

Briefing: Looking Under the Hood of Prescription Drug Importation July 22, 2004

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ED HOWARD: My name's Ed Howard. I'm with the Alliance for Health Reform. Welcome to a somewhat more luxurious setting than we're used to in the Senate, and a somewhat better meal than you're used to. Don't get used to it, as we say. On behalf of Senator Rockefeller and Senator Frist and the rest of our board, we're happy to have you here to help us look at perhaps the most hotly contested health policy topic today, that is re-importing prescription drugs from Canada and other places. Our partner in today's program—all compliments about the food should go to the Kaiser Family Foundation, who is offering support for this program, and you'll hear from the Foundation's Executive Vice President, Diane Roland in a moment.

Let me just offer you a few logistical notes. Those of you who have been to these briefings before have heard them before, but we have lots of new faces here. In the packets you're going to find a lot of background material that we hope will be useful, including—if we had them when the packets were done—the speakers' slides in hardcopy so that you can follow along. Those that aren't in there are already posted on our website so that you can go and get them when you get back to your office. You will also, by the end of today, be able to watch a video on Kaisernetwor.org and have most of the materials in your packets available electronically as well. In those packets you see a green question card. At the appropriate

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time you can write a question on it, and pass it forward. The last couple of times, we've had a lot more cards than we've had time to read, so I would urge you, if you absolutely, positively have to have to have your question asked, to get up and ask it verbally, at one of the mics that are very visible. And there is a blue evaluation form that we would ask you to fill out, and help us improve these programs.

There are really two basic arguments in the debate about re-importation, I guess, safety and savings. We're going to hear about both of those arguments today, but frankly it's impossible to do justice to either one in a program of this format and length. There's not going to be any detailed discussion of international trade arrangements or reference pricing in the European Union or macroeconomic issues that could and rightly do take up an awful lot of time of discussion in other forums on this issue. What we do hope to do is equip you with an understanding of what those safety concerns are, why states and individuals are exploring the importation, what the federal law is about that today, and what some of the proposals for changing it look like. So again, thanks to the Kaiser Family Foundation for its support and participation in today's session, and for the participation of its Executive Vice President and one of the country's leading health policy experts, Diane Rowland. Diane?

DIANA ROWLAND: Thank you, Ed, and as always, it's a

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pleasure to co-sponsor an event with the Alliance and also to have all of you join us for lunch. We're pleased that today we can offer you a little different cuisine than in some of our other briefings. I would also really like to compliment Ed for putting together this panel and for Senators Rockefeller and Frist for trying to shine a light on some of the contentious issues in this debate. We know from our work in public opinion that growing concern among Americans is rising healthcare costs, and among those costs, prescription drugs seem to increasingly dominate the discussion. When we polled the public on the issues, especially around re-importation, we see that overwhelmingly even when the arguments about quality are given, 66 percent of the public supports that they are in favor of being able to import drugs from Canada, compared to about 27 percent who have concerns and are opposed. So it's clearly an issue that has captured the public's imagination as a way of dealing perhaps less painfully than other ways, with rising healthcare costs. But I'm looking forward to our discussion today to really focus on some of the things the public really needs to know and could benefit from hearing from this kind of debate about what the real issues are behind this re-importation question. So I'm pleased to join all of the members of the panel in working with you and having you work to get the public more up to speed on this issue. Thank you.

ED HOWARD: Thank you Diane. We have some great

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speakers for you. I refer you to the biographical information in your packets as an excuse for not giving them the introductions that they deserve, or for that matter, the time that they deserve to explore the topics that we've assigned them, but we want to save as much time as we can for you to get into the act and ask the questions that you need to have better answered to understand this topic. First we're going to hear from Tom McGinnis. Tom directs pharmacy affairs for the Food and Drug Administration's Office of Policy. He's a pharmacist by training. He's been a part of the FDA for more than a quarter century. He's held a range of key positions, usually focusing on prescription drugs, and as one might infer, he is a captain in the public health service. We're very pleased to have him join us today, and a very busy day for him, having made an appearance this morning on Capitol Hill. Tom, thanks very much for joining us, and we'll look forward to hearing from you.

TOM MCGINNIS: Thank you very much. What I'm going to present to you this morning are the slides that we use in this morning's hearing in the Senate on government affairs. Senator Norm Coleman chaired that committee. John Taylor, the Chief Enforcement Officer of the agency, and Bill Hubbard, my boss, the Commissioner's Chief Policy Officer testified this morning. John gave an overview of our written testimony, and Bill provided these slides that I'm going to go over with you in the

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next ten minutes or so.

If I can have the first slide, please? This is an international mail facility. This one happens to be John F. Kennedy Airport. As some of you might know, Senator Coleman and Mayor Guiliani recently visited. JFK Airport. And if we can go to the next slide please, this is the customs officer waiting for the mail. When they see prescription drugs coming through the mail, they put them in these bins here. And the number of drugs coming in has been growing rapidly, exponentially over the last three years. Three years ago we testified that there were about a million of these little packages coming into the twelve mail facilities around the United States. A year we asked our investigators how many they thought they were getting and they told us it was about double, so we upped our testimony to about two million of these little packages coming in. Today that might be between five and ten million, so it just keeps growing exponentially. Next slide, please.

These packages here at JFK, these bundles are controlled substances. There have never been this many controlled substances in the three years that I've been going up to JFK to look at this volume. This is incredible, the amount of controlled substances that Customs actually found and are holding here for destruction. Next slide please.

The FDA contracted with a firm called Syveillance, and this is a firm that uses a web crawler to go out into the

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Internet. What we asked them to do in this particular study is to look at websites that are purporting to be Canadian in origin for selling Canadian drugs, and then pull out of those websites the sites where the registered owner is not in Canada or the ISP, the internet service provider, is not in Canada. WE suspect that those might be somewhat suspicious. We found coming back from Syveillance that there were just over a thousand such websites, that purported to be in Canada selling Canadian drugs, but the ISP or the registered owner was outside of the country. We picked every tenth one off the list and analyzed it to see what was behind there. We found that 47 of the sites we offering controlled substances to U.S. citizens, that 77 sold restricted distribution drugs. These are drugs that the FDA has approved that have serious side effects that we want patients to be in some type of registry where the firm has to follow them closely and watch adverse events. If we see an abnormal number occurring after approval, FDA will work with the firm to either restrict it even further, or withdraw that from the market. Accutane is in there. It has some serious side-effects to women of childbearing age. It will almost for certain cause a birth defect if you get pregnant while you're on that drug. Forty two contained language that said, "All of the drugs that we're shipping to you, U.S.Consumer, are FDA approved drugs," which is a falsity, and 94 had liability disclaimers which said, "If anything happens to you with these

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drugs, we claim no responsibility. You're pretty much on your own." Some of them go on to say, "If you're going to sue us, you have to come up to our country wherever we are and sue us there. Next slide, please.

This is some of the drugs that have disclaimers that I told you about, the list of drugs that claim to be FDA approved drugs. Next slide, please. Where is this organization? They say they are in Winnepeg, Manitoba. The registrant is this name here, and they happen to be in Viet Nam. Again, this is the type of suspicious slide that we pulled out. Why do they claim to be a Canadian pharmacy offering FDA approved drugs? Again, some of these sites are offering this brand name Lipitor drug, claiming to be a Canadian pharmacy, yet they let you pick what country you want it to come from, through not only Canada, but also Great Britain or Australia, are the prominent ones right now. If they run short of supply in Canada right now, they're looking elsewhere around the world for supplying these medications. So the consumer may be sending the prescription to Canada, yet it will be filled from around the world. Again, the same thing here. You get to pick where you want your drugs to come from, whether you want a generic or not. And again, Canadian generics are not the same as U.S. generics. Very few Canadian generics are approved by the FDA, because U.S. generics are cheaper. Our average survey done by the Frasnier [misspelled?] Institute in Canada found U.S. generics to be

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cheaper. If you tack on any shipping and handling charge, U.S. consumers are paying more for that generic in Canada.

