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HB 1346

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**HB 1346 – VERSION ADOPTED BY BOTH BODIES**

22Feb2006... 0738h

05/04/06 2067s

## 2006 SESSION

06-2404

01/03

HOUSE BILL ***1346***

AN ACT requiring certain persons to keep the contents of prescriptions confidential.

SPONSORS: Rep. Rosenwald, Hills 22; Rep. MacKay, Merr 11; Rep. Miller, Straf 7; Rep. Price, Hills 26; Sen. Gottesman, Dist 12; Sen. Foster, Dist 13; Sen. Martel, Dist 18; Sen. Larsen, Dist 15

COMMITTEE: Health, Human Services and Elderly Affairs

## AMENDED ANALYSIS

This bill declares that prescription information shall not be used, transferred, licensed, or sold for any commercial purpose except for limited purposes.

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Explanation: Matter added to current law appears in ***bold italics***.Matter removed from current law appears [~~in brackets and struck through.~~]

Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

22Feb2006... 0738h

05/04/06 2067s

06-2404

01/03

## STATE OF NEW HAMPSHIRE

*In the Year of Our Lord Two Thousand Six*

AN ACT requiring certain persons to keep the contents of prescriptions confidential.

*Be it Enacted by the Senate and House of Representatives in General Court convened:*

1 New Sections; Pharmacists and Pharmacies; Prescription Information to be Kept Confidential. Amend RSA 318 by inserting after section 47-e the following new sections:

318:47-f Prescription Information to be Kept Confidential. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this section shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

318:47-g Patient Assistance Program.

I. Following the close of each calendar year, any clearinghouse that provides information to New Hampshire residents about pharmaceutical manufacturers' patient assistance programs shall, to the extent that the clearinghouse collects such information, provide aggregate information to the commissioner of the department of health and human services relative to either:

- (a) The number of people in New Hampshire who may qualify for any manufacturer or government program during the calendar year; or
- (b) The number of patients served during the calendar year.

II. An individual company may provide additional information about the individual company's patient assistance program; however, the commissioner shall combine all information from all sources, including individual companies and the clearinghouse, and shall report only aggregate information to the public.

2 New Paragraph; Controlled Drug Act; Prescription Information to be Kept Confidential. Amend RSA 318-B:12 by inserting after paragraph III the following new paragraph:

IV. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy

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reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise required by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

3 Effective Date. This act shall take effect upon its passage.

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History

SENATE COMMITTEE

# HB1346 Docket

[Next](#)|[Prev](#)|[Results List](#)|[Main](#)|[Bill Status](#)**Bill Title:** requiring certain persons to keep the contents of prescriptions confidential.

<u>Date</u>	<u>Body</u>	<u>Description</u>
1/4/2006	H	Introduced and ref to Health, Human Services and Elderly Affairs HJ 7, pg 341
1/4/2006	H	Public Hearing Jan 24 10:00 RM205/LOB
1/24/2006	H	Subcommittee Work Session Jan 26 12:00(noon) RM205/LOB
1/26/2006	H	Subcommittee Work Session Jan 31 9:00 RM205/LOB
2/14/2006	H	Comm Rprt: OTP/AM {0738h} for Feb 22 (vote 13-0; CC) HC 16, pg 870
2/22/2006	H	Passed with AM {0738h}, MA, VV by nec. 2/3 HJ 20, pg 1209-1210
2/23/2006	S	Introduced and Referred to Executive Departments and Administration; SJ 6, Pg.149
3/8/2006	S	Hearing; === CANCELLED === March 29, 2006, Room 102, LOB, 1:45 p.m.; SC10
3/21/2006	S	Hearing; === RESCHEDULED === April 19, 2006, Room 102, LOB, 1:45 p.m.
3/30/2006	S	Hearing; === TIME CHANGE === April 19, 2006, Room 102, LOB, 2:05 p.m.; SC13
4/26/2006	S	Committee Report; Ought to Pass with Amendment{2067} [05/04/06]; SC17, Pg.18-19
5/4/2006	S	Committee Amendment{2067} RC 18Y-4N, AA
5/4/2006	S	Ought to Pass with Amendment{2067} RC 22Y-0N, MA; OT3rdg
5/4/2006	S	Passed by Third Reading Resolution
5/11/2006	H	House Concurs with Senate AM, Rep. Batula, MA, VV

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## Docket Abbreviations



JMB

Sometimes patients will get a coupon or an advertising in the mail for a medication that treats a private medical condition and they wonder how the drug company knows who they are. I have two examples of this. I was hoping that the state rep from Manchester who received these in the mail would come, but she is recovering from surgery and wasn't feeling up to it. This is a letter addressed to her by name for the prescription nasal steroid flonase and this is another one addressed to her by name for a product called immitrex. I think maybe it treats migraine headaches, but I'm not sure. They are both prescription brands. So, I will leave those with you.

The Pharmacy Board's Compliance Division does get complaints from consumers about this kind of direct mail marketing and advertising. At the public hearing in the House, we learned that not every pharmacy actually removes the patient's name from the data, the pure data, before they are released to other vendors. So, the result is that there is incomplete patient privacy protection even though HIPAA is supposed to ensure it. There is little that we can do about it either. The Pharmacy Board gets complaints from consumers, but HIPAA is a federal law and enforcement has to be through federal agencies. In addition, the civil fine for a HIPAA violation is a maximum of \$100. That is less than the value of many prescriptions and it is probably not worth federal investigation unless it is part of a broader criminal effort where the fines would be really major.

If we enact HB 1346 we will better protect the privacy of patients in New Hampshire from having their identity sold when they fill prescriptions. It makes the use of their identity for marketing prescription drugs a violation of our Unfair Trade Practices Act, which is enforceable by the New Hampshire Attorney General's Office.

Now, not only is patient identity inappropriately used for pharmaceutical marketing, but the identity of the prescribers – doctors, nurse practitioners, optometrists and physician assistants – is routinely bought and sold for marketing. Large data mining corporations produce very sophisticated reports that track the individual behavior of our health care professionals. The use of personal identity is both an unwarranted intrusion into professional privacy and, more to the point, it adds to the financial burden of New Hampshire's health care system by increased pharmaceutical costs for the state, our consumers, and our businesses.

In New Hampshire, I believe that we place a high value on privacy. When I do my grocery shopping at Shaw's and I give them that little rewards card with the unique identifier bar code, they know exactly what I'm buying. They have a complete record and I'm sure that they sell it to their vendors. But, I don't have any basis for complaints because I have signed up for that

program. I voluntarily gave my permission and I get something out of it in terms of special sales. Further, if on a particular day I don't want them to see the six pack of beer I have in my cart, I just keep that little bar code card in my wallet and I'm more anonymous for Shaw's that day. But, our health care providers don't have that choice. With data mining, doctors lose their privacy involuntarily and, without any permission, drug companies know how doctors and nurses think and how they behave. I believe our health care providers deserve the privacy of their own intellectual activity and professional practice. But, even more important than this, protection of their privacy will save us money in the health care system.

It is a truism in marketing that you spend your money more efficiently by investing in the customers you already have rather than trying to gain new customers. That is why it is so important to drug companies to identify who their biggest volume prescribers are. The pharmaceutical industry spends on average \$13,000 per doctor per year on marketing. They want to focus their marketing dollars and sales force time to convince high buyer prescribers to write more prescriptions for their drug brands. The more they know about an individual doctor's actual prescribing behavior, how it is influenced by a specified marketing approach, and how many times the doctor prescribes each product in a drug class week by week, the more prescriptions they can get and the more sales revenue they will generate. Over the past decade, drug companies have come to rely on these reports simply because they work.

Now, I said at the beginning that HB 1346 will save money for the state, consumers and businesses and another speaker, Representative Price, is going to speak more about this. But, I want to make it clear to you that high prescription drug utilization in New Hampshire leads to a significant burden on our health care system. You are going to hear opposition to this from the pharmaceutical industry and those companies, but I want to reassure you that the drug companies will still be able to purchase aggregated data by zip code and/or by medical specialty that will enable them to know how their brand and their sales forces are performing.

IMS, who is also here today, the world's largest health care data mining company, has also objected to this legislation. They have said that its unintended consequences will undermine law enforcement and fraud investigation and health care research. According to IMS, this work is funded by the profits generated by selling information to the pharmaceutical industry, but that they will stop collecting physicians' names if they can't make a profit selling this data to the drug companies. Please understand that the prescriber identity information is already included in the data when it is sold by the pharmacies to IMS. It would be work to take the names out. In addition, they will generate profits by selling aggregated reports to the

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drug companies. Further, on the subject of fraud and law enforcement investigation, data from this company is not actually necessary to investigate either medicaid fraud, drug diversion or any kind of drug abuse. Health care researchers generally have grant money to obtain their data. And, importantly, Dartmouth Medical School has expressed no opposition to this legislation.

I have an amendment with me today that clarifies in more detail what can and cannot be done with patient and prescriber identity and reinforces that law enforcement, research, and care management functions are all protected. The amendment also addresses issues raised by the pharmacies. It makes it clear that identity data included in electronic prescribing, parents picking up medications for their children or for anybody else, patients transferring prescriptions between pharmacies, and records transferred when a pharmacy is sold, are all acceptable uses.

We were also asked by companies that produce patient compliance educational materials to protect this kind of communication. Since these materials do not try to influence what drug is prescribed, we agreed to not prohibit these uses.

Members of the Committee, I understand that there is often reluctance to regulate business. But, we must also consider the public policy goals of protecting privacy and saving money on prescription drugs here in New Hampshire because really, when you consider it, the effect of selling somewhat fewer marketing reports on individual prescribers in a small state like New Hampshire would have a very limited impact on large multi-national corporations with revenues in the billions. Yet, for our small state, the positive financial impact on our consumers, businesses, and our state budget would be significant. I urge you to support this bill.

I thank you for your consideration and I would be happy to answer questions.

**Please see Representative Rosenwald's prepared testimony, together with attachments, attached hereto and referred to collectively as Attachment #1.**

**Please see also Amendment to HB 1346 #2006-1887s, attached hereto and referred to as Attachment #2.**

Senator Joseph D. Kenney, D. 3: Are there any questions from the Committee? Senator Fuller Clark?

Senator Martha Fuller Clark, D. 24: Yes. I am looking at a letter that I received today from Biotechnology and, in this letter, they talk about that without patient population and usage data, biotechnology companies would have a very difficult time raising venture capital. Could you talk to...? My understanding is that there is an amendment that will be able to get patient population and usage data, they just won't be able to get specific physicians' names and addresses. Is that correct?

**Please see letter from Biotechnology, attached hereto and referred to as Attachment #3.**

Representative Rosenwald: Actually, they could get specific physician names, too, if it is for research purposes. That is protected. What can be sold for marketing is the identity data on both patient and prescriber. But, health care research is protected on both the patient side and the prescriber side.

Senator Martha Fuller Clark, D. 24: Thank you.

Senator Joseph D. Kenney, D. 3: Any other questions? If not, thank you for your testimony, Representative.

Representative Rosenwald: Thank you.

Senator Joseph D. Kenney, D. 3: Our next speaker will be Representative MacKay. Good afternoon. We usually see you in the Health and Human Services Committee.

Representative MacKay: Thank you, Mr. Chair. For the record, my name is Jim MacKay and I represent Merrimack 11, which is the city of Concord. I'm here primarily as vice chairman of the Health Committee of the House to say that we unanimously supported this legislation. When we took it to the floor, it was unanimously supported, I believe, in the House. We felt very strongly about the need for the protections that this bill, the details that you just heard. I had read the level of detail, so I don't feel that I want to ... (inaudible)... That's a lot more detail than I want to speak to. So, that's essentially what I wanted to say.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. If there are no questions, Representative Price.

Representative Price: Thank you, Mr. Chairman, members of the Committee. For the record, my name is Pamela Price, Representative from Hillsborough District 26, proudly here today as a co-sponsor of this legislation.

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I believe that it is important to balance the privacy of the individual patient and the prescribing physician with the ability of the drug companies to still market their products.

I'm here today to speak very briefly to the potential financial impact upon the state. I have distributed to you for your review a list of three sample drugs which are on the formulary medicaid preferred drug list and looking at some of the various products. These are listed by category and they are acceptable within their range based upon the prescribing physician's interest or, I shouldn't say interest; perhaps I should say their belief that one product better suits the needs for an individual patient than another. You will see on the top list the calcium channel blockers, thirty day medicaid costs. It is \$13.50 for the first drug and I'm not going to pronounce it because I wouldn't have a clue how to pronounce these names. And, you go to the most expensive drug within that same category - \$87.30. Over to the right what we have done is annualized the cost of each medication and, within that category that I'm speaking about, the first drug has an annual cost of \$162. The drug at the top of the list \$1,047, an \$880 difference on the product. With a hundred thousand medicaid patients, this has a potential to have a huge financial impact upon the state and I believe that that is a significant issue. I believe also that, as we all know and I won't belabor the point, health insurance is becoming more and more unaffordable for everyone and I think that these drug costs are becoming an increasing percentage of the overall cost of health care.

So, I'm here today to speak in support. I think that it is important that we balance privacy and we need to insure that the prescription authority and direction is kept where it belongs and that is with the prescribing physician.

Thank you very much, Mr. Chairman.

**Please see Representative Price's document, attached hereto and referred to as Attachment #4.**

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Are there any questions? If not, thank you.

Representative Price: Thank you.

Senator Joseph D. Kenney, D. 3: Is there any other House members that wish to speak on this that I am missing? Representative Pilliod, would you like to speak?

Representative Pilliod: Thank you. Actually my main reason for speaking is to correct the indication on the sheet there that I am for or against. I think it probably says against and what I was really against... I am Jim Pilliod, by the way, representing Belknap County District 5 and I am speaking for the bill as amended.

I really feel that the amendment should be incorporated into the discussion and I will only say that in fact what it does is to make sure that what is transmitted is de-identified because that is the key. Although it says it in other ways in the bill itself, this makes it very sure what we're talking about. When I attended, our co-chair, Representative Kurk, Doug Hall was incensed because we were denying him the data needed to make studies. This does not. In fact, research is allowed and should be done. What we did agree to at that time was that the aggregate figure could be transmitted and that is fine and that is the way it works.

So, I will get out of your way. There is more detail here by virtue of saying that I am for the bill as amended and, even without the amendment would be good, but not as good as the amended version to protect the patients from the commercial interests which are for designing ways of marketing and not research.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Are there any questions from the Committee? Is Commissioner Stephen here?

Representative Pilliod: Thank you, Mr. Chairman.

Senator Joseph D. Kenney, D. 3: Thank you, Representative.

Gregory Moore: I apologize. Obviously, I am not Commissioner Stephen. I have more hair. He is unfortunately over in the hot seat in Senate Finance Committee, so I will speak on his behalf.

The Department believes this is an important bill to protect the privacy of the doctors and other prescribers in the state of New Hampshire. We take for granted that our patient information will be kept private and there are federal laws and state laws in place such as HIPAA designed to protect that privacy. Yet, doctors across New Hampshire and other providers are not afforded the same privacy for the prescriptions they write.

This information is sold, traded within the drug industry for the purposes of changing doctors prescribing medicine. How big is this practice? One division of one data mining company which collects in this state has revenues in excess of \$800 million a year. Why are drug companies so interested in this

information? One data mining company puts out a brochure spelled out clearly. If that company can get one doctor to change one prescription a month across the country, they can have doctors change one prescription a month, that results in \$15 million in new revenue to the drug company. So, the drug companies buy this data to build physician files so that they can target doctors and convince them to switch medications that they prescribe. This is not for clinical reasons; this is for marketing reasons.

HB 1346 simply says the companies cannot sell prescriber level information for the purposes of marketing. It does not prohibit the collection of this information for law enforcement, care management or research purposes. Why is this important? First of all, there is the matter of privacy. Doctors, and we have spoken to a number of them, feel that their prescribing habits are their trade secrets that are being given out without their permission. Could you imagine if every chef had their recipes available without their permission, or perhaps the military had troop level information being given out and it was available for anyone who wished to purchase it?

Interestingly, this is data buying companies who oppose this bill understand the importance of trade secrets. When asked to whom they sell their data and how much they get for this information, they are quick to point out that this information is proprietary and should remain confidential. Yet, they don't feel that way when it comes to doctors' prescribing patterns and they feel that that should be treated differently.

The Department also believes that these activities ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug companies are sending details into doctors' offices for the purpose of selling doctors cheaper medication. In fact, I'm confident that, if you're a doctor, that one of the best ways to get a detailer into your office would be if you switched to prescribing a generic drug over a brand drug.

For these reasons, we would ask the Committee to support HB 1346 and I would be happy to answer any questions.

Senator Joseph D. Kenney, D. 3: Any questions from the Committee? If not, thank you. Send my regards to the Commissioner. Next speaker would be Senator Flanders.

Senator Robert B. Flanders, D. 7: Thank you, Mr. Chairman, members of the Committee. My name is Bob Flanders. I represent Senate District 7.

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This is a very difficult bill. I have read it, I don't know how many times and had a lot of calls and a lot of e-mails. I'm sorry that it came so late in the session that we didn't have more time to look at it. Obviously, there was not much support for the original bill as we see with the people signed up and my e-mail.

I am proposing an amendment for you to consider. There's going to be people testifying behind me that will give you the details of this amendment. I am asking you to look at this and see if this does help solve some of the differences that we have behind us. I would like to offer an amendment this afternoon to HB 1346 that will protect patient confidentiality as well as addressing many of the concerns that have been expressed to me by constituents, industry representatives and Senate colleagues.

With respect to patient privacy, I want to be very clear. This amendment will not weaken or compromise those very real issues for all of our constituents. This amendment clearly limits the use of any patient information to those users identified under the HIPAA Act. In addition, this amendment is explicit that prescription information can be used for activities that would improve patient care, activities such as medical or biotech research, public health initiatives, and care management.

Some have expressed their desire for the state to be better able to monitor the impact on patient assistance programs that are offered by pharmaceutical manufacturers and this amendment includes provisions to achieve that goal as well.

The amendment achieves much without creating unintended consequences that would arise under the bill as originally proposed. I understand another amendment has been proposed that seeks to address these unintended consequences as well. The problem is very difficult, if not impossible, to predict every problem that HB 1346 might cause. I ask you to consider this amendment so that we can present to the Senate the best possible bill that we can from the difficult start that we had.

Thank you very much.

**Please see Senator Flanders' prepared testimony, attached hereto and referred to as Attachment #5.**

**Please see Senator Flanders' proposed amendment to HB 1346, attached hereto and referred to as Attachment #6.**

Senator Joseph D. Kenney, D. 3: Thank you, Senator Flanders. Are there any questions from the Committee? Thank you. Richard Head from the Department of Justice. Good afternoon.

Attorney Richard Head: Good afternoon. Thank you, Mr. Chairman. Thank you, members of the Committee. My name is Richard Head and I am Bureau Chief of the Consumer Protection and Anti-Trust Bureau.

I don't intend to repeat the testimony you heard from Health and Human Services, and I would simply concur with that. I agree with the suggestions on the amendments that the provision regarding law enforcement, care management and research. I think those amendments are well intended and make sense in light of the scope of this bill. But, I am here to testify in support of the bill, specifically with regard to the patient confidentiality provision and the protection of patient confidentiality.

With that, I will be happy to answer any questions.

Senator Joseph D. Kenney, D. 3: Are there any questions? Thank you for your testimony.

Attorney Head: Thank you, Mr. Chairman.

Senator Joseph D. Kenney, D. 3: Do I have another sign up sheet?

Rachel Durazzani: Yes, but no speakers.

Senator Joseph D. Kenney, D. 3: Could I have the sheet, if possible? Great. I just want to make sure. Okay. What I am going to do now is proceed chronologically as to how you signed up. So, the next speaker is Stuart Trachy, New Hampshire Association of Chain Drug Stores, to speak in opposition.

Stuart Trachy: Good afternoon, Mr. Chairman, members of the Committee. My name is Stuart Trachy and I'm here representing the New Hampshire Association of Chain Drug Stores. We are opposed to HB 1346 as it came across from the House.

The issue of confidentiality of medical information is often portrayed in very simple terms and sometimes is addressed by trying to limit the flow of information in one way or another. We know, however, it is really not that simple, as the recent HIPAA legislative and regulatory experience has shown us. We believe this proposal directed at prescription records is too broad and

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causes many problems as a result of the unintended consequences due to the unique nature of the pharmacy practice.

Representative Rosenwald and Senator Flanders presented amendments which, I think perhaps address some of the concerns that we had and some of the concerns that we brought forward to the House. My testimony is going to be limited to the bill as it was presented at the House and as it came over from the House. We are concerned about the legislation preventing the common and necessary occurrence of prescriptions being transferred from one pharmacy to another. Sometimes people will call up a pharmacist and say, "Could you please move my prescription from your CVS over to Brooks?" It could be a convenience, perhaps their spouse gets their prescriptions at the other pharmacy and they think that would be in jeopardy.

Electronic prescriptions and prescribing we believe would be in jeopardy. This would put a stop to the beneficial practice at the very time that this is being promoted by the federal Medicare Modernization Act.

The sale of a business was also addressed this afternoon, but we are very concerned that, in the bill as it is coming over, it does not address when a pharmacy is sold and the facts that were not addressed in an amendment. Theoretically, each patient would have to sign off before those records could be transferred from one pharmacy to another.

Also discussed this afternoon was the issue of minors having their prescriptions picked up either a parent or whatever and there is also the issue of people picking up prescriptions for friends. That is not introduced here. Fully 25% of all prescription drugs in the country that are picked up at a community pharmacy are picked up by somebody else other than the patient. So, if your neighbor is known to your pharmacist and they go and pick up your prescription, perhaps the issue of the fact that you don't have a written authorized form that states that Mary Jo, your neighbor, can pick up your prescriptions, even though your pharmacist knows you. We are concerned that that might also be in jeopardy.

The law enforcement issues we feel should also be addressed, but I think the bottom line is we continue to believe this legislation is not necessary. This bill goes beyond where forty-nine other states have ever gone. This is the most restrictive legislation that would be on the books if in fact it passed. The American Medical Association has addressed this and they have put out some guidelines, best practice guidelines, for how the people who use this data and this technology, how they would act under the transfer of this information. So, I would like to submit to the Committee those best practice guidelines for your consideration. Please see "AMA Best Practice

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**Guidelines For Use of Prescribing Data by Industry”, attached hereto and referred to as Attachment #7.**

Also, I have copies of my testimony which I will leave with you which expands upon the points that I brought up in terms of the unintended consequences. **Please see Stuart Trachy’s prepared testimony, attached hereto and referred to as Attachment #8.**

I also want to leave with you the latest position paper from the AMA regarding state proposals that attempt to restrict the disclosure of prescribing data. **Please see “AMA’s Position Regarding State Proposals to Restrict Disclosure of Physician Prescribing Data”, attached hereto and referred to as Attachment #9.**

I think that the opt out program that the AMA is going to be instituting should take care of the concerns that we have heard in terms of specific doctors being concerned that their prescribing data is out there. I think that, if they would subscribe to the program that is going to be administered through the AMA, then their concerns should be taken care of.

So, at this juncture, we would feel that this bill should be found inexpedient to legislate for the reasons we outlined and perhaps with working with some of the sponsors of the amendments, we might be able to craft something. But, at this point, I am not prepared to specifically address what is in the amendments that were presented this afternoon. I will answer any questions.

Senator Joseph D. Kenney, D. 3: I’m not sure who was up first, but I will call on Senator Fuller Clark.

Senator Martha Fuller Clark, D. 24: Thank you, Mr. Chair. Would you be willing to look at the amendments and in addition to sitting down, to support the amendments after you have had time to evaluate them perhaps with some written comments as to your position on those amendments?

Mr. Trachy: Certainly. I have looked at them. I have forwarded them to our client and I just have not heard back from them today. So, I don’t think that should be a definitive read on the amendments. I think one is much better than the other.

Senator Martha Fuller Clark, D. 24: We’ll look forward to hearing from you.

Mr. Trachy: I will be glad to do that. Thank you.

Senator Joseph D. Kenney, D. 3: Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Thank you, Mr. Chairman. A question for you first. Don't we have to have our pieces of legislation out by next week?

Senator Joseph D. Kenney, D. 3: That's correct.

Senator John S. Barnes, Jr., D. 17: So, what I'm relaying is that you have a week to bring something back to the Committee, I guess. Is that what I'm saying, Mr. Chairman.

Mr. Trachy: We will get that to you.

Senator John S. Barnes, Jr., D. 17: Second point. I listened to you very carefully to your eloquent as always, testimony, but I have never had a problem transferring my drugs or a prescription to another drug store. All I do is call my doctor and my doctor has always been able to do that for me in all the years that I have done that. I do shop around for a better price and some chain drug stores are higher than others. So, when I find a better deal, I call my doctor and he transfers it. So, that doesn't affect my doctor being able to do it.

Mr. Trachy: Well, currently, that is not a problem. What we're saying is that if you have on record a prescription at the local CVS and you want to take that prescription, which could be subject to renewal and transfer it to another one, there would be a concern that one pharmacy relating that to another without you signing authorizations. It is done routinely at this point.

