time you become very comfortable and familiar with one another. And a new client, we certainly would want to please, particularly on a first-time level.

UNIDENTIFIED FEMALE: So there's a good deal of back and forth?

MR. FRANKEL: Yes. There's collaboration there, yes.

UNIDENTIFIED FEMALE: Okay. And you have already told one of these people that if it were for a bad purpose or an illegal purpose, that you simply wouldn't sell the data?

MR. FRANKEL: Bad purpose like using it for pricing.

UNIDENTIFIED FEMALE: But if it were for a good purpose, you would sell the data.

MR. FRANKEL: It sounds like we have a judge and jury. We don't do that.

UNIDENTIFIED FEMALE: If it was acceptable.

MR. FRANKEL: By and large, if a customer comes and wants to buy something from you, you

want to make sure the data will be appropriate. We don't sell something if it's not going to work.

We add services. Many of them don't have the analytical or the epidemiologic or the staticians involved. We add value depending upon what they need.

The pharmaceutical and biotech industry is our major client. And it's because RX data was what was available and that was the base of our business. We have evolved to other areas and now the federal government is involved.

We are now here saying we're trying to do it at the state level. We don't have a finished product or a defined portfolio here. We're trying to tell you we have an asset. This is the kind of meeting I know we've had as a company. We approach states. And unfortunately it's not antagonist but it's confrontational in a way.

And what we've come out with is almost we don't trust you and we don't want to use your data. And when you have that happen in a number of states, you stop trying to place it there.

So unfortunately as a result you don't have

the experience you need with these data and we don't have the relationship. I'm trying to say to you, you know, there's an olive branch here somewhere, we're trying to work with you.

UNIDENTIFIED FEMALE: Do you understand that the Bill speaks about the commercial purpose?

MR. FRANKEL: Yes.

UNIDENTIFIED FEMALE: And that your relationship with your client might also -- I understand that aspect of it is commercial, their use of the data, it could be academic, it could be research, it could be best practices, it could be counterdetailing, it could be commercial. And you understand that this is talking about commercial use?

MR. FRANKEL: I don't believe from a legal perspective that it will work that way. If you say it can't be used for commercial and you define commercial as anything that shifts market share, then what we will do is we will not provide it for academic or any purposes.

Because if we give the study to Dartmouth and they look at variability and as a result they determine that one drug is far superior

than the others because variability is smaller, and they publish it, and everybody starts using that drug, you are shifting market share and we will be breaking the law. We will not do it. It will simply not be made available. There are unintended consequences all around this.

UNIDENTIFIED FEMALE: And you're a lawyer?

MR. FRANKEL: No. We just came out of New Hampshire and I was a witness. I was very much involved, and I can tell you that's what we told the judge there.

I can't say more. Yes, you can imagine, I'm not supposed to. Now, I understand why that would be the case, the way it's being defined and structured. Anything we do can shift share.

UNIDENTIFIED MALE: I just want to -- first of all, I mean, I don't think it's our intent to interfere with its use for other than marketing.

And so you if have suggestions for changing the language, I certainly would welcome that. I also think -- I want to make the distinction, when you say "bad," you're using it from a technical point of view rather than from a value to society point of view.

MR. FRANKEL: Yes. Thank you. I really

appreciate that clarification.
UNIDENTIFIED MALE: But to that end, I want to just follow up on that. Normally in the practice of doing research there is an (inaudible), the IRB, the Investigational Review Board, kind of makes a determination on any research project, and they do it on many criteria. One of the criterias is the adequate consent.
Julie actually went through that that she didn't think that this would fit a normal consent in terms of using information. But they also make a determination is this data being used for the greater good and is that -- whatever risks there are, whether they be privacy risks or infringements or whatever in terms of side effects, whether it is justified based on the good in the information obtained.
So I'd just ask you to kind of compare your process for who you sell your data to to what might happen in an IRB.
MR. FRANKEL: I would not profess to know the IRB process as well as I would need to to answer the question. I can simply say that there is a public good use for the data. There

are numerous studies and outcomes and interventions. We know --
UNIDENTIFIED MALE: My question is, do you make any judgment about if there is a public good or a lack of public good in the use of your data?
MR. FRANKEL: Well, I think that inherently if we look at the use of the data, it's certainly within the framework of FDA guidelines. I mean, people are studying utilization.
I really -- I'm stumped on how to answer that. I think there's an assumption that since the data are used to study drugs that are in compliance with FDA guidelines, that that framework certainly is sufficient to -- you know, for our business to operate the way it does.
But we also study off-label use for the FDA. So what does that say. You might have to help me clarify this, the same way you did with "bad."
REPRESENTATIVE MAIER: Are you done?
UNIDENTIFIED MALE: Yeah.
UNIDENTIFIED MALE: Harry talked to you

about the dislike that a lot of people have about the market. John talked about help us get there. That was going to be my quest.
I'm not in the business and I don't ever want to be in the business of putting other businesses out of business. Help us get to the point where the part of what's going on with your data becomes acceptable to us.
MR. FRANKEL: Well, first we're trying --
UNIDENTIFIED MALE: You don't have to do it right now. All I'm saying is I'm looking for a bridge here to figure it out. I believe there's a part of the data that's very useful, there's no question about it. But there is a part of it that some people --
MR. FRANKEL: You realize that part of what is being projected my way is the data are perfectly useful for drugs you like and not for drugs you don't like; drugs that are beneficial for Alzheimer's disease and multiple sclerosis, that that would be all right to assist. But drugs that are E-2's, that we wouldn't want. But in my world, that has been done by formulary adherence and then follow up with the physicians who aren't adhering.

And that uses all the same data. The application for the data is essentially different, but the data are the same.
UNIDENTIFIED MALE: So maybe what you just said --
MR. FRANKEL: It's about an application, counterdetailing. Jerry Avorn (phonetic) has been here and says we're doing it in Pennsylvania. They're doing it in Australia, they're doing it in a variety of areas.
If you chose to do that, you would need a review board to chose the interchanges you're looking for, then you would have to identify which doctors you'd be talking with. You'd be using these data.
So that's all doable. And that then keeps it within the purview of the physician, so that you don't mandate a decision that could hurt a patient. So the question is how do you get the right information into the physician's hands and you have do it on a timely enough basis so you're not looking at three-year-old data after the fact.
Ideally, when you have -- you're prescribing in the state, when they write a

prescription, it tells them what's on the formulary or it tells them what the costs are. We're just not there now. This has changed management up to that point.

