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

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-payer 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
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 end of the matter.

ATTENDEE: But the fact is the Commissioner
has to do that if the AG --
MS. LUNG: Correct.
ATTENDEE: -- has to consider it?
MS. LUNG: 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. LUNG: Sure.
REPRESENTATIVE ZENIE: About most favored
purchase price.
MS. LUNG: Yep.
REPRESENTATIVE ZENIE: To make sure I'm clear
about the definitions of seller and purchaser.
MS. LUNG: Yep.

4655 is the next step in the process and --
ATTENDEE: Go ahead.
ATTENDEE: How about 6, number 6 under this?
MS. LUNG: Yes, yep.
ATTENDEE: What does that mean?
MS. LUNG: 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. LUNG: Yep.
ATTENDEE: What, what --
MS. LUNG: Happens?
ATTENDEE: -- authority does the Attorney
General's request have then?
MS. LUNG: None. The AG has the right to
ask them to consider it, but that's it.
ATTENDEE: Has the right to ask?
MS. LUNG: Right, so they can -- the AG can

REPRESENTATIVE ZENIE: So a seller could be a
PBM or a manufacturer?
MS. LUNG: 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. LUNG: I'm not sure if it may -- if it's
a PBM.
ATTENDEE: Or a wholesaler.
MS. LUNG: Maybe a PBM who operates mail
order.
ATTENDEE: Okay.
MS. LUNG: Because then they would be
reselling.
ATTENDEE: And then a wholesaler?
MS. LUNG: A wholesaler.
ATTENDEE: Then on the purchaser's side --
MS. LUNG: Yep.
ATTENDEE: -- is that ever a wholesaler or a
PBM?
MS. LUNG: 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
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| 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: No. 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 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
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'CONNELL: Well, certainly, high blood pressure, diabetes, those are -- those are over the past many years --

MS. LUNGE: Uh-huh, uh-huh.

REPRESENTATIVE O'CONNELL: -- 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 O'CONNELL: 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 O'CONNELL: By the Commissioner of Public Health.

MS. LUNGE: Right, right.

REPRESENTATIVE O'CONNELL: -- been an official declaration.

MS. LUNGE: Right.

REPRESENTATIVE O'CONNELL: But not only by her, but the past Commissioner.

MS. LUNGE: Uh-huh.

REPRESENTATIVE O'CONNELL: There have been pretty big statements --

MS. LUNGE: Uh-huh.

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
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| 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. |

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| 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. |

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| 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 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. LUNG: 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, 50 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. LUNG: But again, this is the manufacturer's price compared -- so it's the manufacturer's price compared to --

ATTENDEE: Oh, I see.

MS. LUNG: -- 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. LUNG: 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. LUNG: 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. LUNG: 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. LUNG: I definitely have no clue about that.

FEMALE ATTENDEE: Oh, God.

ATTENDEE: Oh, come on.

MS. LUNG: 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.


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 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 statement 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).
RE: SENATE BILL 115

DATE: 4/18/07

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 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 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,
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<td>&quot;We're making a ton of money selling this data, so we, therefore, want to keep doing it.&quot; They're coming in with objections that are more socially acceptable, like, &quot;This is going to hurt patients. Doctors are not going to be able to learn anything about drugs.&quot; 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-steroidal, and they would be able then to start undercutting the concept of 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.</td>
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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're not 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 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. There's 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.
A-1248

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 prefer 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
Veterans Administration, and from a lot of other sources. There is nothing that IMS can provide through its commercial marketing, that cannot be replaced by access to the Medicare program, the Medicaid program, the clinical information, and the patient data, that we get through the CMS data warehouse that isn't available in any other data warehouse.

MS. O'BRIEN: I have two questions. It it is not possible to get data from the program in Pennsylvania. They just sold the tapes to us.

DR. AYROWN: We actually don't pay a thing to get data from the program. We don't own the data. It is available for free. The cost of copying the tapes is the cost of copying the tapes.

MS. O'BRIEN: Can researchers afford to do the research and the analysis of the data if it is available for free? The cost of processing the data is very affordable. The cost of processing the data is a trivial amount. When we get the data from the Medicare program, we just charge us the programming costs to process the data. This is usually a very affordable cost.

DR. AYROWN: I think it is not possible to get the data from IMS. IMS and the other data providers have told me that the data is not available.

MS. O'BRIEN: I have one more question. There are other sources of data. There is a lot of data that is available for free. Could IMS sell the data and the other data providers? IMS doesn't have the data. It is available for free. The cost of processing the data is very affordable. The cost of processing the data is a trivial amount. When we get the data from the Medicare program, we just charge us the programming costs to process the data. This is usually a very affordable cost.

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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
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.