Senator John S. Barnes, Jr., D. 17: Follow up?

Senator Joseph D. Kenney, D. 3: Follow up question.

Senator John S. Barnes, Jr., D. 17: My doctor can do it.

Mr. Trachy: Yes.

Senator John S. Barnes, Jr., D. 17: So, it is not really a concern for me because I'm not going to have to worry. I just go to my pharmacist and ask him to transfer it; I just call my doctor and say, "Doctor, I want to go to Hannaford's Pharmacy now".

Mr. Trachy: You can do that now.

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Senator John S. Barnes, Jr., D. 17: Yes. This bill isn't going to affect my ability to be able to do that?

Mr. Trachy: Correct.

Senator John S. Barnes, Jr., D. 17: Thank you very much.

Senator Joseph D. Kenney, D. 3: Seeing no other questions, thank you for your testimony.

Mr. Trachy: Thank you.

Senator Joseph D. Kenney, D. 3: The next speaker will be Scot Ganow. Is that correct?

Scot Ganow: Yes. Thank you. I will give you my statement. Good morning. I have prepared a statement that is drafted for the bill as it did come over from the House. However, my company, Verispan, would be in support of the amendment proposed by Senator Flanders.

**Transcriber's note: Scot Ganow read his testimony verbatim. It is, therefore, not transcribed, but is attached hereto and referred as Attachment #10.**

Senator Joseph D. Kenney, D. 3: Just so I can clear it. This is wonderful written testimony, but from the Committee's standpoint, could you just highlight so we can read this testimony later, just so that we can get through this. Okay? Question Senator Barnes?

Senator John S. Barnes, Jr., D. 17: Thank you, Mr. Chairman. Thank you, Scot, for being here to testify. I appreciate it. I heard you start off your testimony saying that you're in favor of Senator Flanders' amendment.

Mr. Ganow: That is correct.

Senator John S. Barnes, Jr., D. 17: I didn't hear you mention Senator Kenney, Senator Larsen, or Representative Rosenwald's amendment. Does that mean you're not in favor of that?

Mr. Ganow: That is correct, primarily because of the prescribing information I discussed.

Senator John S. Barnes, Jr., D. 17: Thank you very much.

Mr. Ganow: Thank you.

Senator Joseph D. Kenney, D. 3: Any other questions? If not, thank you for coming this morning. Our next speaker will be Marc Sadowsky from the New Hampshire Medical Society.

Dr. Seddon Savage: If I may speak before Dr. Sadowsky?

Senator Joseph D. Kenney, D. 3: Sure. Absolutely. Good afternoon.

Dr. Savage: Good afternoon and thank you for the opportunity to speak with you. My name is Seddon Savage. I am President elect of the New Hampshire Medical Society and we are speaking in support of this bill. Dr. Sadowsky will follow me with some comments.

As we all are aware, we live in a society where information is very, very powerful and, as such, it is also very valuable. We also live in a time when the privacy of our personal information is under constant assault. Data mining is very large business. I had hoped that perhaps our citizens from IMS might go before us and let you know a bit about their company. But, make no mistake, for all the companies involved, this is large business.

IMS identifies itself as the world's leading provider of market intelligence in the pharmaceutical and health care industry. It operates in over a hundred countries in the world and had revenues of \$1.8 billion in 2005. So, as such a large and powerful and valuable entity, these corporations really have the power to do tremendous good. They have the power to affect enormous change in the health care industry and we have heard some of those to directly affect how we spend or just direct our public health care dollars to areas of need, to help shape medication development and technology development, to stimulate public health research resulting in innovations that save lives and reduce morbidity. In fact, IMS and other data mining companies are active in this.

I have, as a physician interested in prescription drug misuse, have participated in projects where this type of data was very helpful through IMS. But, these corporations also have the power to undermine doctors' prescribing patterns in a way that serves the interests of the particular companies that they are making data available to, but does not necessarily serve the clinical needs of our patients. Often this is at the expense of equally effective and less costly alternatives. So health care prices or health care costs will go up. Now, virtually all of us who work in health care today, whether physicians or other health care providers, have interactions with

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pharmaceutical representatives on a regular basis, and it is quite unavoidable and it is often very helpful. They will visit our offices in order to provide information, prescribing materials and samples. They fund continuing medical education events. They host exhibits at conferences which often can be educational. They fund important health care research and they participate in legislative processes such as this, often providing a certain balance to the proceeding.

But, the medical community is continually working to find a healthy balance in our relationship with the pharmaceutical industry. We're very appreciative of their products, their innovation, the educational opportunities they afford us. We are always trying to sort out the truth, the science, the clinical realities from the influence in the marketing and their need to increase their market share. We are aware that marketing can influence our decision making.

Now, most health care providers are highly educated people. We like to think that we are thoughtful people and reflective, but we are not immune to skilled marketing influences. So, we like to think we're objective and we always base our decision making on science and on clinical considerations. Numerous studies have shown that in fact our decision making can be and sometimes is shaped by marketing efforts, skilled marketing efforts. Because of this, in most settings where there is a risk of influence, we have developed systems that will maintain the balance.

For example, the ACCME, the Accreditation Council on Continuing Medical Education has increasingly stringent requirements regarding our medical education programs that are funded by industry. We have to disclose our relationships between speakers and funders, resolve conflicts of interest where possible, disclose in advance our mention of products that we might have an interest in, and many, many other controls on this type of input. Most hospitals, most clinics, and many individual providers also have their own policies in place to limit the influence. We have no control at this point on the information that is being bought and sold that is intended to be used to influence our prescribing and we believe that bill 1346 begins to create the same type of accountability with respect to industry marketing that is directed at the shaping of our decision making.

It deters the sale of physician specific prescribing information and I am addressing here primarily this part of it rather than patient confidentiality which others have addressed and which is well covered by HIPAA. But, it will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision making for the

patients. You should know this doesn't interfere with patient and prescribable identifiable data for insurance reimbursement, dispensing of medications, utilization review, public health research, or law enforcement. And, if there is interest in law enforcement, I would be happy to talk more about that, but I don't want to take your time now. But, that is an area of interest with respect to another bill.

We always have the reality that our personal information is widely available as information technology has increased. In a way, we are kind of scrambling to put the horse back in the barn and develop guidelines and rules for the dissemination. I think most would agree that preserved individual dignity and privacy and agree that this information should be used in a way that, at the very least, doesn't undermine a common good; at the best, even serves the common good, and that such information exchange be continuously monitored to assure these souls are preserved.

I don't believe that the current buying and selling of physician prescribing information honors these principles. I think that this bill is a very small step towards preserving and serving those principles.

Thank you.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony.

Dr. Savage: You're welcome.

Senator Joseph D. Kenney, D. 3: Senator Larsen for a question.

Senator Sylvia B. Larsen, D. 15: The last speaker representing Verispan indicated that the physician opt out program that is part of the AMA proposal, I don't even think it is in effect yet. But, they implied that that was enough, having an opt out program would be enough to protect what you're advocating, which is preserving dignity and privacy of, not only the patient, but the physician and their prescribing practices.

Dr. Savage: Right. I think it depends on the details of that program. We haven't been able, as I understand at the Medical Society, to get the details of the program from the AMA. We have to take a look at that in order to see if it meets the situation.

Senator Sylvia B. Larsen, D. 15: Would it not require with an opt out to perhaps... I know when you want to opt out of credit card information being sold to other vendors that you have to actually get an envelope out and address it to the Consumer Society of America and write it, put a stamp on it.

So, the opt out requires extra effort by the busy physician. Do you think that will work?

Dr. Savage: I think that is a good point. I think it is generally better to start from the position of more restrictive access to information and to really specify what can be released rather than to work backwards as we are doing now. So, I think that would be problematic. I think informing all doctors that this is going on. Many of us were really surprised to hear about it. We didn't know this information was being given out.

Senator Joseph D. Kenney, D. 3: Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Thank you, Mr. Chairman. I would like to ask you the same question I asked the last folks. Which one of these amendments, Senator Kenney's, Senator Larsen's, Representative Rosenwald's, or Senator Flanders' amendment, which one appeals to you to be the better one?

Dr. Marc Sadowsky: Representative Rosenwald's.

Senator John S. Barnes, Jr., D. 17: Thank you very much.

Dr. Sadowsky: I would just like to add a couple of things. I am Marc Sadowsky and I am the President of the New Hampshire Medical Society. I am a psychiatrist who practices in Nashua and Salem. I want to make a couple of comments.

One is that we have broken with the AMA on this. That is, the New Hampshire Medical Society supports this bill while the AMA opposes it.

And, getting back to your point about the opt in and the opt out, I think, as Dr. Savage said, many of my colleagues don't even know that this exists. Most of us are inundated by mail from managed care companies, drug companies, and it would be interesting to know why we don't have an opt in option rather than opt out option.

So, third is I think there has been some concern about why don't we just not see the drug reps when they come in. That way, they wouldn't be able to market directly to us.

Now, as you may know, particularly in New Hampshire, much of the medicaid budget is devoted to psychotropic medications. Some of the medicines I prescribe are \$8 a pill, \$8-10 a pill. I have patients who are stable on these medicines and then they lose their job, don't qualify for any

insurance and I am carrying them to keep them stable. That is, I'm giving them samples. I have to sign for the samples every time I get them. So, when the drug reps come in, I have to talk to them. I can't just have my secretary sign for them. So, I think it is kind of an important thing because these medicines can cost people thousands of dollars a year and I have a good number of citizens of New Hampshire that I am giving free samples to and I know this is due to the largess for the drug companies, but it is through the instrument of me who is doing it.

So, I wanted to make those points.

Senator Joseph D. Kenney, D. 3: Any questions for the doctor? Senator Larsen?

Senator Sylvia B. Larsen, D. 15: You are handing out those... There is some benefit from the pharmaceutical industry for you to be handing out the samples because it gives you an opportunity to see that that drug will work with certain personalities.

Dr. Sadowsky: Exactly.

Senator Sylvia B. Larsen, D. 15: So, you might prescribe it to the people who buy it as well as the samples?

Dr. Sadowsky: Right. Well, sure. I guess that gets into a whole other issue that I think Representative Rosenwald alluded to, that getting people onto medicines that are proprietary medicines, which are much more expensive than some of the equivalent generic medicines. I think that, as physicians, we're going to have to do a better job of being aware of that.

I have had other doctors switch people from a generic medicine to a trade name medicine for no apparent reason except presumably that they have been marketed to effectively. I had this happen last week. A patient called me and said her primary care physician said that a trade name medicine might be better for her than a generic medicine. I said, "Well, you're doing fine on the generic and your co-pay is going to go up \$40 a month, \$500 a year. So, it is not entirely clear to me why we're doing this." I'm not averse to... I think that that was an example of the primary care physician having been marketed to directly and didn't really have a clinical reason for doing it except that that was the last drug rep who came to see him and said this is a better medicine for anxiety, even though the person was asymptomatic at the time. The literature doesn't support.

Senator Joseph D. Kenney, D. 3: Are there any other questions? If not, thank you for your testimony.

Dr. Sadowsky: Thank you very much.

Senator Joseph D. Kenney, D. 3: The next speaker will be Bill Hamilton, AARP New Hampshire.

Bill Hamilton: Thank you. I have written testimony and I won't take long at all. I guess what I would just like to say is that AARP. I am advocacy director for AARP New Hampshire. AARP is committed to reducing the price of prescription drugs. Senator (sic) Rosenwald's legislation, with the amendment, has been taken by AARP as model legislation and been sent to my counterparts in all the other states encouraging them to pass this legislation in those states. So, while we may be the first, it will be appearing in other states. I just think it would be great if Representative Rosenwald's bill could be passed first in New Hampshire before it is passed in another state.

**Please see AARP New Hampshire Testimony on HB 1346, attached hereto and referred to as Attachment #11.**

Senator Joseph D. Kenney, D. 3: Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Same question. What about Senator Kenney's amendment; what about Senator Flanders' amendment?

Mr. Hamilton: The model legislation we're using incorporates Senator (sic) Rosenwald's bill with Senator Kenney's amendment and which Senator Larsen and Senator (sic) Rosenwald were on that. So, those two together are what we're considering model legislation. It addresses, especially a lot of the drug stores are addressed in Senator Kenney's amendment.

Senator John S. Barnes, Jr., D. 17: So, Senator Flanders' you're not in favor of?

Mr. Hamilton: No, sir.

Senator John S. Barnes, Jr., D. 17: One further.

Senator Joseph D. Kenney, D. 3: Follow up.

Senator John S. Barnes, Jr., D. 17: I think you folks did a great job. I received more phone calls from people last night that received a card from

your organization asking them to call me and it was successful because I got about twenty calls.

Mr. Hamilton: Thank you very much, Senator.

Senator Joseph D. Kenney, D. 3: Could I ask a question? I think one of the companies here suggested that the cost of the pharmaceutical products could actually go up if this legislation were to pass. I'm just wondering what your thoughts are on that.

Mr. Hamilton: No. We don't see that. We see that the benefit is going to be... especially, I think, the confidentiality is good. But, this issue if you are a pharmaceutical salesman, you're going to have the ability to know that this doctor is writing my competitor's product and if I can incent him in some way to switch over, I'm going to make a lot of money and I'm going to be successful. So, you can really hard hit that guy and this is where people, physicians have testified before me, said if you're allowing these factors to come into play here as to what they prescribe to you beyond what would be an objective decision by having other information available. But, no, we do not see that it is going to increase the cost.

Senator Joseph D. Kenney, D. 3: Thank you. Senator Fuller Clark for a question.

Senator Martha Fuller Clark, D. 24: Could you comment then on the issue that by not being able to target the marketing initiatives to specific physicians that it will actually cost the drug companies more to do their marketing because they won't be able to be selective? They will have to spread their marketing efforts over a larger field of physicians and that would be more costly.

Mr. Hamilton: You know, not being in the business and understanding that, I couldn't guess at an answer, Senator, and I would rather not guess if I don't know the answer directly.

Senator Martha Fuller Clark, D. 24: Sure.

Mr. Hamilton: But, I do say that we did an analysis and we don't feel it necessarily will increase the cost of drugs.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Our next speaker will be Robert Hunkler. Good afternoon.

Robert Hunkler: Good afternoon. Mr. Chairman, Committee members. I am Robert Hunkler, Director of Professional Relations at IMS Health, speaking against HB 1346 in its original version.

We at IMS are in favor of Senator Flanders' amendment to the bill because it bolsters the protections that patients would have in confidentiality without carving out a specific privacy right to be enjoyed by doctors in their professional endeavors.

I would like to point out four particular problems that we see with 1346. First, we think that the bill will not fulfill its intended purpose. The restriction or removal of subscriber identified information from prescription information will not remove costs from the health care system. In fact, the opposite is likely to be true. As Senator Fuller Clark just pointed out, without the ability to target marketing appeals, pharmaceutical manufacturers will, in all likelihood continue to send sales reps to all doctors without the ability to more specifically hone in on the right people with the right message. It will likely incur more costs to the system. It won't alter the behavior of the pharmaceutical reps. They will continue to make calls on docs, but if the bill passes, their efforts will be guided either by bad information or no information at all.

Secondly, the enactment of the bill will result in a significant number of unintended consequences...

Tape change.

We anticipate that the flow of an important source of information that is used, not only in pharmaceutical marketing, but also in public health monitoring, outcomes and research studies, pharmacal economic analysis, bio-terrorism surveillance, medicaid part D uptake studies, and physician feed back reporting. That information will dry up and go away.

Third, the legislation is not a reasonable way to level the informational playing field. We have heard from some doctors, the drugs companies know more about my prescribing behavior than I know myself. We are working with several physician organizations to address this perceived imbalance and we think that a preferable solution is to provide this information to doctors, to health researchers and others instead of turning out the light and taking it away from everyone.

At IMS, the creation and dissemination of useful information throughout the health care community is a long standing goal. The AMA and other physician groups elsewhere in the country, we're highlighting information

products and services for doctors. We offer a unique view. We can show doctors what happens to the prescription after it leaves their hands. Doctors know what they wrote. We can show them what was actually filled. By doing that, we can track ratios of patient non-compliance, payer effects, generic utilization rates and we can illustrate peer based benchmarks than just a few applications. In short, our information can help doctors better understand the marketplace and view their own practices from a different and formative perspective.

Additionally, this information can be used to illustrate trends at state and local levels, as is noted in some of the handouts that we have just passed out. I have provided some charts that highlight some New Hampshire observations that you might find interesting. Also, we have just handed out some letters from healthcare professionals at places such as the Mayo Clinic, St. Jude's Children's Research Hospital, Harvard, MIT who use our information in their studies and in conjunction with us. They are concerned about this information going away completely if 1346 is passed.

Fourth, legislating this matter is unnecessary, or at least premature, in our opinion. As has been noted briefly before, the American Medical Association is working with health care information companies and the pharmaceutical manufacturers to launch a program that allows doctors to opt out of having their prescribing information go directly into the hands of the pharmaceutical sales reps. That program's start date in July 1. We're dedicating a significant amount of resources to insuring that this program is effective. We think it should be given a fair opportunity to succeed or fail on its own merits before legislative remedies are sought.

So, in summary, given the likelihood of unintended consequences, unintended negative consequences, the effective flow of information for business and public good applications and the fact that a lot of people are spending significant resources to devise a non-legislative alternative such as the AMA opt out, I would urge you to accept Senator Flanders' amended version of 1346.

Questions?

**Please see documents submitted by Mr. Hunkler, attached hereto and referred to collectively as Attachment #12.**

Senator Joseph D. Kenney, D. 3: Senator Fuller Clark?

Senator Martha Fuller Clark, D. 24: Could you tell me why you're proposing opt out rather than opt in?

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Mr. Hunkler: Expense would be one. Stability of our statistical sample is certainly one of the considerations. If we don't know exactly who has opted in and how representative that is to the universe of physicians within a particular geography, we don't know whether we have a representative sample or not. It could be terribly skewed and we would never know the difference. So, having the ability to choose the sample makes all the difference in the world. With the AMA opt out program, we would still have the ability to collect information and provide it in aggregate for studies such as the pharmacal economic study, the public health application.

Senator Martha Fuller Clark, D. 24: Thank you.

Senator Joseph D. Kenney, D. 3: Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Thank you very much, Mr. Chairman. You were here, I believe, when Commissioner Stephen had his testimony.

Mr. Hunkler: No, sir.

Senator John S. Barnes, Jr., D. 17: You weren't here when Commissioner Stephen spoke? The Commissioner of Health and Human Services.

Mr. Hunkler: The gentleman who sat in for him, yes.

Senator John S. Barnes, Jr., D. 17: His testimony.

Mr. Hunkler: Yes.

Senator John S. Barnes, Jr., D. 17: You were here. What did you think of that testimony?

Mr. Hunkler: I tend to think that, I tend to take the opposite view of much of what he has to say.

Senator Joseph D. Kenney, D. 3: Follow up question.

Senator John S. Barnes, Jr., D. 17: Have you or your representatives had time to sit down with the Commissioner and go over this with him?

Mr. Hunkler: We have tried numerous times, sir.

Senator John S. Barnes, Jr., D. 17: And, you haven't been able to make it or he hasn't been able to make it?

Mr. Hunkler: He hasn't been able. We have been rebuffed at every turn.

Senator John S. Barnes, Jr., D. 17: You have been rebuffed? Okay.

Mr. Hunkler: We have offered information. We have offered to meet.

Senator Joseph D. Kenney, D. 3: Follow up question.

Senator John S. Barnes, Jr., D. 17: Third and final. WERE you and your folks able to help Senator Flanders puts his amendment together? Were you part of that? Did you give him input to help him along with that?

Mr. Hunkler: Some input. Yes, sir.

Senator John S. Barnes, Jr., D. 17: You did. Thank you very much. Thank you, Mr. Chairman.

Senator Joseph D. Kenney, D. 3: Just a quick question. St. Jude's. Did you say they provided testimony?

Mr. Hunkler: I'm sorry.

Senator Joseph D. Kenney, D. 3: Correspondence or testimony, St. Jude's Hospital?

Mr. Hunkler: Yes.

Senator Joseph D. Kenney, D. 3: I'm trying to find that.

Mr. Hunkler: A gentleman named James Hoffman.

Senator Joseph D. Kenney, D. 3: James Hoffman?

Mr. Hunkler: Yes.

Senator Joseph D. Kenney, D. 3: Senator Larsen for a question.

Senator Sylvia B. Larsen, D. 15: The letters that you have given us from physicians who received grants to do data analysis on drug prescribing, for example, Dr. Finkelstein of Harvard, indicates that he wants us to leave open the channels to collect and aggregate data on drug prescribing. But, are they using physicians or patient specific data to do their analysis?

Mr. Hunkler: On occasion. Generally, I think what Dr. Finkelstein has used has not been prescriber sensitive. That's a very important point. If we don't have financial incentives through our commercial application to collect information at the individual prescriber level, the aggregate simply won't exist. The aggregates that are used for dozens of other applications simply won't exist because we're the ones who create those data bases.

Senator Joseph D. Kenney, D. 3: Any other questions from the Committee? I don't think we have any Hoffman letters. Maybe we could get a copy of that. I would appreciate it.

Mr. Hunkler: Sure.

Senator Joseph D. Kenney, D. 3: Thank you. Our next speaker would be Janet Monahan from the New Hampshire Medical Society.

Janet Monahan: Thank you and good afternoon. For the record, Janet Monahan from the New Hampshire Medical Society. I wanted to just respond to a few questions and I have a couple of statements I would like to make. There have been some comments about the American Medical Association and I just wanted to read you a short couple of sentences from an article.

Companies such as IMS Health purchase computer records or tap directly into the pharmacy computer and extract information on the three billion prescriptions US pharmacies fill annually, according to industry specialists. They combine this information with biographies on nearly 850,000 physicians compiled by the American Medical Association, which earns \$30 million annually licensing detailed reports on physicians, including where they went to medical school, their fax machines numbers and their specialties.

All of the opposition here today and including the AMA have significant financial statements. I find it interesting though that I... Again, I can't get details from the AMA on this program. If a physician opts out from the list, are they opting out with IMS? Are they opting out with CVS or Walgreen's? That certainly isn't clear. These companies already have data on 850,000 physicians. If they can't get it from the AMA, they can purchase it from any state medical board and actually get more accurate data, more up to date than the AMA.

I have not seen the amendment from the other side, but that bill takes out the prescriber part that deals with patients. I still wonder from all that I've read and heard whether or not patients are involved in this more than we like to know. I have this from that same report.

Verispan, IMS, and other companies buy data, not just on individual doctors, but on individual patients and the medications they're taking. The executive from Dendrite, which is like a Walgreen's, says that patient data are crucial because they follow individual patients so drug companies can see whether doctors are merely placing new patients on a competitor's drug or whether they're actually switching existing patients off one drug and onto another. And, from the IMS annual report, it says right in here that they analyze the rate at which drugs move out of the pharmacy and into the hands of consumers and measure what is prescribed by physicians and what is actually dispensed at the pharmacy. How can they find that information if they are not also tracking patients? They can't just ... (inaudible)... prescriptions written.

In a report that was done by a consumer group in California in September '04. Because companies focus their promotions on their newest, most expensive medicines, virtually any time that a physician switches to a promoted drug, the price increases. Thus, whenever a physician oriented promotion is successful, consumers, insurers and government programs pay a higher price for their medications. A recent study in Pennsylvania found that 40% of patients in a state assistance program were given hypertension medicines different than those recommended by medical guidelines. If doctors had prescribed according to those guidelines, the state could have save \$11.6 million, or nearly 24% of the total money spent on hypertension medication.

The last thing I would like to read is how important this data is. This is from a January '06 *New York Times* article. A district manager for a pharmaceutical company sent an e-mail to the sales reps. "Our goal is fifty or more scripts per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs, and past preceptorships that you have provided or paid for and get the business!! You can do it!!"

This is all about money and we're here to say that physicians sort of own this information and we think that this bill is really a small step in protecting that. The amendment clarifies that this information can be used for research, for law enforcement. It is not stepping on anyone's toes. I encourage you to vote for the amendment.

**Please see documents provided by Janet Monahan, attached hereto and referred to collectively as Attachment #13.**

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Thank you, Mr. Chairman. I'm a little confused. Thank you for being here and giving your testimony. You mentioned you hadn't seen or hadn't been able to look at the amendment on the other side. Which amendment was on the other side?

Ms. Monahan: That was the Flanders amendment. It takes the prescriber out of the bill.

Senator John S. Barnes, Jr., D. 17: That's the one you were referring to?

Ms. Monahan: Yes. We are opposed to that.

Senator John S. Barnes, Jr., D. 17: This one, the Kenney, Larsen and Representative Rosenwald is the one that you're speaking in favor of?

Ms. Monahan: We are for that.

Senator John S. Barnes, Jr., D. 17: Thank you very much. I appreciate your clearing that up for me.