UNIDENTIFIED MALE: I would remind the committee we've had testimony from our own Bishka office that have our own sources of that data starting next January.

UNIDENTIFIED FEMALE: Can I just correct what I said about --

MR. FRANKEL: I'm sorry, I didn't mean to interrupt you.

UNIDENTIFIED FEMALE: I'll be extremely brief. You characterized what I said as drugs we like and drugs we don't like. And I believe what I was talking about was drugs that have a public health benefit versus drugs that cost more and provide little or no additional benefit.

MR. FRANKEL: Well, I apologize. I looked at you, but I wasn't referring to your comment. I've heard --

UNIDENTIFIED MALE: That's exactly what I said. So apology accepted.

MR. FRANKEL: I apologize.

UNIDENTIFIED FEMALE: This whole thing is about information. And this is my problem: Taking not the 30,000-foot view, but the view from the women on the moon looking at the earth.

MR. FRANKEL: I'll do the best I can.

UNIDENTIFIED FEMALE: The problem is -- okay. So to me the problem when you said god, we've been doing this for years and everyone thought we were fine. You know why I think that is, is because the people who were gathering your data were doing so unaware that they were doing it and not compensated.

So to me I think part of the problem is the physicians I don't think should opt out; I think they would need to opt in. My guess is if the physicians knew how the data was going to be used, they may not opt in at a level that would provide you, as you said, a good sampling.

So I actually think that if what you're all about and what world is providing good information, if truly good information were provided you'd be out of business anyway because the physicians I don't think would go along with it.

Or unless we wanted to be really

transparent we'd say, well, physicians, you can go along with it and if the AMA can make $30 million, gee, I should make some, get a cut of that pie, so I'll opt in if you pay me this much.

And if the patients knew that was going on, they wouldn't have a whole lot of confidence in their physicians; I wouldn't. If I knew that they were paying, if this money trail is just a contaminant. That's the problem.

You've been in business 50 years and you know how the medical industry has been contaminated by "for profit," so the greater extent that it goes that way and the less information that people truly have, I think that's the problem.

You said you were bothered by the fact that the physicians didn't have -- didn't consent, but for the greater good it was okay not to have consent; and I would suggest to you that that is a real slippery slope and that's a slippery slope that landed somebody flat on their butt. And I think that's the issue.

And so if you were to say everybody is going to consent and come in, but you know what,

I just think you'd be out of business right there, so you wouldn't even have to worry about Vermont because you'd have California and New York, everybody else, those physicians not opting in.

And I would be curious to know if you've looked at that and have any projections to say well, that's fine, we've looked that and we have good information that says that 80 percent of the physicians are willing to opt in. Not opt out, opt in.

MR. FRANKEL: I can just tell you that if you -- part of the reason that manufacturers give rebates that you have to mail in, even if it's worth hundreds of dollars, is because most of the people will never take the time to mail it in. It's called the shoe box effect.

There is a dynamic where people just, whether they believe it or not, whether they're motivated or not, just won't send it in.

And I'm guilty of doing that, and I'll bet everybody in the room at one time or another has done it. They count on that.

So it's not that by doing on opt-in physicians actually will be voicing their

opinion. They'll be simply demonstrating human behavior and -- normal human behavior.

But you're right. An opt-in because of that would reduce the sample size to a point that it would probably be useless, So yes, you'd effectively be eliminating the database for the nation.

The question is, do you want to do that or do you want to use a really concerted effort. And I have a list here, for example, of AMA of the hundreds and hundreds of places they are continuing to insert ads for PDRP for therapeutic insights.

They are going to get the awareness level up to between 70 and 80 percent and they will keep spending until they do, so anyone who really wants to opt out will. But the other one is almost a foregone conclusion, not because that's what doctors want, but because they're busy people and they just won't do it.

That's why the "do not call" list in this country is an opt-out, not an opt-in, because they knew the people simply wouldn't make the phone call. It's just human behavior.

So it's hard. These are trade-off

decisions. And you all decide for yourselves. I mean, I'm not the magic purveyor of truth here. I'm simply telling you what I know to be true.

REPRESENTATIVE MAIER: Lucy?

REPRESENTATIVE LERICHE: Yeah. I just wanted to -- this is not a judgment. I guess I was looking for clarification. You're in the business of buying, configuring and selling data solely; isn't that correct?

MR. FRANKEL: Well, we do research, we do analyses.

REPRESENTATIVE LERICHE: So you do research and analyses for clients, but you don't do research and analysis for your own purposes to educate physicians or for your own public awareness campaigns? I mean, you wouldn't do that? You're not in the business of that?

MR. FRANKEL: Actually, we have decided we're probably going to start doing that simply because we've been very quiet in the world of providing data legally and in a way that we thought was responsible and was well appreciated.

Government has bought it. We always felt

we had somewhat of a good presence. We now realize -- this meeting like today certainly makes me very much aware that we haven't done a good job of realizing we're operating in a bigger fish bowl than just our market.

So we are trying to do these studies. We have done this. This is actually a study, if you will. And we're committing millions of dollars to help physicians self-evaluate.

The study we just did here, you have a copy of it, the Impact of Provider-identifiable Data." Let me start by saying this is the dammed if you will and dammed if you don't kind of situation.

Because you have all asked very good questions and you need third parties for the answers. No one but us is willing to pay for it. So we paid for this. So you're getting a data, the data, and it's here, it's for you to read about the various values and aspects of provider-level data.

Please take it with a grain of salt, I'm sure you will. I don't ask you to believe it all. But you'll find a lot of it is simply quite intuitive and it will give you that

information.

This is a study we've done. We're doing studies in variability with Dartmouth, for example. Just look at variability and practice variability around the nation.

As I mentioned earlier, they're thinking of a Dartmouth Atlas for prescription drugs. And we're working at the University of Chicago and Stanford and Harvard and a variety of other universities.

