Senate Commerce, Science and Transportation Committee
Drug Importation
November 20, 2003
SENATOR JOHN MCCAIN: Good morning. Today’s hearing focuses on the debate over prescription drug importation. This committee held its last hearing on this issue just over two years ago. As I think back to that hearing, I must say I’m disappointed that to this day our laws still do not give American consumers the right to import prescription drugs. To be clear, we’re not talking today about just any drugs. Rather, we’re talking about prescription drugs that have had their safety and effectiveness certified by the US Food and Drug Administration. Nevertheless, FDA approved prescription drugs remain an exception to the free flow of trade between the United States and the rest of the industrialized world. This trade problem is stoking the fire of America’s prescription drug price crisis. The prescription drug prices paid by our sick, elderly, and uninsured are significantly higher than those of other industrialized countries like Australia, France and Switzerland. As a result, millions of our citizens travel across the border to Canada each year to purchase prescription drugs. Other purchase imported pharmaceuticals over the Internet. In all, Americans spend hundreds of millions of dollars on imported pharmaceuticals, not because they don’t want to buy prescription drugs in the US, but because they simply can’t afford to. I fully agree that demand for lower prices should not lead us to sacrifice the health and safety of our citizens. That’s why any legislation that permits the free
importation of pharmaceuticals must contain safeguards that protect American consumers from tainted or counterfeit prescription drugs. But those who oppose the importation must be to engage in a dialogue to tell us what additional or alternative safety measures they believe will work. They must stop repeatedly telling us only that there’s nothing we can do to implement an effective importation system that protects both the health and the pocketbooks of American consumers. Indeed, it seems to me that most Americans and especially those in need of prescription drugs to treat serious illnesses want us to stop listening to the naysayers and start working on a reasonable solution to the ever growing problem of excessive prescription drug prices in this country. To that end, I sponsored S-17.81, cosponsored, the Pharmaceutical Market Access Act of 2003 with several of my colleagues including Senator Dorgan and Snow. Though the act is likely not the cure all for problems with skyrocketing prescription drug prices in this country, it’s the type of legislation that would allow our citizens great access to the pharmaceutical markets of other industrialized countries while still maintaining the safety of our prescription drug supply. The act would do so by permitting American consumers to import FDA approved prescription drugs from Canada, European countries, and other industrialized nations while required safety measures such as anti-counterfeiting technology for prescription drug packaging that
is virtually identical to the technology used to secure US
currency. I hope our witnesses today will engage in a
constructive discussion about how best to strike a balance
between affordable prescription drug prices and a safe
prescription drug supply. Before we proceed any further, I
want to note my disappointment, but not surprise, that the
Pharmaceutical Research and Manufacturers of America, which has
repeatedly spoken out against the liberalization of our
prescription drug importation laws, and by the way has a very
restrictive clause in the Medicare Prescription Drug benefit
that succeeded again, they’ve declined to appear today. What a
surprise. I find it extraordinary that an organization cast for
speaking for several major pharmaceutical manufacturers on this
issue and has spent roughly 8.5 million dollars in lobbying
expenses this year, couldn’t make the time to share with us
some views of the companies that it represents. I thank the
witnesses who did accept our invitation. I look forward to
hearing your testimony and first I’d like to hear from Senator
Dorgan and Senator Wyden and Senator Lautenberg if they have
opening statements.

SENATOR BYRON DORGAN: Mr. Chairman, first of all, I
know we have a lengthy hearing so I will try to be brief, but I
do want to make a couple of comments that are important to this
subject. First of all, the subject is drug reimportation. The
fact is we import a substantial amount of prescription drugs in
this country. It’s done by the manufacturer of the prescription drug. Lipitor is manufactured in Ireland and shipped to this country. Prevacid is manufactured in Japan. Nexium in Sweden and sent into this country. So, there’s a lot of the importation of drugs going on. It is just that the pharmacists and the licensed wholesalers are prevented from reimporting, and consumers are allowed to reimport a personal amount for personal use, a very small amount, but the issue of safety has been raised, and I want to make a couple of points with some bottles here in which the same pill is put in the same bottle made by the same manufacturer and sent to two countries. And, this perhaps demonstrates it better than anyway I know. This is Celebrex and you can see the bottle is shaped the same. It’s an identical bottle. They’ve reversed the coloring on it, but the whole difference – this is an FDA approved drug, produced in an FDA approved facility, and it is the same pill in the same bottle made by the same company, 79 cents per tablet in Canada, 2.22 in the United States. The only difference between these two tablets are the price. It is identical in every other way. Lipitor, as you can see, it is the same container, same pill made by the same company, put in the same bottle, sent to Canada for 1.01 per tablet, the US 1.86 per tablet. Or Vioxx, same bottle, same shape, reverse the color just a bit and the same pill put in the same bottle made by the same company, FDA approved. US consumer pays 2.20 per tablet, the Canadian
consumer 78 cents per tablet. The only difference is the price. The US consumer pays the highest prices in the world. Now, the pharmaceutical industry has aggressive supporters here on Capital Hill, and we have an uphill battle. Let me compliment my colleague Congressman Sanders and Congressman Gutknecht for the aggressive fight they have waged in the Senate and my partner here - in the House I should say - and my partner in the Senate, Senator Stabenow and Senator McCain and so many others who have worked on this issue, but it has proven to be a steep hill to climb, and we’re going to have testimony today about this subject. One person who will present testimony is Lou Lupka from Fargo, North Dakota. He’s in the audience, and he actually went to Canada with me one Friday morning when it was snowing, and we went to a one room pharmacy in Emerson Canada five miles north of the North Dakota border, and what we discovered is the same pill five miles apart between a Pimada (misspelled?) North Dakota pharmacy and a pharmacy in Emerson Canada - identical pills, but dramatically different prices, unfair to the American consumer. So, let me make one final point. I, along with my colleagues including Senator McCain and Senator Stabenow, have introduced legislation that has passed the House of Representatives and we are very disappointed by what it appears will be included in the Medicare Prescription Drug Bill on the reimportation issue. It looks like the pharmaceutical industry wins there. So, we will have to then
try to move the bill that’s already passed the house here in
the Senate, and we are intending to try to do that with all the
aggressiveness we can on behalf of the American consumer who
now pays the highest prices in the world for prescription
drugs, and it is wrong, and it’s unfair, and it has to change.
I, too, Mr. Chairman, am terribly disappointed that the
commissioner of the FDA is not here to answer. He’s been the
biggest support the pharmaceutical manufacturers have to try to
prevent the American consumers from accessing decent prices,
and I’m also disappointed that PHARMA is not with us this
morning. But, nonetheless, I appreciate the chairman calling
this hearing on this very important subject.

SENIOR JOHN MCCAINT: But, I’ve never been to a
fundraiser that there isn’t a PHARMA representative there. I’m
sorry to say. Senator Wyden.

SENIOR RON WYDEN: Thank you Mr. Chairman, and I too,
appreciate you holding the hearing and you and Senator Dorgan
and all of our colleagues at the table have done a lot of work
in this area, and I think it’s very timely that this hearing be
held now because my understanding is with respect to drugs
overseas now, we’re starting to see the same problems there
we’ve seen everywhere else. The prices are starting to go up.
The wait that seniors face for their medicine is increasing.
And, it seems to me that as we look at this issue of drug
importation particularly the developments in recent days, we
also focus on the fact that there really is no substitute for what’s going to help seniors contain costs, and that is bargaining power. Until there are steps taken either in this legislation that we’re going to vote on in the next few days, or some other piece of legislation to give seniors bargaining power in the marketplace, I don’t think we’re going to see any real change with respect to the price of pharmaceuticals. My understanding about the legislation that we’re looking at now, not just in the area of drug reimportation, but with respect to what’s done in managed care plans, what’s done in private plans, there still is not yet the bargaining power that seniors are going to need with respect to actually holding costs down. I think we understand what a disgrace it is that in the richest country in the world with all of this talent in the healthcare arena, we have senior traipsing throughout the world trying to find affordable medicine. So, put me down on record that for any kind of cost containment strategy that is safe and that promotes more affordable medicines for seniors, but I think we ought to be looking at this issue now because my understanding, just in the last couple of days from seniors, is when they are looking to Canada and other parts of the world, in the last few days they have seen price increases in those areas. They have had to wait longer for their drugs, and I think this reinforces the question of doing this job right, and the way you’re going to do it right is by creating bargaining power for seniors in

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the marketplace. And, I wrap up by –

SENATOR JOHN MCCAIN: Which is prohibited in the Medicare Bill.

SENATOR RON WYDEN: Correct. I wrap up by way of saying almost 30 years ago, Mr. Chairman, when I was co-director of the Oregon Gray Panthers, I did what Senator Dorgan is eloquently doing today which is I brought a prescription drug bottle, and at that time we were working for generic drug pricing. Through your leadership and Senator Schumer and others, we’ve made a little bit of headway there. I think we ought to understand that we have a long, long way to go in this fight, and I look forward to hearing from our witnesses today.

SENATOR JOHN MCCAIN: Senator Lautenberg?

SENATOR FRANK LAUTENBERG: Thank you, Mr. Chairman. I look at the material that our friends from North Dakota produced, and it looks - the bottles look the same apart from perhaps some coloration, but on one package or another. The question is exactly what’s in the package? I would suggest that just to be sure because on of the concerns, one of the criticisms is that there have been in the past incidents where a drug sold under one name does not have the same content or the same quality, and I would suggest to the Senator from North Dakota that just to put a total cap on this is perhaps to have a laboratory access these, make sure the ingredients are identical and to make sure that we get what we see.
SENATOR BYRON DORGAN: I might just say to the Senator from New Jersey, that was part of the Senate Bill that was passed, and those protections are in the reimportation legislation.

SENATOR FRANK LAUTENBERG: Well, they are now, but what we’re looking at at the moment doesn’t pass the same quality test that’s required.

SENATOR JOHN MCCAIN: We have witnesses Senator Lautenberg. Would you complete your opening statement, and Senator Snow is here, so we can get to the witnesses?