Ms. Monahan: I wanted to add another point that a previous speaker said this bill had little support in the House. It was unanimous out of committee and it went to the House on the consent calendar with absolutely no ... (inaudible)...

Senator Joseph D. Kenney, D. 3: Senator Larsen for a question.

Senator Sylvia B. Larsen, D. 15: You expressed concern and I noted that, too, that IMS, in saying that they have the ability to track patient non-compliance in not filling their prescriptions, that there has to be some patient identifier to be able to get to the ... (inaudible). They said they can track patient non-compliance for doctors as a service to the physician. But, to do that, I think I heard you say as well that you have, that IMS wants to know who the patients are.

Mr. Hunkler: May I answer that?

Senator Sylvia B. Larsen, D. 15: I'm sorry. I didn't get a chance. That's up to the Chairman. I didn't get a chance to ask IMS that question.

Senator Joseph D. Kenney, D. 3: Okay. Why don't we ask IMS right now just so we can get it out of the way?

Mr. Hunkler: The information that IMS gets on prescription information is patient de-identified. There is no way that we can re-identify who the individual is. In a sample of our information, we have an encrypted number so that we can track... An individual doctor writes a prescription for 12345. We can track 12345 over time. We have no way of knowing or any interest in knowing who that individual is, but we can ascertain resale rates, etc. for that individual.

Also, we have additional data base completely apart from our prescription information in which a panel of about 4,000 physicians keep essentially a diary for us and tell us what they prescribe and what the complaints are. Yet another stand alone data base, we have patient opt in data bases where patients freely give us information in exchange for getting medicines. So, it is not as simple as just one data base.

We are absolutely HIPAA compliant and everything that comes in, all of our prescription information is patient de-identified.

Senator Joseph D. Kenney, D. 3: Thank you. Is that a good answer? Or is it the answer?

Senator Sylvia B. Larsen, D. 15: I wonder if you would either share the *Boston Globe* article you're referencing.

Ms. Monahan: I gave them all to you.

Senator Sylvia B. Larsen, D. 15: Okay. Thank you.

Ms. Monahan: I did testify at the House hearing that some times they get patient information by mistake. So it does sometimes oget ut unfortunately.

Senator Joseph D. Kenney, D. 3: Senator Barnes for a question.

Senator John S. Barnes, Jr., D. 17: Thank you, Mr. Chairman. I just wanted to clarify something that wasn't clear. You read a letter over there talking about that doctors should be reminded of the lunches that they were provided and the deals. Where did that come from? Who sent that letter?

Ms. Monahan: Either the *New York Times* article or the *Boston Globe* that I just gave to you.

SUB

Senator John S. Barnes, Jr., D. 17: Who sent the letter?

Ms. Monahan: That was from a retail rep telling her people that are out in the field to go out and get more prescriptions.

Senator John S. Barnes, Jr., D. 17: Who does she work for?

Ms. Monahan: The company was Novo, N-o-v-o.

Senator John S. Barnes, Jr., D. 17: Novo. Thank you for clearing that up for me.

Senator Joseph D. Kenney, D. 3: Okay. I think we have answered all of our questions. Thank you for your testimony. Our next speaker that I have here is Marjorie Powell from PhRMA. Good afternoon.

Marjorie Powell: Good afternoon. Thank you, Mr. Chairman, members of the Committee. My name is Marjorie Powell and I represent the Pharmaceutical Research and Manufacturers of America, or PhRMA for short. You have a copy of my testimony.

I would like to make two points. The first one is in response to a question from Senator Fuller Clark. You had asked about the ... (inaudible) ... and whether the amendment offered by Senator Kennedy (sic), Senator Larsen and Representative Rosenwald was allowed for research. Representative Rosenwald said yes because there is an exemption for health care research. I would like to respectfully disagree with Representative Rosenwald's interpretation of the language. The language in the amendment and the language in the basic bill say that research intended to support marketing of a prescription drug would not be allowed from any information.

Well, in reality, every single study being conducted by any biotechnology or any pharmaceutical company is intended eventually to lead toward a marketed drug. That is the purpose of doing that research. Much of the research that goes on in medical schools, in academic medical centers, in research hospitals, is intended to improve health care by finding ways to make drugs and medical technology more useful to patients for specific conditions and to communicate the appropriate use of those medicines and those technologies, surgery techniques, whatever it might be to the health care providers who are doing that. As I read the amendment, it would prohibit much of that research because it is eventually intended to lead to marketing. I think that is an example of the unintended consequences and it is the reason that we support Senator Flanders' amendment because it

explicitly deals with improved care, improved patient care, improved programs to improve patient compliance, those sorts of things.

I would also like to address one thing that is not in our written testimony and that is another area where health care is moving. FDA, when it approves new medicines is, in some instances approving limited initial distribution of a medicine so that, if the medicine is given, they are occasionally now saying you can market this only to those health care specialists who deal explicitly with this disease, not to family practitioners. With this kind of legislation in New Hampshire, a pharmaceutical company would not be able to implement that kind of restricted marketing when a product initially comes on the market because they wouldn't be able to identify who the physicians were who were treating that particular class of patients. So, new drugs with restrictive marketing provisions from the FDA would not be available to patients or to health care providers within New Hampshire. There are a number of those kinds of consequences.

One of the things that pharmaceutical companies do when they learn of a serious problem with a marketed drug, for example, something that happened to the manufacturing where they have to do an immediate recall. They start with their wholesalers, they move to the pharmacies, but they very often go to the physicians who they know are prescribing that medication. That would eliminate the ability of pharmaceutical manufacturers to do that within New Hampshire. Their recall process would be delayed because they would have to go to multiple people to get to the physicians and eventually the patients.

There are a number of those kinds of unintended consequences that we think make both the original bill and the first amendment to the bill problematic. We think that, given that the AMA is moving toward a system where physicians can opt out and the kinds of protections that the federal legislation provides, we would support Senator Flanders' amendment.

I will stop there and address any questions.

**Please see Marjorie Powell's prepared testimony, attached hereto and referred to as Attachment #14.**

Senator Joseph D. Kenney, D. 3: Senator Fuller Clark for a question.

Senator Martha Fuller Clark, D. 24: I have two questions. The first question is we heard that it wasn't clear if the AMA proposal for opt out goes forward that that would transfer to those different pharmaceutical companies

that are doing the marketing. Could you clarify that part? Would it or would it not apply across the board?

Ms. Powell: Well, I understand that the way the AMA system works, the physician would be opting out of the collection of prescribing information at the physician or the pharmacy level, which would mean that a manufacturer would not be able to identify that that physician was in fact treating patients, say pregnant women who are also diabetic, as one category.

So, a pharmaceutical sales representative with a new product aimed at that category of patients wouldn't be able to identify that they probably should call on that physician. They would then, the physician would just be treated as all physicians with a pharmaceutical sales rep calling on them, but the sales representative wouldn't be able to identify that shouldn't be talking about medications for some other kinds of conditions. I should focus.

Senator Joseph D. Kenney, D. 3: Follow up question.

Senator Martha Fuller Clark, D. 24: The other question has to do with referencing and your comments. If you don't have the specific information with regard to marketing the product and that there ever going forward that you would, let's use the example of marketing to family practitioners because the product wouldn't be a reasonable product to be marketing to them. But, you would still be able to market to specialized practices if you were even if the individual information about physicians was not available. Is that true or not true?

Ms. Powell: That would be true, but to the extent that family practitioners in rural areas, for example, may be dealing with a population that has a problem, you wouldn't be able to identify that and therefore direct your marketing to those people. The marketing would be much... It couldn't be targeted in the same way because you would have to be giving everybody within the specialty groups, even if you had a medication that was just directed to a smaller subset of patients within that specialty.

Senator Martha Fuller Clark, D. 24: Thank you.

Senator Joseph D. Kenney, D. 3: Any other questions? If not, thank you for your testimony. Carolyn Finocchiaro. Are you representing yourself?

Carolyn Finocchiaro: I am with Representative Rosenwald.

Senator Joseph D. Kenney, D. 3: But, you're not a Representative, so you are speaking for yourself.

Ms. Finocchiaro: Yes.

Senator Joseph D. Kenney, D. 3: Okay.

Ms. Finocchiaro: I have never done this before. I'm a practitioner.

Senator Joseph D. Kenney, D. 3: Okay. I just wanted to know who you are representing here.

Ms. Finocchiaro: I just ... (inaudible)... the bill. Just to kind of put a lit bit of a different spin on it. I am a provider and I have nothing to do with passing bills or not passing bills. I am the director of the Cholesterol Management Center at Catholic Medical Center. I am a practitioner. I see patients. That's what I do all day. I have no part in business or anything.

The drug reps help us out a lot. I use a very limited set of drugs. I just treat cholesterol, so there's ten or fifteen drugs that I use all the time. I work very closely with my reps. They provide samples for me like we've been told. But, there are some that ruin it for a lot of people. For example, I had one rep come in. She brought coffee and bagels on Tuesday and said, "I will bring you these things every Tuesday if you write me two prescriptions every week". You blow it off. I don't care. She comes back the next week. "You didn't write my two prescriptions". Does she have a right to know that and do I have to deal with that? Do you know what I mean? It is maybe a couple bad people ruining it for everybody.

Then I had a rep come in from another company and said if I used Niaspan my patients would have better outcomes. She doesn't know my patients; doesn't know their outcomes. I shouldn't have to deal with that kind of situation at work. That crosses an ethical line where a rep is telling me how to prescribe my drugs. I have a license to prescribe medicine and, as far as I'm aware, they do not.

So, it crosses that line, I think, of being helpful to being something that is detrimental and not really something that I feel a sales rep has a right to know about me. So, just clearly, from a clinical standpoint.

**Please see Carolyn Finocchiaro's prepared testimony, attached hereto and referred to as Attachment #15.**

Senator Joseph D. Kenney, D. 3: Are you an MD?

Ms. Finocchiaro: Nurse practitioner.

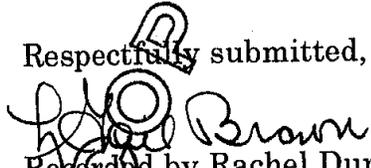
Senator Joseph D. Kenney, D. 3: Nurse practitioner. Okay. Thank you.

Ms. Finocchiaro: I have been doing this, working in cholesterol for ten years, and I think it is information that is not necessary and I think some of these statements like you want to target certain practices. It is called the Cholesterol Management Center. I treat cholesterol. Rural populations are treating cholesterol, you know you need to go to those offices. I just sort of think that. Our reps go everywhere. Do they need to know to target more here or there? I don't necessarily think that's true. They pretty much go to all offices, at least in the Manchester area. That is not a necessary reason for them to know how much Lipitor I use.

Senator Joseph D. Kenney, D. 3: Thank you. Questions? Senator Barnes? Thank you. Have I missed anybody? If there is no one else who wishes to speak on HB 1346, I will go ahead and close the hearing.

Hearing ~~concluded~~ at 3:35 p.m.

Respectfully submitted,



Recorded by Rachel Durazzani  
Transcribed by L. Gail Brown  
Senior Senate Secretary  
5/21/06

15 Attachments

HB 1346

Cindy Rosenwald, Hillsborough 22

April 19, 2006

Good afternoon, Chairman Kenney and members of the Committee. I am pleased to introduce HB 1346. This legislation has 2 goals: it will protect privacy, and it will save money for the state, consumers and businesses. It will accomplish these goals by prohibiting the sale or use of individual patient and prescriber identity for marketing brand name prescription drugs. I'd like to give you an overview of the bill.

HB 1346 will add state protections to patient privacy. The federal HIPAA law is supposed to do this, but it has loopholes, doesn't always work, and has only the federal enforcement mechanism. As I say, there are loopholes. Sometimes patients will get a coupon or advertising in the mail for a medication that treats a private medical condition, and they wonder how the drug company knows who they are. The Pharmacy Board's compliance division gets complaints from consumers about this. You will hear testimony today from someone who has received this kind of intrusive mail. In the public hearing in the House, we learned that not every pharmacy actually removes the patients' names from the computer files before they are released to other vendors. The result is that there is incomplete patient privacy protection even though HIPAA is supposed to ensure it. There is little we can do about it, either. While the pharmacy board gets complaints from consumers, HIPAA is a federal law, and enforcement must be through federal agencies. In addition, the civil fine for a HIPAA violation is a maximum of \$100, less than the value of many prescriptions, and probably not worth federal investigation unless it is part of a broader criminal effort.

Enacting HB 1346 will mean that we can better protect the privacy of patients in New Hampshire from having their identity sold when they fill prescriptions. It makes the use of their identity for marketing prescription drugs a violation of our Unfair Trade Practices Act, enforceable by the NH Attorney General's office.

Not only is patient identity inappropriately used for pharmaceutical marketing, but the identity of the prescribers—doctors, nurse practitioners, optometrists, and physician assistants—is routinely bought and sold for marketing. Large data mining corporations produce sophisticated reports that track the individual behavior of our health care professionals. This use of personal identity is both an unwarranted intrusion into professional privacy, and—more to the point—it adds to the financial burden of New Hampshire's health care system, increasing pharmaceutical costs for the state, our consumers, and our businesses.

In New Hampshire, we place a high value on privacy. When I do my grocery shopping at Shaw's and give the cashier my rewards card with its bar code identifier, they have a record of everything I buy, and I'm sure they sell this data to their vendors. But I have no basis for complaint. I have voluntarily enrolled in this program, and I get something out of it with special sales. And if on a particular day I don't want Shaw's to have a record of the six pack of beer in my cart, I just don't use my rewards card. Our health care providers have no such choice. With data mining, doctors lose their privacy involuntarily. Without any permission, drug companies know how doctors think and how they behave. I believe our health care providers deserve the privacy of their own intellectual activity and professional practice.

It's a truism in marketing that you spend your money more efficiently by investing in the customers you already have rather than trying to gain new customers. That's why it's so important to the drug companies to identify who their biggest volume prescribers are. The pharmaceutical industry spends on average \$13,000 a year marketing to a physician. They want to focus their marketing dollars and sales force time to convince high volume prescribers to write more prescriptions for their drug brands. The more they know about how an individual doctor's actual prescribing behavior is influenced by a specific marketing approach, and how many times a doctor prescribes each product in a drug class week-by-week, the more

prescriptions they can get, and the more sales revenue they will generate. Over the past decade, the drug companies have come to rely on these individual prescriber reports because they work.

I said at the beginning that HB 1346 will save money for the state, consumers, and businesses. Rep. Price will speak more about this, but I want to make it clear that high prescription drug utilization in New Hampshire leads to a significant burden on our health care system. You will also hear about opposition to this bill from PhRMA, but I want to reassure you that drug companies will still be able to purchase aggregated data by zip code and medical specialty that will enable them to monitor how their brands and their sales reps are performing.

IMS, the world's largest health care data mining company, has also objected to this legislation. They say its unintended consequences will undermine law enforcement and fraud investigations and health care research. According to IMS, this work is funded by the profits generated by selling information to the pharmaceutical industry, but that they will stop collecting physicians' names if they can't make a profit selling this data to drug companies. Please understand that prescriber identity information is already included in the data when it is sold by the pharmacies to IMS. It would be more work to take the names out. In addition, they will still generate profits by selling aggregated reports to the drug companies. Further, data from IMS is not actually necessary to investigate either fraud or drug crime. And health care researchers generally have grant money to obtain their data. Importantly, Dartmouth Medical school has expressed no opposition to this bill.

I have an amendment that clarifies in more detail what can and cannot be done with patient and prescriber identity data, and reinforces that law enforcement, research, and care management functions are all protected. The amendment addresses issues raised by pharmacies. It clarifies that identity data included in electronic prescribing, parents picking up medication for children, patients transferring prescriptions between pharmacies, and records transferred when pharmacies are sold are all acceptable uses.

We were also asked by companies that produce patient compliance educational materials to protect this kind of communications. Since these materials don't try to influence what drug is prescribed, we agreed to not prohibit these uses.

Members of the committee, I understand there is often reluctance to regulate business. But we also must consider the public policy goals of protecting privacy and saving money on prescription drugs here in New Hampshire. Really when you consider it, the effect of selling somewhat fewer marketing reports in a small state like New Hampshire would have a very limited impact on large multinational corporations with revenues in the billions. Yet for our small state, the positive financial impact on our consumers, businesses, and state budget would be significant. Thank you for your consideration, and I would be happy to answer questions.

## **HB 1346, confidentiality of prescription information**

### **✓ What HB 1346 will do:**

Require all entities that handle prescription information to keep both the patient-identifiable and prescriber-identifiable data confidential.

Protect privacy rights of the patient (Federal law requires patient confidentiality but there are certain marketing loopholes in the HIPAA law that would be closed.)

Protect privacy rights of the prescriber.

Prohibit the use of patient-identifiable and prescriber-identifiable data for the purpose of pharmaceutical company sales or marketing or for analysis of prescriber-specific effectiveness of their sales force.

Hopefully reduce the prescription drug costs for patients, employers & the State Medicaid program.

### **✓ Who supports HB 1346?**

NH Attorney General, NH Commissioner of Health & Human Services, NH AARP & NH Medical Society.

The bill passed the House Health Committee by a vote of 13-0. The bill passed the House by voice vote on the Consent Calendar.

### **✓ What HB 1346 will NOT do:**

The bill will NOT interfere with the use of patient or prescriber-identifiable data for the purpose of insurance reimbursement, dispensing prescriptions, utilization review, public health research or for law enforcement purposes.

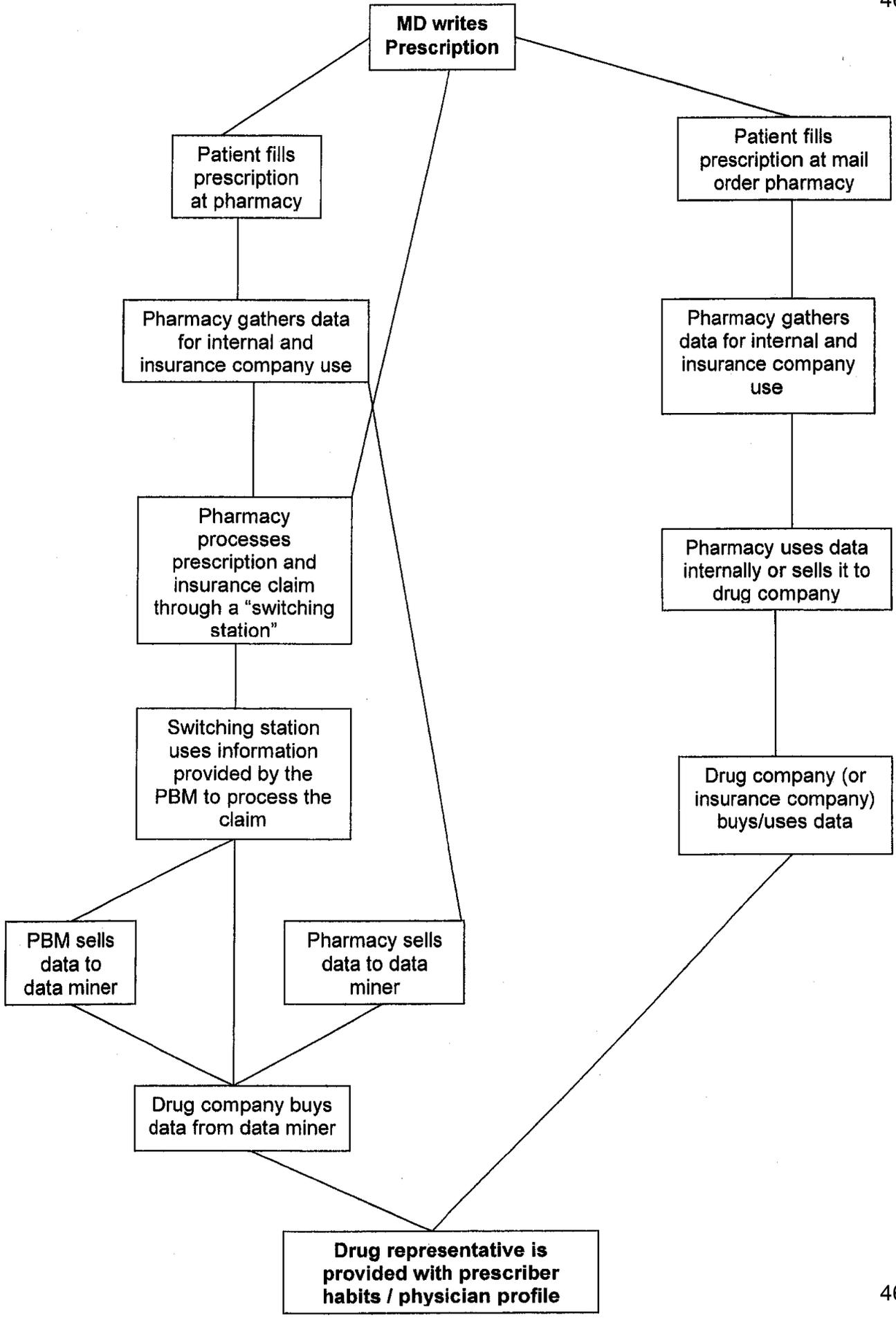
The bill will NOT prohibit the use of prescriber-identifiable data for the current drug utilization review under State Medicaid laws.

The bill will NOT prohibit the use of prescriber-identifiable data for analysis of drug formulary compliance under Medicaid or private insurance.

The bill will NOT prohibit pharmaceutical manufacturers from using prescriber de-identified data for sales and marketing analysis. There is NO prohibition from using prescriber de-identified data by zip code, town, geographic region, or by medical specialty.

### **✓ Who opposes HB 1346?**

The entities that make and/or spend millions of dollars on prescription data: pharmaceutical manufacturers, chain drug stores and data mining companies (IMS).



## Data Mining at IMS HEALTH How We Turned a Mountain of Data into a Few Information-rich Molehills

Paul Kallukaran & Jerry Kagan  
IMS HEALTH, Plymouth Meeting, PA USA

### ABSTRACT

*IMS HEALTH is the principal source of information used in marketing and sales management by health care organizations throughout the United States. Of the various potential applications of neural networks, pattern recognition is considered one of major importance. This paper presents the results of using neural networks to classify time-series data into several trend pattern classifications [e.g., Increasing Trend, Decreasing Trend, Shift Up, Shift Down, Spike Up, Spike Down, and No Pattern], and the information generated from the classifier is used to detect various marketing related phenomena [e.g., Brand Switching, Brand Loyalty, and Product Trends].*

*The data used for the test consisted of prescription data for 12 months, for 600,000 prescribers writing four drugs in the Anti-ulcer market. Using the neural network classifier and brand switching algorithm, the system was able to detect 2500 prescribers who were changing their prescribing behavior. The model is a promising formula for analyzing times-series information from extremely large databases, and presenting the user with only information relevant for decision making. This data-mining system, designed as part of the IMS Xplorer<sup>®</sup> product, uses SAS<sup>®</sup> System components for data retrieval, data preparation, graphical user interface, and data visualization. The IMS Xplorer product is a sales and marketing decision support system based on commercially-available, client-server technology created for pharmaceutical companies in their effort to fully utilize the mission critical information found in the Xplorer data warehouse.*

KEY WORDS: Time-Series Data, Neural Networks, and Data Mining

### INTRODUCTION

During the past decade there has been a significant increase in the use of artificial intelligence technology for process control, predictive modeling, data analysis, pattern recognition and signal processing (Nibset, McLaughlin, and Mulgrew 1991). Artificial, neural-network architectures have shown to be particularly powerful tools for such applications (Nelson and Illingworth 1991). Thus, neural networks have become viable, competitive alternatives to the more

traditional time-series analysis (de Groot and Wuertz 1991), linear and nonlinear model fitting (Cooper, Hayes, Whalen 1993), and cluster and discriminant analysis techniques.

In fact, there is research to indicate that back propagation neural networks may produce predictive results superior to traditional statistical methods in the areas of forecasting (Sharda and Patil 1992). The use of artificial neural networks is well established in applied fields, where neural networks are recognized as flexible and powerful tools for

solving prediction and pattern recognition problems.

This paper outlines a neural network approach to classifying time-series data into various groups [e.g., Increasing Trend, Decreasing Trend, Level Shift Up, Level Shift Down, No Pattern, or Spike Up]. [See Figure 1] The results from this neural network model are being used to identify various trend relationships of pharmaceutical products and are also used at IMS to detect prescribers that have changed their prescribing behaviors. Other statistical techniques [Multinomial Logit, CART etc.] can then use the classifications from the neural network model as dependent variables to help us to understand the influence of factors that caused these pattern changes.