And we're building a consortium or coalition, if you will, of academics and researchers to use the data toward improving outcomes. That's what we're trying to do.

UNIDENTIFIED FEMALE: So then how do you make money doing this kind of work?

MR. FRANKEL: We will lose money doing this. This is all giving away. We haven't done a good job of showing the public outside of our sphere what we do and how we do it and the value of the data; we know that, that's why we're here, because you don't know us well enough and we haven't demonstrated the value.

That is only possible because we are making money somewhere else. You can't do tiers. If

it's no profit, loss and big loss, I mean, that those tiers don't work. We need a profit.

UNIDENTIFIED FEMALE: You don't expect your business to operate without a profit.

MR. FRANKEL: This is the public good work, and it's in the many millions of dollars a year, and it's just going to keep growing because we have to make the data available, we're guilty of that.

UNIDENTIFIED FEMALE: The one point I wanted to make with this question is that when you're relying on businesses or organizations that are using your data for commercial purposes to inform physicians, like you were talking about all the positive things that your data can do for human health and for patients, it's really, yes, that potential might be there.

But when you have no -- what I was going to say is you really have no control of that. You're simply selling a configured product. You're selling data and saying, oh, look, they could inform physicians about better practices or they, you know, with this data they can do these things. But they also are businesses and they also are in the business of making money

and that's not their primary focus.

MR. FRANKEL: Right.

UNIDENTIFIED FEMALE: And that's not a judgment either, but that is just the reality. So in and of itself, you know, the data -- the fact that the data could be used that way doesn't mean that it is being used that way.

MR. FRANKEL: Right. It's a potential versus actual value. And in the past we've funded work for people who have requested the data. They've come to us.

We've looked at programs of treatment of asthma and low socioeconomic areas. We've looked at the fact there was something that had to do with hypertension and the Allhat study and how that was being adopted.

We've looked at a variety of things and we've actually supplied data. And there have been publications, and I believe you have that in some of the documents.

What we're doing now is being more proactive. Because in the end if you do it through a passive or osmosis process, it's just too slow.

So we are picking universities around the

country that are doing this work, starting with Dartmouth, Stanford, Harvard and others. We are probably going to be turning it into something along the lines of an institute where we will give the data to the institute and allow them to fulfill their --

UNIDENTIFIED FEMALE: I'm glad to hear you say that. Because I think on some level that there's a huge weight, responsibility that must come with possessing this kind of information.

MR. FRANKEL: We're very naive. Not naive. We're young as a company in understanding that. And I would have to say that at this point in time you have our attention.

UNIDENTIFIED FEMALE: And I just wanted to ask you one other question related to the AMA opt-out. If the AMA is successful in reaching awareness of 70 to 80 percent of physicians about the opt-out, have you done an analysis of the impact that this will have on your business?

MR. FRANKEL: It doesn't matter.

UNIDENTIFIED FEMALE: It doesn't matter to you?

MR. FRANKEL: No, it doesn't matter, because in the end that is the way this should

be determined. If the data go away because doctors really are against it, it's done privately, it's done through a program that can evolve over time.

It gives us an opportunity to go back to doctors over time and say, you know, we can provide you services and things if you do allow the data.

It almost puts us and the pharmaceutical industry in a position of having to add value back to the doctor to make it worth their while to be in. If doctors all decided to opt out, then so be it. We won't be --

UNIDENTIFIED FEMALE: So you support the opt-out program, the AMA?

MR. FRANKEL: We support the AMA program. And the reason we like AMA is that it's a nationwide program and it's standardized around the nation. It is a dynamic living program that can change.

We're against codification in law, because when you do that you're basically etching it in stone. Imagine a situation where we have done surveys and doctors tell us they want to change the program and we have to go to 50 states to

change state law; it won't happen. We can't do it, no one could.

We'd rather it be referring to PDRP in support of a PDRP. I know AMA would be happy to sit here by our side talking with you about your concerns and how they can change it.

But we are very fearful of being in a situation where it's just regulated and fragmented to the point where it's no longer useful, it can't evolve. So, yes, we support the AMA program.

UNIDENTIFIED FEMALE: Can I just follow up with that? With the opt-in, I thought with the opt-in, that people generally don't respond, so it's not that useful because even though they may say yes or no, but they don't respond. So I don't understand how the opt-out is different. They'll get the information, they won't respond. Same thing as opt-in.

MR. FRANKEL: One of the things that the AMA suggested is sending a certified letter to every doctor in the state of Vermont so that you know they all received it.

I know that they've looked at the web site. There have been some discussions that it should

be even easier, that it should be brought out on the page so that people don't have to look for it.

AMA is already doing it. So you can see that by having the comments, AMA and we have a way to respond, It's mostly AMA. It's their program. But they will continue to change it.

Now, if it were a law and you created a situation and then it needed to change, then you'd have to change law, and every state would have to change law.

And the idea of or the thought that they'd all be the same or consistent is pretty remote. So we're hoping that you can all find a way to work with AMA and with us as needed as you want, and just keep the dynamics of the situation improving over time until we get to a point where you know enough doctors -- doctors are aware, and what they're doing is out of choice and not because of ignorance.

REPRESENTATIVE MAIER: Do you have just a minute or two? I want to make sure Scott gets in, so Scott will be our last question.

MR. WHEELER: Just to clarify, so the pharmaceutical companies basically come to you

and buy the information. And what percentage of your business is pharmaceutical as in sold to the pharmaceutical companies versus other --

MR. FRANKEL: It's the vast majority of it. I don't have the exact numbers. We have in the last four or five years bought I think somewhere between six and nine companies worldwide in outcomes research.

It's going to be a multi hundred million dollar business over time. That is how you compare drugs to figure out which one actually gives you the best outcome, and that would feed formularies and decisions in MMA and a variety of other areas.

People are getting into cost-effectiveness, they're getting into outcomes research and incorporating them in formulary decisions. But right now it's a very fragmented market and we are using our data to help do that.

MR. WHEELER: I'll ask you this: Do you think then that this is comparable to a -- to us cracking down on car dealers because too many people are driving DWI -- driving while intoxicated?

Like, would you consider yourself the car

dealer? And because other peoples, quote, misusing your information or the perceived misuse, are you the car dealer do you believe?