SENATOR FRANK LAUTENBERG: All Americans are affected by the high costs of prescription drugs. This burden falls largely on the senior citizen population. And, nearly 14 million seniors have no insurance that provides for them to get the prescription drug benefits. So, they’re forced to pay full rate. Additionally, 50 million Americans under the age of 65 also lack prescription drug coverage. With drug prices increasing, 15 percent in 2001 - the seventh straight year of double digit increases - seniors and working class Americans are forced to make impossible changes between the medication that they need and food and shelter. I’m concerned as the chairman or anybody else is about the fact that prices can be substantially lower in Canada for the same prescription drug sold here in the United States. And, we know the reason for this price, and I assume that my colleagues who were to use the
expression used by the Senator from North Dakota, aggressive about this, and we should be aggressive. Included in that framework is price controls. Now, if that’s what we’re looking for here as a substitute for the free market where the most of the development of these new products is done and with lots of failures along the way, then we have to step up and say so. In Canada, the price of a newly founded prescription drug can not exceed the highest price of an existing drug used to cure or treat the same disease, and drug price increases generally can not exceed increases in the Canadian DPI. The system’s good for Canadians, and we are basically subsidizing. It’s our drugs that they’re taking. They develop few new drugs of their own. There’s not economic incentive to do so. American pharmaceutical manufacturers develop 45 percent of all new drugs worldwide, and it can take up to 15 years, as much as 500 million dollars to get a new drug to market. I want to be clear here. I agree that drug prices in the United States are too high. The products are too good. The longevity has improved substantially. I’m one of those who’s a, I hope, a shining example. I don’t think that it’s the same prescription. I don’t think it’s right that the same prescription drug can be found for retail prices that are 30, 40, even 50 percent less in some European countries. What’s going on here is that these countries get a free ride. They benefit from the new drugs that are developed here, while they leave American consumers to bear
the financial burden of developing and testing a drug, but I don’t think that reimportation, even if it’s coming into Canada, is necessarily the best way to reduce the burden on American consumers. What works for a country of 30 million people isn’t necessarily the same prescription for a country with close to 300. Canada simply doesn’t have a system in place to handle large cross-border trade in pharmaceuticals and guarantee their safety. Do we want to reduce prescription drug costs in this country? Then Congress should develop the legislation, have an honest debate on the issue, instead of an ad hoc backdoor policy where the risks sometimes outweigh the benefits. Wednesday’s New York Times reported Internet pharmacies have recently sprung up that claim to be based in Canada, but do business from other country using a Canadian domain name. Now, I don’t whether there’s a network of entry that we’re looking at here, but I think we have to make sure that we fair it out. American’s looking for cheaper drugs abroad should not be gambling with their health. We had an opportunity to fix the problem of high drug costs for seniors by expanding Medicare to include a prescription drug benefit, and then using the enormous bargaining power of the federal government to negotiate buy-in discounts, but we didn’t do that. Instead, Congress is posed to adopt a haphazard prescription drug plan that contains significant gaps in coverage and doesn’t an awful lot to bring the crisis down even

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though it will cost us 400 billion dollars. So, I regret that we missed an opportunity to do something that would have made, perhaps, this hearing unnecessary. We must get on with the price differential, and I want to do something about it as well.

SENATOR JOHN MCCAIN: Senator Snowe.

SENATOR OLYMPIA SNOWE: Thank you, Mr. Chairman, and I appreciate the fact that you’re holding this hearing to focus on this most critical issue that’s facing so many Americans, and it’s a problem for which a solution is long overdue, and so I appreciate your leadership, and I think the Congress does have a responsibility to address this issue. As I know Senator Dorgan has done so much in the past, and Senator Wyden, on this issue and passing this legislation for the last three years in two consecutive Congresses, and yet we have not been able to implement this legislation because it’s predicated on the Secretary of Health and Human Services Safety Certification requirements. And, as the prescription drug medication – the conference report is pending before the Senate, it will include this similar positions, but we have yet to overcome the hurdles of those safety certifications. And, I think it’s unconscionable, I think it’s unreasonable that we have not been able to surmount these hurdles in order to make sure that our consumers, our seniors, have access to affordable medications. The fact of the matter is our American seniors are desperate
enough to have to travel across the borders. That is true for Maine seniors who have taken busload after busload to go to Canada to access affordable medication because otherwise they have no access to prescription drugs that they so desperately need and otherwise would be out of reach. It’s not only a matter of quality of life, it can be a matter of life and death. And, it’s interesting in the papers the other day, as we’re all familiar with the charts, but they showed a survey in Maine to low-cost providers and they compared drugstores. One in Maine and a number in Canada as well for 15 drugs, there was 804,000 dollars. The lowest price in Canada was for 355,000 dollars - 50 percent less, and that’s the problem. And, so albeit that we’re going to have a prescription drug benefit as part of the Medicare program, it will do nothing to address the costs. There’s no wonder that more than 70 percent of Americans want reimportation. They want the ability to access those lower cost medications because we all know the fact that drugs sold in other industrialized nations are selling for far less than they’re selling for here in the United States. In fact, the National Institutes of Health did a survey on the top 21 most important drugs, and 15 were found to have been developed using knowledge and techniques from federally funded research. The fact of the matter is America’s investments and philanthropy has been shared worldwide. The one thing that hasn’t been shared are lower price medications. We are paying the highest
prices in the world. Americans are bearing the disproportionate burden for the research and the development, making these new medications and innovative medications available to consumers worldwide, and yet their bearing the highest price in prescription drugs. Now, people say importation, reimportation, isn’t safe. Now, we – I can’t believe in America we can’t develop innovative techniques to ascertain the safety standards that are necessary to meet the requirements under the legislation and the laws that have passed previously in the current pending legislation in the Medicare conference report. I can not believe that the FDA can not meet those standards or the challenges involved in that legislation. We can’t develop anti-counterfeiting packaging. We mandated a 1992 pedigree requirements so that you can add the bar codes to track the medication. I can not believe that the FDA hasn’t been working diligently and vigorously with the – within the government, with consumers to make sure that we could meet those standards when Congress has passed this legislation time and time again. Yet, FDA’s spending more time in Canada convincing the government not to sell medications here in the United States and scaring seniors, essentially trying to shut down the borders, and yet their not investing the appropriate time to meet the standards within the laws, and meet the intent of Congress that has passed this legislation on two different occasions that has become law. So, I think we do have a
responsibility. Reimportation of drugs isn’t a problem. It’s one of a number of solutions. And, I think we have to address not only the issue of providing a benefit to American seniors, but we also have an obligation to address the cost that’s associated with prescription drugs that can make all the difference for the life of an American senior and American consumer. So, Mr. Chairman, I appreciate your efforts here today, and hopefully this will be the beginning of developing and facilitating a process by which we can solve this problem. Government should be helping to serve American seniors, not being an impediment to preventing their access to something that they clearly depend on and need. Thank you, Mr. Chairman.

SENATOR JOHN MCCAIN: Thank you very much, Senator Snowe. We had a hearing a few weeks ago, you know, on these dietary supplements, and in nine years since the passage of that bill and the FDA still has not written the regulations associated with it. So, placing our trust in the FDA is, I would say, somewhat misplaced. I want to welcome our colleagues in the House and the Senate here today. Senator Rick Santorum and Senator Debbie Stabenow and Representative Gil Gutknecht and Representative Bernie Sanders are here. We’ll begin with Senator Santorum. Welcome, Senator Santorum.

SENATOR RICK SANTORUM: Thank you, Mr. Chairman. I appreciate the opportunity to be here and to share my perspectives on this very, very important issue. I know a lot
of people here believe that the reimportation of prescription drugs from Canada will solve what ails the American healthcare system. I would argue that you, by doing so, would be attempting to treat the symptoms. You will not cure the disease, and I would argue to kill many patients in the process. Foreign drug importation may seem like a straight-forward and attractive remedy to prescription drug access. It in fact, will create a host of serious healthcare consequences. Number one – it will import, potentially import, foreign price controls into this country. Two – it will decimate the research and development of pharmaceutical products in this country, and I know there are a lot of people on this panel who hate the tariffs that have been posed on steel, and we do so much around here to help save an industry. We have an industry here in the pharmaceutical industry which is one of the most competitive industries in the world, and exports pharmaceutical products all over the world, and so the answer is here is try to somehow knock it on it’s heels. I don’t think that’s necessarily a good thing for this country or for our economy. It undermines – reimportation undermines the FDA’s authority to regulate drugs and opens up US borders to diverted and counterfeit drugs from foreign sources. That, to me, is not necessarily a prescription for better healthcare in this country. The side effects are all too predictable, and much worse than the perceived disease itself. The proponents of foreign drug importation claim

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they’ve discovered a miracle cure for American healthcare, and what they’re doing is basically selling snake oil to the American public. While the problem of affordable access to prescription drugs is real particularly in the elderly, there are better and safer ways and effective ways to solve this problem, more so than simply opening up borders to cut-rate foreign drugs. In fact, the best way to do it is something that we’re considering this week, which is to pass a Medicare drug benefit. This will assure seniors to affordable access through safe and the best prescription drugs in the world. This means access to drug products that FDA has stamped with approval, and it comes with the iron-clad assurance that they’re safe, authentic, and effective, which is something that reimported drugs could never be claimed to be. What the Congress should focus its attention on candidly is the international drug price disparities that have given rise to this debate in the first place. I agree with everybody here that it’s unfair for Americans to pay more for their medicines then the rest of the world, but the answer is not to adopt what the rest of the world has done which is price controls and import them into this country. What we should do is insist that other countries pay their fair share. This is a trade issue, and we should be out there aggressively trying to work through our trade offices and through here in the Congress to get the rest of the world to pony up and to bear their costs of that we
bear here in America which has to do with the research and
development of new drugs. While Canada is by no means a third
world country, many of the drugs that are funneled through
Canada come from third world countries with significant
counterfeit problems. A recent five part series in the
Washington Post, my favorite newspaper, highlights the threat
posed by counterfeiters, and if you’ve not read this series, I
urge you to do so. While America’s drug supply remains the
safest in the world, it is under constant attack from well-
funded, highly organized and technologically savvy foreign and
domestic counterfeiters, some connected to organized crime and
some connected, perhaps, to terrorist organizations. Under
current law, these counterfeiters face significant hurdles
getting their products into commerce, but if we open up the
borders to Canadian drugs, we will, in fact, increase the risk
of these counterfeit drugs coming into this country - not a
positive thing for the health and safety of our population. The
lesson here is that we should be focused on strengthening
protections, not opening up our borders to new assaults on the
safety and health of the American people. We recently
strengthened the protections regarding imported food, which I
know some members of this committee were very strongly in favor
of. It’s inconceivable while we’re doing that that we are going
to weaken our borders when it comes to something that is
critically important and something that can be counterfeited