Here's some of the language that you see, "Any and all suits," "Any damages"—they're trying to waive their liability if a U.S. consumer gets hurt. No U.S. pharmacy would try to do this. If you are injured with a medication, manufacturers, the pharmacy, the physician don't have any waivers of liability, as long as they follow.

This is again, one of the letters that we've seen going to Canadian pharmacies, if you run out of supply, if you're getting short, their guy's in the supply chain ready to supply product to you. This person happens to be in Pakistan, who's got product ready to go to this Canadian pharmacy if they need it.

This is another slide that we've done our investigation on called Canadian generics.com. We became suspicious when we saw what they were supplying: all those drugs down the right side, you can see are knock-offs of the brand name drugs that are still under patent, still have intellectual property rights. They're not copying the drug exactly, as the innovator firm, nor are they using the trade name of the innovator firm, so we don't call it counterfeiting under our statute. We call them knock-offs or fakes. We bought some from that site to see what they were selling. The registered owner was in Dam Dung Province, China. When we ordered our drugs they were postmarked

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from Dallas, Texas. We noticed the return address if we wanted to return them was from Miami, Florida. Our undercover credit card that we used to buy there, when we called the card company, they told us it was being billed through St. Kit's in the Virgin Islands. The phone number to call to reorder these drugs was in a country called Belize in Central America. Here's what we found when we ordered these three drugs. We ordered Lipitor, Viagra and Ambien and got the knock-off version. We checked the potency of Lipitor. It was about 50 percent. We checked Viagra; again it failed. Ambien was a little different. It was about 150 percent on average. Some of those tablets contained twice the amount of what was legal. That's a sleeping pill. So you know, you're taking two pills instead of one there. That's very dangerous. Dissolution, meaning, does that tablet disintegrate, does it come apart or remain like a brick or a stone, whereby you never get any effect from the drug, and the first two failed. Ambien passed, probably because it had so much of the drug in there. And impurities. These are truly heavy metals found as contaminants. When you're making a drug product, if you're using inferior ingredients or inferior equipment. The first two, Lipitor and Viagra did not fail in purity tests. They had some heavy metals in there. And we saw some similar results in drugs that some reporters had bought in India having these impurities in there. The Ambien passed, but the first two had impurities in there that would not be allowed

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by the FDA.

This is Governor Doyle's website in Wisconsin. Again, with a disclaimer, the Governor pretty much says, if you get hurt, you're on your own. We take no responsibility. He's making the three pharmacies in Canada, tell citizens, "You can go here and order your drugs. We've checked these pharmacies out." This is a price list. Citizens can go to one of these three pharmacies and order. Here's the price they would be paying for those drugs. There have been multiple violations of the agreement that the state has with those three pharmacies. The Wisconsin Society of Pharmacists found that about a third of the total prescriptions sent into the state, and these pharmacies have to do monthly reports for the state, so the Pharmacy Society is watching them like a hawk. About a third of the prescriptions are violating the agreement, the pharmacy is just violating them. Again, 233 of the drugs that were coming in that weren't allowed to come in on this report were being reported; 134 were non-FDA approved drugs. Six drugs required refrigeration, and the contract with these pharmacies said they're not allowed to send any refrigerated drugs in because they know in the time it takes to get to Wisconsin citizens, that icepack's going to be well melted, and that drug's going to be exposed to either high heat or high cold. We did our own review. The state actually sent warning letters to these sites telling them they have to follow the terms of the contract. We

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looked in June and July on five different dates, collecting everything coming from these three pharmacies, and we found that two thirds of the prescriptions are still violating the Wisconsin site. The pharmacies pretty much paid no heed to the warning letters they got from the state. Most of the violations are generic drugs. As I said earlier, the Wisconsin citizens would have been paying less money for those drugs at the local Wisconsin pharmacy, getting FDA approved drugs, yet they were some of these generic drugs bought at Canadian pharmacies. The contract of course, does not allow generic drugs, because the governor knows they're cheaper at his local pharmacies.

One of the things we're really worried about is counterfeiting. In the world there's a lot of counterfeiting. We've been fairly successful in the United States keeping these outside of the country. Most of the counterfeiting we've encountered in the United States has been domestic, but there have been some coming in from outside the United States. No country is immune. We're working with the Royal Canadian Mounted Police on at least three counterfeiting cases right now that I know about. This what they look like. These guys today can knock off an innovator's labeling. Even if they change it tomorrow, within six months there'll be a label that looks exactly like the innovator's where even I won't be able to tell the difference. This one looks a little beat up there because so many congressmen and senators handled them. The counterfeit

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version is not as good. They've got a nice coating on there to protect their label a little bit more than the counterfeiters, but for passing it within the distribution chain, where not too many people handle it, it stays intact. I can't really tell the difference. Here's some of the equipment that's being used to make these counterfeits. That's a rusty die. You can see the Pfizer carved out of there, just as the Secret Service sees these counterfeiters of U.S. currency carving these plates, hand carving them. Using counterfeiting machines. Again, that's the back of the plate with the stamp. Here's a tableting machine. You'd never see this tableting machine like this in an FDA-approved facility. This is what the counterfeiters are using. Here's how they dry their tablets after they coat them, again, never seeing this type of drying in an FDA-approved facility. Here's how they package them in a rented apartment here, the drugs on the bed, the vials over there ready to be packaged and a label that will fool me will be placed on there, on that counterfeit product. It will even fool the firm. The firm is going to have to do sophisticated chemical analysis on that product that's laying on that bed there before the firm will be able to tell for sure that it's not their product, these counterfeiters are so good today. Again, here are filthy conditions where these knock-off tablets are being made. Again, those tablets are being held there. Your pharmacist uses a mortar and pestle made out of ceramic. There's a big mortar

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they're using to hold these drugs. That's all for my presentation. Thank you.

ED HOWARD: Pretty good. Thanks very much, Tom. This has to be the most unusual set of slides that we've had in one of our forums in a long time. Usually I complain that speakers put too many words on their slides. You must have heard.

Now we're going to hear from Susan Thaller [misspelled?] and Donna Vogt [misspelled?] both of the Congressional Research Service. Some of you may not be aware of how important CRS is, not just keeping Congress and members of their staff up to speed on these complicated issues, but I can remember in my days on the Hill, CRS being very important to our sanity, in being able to hang onto it. When my boss threw an issue at me and needed an explanation yesterday, I had the phone number of the appropriate CRS person taped on the wall right next to me, and it was usually a person or a publication, or both, ready to help. So I have never lost respect for CRS. It's still the case, and we've got two exemplars of the depth and breadth of that understanding here today. [Inaudible] spoke with them, and we'll hear from them, serially. Donna Vogt's [misspelled?] been with CRS helping congress members and their staffs for nearly two decades. She's done a number of substantial reports on FDA-related topics. She and Susan Thaller [misspelled?] are the co-authors of the excellent summary of some of these pretty important importation bills

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that you find in your packets. Susan, in turn, came to CRS in 2002 after a decade at the Institute of Medicine. She is a specialist in the regulation of prescription drugs and biologicals, and in an earlier life headed the health staff of the Senate Veterans' Affairs Committee, which would please Senator Rockefeller, I'm sure. Today we're going to hear, first from Donna to describe current law and a little bit of history affecting the importation and then from Susan to help us understand how some of the pending bills would help to change that law. Donna, want to start us off?