MR. FRANKEL: I suspect we are. I personally think we're the messenger. I don't think we're actually the ones doing the harm here.

They are our clients. I don't like to be disrespectful. But none of us is in favor of inappropriate marketing practices, but that's not addressed by taking away the data. The practices go on.

UNIDENTIFIED MALE: That was just my question, whether it was the same relationship or not. Because if it is, we don't have -- with Ford, I don't think they're responsible for people driving drunk. But if I can make that connection or not?

REPRESENTATIVE MAIER: We can perhaps play around on that metaphor later. I think we've run out of time. We have a conference call here that is the only time we could get someone on a Bill we want to try to pass out later today. But I just wanted to take a moment and thank you for all your time here this morning.

MR. FRANKEL: Thank you. I know this isn't easy.

REPRESENTATIVE MAIER: Nor was it easy for you, I'm sure, to sit there for almost two hours and take our barrage of questions.

I appreciate you coming and being here and helping us to understand how this is --

MR. FRANKEL: I would come back in a heartbeat if you had more questions or wanted to spend time. This is important to us and I know it's important to you. Anything we can do to help, anything I can do to help, I certainly volunteer that.

REPRESENTATIVE MAIER: Thanks again.

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF PASCO)

I, JULIE A. COX, Court Reporter and Notary Public, did listen to CD 143, Tracks 1 through 3, and and CD 144, Track 1, the House Committee on Health Care, Thursday, April 19, 2007, proceedings and stenographically transcribed the foregoing proceeding, and that the transcript is a true and accurate record to the best of my ability.

Dated this 14th day of August, 2007.

_____
JULIE A. COX, Court Reporter

STATE OF VERMONT

HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: Friday, April 20, 2007

Type of Committee Meeting: Standard

Committee Members:

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

CD No: 07 - 148/T1

PROCEEDINGS

- - -

REPRESENTATIVE MAIER: Marketing practices and provision in front of us that would possibly make it illegal for data to be put together in ways that target specific physicians and their prescribing patterns, and I understand you have some -- something you would like to say to us about that. And perhaps also given your -- I didn't -- I didn't know until Madeline just told me a little while ago that you also serve on the DUR board. So I'd be interested in your perspective from that experience. And we may have a question or two relating to that as well.

DR. LANDRY: All right. I can give you my background so you can know in terms of -- I really have a great interest in the pharmaceutical industry dating back to about 15 years where I actually did research on -- just given to physicians and public opinion regarding that, as well as I served on many hospital regularization committees here at Fletcher Allen. I did that for a period of years and the covering on that one, but

military both at Walter Reed and Madigan Medical Center.

I've served on regularization committees for the government and also now in Vermont I think I've been on the Drug Utilization Regularization committee for, oh, for the last three to four years. So I bring that experience.

The other part of my experience is I have a large private practice, mainly geriatric practice so I prescribe a lot of medications.

So a couple of thoughts I have. Did you want me to just give you my thoughts?

REPRESENTATIVE MAIER: Yeah, that would be great. Thank you.

DR. LANDRY: Yeah. A couple of my thoughts about this bill, is I think -- again, I think, you know, everyone is really thinking good things about these issues and I'm actually proud to read this bill and support it.

The way I look at that is I see no public good whatsoever for the pharmaceutical industry to have information on my prescribing habits.

An example, a couple years ago I was really unaware of this, probably five or six

years ago, when a detailing pharmaceutical representative came into my office and asked me specifically why I was not prescribing a new pharmaceutical, and I said, how do you know that I don't prescribe this drug?

And he says, we have data that says you've never prescribed this drug so I need to tell you about it.

And I was very interested by that in that -- in that manner.

I can't understand why AMA and organizations like that would sell -- sell information regarding physicians and to allow them to have, you know -- anybody to have this data about what I prescribe to my patients. I just, you know, see really no public good on that.

And I know you heard a lot of background about detailing and marketing of drugs and what it does to pharmaceutical prices, what it does for physician prescribing practices. And we know that that pharmaceutical representative in the office talking to doctors, you know, makes doctors prescribe certain drugs, more expensive drugs than generic drugs than all the rest and

that's, you know, well founded in medical research.

And now we're battling direct marketing to patients which is probably more powerful or as powerful as the pharmaceutical representative in the office where patients come in and request specific drugs. So I see that data as really -- as of no public good. I really am concerned about the fact that why they want to have that information. Certainly, I know why. But when they explain to -- well, this may have a public good; for example, if a drug is recalled, it can tell the doctor. Well, I can tell you in the years I've been practicing, when drugs are recalled, the pharmaceutical representative never comes to the office to say, let me take back the samples. In fact, if they provide samples to physicians, they don't really care if the drugs on the shelves in the doctor's office are outdated or not. So there is no coming in and taking back old drugs. There's no coming back in, you know, taking back drugs that have been pulled from the market. Drugs like Vioxx and Bextra are recent ones and Zelnorm.

We certainly get recall notices from the FDA and from the manufacturers but -- but there's no -- there's no incentive of these representatives to come and take back these drugs. So again I don't see any public good that take serves.

The managed-care companies and the insurance companies as well Medicaid are able to link diagnoses to drug prescribing, and all of these companies as well as Medicaid do this in a educational format for physicians.

For example, patients that have MMIs, are they on beta blockers and so forth so that there's enough of that information available that that can be helpful information to the specific physician where there's a link to a specific diagnosis. So those are some of the first thoughts I have. And I certainly would answer any specific questions you guys may have.

REPRESENTATIVE CHEN: So, Frank, when you -- this is Harry Chen here -- when you get a -- when a drug is recalled and you have patients on it, you find out -- how do you find out?

DR. LANDRY: Well, that's a good -- that is a good -- that's a great question. You know, the hope and the future -- and many of us still don't have electronic medical records where that would be easy. If I had a drug listed in a electronic medical record, I could link it immediately and know what drug the patients are on. And that's coming. You know, many of us are in the beginning stages or some of us have had that and have that available to us.

Now, the current companies -- for example, we just did this with the drug Zelnorm, one of these drugs that was taken off the market through Medicaid database where we contact physicians. And insurance companies often do that as well. That's typically how we -- we move that. And so you have to use some sort of electronic record to do that and that's usually through the insurers now or Medicaid which has access to that data.