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 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 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 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 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
REP. PAT O'DONNELL
REP. SCOTT WHEELER

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 Australia. 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-1256

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

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doesn't serve any useful purpose in medical
education. They have an unfair advantage,
especially if that's used to incentivize them
1 to just push their own product, so they can
2 get a bigger commission.
3 The consequence, as I said, and the reason
4 I care about it as a problem, is that all it
5 does is push prescribing to the expensive new
6 products, and it undercuts all the folks
7 throughout the medical world who are saying,
8 "Use the tried and true drugs. Use the
9 generics. Worry about the patient's
10 pocketbook." The shift to prescribing more
11 and more expensive products is hurting both
12 state Medicaid programs, and also individual
13 payors in the state who are having to shell
14 out more than they need to get their
15 treatments.
16 SPEAKER 3: Thank you.
17 MR. MAIER: Okay. Thank you so very
18 much Dr. Avorn. We never heard Dr.
19 Kesselheim's voice, but thank you for being
20 there.
21 DR. AVORN: He has been nodding. If any
22 of you want to follow up, just drop me a
23 note, and I'll be happy to send you -- you
24 know, we don't do this as a business, we
25 just do this because we believe in it. If
26 we can be of any help in this courageous
27 legislation, we'd be happy to do whatever we
28 can.
29 MR. MAIER: Thanks very much. Bye.
30 We're just going to keep moving here,
31 because we had David Balto, who we're now
32 about ten minutes late for. If you need to
33 take a little break, do it on your own.
34 SPEAKER 3: David Balto is the next
35 person. He's a former federal trade
36 commissioner here. I just got a copy of his
37 testimony. I will pass that out while I'm
38 setting up the new Pod Phone.
39 (Pause.)
40 (Phone Rings.)
41 MR. BALTO: David Balto.
42 SPEAKER 3: Good morning, David Balto.
43 The is the House Health Care Committee. I
44 will pass you over to the chairman of the
45 committee, Representative Steven Maier.
46 MR. MAIER: Good morning. How are you?
47 MR. BALTO: Good morning Representative

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Maier.
1 MR. MAIER: Mr. Balto, I'd like to thank
2 you for sending us some testimony. It's
3 just been handed around. We haven't had
4 much of a chance to -- we're just starting
5 to glance at it. Perhaps if you could give
6 us a quick summary of what you sent here,
7 I --
8
9 (End of CD 140 T1, Track 1).

4 (Pages 10 to 13)
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 MCFUAN           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
PBM 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
PBM 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
cost, 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 prospectively. And again, to 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

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 employees who belong to HR Policy Association. A small handful of those Fortune 50 employers have taken advantage of this model contract. 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 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 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. FRANCIS MCAFUIN
REP. WILLIAM KEOGH
REP. VIRGINIA MILKEY
REP. HILDE OJIBWAY
REP. JOHN ZENIE

REP. HARRY CHEN, VICE CHAIR
REP. SARAH COPELAND-HANZAS
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REP. PAT O'DONNELL
REP. SCOTT WHEELER

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 unconscionality 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 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.

SPKAKER 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.

SPKAKER 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 create 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 corrolate to run afoot 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 legalization of 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 it 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
unsophisticated 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, 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
referred to 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. William Keogh
Rep. Virginia Milkey
Rep. Hilde Ojibway
Rep. John Zenie

Rep. Harry Chen, Vice Chair
Rep. Sarah Copeland-Hanzaz
Rep. Lucy Leriche, Clerk
Rep. Pat O'Donnell
Rep. Scott Wheeler

CD No. 07-143/T1, T2, T3
CD No. 07-144/T1
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
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
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
whatver 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.
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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 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.

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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

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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, so they don't 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 about 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 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 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.
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

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?
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 '70s and '80s 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 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 competitiveness maintains
some level of control. The second thing the
data does has to do with efficiency. Frankly,
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 which 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,
thing 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 opioids, 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 if there is 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 out 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 engraved. 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
data 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 statistician. 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 A1C'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 A1C. 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 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. Countering 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 an impact. Canada
is not the United States, and I know that.

So but I don't know where anyone could
honestly say -- except based upon opinion --
that cost will 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 for
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 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 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 MALE: 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 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 healthcare
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 data 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'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 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.

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 biostatisticians 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 statisticians 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 criteria 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 that 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

transient 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,
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
ture.

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.
A-1300

1. it's no profit, loss and big loss, I mean, that
those tiers don't work. We need 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 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 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 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

CD No: 07 - 148/T1

Rep. Harry Chen, Vice-Chair
Rep. Sarah Copeland-Hanzas
Rep. Lucy Leriche, Clerk
Rep. Pat O'Donnell
Rep. Scott Wheeler
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 is that 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 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.
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 away 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.

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.
1 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 and there's plenty out there -- the data they provide isn't educationally in an unbiased sense ever, it just isn't.
14 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.
21 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.
20 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 --

1 on drugs.

1 To say that the pharmaceutical representatives are providing doctors with education on drugs is really, really pathetic.
1 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 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
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
REP. 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.

REP. 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.

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 not to 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

ATTENDEE 1: Bill Keogh.
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
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 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: 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.
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.

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