## DATABASE BACKGROUND

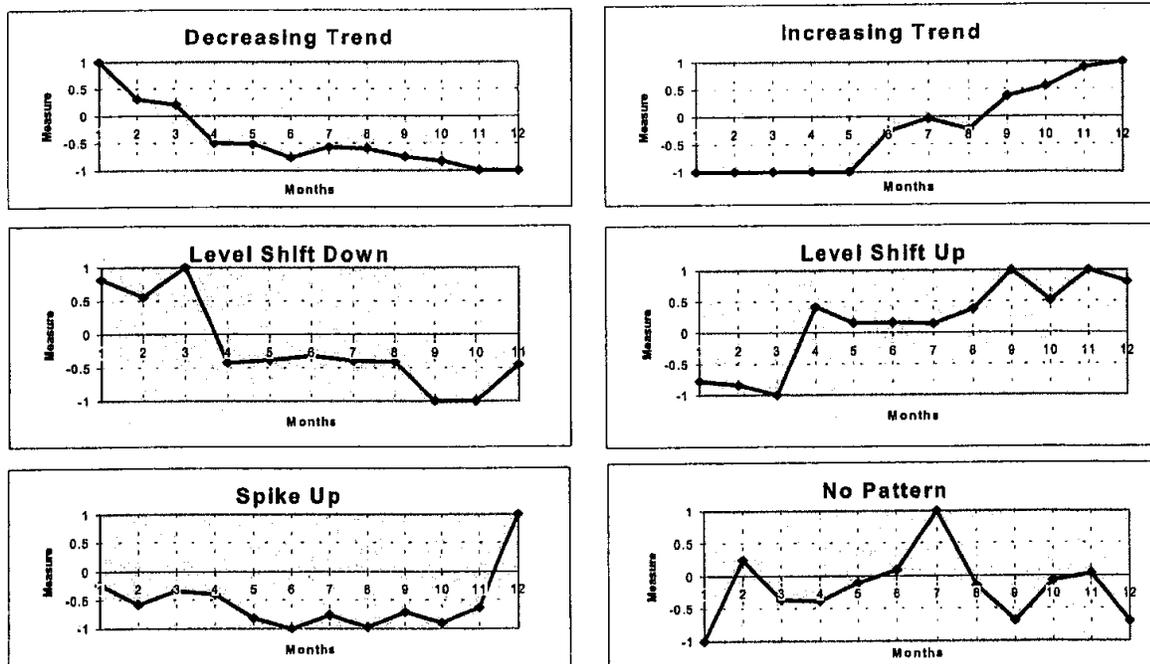
With the advent of computer technology and electronic communication, databases are

growing at an alarming rate. As these databases are used more and more for critical strategic marketing decisions, market segmentation, and sales promotion effectiveness, data-mining techniques gain significant importance.

IMS HEALTH collects data from over 175,000 sites across the United States. Physicians, pharmacists, veterinarians, drugstores, hospitals, distributors, and retailers provide data in various forms including computer tape, microfilm, purchase invoices and surveys. Xponent<sup>®</sup>, the first true physician level database for the health-care industry, is used in making a variety of sales and marketing decisions. Each month, Xponent delivers the most precise estimates available for individual prescribing activity by using a customized projection factor for each prescriber.

Xplorer is a customized decision support data delivery infrastructure that allows IMS clients to integrate Xponent data with their

Figure 1: Examples of Classifications



own data sources. Custom and third party best-of-breed software tools allow clients to access the data, conduct a broad range of analyses, and produce easy-to-read on-line reports and graphs. Xplorer operates in a client/server environment using the capabilities of mainframes to handle the large volume of data with the ease-of-use and graphic capabilities of PC's.

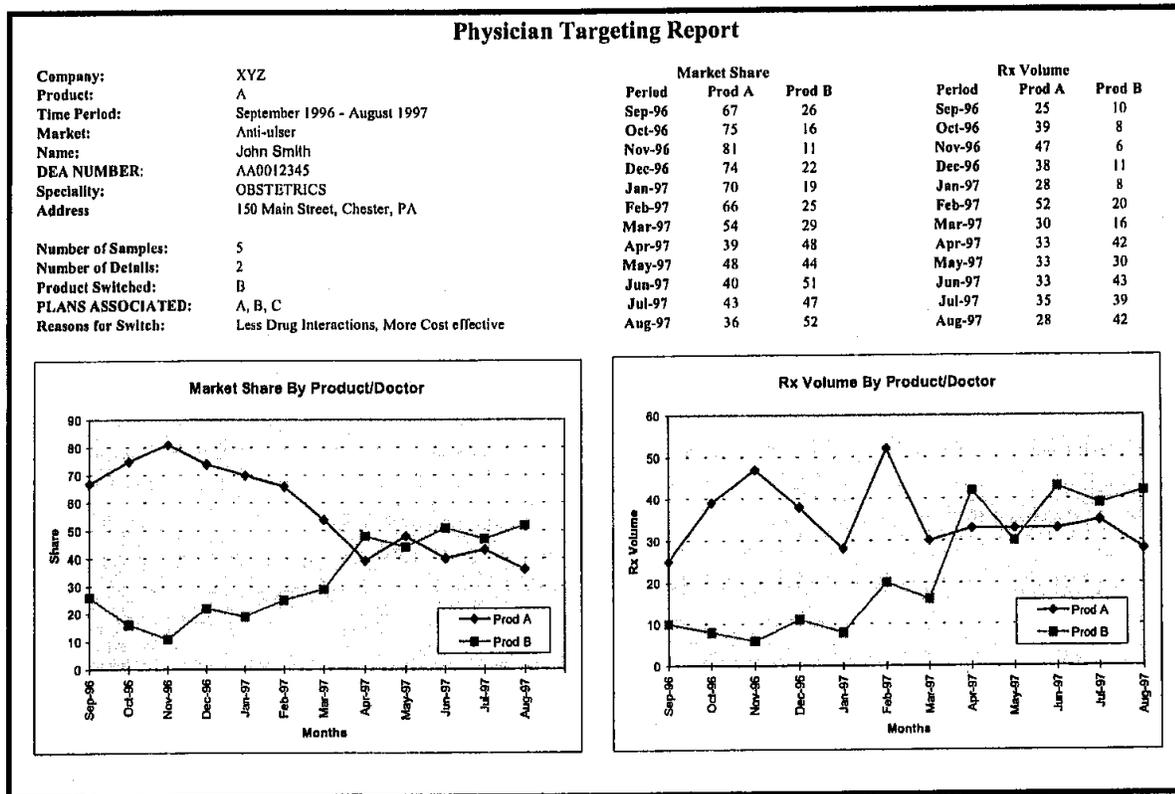
The Xponent database, in the last couple of years, has grown extremely large [Terrabytes], and currently maintains prescription information by prescriber, product and payment type [cash, Medicaid and HMO]. As this database grows, it becomes extremely difficult to identify physicians changing their prescribing behaviors. The neural-network model provides a method of analyzing times-series data and identifying physicians that have

changed their prescribing behavior over time. The method provides a tool for the sales force to use in identifying physicians to target when making sales calls. Research has shown that winning just one more prescription per week from each prescriber, yields an annual gain of \$52 million in sales. So, if you're not targeting with the utmost precision, you could be throwing away a fortune.

### APPLICATIONS OF THE DATA MINING TECHNIQUE FOR TARGETING

The massive amounts of data make it impossible for human analysts to visually examine all of the time-series data and to understand the various trends. This neural-network model is designed to classify time-

Figure 2:



**Table 1: SAS System Components Used in the Project**

<i>SAS COMPONENT</i>	<i>FUNCTION</i>
1. SAS/AF <sup>®</sup>	All the graphical user screens, to select type of analysis, data elements and viewing the final results
2. SAS/CONNECT <sup>®</sup>	Connectivity to the UNIX server and interface to the Oracle Database from Client [Windows 95]
3. SAS/ BASE <sup>®</sup>	All data preparation, transformation and statistics
4. SAS/GRAPH <sup>®</sup>	All the graphical reports for data visualization

series data into the various trend types. A time series, as its name implies, consists of statistical data collected over successive time intervals. The data can be product volumes for a particular market or prescription data for individual physicians. A time-series model is applicable regardless of the data measure or magnitude. Marketing-research analysts, economists, behavioral scientists, security analysts, and others, study time series to gain an understanding of general market trends and to take subsequent action based on the trends.

At IMS, neural networks have been developed to classify time-series data into

various trend patterns and to detect various marketing related phenomena like brand switching, brand loyalty, and brand performance. For our data-mining test, the model was used to detect physicians that switched from prescribing product A to product B, C, or D over a 12 month period. The data used for the test consists of prescription data for twelve months, for 600,000 prescribers, writing four drugs in the Anti-ulcer market. The purpose of the test was to detect physicians who have changed their prescribing behaviors by switching brands. The results of the test provided a list of prescribers who have switched from the product of interest to the competitors' products.

**Table 2: List of Information Provided by the Client to Run the Model**

<i>CRITERIA</i>	<i>SETTING</i>
<b>Time Periods</b>	March 1995 - February 1996
<b>Doctor Specialty</b>	Cardiology, Internal Medicine
<b>Payment Type</b>	Prescription paid for by Cash
<b>Distribution Channel</b>	Retail Pharmacies
<b>Geography</b>	Client defined geographic area
<b>Products</b>	A,B,C,D

Using the neural network model, the system detected 2,500 physicians who were changing their prescribing behavior. The model running on a UNIX server was able to process 600,000 physicians in approximately 15 CPU minutes and present the results to the user in a graphical format [see Figure 2 as an example]. Here, the report shows a physician that was previously loyal to the drug A, and in the last 5 months switched to prescribing drug B. This report provides a useful tool for the pharmaceutical company's sales-force to use when targeting the *right* prescribers for sales calls. The ability of the model to detect these trends and report relevant information back to the user in a quick, automated fashion is one of the advantages in applying this technique to extract information from extremely large databases.

### IMPLEMENTATION OF A DATA-MINING SOLUTION USING THE SAS® SYSTEM

At IMS we explored several options and tools that could be used to implement a data-mining solution as part of the Xplorer decision support system. The tool had to have the ability to operate in a client/server environment, to have access to relational databases, to provide graphical-user-interface (GUI) capabilities, to have the necessary data transformation and statistical functions, and to furnish the user with several graphical and text reports to make the required business decisions. The SAS® System was the only software tool that provided all the functionality that was required to implement the data-mining solution.

Figure 3: Application Process Flow

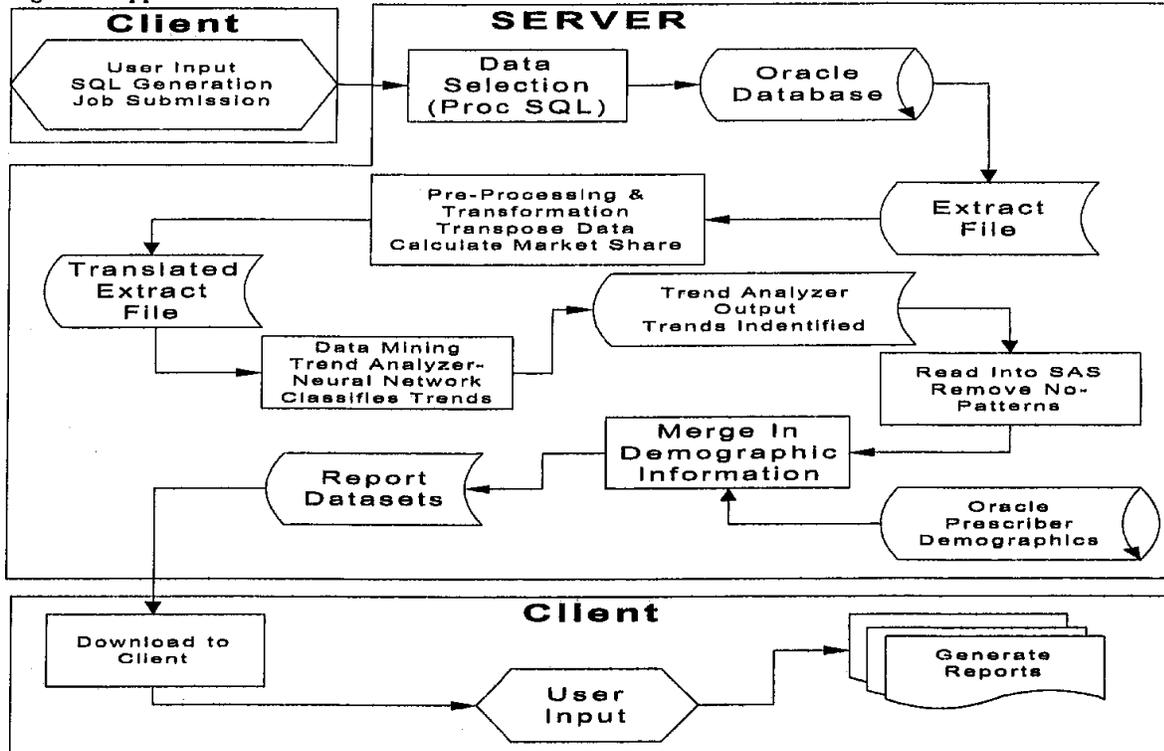


Table 1 lists the SAS tools that were used to implement the system. A process flow diagram in Figure 4 illustrates the series of steps that the system must undergo to deliver the switching information.

For a typical analysis, the user may specify the information shown in Table 2 through the GUI. After the criteria are selected for the data-mining run, the user can initiate the analysis from the client machine. All of the subsequent steps involved in the analysis are shielded from the end user. [See Figure 3]

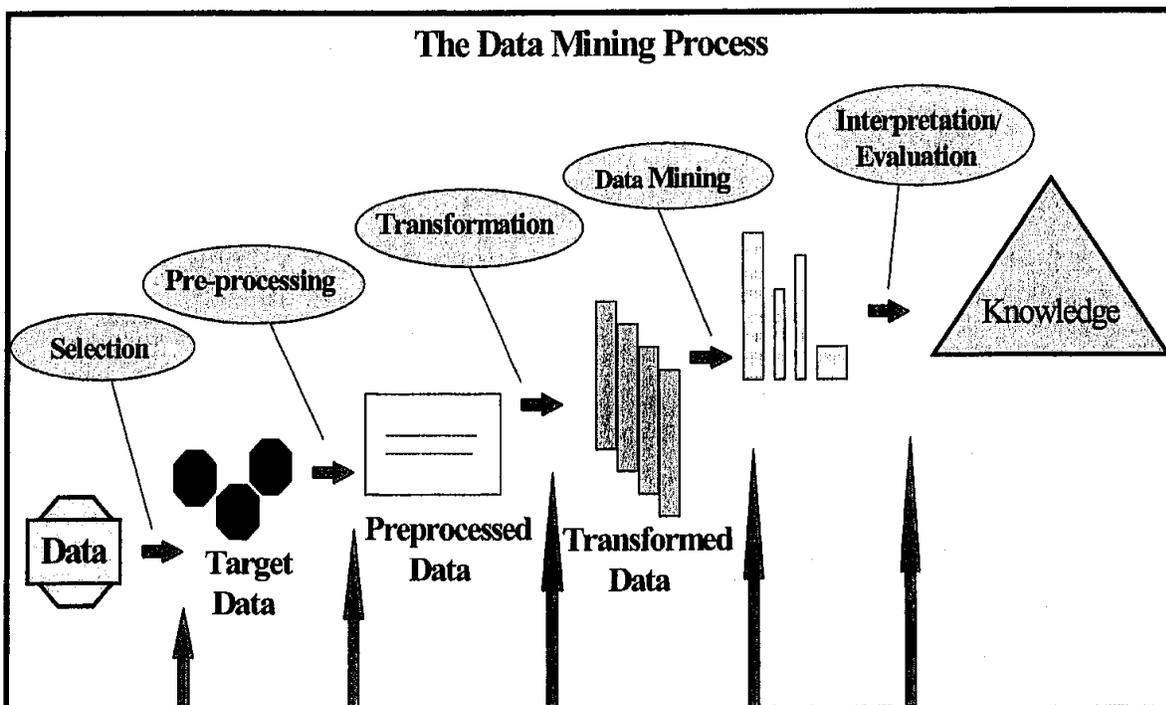
First, the analysis uses SAS to build SQL queries to extract data from the Oracle database residing on the server, and transforms and manipulates the data set to provide the correct input formats for the neural-network model. Then, the results from the neural-net model are used to

identify the physicians who have reduced the prescribing of one medication over the 12 month period and have increased the prescribing of another.

The final results from the analysis are saved in a SAS data set. The complete analysis is performed on the server, which usually involves processing approx. 600,000 records and producing a final SAS data set of about 2,500 records in length.

The results are viewed within a GUI, and the user is required to download the final SAS data set from the UNIX server. The report details are then viewed using custom SAS graphs and reports. The entire process is seamlessly integrated with the SAS System, giving the user complete flexibility in running the process without knowing the SAS programming language.

Figure 4:



## CONCLUSION

Using a classical subjective approach to the examination and analysis of 600,000 time series would take weeks of work. By using a data-mining solution, IMS can pinpoint prescribers who are switching from one medication to another. A sales person can use this model to target doctors who have switched from the drug they are selling and to devise a specific message to counter that switching behavior.

The implementation of a data-mining solution is comprised of numerous steps [See Figure 4], such as, interacting with the data-warehouse, providing the data preprocessing capabilities, and offering the statistical functionality and graphical visualization. SAS provides all the tools required to implement such a system.

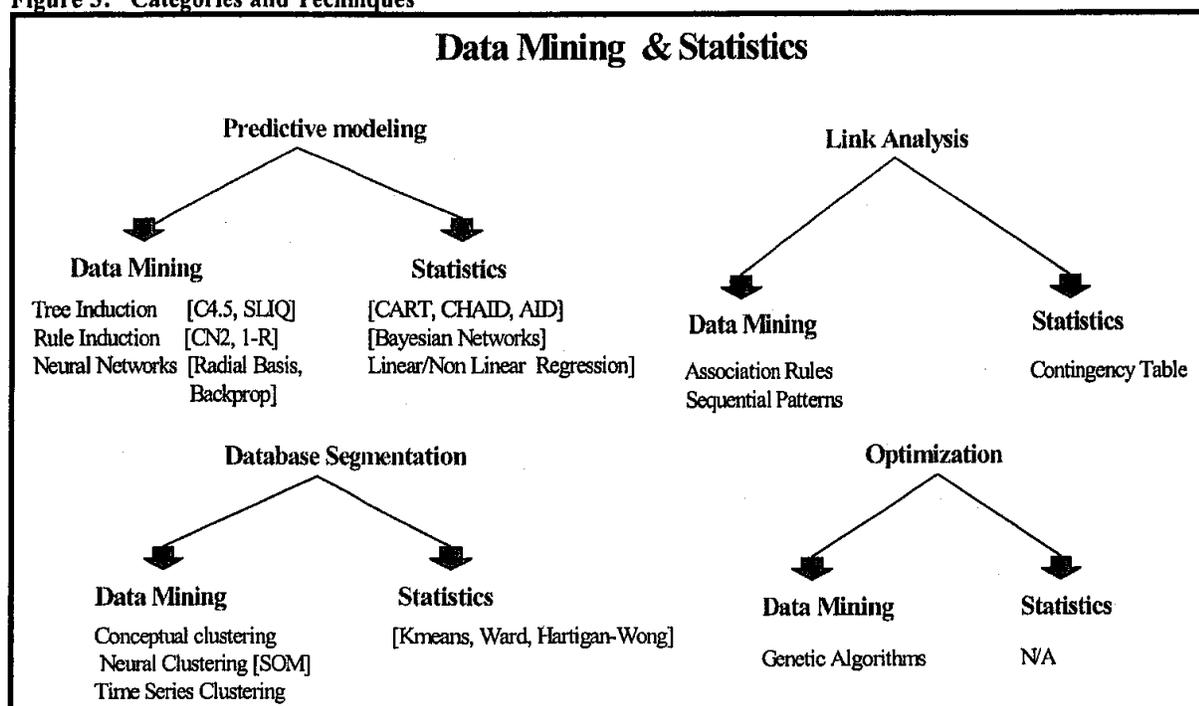
To help the user to understand the factors that caused these time-series changes, various statistical techniques [Multinomial

Logit, CART, etc.] can use the pattern classifications from the neural-network model as a response variable. [See Figure 5]

In the future, IMS plans on expanding the product to include the prescribing behavior of managed care plans, enabling pharmaceutical companies to identify trends in HMOs and PPOs across the United States. IMS is also planning to provide statistical tools that would allow companies to do more in-depth analysis, finding out not only who is switching brands, but more importantly, why they are switching. This might include using some of the newer algorithms, such as CART or other tree-building methods.

"We chose SAS software because we wanted to move up the ladder in terms of what we could do with the data," says Kallukaran. "We wanted to move from providing simple reporting services to our clients, to providing complex decision support. Using SAS software, we have been

Figure 5: Categories and Techniques



able to provide our customers with a powerful data mining tool that can give them a competitive advantage in the pharmaceutical industry."

## BIOGRAPHY

Paul Kallukaran is the Director of Advanced Analytics at IMS HEALTH. Paul has worked in the marketing research industry for the past ten years using his expertise in statistics, operations research, software engineering and artificial intelligence to build advanced applications for decision making.

Jerry Kagan is a Senior Programmer in the Advanced Analytics Group at IMS HEALTH in Plymouth Meeting, Pennsylvania. Jerry has been using SAS software for the past nine years, working primarily in the pharmaceutical and health care industries, and now specializes in SAS applications development.

## CONTACTS

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## ACKNOWLEDGMENTS

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January 28, 2006

## Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny

By GARDINER HARRIS and ROBERT PEAR

WASHINGTON — For years, Novo Nordisk, a Danish company and one of the earliest makers of insulin, has raced behind Eli Lilly to capture the lucrative insulin market in the United States.

When in 1996 Lilly started selling Humalog, a synthetic insulin with speedier blood-sugar control, Novo needed four more years to get approval to market a similar product.

When Lilly's huge sales force put Novo at a disadvantage, Novo fought back. The company hired hundreds of sales representatives. When Lilly struck a marketing deal with the Eckerd pharmacy chain, Novo responded with a partnership with Rite Aid.

But in its race, several former Novo sales representatives say, Novo may have crossed the line. Sales representatives paid at least one Rite Aid pharmacist to encourage switches from Lilly products or Novo's own lower-priced versions to higher-priced ones, according to documents and former and present company officials. Novo also paid doctors' assistants when prescriptions were switched, according to two former sales representatives.

Several former sales representatives said they were told by pharmacists and doctors' assistants that some patients first became aware of the switches when they picked up the new medicines at a pharmacy.

Officials from Novo and Rite Aid said that their activities were intended primarily to educate patients or improve care and that similar programs were common in the industry.

Karen A. Rugen, a spokeswoman for Rite Aid, said, "Our alliance with Novo Nordisk is standard industry practice." Ms. Rugen said, however, that Novo had paid one of Rite Aid's pharmacists directly, although she said that top Rite Aid executives had been unaware of the practice.

Susan Jackson, a spokeswoman for Novo Nordisk, said that the overall agreement between Novo Nordisk and Rite Aid "has benefited many people with diabetes."

Ms. Jackson would not address questions about payments made to doctors' assistants or a Rite Aid pharmacist, nor would she say how much Novo paid Rite Aid. But she said the partnership "is not unlike other agreements common in the industry that provide 'preferred status' for branded drugs."

But prosecutors are now investigating possible criminal violations. On Dec. 20, Novo said it had received a subpoena from the United States attorney for the Eastern District of New York for documents relating to its marketing practices.

The company said that it "believes that the investigation is limited to its insulin products." The subpoena indicated that "the documents are necessary for the investigation of potential criminal offenses," the company said.

Drug companies may pay for consulting or educational services, but federal anti-kickback statutes prohibit them from offering financial incentives to doctors or pharmacists to encourage or reward the prescribing of particular drugs, according to a 2003 guidance from the Department of Health and Human Services.

"In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful" in health care, the guidance states.

#### A Marketing Battle

The rivalry between Novo and Lilly illustrates the efforts companies will undertake to become No. 1 in a drug market, especially for chronic diseases like diabetes, which in the United States is a \$3.3 billion market annually, according to IMS Health, a pharmaceutical information and consulting company.

From a business perspective, Novo's efforts were a great success. From December 2001 through November 2005, Novo's insulin sales rose 364 percent to \$963 million while Lilly's insulin sales rose only 13 percent to \$1.43 billion, according to figures provided by IMS Health.

The marketing programs were detailed in dozens of internal Novo and Rite Aid documents obtained by The New York Times. Three former Novo sales representatives described the programs. These people, some of whom spoke to The Times separately from one another, do not wish their names to be used because all still work in the industry and fear retribution. Parts of the programs were also confirmed by company officials and another sales representative who allowed their names to be used. The former sales representatives would not comment on whether they had filed whistle-blower lawsuits against Novo.

In its marketing battle with Lilly, Novo's sales representatives undertook a variety of efforts to persuade doctors to prescribe Novo's insulin products, one of which was known as the "anchor in the office" program.

Under this program, Novo sales representatives established contacts in some medical offices that served many diabetics, three former sales representatives said. The contacts were generally

nurses or medical assistants responsible for monitoring diabetic patients. Officially, Novo paid these "anchors" to educate patients about Novo's products.

But two of the three former sales representatives who participated in the program said that Novo paid anchors as much as \$25 for each prescription they helped switch to higher-priced insulin products.