And in the DUR Board and the Medicaid system we do that when a drug is recalled. We inform the physician that they have -- they have prescribed this drug to their patients.

ATTENDEE 2: I'm sorry. And when you inform physicians, does that -- does that include -- the data for Medicaid or insurance company, would that tell the physician which patients?

DR. LANDRY: Yes, it would. Yes, it can be that specific. Yes.

ATTENDEE 3: And just to follow up on that, how do you -- what about people who don't have insurance?

DR. LANDRY: What if they don't have insurance --

ATTENDEE 3: Yes.

DR. LANDRY: -- on the prescribed drug? Well, all we can rely on is our medical records. Either physicians use electronic data records can -- can inform the patients.

I know of no instance where currently the pharmaceutical companies directly contact patients regarding recalled drugs.

We know they send out general alerts to physicians in general that these -- these drugs have been recalled but it's never patient specific ever in the history -- you know, in the 20 years I've been practicing.

ATTENDEE 2: Do you know if pharmacies do any of that?

DR. LANDRY: Say that again.

ATTENDEE 2: If pharmacies have participated at all in any of these activities.

DR. LANDRY: Yeah, the pharmacies -- the pharmacies can also do that and they are typically pretty good at that. Yeah, they can pull up that data, the specific pharmacy. But, of course, you know, patients are going everywhere for their drugs, all different pharmacies, mail aways and so forth.

ATTENDEE 1: Yeah. Hilde Ojibway with a question.

REPRESENTATIVE OJIBWAY: Yes, and thank you very much. When you came in, I was very impressed with your time management so I was feeling terrible we weren't on the phone with you right at 8:30.

DR. LANDRY: Oh, that's fine.

REPRESENTATIVE OJIBWAY: You're very precise.

Two questions. You made a comment. One of the things we heard is that while there is a lot -- obviously a lot of money spent on

marketing, by far the marketing dollars are spent more on physicians than patients and -- but you made a comment about how many -- you're seeing a lot more patients coming in and requesting specific drugs. So just a general comment. I was wondering if you could kind of talk about that for just very briefly. I'm just interested in how often does that happen and how strong are people's convictions when they come in. I mean, do you really have to negotiate and argue with them, that no, they don't really need that or how does that work?

DR. LANDRY: Well, it's a very powerful marketing tool, you know. Obviously, you know, if you watch the evening news, you know, the greatest example I know is of -- you know, some examples are restless leg syndrome. You know, in the course when they've had this new drug that they use for restless leg syndrome, which I can tell you has more side effects than you can imagine, at least in the last three months I've had six patients come in and request that specific drug for their restless leg syndrome.

The other one I can give you an example of is peripheral vascular disease where people

have blocked arteries to the legs and they get kind of pain in their calf when they exercise. And there's been some advertisements regarding that and I've had a number of young people, which they have absolutely no indication that they have this disease, convinced that they have that and think they need not only evaluations but a specific drug for that so it takes time too, you know, in terms of education. And, you know, there's just so many examples of this.

The whole -- the best example of this is the whole Vioxx and Bextra. These were anti-inflammatory drugs which were -- have been pulled from the market. Celebrex is still on the market. And there's many studies -- and I did one of these studies back in 1990 where we compared different anti-inflammatory drugs and really showed that there's really no difference between them. Some patients seem to respond to one better than the other, yet these drugs became the number one sellers in America. And then they were pulled because they were killing people. And what's fascinating about that is that there's no one begging for these drugs

anymore. In fact, since the news has come out -- you know, obviously the drugs were pulled from the market but even the use of Celebrex has declined so substantially and people are going back to the traditional cheap generic Advils, you know, Ibuprofen. You know, it was complete marketing based on, you know, TV marketing that drill patients to believe that these drugs were superior, you know, because always the new drug that comes out has less side effects, it's supposed to be better than the old drug, you know, new and improved with a cost that's expensive. And patients just like everything else, they want the best all the time and they're great advocates for their own health. You know, we listen to our patients, you know. We try to do the right thing but we're greatly influenced by what our patients' needs are or what they think they are. But it's educational and it takes a lot of time and energy and, you know, these drugs wouldn't be the top sellers if it wasn't for that type of marketing.

REPRESENTATIVE OJIBWAY: Well, the other question that I have is one of the arguments

against making the sale of this data illegal is, well, you're going to put companies out of business, that they're just trying to provide good information and they don't have control over how it's used. So there's a couple of options of making it completely illegal. One is the opt-out so you've, you know, signed a form through that AMA I guess saying that no, you don't want that information, or the other one that I don't think is promoted by the AMA or anyone else is the opt-in. So unless you specifically sign up for it, they can't share the data.

Do you have any comments on either one of those?

DR. LANDRY: Yeah. Well, I always think this that -- you know, I can only speak for myself and my thought is that if you asked 100 doctors whether they would want their personal prescribing information sold to the pharmaceutical industry, boy, if you found two physicians that said yes to that, I would be surprised.

So these opt-in and opt-out things, they don't make a lot of sense to me. I mean,

it's -- it's a fact that -- you know, it doesn't make any sense that they should have my prescribing data.

I doubt the companies will go out of data -- out of business. And for them to send their representatives to market hard to specific physicians because they're not prescribing a specific drug doesn't make any sense to me. The information they provide -- and I think you have some data regarding that and there's plenty out there -- the data they provide isn't educationally in an unbiased sense ever, it just isn't.

And so you're giving them heads up to say this doctor is not prescribing this medicine, let's see how hard we can hit them in all directions for them to prescribe the drug. And, you know, if they hit them hard enough in all these directions, they will start prescribing the drug. So they get samples. They get -- you know, I've had coat hangers sent to me with Lexapro on them.