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and tainted very easily, which is prescription drugs. The price of drugs in Canada is lower than in the United States purely and simply because Canada has price controls. I find this an incredible argument that this is a fair trade or free trade issue when what the free trade is – is to import drugs that have price controls on them. There hasn’t been an increase in prices in Canadian drugs in eight years – eight years, they’ve controlled prices haven’t increased those levels. This is free trade allowing price controlled drugs into this country? Manufacturers that refuse to meet these price controls, what happens to them? Well, they can have their license revoked to sell their product up there. In other words, they can have their products stolen. They can have a compulsory license, have their patent stolen, and have it produced in Canada. This is free trade? This is what we want to condone by the Canadian government and other governments by taking the drugs and having them reimported back into this country? I don’t think this is a free trade argument. This is trying to use the bullying tactics of the Canadians to beat drug companies up in this country to lower their prices. Importing cheap prescription drugs from Canada means importing price controls and all that comes with it – long lines, drug shortages, and the decimation of research and development. The drug industry is the most vibrant, innovative, and productive in the world in this country, in part because the market base system permits it to recoup it’s
massive costs in research and development. In spite of the
subsidizes that are received by getting research done through
the federal government, which the lady from Maine talked about.
It cost roughly one billion dollars to bring a new drug to
market. Someone has to pay those costs, or those drugs are
simply not going to be produced, and the fact is Canadians are
not paying that cost, which is obviously one of the issues that
we need to address. I would say two things in closing – number
one is the safety issue, and I know people seem to dismiss
this, but the fact is you have two Secretaries of Health and
Human Services under two different administrations says it’s
not safe. DEA, US Customs, the FDA has described the present
situation as “buyer beware”, and we want to make this a more of
a common thing in this country. I just find completely
unacceptable for the health and safety of the people in this
country. And, finally, I would just say that anyone who
believes that the pharmaceutical industry that reimportation
would put in place to the small country of Canada, they sell
drugs up to Canada basically in sufficient numbers to meet the
demand in Canada. Now, if we’re going to have reimportation
which means Americans are now going to be able to buy drugs in
Canada, do you think the drug companies in the United States
are going to produce enough drugs to supply all the drugs
through Canada back to the United States? Well, the answer to
that is of course they won’t. They’re going to produce enough

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drugs in America to sell to meet the market in Canada. Well, what will that mean to - what drugs will then be coming? Do you think the Canadian government is going to give these good quality American drugs to be sold back into the United States? Of course they won’t. They’ll save those for their own people. So, what are we going to get reimported? Nothing will be reimported back to this country. We will get imported drugs from third world countries because Canada simply doesn’t have the ability to manufacture them in their country. So, we’ll get third world counterfeit drugs coming through Canada with a stamp of approval from the Canadian government when they haven’t inspected them in the first place. This is not reform. This is a safety boondoggle for a lot of folks who are not necessarily looking out for the best interest of the American public and something that we should not count and support. We should go out and aggressively go after countries who fix prices, who don’t pay their fair share. That’s the answer to the problem. Thank you, Mr. Chairman.

SENATOR JOHN MCCAIN: Thank you very much Senator Santorum. I know you have other responsibilities. I know that Senator Dorgan would love to discuss this with you.

SENATOR BYRON DORGAN: Mr. Chairman, surely Senator Santorum will not leave now. We do have questions.

SENATOR RICK SANTORUM: I’d be happy to stay for questions.
SENATOR BYRON DORGAN: I would hope you would. Since you talked about killing patients and so on, I certainly want to ask him about killing many patients. So, if he has the time, I think it will be helpful to our committee if I was to ask him a few questions.

SENATOR JOHN MCCAIN: I would ask if it would be possible for Senator Santorum. This is an emotional issue. I think we all realize it, but I think it would be fair to the other members if they could give their statements. I know your time is limited, Senator Santorum, but I think it wouldn’t be appropriate if we engaged debate with Senator Santorum, and not allowed our other colleagues to make their statements. Would that be great release Senator Santorum?

SENATOR RICK SANTORUM: If I could run for a few minutes while these folks – I have something that I have to do, and I can come back.

SENATOR JOHN MCCAIN: Thank you. Obviously, we would appreciate it, and I also would remind my colleagues, we have two other panels following this one. Senator Stabenow?

SENATOR DEBBIE STABENOW: Well, thank you Mr. Chairman, I very much appreciate the opportunity to be here, and I, too, would love the opportunity to debate Senator Santorum line by line in terms of his testimony, and I realize that there are many opportunities for the committee to ask questions today. I want to first thank you for your leadership as it relates to

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the issue of closing patents and putting more generic drugs onto the marketplace. I’m pleased to be a co-sponsor of the legislation that we originally passed in the Senate that actually, on a bi-partisan basis, would make a real difference. I’m very concerned about what appears to be watering down of that legislation, and the final Medicare bill. But, I thank you for your leadership and for all of my colleagues on the committee who have been involved in the issue of reimportation, particularly Senator Dorgan, who has I know been a leader far beyond my time in the Senate and Senator Snowe, and I would only say that my first legislation, my first bill introduced and coming to the Senate in 2001 was on this issue. I believe we have two important challenges in front of us. One is a real Medicare prescription drug benefit, and the other is lowering prices for everyone, and if we were to pick the one that would make the difference the quickest, it would be this issue. Even the bill in front of us on Medicare does not take effect until 2006. It has a very large price tag, although I would argue it is no where near what our seniors deserve or need, but if we frankly, instead of that, simply today, pass the legislation that is already passed the house, we would be doing a major service for the people of this country. It would cost very little. It would help beef-up the FDA to address the issues that Senator Snowe talked about in terms of bringing the safety issues together. Certainly in the United States of America we
have the capacity to design a system that frankly, is already designed for the pharmaceutical industry who brings back drugs every single day across the board and we just want others to have the same benefit from this. But, if we simply took away this prohibition, we would not only help seniors in this country, we would help every business large and small, every worker. When I sit down with those in my state who manufacture automobiles, and look at their numbers, at least half the costs of their explosion in healthcare premiums is as a result of the explosion in prescription drug prices. So, this is a real issue for business. It is a real issue for every senior and every consumer. And, in fact, this year, the Medco Health 2003 Drug Trend Report found that prescription drug prices will rise this year anywhere between 14 and 17 percent. They predict next year they will rise another 18 percent, and the next year another 18 percent. We are talking about an explosion in prices that businesses and seniors and any consumer can not sustain. That’s why I believe this issue is so critical. We know that if we simply pass the House bill that has already been passed by my colleagues on a bi-partisan basis, that all tax payers and consumers will save some 40 billion dollars by doing that. I’m very concerned that not only in the legislation in front of us now coming to the floor on Medicare do we not see these provisions, but it’s even worse because they are prohibited from doing what Senator Wyden has talked about which I totally
agree with which is the leverage, the group purchase, to be able to bring the price down. The bill in front of us doesn’t allow that. It has specific language to prohibit that kind of group leverage. So, we have the worse of the worse in the bill coming before us. A core benefit and a new group of consumers, a new group of customers for the industries locked into the highest prices possibly in the world. There’s only one group that benefits by that, Mr. Chairman, and it’s certainly not the seniors of this country. I’ve taken many bus trips. From Michigan to Canada, it’s only five minutes across a bridge. It’s astounding to see the differences we all know the differences in prices. Senator Dorgan has already spoken about the differences. I would just share one thing. Last month in the town of Howell, Michigan which is about 60 miles away from Detroit and the border, the senior center took a group to Canada and it was interesting to note that one couple flew up from South Carolina to visit their daughter who lives in Howell, Michigan, and the savings from just one of the drugs that they purchased in Canada paid for their trip, their flight to come up and be able to join their daughter and go to Canada. Now, there’s a lot of talk about the free marketplace, and I want to mention just one of the price differences, and why I don’t think this holds water when we talk about some of the comments of our colleague, Senator Santorum. Let me give an example of Tamoxifen. We’ve all heard this before, but right

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not Tamoxifen is one of the drugs to battle breast cancer. It’s about $340.77 in the United States. When we took the seniors to Canada, they received it for $39.19. Now, eight times more expensive - does the marketplace work for this? Can a breast cancer patient who’s diagnosed today say, “You know, I think I’ll wait. I don’t think I’ll Tamoxifen which I need to possibly save my life. I think I’ll wait and take it another time when the price is better.” Of course they can’t do that. This is not like buying an automobile or a pair of tennis shoes or a new shirt. You can’t just say, “I can’t afford it today. I’ll do it tomorrow.” These are life-saving medicines, and the marketplace works differently. When someone says, “You’ve got to pay $340.77 for your Tamoxifen because you have breast cancer.” You’re going to do everything in your power to find that $340 a month because it is critical for your health and possibly your life. So, this is different, and I believe we need to look at it differently and have a sense of urgency about what it is we’re talking about. I would simply add one more thing, and that relates to what we’re really talking about here, and Mr. Chairman, I will submit my full testimony for the record. I know we have other colleagues here. But, let me say that this is not an issue about the Internet or about mail order, and I do think we have some issues with the Internet and with mail order that need to be addressed in terms of where drugs are coming from. Reimportation is about allowing the
local pharmacist at the local pharmacy to be able to do the same thing that the pharmaceutical companies do every single day, to bring back drugs, to have a business relationship with the pharmacists or the wholesaler in Canada. Right now, every single day, every single day there are prescription drugs coming across the border from Canada into Michigan. The only difference is they’re being brought across by the industry and not by the licensed pharmacists. The FDA sends inspectors to the countries where these (UNINTELLIGIBLE) are made. They inspect them. They make sure there’s a closed supply chain, and they make sure it’s safe. They can do exactly the same thing if we choose to give our seniors lower prices and licensed pharmacists the same ability to do that. We also know that there is ample technology available both in the Senate bills that we have talked about as well as the House to address the issues of safety. Mr. Chairman, I would just say in closing, this is not an issue of safety. This is an issue of competition and the fact that the prescription drug industry does not want to be in a position they have to lower their prices to American consumers, and shame on us if we can’t get this right. We helped subsidize making the drugs. We give tax credits and tax deductions for the development of the drugs. We give us to a 20 year patents in order to protect them so they can recover their costs, and what do we get at the end of that? The highest prices in the world. It is not a good deal for us, Mr.
Chairman, and I hope that with your leadership and the leadership of the committee that we will change that.

SENATOR MCCAIN: Thank you very much, Senator Stabenow. Thank you, Congressman Gutknecht, and thank you for all of your hard work on this issue.

CONGRESSMAN GIL GUTKNECHT: Well, thank you, Mr. Chairman, I am so happy to be here today, and I’m so happy that you’re having this hearing. One of my mentors in this subject is a gentleman by the name of Dr. Steve Shondameyer (MISSPELLED?) and he is a professor of pharmacology at the University of Minnesota, and he teaches pharmacology. He is a pharmacist. He has studied this issue for more than 15 years, and one of my favorite quotes from Dr. Shondameyer is this, “A drug that you can not afford is neither safe nor effective.”