Vikki Tolbert, a Novo district sales manager, said in an interview that "people are up in arms for no reason."

"Novo, like other companies, used to have a program to reimburse nurses and medical assistants," Ms. Tolbert said. "The purpose was not to switch patients, but to educate them and train them on insulin and insulin devices."

The formal program and the payments ended several years ago, Ms. Tolbert said, but some sales representatives still wanted to have trainers, or "anchors in the office."

"We would never tell a sales rep to pay anyone," Ms. Tolbert said. "That's crazy. But some reps do things of their own volition. They are out in the field by themselves every day. Managers are not with them. A pharmaceutical company cannot know what each individual sales rep is doing."

#### Deals Becoming Routine

A number of drug companies are running afoul of the anti-kickback law. In October, Serono Laboratories pleaded guilty to two counts of conspiracy and agreed to pay \$704 million to settle criminal charges that it engaged in an elaborate kickback scheme to encourage sales of its AIDS drug, Serostim. In 2004, prosecutors accused Pfizer of paying doctors to prescribe its epilepsy drug Neurontin, and the company pleaded guilty to two criminal charges and paid \$430 million.

State and federal prosecutors are investigating scores of other criminal and civil cases of marketing abuse, all of which are under seal. The possible health consequences for patients are rarely emphasized, however. For instance, physicians say aggressive marketing of insulin products can hurt patients.

Dr. David M. Nathan, director of the diabetes center at Massachusetts General Hospital and professor at Harvard Medical School, said that switching insulin prescriptions without providing thorough counseling to patients can be dangerous.

Newer, more expensive rapid-acting insulins begin working within five minutes. Older, cheaper insulins take 30 to 40 minutes to lower blood-sugar levels. Patients who are switched from older to newer insulins without their knowledge may wait too long to eat, Dr. Nathan said.

"If their blood-sugar levels drop too low, they can become confused, lose coordination, lose consciousness and have seizures," Dr. Nathan said. "This can result in accidents and even death."

Drug makers routinely provide financial incentives to managed-care firms for greater sales, but providing similar incentives to pharmacy chains can raise legal and ethical questions in part because pharmacists' advice to patients, like that of doctors', is supposed to be based on the best interests of patients, not pharmacists.

Still, deals between drug makers and pharmacy chains are now routine. As part of these deals, drug companies pay pharmacy chains for drug promotions that can range from simple refill reminders to efforts to switch patients to higher-priced drugs. If sales then rise, payments can increase, said Jeffrey Krinsk, a lawyer in San Diego who specializes in suing over the deals.

The companies say that these arrangements benefit patients, but some pharmacy regulators disagree, saying the partnerships may result in prescriptions being switched inappropriately, hurting patients.

David R. Work, executive director of the North Carolina Board of Pharmacy, said that his board had tried unsuccessfully to restrict such deals, one of the few boards to make such an effort. The practice of pharmacy, like that of medicine, is regulated by state boards.

"These switches have nothing to do with patient interest, they're all about money," Mr. Work said.

Novo's marketing campaigns also highlight the conflicting loyalties of many health care professionals. Doctors and their staff often consult for or receive gifts from drug makers, which may affect prescribing decisions. Pharmacists sometimes suggest one drug over another to patients for financial, not medical, reasons, pharmacy regulators say.

In April 2004, Novo Nordisk sent information to its field managers and sales representatives about marketing guidelines issued by the federal government and by a trade association for the pharmaceutical industry.

After reviewing the guidelines, a Novo sales representative sent an e-mail message to Ms. Tolbert, the Novo district manager, asking, "Are we allowed to do the anchors in the office then?" Ms. Tolbert replied, "As far as I know, and in discussing it with other managers, we are allowed to compensate for patient education."

In March 2004, Ms. Tolbert sent an e-mail message to sales representatives describing the purpose of Novo's marketing efforts.

"Our goal is 50 or more scripts per week for each territory," Ms. Tolbert wrote, according to a copy of the message provided to The Times. "If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!!!"

Preceptorships are consulting arrangements with doctors.

After Novo announced its partnership with Rite Aid in March 2002, Ms. Jackson, the Novo spokeswoman, was quoted in Diabetes Health magazine explaining that Rite Aid pharmacists "will actively intervene to introduce Novo Nordisk products."

Novo Nordisk produces a variety of insulin products, including preloaded syringes and synthetic versions. These products are often more convenient to use but are also more expensive than standard insulin. Since diabetes is a difficult disease to manage, convenience is important. But some doctors question whether the convenience of the new products is worth the premium prices.

#### One Pharmacist's Role

Lawrence M. Schultz, a Rite Aid pharmacist in Maryland, was paid by Novo to identify diabetics from databases in Rite Aid pharmacies, according to the three former Novo sales representatives.

Mr. Schultz or a pharmacy technician then contacted doctors to persuade them to switch their patients to higher-priced insulin products, according to the three former sales representatives. It is not known why doctors agreed to the changes, but the sales representatives say that they may have assumed the switch was required under the patient's insurance policy.

Two former sales representatives who contracted with Mr. Schultz and hired "anchors" say that Mr. Schultz, doctors' assistants and others told them that patients often only became aware that their prescriptions had been switched to a different insulin when they arrived at the pharmacy to pick up their medicines. The sales representatives said they knew of no patients who were directly harmed by these surprise switches.

Ms. Rugen of Rite Aid acknowledged that Rite Aid has a partnership with Novo but says that "no official at Rite Aid knew that Larry Schultz," the Rite Aid pharmacist, "was being paid by Novo Nordisk."

Mr. Schultz confirmed that he had "pushed Novo Nordisk" products. He refused to give details, but said: "Everything I did was done completely ethically. The one thing I would never do is put my job, or Rite Aid, in jeopardy."

Three Novo sales representatives who described Mr. Schultz's efforts on their behalf said they knew of no other Rite Aid pharmacist who received payments directly from Novo. But internal documents from Rite Aid provided to The Times show that Rite Aid executives urged pharmacists throughout the chain to dispense Novo products.

Rite Aid encouraged pharmacists to run computerized "drug utilization reports" to identify patients who could be switched, documents show.

Rite Aid had powerful financial incentives, documents show. In a letter to Rite Aid pharmacists in February 2005, top Rite Aid executives said, "Each Novo Nordisk product we dispense brings us 20 to 40 percent better profit margin." Moreover, they said, such sales add millions of dollars to Rite Aid's "bottom line."

Ms. Jackson, the Novo spokeswoman, said the company was "pursuing this matter with great urgency" and intended "to take remedial action in the event we find violations of our policies."

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, said marketing deals between drug companies and pharmacy chains had often misled doctors and hurt patients. .

"We are opposed to plans where the financial interest of the manufacturer takes precedence over the patient's health," Mr. Catizone said. "To call a physician and say that we're changing a patient's medication and make it seem as if it's on behalf of the patient when it's actually part of this marketing deal is not right."

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**Medicaid Preferred Drugs**

<b><u>Drug</u></b>	<b><u>30 Day Medicaid Cost (\$)</u></b>	<b><u>Annual Cost (\$)</u></b>
<b><u>Calcium Channel Blockers (Blood Pressure)</u></b>		
Verapamil 240 mg (generic)	13.50	162
Diltiazem SR 240 mg (generic)	39.00	468 (+306)
Norvasc 10 mg	61.80	741 (+579)
Plendil 10 mg	68.40	820 (+658)
Dynacirc CR 10 mg	87.30	1,047 (+885)
<b><u>Statins (Cholesterol)</u></b>		
Lovastatin 20 mg (generic)	30.30	363
Altoprev 20 (extended release Lovastatin)	77.70	932 (+569)
<b><u>High Potency Statins (Cholesterol)</u></b>		
Crestor 20mg	78.00	936
Zocor 40 mg	137.70	1,652 (+716)

Cindy Rosenwald  
State Representative  
Hillsborough District 22

April 18, 2006

Dear Representative Rosenwald:

I am a Director of Pharmacy Services at a New Hampshire Community Hospital. Our hospital provides both inpatient and retail pharmacy services. I wish to speak in favor of your legislation HB1346, "An act requiring certain persons to keep the contents of prescriptions confidential".

In my Practice, I know that pharmaceutical representatives are pressured by their companies to sell. In 2004, the Pharmaceutical Research and Manufacturers of America (PhRMA), developed a code of conduct on interactions with healthcare professionals. The code states: "Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education." The code is the pharmaceutical industry's attempt to police itself by providing an ethical framework for its' marketing activities. Marketing efforts may include provision of meals in which a health related topic is discussed, sampling of medications, books, sponsoring of lectures, and education, among other things. Unfortunately, for the pharmaceutical representative the PhRMA Code makes it much more difficult to gain access to physicians to detail their product.

The pharmaceutical industry recognized that it needed to seek other ways to become more efficient in the face of increasing generic competition, increases in the number of tort cases and more requirements for FDA approval of new medications. Over the past couple of years, these things seemed to come together simultaneously and propel the "data mining industry" into mainstream pharmaceutical marketing. Data mining is the anabolic steroid of the pharmaceutical industry...If you aren't doing it, then the competition is likely hitting more home runs than you are!

Writing a prescription for a patient is unlike any other form of purchase. A physician makes a decision that not only influences, but "prescribes" what his patient needs to purchase. Think of the financial stability that General Motors would experience if one person could decide which car others must purchase! When a drug rep knows which physician, nurse, or physician assistant is writing for their product, they can tailor their time and efforts directly to the prescriber who hasn't written a prescription for their product.

In recent years, the growth in the costs of prescriptions exceeds inflation. This is due to a number of factors including the use of newer agents to treat patients. New medications are often, but not always better than currently available products. When a physician

receives repeated detailing about a medication, either face to face or through another marketing medium, he/she is more likely to prescribe the newer agent. If we continue allowing data mining of prescriptive information, the targeted marketing will continue and the proliferation of expenses to the healthcare system continues its' path of growth.

Retail pharmacies depend upon computer systems to process prescriptions through insurance companies. Prescription data is sent to a "switch" to process the claim through the insurance carrier. The switch may sell this information to data miners. Pharmacy software vendors even promote to pharmacies the ability to share in profits garnered by selling prescription data. In fact, you must "opt out" of most data sharing agreements with these vendors in order not to provide prescribing information to the data miners.

In conclusion, I wish to reiterate that rejecting this bill will not only increase our healthcare costs but it interferes with doctor-patient relationships by pressuring prescribing physicians to order products that they may not have chosen.

Sincerely,

Lee Carver, RPh, MBA

Sen. Kenney, Dist. 3  
Sen. Larsen, Dist. 15  
Rep. Rosenwald, Hills. 22  
April 19, 2006  
2006-1887s  
01/09

Amendment to HB 1346

1 Amend the bill by replacing all after the enacting clause with the following:

2

3 1 New Section; Pharmacists and Pharmacies; Prescription Information to be Kept Confidential.

4 Amend RSA 318 by inserting after section 47-e the following new section:

5 318:47-f Prescription Information to be Kept Confidential. Records relative to prescription  
6 information containing patient-identifiable and prescriber-identifiable data shall not be licensed,  
7 transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic  
8 transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any  
9 commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary  
10 compliance; care management; utilization review by a health care provider, the patient's insurance  
11 provider or the agent of either; health care research; or as otherwise provided by law. Commercial  
12 purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could  
13 be used to influence sales or market share of a pharmaceutical product, influence or evaluate the  
14 prescribing behavior of an individual health care professional, or evaluate the effectiveness of a  
15 professional pharmaceutical detailing sales force. Nothing in this section shall prohibit the  
16 dispensing of prescription medications to a patient or to the patient's authorized representative; the  
17 transmission of prescription information between an authorized prescriber and a licensed pharmacy;  
18 the transfer of prescription information between licensed pharmacies; the transfer of prescription  
19 records that may occur in the event a pharmacy ownership is changed or transferred; care  
20 management educational communications provided to a patient about the patient's health condition,  
21 adherence to a prescribed course of therapy or other information about the drug being dispensed,  
22 treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use,  
23 transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical  
24 specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a  
25 violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2.  
26 Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

27 2 New Paragraph; Controlled Drug Act; Prescription Information to be Kept Confidential.

28 Amend RSA 318-B:12 by inserting after paragraph III the following new paragraph:

29 IV. Records relative to prescription information containing patient-identifiable and  
30 prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits

Amendment to HB 1346

- Page 2 -

1 manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet  
2 pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of  
3 pharmacy reimbursement; formulary compliance; care management; utilization review by a health  
4 care provider, the patient's insurance provider or the agent of either; health care research; or as  
5 otherwise required by law. Commercial purpose includes, but is not limited to, advertising,  
6 marketing, promotion, or any activity that could be used to influence sales or market share of a  
7 pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care  
8 professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.  
9 Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to  
10 the patient's authorized representative; the transmission of prescription information between an  
11 authorized prescriber and a licensed pharmacy; the transfer of prescription information between  
12 licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy  
13 ownership is changed or transferred; care management educational communications provided to a  
14 patient about the patient's health condition, adherence to a prescribed course of therapy or other  
15 information about the drug being dispensed, treatment options, or clinical trials. Nothing in this  
16 section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data  
17 by zip code, geographic region or medical specialty for commercial purposes. In addition to other  
18 appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act  
19 or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be  
20 used to enforce the provisions of this paragraph.

21 3 Effective Date. This act shall take effect upon its passage.

April 19, 2006

The Honorable Joseph D. Kenney  
Chair, Senate Committee on Executive Departments & Administration  
Legislative Office Building  
Room 102  
Concord, New Hampshire 03301

**Re: House Bill 1346 -- Oppose**

Dear Senator Kenney:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our concern with HB 1346, a bill that would make it unlawful to access information related to physician prescribing information from pharmacies.

BIO is the national trade association for the biotechnology industry, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. We work closely with the **New Hampshire Biotechnology Council** and the industry and educational members they represent.

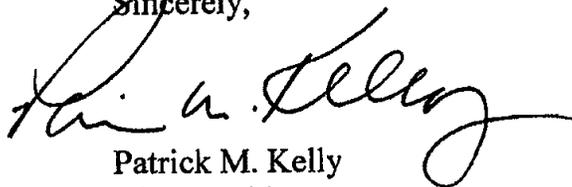
Our primary concern with HB 1346 is that it will have a direct impact on many of our member companies. Our companies, most of which do not have products on the market, rely on a variety of information when conducting research. Prescribing data, collected under strict American Medical Association (AMA) confidentiality guidelines, enables small biotech companies to review and target their research towards specific therapeutic categories. Without patient population and usage data, biotechnology companies would have a very difficult time raising venture capital - the lifeblood of the biotechnology industry.

Kenney Letter  
April 19, 2006  
Page 2

We support legislative efforts to protect and preserve patient confidentiality. However measures that restrict disclosure of physician prescribing data could severely hinder medical research, and potentially jeopardizes the state's ability to promote and grow the biotechnology (including life sciences, biosciences and medical sciences) industry in New Hampshire.

**We strongly encourage the Senate Committee on Executive Departments and Administration to oppose HB 1346.** Thank you for your consideration. If you have any questions, please feel free to contact me at (202) 962-9200.

Sincerely,



Patrick M. Kelly  
Vice President  
State Government Relations  
Biotechnology Industry Organization

cc: Senator Robert B. Flanders  
Senator John S. Barnes, Jr.  
Senator Sylvia B. Larsen  
Senator Robert K. Boyce  
Senator Martha Fuller Clark

Attachment

Medicaid Preferred Drugs

<u>Drug</u>	<u>30 Day Medicaid Cost (\$)</u>	<u>Annual Cost (\$)</u>
<b><u>Calcium Channel Blockers (Blood Pressure)</u></b>		
Verapamil 240 mg (generic)	13.50	162
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Norvasc 10 mg	61.80	741 (+579)
Plendil 10 mg	68.40	820 (+658)
Dynacirc CR 10 mg	87.30	1,047 (+885)
<b><u>Statins (Cholesterol)</u></b>		
Lovastatin 20 mg (generic)	30.30	363
Atoprev 20 (extended release Lovastatin)	77.70	932 (+569)
<b><u>High Potency Statins (Cholesterol)</u></b>		
Crestor 20mg	78.00	936
Zocor 40 mg	137.70	1,652 (+716)

*Attachment #69*

**Senator Robert Flanders, District 7**

**Re: Statement on Proposed Amendment to 1346**

Thank you Mr. Chairman and Members of the Committee:

I would like to offer an amendment this afternoon to House Bill 1346 that will protect patient confidentiality while at the same time addressing many of the concerns with the bill that have been expressed to me by constituents, industry representatives, and Senate colleagues.

With respect to patient privacy and confidentiality, I want to be very clear. This amendment will not weaken or compromise those very real issues for all of our constituents as this amendment clearly limits the uses of any patient information to those uses identified under the federal health privacy act (HIPPA – Health Insurance Portability and Accountability Act).

In addition, this amendment is explicit, that prescription information can be used for activities that would improve patient care, activities such as medical and biotech research, public health initiatives, and care management.

Some have expressed a desire for the state to be better able to monitor the impact of patient assistance programs that are offered by pharmaceutical manufacturers and this amendment includes provisions to achieve that goal as well.

This amendment achieves much without creating the unintended consequences that would arise under the bill as originally proposed. I understand another amendment has been proposed that seeks to address those unintended consequences. The problem is difficult, if not impossible, to predict every problem that HB 1346 might cause. The Senate should not pass a bill that poses such risks when it can opt for a bill that provides benefits to the state. And prescribers who do not want to see pharmaceutical sales reps or have their information shared can simply refuse to meet with the reps and/or contact the American Medical Association to opt out of such visits.

Benefits –

Clarifies protection of patient-identifiable information and

Allows state (DHHS) to monitor pharmaceutical manufacturers' patient assistance programs.

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1 New Section; Pharmacists and Pharmacies; Prescription Information to be Kept Confidential. Amend RSA 318 by inserting after section 47-e the following new section:

318:47-f Prescription Information to be Kept Confidential. Records relative to prescription information containing identifiable patient data shall not be used, transferred, licensed, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy, or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement, care management, utilization review by the patient's insurance provider or the provider's agent, participation in constructive programs designed to improve the health of patients, maintaining quality patient care, or any other permitted purpose pursuant to the federal Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any other purpose that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, except for evaluation by an insurance provider or the provider's agent for the purpose of compliance with the provider's formulary, or evaluate the effectiveness of a professional detailing sales force. In addition to other appropriate remedies under this chapter, a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

318:47-g Patient Assistance Program. Following the close of each calendar year, any clearinghouse that provides information to New Hampshire residents about pharmaceutical manufacturers' patient assistance programs shall, to the extent that the clearinghouse collects such information, provide aggregate information to the Commissioner of the Department of Health about either:

- (1) the numbers of people within New Hampshire who potentially qualify for any manufacturer or government program during the calendar year, or
- (2) the number of patients served during the calendar year.

An individual company may provide additional information about the individual company's patient assistance program, however, the Commissioner will combine all information from all sources, including individual companies and the clearinghouse, and report only aggregate information to the public.

2 New Paragraph; Controlled Drug Act; Prescription Information to be Kept Confidential. Amend RSA 318-B:12 by inserting after paragraph III the following new paragraph:

IV. Records relative to prescription information containing identifiable patient data<sup>72</sup> shall not be used, transferred, licensed, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail, or Internet pharmacy, or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement, care management, utilization review by the patient's insurance provider or the provider's agent, participation in constructive programs designed to improve the health of patients, maintaining quality patient care, or any other permitted purpose pursuant to the federal Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any other purpose that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, except for evaluation by an insurance provider or the provider's agent for the purpose of compliance with the provider's formulary, or evaluate the effectiveness of a professional detailing sales force. In addition to other appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

3 Effective Date. This act shall take effect July 1, 2006.

**AMA Best Practice Guidelines  
For  
Use of Prescribing Data by Industry**

The guidelines are intended to provide ethical guidance to the healthcare industry, in particular manufacturers of pharmaceuticals, devices and medical equipment and their related entities and business partners, regarding the responsible use of prescribing data. The AMA encourages organizations and their representatives to adhere to these guidelines in their direct relations with physicians.

**Guideline 1:**

Understand the physician's perspective that prescribing data is personal and sensitive in nature.

**Guideline 2:**

Keep prescribing data confidential and expressly prohibit disclosure of prescribing data by sales representatives to any other party.

**Guideline 3:**

Continually reinforce that use of prescribing data to overtly pressure or coerce physicians to prescribe a particular drug is absolutely an inappropriate use.

**Guideline 4:**

Continually educate and reinforce to all employees and agents, including contract sales force organizations, the appropriate uses of prescribing data (e.g. safety notices, recalls, drug samples distribution).

**Guideline 5:**

Maintain an internal contact person to handle inquiries or grievances about your organization's use of prescribing data.

**Guideline 6:**

Based on you organization's policies, identify appropriate disciplinary actions which may be taken against individuals who misuse prescribing data.

Attachment #48

House Bill 1346  
Requiring persons to keep the contents of prescriptions confidential  
NH Association of Chain Drug Stores  
Stuart D. Trachy  
April 19, 2006

I am here today representing the NH Association of Chain Drug Stores in expressing our opposition to House Bill 1346.

The issue of confidentiality of medical information is often portrayed in very simple terms and is sometimes addressed by trying to limit the flow of information in one way or another. We know, however, it is really not that simple as the recent federal HIPAA legislative and regulatory experience has shown us. We believe this proposal directed at prescription records is too broad, and causes many problems as a result of the unintended consequences due to the unique nature of pharmacy practice.

Here are some examples of problems from this approach:

Prevention of necessary prescription transfer

This legislation would prevent the common and necessary occurrence of prescriptions being transferred from one pharmacy to another. Often patients ask to have their prescriptions transferred to another pharmacy for their convenience or particular health care needs.

Electronic prescriptions and prescribing

This legislation would prevent the use of electronic prescribing and sending electronic prescriptions to pharmacies. This bill would put a stop to this beneficial practice at the very time that it is being promoted by the federal Medicare Modernization Act.

Sale of business

Many privacy bills are silent on mergers or business sales and may require obtaining individual consent... from each patient who ever filled a prescription at the pharmacy... to transfer their prescription records prior to any sale or merger. Unless appropriate provisions are included, every time a pharmacy (or medical or dental practice) is bought or sold, the business will have to acquire consent from every patient for whom they have ever filled a prescription or treated. The cost alone, not to mention the logistics, are staggering. This provision will fall particularly hard on retiring pharmacists, destroying any "good will" value their pharmacy might have when they attempt to sell.

Minors or persons deemed incompetent

Who may consent for minors is often not stated or unclear at best. Some laws speak of "legal guardians" and this implies a specific legal standing and may not include joint custody or non-custodial parent situations. It is often unclear who could pick up a prescription for a child, how the pharmacist can instruct the parent or how the pharmacy could get paid for the medication. Without specific consent from the minor patient or an exception prescriptions could not be provided to parents for their children. To encourage children to receive care for conditions they

might be reluctant to tell their parents about, many states already have laws allowing children to receive treatment without their parents consent for conditions such as psychiatric problems, drug abuse treatment or sexually transmitted diseases. Almost always privacy bills are entirely unclear as to what the appropriate procedure is in these cases.

*Others picking up prescriptions for their family members or friends*

This bill would prevent the common and helpful practice of a patient's relatives or friends picking up prescriptions when needed. Pharmacy is the only segment of health care that is *routinely* asked to provide confidential health information to someone other than the patient. Patients *expect* this service and would not want this type of complication. Presently in the United States, someone other than the patient picks up a full 25% of prescriptions filled in community pharmacies. The bill as presently written will deny care and infuriate patients by crippling a desirable and necessary community pharmacy practice.

*Law enforcement*

Bills often omit an exemption from obtaining consent to release information in compliance with court orders, subpoenas, or requests from the Board of Pharmacy, Board of Medicine, DEA, FDA or the police. A pharmacist must be allowed to notify the DEA or the police about potentially forged prescription or to comply with court orders and subpoenas without obtaining consent from the person presenting the prescription. If not, when a pharmacist is presented with a suspicious prescription, the pharmacist would actually be forced to ask the forger to consent to call law enforcement.

In addition to the above consequences, it should be noted that even the American Medical Association recognizes the legitimate use of prescription data by pharmaceutical companies. The following is from the AMA web site:

***How Pharmaceutical Companies Use Physician Prescribing Data***

*Although the AMA rejects the inappropriate use of prescribing data, it recognizes the legitimate use of these data by pharmaceutical companies that support sound health care practices. For example, prescribing data is used to detect drug diversion, target promotional and marketing materials, and distribute pertinent drug samples and educational materials to physicians. Prescribing data can also have numerous applications that are critical to public health. By providing integrated national pharmaceutical information, researchers can study mortality and morbidity, long-term drug effects, orphan drugs, drug safety, and interaction. Absent specific prescribing data, pharmaceutical companies would likely market products and materials by geographic location and practice specialty, resulting in irrelevant sales calls and materials.*

Also at the AMA web site are the best practice guidelines for the use of prescribing data by Industry. The chain pharmacy industry also embraces these guidelines and believes those who operate in this area should embrace them, too.