You know, the marketing is unbelievable what -- what they do. They'll use every single angle to get at you to think about that drug,

you know. So, you know, to me to say the companies will go out of business is ridiculous. They won't. It may make it more difficult for the pharmaceutical representative to hone in on a specific prescriber. And I can tell you they know who the big prescribers are. I'm one of them. I'm a very big prescriber of medications, and they love to see my face. They, you know -- it's -- you know, unfortunately what we need to do in the public sector -- and, you know, Fletcher Allen and I was involved in this before I left Fletcher Allen and Rich Pickney (phonetic) is a doctor that's involved in this, is this academic detailing. You've heard about this before. We need more education around that. We need to give doctors unbiased sources for information on drugs. And they shouldn't come from the pharmaceutical industry because it's -- it's biased information.

And there's things like the medical letter. There's things like the American College of Physician Peer which is an online resource where we can get this unbiased information to make the better decision on --

on drugs.

To say that the pharmaceutical representatives are providing doctors with education on drugs is really, really pathetic. It's just not -- it's not scientific. It's not, you know -- it's not good information; you know, it's not unbiased information. They never compare drugs and so we're really -- we're really caught in a system to say we're promoting this practice and it's not for the good of our patients. I can't believe that's -- that's the case.

ATTENDEE 1: John Zenie.

REPRESENTATIVE ZENIE: Dr. Landry, this is John Zenie. Okay. If -- if they're doing such a bad job even before this data and -- or after this data relative to being helpful to the physicians, why do physicians even bother seeing them?

DR. LANDRY: Well, you know, physicians -- physicians see them because they feel that they -- they need to get some sources of information and they like the free samples, and it's another -- it's -- unfortunately it's kind of a tragedy of our health-care system that

physicians take samples. And the reason they really take them is there are patients -- we have many patients that have no health insurance. I have patients in my office that have coronary artery disease that had a heart attack, they don't have health care and their cholesterol is 220, their LDL level is 220 and I know if I can give them a statin drug that they can't afford $30 a month for a generic single statin and I know if I can give them, you know, Lipitor from a pharmaceutical rep's free sample, you know, you feel that you're helping them because they won't be on the drugs otherwise. Or a diabetic that doesn't have health insurance.

So, unfortunately, we have a system that's so broken. Our health-care system does not work well for the patients and the physicians feel this is a source of a free drug I can give to a patient. Unfortunately, there's no question about it, that drives us to write prescriptions of these brand named products. No question about it.

I've argued for years if we can have a system with a generic drug sampling where we

can have generics in our office and not drug samples, we wouldn't see these people around. But there's no system and no funding to do so. So it's really a blight on our health-care system that this happens and it's the free market economy that drives that.

Vermont has done a great job. When I first came to Vermont I came from the military sector where we really didn't meet with pharmaceutical representatives, where we didn't have, you know, free dinners and lunches.

I was amazed a decade ago that you could go out and eat at any restaurant in Burlington, you know, Monday through Thursday night with a pharmaceutical representative, a nice restaurant, to hear some little spiel on a drug. Now that's changed dramatically from the prior laws you guys have worked on in the past in terms of the reporting and all the rest. That has dried up substantially which I think is -- is a good thing.

And some of the programs they have available now, you know, you can't bring your spouse unless they're a doctor. They tend to be a little bit more educationally balanced.

So there's been some great improvements in -- in what we did there. So that's -- you know, doctors do that because they feel they want those samples to give to patients that don't have access to -- to drugs. And that's more and more every single day.

And the second part that we've seen is these high deductible health plans, one of which I have myself where people have a $4,500 deductible and, you know, people are barely making it in Vermont. I can tell you I talk to patients every day. They can't pay $60 for -- for medicine. They may not be able to pay $20 for a medicine. So the doctors supplement them with these free samples.

ATTENDEE 1: Follow-up.

REPRESENTATIVE ZENIE: That's what I thought you had said and it sounded like earlier you even addressed one of those things regarding the educational piece when you talked about the academic detailing. It sounds like a very good idea. I'm not sure how much more we can do with that. I mean, is there more we can be doing with academic detailing to get the education to the physicians?

DR. LANDRY: It all has to do with timing and it's -- you know, again I think it's -- you know, it's -- it's out there, it's done. Physicians get their information from multiple sources and, you know, from the continuing medical education which when they get CME credited, it's typically unbiased and that's where they should be getting their information. And everyone has a certain requirement they have to do every year.

A lot of this other stuff is, you know, excess. And I can't tell you, you know, is it because they get free lunches why they go to these things. I don't know. I don't attend them. Personally, I just have a -- you know, I can't see going for a free lunch to hear about something that -- that -- you know, I have no idea how truthful it is. It makes no sense to me. I mean, that still -- that still does happen so, you know, I don't know.

I think the academic detailing works to a point. I think physicians need to be, you know, directed towards sources of good information at their fingertips and whether that's -- you know, there's a lot of free

information can get now on these things right on the Internet so. . . .

REPRESENTATIVE ZENIE: And the second part is do you have any thoughts about what could be done relative to the need of the free samples?

DR. LANDRY: Say again.

REPRESENTATIVE ZENIE: What -- what -- do you have any thoughts or ideas about what we can do to get around this particular way in which physicians get free samples? In other words, I hear the need.

DR. LANDRY: Yeah.

REPRESENTATIVE ZENIE: I don't know if we like the delivery system.

DR. LANDRY: Again, it's just a comment on our health-care system, it's not -- it's -- it doesn't work well for many people that are in between insurances and so forth and I don't -- I don't see an easy way to get about that.

I do think if there was a system in place where we could have generic samples for especially run diabetic medications and high blood pressure medication and -- you know, the big one is depression. I mean, you know, those are the samples I tend to take because, you

know, there's many people that are on
ntidepressants and the trouble with those
drugs is some people don't tolerate them well.
And so having some samples of those drugs are
sometimes useful to get people started and so
forth because there's not a lot of generic ones
and we do use generics when we can. So I
don't -- I don't have a good idea of how to
handle that to be honest.
REPRESENTATIVE ZENIE: Well, what you just
said was a good answer in my mind.
DR. LANDRY: Yeah. I think the free
market -- it's going to be tough to change that
free market.
My point on this bill is I still don't
understand why they should have information on
what I write for my specific patient and why I
should have a drug rep come in to me and say,
you know, Dr. Landry 90 percent of your
prescriptions are for Lipitor, why aren't you
using this Crestor, this new drug? We don't
understand. We want to show you proof of why
you should be using this drug. You know, why
should they do that?
Now, I can tell you I really don't meet

with pharmaceutical representatives other than
the fact they contact me sometimes regarding
the Drug Utilization Review and -- and the
state will try to give me some information on
drugs. But I just don't understand why they
should have my specific information. I feel as
though they have my bank account number.
They're selling something. They're gathering
data for no purpose. I don't see that why they
should have that information. It would be as
though, you know, they were selling -- you
know, I guess people do that. They can -- they
can figure out what you buy in the supermarket
now and all these things.
But I think when the patient is the
intermediary regarding drugs, they're not
buying the drugs typically. I determine the
drug for them and gear them in that manner and
I -- I just don't see how this benefits the
consumer by -- by having that information
available and the doctor specific prescribing.
I guess it's helpful to the industry, that's
for sure, but I -- I don't understand how it
helps the patient.
ATTENDEE 1: Bill Keogh.