And, what we have in America today is we have the worst of all worlds for consumers. As my colleagues from Michigan just said literally, what we do is we grant these long-term exclusive franchises and then we hold American consumers captive. And, the results are absolutely predictable. And, I’m one who doesn’t necessarily say, “Shame on the pharmaceutical industry.” It really is shame on us because ultimately the FDA works for us, and we have a responsibility and an obligation and more importantly an opportunity to do something about it. I’m so glad that you have co-sponsored this bill. We hope that it will move through the Senate. We are considering legislation

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as has been mentioned in the House and Senate, but what it essentially just transfer the responsibility of paying for most of these drugs from the consumers of the drugs to the tax payers. And, some say that’s the answer. Well, I’m not convinced it is because I think we’ve asked the wrong question. I think from the very beginning on this debate about prescription drugs for seniors, we have framed the issue around coverage. Ladies and gentlemen, if you go out and meet with real seniors, and many of you have, you know that the issue isn’t so much coverage, its affordability. And, Senator Stabenow pointed out Tamoxifen. I want to come back that, but I also want to mention that I happen to believe that markets are more powerful than Armies, and at the end of the day, markets work, and the reason why we have the situation today is because we don’t allow markets to work. Now, it’s interesting because Representative Sanders and I agree on very few issues, but we agree on this, and what I’ve always said is that this is not a matter of right versus left because we have some of the most conservative members of the house and some of the more liberal members of the house who both agree on this issue. So, it’s not a matter of right versus left. It really is a matter of right versus wrong, and it is wrong to hold American consumers captive so that they have to pay by far and away the highest prices in the industrialized world. Now, the issue that’s continuously raised by the FDA and the other critics is safety,
but I hope you’ll take an objective look at this basic issue of safety because when you do you will find out that it really is a bogus issue. Now, we know for example that the CDC and other government agencies keep incredibly good records. We know how many people have died from taking drugs from other countries. We also know from studies that at least a million Americans, in fact that number may well exceed five million Americans, are currently buying their drugs from other countries. In some respects, that’s a tragedy in and of itself. I represent Rochester Minnesota, home of the Mayo Clinic, every day (UNINTELLIGIBLE) all over the world to get their healthcare here in the United States, but tragically Americans must go to other countries to get affordable prescription drugs. When we talk about safety though, we keep records. We know how many people have died from taking drugs from other countries. It’s a nice round number. It’s easy to remember. It’s zero. We know that you are more likely to become seriously ill from eating raspberries from Guatemala from the government’s statistics than you are from taking prescription drugs from Canada. We know today that five people in Western Pennsylvania have died from green onions from Mexico, and yet we know of no one who has died from taking prescription drugs from Canada or Mexico, and so the safety argument I think is widely and wildly exaggerated, but the important part about the bill that you are co-sponsoring is it will make the safety even safer because

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we’re, for the first time going to require counterfeit proof, tamper proof packaging. That technology exists today, and we have and we can show some of that technology, and you got some great witnesses that can talk about that as well. One of the other arguments is about counterfeiting, but remember this members, no one counterfeits one dollar bills. The reason we have counterfeiting is because of the expense of the drugs, and interestingly enough I think the FDA would admit that most of the counterfeiting that we see happening today is happening inside the United States. It’s not happening somewhere else and being brought in. The other argument that was raised is about free trade in these countries might steal patents. Well, members you need to understand that every country has to sign before they’re permitted into the WTO what is called a “Trips Agreement” where they literally pledge that they will not steal intellectual property rights, and I’m one who believes in intellectual property rights. Finally, I want to talk a little bit about how we subsidize this industry, and I’m not here to bash the pharmaceutical industry as I’ve said earlier. It’s not “Shame on them.” It’s shame on us. But, do understand that we subsidize this industry in three separate ways. First of all, we subsidize them through the research that we do with tax payers’ dollars. This year, we will fund the NIH the CDC and other groups that do research in the United States to the tune of about 27 billion dollars, much of that information is
available to the pharmaceutical companies free of charge. The second way we subsidize is with tax code. The pharmaceutical companies who talk about how much they spend on research; neglect to mention that they deduct every penny of that research from their federal taxes. More importantly, they also qualify in many cases for research and development tax credits. Over the last ten years, they’ve taken advantage of 28 billion dollars in those tax credits. But, finally, we subsidize the pharmaceutical industry in a very important third way, and that is in the price that we pay for prescription drugs. I have and I think we’ve made available to you and you’ve got all the charts, you can see this chart. This is a chart of ten of the most commonly prescribed prescription drugs. And, when I was in Germany in May, in fact, we stopped at the Lanchdual (MISSPELLED?) Hospital there, but on our way home we stopped at Communicare Port Pharmacy (MISSPELLED?). And, most of you travel quite a bit, and you probably realize that if you want a bargain, you don’t go to the airport to buy things. But, on our way out of town, we bought ten of the most commonly prescribed drugs, and I would invite you to look at that chart. And, the total for those ten drugs bought in Germany was $373.30. We came back to the United States and priced those same ten drugs at a pharmacy here in Washington, DC. The total was $1,039.65. The one that really sticks out is a drug that Senator Stabenow mentioned, Tamoxifen, one of the most amazing drugs ever

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developed in the United States, but here’s the interesting thing - that drug was developed at the expense of the American tax payers. We literally took the development of that drug through phase two trials, and the reward for the American consumer, well, we pay about $360 for that drug. It’s available in Germany for about $60. Now, I’m not saying that we shouldn’t pay our fair share for the cost of research and development. Clearly, America is a blessed country. We ought to pay our fair share. We ought to pay more, for example, than the people in sub-Saharan Africa. But, I don’t think American consumers and tax payers ought to have to subsidize the starving Swiss, and that is what is happening today. And, one of the ways you can change the arithmetic and the entire pricing structure of these pharmaceuticals is to open markets. Now, let me say, it is not my vision that American consumers will go to Canada or Germany or wherever to buy their drugs, because ultimately once you open markets, they will be forced to adjust their prices here in the United States downward. You’re going to hear later from someone who’s called a “parallel trader”, and ultimately that’s what we were looking for so that pharmacists whether they be in Arizona or Montana or wherever, will be able to buy their prescription drugs wherever they can get them the cheapest. If they can buy them from pharmaceutical supply house in Munich, Germany cheaper then they ought to have that right. That’s called parallel trading. It happens everyday in Europe. And,

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let me just say something to you members. The Europeans are not intrinsically smarter than we are. So, again, this is not about shame on them. It’s about shame on us. It’s about basic fairness. It’s not right versus left. It’s right versus wrong. We have an opportunity to change it. I thank you very much for this hearing. I look forward to the hearing, and I will do everything in my power to help you get this billed pass through the Senate. Thank you very much.

SENATOR JOHN MCCAIN: Thank you sir. Congressman Sanders.

CONGRESSMAN BERNIE SANDERS: Mr. Chairman, thank you very much for holding this important hearing, and for your work and Senator Dorgan and Senator Snowe and Senator Stabenow, thank you very, very much for all that you have done fighting for consumers in this country. Mr. Chairman, as the first member of congress to take American citizens over the Canadian border, this is an issue that has obviously concerned me for a very long time because the state of Vermont borders on Canada, many of our people for years have purchased safe, affordable medicine in Canada. And, like many of my friends here, I will never forget the first trip that I took where women who are fighting for their lives against the killer disease of breast cancer, women who do not have a lot of money, were able to purchase safe Tamoxifen at one-tenth the price that they are paying here in the United States of America. I’m glad Senator

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Santorum is back. He used the words “killing people”. Well, Senator we have a study that we have asked the CRS to ask how many thousands of Americans have died because they can not afford the outrageously high prices that the pharmaceutical industry is shoving down our throats. How many millions of Americans have seen a deterioration in their health? There are studies done by the Kaiser Foundation which suggest that 25 percent of senior citizens in the United States of America are either skipping doses or are not taking the medicine that their doctors prescribe because of the outrageously high prices. You talk, Senator, about people dying. Well, I want to know how many thousands of people are dying because they’re being ripped-off by the greediest industry in the United States of America. Now, one of the exciting aspects of this whole issue is we have brought together a very strong tri-partisan coalition in the House of Representatives. Gil Gutknecht, Dan Burton, Joann Emerson, some of the republicans have played a great role. We have democrats. I am an independent. And, we have stood up to the pharmaceutical industry. We have stood up to the hundreds of millions of dollars that this industry has thrown into Congress. We have stood up to the 650 paid lobbyists. We have stood up to their campaign contributions. And, what we and the American people are asking the United States Senate, will you also have the courage to stand up to the most profitable, the most powerful lobby in the United

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States of America? Senator, I know that you have been concerned in your years in the Senate about the power that money has over the public process, and I applaud you for your efforts. I would like to introduce to the record some information by the Center for American Progress, which was prepared by the Center for Responsive Politics talking about the millions and millions and millions of dollars in campaign contributions that are (unintelligible) into the people who are sitting in the conference committee right now on this Medicare conference from people who I find the most outrageous act by putting language into a bill which says that the United States government can not negotiate lower prices on prescription drugs, beyond belief. The question that we are dealing with therefore today, Senator, is not just a healthcare issue, and I agree with what these people have said. The issue even goes deeper than that. The issue whether the United States Congress is any longer capable of standing up for ordinary people or will continue to succumb to the power of big money. Now, let’s deal with the two issues that the pharmaceutical industry so aptly represented by Senator Santorum today. You don’t need the pharmaceutical industry here. Senator Santorum has given their line. Let’s talk about the two issues. The issue of safety – we had in our subcommittee, William Hubbard (MISSPELLED?) who is a senior official with the FDA, and one of the leading critics of reimportation working with the drug industry. And, we asked Mr.
Hubbard, we said, “Well over one million Americans – over one million Americans are purchasing their prescription drugs from Canada. That number is through Gil Gutknecht is growing everyday. How many of those people have been made sick or have died?” And, the answer was to the best of his knowledge, he did not know of any. Senator Santorum and others, the industry has said, “Price controls. We don’t want to import price controls.”

Well, this is an amazing remark. And, everybody knows we have lost millions of decent paying manufacturing jobs in this country because China is selling us every product in the world. Now, we can’t get safe affordable FDA approved medicine from our neighbors in Canada because we’re importing price controls, but we can import slave labor from China. We can import 20 cents an hour labor from China. We can import the fact that anybody who tries to form a union in China goes to jail. We can import billions and billions of dollars of those products, but somehow as Senator Snowe indicated, we just can not through the United States of America, our government, the FDA, regulate a handful of factories and plants through the kinds of efforts that we have put into this legislation to make sure that that product is safe. I think anyone who looks at that for one moment understands that that is absurd. Senator Santorum said, “Gee, those terrible Canadians. In eight years, they have not had to experience an increase in the cost of prescription drugs. What an awful country.” How terrible can they be to
their consumers? Well, I would suggest that if the American people would know that we have the courage to stand up to the industry, and by the way, let’s talk about this industry. This is the most profitable industry in the United States of America. This is an industry struggling, no doubt, it is able to pay 150 million dollars in compensation to the CEO, I think it was of Bristol-Myers. This is an industry so struggling, that it could spend hundreds of millions of dollars trying not only to buy this institution but legislatures all over the country. Senator, we have an opportunity to do something important. Let’s do it. Thank you.