DONNA VOGT: It's good to be here today. And I certainly do feel old, so I'm going to give you from my perspective, a history, a very brief history about how Congress has tried to come to grips with what they perceive as the high price of prescription drugs. That is, by allowing through legislation the importation of lower-priced pharmaceuticals from abroad. The import policy discussion is dominated by two types of drug imports, commercial and patients' personal use. Both types of imports have systems that have evolved over time. The commercial use imports: In the early 1980's the staff of the House Energy and Commerce Committee put together a series of hearings and two reports dealing with a \$10 billion problem of drug diversion, as it was called. Samples of drugs manufactured in the United States and exported were reentering the U.S. marked "American Goods, Returned." The samples of drugs,

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usually give to physicians, hospitals, non-profit organizations to distribute overseas were allegedly improperly stored or handled, labeled, were at times subpotent, or in some instances even counterfeit. So in 1988 Congress passed the Prescription Drug Marking Act, which amended the federal Food and Drug Cosmetic Act. This new law set up a whole new system of licensing of wholesalers, storage, handling and counting of drugs, and a range of criminal and civil penalties for violation of these provisions. The key here is that the new law created Section 801D1, which prohibited any imports of drugs by anyone other than the manufacturer. Under the authority of this provision the FDA established the current closed distribution system. That makes the manufacturers responsible for ensuring the safety and effectiveness of pharmaceuticals that are in retail pharmacies today. I want you to, if possible, follow along with the slides that are in your packet. The slides that are up there are an earlier version and I think this is a little more complete and you'll find it more helpful.

Personal use: Simultaneously, a different policy was developing. Begun in the mid 1980's the AIDS epidemic was expanding. Pressure was building on the Agency to allow patients who went abroad to be treated for AIDS to return to the United States with non-FDA approved medications that they thought would help them. The then commissioner of the FDA said in a speech that FDA would allow imports of drugs for

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compassionate use. This statement turned into the personal use tolerant enforcement policy of today. This new policy was useful because the agency supposedly had insufficient reviewers to handle the new pending drug applications. It took years to get a new drug application reviewed and approved. Eventually, in 1992 the Prescription Drug User Fee Act, or PDUFA was enacted. You might have heard of that. I'm sure you have. It allowed the FDA to hire over 800 reviewers to speed up the review process so that drug applications which took three to five years to approve then are now reviewed in between six and twelve months. Following the enactment of PDUFA many new drugs reached the market expeditiously. Prices for these drugs tended to be higher and continued to rise. In addition, the cost of research for new drugs keep growing. However, prices for pharmaceuticals abroad remain low, because most other countries have drug prices controlled by their governments. The price disparities between the same medications in the U.S. and abroad became more noticeable. I think you all know that now. By 2000, Congress began to get complaints from constituents about the prices of drugs. In that year, the House considered two amendments to the FY2001 Agricultural Appropriations Bill, the aim of which was to broaden who could import drugs besides the manufacturers. The Crowley Amendment said that no funds could be expended to enforce the provision that prohibits anyone but the manufacturer to import drugs. The Coburn Amendment would

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have blocked drugs from being used in a few with imports of drugs that have been approved for use within the United States and were manufactured in FDA-approved facilities in the United States, Canada and Mexico. The FDA was very concerned that these amendments would prevent them from ensuring the safety of drug imports. They said that, say, a routine inspection of a Canadian or Mexican firm could reveal problems with good manufacturing practices, in the requirements for labeling, or the agency would be prevented from taking regulatory action against unsafe or adulterated drugs. Neither amendment made it into the law. At this time, personal imports grew in volume, even though they were illegal. And they still are growing, as we've just seen. When the FDA found these packages in the mail, it would at times confiscate the product and send a letter to individuals, warning them that the FDA may take further action. Many constituents, worried that they would be prosecuted. The Appropriations Conference that year included the Drug Import Fairness Act of 2000 which prohibited FDA from sending warning letters to individuals who import drugs for personal use, unless the agency specifies how the imported drug violates the law. In the same year, 2000, the Senate took a different approach. It proposed the Medicine Equity and Drug Safety Act, the MEDSAct of 2000, which created a five-year program to allow pharmacists and wholesalers to import drugs from overseas. It also was attached to the 2001 Ag Appropriations bill. You do

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know the Ag Appropriations bill is where the FDA is from, has it appropriations. So in 2000, both the Drug Import Fairness Act and the MEDSAct were enacted. In the MEDSAct, however, Congress added a stipulation that the FDA could not implement this legislation unless the Secretary of Health and Human Services guaranteed that all imported drugs were safe and at reduced costs for consumers. Neither Secretary under the Clinton Administration nor the Bush Administration has made this certification. In December 2003, Congress included in the Medicare Modernization Act provisions. This entirely replaced the MEDSAct, so it is now our law, and it would have also permitted a program to be developed allowing pharmacists and wholesalers to import drugs from registered Canadian resources, while giving more waivers to individuals to bring in personal use imports. However, the same conditions of safety and reduced costs to consumers were included. Consequently, no import program has been initiated. Still, prices for pharmaceuticals continue to rise. Congress is under pressure currently from consumers, state governors and localities to bring down these prices. As of July legislators in 22 states have introduced more than 44 bills and resolutions that address drug imports, mostly from Canada. Some states have created websites to direct U.S. consumers to Canadian sources. You'll be hearing about Minnesota's program in just a bit. Others have suggested pilot programs to gain information on the savings benefits. Still a

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few governors sought waivers from Secretary Thompson for drug import programs.

So, the current situation remains: It is still illegal to import prescription drugs for commercial or personal use, and only manufacturers can import drugs. Last July, a year ago, the House passed HR2427, known as the Gutknecht Bill, that would allow imports of drugs. Three other proposals are under serious consideration in the Senate. All bills combine policies to make imports of drugs safe, whether for commercial or personal use. These bills would likely increase the supply of lower-priced drugs without the need for certification by the Secretary. Their effect may, and that's a big may, make drugs more affordable for U.S. consumers. Now Susan will talk about the content of these proposals.

SUSAN THAUL: Okay, Donna is the historian by training, and her CRS tenure. I'm the compulsive list maker and epidemiologist, so I'll show you a lot of lists and tables. But first I'll start with stating the problem. The immediate problem is how to set up an import drug program that ensure safety and effectiveness, and is feasible. Later we can talk about broader questions. These four bills represent the current range of options that Congress is considering. Donna has already mentioned them, so I will go on.

All four bills deal with three obstacles to making imports legal: Ensuring safety and effectiveness, covering the

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cost of the import program, and influencing the industry response. I'll go through these bills and how they deal with the obstacles, sometimes in the same way, and sometimes they differ. I'll start with safety and effectiveness: All of these bills drop the stumbling block to importation that Donna mentioned. That's the requirement of the Secretary to certify about safety and savings. So, they need to offer other approaches to offering safety and effectiveness. I really see this as two-pronged. The first one is product integrity. How do we know that the Lipitor tablet has atorvastatin calcium and not sugar? How do we know the medication labeled "Keep refrigerated" has been maintained at the right temperature in the warehouse and the truck? The other warehouse, the docks, the ship, the warehouse, the truck and the pharmacy? Or something like that. You can read this information on the flags another time. The import bills focus on the second concern, and that's appropriate use. How do we make sure that your father orders Zantac for his ulcer, and not Xanax for anxiety, or that your daughter cannot use the internet to buy Vicodin? To ensure product integrity, all four bills and current law exclude certain kinds of drugs from importation. On my computer those are check marks. For example, they all exclude controlled substances and biological products, so no Ritalin, no vaccines, and next slide. Another way the bills approach integrity is by limiting the countries eligible to take part. Mostly they try

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to select those with regulatory approval systems similar to those in the United States. The most inclusive is the Gutknecht Bill and the most limited is the Gregg Bill. I'll point out that the Jordan Bill alone distinguishes between allowable countries for personal use imports - Canada, and those for commercial imports, which is a slightly larger list. For reference currently law includes only Canada and allows the Secretary to grant waivers to other countries.