REPRESENTATIVE KEOGH: Bill Keogh from
Burlington, Doctor. Sorry I was a little bit
late. I have two issues.
One, when you were on the staff of
Fletcher Allen, did detailers have access to
you?
DR. LANDRY: Yes, they did. In the --
typically speaking in the primary-care
practices, they -- less access because that was
the -- the notion of the Chief of Primary Care
at the time. But absolutely they have access
and I still think they do have access to
pharmaceutical representatives. Yes.
REPRESENTATIVE KEOGH: I've asked Pat
O'Donnell in an e-mail yesterday, as a matter
of fact, for -- to take a look at that policy
so --
DR. LANDRY: Yeah. I was on -- I was the
head of the pharmacy committee there and we
grappled with this, and I can tell you the
bottom line is places like Stanford is looking
to not have them, okay, to take no money.
You know, the issue comes up with -- and I
can't speak for Fletcher Allen because I was on
the committee a few years back. The reality is

industry in general -- and it's not just
pharmaceutical money. It's the vendors that
sell the ships and the joints and this and
that. They give educational money to Fletcher
Allen. And many people feel, where do we get
that money if it doesn't come from the
industry? Okay. And that happens even at
national meetings. We grappled this with the
American College of Physicians.
Locally in the state I've been the
governor -- I just finished my governorship for
the American College of Physicians for the
state of Vermont. We voted last year at our
conferences to have absolutely no
pharmaceutical funding whatsoever. It's easier
said than done. It's bankrupting my chapter.
Okay. Even though they were given -- we had
some grants for a couple of years that were
unrestricted educational grants. They had no
input on our topics whatsoever. And this
happens at the national meetings.
Right now the National ACP meeting's
happening in San Diego and, you know, they will
have displays from pharmaceutical companies
that provide a lot of money to the

organization. The physicians have access to those representatives if they feel they want to. But a lot of these organizations depend upon that money; yet, on the other hand, when they turn their back, they say, well, you shouldn't be taking this money. But it's an economic reality.

Big institutions like Stanford can say no because they have huge endowments, they can get this money from somewhere else. Small hospitals and small universities, it's very difficult right now because a lot of this money, I can tell you, is -- because I work for this APC -- is, you know, you have a company that comes up and says, you know, we've got, you know, a couple of years unrestricted educational money we want to give you. We have no input in your meeting whatsoever. Hard to say no to that when you meet all the criteria for the continuing medical education that it's educationally funded money. And typically we put our money towards resident and student education to allow them to come to the conference for free. So there's a lot of good in some of that educational stuff but it comes

with a price, meeting with the representatives.

REPRESENTATIVE KEOGH: As an aside, I play basketball with a veterinarian and veterinarians are subject to the same issues with detailers in their business as well as human beings I guess.

DR. LANDRY: Yeah.

REPRESENTATIVE KEOGH: My other issue is if this is such an important matter and apparently it is, I think the state medical society and the other professional organizations ought to be doing a lot more, be more aggressive with respect to educating physicians on how to do this.

Do you think that's accurate or is this something that the -- that someone else should be doing?

DR. LANDRY: Well, I think we all -- I think interesting, being like I said involved in the American College of Physicians, which is the largest subspecialty group in the United States, we've been discussing this for 10 years and trying to say what -- what is the balance between industry and academics, so to speak? And we do do that. We work on the medical

school that -- at the University of Vermont there's forums every single year that talk on these things here.

As long as the free market exists, my concept is we need to teach other physicians how to interact with the pharmaceutical industry, not necessarily shut them out because there are things they do well and they help us with education. So there's a lot of positives that they do and we need to have a better relationship with them to say how does this work, you know, but I think the reality is we have to find a way to be balanced and unbiased as best we can in doing that. So I think it's -- it's not an all or none, shut them out.

I've never been an advocate of that. I've been more of an advocate of how to teach young people how to interact with the industry because you're going to face this your whole life. If it's not drugs now, it will be, you know -- it will be pacemakers or knee replacements or artificial limbs. There's always going to be something in the medical world where -- where people are going to try to influence, you know, what we prescribe and what

we do because at the end of the day we're the ones that have to put our initials on that. We put our initials on everything from physical therapy to wheelchairs, to, you know -- the same point comes with people who are looking for these scooters. You know, we get pressure from patients to prescribe them a scooter so that Medicare will pay for that. But it's a whole industry approach. And so it's an educational thing we do need to work with in the medical society and the medical schools with, to teach people at an early age how to interact. A lot of medical schools say shut them out, you know. My belief is we've got to teach people because once you let them loose in private practice, they're going to be influenced.

REPRESENTATIVE KEOGH: Thank you.

ATTENDEE 1: Topper.

TOPPER: Good morning, Doctor. I have one question.

When you decide to prescribe a specific drug, what triggers you to prescribe that drug?

DR. LANDRY: Well, many things. Obviously, the disease, the severity of the

Page 30

disease and in most of our minds, you know, as an internist I can tell you, you know, it is repetition, you know. Once you get used to a drug, the dosage of the drug and the side effects of the drug, it's a lot easier to prescribe the same drug time and time again if it works and it's effective. So we do do that.

I'm the one that takes new drugs with great caution. You know, I usually use the rule once it's on the market I don't prescribe it for at least six months because I let my other -- let other people's patients, you know, suffer the consequences because there's many examples of drugs that are on the market for six months to a year and they're pulled.