SENATOR JOHN MCCAIN: I mentioned to my colleagues, I’ve been on this committee for 17 years, and very rarely do we have opening statements that generate so much interest. It’s usually senator of a pro forma affair (misspelled?), but not in this case. We do have two other panelists waiting. We’ve already been in for an hour. All members of this first panel do have other things to do, but I know that there is a desire here for a back and forth. So, could we compromise and say we could use ten minutes for Q&A back and forth? We have the governor of Minnesota is waiting to testify, and I think it would be a bit discourteous for us to extend this too much longer. So, if we set it for ten minutes and I’ll ask – for ask Senator Santorum, if he’d like to respond to any of the comments that were made, and perhaps Senator Dorgan, Senator Wyden, and Senator Snowe.
SENATOR RICK SANTORUM: Well, Mr. Chairman, I know you’re short on time. I would just say in response to Senator from Vermont, the point I was making is that — and to all the Senators and Congressman — that I agree that we’re paying too much for drugs here and that we are underwriting the world’s cost of research and development. I admit that freely. The question is what do we do about it, and I would suggest that what we need to do is not import what the other countries have done which is price fixing and price controls which I can’t imagine that most members here would recognize that we shouldn’t go out and set price controls artificially below the reimbursement to make these drugs profitable for any company to want to produce. In fact, the information I received when it came to the question of all this underwriting the federal government does for these pharmaceutical products that scholars (UNINTELLIGIBLE) 284 new medicines approved in the US in the 1990s. They found that 93 percent originated from the pharmaceutical industry with no government support, seven percent split between government, academic, and no-profit sources. So, the idea that the government is funding all this research and that all we should be doing is recouping our money, I mean, it’s just the facts don’t bear that out. There’s an enormous amount of risk in producing new drugs. Most of them
fail. Most of them don’t come to market. And, the question is do we want to have a vibrant drug industry? I don’t think a drug industry that’s profitable is a bad thing. I think it’s a good thing. It produces more drugs. I think we’re all here for the same reason. We all want to have lower cost drugs here and the people around the world to be able to sort of pay their fair share. The question is how do we get there. I would argue this doesn’t get us there.

SENATOR JOHN MCCAIN: I would just make one comment very quickly. We all know that the Veterans Administration and DOD currently use their market share to negotiate lower prices for drugs. Why in the world if we’re interested in lower prices for prescription drugs would we put a prohibition in that Medicare can’t use its market share to negotiate better prices for drug companies? I mean, it makes no sense. It authenticates Congressman Sanders’ argument of the power of the pharmaceutical companies. There’s no reason. If we’re going to prohibit Medicare from doing it, then let’s prohibit the Department of Defense and the Veterans’ Administration from doing it. Why in the world would do such a thing if we’re interested in lower prices? I know this has nothing to do with reimportation. It has to do with giving government the power to negotiate lower prices.

SENATOR RICK SANTORUM: Since, I don’t represent the pharmaceutical industry, contrary to what everybody says I
(UNINTELLIGIBLE) of American consumers in an industry that I think is a very important industry to this country. I agree with you. I don’t know why we did that. I wasn’t on the conference, so I can’t speak for the conf reason for why they did that.

SENATOR JOHN MCCAIN: Thank you. Senator Dorgan, real quick.

SENATOR BYRON DORGAN: Mr. Chairman, I’ll just – I want to ask Senator Santorum a question because as usually the case, he has sparked my interest with his language. Two points, and both in the form of a question. There’ll be very quick. One of the inconveniences of globalization is that when you trade with other countries, you inherit whatever those other countries are doing. In this case, with Canada, price controls, and I want to ask the Senator from Pennsylvania to demonstrate today, but I will bet that on his person – his shoes, his shirt, his necktie, his cuff links or his handkerchief – somewhere is something that he’s purchased from China, and he is therefore giving comfort in importing the retirement pay for Jung Xiaming (MISSPELLED?) a noted communist leader. Does that make him uncomfortable? No, part of globalization is you inherit and import all that which other countries are involved in. So, let me finally make this point – the Senator from Pennsylvania said that “this will kill many patients” “kill many patients”. We have millions of Americans who are now importing drugs. Name

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one patient that it has killed, just one.

**SENATOR RICK SANTORUM:** When I say it will kill many patients, I mean in the future because new drugs will simply not be developed and those cures that will save lives in the future simply won’t be available for people to take. You list all these wonderful miracle drugs. Companies don’t produce miracle drugs to lose money. Let’s just be honest about this. I mean, you make it sound like all we’re going to do is we’re going to beat back these horrible drug companies that produce life-saving therapies and we’re going to make sure that they don’t make any money and they’re going to go and continue to make drugs. I mean, this is — I mean it doesn’t make any sense. Let’s be honest about this.

**SENATOR BYRON DORGAN:** Mr. Chairman, you’re support for the pricing strategy of the drug industry is eloquent but wrong. The fact is those manufacturers are not selling drugs at a loss in Canada. Would you agree with that? They’re not selling drugs at a loss in Canada because if it were a loss they wouldn’t sell in Canada. Because they’re selling drugs in Canada at a fraction of the price here, but still making money in Canada suggests to me they are overpricing prescription drugs in this country, and that’s the issue.

**SENATOR RICK SANTORUM:** I’d be happy to respond to that. I will say that first off, as you know, to sell a drug in Canada, you have to get approval to sell a drug in Canada, and
you do know that. You have to get approval by the government, and of course if the government doesn’t – if you don’t accept the price is willing to pay you, you can’t sell your drug there. If you don’t accept the price the government’s going to pay and you don’t sell your drug there, the government has the ability to steal your patent, have that drug manufactured in that country. So, it does provide a little incentive for you to cooperate when it comes to selling your drug. So, I would agree with you that no they do not sell it at the price they do here, because they have certain extraordinary circumstances to deal with, but they probably do make a profit in that they sell it for more than it costs for them to manufacture and therefore it adds some what to the profitability but it doesn’t underwrite the billion dollar costs that it takes to research and develop this drug, and I agree with the senator from – I mean, we’re in agreement that we need to do something about that. Canadians should pay more. Germans should pay more for underwriting the costs of research and development of new drugs. That’s the issue. It’s not that they’re not paying their fair share, and we are paying too much. I agree with you.

SENATOR JOHN MCCAIN: Senator Snowe?

SENATOR DEBBIE STABENOW: Mr. Chairman, I’d like to just add that –

SENATOR JOHN MCCAIN: Could we just go to Senator Snowe and then Senator Wyden, and then will have responses and

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Senator Boxer who is short of stature and has evaded my gaze.

And, then we’ll (UNINTELLIGIBLE) real quick, if we could, because we really are – we’re doing what we usually do on the floor, perhaps not very well. Senator Snowe, real quick.

SENATOR OLYMPIA SNOWE: Senator Stabenow was talking.

SENATOR JOHN MCCAIN: Senator Stabenow.

SENATOR DEBBIE STABENOW: I just wanted to throw in one comment. We keep talking about research costs. According to the latest numbers that the industry is spending 2.5 times more on advertising, marketing and administration than research, and so it’s very important to look at where they put their dollars. We can do this and not affect research in this country. I’m absolutely convinced.

SENATOR JOHN MCCAIN: Congressman Sanders.

CONGRESSMAN BERNIE SANDERS: Senator Santorum, briefly. Senator Santorum, you said you just don’t know. You can’t understand how that language ends up in the bill which prohibits the government from negotiating. My question is I hope that you will tell us now that you want to get that language out so the government can negotiate with the pharmaceutical industry. Senator?

SENATOR RICK SANTORUM: I hadn’t seen the language. I’ll take a look at it, and if it’s not comports with what I think are best practices, then I would be for removing that language. I haven’t looked at it yet.
SENATOR JOHN MCCAIN: Congressman Gutknecht, did you want to say something real quick?

CONGRESSMAN GIL GUTKNECHT: Well, just real quickly, Mr. Chairman, we had asked PHARMA and we had asked all the experts in the FDA how many countries have expropriated a patent from a company for refusing to deal with their regimen of working on controlling prices, and the answer is zero. It’s never happened.

SENATOR JOHN MCCAIN: Senator Snowe.

SENATOR OLYMPIA SNOWE: Thank you, Mr. Chairman, I want to thank all of the testimonies from all the witnesses here today. I think you made some excellent points, Senator Santorum with the one exception.

SENATOR SANTORUM: I thought you were complimenting.

SENATOR SNOWE: When you were referring to counterfeiting, I mean primarily that was focused here in this country in domestic distribution, I might add with respect to the issues in this area that focus on that particular issue. There’s no question, if we can do it with $20 bills and preventing counterfeiting, I think we certainly can do it when it comes to life-saving medications. I think one of the issues here today, and Senator Stabenow raised the point about the rising prices of prescription drugs, 16-18 percent a year. That’s seven, eight times the rate of inflation. I mean, the cost of prescription drugs are not declining over time which we

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would expect would, but not and that’s the issue because they
don’t have any competition, and we would have competition by
bringing those drugs across the border. There is competition as
we’ll hear later about parallel trading and opening markets,
but that’s we’re facing in this country – 16-18 percent a year,
and it’s not just been one year, that’s not an exception. It is
the norm. That is the pattern, and what it counts is the
skyrocketing increases when it comes to the cost of
prescription drugs. I mean how long can you recover your
investment. So, these prices normally should be declining over
time and are not. And, I’d like to have you or other members of
the panel to speak to that issue.

SENATOR RICK SANTORUM: Well, I would just say with
respect to competition, as you know, the competition is once
the patent expires, you have generics who go in and compete,
and that is one way. But, the patent protection –

SENATOR OLYMPIC SNOWE: And, more difficult too.

SENATOR RICK SANTORUM: Actually, we’ve made it easier
under this bill for generics to be able to compete. At least,
that’s what I’ve been told is in the underlying Medicare bill.
But, and I agree with that. I think that we should have
competition. At the same time, patents are there for a reason.
They’re there for companies to be able to protect their
intellectual property so they can get reimbursement and recoup
the expense. I mean, generic manufacturers aren’t inventing
Tamoxifen. I mean, they’re basically waiting until the patent expires, and then they’re going to produce it and sell it a lot less. Why? Well, they can sell it for a lot less because they don’t have any research and development costs into other than the fact of what it takes to make it, but not invent it. And, so, the question is are we going to reward companies for doing what we want them to do, which is to invest in research and technology and develop new life-saving, quality enhancing drugs, and I would argue that we need to. At the same time, that cost should be bore not just by Americans but by the rest of the world, and that’s the issue that I think we need to focus on, not trying to take the pricing structure which is artificially low around the world, and impose it here in America. By doing so, I mean, just let me assure you, the number of drugs in this country that are going to be produced are going to dramatically decline, and that may be okay. I mean, that’s a trade-off, and it’s a trade-off that I know some people are willing to accept, and if you advocate for that, I have no problem advocating for that if that’s what you want to do. But, understand that that cost and the benefit that’s going to be incurred when you do that.