If the exporter's name and address is in the FDA's files, then we'd expect the exporter to at least thing twice before giving you a counterfeit, damaged drug. Therefore, information gathered from registration, licensure and required reports for manufacturers, exporters and importers and middle people helps with enforcement--this is the theory in the bills--and also allows authorities to trace the suspect shipment back to its source. This slide and the next few present only a shorthand view of the approaches that these bills take. All of the checkmarks are not equal, though, so you have to root out side-by-side in reports or the bills, if you want for detail.

Let's see, a little farther back towards testing, monitoring and inspecting: how do you know that the drug is what it says it is? What you can see here is that current law and the Gutknecht Bill go for laboratory testing for authenticity, and the others look more at supervision of the whole process, starting with an FDA-approved manufacturing

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facility. They go all the way through the retailer, requiring a documented and subject-to-inspection chain-of-custody record. All the bills require specific labeling, and two of them have packaging requirements relating to counterfeits. The Gutknecht Bill the counterfeit requirements are for all drugs sold in the U.S., not only imports.

Here are four ways to make sure that drugs are used appropriately: Require prescriptions, require adequate labels with instructions for use in English, allow for personal use only, and limit the supply to, say, 90-days' worth, and find a way to regulate Internet sales. This is an issue that no one really cared about five years ago, but now, think of all the e-mail spam you get. "Buy Vicodin. Buy Viagra. No prescription needed." How do you know you're not getting conned? You know by looking at what the slides that the FDA showed. Those are great stories. Only the Gregg Bill deals with Internet pharmacy. On the slide I marked in the wrong spot, under Gregg, but in Yesterday's Inside Health Policy Newsletter, they report that the Jordan Bill sponsors have added in an Internet provision. I haven't read that yet, but maybe I have some clairvoyance there. Among other points, the Gregg bill requires a prescription from a treating provider who performs an evaluation, including patient history and physical exam, and the pharmacist must provide interactive and meaningful consultation. Okay, I think I'll keep going.

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Ensuring safety and effectiveness costs money, a lot of money, and here are ten reasons why: Here's how the bills differ on how to raise that money. The big difference is the split between relying on FDA's appropriations and collecting user fees to cover the program's expenses. One of the thorniest issues is, what if industry doesn't want to cooperate? Let's say that Canada, which has been—and I'm just making up these numbers—has been making up five percent of the drug company sales, suddenly orders what would be fifteen percent. Meanwhile, U.S. drug orders go down in an equivalent amount. The drug companies will make less money. What stops them from saying, "Okay, Canada, we're going to limit you to the five percent that you've always ordered"? Not hypothetical. Drug companies are already doing that. Some of these bills try to address that with both carrots and sticks. The Gutknecht Bill prohibits companies from favoring distributors that do not import drugs under programs. The Grassley Bill has a carrot and a stick. They will increase research and development tax credit if you cooperate, and if you don't, you lose your advertising expense tax deduction. The Jordan Bill would amend both patent and anti-trust laws. It's interesting that they say that it would be illegal to produce different versions of a product, let's say blue for the United States and green for Canada for the purpose of restricting importation.

Finally, when would all these changes take place? We

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see that under the Gregg Bill, individual importations would take place first, and commercial importations would take place later. There's a lot of discussion over feasibility there. So even if an importation bill passes, will the importation program do the trick? If the FDA decides to exercise its authority, will Congress adequately fund the FDA to do so? I lasted long without coughing. How will this play out in trade agreement negotiations? How will patent and anti-trust issues play out in court? To what extent will the industry cooperate? We're talking about impact. CRS doesn't do predictions, and we don't have opinions, but we are allowed to suggest questions. So, will an import program save U.S. consumers money? Will it increase access to lower-priced foreign drugs? Would it actually lower prices in the months that follow implementation? Would these prices remain lower a year, or two, or ten years from now? Which leads to the big picture, or a big picture. If Congress wants to lower the cost of drugs to U.S. consumers, there are options, some more feasible than others beyond importation. We could encourage the use of generics or disease management techniques, provide research and development incentives to industry, encourage purchasing agreements, encourage reciprocal arrangements with other nations' regulatory authorities, institute price controls and other regulatory measures, study the comparative effectiveness of similar drugs and apply that information in benefit-package and

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prescribing decisions. Promote or provide prescription drug insurance coverage to more people. It will be interesting to see what happens when the new Medicare drug benefit begins. And we can talk more about all of these in detail, but not today. We go to my last slide, which shows how to get in touch with Donna and me. We've probably raised more questions today than we'll get to answers. You have the side-by-side comparisons in the packets, and we have a new paper issued that CRS should put out any day now. Call us when you know what your questions are, to find who you should be helping. I think I've finished.

ED HOWARD: Thank you Susan. Our final speaker today is Cal Luderman, Commissioner of the Minnesota Department of Employee Relations under Governor Tim Pawlenty. As Commissioner, Cal's responsible for the wages and benefits of [inaudible] so Governor Pawlenty's Chair of the Health Cabinet He's as former state legislator. He's involved in funding operations in South Dakota and Minnesota. We're pleased to have him joining with us today to tell us about the Minnesota experience. Cal?

CAL LUDEMAN: Thank you very much, Ed. You will notice in that biography that I know more about farming than about pharmacy. Mr. McGinnis and probably everyone on this panel can talk about drugs in a more legitimate way than I. But I think I do know when the calves are out of the barn. And so that's what we would like to talk a little bit about today. Thank you for

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the opportunity for the short visit to Washington to talk about Minnesota's program for bringing Canadian drugs to Minnesota citizens. This is a modest, not massive program, but we think it's important for you to know the details of how we think we've done this, to be looked at and talked about safely, saving Minnesotans money on prescription drugs. We're proud of what we have accomplished for the citizens of Minnesota, and think that all American consumers will be able to access more affordable prescription drugs. AS you know, Minnesota Governor Tim Pawlenty has challenged the efficiency and effectiveness of Minnesota's healthcare system, and more specifically the high costs of prescription drugs. In the fall of 2003, Governor Pawlenty announced his three-phase initiative to help reining in the high cost of prescription drugs. The first phase was to develop a website for Minnesotans to purchase prescription drugs through Canadian Pharmacies. The second phase was a website for state employees and their dependents to purchase prescription drugs from Canada. The third phase was to work with the Department of Health and Human Services and other federal officials to remove barriers for importing prescription drugs from Canada. As you know busloads of Minnesotans were traveling to Canada to purchase prescription drugs before the governor took any action. We did not know if the prescription drugs purchased were safe and effective. We did know that they cost less than if purchased in the United States. Governor

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Pawlenty believed it imperative that the states address the costs and safety issues surrounding prescription drugs, as well as the fairness of the cost issue. The Governor directed his commissioners to establish a method for purchasing prescription drugs through Canadian pharmacies to ensure that those dispensed are appropriate, safe and meet U.S. standards. In order to accomplish this Minnesota Department of Human Services staff went to Canada personally and inspected Canadian pharmacies. Their inspections, including reviewing the quality of the facilities, the source of the medications, and the licensing. The MinnesotaRX website was developed and based on staff expertise and information gathered from the Canadian pharmacy inspections. This website allowed more Minnesotans access to lower cost prescription drugs and ensures all are receiving the prescriptions as written by their doctor.