Given the concerns we have raised today, in addition to those we might not have considered, we hope you will find HB 1346 inexpedient to legislate.



Attachment #6

## AMA's Position Regarding State Proposals to Restrict Disclosure Of Physician Prescribing Data

### Background

- The American Medical Association (AMA) is troubled by pending legislation that would prohibit or severely restrict the collection and disclosure of prescribing information that identifies a specific *physician* prescriber.
- The AMA has been a long standing advocate of legislative efforts to protect patient confidentiality and agrees strongly that the unauthorized dissemination of any identifiable *patient* information is inappropriate and illegal pursuant to federal HIPAA law.
- The AMA believes that physician prescribing data do not undermine patient confidentiality laws because all patient data have been de-identified prior to the collection and aggregation of this information.
- There are many important reasons for state legislatures to reject measures to impose broad limitations on disclosure of *physician* prescribing data. Most significantly, this information is critical to improving the quality, safety and efficacy of pharmaceutical prescribing through evidence-based medical research.
- All Healthcare Information Organizations (HIOs) that compile and market prescribing data for commercial use are licensees of the AMA Physician Masterfile. The AMA imposes safeguards on the appropriate use of physician prescribing information through carefully-monitored provisions in licensing agreements with HIOs. HIOs utilize the Masterfile to match and append prescribing data, package these data into various products, and license the resulting information to the pharmaceutical industry, academia and government entities. This commercial use of prescribing data generates profits to make possible the development of a variety of derivative research databases that would otherwise go unfunded. Through these databases, hundreds of studies are made available to the medical community for a wide variety of activities to improve health care quality and safety.
- The AMA has worked proactively to address concerns involving instances of misuse of prescribing data by pharmaceutical sales representatives. As an advocate for physicians and ultimately their patients, the AMA has created a solution to address physician concern over use of these data. As described more fully below, the AMA is launching the Prescribing Data Restriction Program (PDRP) that will give physicians the option to restrict access to their prescribing data, making government-imposed restrictions unnecessary. All companies that purchase data from HIOs will be contractually obligated to adhere to this program.



### **The Importance of Prescribing Data In Evidence Based Research**

Restrictions on the use of prescription information will disrupt health care research and its corresponding benefits for patients, government agencies, health planners, academicians, businesses and others. This research supports many beneficial applications, including: (1) setting and promoting public health policy, (2) accelerating healthcare innovation, (3) driving best clinical practice, (4) maintaining safety, (5) enabling physicians and patients to make better decisions, and (6) balancing value and cost. In addition, prescription information is used in bioterrorism surveillance, Medicare Part D uptake studies and physician feedback reporting. Commercial uses of the information underwrite the substantial costs to collect and process this information. The unintended consequence of restrictive state legislation is that this information would no longer be available for those public benefits.

### **AMA's New Prescribing Data Restriction Program (PDRP)**

- The AMA will launch a new web-based Prescribing Data Restriction Program (PDRP) on July 1, 2006. This program will address physician concern over inappropriate use of prescribing information while ensuring these data continue to be available for evidence-based research. The AMA believes this approach provides physicians with the tools they need to restrict information that they do not want shared while avoiding legislatively-mandated restrictions that could have unintended consequences.
- The PDRP is being implemented in response to feedback from AMA constituents. The overwhelming majority of a sampling of America's doctors have told AMA that where concerns exist, they will be alleviated through the existence of a formalized program that allows them to restrict this information from going to pharmaceutical sales representatives.
- Based on the direction of the AMA Board of Trustees and its physician constituents, AMA has created exactly such an opt-out mechanism. In addition to it enabling physicians to restrict access to prescribing information, it provides doctors with a avenue to register complaints against a company or individual who has used the information inappropriately. The AMA will take appropriate action on behalf of the physician based on the specifics of the complaint.
- As part of the PDRP the AMA has developed a web-based Prescribing Data Information Center that provides information to physicians on what the AMA considers responsible use of prescribing data by HIOs and pharmaceutical companies. The AMA has also developed Industry Best Practice Guidelines on the appropriate use of physician prescribing data.



## Summary

- The AMA strongly supports state legislative efforts to protect the confidentiality of patient information. However, one should not confuse confidential patient data with physician prescribing data. Measures that restrict disclosure of physician prescribing data would greatly harm research and development activities dependent upon this information. The safeguards offered by the AMA's PDRP offer a much more reasonable and targeted approach to protecting unwanted disclosures.



**To: The Honorable Senators of the Executive Departments &  
Administration Committee  
State Capitol  
Concord, New Hampshire**

**From: Scot Ganow, CIPP  
Corporate Privacy and Ethics Officer  
Verispan, LLC**

**Date: April 19, 2006**

**Prepared Statement Regarding House Bill 1346**

My name is Scot Ganow and I serve as the Corporate Privacy and Ethics Officer for Verispan, LLC. I thank the members of the Committee for this opportunity to appear before you today.

Verispan is a healthcare informatics joint venture of Quintiles Transnational Corporation and McKesson Corporation. We provide a broad array of information products and services to the healthcare industry. In the interest of time, and as Verispan products only contain prescription data that has been de-identified in accordance with HIPAA, I will focus my comments on the prescribing information limitations proposed by this bill.

Verispan supports privacy-centric solutions that address the concerns raised by the New Hampshire Medical Society and other professionals about the proper use of prescribing physician information. Further, Verispan shares these concerns as we believe the Fair Information Practice Principles of Notice and Choice are essential to the ethical and appropriate use of any individual's data, whether it be patient or prescriber-specific. When it comes to the use of prescriber information, we believe that the actual extent of unprofessional interactions with physicians is relatively limited and should be addressed in a focused and appropriate manner. That is why Verispan, along with other companies in the industry, will be in full compliance with the nation-wide physician opt-out-based "Prescribing Data Restriction Program" being launched by the American Medical Association this summer. This program is available to AMA members and non-members alike and provides each the choice as to whether prescribing information can be disclosed. This program complies with the individual's privacy preferences by providing Notice and Choice, as to use of individually identifiable information in the form of prescribing histories or transactions. Restricting access to prescribing data, as proposed in this bill, will not address the key issues underlying it. Instead, I respectfully submit these concerns are best addressed directly by the parties involved and not with legislation that will completely close off access to this valuable information. To this end, the AMA also provides all physicians access to an on-line complaint reporting service which allows them to report inappropriate practices regarding prescribing data.

It is also important to remember the very reason HIPAA, the Health Insurance Portability and Accountability Act, exists today. Where privacy and security of data are most definitely enabling cornerstones of HIPAA, it was principally drafted to drive the simplification of the administration of healthcare. HIPAA encourages the use of technology to improve the accessibility to, and quality of appropriate healthcare information to improve patient care and reduce costs associated with outdated information management practices. HIPAA encourages harnessing the power of the health information, while maintaining strong privacy and security. I respectfully submit the approach to this bill should be made in the same spirit.

I also respectfully submit that New Hampshire should carefully consider other ways to address privacy concerns to avoid losing out on the value this information contains.

Verispan concurs with many of the concerns voiced in numerous letters and in testimony today about the serious unintended consequences of the sweeping data restrictions required by this bill. Restrictions to not only the information itself, but the cost and public health benefits of using that information as our industries do to benefit patients and physicians alike. By preventing the release of prescribing information, it is very likely that New Hampshire will see increased healthcare costs associated with the elderly and Medicaid, inefficient distribution of free drug samples to physicians and their patients, and increased compliance and enforcement costs to affected companies and the government. National security and public health are also directly implicated, with substantial negative impact where prescribing information cannot be used in bioterrorism, pandemic and epidemiology response and management for threats like avian flu, thus hindering speedy and effective response. Timely clinical trials and drug recalls could also be negatively impacted. All of these unintended consequences ultimately may serve to slow or eliminate some of the progress made in the area of healthcare information management promoted in HIPAA.

There are already sound solutions to the privacy concerns voiced in this discussion while maintaining the economic, public health and national security of keeping this information available. These solutions include any model that affirms the Fair Information Practice Principles of Notice and Choice.

I thank you for your time today and the opportunity to appear before you. I would be happy to respond to any questions.

**AARP New Hampshire Testimony on HB 1346  
Senate Executive Departments and Administration Committee  
April 19, 2006**

I am Bill Hamilton Advocacy Director for AARP NH. AARP is a nonprofit membership organization of persons 50 plus years of age and we have over 217,000 members throughout the state. Thank you Chairman Kenney and members of the EDA Committee for the opportunity to share our views with you.

AARP NH worked Rep. Rosenwald to develop HB 1346. This bill will:

- It will require all entities that handle prescription information to keep both the patient-identifiable and prescriber-identifiable data confidential.
- Protect privacy rights of the patient (Federal law requires patient confidentiality but there are certain marketing loopholes in the HIPAA law that would be closed.)
- Protect privacy rights of the prescriber.
- Prohibit the use of this data for pharmaceutical sales or marketing programs that might influence a decision on which medication is prescribed to a patient or for analysis of effectiveness of their sales force.
- Reduce the prescription drug costs for patients, employers & the NH Medicaid program.

HB 1346 will not:

- The bill will NOT interfere with the use of patient or prescriber-identifiable data for the purpose of insurance reimbursement, dispensing prescriptions, utilization review, public health research or for law enforcement purposes.
- The bill will NOT prohibit the use of prescriber-identifiable data for the current drug utilization review under State Medicaid laws.
- The bill will NOT prohibit the use of prescriber-identifiable data for analysis of drug formulary compliance under Medicaid or private insurance.
- The bill will NOT prohibit pharmaceutical manufacturers from using prescriber de-identified data for sales and marketing analysis. There is NO prohibition from using prescriber de-identified data by zip code, town, geographic region or by medical specialty.

Thank you for the opportunity to testify.

## The Unintended Consequences of Passing HB 1346

IMS Health is the world's leading provider of information, research and analysis to the health care industry, with data collection and reporting activities in more than 100 countries and a strong 50-year reputation for respecting patient privacy by building commercial databases without patient-identifiable information. In the United States alone, IMS Health collects information from tens of thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospital, and clinics, processing more than 72 million records each month.

IMS Health opposes House Bill 1346, which would restrict the release of health care information that contains *reference to the prescribing physician* in his/her professional capacity.

**Adverse Impact on Health Care Research.** Restrictions on the use of prescription information will disrupt health care research and its corresponding benefits for patients, government agencies, health planners, academicians, businesses and others. This research supports many beneficial applications, including: (1) setting and promoting public health policy, (2) accelerating healthcare innovation, (3) driving best clinical practice, (4) maintaining safety, (5) enabling patients to make better decisions, and (6) balancing value and cost. In addition, prescription information is used in bioterrorism surveillance, Medicare Part D uptake studies and physician feedback reporting. The unintended consequence of HB 1346 is that this information would no longer be available for those public benefits. Commercial uses of the information, restricted by HB 1346, underwrite the substantial costs to collect and process this information; the restrictions contained in HB 1346 would make this information unavailable for research and many other important uses.

**Increased Cost of Healthcare.** Restrictions on access to prescription data lead to inefficient distribution of drug samples and other research, commercial and educational activities, leading to increased drug costs.

**New Privacy Rights in Professional Information Threaten Patient Access to Information.** If physicians can assert a right to privacy over professional information, then patients may have difficulty gaining access to information in the future to make informed health care decisions.

**Patient Information Is Already Protected Under Federal Law.** HB 1346 will not add protections for patient information, because those already exist under the federal HIPAA law.

**Every State That Has Considered Similar Legislation Declined to Enact It.** Over the years, more than a dozen states have considered legislation like HB 1346 that restricts access to physician-identifiable information. Each of those states ultimately declined to enact the proposed legislation after carefully considering both the benefits and the drawbacks of restricting access to prescription information.

**Legislating this matter is unnecessary --- or at least premature.** The American Medical Association is working with health information companies and pharmaceutical manufacturers to launch a program that **allows doctors to opt out** of having their prescribing information go to pharmaceutical sales reps. This program has not been given the opportunity to work; its start date is July 1, 2006.

**Correspondence  
In Opposition to  
New Hampshire HB 1346**

**from**

**Stan Finkelstein, M.D.  
Senior Research Scientist  
The Harvard-MIT Division of Health Sciences and Technology  
Cambridge, Massachusetts**



The Harvard-MIT  
Division of  
Health Sciences  
and Technology



March 30, 2006

Hon. Joseph Kenney  
Chair Senate Executive Departments and Administration Committee  
Legislative Office Building, Room 102  
Concord, NH 03301

Dear Senator Kenney,

My colleagues at IMS Health have brought to my attention HB1346, which, if passed would greatly reduce the availability of data on drug prescribing, that is used in critical public sector health policy research aimed at improving health care quality and lowering cost.

Over the past thirty years, my research has benefited from access to this kind of data, from multiple commercial sources. My own research has been largely supported by grants from the federal government and charitable foundations. Over most of that time period IMS Health has provided me access to data for use in this work.

The kinds of data on drug prescribing that are available allow health care researchers to address critical policy questions relating to how and why physicians make decisions to describe specific medicines. These questions are important, as they relate to safe use of medications by patients. Additionally, understanding the drivers of the cost impact of drug prescribing has become critical, given the implementation of the new Medicare drug benefit.

Some might suggest that data collection for research, like mine, conducted in the public interest, should properly be supported by government research funding. Unfortunately, that is unrealistic. The federal agencies that have traditionally supported the kind of research in which my colleagues and I engage, the National Institutes of Health and its sister agency, agency for Healthcare Research and Quality have seen great budget reductions.

As you and your colleagues in the New Hampshire Senate deliberate over HB1346, I urge that you give serious consideration to leaving open the channel to collect and aggregate data on drug prescribing. Not doing so could have great adverse impact on the ability to make informed policy judgments in the health care arena.

Thank you very much for your consideration.

Sincerely,

Stan N. Finkelstein, M.D.  
Senior Research Scientist

cc: Robert Hunkler, IMS Health

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Cambridge, MA 02139  
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**Correspondence  
In Opposition to  
New Hampshire HB 1346**

from

**Nilay D. Shah, Ph.D.  
Division of Healthcare Policy and Research  
Mayo Clinic  
Rochester, Minnesota**

March 27, 2006

Honorable Joseph Kenney  
 Chair, Senate Executive Departments & Administration Committee  
 Legislative Office Building  
 Room 102  
 Concord, NH 03301

Dear Chair Kenney,

I am a pharmacist, health services researcher, and health economist, with a research focus on quality and efficiency of the health care system. This week I was dismayed to learn of New Hampshire House Bill 1346 that would effectively outlaw the collection and dissemination of prescribing information. It appears this legislation would establish a national precedent that would severely threaten the availability of valid and reliable prescription information.

As you are aware, the increase in prescription drug expenditures is an important challenge for many constituencies, especially patients and health care providers such as hospitals. Valid prescription information is essential for research to provide insights on ways to contain the increase in prescription expenditures. In collaboration with other pharmacist researchers and colleagues from a leading prescription information provider, I have had the opportunity to use prescription information to publish a series of peer-reviewed papers on prescription drug expenditures that have appeared in the *American Journal of Health System Pharmacy*. (e.g. Hoffman et al. Projecting Future Drug Expenditures – 2006 Am J Health-Syst Pharm. 2006; 63:123-38) The consistent feedback our research group has received is that our publications have been an essential reference to pharmacists and other health care professionals that seek to manage and contain drug expenditures in various health care settings. Without valid prescription information, it would be impossible for us to provide objective data on prescription drug expenditures, and therefore our ability to provide guidance on drug cost containment measures would be limited to a great extent. Additionally, this data is used by the National Health Accounts at the Centers for Medicare and Medicaid Services (CMS) to project the national expenditures for prescription drugs. There are numerous other published studies that use similar prescription drug data to explore various drug cost trends and approaches to drug cost containment.

Furthermore, a healthcare challenge upon us that is even more important than increasing drug costs is the safety of prescription drugs, especially newer drugs. There are many widely reported examples of safety concerns, such as the safety of antidepressants in children and the safety of COX2 inhibitors (e.g. Vioxx & Bextra). Large databases of prescription drug information were among the first methods used to understand and address these issues, and such studies are one of the most efficient initial methods to investigate a drug safety concern. This point is validated in published articles in highly respected journals such as the *Journal of the American Medical Association (JAMA)*. IMS Health data were used to evaluate the quality of beta-blocker use in the United States (January 1, 2004) and the prescribing of hormone replacement therapies after negative results were published (October 27, 2004). There are numerous other examples in the published literature of the value of IMS data to study the efficiency and quality of medication use in the United States. To further illustrate this point, a cursory search of the Food and Drug Administration web site reveals many examples of how FDA uses prescription information to study drug safety. Without valid, large databases of prescription drug information, drug safety concerns that appear will take more time and effort to evaluate, and of course, more time leads to the potential for greater patient harm.

In summary, as a pharmacist and researcher, I urge you to carefully consider the potential unintended consequences of this legislation. Passage of this legislation is likely to establish an environment that will constrain (or even eliminate) the availability of large datasets of valid prescription drug information, and therefore, limit research that examines methods for drug cost containment and the safety of new drugs. The potential negative consequences of this legislation appear legion. If you are interested in further perspectives on this legislation, I would be very willing to discuss these issues further with you or a member of your staff. My direct daytime telephone number is 608-334-7282.

Sincerely,



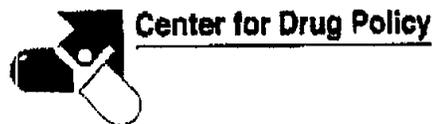
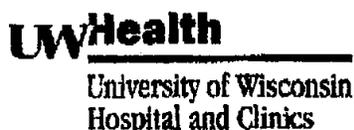
Nilay Shah PhD, RPh  
 1123 23<sup>rd</sup> Ave SW  
 Rochester, MN 55902  
 Daytime Direct Phone: 608-334-7282

CC: Robert Hunkler

**Correspondence  
In Opposition to  
New Hampshire HB 1346**

**from**

**Lee C. Vermeulen, B.S. Pharm., M.S.  
Director, Center for Drug Policy  
University of Wisconsin Hospital and Clinics  
Madison, Wisconsin**



April 13, 2006

Hon. Joseph Kenney  
Chair, Senate Executive Departments & Administration Committee  
Legislative Office Building  
Room 102  
Concord, New Hampshire 03301

Dear Senator Kenney-

A bill before your committee has been brought to my attention and, while I am not one of your constituents or even a resident of New Hampshire, I would be grateful if you would consider my concerns before taking action on it.

I have reviewed the text of HB1346, regarding restriction on the accessibility of prescription drug records. As a health care provider in Wisconsin, I am particularly sensitive to the issues surrounding patient confidentiality and privacy; however I feel that the importance of ensuring that right must be balanced with the importance of collecting and utilizing health care data. We must collect and use data on the care we delivered in the past in order to improve the care we will deliver in the future. In 1988, Paul Ellwood described the use of health care data as a "technology of patient experience" and called for the archiving of de-identified patient-specific data for the purpose of research intended to improve the ways in which we deliver care and the outcomes of that care (Ellwood, *New England Journal of Medicine*, 1988;318:1549-1556). We have not only failed to produce a nation-wide repository of health care data, but (through laws such as HIPAA and the bill before you today) we have actually taken steps to make the creation of such as database (and the important research using it) less feasible.

Allow me to briefly suggest one such study that may be done today using existing data resources that may not be possible if your bill is passed. Consider the number of medications that have recently been removed from the market in the United States due to safety concerns. Despite the rigorous review conducted by the US Food and Drug Administration before a new medication is approved for marketing, it is nearly impossible to detect rare, yet significant adverse effects of new medications before hundreds of thousands of patients receive them. The "signal" necessary to detect those events is simply too weak to detect given small numbers of patients typically studied in trials conducted for FDA approval. Without the availability of large data sets of prescription drug use, we will lose one of our most powerful tools that help us monitor the safety of new medications and ensure that patients taking medications are not harmed by them.

It is not only the clinical well being of New Hampshire residents that will suffer if access to prescription drug data is limited. Consider the financial implications of that action as well.

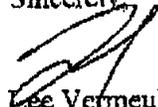
Hon. Joseph Kenney  
April 12, 2006  
Page 2

Annually, my colleagues and I use prescription drug data provided by IMS HEALTH to produce a forecast of expenditures expected in hospitals during the following year. The paper is used by many hospital pharmacy leaders as they create their drug budgets and identify ways of increasing the efficient use of medications at their facilities (saving New Hampshire taxpayers a great deal of money!). Without data from IMS, such financial projections could simply not be made.

I urge you to consider this bill carefully and not take act to limit the collection and dissemination of prescription drug data. If I can offer you or your Committee any further information on this subject, please do not hesitate to call me at 608-262-7537 or contact me via Email at [L.C.Vermeulen@hosp.wisc.edu](mailto:L.C.Vermeulen@hosp.wisc.edu).

Thank you for your kind consideration of this information.

Sincerely,



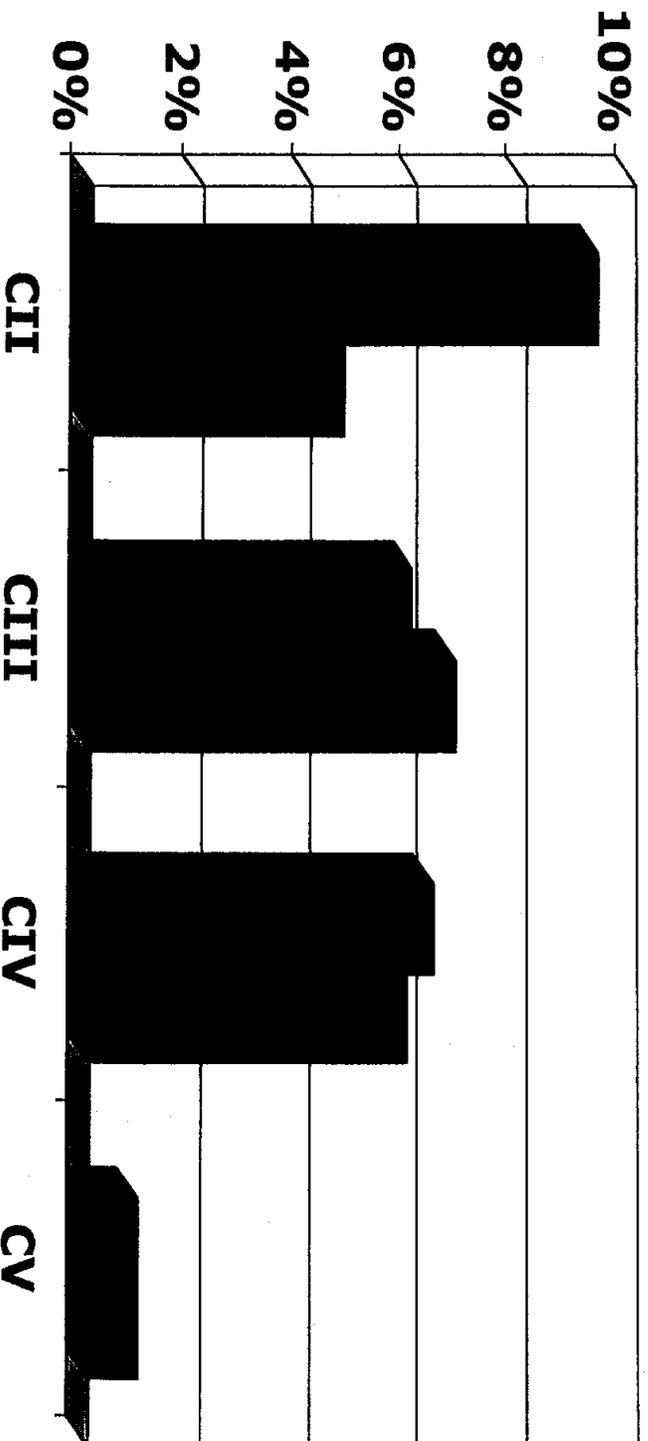
Lee Vermeulen, R.Ph., M.S.  
Director, Center for Drug Policy  
UW Hospital and Clinics  
Clinical Associate Professor  
UW- Madison School of Pharmacy

cc: Bob Hunkler, IMS HEALTH

# Controlled Substance Prescriptions

## Comparative Proportion

### New Hampshire vs. Remainder of U.S.



Controlled Substances, by schedule, as percentage of all prescriptions filled in retail pharmacies  
**New Prescriptions, 2005**