SENATOR JOHN MCCAIN: Senator Wyden.

SENATOR RON WYDEN: Thank you, Mr. Chairman. As you all heard me say, I think this ball game’s about bargaining power for seniors, and that’s what Senator Snow and I had in our bill
four years ago to basically give seniors bargaining power like members of Congress have, and I want all of you because you’ve been very eloquent to kind of give me a response to an example of how the Canadian situation is going to affect bargaining power. I want to be very specific. Somebody that I’ve used for a lot years for counsel on prescription drugs told me yesterday that he order Lipitor in the United States from Canada on August 31st. It arrived on October 17th. He got a 90 day supply for $255 or about $2.83 a pill, but because the order took so long, he had to go out and buy a 60 day supply in the United States at $259. So, in effect, he got a third more from Canada for roughly the same price. My question for all of you is Canada’s got a pretty small population. If we have millions of people in the United States ordering their drugs from Canada, the Canadians are going to serve their citizens first. What is this going to do for our joint goal of trying to get more bargaining power for the consumer? That’s what we’ve always felt this is about. That’s what Senator Snowe and I have been trying to do for four years, and because you all are the experts in it, just walk me through what the Canadian situation will do with respect to the key issue of bargaining power?

**SENIATOR JOHN MCCAIN:** And, walk him through briefly please, beginning with you Congressman Sanders.

**CONGRESSMAN BERNIE SANDERS:** We understand when Senator Santorum referred to us in a different context, that the
industry will do everything it can to sabotage our ability to lower prices in this country. One way that they are doing it is trying to limit supplies to Canada. In our legislation, we are very clear that is against the law for them to do that. That, in fact, they will have to not discriminate against American citizens and if people in Canada - the pharmacists in Canada want the medicine, they will get the medicine they need. So, it would be against the law for them to sabotage the effort.

SENATOR JOHN MCCAIN: Congressman Gutknecht.

CONGRESSMAN GIL GUTKNECHT: Part of the reason that the bill we passed in the House - the bill before the treaty here - includes 26 countries, which incidentally we didn’t make up. Those are 26 countries that was given to us by the FDA, saying they had similar regimens to ours relative to the safety of drugs, and you will later hear in this hearing from a parallel trader. Ultimately, I don’t believe we’re talking just about Canada, and more importantly long-term we’re not talking about mail order. We want to open up markets so your local pharmacist can get the same price. Can I come just briefly back to a point that Senator Snowe made because I think it’s very intuitive, because you’re really talking about intellectual property rights. The argument that’s made is if we open up markets and force competition here in the United States, they’ll lose intellectual property rights, people won’t do research. If you step back just for a moment and compare that to the technology

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industries, I mean, Intel lives and breathes on intellectual property rights just like the pharmaceutical companies. We don’t give them the same protection. They understand that if they don’t invest in new technologies and new innovations, they’re going to be out of business, but they don’t get the same kind of protections as the pharmaceutical industry. Incidentally, we got the CRS report. No other industry gets the protections that the pharmaceutical industry does.

SENATOR JOHN MCCAIN: Senator Stabenow.

SENATOR DEBBIE STABENOW: Thank you, Mr. Chairman. I think that’s a very important point. We – no one else gets the same protections that we’re talking about here. Senator Wyden, I think that as we look at this, particularly if it’s beyond just Canada as Representative Gutknecht was indicating. What we’re going to see is a shift in the market. If the pharmaceutical industry isn’t able to stop it by manipulating supply, what you’ll see is a shifting and a changing in all of this in terms of prices and the competition can’t help but bring prices down in the United States. Again, we’re not talking about mail order, Internet. We’re talking about going to the local pharmacy, having the pharmacist there be able to do business with pharmacists in other place for safe FDA approved drugs. One other quick point, and that is we keep talking about, “Well, there’s competition when a patent runs out from generic drugs.” In the last five years, the FDA has
approved patents and over 65 percent of them have not been for new life-saving drugs. They have been for what’s called a standard drug or often called a “me, too” drug, meaning the packaging is changed. The daily dose becomes a weekly dose, or some other change is made to keep the patent going to stop competition. So, we have the industry – the most highly subsidized, the most highly profitable in the world – doing everything they can to stop competition by continuing patents, by stopping competition and putting more than 2.5 times more into aggressive marketing and advertising now for on purchasing rather on life-saving research. I’m all for investing in research doing everything we can to partner with the industry to do that, but we’ve seen an industry dramatically shift to a marketing and sales industry as opposed to research.

SENATOR JOHN MCCAIN: Senator Santorum.

SENATOR RICK SANTORUM: And I’d be happy to enter into the record for the committee that the numbers with respect to how much the industry spends on corporate marketing and advertising versus research, Senator Stabenow and I have done a couple of charts on the floor many times on this, and I’d be happy to submit it to the record, and just suffice to say the vast majority of the advertising and marketing are free drug samples given to doctors that end up in the pockets of poor people who can’t afford drugs. So, that’s number one. Number two, with respect to what’s going to happen in response to the
Senator from Oregon’s question, I do agree that as I said before, I think they will attempt as I would think any industry would to say, “Look, we’re only go as much drugs up to Canada as the Canadian market needs.” If that is against the law, which I don’t know how they do that, but if it’s against the law, then my guess is you’ll see a lot of pharmaceutical companies pull out of Canada, and simply not make those available particularly if they’re not getting very high reimbursements for their drugs and they’re not making any money if in fact it’s going to sell basically all of their drugs through Canada at this point at that low price, they simply won’t sell the drug in Canada and sell it here. If, as others have suggested that we broaden it beyond Canada to the rest of the world, then the ultimate consequence will be you’ll see a lot less drug research and a lot less new drugs.

Senator John McCain: Senator Boxer.

Senator Barbara Boxer: Thanks. I’m not going to ask a question. I’m going to sum up what I think is happening here in a minute and a half. Drug companies get the benefits of research paid for by American taxpayers. Don’t forget it. Taxpayers pay a lot of money, and by the way, I support that research and I want to spend more on that research. Secondly, they get the R&D tax credits for what they do or R&E, however define it, and I support that. As a matter of fact, I want to make it permanent. They get patent protection, and if that

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isn’t abused, I’m all for patent protection. They get to write off their advertising budget. There are some people that don’t want that to be a write-off. I think that would be a violation of free speech. I support them being able to write-off their advertising budget. What I don’t support is they’re turning their backs on the American people and using their clout to stop any of kind of reform here, and this latest one and the timing of this hearing is exquisite. You’ve got the conferees over there. I trust they’re all there right now, and they’re imposing basically a gag rule on Medicare, saying, “You are prevented from bargaining for good prices, but the private sector, you can go out and bargain.” What is that? That is outrageous. It’s on a space beyond outrageous. We’ve also got a generic provision, and although I haven’t read the fine print, it looks to be weakened from what I hear, and you have an importation situation where that will never happen. So, what you’ve got is the pharmaceuticals with a lot of help from around here which I’m embarrassed to say is happening, just walking away with everything. And, it’s to the point where I think our people are going to be hurt eventually on this, and I’m just glad you have this hearing. Thank you.

SENATOR JOHN MCCAIN: I thank the panel and I thank you for being here and this has been a very interesting and enlightening discussion and I appreciate it very much. Thank you. Thank you very much. Our next panel is the Honorable Tim
Pawlenty, who is the governor of the state of Minnesota, and Mr. John M Taylor, Associate Commissioner for Regulatory Affairs US Food and Drug Administration. Governor Pawlenty, we are not usually this rude to our visiting governors. We appreciate your patience and we thank you for your very significant involvement in this issue. I know it was a major issue when you campaigned for your present office, and I would like to say you are highly respected and regarded on this issue, and we thank you for being here. We’ll begin with you governor.

GOVERNOR TIM PAWLENTY: Mr. Chairman and Senators, thank you for the honor to be here today and present some thoughts about this important issue facing our country, and actually the panel before us was a great pleasure to listen to that testimony. We appreciate that. My formal testimony has been submitted. I know time is short, Mr. Chair, and you want to move things along so I will cut to the chase. We have a healthcare crisis in America as this committee well knows. The crisis in part is a cost crisis. We have healthcare in the United States going up between 10 and 25 percent a year. We can’t keep up. Families can’t keep up. Employers can’t keep up. Employees can’t keep up. Governments can’t keep up. It’s going to consume us, Mr. Chair if we don’t get our arms around this crisis, and it’s about to get worse as we experience the demographic shifts that we all know are coming with the grade...
of America. One component of that crisis is the prescription drug crisis and the cost associated with that. It’s been eloquently discussed in your previous panel. One element of that crisis is that prescription medicines for too many Americans are out of reach because of cost. The Medicare bill that may well pass in the coming days will help with respect to coverage, but as Senator Snowe so eloquently said earlier, extending coverage to more Americans while helpful and is good progress does not address the cost issue. And, so we are going to continue to have as governments, as families, and as individuals, cost pressures that are unacceptable that we’re not going to be able to keep up with. Americans pay 20-80 percent more for their prescription medicines. The main justification for that as you heard this morning is that we need innovation. We need research and development. I will concede, Mr. Chair, that we should pay a premium for that world-leading innovation, but there’s a difference between paying a premium and being a chump, and we’re being played. The American consumers are being played by this industry, and we’re being chumps. And, so, I don’t think that’s a good thing for our country. I don’t think it’s a good thing for American consumers and we need to take action. Franklin Delano Roosevelt said we need to try things. In the face of crisis, we need to try things. And, so, as we sit here and it is ironic that not far from here they’re perhaps closing up the Medicare

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conference report, and as an aside, if they prohibit Medicare from using group purchasing power, I would be stunned and alarmed. That’s an alarming development. I hope that’s not-

**SENATOR JOHN MCCAIN:** A commentary on the way the system works here as well as the specifics of the legislation, wouldn’t you think governor?