[Inaudible] Minnesotans can access 829 prescription drugs. The website was designed to be user-friendly and informative. It allows the comparison of prices, and then permits the purchaser to mail their order to the Canadian pharmacy. AS of last week, over 2400 prescription drug orders have been placed, showing great interest in this program. The second phase of Governor Pawlenty's initiative, which I had responsibility for was addressing the medication costs of 120,000 state employees and their eligible dependents. State employees receive health insurance through a self-funded insurance plan run by the state

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called the Minnesota Advantage Health Plan. The website was launched with over 45 available medications, but only 45. These selections cover eight of Advantages ten most used name brand drugs, most without generic alternatives. Medications selected for this website were designed to maximize cost savings for both the state as an employer, as well as its employees. Through this program, employees and their dependents have access to certain prescription drugs at no cost to them. Employees save because the \$15 co-payment is waived, saving \$180 per year, per drug in co-payments for maintenance prescription drugs. In addition, no shipping and handling fees are charged. Although the employee receives prescription drugs at no cost to them, the state is also saving a significant amount of dollars as well. Purchasing prescription drugs through Canadian pharmacies saves the state an average of \$208 per year, per drug. For example, Wellbutrin saves \$332 per year for the state. Lipitor saves \$192 per year. Last year alone, the state spent \$362 million on healthcare coverage for Advantage members, of which 74 million, or approximately 20 percent was spent on prescription drugs. If the participation reaches expected levels, the state could realize \$1.4 million savings through 2005. These savings will help contain healthcare costs. As of last week, over 1,110 prescription drug orders had been placed. You should also know that we continue to inspect the Canadian pharmacies to ensure quality and

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safety. Both of these programs are designed to empower individuals to take control of the healthcare decisions. We believe this is a key step in controlling healthcare costs in general.

The third phase, working at the federal level to remove barriers to purchasing prescription drugs from Canada, is well underway. We are taking a series of steps to accomplish this goal. The Governor has sent a letter to legislative leaders—I think that's in your packet—urging comprehensive legislation allowing the purchasing of prescription drugs through Canadian pharmacies. In addition, the FDA has asked us to work with the National Association of Boards of Pharmacy to ensure the Canadian pharmacies providing prescriptions through our program meet U.S. standards. We are pleased to do this. We are committed to working toward all citizens having access to fairly priced and safe prescription drugs. Thank you for your time.

ED HOWARD: Thank you very much. That's a comprehensive and pithy description of a very interesting program. We're now at the stage that we want to hear from you to ask as many questions as you would like. If you have a green card, hold it up and someone will pluck it from your hand. And I remind you that we encourage you to come to the microphone, identify yourself and ask the question orally. Let me get things started by picking up on something that I guess Tom had referred to in

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his presentation about Internet pharmacies and the vagaries that might surround ordering through them. I wonder if you'd like to comment on the findings of the GAO in purchasing drugs from a variety of Internet sources, and concluding that the Canadian websites offered the most protection for consumers?

It depends on the sample taken. I showed you a commercial firm who was able to use tools to go behind the Internet. Most of those 1,000 pharmacies that were identified to us are hiding behind the Internet. You won't find them with a Google search. They don't want to be found. They're spamming you. You've got to go to them and find them behind the Internet. So if you're doing a study and just doing a Google-type search, you're not going to find these unscrupulous characters. You'll find a lot of these U.S. sites. They do appear in some of the Google searches. The examples that the GAO got from domestic pharmacies were problematic, and we'd like to follow up with the state boards of pharmacies that have primary jurisdiction to go to those pharmacies and make sure that those pharmacies are meeting the strict standards that the state has set forth for Internet pharmacies. In the United States, the Internet pharmacies have to be licensed in all 50 states if they want to ship product to all 50 states, so that the state has recourse if somebody is injured, hurt, or has some complaint.

ED HOWARD: Yes. Can you identify yourself?

ADAM SHEFFLER: Yes, Hi. I'm Adam Sheffler from

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Chicago. This is a related question. Maybe the FDA can answer this, or the gentleman from Minnesota. Are we making a fair comparison with what the actual situation here in the United States? WE do have a very good system. It's generally safe, etcetera. And we wouldn't want to trade it in for somebody else's system, except for maybe the British or the Norwegian countries, but when we come out and talk about all the hazards of foreign-produced medications, aren't we sort of [inaudible] the more critical issues about again, how well our laws and our system are enforced here, and also about some of the deficiencies in the medications used process, where people, for various reasons, really don't get the right information about how to use the medications, some of them very hazardous or they're legally available and sold everyday, not on the Internet in drug stores.

ED HOWARD: I'll take a shot at that. I agree with you. Consumers deserve information about these drugs. They're prescription drugs, which means that they have some risks associated with them. The Agency doesn't feel that the consumers can use them on their own. We've been pushing quite a bit for information to be given to patients with their medications. The pharmacy industry has come a long way over the 20 years that we've been working with them to get written information that's of quality to consumers. Unfortunately, many of these packages that come in, there's no information, and if

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there is information, it might be in a language that's not understandable by the consumer. We worry about that, especially with the very things that I mentioned earlier, like Accutane of other products that we require a patient registry because of the serious and significant side effects associated with those products that we've approved under those narrow conditions.

CAL LUDEMAN: If I may, this is not to rationalize our program as any—to avoid the issue—but we do take precautions. Most of the prescriptions that we're talking about are not the initial prescription, just a three-month supply. It is the kind of medications that people take for a lifetime, so we're not trying to take away that relationship that you need with a pharmacy, but we have been advocating for years domestic mail-order business, obviously to save money. Whether we challenge the predictability or the safety of what is coming out of the pharmacies in these chosen fields, we don't believe is the issue here. So, the issue is the price differential between the Canadian pharmacies and United States pharmaceuticals.

ED HOWARD: Yes, Allan.

ALLEN: Allen [inaudible], Senator Biden's office. Assuming that we currently do have a problem with counterfeiting of drugs, I wonder if someone can explain in simple terms exactly how this counterfeiting problem would become worse if the [inaudible] we're taking from Canada was legitimized and regulated. Isn't it possible that

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counterfeiting might actually be reduced, as the price-sensitive consumers shifted from the current system of buying from abroad, which is basically defacto unregulated due to the lack of FDA resources, to a more regulated and supervised re-importation program that offered the lower prices that these consumers seek?

I agree with you that right now these processes that you're hearing about are outside of the regulatory system that Congress set up with FDA being responsible for the drug product, then losing their state commerce and the pharmacy boards in each state being responsible for the practice of pharmacy and that state board handling consumer complaints about the practice of pharmacy within the state, and the states requiring out-of-state pharmacies to be licensed with them so there is some recourse if a consumer has a problem. The systems we're talking about are all outside of that. There is no oversight. I showed you the [inaudible] and then packages telling them there are two or three FDA inspectors in that facility. They can look at less than one percent of those packages, so therefore in the United States, nobody's looking at them. They could be counterfeit. There's no regulatory person looking at those packages right now. The system is overwhelmed.

JOHN GREEN: I'm John Green from the National Association of [inaudible] Writers. I'd like to take a crack at

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that as well. By the time the middlemen take their cut for the [inaudible] distribution chain, and you pay for the regulatory oversight and spend the hundreds of millions of dollars necessary to set up the infrastructure, what savings are really left to be had?

SUSAN THAUL: That's a good question. When the Congressional Budget Office scored some of these Bills, in talking about the Medicare debate or talking about the Gutknecht Bill, they thought that there was not going to be a significant cost savings because of the shifting of the market and the middlemen. Other economists—we've read reports that argue the other way. I think without some kind of controlled experiment, which is unlikely to happen, or to just observe what happens in other countries, we won't know.