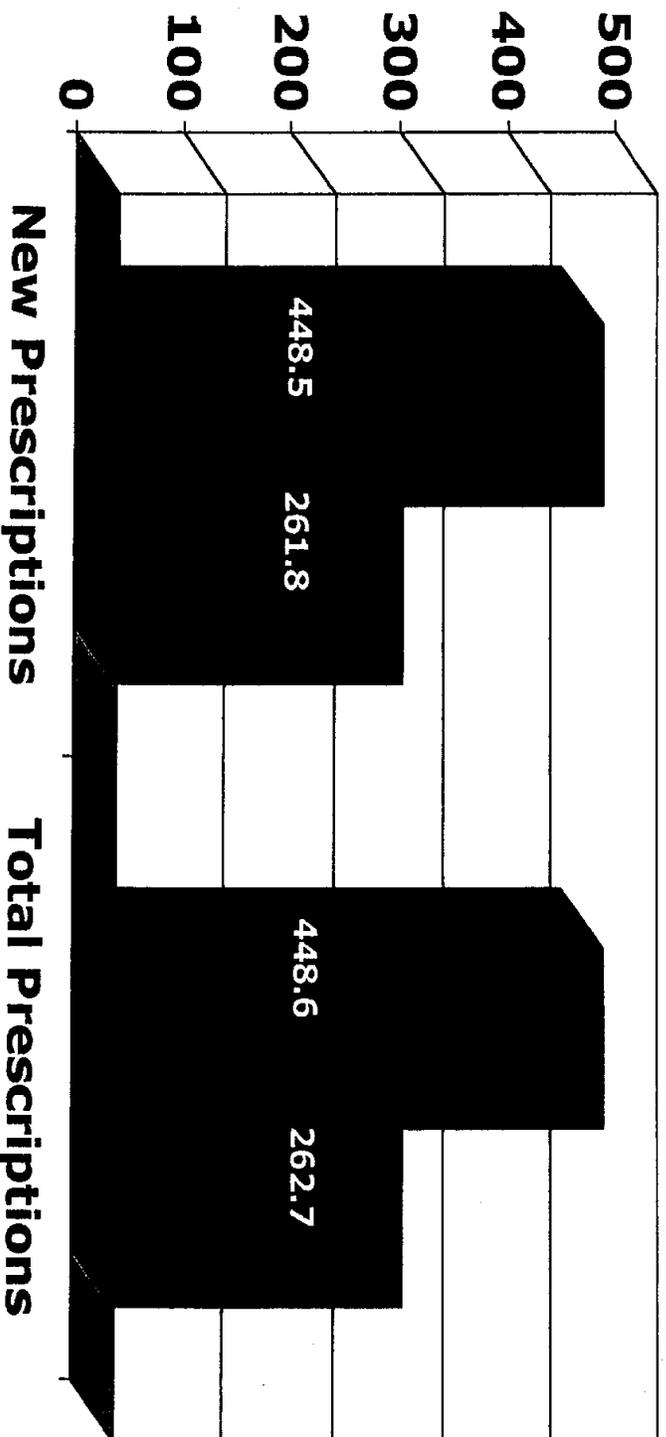
Source: IMS Health *National Prescription Audit* and *Rx Insight*



# CII Controlled Substances

## Comparative Utilization Rates, 2005

### New Hampshire vs. Remainder of U.S.



Retail-filled Prescriptions for CII drugs per 1,000 residents

Sources: IMS Health *National Prescription Audit & Rx Insight* and U.S. Census Bureau



# Top New Hampshire Prescribers OxyContin and Generic Oxycodone Products

Last Name	First Name	Specialty	Ave. Weekly Rx
XXXXXX	XXXXX	PHYSICIAN ASSISTANT	67
XXXXXX	XXXXX	PHYSICIAN ASSISTANT	64
XXXXXX	XXXXX	NURSE PRACTITIONER	53
XXXXXX	XXXXX	NURSE PRACTITIONER	30
XXXXXX	XXXXX	NURSE PRACTITIONER	30
XXXXXX	XXXXX	DENTIST, GENERAL PRACTICE	28
XXXXXX	XXXXX	PHYSICIAN ASSISTANT	28
XXXXXX	XXXXX	FAMILY MEDICINE	26
XXXXXX	XXXXX	ANESTHESIOLOGY	26
XXXXXX	XXXXX	PHYSICIAN ASSISTANT	24
XXXXXX	XXXXX	PAIN MGMT, PM & REHAB	24
XXXXXX	XXXXX	DENTIST, GENERAL PRACTICE	22
XXXXXX	XXXXX	NURSE PRACTITIONER	21
XXXXXX	XXXXX	NURSE PRACTITIONER	21
XXXXXX	XXXXX	DENTIST, GENERAL PRACTICE	21
XXXXXX	XXXXX	FAMILY MEDICINE	20
XXXXXX	XXXXX	FAMILY MEDICINE	19
XXXXXX	XXXXX	FAMILY MEDICINE	17
XXXXXX	XXXXX	PAIN MANAGEMENT	16
XXXXXX	XXXXX	FAMILY MEDICINE	16

Note: No Oncologists among Top 100

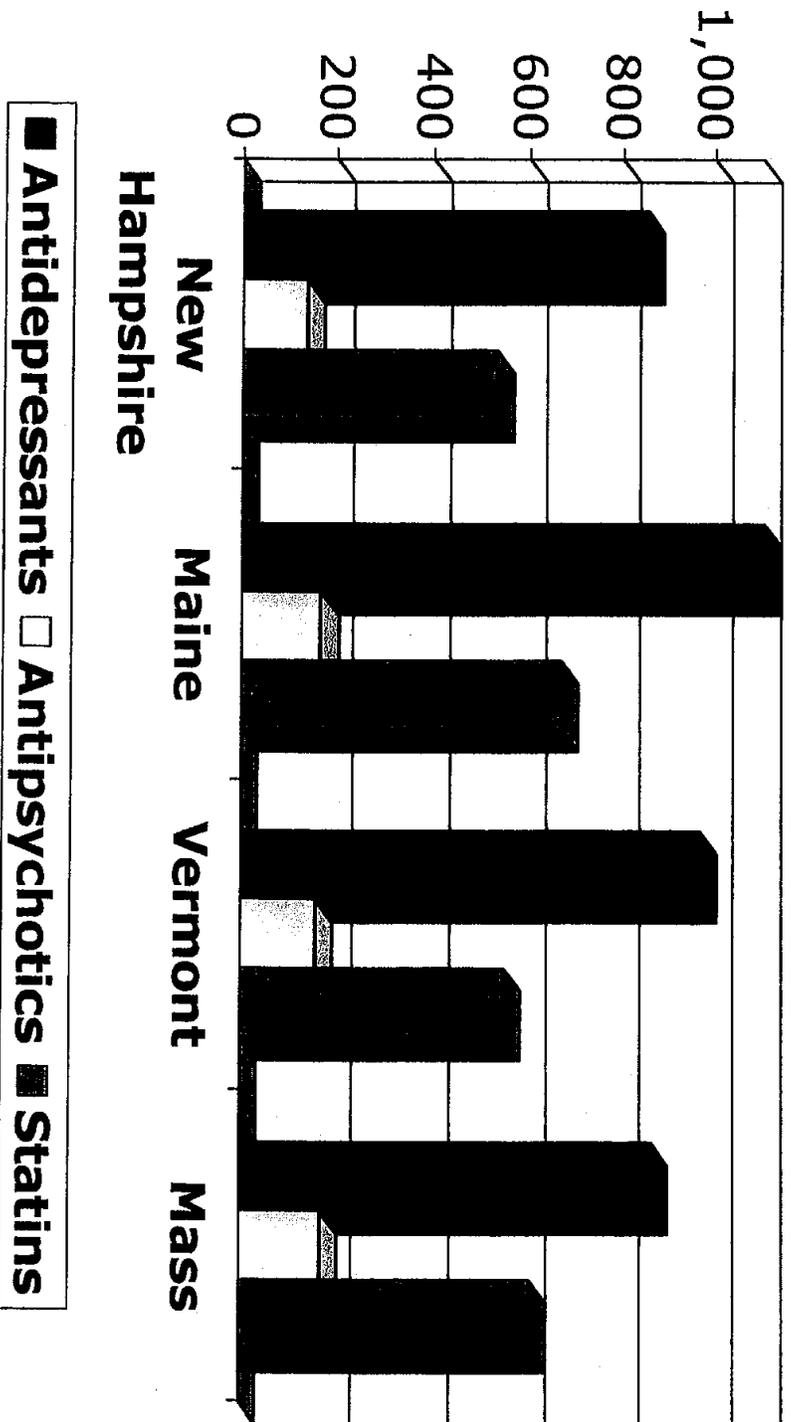
Source: IMS Health RxInsight



# Comparative Use by Drug Class

## Prescriptions per 1,000 residents in 2005

### New Hampshire vs. Neighboring States



Sources: IMS Health *National Prescription Audit & Rx Insight* and U.S. Census Bureau



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The Boston Globe  
May 25, 2003, Sunday, p. A1

## ***DRUG COMPANIES' SECRET REPORTS OUTRAGE DOCTORS***

**BYLINE:** By Liz Kowalczyk, Globe Staff

Several months ago, a pharmaceutical company salesman told Dr. Mario Motta something that surprised him. The salesman, who had scheduled a 15-minute appointment with Motta, said he knew that the doctor had been prescribing a competitor's cardiac drugs - and he wanted Motta to switch.

Motta had never discussed his personal prescribing habits with the salesman. "I said, 'How would you know that?' " Motta recalled. "I couldn't get it out of him, so I told him to leave."

Drug makers, in a level of detail unknown to many physicians, are spending millions of dollars to develop secret reports about individual doctors and their patients, according to consultants to the drug companies.

Most physicians know drug companies collect some information about which medications they prescribe. But they are often surprised by the depth of detail pharmaceutical makers now are buying about almost every US physician, mostly from large pharmacy chains. The details include whether doctors are switching specific patients from one drug to a competitor within days of it happening, and whether they treat many poor patients and may want free samples.

With many doctors now holding sales representatives to strict time limits when they visit, these "prescriber profiles" allow reps to tailor their pitches to individual physicians. They are an increasingly important tool in drug company marketing to doctors, which accounts for the largest portion, \$16 billion, of the \$19 billion that pharmaceutical companies spent on marketing in 2001, according to IMS Health, a Connecticut-based company that collects prescriber data.

"Average sales calls are shorter, and physicians are seeing fewer sales reps," said E.M. "Mick" Kolassa, a professor at the University of Mississippi and managing partner of Medical Marketing Economics, which provides consulting services to drug companies. "Because of this, the sales call has become a more precious commodity and companies need to make sure they're putting their resources in the right place."

But even though patient names are removed from the data, some doctors believe these secret reports - which they say sales reps almost never discuss openly with them - are an unwelcome intrusion into the doctor-patient relationship. Doctors worry that the reports

allow sales reps to push expensive drugs more effectively in a health care system that already is struggling with soaring costs.

"The amount of information they have about us and our prescribing is staggering," said Dr. Mark Rohrer, an internist and geriatrician at St. Elizabeth's Medical Center in Boston. "The important thing is how it's used. If it's used by a rep to pressure me to provide a different drug than the one I'm prescribing, especially if there's a generic alternative, I don't think that's right."

Several drug makers, including Eli Lilly and Wyeth, and the Pharmaceutical Research and Manufacturers of America, the industry trade group, would not comment on prescriber profiling.

Michael Barnes, vice president of business intelligence solutions at Dendrite International Inc., which provides prescription data to drug companies, said the data are used to promote safety.

For instance, the Food and Drug Administration buys Dendrite's prescribing data, which allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions, he said. The agency can then direct the company to educate doctors about the potential harm.

Prescriber profiles, albeit in a more rudimentary form, are a key element in the whistleblower lawsuit David Franklin filed against his former employer, Parke-Davis, now part of Pfizer, alleging illegal and off-label marketing of the company's top-selling epilepsy drug, Neurontin. Federal investigators are in settlement talks with Pfizer, which declines to discuss the case.

Franklin, who worked as a medical liaison for Parke-Davis from April to July 1996, said his supervisors would provide him with a doctor's prescribing record for the previous month before he went on a sales call.

A month later, they would send him the physician's new prescriptions, so he could see if the information he gave to the doctor led him to prescribe more Neurontin or other Parke-Davis drugs. Now sales reps can see within days if a doctor is responding to a pitch, he said.

If a doctor was prescribing a competitor's product, Franklin knew that his presentation should focus on undermining that product, he said.

Sales people also reviewed doctors' prescribing habits to determine who was loyal and should receive trips and gifts. The industry has since put in place voluntary guidelines discouraging lavish trips and gifts.

"The doctors it didn't work on didn't get the gifts anymore because it was throwing money away," he said. "Your physician would be stunned to find out what

pharmaceutical reps know about them before they walk into the office. We were trained in how to use this information without letting the doctor know we had it. It was absolutely imperative that you never referred to the report."

Documents recently unsealed in Franklin's lawsuit in US District Court in Boston also show Parke-Davis conducted prescriber profiling to determine whether dinner meetings, lectures, and teleconferences persuaded physicians who attended to prescribe more Parke-Davis drugs. Sometimes it worked, according to the company's analyses, and sometimes it didn't.

Since the mid-1990s, drug companies have hired outside firms that purchase data on physicians from pharmacies and used the information in marketing. It's legal in the United States as long as patients are not identified. However, the Canadian province of British Columbia outlawed the practice in 1996. But in the last two years, the data have gotten more sophisticated.

"What's really changed in the last year or two is the speed at which they can get it," Kolassa said.

Companies that buy data and sell it to drug makers are creating and advertising new products.

Verispan, based in Pennsylvania, promises on its website that a new product called Market Mover will deliver changes in doctor prescribing behavior four days after the close of the week. It's "the fastest available indicator of changes in individual prescribing behavior," the company says. The company now sends these prescriber "alerts" directly to the sales rep's laptop. Verispan executives would not discuss prescriber profiling.

Companies such as IMS Health purchased computer records or tap directly into the pharmacy computer and extract information on the 3 billion prescriptions US pharmacies fill annually, according to industry specialists. They combine this information with biographies on nearly 850,000 physicians compiled by the American Medical Association, which earns \$30 million annually licensing detailed reports on physicians, including where they went to medical school, their fax numbers, and their specialties. About 20,000 doctors have opted to be removed from the list.

AMA past president Dr. Richard Corlin said the list serves an important safety function: It allows drug companies to immediately alert doctors to a problem with a drug or change in how a medication should be used. But after some of its own members began criticizing the AMA for providing the list for marketing purposes, the organization a year ago adopted guidelines for drug companies that license the data, saying they should not use it to pressure doctors to change drugs.

AMA officials said they would consider suspending a licensing agreement with any drug company that violated these guidelines, but that they haven't received any complaints from doctors to that effect.

Verispan, IMS, and other companies also now buy data not just on individual doctors, but on individual patients and the medications they're taking. Executives at CVS and Walgreens, as well as Dendrite's Barnes, said pharmacies remove patient names and identifying details from the data and assign each person a non-traceable number. But the data include information such as a patient's insurance provider, all the drugs a patient takes, and the doses. Pharmacies would not say how much they charge for the data.

Barnes said the patient data are crucial because they follow individual patients, so drug companies can see whether doctors are merely placing new patients on a competitor's drug or whether they're actually switching existing patients off one drug and onto another - a greater cause for alarm.

If a drug company, for example, finds doctors are switching patients off of its cholesterol-lowering drug after they don't respond to a 40-milligram dose, the company can direct its sales force to focus on telling doctors to increase the dose.

With doctor-specific data, drug companies could tell only if a doctor was writing more prescriptions for a particular medication, but nothing about who was getting the drugs. The patient-specific data allow drug companies to see changes in physician prescribing behavior eight months sooner, "which could save tens of millions of dollars for the company," Barnes said.

Barnes said the more advanced data also are used to promote safety. The FDA buys Dendrite's prescribing data, for example; this allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions. The agency can then direct the company to educate doctors about the potential harm.

But even when it comes to pure marketing, Kolassa said he doesn't believe prescriber profiling is unethical. "It's done throughout business. Frito-Lay knows a lot more about you than Merck knows about individual physicians. They know whether you bought beer or Diet Coke with your corn chips. Besides, physicians can always tell sales reps to take a hike."

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**GRAPHIC: PHOTO**, Some physicians are surprised by the details pharmaceutical companies know about them. Dr. Mario Motta (above), a cardiologist, said he was shocked when a salesman recently making a sales pitch brought up his prescribing habits.

NY TIMES

January 28, 2006

## Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny

By GARDINER HARRIS and ROBERT PEAR

WASHINGTON — For years, Novo Nordisk, a Danish company and one of the earliest makers of insulin, has raced behind Eli Lilly to capture the lucrative insulin market in the United States.

When in 1996 Lilly started selling Humalog, a synthetic insulin with speedier blood-sugar control, Novo needed four more years to get approval to market a similar product.

When Lilly's huge sales force put Novo at a disadvantage, Novo fought back. The company hired hundreds of sales representatives. When Lilly struck a marketing deal with the Eckerd pharmacy chain, Novo responded with a partnership with Rite Aid.

But in its race, several former Novo sales representatives say, Novo may have crossed the line. Sales representatives paid at least one Rite Aid pharmacist to encourage switches from Lilly products or Novo's own lower-priced versions to higher-priced ones, according to documents and former and present company officials. Novo also paid doctors' assistants when prescriptions were switched, according to two former sales representatives.

Several former sales representatives said they were told by pharmacists and doctors' assistants that some patients first became aware of the switches when they picked up the new medicines at a pharmacy.

Officials from Novo and Rite Aid said that their activities were intended primarily to educate patients or improve care and that similar programs were common in the industry.

Karen A. Rugen, a spokeswoman for Rite Aid, said, "Our alliance with Novo Nordisk is standard industry practice." Ms. Rugen said, however, that Novo had paid one of Rite Aid's pharmacists directly, although she said that top Rite Aid executives had been unaware of the practice.

Susan Jackson, a spokeswoman for Novo Nordisk, said that the overall agreement between Novo Nordisk and Rite Aid "has benefited many people with diabetes."

Ms. Jackson would not address questions about payments made to doctors' assistants or a Rite Aid pharmacist, nor would she say how much Novo paid Rite Aid. But she said the partnership "is not unlike other agreements common in the industry that provide 'preferred status' for branded drugs."

But prosecutors are now investigating possible criminal violations. On Dec. 20, Novo said it had received a subpoena from the United States attorney for the Eastern District of New York for documents relating to its marketing practices.

The company said that it "believes that the investigation is limited to its insulin products." The subpoena indicated that "the documents are necessary for the investigation of potential criminal offenses," the company said.

Drug companies may pay for consulting or educational services, but federal anti-kickback statutes prohibit them from offering financial incentives to doctors or pharmacists to encourage or reward the prescribing of particular drugs, according to a 2003 guidance from the Department of Health and Human Services.

"In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful" in health care, the guidance states.

#### A Marketing Battle

The rivalry between Novo and Lilly illustrates the efforts companies will undertake to become No. 1 in a drug market, especially for chronic diseases like diabetes, which in the United States is a \$3.3 billion market annually, according to IMS Health, a pharmaceutical information and consulting company.

From a business perspective, Novo's efforts were a great success. From December 2001 through November 2005, Novo's insulin sales rose 364 percent to \$963 million while Lilly's insulin sales rose only 13 percent to \$1.43 billion, according to figures provided by IMS Health.

The marketing programs were detailed in dozens of internal Novo and Rite Aid documents obtained by The New York Times. Three former Novo sales representatives described the programs. These people, some of whom spoke to The Times separately from one another, do not wish their names to be used because all still work in the industry and fear retribution. Parts of the programs were also confirmed by company officials and another sales representative who allowed their names to be used. The former sales representatives would not comment on whether they had filed whistle-blower lawsuits against Novo.

In its marketing battle with Lilly, Novo's sales representatives undertook a variety of efforts to persuade doctors to prescribe Novo's insulin products, one of which was known as the "anchor in the office" program.

Under this program, Novo sales representatives established contacts in some medical offices that served many diabetics, three former sales representatives said. The contacts were generally

nurses or medical assistants responsible for monitoring diabetic patients. Officially, Novo paid these "anchors" to educate patients about Novo's products.

But two of the three former sales representatives who participated in the program said that Novo paid anchors as much as \$25 for each prescription they helped switch to higher-priced insulin products.

Vikki Tolbert, a Novo district sales manager, said in an interview that "people are up in arms for no reason."

"Novo, like other companies, used to have a program to reimburse nurses and medical assistants," Ms. Tolbert said. "The purpose was not to switch patients, but to educate them and train them on insulin and insulin devices."

The formal program and the payments ended several years ago, Ms. Tolbert said, but some sales representatives still wanted to have trainers, or "anchors in the office."

"We would never tell a sales rep to pay anyone," Ms. Tolbert said. "That's crazy. But some reps do things of their own volition. They are out in the field by themselves every day. Managers are not with them. A pharmaceutical company cannot know what each individual sales rep is doing."

#### Deals Becoming Routine

A number of drug companies are running afoul of the anti-kickback law. In October, Serono Laboratories pleaded guilty to two counts of conspiracy and agreed to pay \$704 million to settle criminal charges that it engaged in an elaborate kickback scheme to encourage sales of its AIDS drug, Serostim. In 2004, prosecutors accused Pfizer of paying doctors to prescribe its epilepsy drug Neurontin, and the company pleaded guilty to two criminal charges and paid \$430 million.

State and federal prosecutors are investigating scores of other criminal and civil cases of marketing abuse, all of which are under seal. The possible health consequences for patients are rarely emphasized, however. For instance, physicians say aggressive marketing of insulin products can hurt patients.

Dr. David M. Nathan, director of the diabetes center at Massachusetts General Hospital and professor at Harvard Medical School, said that switching insulin prescriptions without providing thorough counseling to patients can be dangerous.

Newer, more expensive rapid-acting insulins begin working within five minutes. Older, cheaper insulins take 30 to 40 minutes to lower blood-sugar levels. Patients who are switched from older to newer insulins without their knowledge may wait too long to eat, Dr. Nathan said.

"If their blood-sugar levels drop too low, they can become confused, lose coordination, lose consciousness and have seizures," Dr. Nathan said. "This can result in accidents and even death."

Drug makers routinely provide financial incentives to managed-care firms for greater sales, but providing similar incentives to pharmacy chains can raise legal and ethical questions in part because pharmacists' advice to patients, like that of doctors', is supposed to be based on the best interests of patients, not pharmacists.

Still, deals between drug makers and pharmacy chains are now routine. As part of these deals, drug companies pay pharmacy chains for drug promotions that can range from simple refill reminders to efforts to switch patients to higher-priced drugs. If sales then rise, payments can increase, said Jeffrey Krinsk, a lawyer in San Diego who specializes in suing over the deals.

The companies say that these arrangements benefit patients, but some pharmacy regulators disagree, saying the partnerships may result in prescriptions being switched inappropriately, hurting patients.

David R. Work, executive director of the North Carolina Board of Pharmacy, said that his board had tried unsuccessfully to restrict such deals, one of the few boards to make such an effort. The practice of pharmacy, like that of medicine, is regulated by state boards.

"These switches have nothing to do with patient interest, they're all about money," Mr. Work said.

Novo's marketing campaigns also highlight the conflicting loyalties of many health care professionals. Doctors and their staff often consult for or receive gifts from drug makers, which may affect prescribing decisions. Pharmacists sometimes suggest one drug over another to patients for financial, not medical, reasons, pharmacy regulators say.

In April 2004, Novo Nordisk sent information to its field managers and sales representatives about marketing guidelines issued by the federal government and by a trade association for the pharmaceutical industry.

After reviewing the guidelines, a Novo sales representative sent an e-mail message to Ms. Tolbert, the Novo district manager, asking, "Are we allowed to do the anchors in the office then?" Ms. Tolbert replied, "As far as I know, and in discussing it with other managers, we are allowed to compensate for patient education."

*\* A Novo district manager sent an e-mail to:*  
 In March 2004, Ms. Tolbert sent an e-mail message to sales representatives describing the purpose of Novo's marketing efforts.

"Our goal is 50 or more scripts per week for each territory," Ms. Tolbert wrote, according to a copy of the message provided to The Times. "If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!!"

Preceptorships are consulting arrangements with doctors.

After Novo announced its partnership with Rite Aid in March 2002, Ms. Jackson, the Novo spokeswoman, was quoted in Diabetes Health magazine explaining that Rite Aid pharmacists "will actively intervene to introduce Novo Nordisk products."

Novo Nordisk produces a variety of insulin products, including preloaded syringes and synthetic versions. These products are often more convenient to use but are also more expensive than standard insulin. Since diabetes is a difficult disease to manage, convenience is important. But some doctors question whether the convenience of the new products is worth the premium prices.

### One Pharmacist's Role

Lawrence M. Schultz, a Rite Aid pharmacist in Maryland, was paid by Novo to identify diabetics from databases in Rite Aid pharmacies, according to the three former Novo sales representatives.

Mr. Schultz or a pharmacy technician then contacted doctors to persuade them to switch their patients to higher-priced insulin products, according to the three former sales representatives. It is not known why doctors agreed to the changes, but the sales representatives say that they may have assumed the switch was required under the patient's insurance policy.

Two former sales representatives who contracted with Mr. Schultz and hired "anchors" say that Mr. Schultz, doctors' assistants and others told them that patients often only became aware that their prescriptions had been switched to a different insulin when they arrived at the pharmacy to pick up their medicines. The sales representatives said they knew of no patients who were directly harmed by these surprise switches.