**GOVERNOR TIM AWPLENTY:** It would seem that way, Mr. Chair, it would seem that way. The importation from Canada, and perhaps other developed countries is not the ideal solution. It probably not the long term solution, but it is in the spirit of trying something. It is in the spirit of trying to break the logjam and bringing awareness and pressure for change. I’ll tell you briefly what our plan in Minnesota is. We hope that you make a federal law change that allows importation to go forward. If you don’t, we understand the current FDA’s position to be that individuals can make purchases for personal use for up to 90 day prescriptions. We would like to facilitate those kinds of purchases via Minnesota and we’re actively developing this as we speak. We hope to have it up and running in a matter of a couple of months. A website that will list and feature those pharmacies in Canada that we’ve identified as established and credible and reputable and safe and accredited that are willing to provide prescription medicines to Minnesota consumers are a hopefully discounted price savings. That website will also feature generic alternatives and information
regarding that. The individual who accesses the website will be able to download instructions and order form and a health questionnaire. They, the consumers, then will make the purchase. They will send the information to a Canadian pharmacy, the prescription as well as the health questionnaire. The Canadian pharmacy will then have that prescription reviewed by a doctor, a Canadian doctor, which is a step we don’t even require, by the way, in the United States. These pharmacies, we’re not talking, Mr. Chair, the press coverage gets lumped together and confused - we’re not talking about rogue Internet sites or pharmacies, virtual pharmacies, in the United States or elsewhere. We’re talking about established, credible, reputable, pharmacies in Canada that the state of Minnesota, ideally the federal government, but at least the state of Minnesota has reviewed as being appropriate for this purpose, and they have very substantial protocols that they follow. We were in Canada recently, and received that information. We’re in the process of verifying it, but there is no reason to believe that those types of pharmacies, established, credible reputable accredited pharmacies in Canada present a safety threat at all to the American consumer. There is no evidence of that. In fact, the FDA was recently in Canada meeting with Health Canada, and they made certain suggestions or claims previously about the safety of the distribution or pharmacy system in Canada. The day after the FDA left, the folks from

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Health Canada issued a clarifying press release saying “The FDA’s concerns have been reviewed. They have been investigated, and they are ‘not substantiated.’” Not substantiated. So, we’re asking, Mr. Chair, that the FDA, if they would be willing - the idea would be to help us. So, they’re the organization that has the expertise. They’re the organization that has the ability to help a system like this go forward. We’d love to have the help. In fact, we’ll cut them in on the action. We’ll take some of our savings, and we’ll give it to the FDA if they want send up some staff and sit in these pharmacies and help us review and do the due diligence, we will help them. But, we’re going to go forward under the guise that current law allows individual purchases for personal use. The protocols I’ll be happy to talk to you about in more details in my testimony, but they can be confident in the safety of these pharmacies that we will select. And, I also want to just address quickly, if I could, Mr. Chair, this notion that the retaliation by the pharmaceutical companies because that’s a growing concern in Canada in terms of the government and their consumers. I think the threat on national television by the CEOs and leaders of our pharmaceutical companies, that they are going to cut off supply to their Canadian pharmacies is reprehensible, and it may be, it may be a violation of anti-trust and trade laws, and I hope this committee or other federal authorities or state authorities will pursue that. In closing Mr. Chair, let us try
it. Let us try it. Even if you don’t change federal law, we just ask the FDA to maintain their current posture, allow these personal purchases to go forward, let us try it. We’ll see if it works. If it doesn’t work, we’ll come back. We’ll admit it frankly and move on, but we need to try something different. Thank you for the time and the chance to present a few thoughts this morning.

SENATOR JOHN MCCAIN: Thank you, governor. Mr. Taylor, welcome back.

JOHN TAYLOR: Thank you very much. Before I start my oral testimony-

SENATOR JOHN MCCAIN: You might want to move that microphone.

JOHN TAYLOR: We’d be more than happy to meet with the governor either before or after the introduction of your plan, and we can discuss that.

GOVERNOR TIM AWPLENTY: Thank you.

JOHN TAYLOR: Mr. Chairman, I appreciate the opportunity to discuss the Food and Drug administration’s concern related to the importation of drugs into the United States. FDA shares with Congress in it’s great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the administration has been working so closely with Congress to enact landmark legislation to provide millions of American seniors with coverage for prescription drugs.
drugs under Medicare. As part of that legislation, the
administration supports provisions that build on FDA action
earlier this year to expand access to more affordable generic
drugs. FDA is also taking a number of other significant steps
to provide greater access to affordable prescription
medications without compromising safety including unprecedented
steps to lower drug costs by helping to speed the development
and approval of low cost generic drugs after legitimate patents
had expired on branded products. This includes the biggest
expansion in history of our generic drug program – a series of
regulatory changes to make it easier for generic manufacturers
to compete. However, FDA continues to have serious public
health concerns regarding legislation that will allow the
importation of drugs from outside the current safety system
established by Congress under the Federal Food and Drug and
Cosmetic Act. When it comes to buying drugs outside our
existing regulatory protections, FDA has consistently concluded
that the agency is unable to endorse a “buyer beware” approach.
Currently, new drugs marketed in the United States, regardless
of whether they are manufactured in the United States or a
foreign country, must be approved by the FDA based on
demonstrated safety efficacy. They must produced in a FDA
inspected manufacturing plant that meets FDA’s good
manufacturing practice regulations. Also, the shipment and
storage of these drugs must be properly documented and where

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necessary, inspected. Another the Food, Drug, and Cosmetic Act, unapproved, misbranded and adulterated drugs can not be imported into the United States. This includes foreign versions of US approved medications as well drugs that are made in the United States exported to other countries, and then subsequently reimported to the United States. Our safety concerns are heightened by the proliferation of websites, both domestic and foreign that sell prescription drugs to consumers. The Internet has opened up vast new opportunities for commerce and the exchange of information. However, as beneficial as this technology can be, it also creates a new place for activity that is already illegal. FDA’s doing it’s best to stop the increasing flow of drugs in this country, but the task is daunting. Our regulatory affairs has inspectors who work the field and perform investigational work pertaining to imported prescription drugs. The job is not limited to inspections at ports of entry, but while the volume of imported drugs has increased enormously, FDA has not received additional resources authority to address these thousands of shipments, in contrast, in the case of food security where Congress two years ago, approved substantial new funds and authorities for border protections. FDA has long taken the position that consumers are exposed to a number of risks when they purchase foreign drugs from Internet sites or from pharmacies that are not licensed and operated under state pharmacy law. These outlet may
dispense expired, subpotent, contaminated or counterfeit products, or medications unaccompanied by adequate directions for use. In addition, FDA can not provide consumers with any assurance that these are products or active ingredients were manufactured under current good manufacturing practice standards or stored properly. Taking such unsafe or inappropriate medications put consumers at risk for dangerous drug interactions and other serious health consequences. Moreover, patients are at greater potential risk because there’s far less certainty about what they’re getting when they purchase drugs over the Internet. Although some purchases of drugs from foreign sources may receive the genuine products, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resalers, or dangerous subpotent or superpotent products that were improperly manufactured. Also, in the case of foreign based sources that a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the physical location of the manufacturer is unknown, or because the operator of the pharmacy is often not known or the seller is beyond the consumer’s reach. FDA has only a limited ability to take action against these foreign operators. To help access the extent of the problems posed by imported drugs, FDA and the United States Customs and Border Protection conducted import blitzes at four
mail facilities this summer. The purpose of these blitzes was to attain a representative picture of the type drugs that were entering into the United States through the mail, and to identify and stop counterfeit and potentially unsafe products from entering the United States. Although many drugs obtained from foreign sources purport and or may appear to be the same as FDA approved medications, in fact, they are of unknown quality or origin, have not been approved in the US, and may pose potential serious safety concerns. Eighty percent of the drug products that were examined during the blitz were violated because they were unapproved drugs. The potentially hazardous products and counterfeits in the blitz included drugs that FDA has never approved, drugs that required careful dosing, drugs with inadequate labeling, drugs inappropriately packaged, drugs withdrawn from the market, drugs with clinically significant drug interactions, drugs requiring initial screenings and a periodic monitoring, and controlled substances. Clearly, many of these imported drugs may pose safety problems. Sixty-five years ago, Congress responded to wide spread fears of unsafe ineffective domestic drugs by directing FDA to create a system assuring that Americans have a drug supply that they can trust. Thirteen years ago, Congress responded to serious safety problems created by imported drugs that we’re not tightly regulated by passing the Prescription Drug Marking Act. Congress limited access to these foreign drugs because of
safety concerns they had identified with the importation of significant volumes of adulterated and counterfeit drugs. This has shown that this closed regulatory system has worked well. FDA however, can not offer the same assurances of the safety and quality drugs purchased from foreign sources that are outside our US regulatory system. Unfortunately, the drug supply is under unprecedented attack by a variety of increasing sophisticated drugs. FDA has seen its number of counterfeit drug investigations increase four fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. Evidence strongly suggests that the volume of these drugs of these foreign drug importations is increasing steadily and presents a substantial challenge for the agency to adequately assess and process these parcels resulting in an increased workload for agency field personnel, course of entry, mail facilities and international courier hubs. With available resources and competing priorities facing the agency, experience shows that we are unable to visually examine the large volume of parcels containing prescription drugs that arrive each day. The agency responded to this challenge by employing a risk-based enforcement strategy to
target our existing enforcement resources affectively in the face of multiple priorities including homeland security food safety and other important tasks. However, the system is already overwhelmed by the number of incoming mail packages that must be evaluated. And this state of affairs presents a significant ongoing challenge for the agency. At a time when the FDA faces more challenges than ever in keeping America’s supply of prescription drugs safe and secure, legislation liberalized drug importation could cause additional drug safety concerns. The volume of importation that could result from enactment of these bills could easily overwhelm an already overburdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the distribution system for incoming foreign drugs. Some of these proposals will take away our existing authorities creating unprecedented prohibitions on FDAs authority to inspect and contest drugs, and FDA’s authority to block the distribution of drugs within (UNINTELLIGIBLE). Perhaps most importantly, in addition to allowing in some drugs that may be safe, these bills create wide and poorly regulated channels through which counterfeit drugs, controlled substances, and other unsafe drugs may enter our drug supply.

In closing, Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We appreciate the committee’s interest in
assuring that the American public has access to safe and approved medicines. We believe that this is an important goal to attain, but affordability must not come at the expense of safety. Thank you again for this opportunity to participate in today’s hearing. I’ll be happy to answer any questions.

**SENIOR JOHN MCCAIN:** Thank you, sir. I think it might be important to enter in the record a congressional resource that was given to Congressman Gutkencht which was very interesting. It says this memorandum is in response to your request regarding statutory language that expressly limits the reimportation of products to the manufacturer of product as is the case with respect to pharmaceutical importation. It goes on to say, we have been unable to locate any statutory provisions similar in language and structure to the one in the Food, Drug and Cosmetic Act. In other words, anything else can be reimported – chemicals, pollutants, munitions, anything else, except for drugs. It’s remarkable testimony to the power of the pharmaceutical industry in the legislative body. Governor, your Minnesota plan, now has it been adopted by the legislature?

**GOVERNOR TIM AWPLENTY:** Mr. Chairman, we don’t believe we need legislative authority for it. We’re pursuing it administratively, and we believe we can implement it without legislative approval.