ED HOWARD: Susan, isn't it true that in some of the European countries, some of the parallel practiced, parallel trade that is really re-importation in another guise, brings a result like that, that the savings really aren't that great?

SUSAN THAUL: As her presentation says, most of the benefit goes to the middleman. We had the other people at—June [inaudible] is sitting there at the middle take is an economist who works at CRS and we are working with him, looking at some of these economic issues also.

ED HOWARD: Yes.

JIM WITTENBURG: I'm Jim Wittenburg. I'm a retired

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pharmacist from Oregon, Washington, Washington DC and Maryland, where I practiced pharmacy over the last 40 years. [Inaudible.] I don't know what you're talking about up here. I don't understand this. It's mostly a different language that we're speaking again. We're trying to make a difficult problem out of something very simple to resolve. I turned 65 last year, and three years ago I was diagnosed with polyneuropathy, and I never knew that a big strong guy like me could become crippled the way that I am today. What angered me other than the metro system in this town more than anything else that I've ever had to deal with—an hour and a half to get here today from Tacoma Park—I have been trying to get medication through this pharmacy drug company for over two years now to pay for something called Neurontin. At present now it's over \$450 a month, is what it costs me to keep the pain out of my hands and legs and shoulders and arms to get some relief. Six weeks ago I had to give it up. I can't afford it any longer. I no longer take Neurontin and I am in constant pain, continually, because I can't afford to buy this drug anymore. I am very bitter at the drug companies. I'm very bitter at the Food and Drug Administration. I'm very bitter at the government that doesn't protect the guy that worked all of his life, 40 years in pharmacies, and I'm seeing that the thing that I worked for the most, to be quite frank is the lowest form of life that is walking today. I fairly detest the drug companies and the Food

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and Drug Administration. You could do something about this today, and people are out there dying. They're dying because they don't have the money to pay for their medications, because they're trading medications with other seniors because they can't afford it and they're ending up in the emergency rooms dying, and you guys keep having little forums and little hearings up here, when any pharmacist could solve this problem in 30 or 40 minutes, if you just allowed someone who works in the profession to do it. I don't get it. I'm angry. I'm bitter. I hate my government. I hate my FDA and I hate the drug companies that I worked for. I'm ashamed to admit that I was a pharmacist. I apologize to all of you. We have taken advantage of you and we've used you. We've ripped you off.

ED HOWARD: I think we should go to the next question.

DAN THOMAS: Dan Thomas, Daniel R. Thomas and Associates, but also affiliated with Summit Health Institute for Research and Education, and a number of other organizations. I really should sit down after that, but I'm going to say that I am confused. We're talking about an appropriate concern for safety. Often in this discussion about healthcare delivery, including drugs, we talk about letting the market work, and yet through this discussion to date, we aren't talking about letting the market work, and we are completely forgetting what the previous question mentioned, which is, we got into this idea of drug re-importations because a

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substantial percentage of Americans, middle class or poor, aged or young, can't get medication. We've refused to look at the second part of this question, which is not just safety, and with all due respect, that is critical, but we insist on allowing the drug companies to charge whatever they care to charge, which keeps many Americans from having pharmaceutical benefits. It's at least a two-part question, and solving one part of it, only the safety part, isn't going to help us. Thanks a lot.

ED HOWARD: The people on the panel want to talk a little bit about drug costs?

TOM MCGINNIS: Yes, I guess. Let me rephrase what Dan said, not nearly so eloquently, either. If we're not going to do re-importation, what are we going to do to make drugs more affordable? Either for people on Medicare when we finally get a benefit, or for everybody else who needs help with prescription drug costs. And I would—

CAL LUDEMAN: Well that is the question. It's whether, though, the safety issue ever gets off the table, and it should never be off the table. Safety is a big issue, here and you have to be able to make sure that this is done safely. This cost thing, and you're talking to a fairly conservative Republican Commissioner from Minnesota, what has happened to drug costs is eating our lunch, and so what we had to do, and I work in a very strong collective bargaining environment in

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Minnesota, negotiating state contracts with 48,000 state employees, in fact, where they had to take zero percent and zero percent for consecutive years in wage increases because of the healthcare cost increase, and the largest, fastest growing part of that increased cost was prescription drugs. And so this little website that I talked about here doesn't solve that problem. The Governor admits that, too. It doesn't solve the problem. This unbridled cost and utilization of marketing of prescription drugs is consuming our country's mind and our thoughts in trying to find the medication that can relieve pain. At the same time the profit centers for drug companies may not be about pain anymore. It's about other, more profit-centered ideas. So what to do about that huge issue? The FDA's a role in that, but not [inaudible] role, and the costs sides. I suspect we need to confront those who need confronting, either here in Washington or in every other place, every little place we can. [Inaudible] has a concern we have to pay attention to our utilization of what goes in our mouths and [inaudible] also, very dramatically.

SUSAN THAUL: Also, I think we tried to focus our discussion today on the import legislation, because that seems to be what's moving now, where everyone's interested. It's not the only thing that Congress, or policy people or advocates are working on having to do with prescription drug prices. This is just one little piece of the picture. It may be a quick fix for

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some of the issues and not address some of the others at all.

TOM MCGINNIS: I might add too, that the Congress gave quite a bit of money to the FDA last year to beef up our generic drug program so that we can get generic drugs to the marketplace as soon as that patent expires on drugs. I've done a number of programs with congressmen who've gone out to talk about this issue with their constituents in their states. Not many of you citizens understand that there's a generic drug for almost any disease state that they have today, that they need to tell their pharmacist right up front, "I don't have any insurance coverage for these medications. I'm going to be paying for this out of my pocket. If there's a generic drug available, I want it." Many times when I was practicing pharmacy somebody would come in with a prescription for a brand new antibiotic, and I knew they didn't have any money, and I'd always ask them, "Did the doctor tell you this was going to be \$100?" And they'd say, "No. And I can't afford \$100." I'd call up the doctor and tell him, "They came in and gave me the prescription, and I told them it was going to be \$100," and the doctor would always stop—"\$100! I know they don't have any money. The detail man never told me that was going to be \$100. How much for the amoxicillin?" I'd say, "\$7.95." "Give them that. That's going to work." And the person at least got some antibiotic so they could go home and treat their condition. That's the case for almost disease state today. But patients

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need to know to tell the doctor, or tell the pharmacist, and he can call the doctor back, "Hey, they're not going to take this high-priced medication. Can I give them this?" Also, some of the states, too, have some of these programs that citizens can get into with the state subsidizing medications. Some of the states I've been out to, when the Congressman asks how many people know about this, you don't see many hands go up. There's just no oral communications to patients that they might be eligible for some of these state programs. And finally, as we heard some of the firms are starting their own programs with higher income levels for citizens of the states. It sounds like my colleague there, the pharmacist has gotten into a program that's not well managed, but hopefully the firms will get those people who will be eligible better treatment than we're hearing about today, where you absolutely have to have the brand name medication because the generic is a couple of months away from the market place. Once you've got the generic hit the market, the price will be cut 50 percent overnight. When we get three to five generics approved, where it's down to a commodity level, it'll be the cheapest product in the world, about 70 percent cheaper than if we brought it from Canada.

GAIL ALSWICK: Hi. I'm Gail Alswick from Employee Benefit Magazine. I have a question for Mr. Luderman and Mr. McGinnis. First, Mr. Luderman, do you guarantee the safety of the prescription drugs that are coming in from Canada for the

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people who order them from your state?

CAL LUDEMAN: No. Not any differently than we would for a domestic direct mail order, which we also have endorsed and have for years. But no, we do not.