So we're creatures of habit. It's sometimes hard to break our habits. And certainly we get our information from what's, you know, the newest and the greatest in the medical journals in terms of, you know, for example, diabetes, high blood pressure, high cholesterol, you know, how to treat these diseases and with what drugs.

Many of us know that many of the generic drugs are highly effective. Luckily, we have a

Page 31

lot of those available now for us for those disorders, you know, for cholesterol, blood pressure and diabetes. So, yeah, I think we're creatures of habits, we use our past experience and we use, you know, current knowledge to help us prescribe. But typically once we start prescribing certain drugs, we stick to them.

TOPPER: So you wouldn't say then that somebody coming into your office offering you free samples would influence you in terms of prescribing a particular drug?

DR. LANDRY: Well, you know, all doctors will tell you no, they never do.

We have plenty of data, and I've done this research so I know it. We know if the sample is in your office you will start to use that and you'll start to write the prescription. That's all there is to it, no question about it.

So if a new drug walks in the door, lands on the shelf, there will be a patient that comes in within the next two weeks that has the disorder and doesn't have any insurance. So you go to your drug closet and pull out the newest drug and say, here you go, off you go.

Page 32

And pretty soon you'll start prescribing the drug. That's what doctors do. No question about it.

If that wasn't the case, they would not be providing samples. And the great example is once a drug becomes generic, samples stop, absolutely stop. They don't come in. Or if a drug is a complete unique drug -- for example, there's a new drug for smoking cessation called Chantix -- no samples are given for that drug because they know that, you know, it's likely the patient will need -- you know, will use probably one month of that drug and probably not get it renewed. And that's the truth. So it's very interesting what they decide, when to sample and when not to sample and when the sampling stops.

REPRESENTATIVE MAIER: Dr. Landry, this is Steve Maier again. I have a couple of quick questions and we need to try to wrap you up in about five minutes or so.

The other day I -- I went -- started to go down the road of generic, you know, giving out generic samples and I sort of asked somebody -- I forget who it was -- well, why -- why don't

Page 33

you just have a bottle of generic Zocor in your office and give -- you know, give two or three or however many it would take. And then someone said, well, no, that's illegal, you can't, that would be dispensing of a drug. So what's -- what's the -- I don't know if you're the right person to ask this. What's the -- how -- how does a free sample get around that legal restriction?

DR. LANDRY: I don't know the legality of that but, you know, we aren't -- we aren't -- prescribers -- usually, the free sample goes with a prescription. That's the reality, you give a drug and you give a prescription; however, I can be honest with you is that many times we're filling the void. So are we dispensing drugs? I guess we are, you know. But that's -- that's done and so I don't know the legality. Typically a sample is that, it's a one-week supply and a prescription goes with it. So here you go and a prescription goes with it.

Now, many of the drug companies have stopped giving actual pills and they give a card. So the card allows them to go to the

pharmacy and get, you know, a week's worth of medicine and then they fill the rest with their prescription, you know. Doctors don't like those cards though for the reason I just mentioned.

So a lot of times really people -- people take the samples to fill the void for -- you know, if we could fix the pharmaceutical method so that at least basic generic drugs were available to people at a very low cost which places like, you know, Costco I guess and Wal-Mart are doing, that's helping, that's helping.

REPRESENTATIVE MAIER: And my last question is -- I think it was right at the very beginning of your testimony and a couple of times since -- you talked about -- that you can see no -- no public good, no, you know, no good reason why these companies should know what you're prescribing habits are, and -- but -- I think you touched a little bit on the fact that there are -- you know, I'm just sort of struck by the idea that this committee and a lot of other people in the state are -- spent a lot of time talking about managing chronic illnesses

and in fact recognizing that we probably -- we do need to move doctors in certain directions away -- perhaps away from certain ways of practicing, toward other ways of practicing and -- and -- and there may also be some safety issues with certain prescribing patterns but I think -- I just wanted you to talk a little bit about that again. I think there are -- there are other sources of data that can help us do those -- those other things and I think that was your testimony but I wanted you to emphasize that again.

DR. LANDRY: Well, one is -- is certainly what -- what you described is important, absolutely.

The second point I was making is we do not want the pharmaceutical industry being involved in that. Please, please. We don't even want to think about that.

The third thing is that there are mechanisms. We do this with the State Drug Utilization Review where we pick -- we can look at prescribers, we can look at habits, we can look at drug interactions and we can pick dangerous, you know, prescribing practices and

identify those people. And we do do that.

For example, we look at patients that are on multiple narcotics, if -- who are the prescribing doctors and why are they giving this, or we look at dose limits of drugs or drug interactions that could be potentially lethal and feed back to the providers on those things. Other insurance companies do that as well.

You know, I don't mind the state in terms of, you know, we're trying to work and improve health-care. I think that's an important thing. I just do not believe that the pharmaceutical industry has any intention of -- of really wanting to use this data for this means. And if we're going to do that, you know, in terms of pay for performance, let everyone move people in better prescribing and better practicing. There are other mechanisms to do that that are again, one, fair; two, objective; and three, we want to make sure we do focus on the fact that there's -- there should be some confidentiality in what we do.

The fact that -- I would hate to think that the pharmaceutical industry is linking my

prescribing to specific patients. They have absolutely no right to that data. You know, that really frightens me to think that they could do that.

So your question is a great one. I think we need to do those things but I think we need to do that in a better fashion.

REPRESENTATIVE MAIER: Okay. Thank you so very much for your time and thoughts this morning. We'll let you get on with your day.

DR. LANDRY: Okay, well, good luck.

REPRESENTATIVE MAIER: Thank you.

DR. LANDRY: Okay. Bye-bye.

- - - - -

CERTIFICATE

THE STATE OF FLORIDA,)
COUNTY OF BROWARD.)

I, Dona J. Wong, Notary Public, Certified Shorthand Reporter and Registered Professional Reporter do hereby certify that I was authorized to and did report the foregoing proceedings and that the transcript is a true record.

Dated this 10th day of August 2007.

Dona J. Wong, RPR, CSR
My Commission # DD 002741
Expires May 16, 2009