Ms. Rugen of Rite Aid acknowledged that Rite Aid has a partnership with Novo but says that "no official at Rite Aid knew that Larry Schultz," the Rite Aid pharmacist, "was being paid by Novo Nordisk."

Mr. Schultz confirmed that he had "pushed Novo Nordisk" products. He refused to give details, but said: "Everything I did was done completely ethically. The one thing I would never do is put my job, or Rite Aid, in jeopardy."

Three Novo sales representatives who described Mr. Schultz's efforts on their behalf said they knew of no other Rite Aid pharmacist who received payments directly from Novo. But internal documents from Rite Aid provided to The Times show that Rite Aid executives urged pharmacists throughout the chain to dispense Novo products.

Rite Aid encouraged pharmacists to run computerized "drug utilization reports" to identify patients who could be switched, documents show.

Rite Aid had powerful financial incentives, documents show. In a letter to Rite Aid pharmacists in February 2005, top Rite Aid executives said, "Each Novo Nordisk product we dispense brings us 20 to 40 percent better profit margin." Moreover, they said, such sales add millions of dollars to Rite Aid's "bottom line."

Ms. Jackson, the Novo spokeswoman, said the company was "pursuing this matter with great urgency" and intended "to take remedial action in the event we find violations of our policies."

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, said marketing deals between drug companies and pharmacy chains had often misled doctors and hurt patients. .

"We are opposed to plans where the financial interest of the manufacturer takes precedence over the patient's health," Mr. Catizone said. "To call a physician and say that we're changing a patient's medication and make it seem as if it's on behalf of the patient when it's actually part of this marketing deal is not right."

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**September  
2004**

# **'Tis Always the Season for Giving**

**A white paper on the practice and problems of  
pharmaceutical detailing**

# **CALPIRG**

# **'Tis Always the Season for Giving**

**A white paper on the practice and problems  
of pharmaceutical detailing**

**Emily Clayton  
CALPIRG**

**September 2004**

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For a copy of this paper, please visit [www.calpirg.org](http://www.calpirg.org) or send a check for \$10 payable to CALPIRG to the following address:

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## **A white paper on the practice and problems of pharmaceutical detailing**

Desperate to rein in skyrocketing prescription drug costs, lawmakers, healthcare plans and individual consumers are taking a much closer look at the promotional practices of the pharmaceutical industry. One aspect that has come under heavy scrutiny is a marketing technique known as detailing. This white paper examines the mechanics and potential harms of pharmaceutical detailing, describes the steps that have been taken to address those problems, and explores policy options for addressing the issue.

### **The Process and Problems of Detailing**

Pharmaceutical detailing is a marketing method that involves individual pharmaceutical sales representatives (detailers) meeting with doctors to promote specific medications. Detailing is a multi-billion dollar business with closely monitored targets and carefully crafted promotional presentations.

The process begins when drug companies buy – often without the knowledge or prior consent of doctors – the prescribing histories of individual physicians. Purchased from retail pharmacies and then aggregated by data processing companies, this information gives detailers precise information about which classes, forms and dosages of drugs each physician prescribes. Drug companies use this information for direct mail marketing to medical offices and detailers use it to specifically target their sales pitches when they meet with doctors.

### ***Increasing Prevalence***

Pharmaceutical detailing is on the rise. Between 1996 and 2000, the number of pharmaceutical sales reps in the U.S. more than doubled from 41,800 to 83,000.<sup>1</sup> Excluding drug samples, pharmaceutical companies spent a total of \$4.8 billion in one-on-one promotion in 2000.<sup>2</sup> With samples included, total detailing expenditures topped \$12.7 billion in 2000.<sup>3</sup>

As the practice of pharmaceutical detailing becomes more popular, it becomes increasingly competitive. Detailers have a harder time keeping a doctor's attention or even getting through the medical office door. To make a lasting impression, detailers commonly bring gifts and meals along with their promotional information. These gifts and meals can range from pens, notepads and pizza to watches, golf trips and five star dining. A recent New York Times article reports that five and even six figure checks have arrived, unsolicited, in doctor's offices as a means of inducing prescriptions.<sup>4</sup> One former detailer explains the purpose of these gifts: "They buy you time with a doc, time that might change his mind."<sup>5</sup>

Several studies have demonstrated that this gift giving is having its desired effect – increasing the number of prescriptions written for the drugs that are promoted in meetings with detailers. According to research conducted by Dr. Margaret Chren of the University of California, San Francisco, "physicians were more likely to have requested drugs manufactured by specific companies if they had met with pharmaceutical

representatives from those companies or had accepted money from those companies."<sup>6</sup> Another study by J.P. Orłowski and L. Wateska showed that doctors exhibited a "significant increase" in prescribing a company's drugs after attending an all-expenses-paid trip to a drug company symposium.<sup>7</sup>

### ***Increasing Problems***

Given the unique doctor-patient relationship and the already extraordinarily high cost of prescription drugs, this gift giving practice is a cause for concern for a number of reasons. The first problem is one of perception. Regardless of any effect that the promotion may have on the prescribing patterns of a given physician, accepting gifts from pharmaceutical salespeople can create the appearance of impropriety. According to an article by Dr. Michael Steinman in the *Journal of the American Medical Association (JAMA)*, "Surveys show that as many as 70% of patients believe these gifts significantly impact prescribing, and as many as two thirds believe they increase the overall cost of medications for the public."<sup>8</sup>

Because physicians are in the unique position of choosing a specific product that someone else must purchase and use, patients must have absolute confidence in the process that leads a doctor to a prescribing conclusion. An editorial in the newspaper of the American Medical Association puts it like this: "The price to be paid for extravagant gifts isn't measured by the size of a drug company's marketing budget, but in the erosion of trust in the medical profession."<sup>9</sup>

The price tag for this promotion is another reason for concern. A recent study estimates that, not including any meals, gifts or drug samples given to a doctor, the average fixed cost of a detailing call is \$142 for office-based physicians and \$179 for hospital-based physicians.<sup>10</sup> According to the *New England Journal of Medicine*, when visits from all companies are factored in, this amounts to spending between \$6,000 and \$11,000 per doctor, per year, on direct promotion.<sup>11</sup> The U.S. total for detailing expenditures, excluding all medicine samples, is nearly \$5 billion a year. These costs are eventually passed through to the healthcare system and its consumers.

The fiscal impact of these promotions manifests itself directly in patient prescription costs as well. As indicated by a wide range of studies and the ever-increasing prevalence of the practice, this type of promotion is highly effective at changing the prescriptions that physicians write. According to the Center for Policy Alternatives, "Studies consistently prove that the practice of detailing causes doctors to prescribe the newest drugs, even when overwhelming medical evidence shows that less expensive, tried and true remedies would be much cheaper, just as effective, and often safer."<sup>12</sup>

Because companies focus their promotions on their newest, most expensive medicines, virtually any time that a physician switches to a promoted drug, the price increases. Thus, whenever a physician-oriented promotion is successful, consumers, insurers and government programs pay a higher price for their medications. A recent study in Pennsylvania found that 40% of patients in a state assistance program were given hypertension medicines different than those recommended by medical guidelines. If

doctors had prescribed according to those guidelines, the state could have saved \$11.6 million, or nearly 24% of the total money it spent on hypertension medication. The study suggested that pharmaceutical promotion was partly at fault for the variance between the medicines that were recommended versus those that were prescribed.<sup>13</sup>

In addition to the public perception and financial considerations raised by the practice of pharmaceutical detailing, the quality of the information presented by detailers is of significant concern. Numerous academic articles have criticized the incomplete nature of presentations from detailers, and research shows that much of the information presented during these interactions is actually inaccurate. A study published in JAMA found that 11% of all statements made by detailers during monitored presentations were inaccurate and that only 26% of doctors who had seen the presentations were able to recall any false statements.<sup>14</sup> The lack of complete and accurate information from detailers is particularly troublesome because companies promote their drugs most heavily as they first enter the market – a stage when little outside information is available for comparison and doctors are forced to rely more heavily on company sponsored materials and presentations.

## **Content and Inadequacies of Existing Codes and Guidelines**

### ***Content***

The problems caused by pharmaceutical detailing have not gone unnoticed by regulators, doctors, consumers and the pharmaceutical industry itself. To address the concerns raised by various stakeholder groups, a number of voluntary guidelines have been developed.

### ***American Medical Association (AMA) Guidelines***

On December 4, 1990, in response to growing concern both inside and outside the medical community about the appropriateness of gifts from industry, the American Medical Association adopted a set of guidelines to help doctors determine appropriate limits for gifts and other industry supported programs. Two days later, the Pharmaceutical Manufacturer's Association (PMA), a predecessor of today's Pharmaceutical Research and Manufacturers of America (PhRMA), adopted the same voluntary guidelines.

The document consists of a number of guidelines that physicians should consider before accepting a gift, grant, subsidy or any other inducement from an industry representative. The recommendations advise physicians to avoid accepting any gift that is of substantial value or that does not entail a value for patients. They recommend that doctors only attend meetings and conferences where the primary purpose of the event and incentive for attending is the furtherance of medical knowledge. The guidelines also advise doctors against accepting any gift that is given conditionally.<sup>15</sup>

In 2001, as part of a campaign to remind doctors about the existence of the guidelines and to encourage compliance with them, the AMA published updated recommendations with a number of clarifications.<sup>16</sup>

**Pharmaceutical Research and Manufacturers of America (PhRMA) Code**

In response to heavy legislative and public scrutiny culminating in an \$875 million settlement against TAP pharmaceuticals regarding its marketing practices, PhRMA (an industry trade group and the successor to PMA) adopted a new code of conduct in July 2002. The preamble to the code openly acknowledges the industry's desire to limit the negative public reaction to gift giving. It states that "[w]e are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large."<sup>17</sup>

The PhRMA "Code on Interactions with Healthcare Professionals" lays out recommendations for many of the same situations addressed in the 1990 AMA guidelines. In addition to outlining advisable conditions for continuing medical education conferences and consulting agreements, the code recommends a few more specific limitations. It suggests that meals be only occasional and of modest value and that meetings no longer take place during entertainment and sporting events. The code advises that gifts only be offered occasionally, that they primarily entail a benefit to the patient and that no single gift exceed \$100 in value. It further states that cash and gifts intended for the personal use of a physician should no longer be offered. The code concludes with a number of clarifying questions and answers as well as an admonition that "[e]ach member company is strongly encouraged to adopt procedures to assure adherence to this Code."

**Office of Inspector General (OIG) Guidance**

In April 2003, to address concerns about abuses in federal healthcare programs, the Office of Inspector General of the U.S. Department of Health and Human Services issued a document entitled "Compliance Program Guidance for Pharmaceutical Manufacturers".<sup>18</sup> The OIG guide gives pharmaceutical manufacturers recommendations for establishing a program to ensure compliance with applicable statutes, regulations, and requirements of federal healthcare programs.

With regard to pharmaceutical marketing and detailing, the OIG report recommends that pharmaceutical companies carefully scrutinize certain types of relationships and promotional practices in order to avoid liability under existing federal law.

The primary law addressed by the guidance is the federal anti-kickback statute (42 USC § 1320a-7b(b))<sup>19</sup>. The anti-kickback statute "is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business."<sup>20</sup> The statute and the guidance both deal exclusively protecting with public healthcare programs, including Medicaid and Medicare, from unscrupulous marketing and purchasing behaviors.

***Inadequacies***

Despite the propagation of these codes and guidelines, there are still significant shortcomings in the regulation of pharmaceutical detailing.

The OIG guidance, while essential to safeguarding the integrity of federal healthcare purchases, is extremely narrow in scope. Neither the guidance nor the anti-kickback statute addresses two key aspects of pharmaceutical detailing. First, the federal statute has no provisions regulating detailer interactions with healthcare providers who have no connection to public health care business. Second, the anti-kickback statute does not address the offer, acceptance or reporting of any gift or other remuneration not intended to solicit or reward government contracts, regardless of the relationship between the recipient and the federal government. Thus, the everyday interactions between most physicians and detailers are not regulated by the OIG guidance or the anti-kickback statute.

The AMA and PhRMA guidelines suffer from both their vagueness and their lack of enforcement mechanisms. While the revised AMA guidelines and the PhRMA code do recommend a few specific numbers (\$100 upper limit for gifts), they remain ambiguous in many areas. Suggestions that only "occasional meals" of "modest" value should be offered and that gifts "should not be offered on more than an occasional basis" are largely subjective and open to a tremendous degree of abuse. In an interview with the *Washington Post*, a pharmaceutical company spokesman admitted that the AMA guidelines "are not specific enough to be a practical guide for everyday practice in our industry."<sup>21</sup>

Because the guidelines are discretionary, they are essentially unmonitored recommendations for members of the respective organizations. Violations of the voluntary guidelines have no legally enforceable consequences. The TAP Pharmaceuticals settlement and the fact that PhRMA was forced to issue a new code of conduct in 2002 indicate the failings of this voluntary system. TAP's marketing violations were not prevented by the code and were actionable only because they involved federal healthcare programs. PhRMA's new guidelines, while commendable, are a tacit admission of the failure of the first PMA code and still contain no legally binding enforcement mechanisms.

The voluntary nature of the guidelines can also create a business quandary for manufacturers. If following the guidelines would put a company at a competitive disadvantage with a company that disregards the rules, the first company has little choice but to ignore the guidelines as well. As a former detailer posed the problem, "Here you are, working for a company that wants to abide by the guidelines, and you can't compete with a guy who's giving away tickets."<sup>22</sup> With no punitive mechanism for those who violate the recommendations, gift giving can escalate into an arms race with neither side willing to unilaterally disarm. A more uniform and enforceable standard for appropriate interactions would level the playing field for all companies.

### **Policy Options**

Without binding legislative action, there is no way to guarantee or monitor compliance with any set of guidelines or recommendations. To address the shortcomings of voluntary

self-regulation and to create a level playing field, legislators have considered and undertaken a number different of policy options.

### ***Caps and Bans***

In the past year, at least five states have considered either strict monetary limits or outright bans on gifts from pharmaceutical companies to doctors. Minnesota was the first state to set a firm cap on gift value (\$50 per gift, with some exceptions) in 1993. A total ban on gifts, while ardently opposed by the pharmaceutical industry, would entirely eliminate any appearance of impropriety in industry-physician relationships. It could also free up a large part of the \$4.8 billion a year currently spent on detailing for research or lowering the cost of prescription drugs. A legally mandated cap on either per gift or per capita spending could achieve those same goals to a lesser degree.

### ***Disclosure***

In the past two years, Maine and Vermont have enacted, and more than 15 state legislatures have considered, some disclosure requirements for manufacturers or doctors. While some bills would place the reporting requirement on doctors, most would require pharmaceutical companies to report the value, nature, and purpose of any gift or economic incentive over a certain value given to a healthcare provider. Because of the increased possibility for public scrutiny, this type of reporting would require both drug companies and doctors to carefully consider what types of gifts they give and accept. It would also give regulators and the public a clearer picture of the degree to which the voluntary regulations have brought about compliance.

### ***Codification of existing guidelines***

Another policy approach that can be taken to regulate pharmaceutical marketing is the legislative codification and enforcement of existing guidelines. Maine is currently considering a bill that would prohibit marketing practices that violate the PhRMA code or induce physicians to breach the AMA code. The California Legislature has passed legislation, Senate Bill 1765 (Sher), that would require pharmaceutical manufacturers to establish a compliance program that encompasses both the OIG guidelines and the tenets of the PhRMA code. That legislation would also require companies to publish firm, per doctor promotional spending caps and to declare each year that the company is in compliance with its own program and caps. Solutions like these take into account the steps that AMA members and PhRMA companies have already taken toward compliance, and simply work to ensure that all companies play by the same rules. While leaving room for individualized approaches to compliance, this policy option will guarantee substantial public scrutiny of industry gift giving.

- <sup>1</sup> From Scott-Levin, a pharmaceutical industry-tracking firm, as cited at <http://www.usatoday.com/news/health/2001-05-16-perks-usat.htm>. Accessed 3 May 2004.
- <sup>2</sup> "Prescription Drugs and Mass Media Advertising, 2000," National Institute for Health Care Management Research and Educational Foundation, March 2002. Available at <http://www.nihcm.org/DTCbrief2001.pdf>.
- <sup>3</sup> "Prescription Drugs and Mass Media Advertising, 2000," National Institute for Health Care Management Research and Educational Foundation, March 2002. Available at <http://www.nihcm.org/DTCbrief2001.pdf>.
- <sup>4</sup> Harris, Gardiner. "As Doctors Write Prescriptions, Drug Companies Write Checks". *The New York Times*, 27 June 2004.
- <sup>5</sup> Capaldi, Ralph, as quoted in "Visits from Pharmaceutical Reps," by Elizabeth Ellen. *Psychiatric Times*, Volume XVIII, Issue 1, January 2001. Available at <http://www.psychiatrictimes.com/p010121.html>.
- <sup>6</sup> Chren MM, Landefeld CS. "Physicians' behavior and their interactions with drug companies: a controlled study of physicians who requested additions to a hospital drug formulary". *JAMA*. 1994; 271,684-689.
- <sup>7</sup> Orlowski J, Wateska L. "The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch". *Chest*, 1992; 102, 270-273
- <sup>8</sup> Steinman, Michael. "Gifts to Physicians in the Consumer Marketing Era". *JAMA*. 2000; 284:2243. Available at <http://jama.ama-assn.org/cgi/content/full/284/17/2243>.
- <sup>9</sup> Editorial Staff. "Pharmaceutical Marketing to Physicians: Free gifts carry a high price." *American Medical News*, 10 June 2002. Available at <http://www.ama-assn.org/amednews/2002/06/10/edsa0610.htm>.
- <sup>10</sup> ROI Analysis of Pharmaceutical Promotion. Available at [http://rappstudy.org/Rapp\\_Study/definitions.html](http://rappstudy.org/Rapp_Study/definitions.html).
- <sup>11</sup> As cited by Shapiro, Dan. "Drug Companies Get Too Close for Med School's Comfort". *The New York Times*, 20 January 2004. Accessible at <http://www.globalaging.org/health/us/2004/medschool.htm>
- <sup>12</sup> Center for Policy Alternatives, Prescription Drug Marketing 2004. Available at <http://www.stateaction.org/2004agenda/35.pdf>.
- <sup>13</sup> Associated Press article reprinted in the Boston Herald. "Study: Doctors prescribe expensive drugs instead of those preferred under medical guidelines". April 20, 2004.
- <sup>14</sup> M. G. Ziegler, P. Lew and B. C. Singer. *Journal of the American Medical Association*. Volume 273, No. 16. April 26, 1995.
- <sup>15</sup> The text of the original guidelines can be found at <http://www.ama-assn.org/ama/pub/article/4001-7922.html>.
- <sup>16</sup> The text of the updated guidelines can be found at <http://www.ama-assn.org/ama/pub/article/4001-4388.html>.
- <sup>17</sup> The text of the PhRMA code can be found at <http://www.phrma.org/publications/policy//2004-01-19.391.pdf>.
- <sup>18</sup> Office of Inspector General, "Compliance Program Guidance for Pharmaceutical Manufacturers," April 2003. Accessible at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>
- <sup>19</sup> Text of the anti-kickback statute is accessible at <http://www4.law.cornell.edu/uscode/42/1320a-7b.html>
- <sup>20</sup> p. 13, Office of Inspector General, "Compliance Program Guidance for Pharmaceutical Manufacturers," April 2003. Accessible at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>
- <sup>21</sup> Petkus, Douglas, as quoted in "Drug Makers Still Lavish Pricey Gifts on Doctors," by Bill Brubaker. *The Washington Post*, 19 January 2002. Available at <http://www.washingtonpost.com/ac2/wp-dyn/A5328-2002Jan18?language=printer>.
- <sup>22</sup> Capaldi, Ralph, as quoted in "Visits from Pharmaceutical Reps," by Elizabeth Ellen. *Psychiatric Times*, Volume XVIII, Issue 1, January 2001. Available at <http://www.psychiatrictimes.com/p010121.html>.

# Statement

Attachment #156  
115  
PhRMA

Opposing HB 1346

April 19, 2006

**Position: PhRMA is respectfully opposed to HB 1346 because it will eliminate access to information used to conduct health services research and to prevent fraud and abuse. The American Medical Association has guidelines and policies related to the use of prescribing data by third parties, and provides a mechanism for physicians to "opt-out" of the use of this information.**

HB 1346, if implemented, would make the transfer or sale of "records relative to prescription information containing identifiable patient and prescriber data" "by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy for any commercial purpose, except for the limited purpose of reimbursing the pharmacy by the patient's insurance provider or the provider's agent" "an unfair or deceptive act or practice within the meaning of RSA 358-A:2" Federal law protects the privacy of protected health information. Physician names and other identifiers are used to validate and process claims for payment. These "claims data" also play an important role in public health, health services research, and the detection of fraud and abuse.

These data also assist the medical, scientific, government, pharmaceutical and health care management communities conduct to health services and outcomes research and evaluate adherence to disease guidelines and other best practices. Large databases of de-identified claims data are used to implement prescription drug recall programs, evaluate allocation of health care resources, and assess drug utilization patterns. These data are also used to identify fraud, "doctor shopping," and to curb the diversion of controlled substances.

HB 1346 proposes no alternative identifier and there would be no way to identify the prescriber of a patient's medicine. Thus, the research and practice management described above would end. This proposal will reduce the use of information technology solutions to improve the health care system, and does nothing to help patients access medicines, achieve better outcomes, or reduce their overall health care costs.

The American Medical Association (AMA) has developed Best Practices Guidelines for the Use of Physician Specific Prescribing Data to reinforce to the pharmaceutical industry the importance of responsible and ethical use of these data. These Guidelines call upon the pharmaceutical industry and its business partners to respect the confidentiality of prescribing data and prohibit disclosure of these data by sales representatives to any other party. They also emphasize that the use of prescribing data to pressure or coerce physicians to prescribe a particular drug is unacceptable. Additionally, the AMA is working to control the use of physician-specific prescribing data by the pharmaceutical industry by implementing a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales representatives by including appropriate restrictions in the AMA data licensing agreements, and communicating to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf. The AMA is also working with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their

clinical practice. (*AMA Policy D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry*)

Legitimate access to these data is essential to conducting health services research and protecting the public's health. National physician policy guides the appropriate use of these data and provides physicians with a mechanism to "opt-out." For these reasons, PhRMA opposes HB 1346.

*The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested an estimated \$38.8 billion in 2004 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures. In New Hampshire the biopharmaceutical industry employs over 1,100 individuals and the industry generates a total economic impact of approximately \$149 million. Moreover, the industry contributes over \$8.9 million in local and state taxes and supports the Medicaid program to the tune of \$10 million in rebates.*

Good afternoon, Mr. Chairman and members of the committee. I am Carolyn Finocchiaro, Associate Clinical Director of the Cholesterol Management center at Catholic Medical Center. I am here in support of House bill 1346.

I often try to take a few minutes away from my patients to speak with the drug reps that come to our office, and I think I generally have good relationships with them. However, I think they know too much about my practice style, and sometimes they try to intrude upon my treatment relationships with patients. This is inappropriate, and I'd like to give you a few examples of what I mean.

For the past several months, a drug rep has been bringing coffee to our office on Tuesday mornings. We have never asked her to continue doing this since we have a coffee pot, and we routinely make coffee for our staff and our patients. But she does it anyway, which is very nice of her. She calls this "Two for Tuesday." The problem is that every week she also says to me, "If you don't write 2 more prescriptions for my brand today, I'm not going to be able to continue bringing coffee." I prescribe her drug when it is right for my patients. There are many times when it is not right.

We feel pressure from her to prescribe her product even though we have never asked her to bring coffee. This may sound like a small thing, but I feel that since she knows exactly how many prescriptions I write each week for her drug versus the competitors, she is expecting a quid pro quo.

A second example of drug reps knowing too much about my prescribing habits is more serious. Recently, another drug rep from a different pharmaceutical company said to me, "your patients would have better outcomes if you used more Niaspan." I think this is not only inappropriate, but actually unethical for several reasons. First, even though the rep obviously knows exactly how many prescriptions I write for Niaspan, what does she know about my patients' outcomes? If she knows anything about that, it's a HIPAA violation. If she's just implying that I could improve my practice style, it's unethical. Further, there is no clinical data to show that prescribing expensive Niaspan versus generic niacin would have any beneficial effect on outcomes. It would only cost more for my patients and their insurance companies. The benefit is to the drug rep and her company, not the patients.

I feel somewhat conflicted because drug reps also do a lot of good. I can learn a lot from them, and they are always willing to bring drug samples for us to give our patients. But I don't like that they know so much about my practice style and that they try to influence how I treat patients. I think this crosses an ethical boundary into the private relationship I have with my patients. I think we should be able to have a little more privacy to prescribe the right drug for our patients based on therapeutic value alone and not feel so much pressure from the drug reps.

Thank you Mr. Chairman. I would be happy to answer questions.

Carolyn Finocchiaro  
Associate Clinical Director  
Cholesterol Management Center  
Catholic Medical Center