GAIL ALSWICK: Okay. And Mr. McGinnis, if the FDA opposes importation from Canada so strongly, why aren't they doing more to stop it? A lot more states are starting up these programs. I think there are a few more others in the pipeline. More employers are directing their employees to where they might purchase drugs in Canada. Why aren't you doing more about that if they're so opposed?

TOM MCGINNIS: Well, we've been waiting for direction from the Congress. As you saw, there are five bills up there pending, and we were hoping to get direction from the Congress on what to do. Two years ago the Chairman of the House Commerce Committee asked a similar question, "Why aren't you doing anything to enforce this, and my boss, Bill Hubbard said, "Let me understand, Mr. Chairman. As the bus of seniors comes back from Canada, do you want the FDA to go on board the bus, open up the old lady's pocket book and take those prescription drugs away from her?" And the Chairman was in shock. And he looks down the Republican side, and down the Democratic side, and they had real long shocked faces, and he said, "No, that's not what we're telling you to do. We want to work with you on this and give you direction about what to do." And of course, we've

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not heard back from the Hill. That was two years ago. And we're still not getting those pieces of legislation moving forward. What does Congress want?

GAIL ALSWICK: Do employers have any concern, you know, if they're directing people to these sites? Is there any liability problem for employers or for states?

TOM MCGINNIS: When some of these states have contemplated these programs, myself and members from the Chief Councils Office have talked to state employees or city officials, and we outline the parts of the Food, Drug and Cosmetic Act that would be violated if they did some of these things. Virtually all of these drugs coming in are not FDA approved drugs. There's a violation of Section 801 of the act, which means only a manufacturer of these products that sent them out to Canada can bring them back. Individuals would be violating that act doing that, and that there are liability concerns. These are not the FDA approved product. If somebody is injured, you may be exposed in a liability suit. You'd be getting witnesses, that's fine, these were unapproved drugs, that should not have been coming into the country. And if you are directing citizens to these specific pharmacies to order drugs, you may have some liability exposure there.

GAIL ALSWICK: Thanks.

FEMALE SPEAKER: And Cal, we presume that's why your website has the disclaimer waiving responsibility for the

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state.

Again, more of the rationale, this is pre-packed three-months' supply maintenance drugs, that the state employee website is involved with. The RX Connect the Public site, which also has that disclaimer is a little more of a connection with a Canadian pharmacy, with Minnesota citizen, so it's more between the pharmacy and the citizen. We should note, though, as far as our experience with state employees, this is a happy group of folks, the 1100 that have used it. We anticipate this part to grow. The only complaint that I've received in my department from all the employees that have using this is, "How come my drug isn't on the list?" So, that's the only complaint we ever receive.

FEMALE SPEAKER: For Mr. McGinnis, you describe problems with Internet pharmacies, but wouldn't legislation such as the Gregg Bill help with enforcement, and what in your view is unsafe or wrong about the Minnesota approach?

TOM MCGINNIS: As I mention, right now all of this is going on outside of any type of regulatory control, whether it's by the federal government or the state board of pharmacy. It's not the same type of practice we see at the corner drug store. That's the major concern. Some of these bills are going to correct that. They'll bring these programs within the regulatory framework and state oversight, which is where we believe it needs to be.

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LAURIE YOUNG: Yes, I'm Laurie Young from the Older Women's League. I have a comment and then a question. The comment is that you keep saying these things don't happen here. Those of us who live in the Washington area are able to read the rather extensive multiple-day series that the Post did talking about the amount of counterfeit drugs that get stepped on and the number of [inaudible] processes within the United States. There's no guarantee of what I'm getting from my corner drug store is not just as counterfeit as the drug I get from the Internet and Canada. The second question that I have is, do any of you know—I think one thing that would make your argument more serious is if one of you could say, "We've had 35 deaths and 5,000 adverse reactions to drugs that came into this country over the Internet or through bus trips to Canada. To this date, I have not heard one official with the government of any number of adverse reactions or deaths associated with drugs bought from overseas. And I think that it makes it more difficult when you hear about 1100 happy Minnesotans who are getting their drugs and other people who I know are successfully getting their drugs from overseas, to say, "Well, wait a minute. I'd better not do this because I'm at risk." I mean, there's no data to support that.

CAL LUDEMAN: Well, my governor would ask the question, "Where are the dead Canadians?" and so I think he's still waiting for the answer.

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TOM MCGINNIS: I might mention that even in the United States we get the tip of the iceberg when we have those events. We don't get many adverse advents. There are many more out there than what we're getting. When you're dealing with people who've ordered drugs illegally, we suspect that when something happens they don't report. Emergency room technicians don't tend to ask the patient, "Where did you get these medications from?" if the patient comes in with medications in their hand. A lot of times patients don't keep them in the vials or containers that they got them in. When I was working at GWU Hospital for many years, I'd always be called down to try to identify what this patient might be on so the emergency room physician could treat them. If somebody with a heart condition died, then it was because there was no active ingredient in his medication, well, they tend to die from a stroke or something from the high blood pressure, never thinking that it could be a medication with no active ingredient, half strength like we saw on some of those medications we ordered and tested.

LAURIE YOUNG: So are you saying there's really no way to collect the data?

TOM MCGINNIS: Especially when you're dealing with product that's not within the distribution system. No, it would be very difficult. It's difficult enough trying to get data on what we can control.

LAURIE YOUNG: Do we collect data on those kinds of

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deaths or adverse reactions here in the states?

TOM MCGINNIS: Absolutely. And the drug firms are required to give us any of that information, required by law. We've sent some pharmaceutical company executives to jail over the past 20 years for not giving us that type of data.

LAURIE YOUNG: It might at least add credulity to your argument if you were at least to release that data, and say that in this country where we have these controls in place for safety, these are the adverse reactions that occur, and then you can extrapolate what might happen if there weren't. To my knowledge, I haven't seen the data anywhere presented in that cogent kind of a way to give people a sense of what the real risks are that are involved with getting the drugs from overseas.

DIANA ROWLAND: We have a question that relates to some of this. One of our questioners asks where your photos of counterfeit labs were taken. Were they in the U.S.? Out of the U.S.?

TOM MCGINNIS: Those were in the U.S. One was in China, and one was in South America. There are similar photos, though from the United States. It's an easier time in the United States with the jurisdiction that we have. We can go and get a warrant and go into any place in the United States. When we're dealing with foreign countries, we have to get permission from the foreign government to go into these facilities. Sometimes

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it's really easy, especially if they're making a controlled substance. The Drug Enforcement Agency has contacts with other countries and we go in with them, as we've recently done in South America.

VICKIE GOTLISCH: I'm Vicky from the Center for Medicare Advocacy. One brief comment, anecdotally. I have friends who come from doctors' offices with samples in nice plastic bags, and discover that they don't have any directions either on their packages. In fact, one co-worker who is incredibly knowledgeable went to CVS and had to argue with the CVS to give her the information because she wanted to know what was going on with this medicine. After she did all the research, she decided that she did not want to take this medicine. And one of the things she found after several weeks was that she shouldn't take it with grapefruit juice, which is what she had been doing in the morning. So it's not just imported drugs. But I have a question, Mr. McGinnis about this 1009 websites. I guess I was confused by your answer to Ed earlier. You said that some of these websites you can't find through Googling them. So I was wondering, did you 1009 every single website through which you can go to Canada? My other comment on that is on all health websites we know that some of them don't provide legitimate health information, so why is this just a prescription drug issue, and why is this not just part of the overall Internet information issue where we really aren't sure about the

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accuracy of information that we're getting on the Internet.

TOM MCGINNIS: That's a very good question. Some of these bills that are pending on the floor have some disclosure provisions in there. But they have to be like CVS. CVS wants you to know who they are, where they're located, an 800 number to call if you have any questions. They want you to know who they are and where they are. These sites, these 1009 sites, they don't want you to know who they are. If they feel law enforcement is getting close to them they're going to shut down and move. Most of the time they are getting to you by spamming you. And it's free to spam.

VICKIE GOTLISCH: So these are mostly the spam sites? Because there are some sites that are set up on legitimate Canadian pharmacies. So were those included in your survey as well? That's my confusion.

TOM MCGINNIS: No, they would have not been here, because those legitimate Canadian pharmacies using a local ISP and the registered number is generally a Canadian citizen. If you're a pharmacist there, you're living up there. So those would have been eliminated from those 1009. These are where there was some anomaly. The registered owner was in Viet Nam or China. The ISP was someplace else outside the country of Canada, and it raises a flag, "Why?"

ED HOWARD: I've got a question that the person writing it suggests it might be answered by FDA or CRS. Why don't we

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give our friends at CRS first crack at it? It has to do with the claim that re-importation would eventually effect the level of R & D by manufacturers. "From a dollars and cents standpoint wouldn't manufacturers have more to lose in larger domestic sales if they reduced R & D in response to re-importation than they would have to gain?"

DONNA VOGT: I'm going to let Jim wade in pretty soon, but I've got from Pharma a very interesting chart from last year that said they spend about 31 billion dollars on R & D, and I also went to a lecture, this was now two or three years ago, that basically talked about, it's the top 25 pharmaceuticals that are making the money. It's not the others. So you have almost every pharmaceutical companies have blockbusters, the billion dollar makers, and some have one, some have six. It's basically those that are very expensive and very costly, and they are what is paying for the R & D. Jim?

JIM HAAN: Sure. Just to give you a little bit of background, and I know that there are some pharmaceutical company representatives here, and so if I don't have the specifics, I leave the floor to them.

ED HOWARD: You'll have to identify yourself.

JIM HAAN: I'm Jim Haan with CRS. I'm an economist working on some of these issues with Susan and Donna. I think there's no question that the big successes that Donna mentioned fund the research and development for the firm. And so I don't

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think there's any disagreement that the firms, the pharmaceutical companies need revenue, whether it be lower prices because of importation revenue or what have you. I don't think there's any question that in the extreme that's going to affect R & D. The question from the policy perspective and people outside the industry is, we have no idea where that line is, where, how much revenue starts to affect how much investment in new development, new products being brought to the market. And so that's the difficulty because we know that there's likely some room for changes that will not effect the amount of new R & D that is going on. And we also know there is some point at which that will be severely impacted. We just don't know where that level is, and that's the difficulty.

ED HOWARD: Here's a very straightforward question. Is there a federal profiteering law that could be used if U.S. manufacturers try to hold supplies abroad? I should add, any other federal statute, whether it's a profiteering law or not.

SUSAN THAUL: I've heard people talk about restraints of trade things, but each company is acting on its own—that's their right to do that.

DONNA VOGT: Pharmaceuticals are sold usually through contracts, and the contracts are between the pharmaceutical company and the distributor licensed, authorized distributor of record, it's called. They set up a distribution system, in which they then put stipulations, and they can ask them not to

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resell these drugs and so on. The pharmaceutical industry is unique, I gather, from most commodity organizations, because each is quite particular. The product is very particular. That's all I'm going to say.

DIANA ROWLAND: This is a question about our international relations. Does the U.S. FDA have international working agreements with sister-type governmental bodies which allow certain drugs to be imported directly without similar testing because of similarities of the regulatory standards between the U.S. and that country? And secondly, can states negotiate importation of certain drugs under contractual agreement without FDA approval, as long as they're on an FDA approved list?

TOM MCGINNIS: Let me tackle the second, can states negotiate that bringing in products that are not FDA approved. That's the waivers that we heard earlier in the presentation. Those aren't allowed, yet. Now, the Secretary, if he certifies it, things can be brought in safely and effectively, then we can go down and possibly grant one of these waivers, but we're not there yet. That's pending. Currently it can't be done legally.

Going back to harmonization. It's called harmonization with other firms. There's an international conference on harmonization. The FDA is trying to work with foreign countries, our regulatory counterparts to try to harmonize to

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develop the same standards, to use the same standards. This may be ten, 20, 30 years out, a set of standards for the world, there will be only one package that will be marketed throughout the world. That's the ultimate goal. Currently, for FDA approval, we go and visit any manufacturing facility that wants to sell product to the United States, no matter where they are in the world. It's a requirement to see that facility with our own eyes, look at the records with our own eyes. We don't accept anybody else's inspectional standards for manufacturing and active ingredients and inactive ingredients that go into those products.

SUSAN THAUL: There was a recent agreement, a Memorandum of Understanding, I think it's called, between the FDA and Health Canada, saying that they would cooperate and share information. It's not that they're going to honor each other's decisions, but they're trying to share information to try to deal with the problems that are coming up in these kinds of discussions.

TOM MCGINNIS: I might add the World Health Organization is starting to take an active role to pull regulators together just to pretty much introduce us to the regulators, the FDA counterpart in the countries around the world. There are approximately 210 countries around the world, and from what Dr. Rego said at WHO, who is organizing this group, the top 70 countries have a good regulatory authority

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like the FDA. The middle 70 countries have two or three people in their FDA, and the bottom 70 countries of the world, the developing countries have no FDA-type authority there. That's what we really worry about, is these criminals going to those countries where there just is FDA-type authority.

ED HOWARD: Before we go to our microphone, we have just a couple of minutes left. Let me ask you to fill out those evaluations as you're listening to the last questions. I'm sure it's going to be a [inaudible] one.

BRIANNE BOTSCH [misspelled?] : My name is Brianne Botsch. I work for GlaxoSmithKline Pharmaceuticals. I'm a sales representative in DC. I wanted to comment on a couple things. One, it costs \$800 million dollars to bring one drug to market. And we have over a 90 percent failure rate when we're bringing drugs to market. So for that one billion dollar drug, it's not only covering the cost of that drug, but all the other drugs that we've tried and failed bringing to market. I also want to point out, I go into doctors' offices every single day and I have tons of literature that we hand out constantly to give people access to discounts on prescription drugs. There are so many opportunities for people who don't have insurance, who are on Medicare, to get discounts on the prescription drugs. My company really feels that no one should not get medicine that they need and that cost should not be a barrier. I wanted to say thank you for the presentation, and that physicians have

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the information to get patients the discounts on the drugs they need.

ED HOWARD: Can I just ask before you go, is there some room within the pharmaceutical industry to standardize the forms they use in those kinds of programs? What I've heard are complaints from people that were trying to participate in them, that if they're taking four different drugs from four different companies, they have four different sets of hoops to run through.

BRIANNE BOTSCH [misspelled?]: One program that comes to mind is the Together RX program. It's a yellow card in doctors' offices. A number of different pharmaceutical companies have joined together. There's an incredible list of drugs from a number of different pharmaceutical companies that that specific card will give you discounts on. In addition, we've been giving out the new CMS Medicare Drug Discount Card form in doctors' offices, so that's basically under Medicare, so that should apply to all the drugs that patients go to the pharmacies to get. I've been passing out those as well and talking to physicians about having their patients go to the CMS website and get their discount card.

ED HOWARD: Does anyone on the panel want to take one last crack at this? If not, you've given us the last word. I think we're very grateful to you for the attention that you've paid to us. We're grateful to the Senate Health Committee for

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canceling its mark-up on its topic in exactly the same time slot. We're certainly grateful to the Kaiser Family Foundation for its participation and support, and I hope you will join me in thanking our panel for a very rich and useful discussion.

[END RECORDING]