**SENIOR JOHN MCCAIN:** If it went to the legislature, could you get it?
GOVERNOR TIM AWPLENTY: I believe so, yes.

SENATOR JOHN MCCAIN: Let me suggest that you do just so that you get that stamp of approval. What do you see as an impediment to the implementation? What do you foresee roadblocks that are going to be in your way here?

GOVERNOR TIM AWPLENTY: Mr. Chairman, it’s mostly the allegations from the pharmaceutical industry and candidly from the FDA that this could raise safety concerns, and my first response to that is show me the dead Canadians. Where are the dead Canadians? And, we’re not talking about rogue Internet sites in Malaysia, or some third world country. We’re talking about established, reputable, credible, accredited pharmacies that we have identified.

SENATOR JOHN MCCAIN: Do you think legal action will be taken to try to prevent you from implementing this plan?

GOVERNOR TIM AWPLENTY: We hope not. Candidly we’ve gotten some mixed signals. In the Boston newspaper, the FDA official was reported saying they would unlikely go after a state or a government entity that tried an approach like ours, but more recently their comments have been more ambiguous and have said they’re reserving their options. Now, if they sue me, I’m willing to be sued. If they want to throw me in prison, that’s something I at least have to give some pause to, and I’m hopeful that it might deter us, but I at least need to think about that. But, I’d like to get some signals from them before

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SENATOR JOHN MCCAIN: Well, governor, given the threat that this really poses to the pharmaceutical industry, if I were you, I’d be prepared for most anything, and that’s why I suggest that you go to legislature. These people will stop at nothing because if this works in Minnesota, it’s going to work in every northern state, and sooner or later, it’s going to work in every other state. So, stand by sir, because I wouldn’t whatever they would do including what’s already been rolled out and that of course is needless deaths of so many citizens.

GOVERNOR TIM AWPLENTY: I appreciate it. Mr. Chair, can I ask - I had one other quick thing. You visited our Veteran’s Hospital in Minneapolis and thank you for your leadership and I’m glad as well, but at the Veteran’s Hospital in Minneapolis, it’s federally regulated, federally funded, federally administered. They have a pharmacy there. Guess what? They mail out lots of prescriptions every day, and if you assume the pharmacy that we would contract with and identify in Canada are credible, we know - we already have in place the distribution mechanisms because our Vet’s Hospital does it. So do lots of other approved established pharmacies in Minnesota and elsewhere. It can be done Mr. Chair. We’re just asking for a chance.

SENATOR JOHN MCCAIN: I’ve visited that facility, and another point about the pharmacy there - the drugs that they...
acquire are much less expensive than that that are acquired outside of the VA or the DOD because they bargain the prices.

GOVERNOR TIM AWPLENTY: Thank you Mr. Chair.

SENATOR JOHN MCCAIN: Thank you, Senator Dorgan.

SENATOR BYRON DORGAN: Mr. Chairman, thank you very much. First of all, Governor Awplenty thank you for a refreshing approach to this issue. I have written you a letter about two weeks ago, actually a joint letter to you and the governor of North Dakota suggesting that we create an alliance and that both states move together on this. I think what you’re doing is innovative and interesting and I encourage you and am pleased that you are here to present testimony today. Mr. Taylor, I know that you are here on behalf of Commissioner McClellan, and I deeply regret that he is not here. I don’t know the reason for that, but I must tell you that your testimony is extraordinarily disappointing to me. The behavior and the actions of the FDA have been very disappointing to me. They are not in the character, in my judgment of an agency that is really interested in the safety and the well-being of the American people. They seem almost too anxious to find a way not to help the American people on this issue of pricing. I want to ask you a question. Do you know anything about meat inspection, Mr. Taylor?

MR. JOHN TAYLOR: All of it sir.

SENATOR BYRON DORGAN: Do you know how we handle meat
MR. JOHN TAYLOR: My understanding is that USDA actually has people stationed overseas, and help handle - I mean Canada. In other countries, and they help insure that before the product is imported that the product meets standards here in the United States.

SENATOR BYRON DORGAN: Know what we do? Let me tell you what we do because if you were in Perrimer, North Dakota (misspelled?) today at the border, you’d discover that there’s a truckload of meat that comes in from Canada into our marketplace. That meat has been inspected by the Canadians in a Canadian meat plant and we say that we will allow reciprocal treatment with respect to inspections. We accept their inspections, and they accept our inspections as having represented the issue of safety for both people. And, so we have decided that reciprocal treatment across the border with respect, for example, to inspecting meat, and so that meat comes across in a truck. We say, “Inspected in a Canadian plant. Good enough for us, because we’ve taking a look at that.” Now, if that’s the question with respect to meat, you’re saying that drugs are different. So, let me ask this question, if pharmacists from Grand Forks, North Dakota licensed by our state, studied in pharmacy, running a drug store, practicing pharmacy in Grand Forks, goes to Winnipeg Manitoba, and goes to a pharmacist in Winnipeg Manitoba, licensed by that country,
which I think you will admit has nearly identical chain of
supply and custody for their drugs, would you tell me that in
that circumstance there is any danger at all to the consumers
in this country when that Grand Forks, North Dakota pharmacists
acquires that Tamoxifen at the Winnipeg pharmacist and brings
it back and passes the savings along to the consumers? Describe
to me the danger to the consumer in that transaction.

MR. JOHN TAYLOR: Sure, and let me take a step back. We
think that Canadian regulatory system is a good one, and we are
by no means suggesting that Canadian drugs are bad. The problem
though is the Canadian system, like the US system, is
essentially designed to afford protection to it’s citizens. So,
the potential harm here, and the Canadian authorities have said
this, is that their authorities are not really set up to insure
that products that are exported from Canada to the United
States are safe and effective. So, there’s a little bit of a
regulatory gap between the Canadian regulatory system and the
US regulatory system, and so we are talking about our concern
about price of importing to the United States, it’s because
those products are being imported outside the US regulatory
system and they are also being exported outside of the Canadian
regulatory system which allows this gap and the potential for
abuse and the introduction of products of unknown origin or
quality. So, that’s the concern.

SENATOR BYRON DORGAN: Mr. Taylor, that is just not
true. I mean, you can say it, but it is just not true that if in the circumstance of the US pharmacist who is licensed, or a US distributor who is licensed accesses a supply of prescription drugs from a licensed pharmacist or distributor from Canada, it is not true that somehow that is outside of the established regulatory framework. You can say it, but it is not true.

MR. JOHN TAYLOR: With all due respect sir, it is true, because at the end of the day that example does not necessarily get to the quality or the origin of the product that is being discussed and being passed between the two pharmacists. That is one of the potential risks, and we have tangible examples of that.

SENATOR BYRON DORGAN: Mr. Taylor, Vyox. If you are licensed pharmacist in this country, and you drive to Canada today to buy Vyox from a licensed pharmacist in Canada, and you pay not the $2.20 a tablet you would pay as a US consumer, but 78 cents a tablet because the same drug in the same bottle made by the same FDA approved company is marketed in Canada for less than a third, there is no circumstance under which that is leaving the regulatory framework of the US and Canada. The person that sold it to you in Canada is licensed and part of the chain of custody, and you as a licensed pharmacist in this country are part of the chain of custody, you’re simply wrong when you say that some how this outside of the regulatory
MR. JOHN TAYLOR: Sir, as I noted in my written testimony, there is certainly circumstances where an overseas manufacturing facility will manufacture product for the American market, but they will also manufacture product for other markets for example they might manufacture products for Asian, Canadian, European market. In some cases those products are very identical, but they don’t have to undergo the same requirements as a product that is introduced here in the United States. So, there still is a difference in those two products, albeit in some cases smaller than if the product was completely unapproved, it had not gone any type of testing for safety or efficacy.

SENATOR BYRON DORGAN: Mr. Taylor, I’m not trying to browbeat you here, but it just too labored to get to that point and then find out you’re wrong. You say very identical. It’s either identical or it isn’t, and the fact is Lipitor which is sent to this country and Canada from Ireland, and I assumed produced in Ireland as a result of materials that are gathered from Asia and other parts of the world, producing a pill in Ireland put in this bottle and sent in identical form to a pharmacist in Canada and the US, the only thing that is not identical is the price. The US consumer pays triple, and the governor says that there is way to access that supply without at all injuring his constituents because it will still be
within the chain of custody especially with respect to pharmacists and licensed distributors, but let me make one other point if I might. Mr. Taylor, you’ve heard testimony today that we have one million plus people who go across to Canada to buy those prescription drugs. Lewis Lupka’s going to testify. Lewis is right over there. Lewis will you wave? Lewis actually went to Canada with me to the one room pharmacy in Emerson Canada and bought some prescription drugs. He knows what he bought. He bought the identical drug in the identical container made by the same company with exactly the same safety standards. Now, can you site one instance, not a bunch, one instance in which a US consumer has been harmed by accessing a prescription drug from Canada?

MR. JOHN TAYLOR: I do not have any reports of death. However, based on the information, the blitzes that we’ve done and the information that we’ve seen from products coming from Canada for example, as part of our blitzes this summer, we noticed control substances coming from Canada which are per se potentially harmful. We noticed products that did not have the requisite labeling, which is potentially harmful. We certainly know there is the potential for harm that can befall some citizens, and if I may Senator, going back to your Lipitor example and you might not find this compelling, but it’s illustrative of our concerns. In the context of Lipitor, this summer we had one of the biggest drug recalls ever in regards

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to counterfeit product, and it involved Lipitor. One of the challenges for the FDA and one of the challenges in terms of educating consumers is that many of the bottles contained FDA approved Lipitor for Lipitor that was manufactured and approved for foreign countries as well as purely counterfeit Lipitor. One of the difficulties that we’ve had in protecting the public health was getting out the public health message that explained to consumers why they need to be careful, and the reason that was so difficult was when we did the analytical testing, there was very little difference at times between the foreign version, the (Unintelligible) version and the counterfeit version, but that difference was enough so that it could negatively impact the benefits that patients were deriving. So, I’m just saying that that’s a situation where ostensibly it looks so iniquitous, but in this case, the counterfeiters used and introduced FDA approved product, foreign version product, and counterfeit product in the same bottles which had a confounding affect, and so those are some of the situations that are of concern to us.

SENATOR BYRON DORGAN: Mr. Taylor, I’d like to conclude by saying that’s not exclusive to prescription drugs. That could be Similac, baby food, couldn’t it.

MR. JOHN TAYLOR: You’re absolutely correct.

SENATOR BYRON DORGAN: I’ve seen two cans of baby food, one counterfeit, one not. Why don’t we have a law banning the
reimportation of baby food? I could think of a thousand items that we might want to do this to if you start down that road. Our point is this, decent legislation that is protective of the interests with respect to safety and against counterfeiting that allows a chain of custody in Canada to represent a connection to the chain of custody in this country and therefore afford the American consumers lower prices for prescription drugs, is something that I would hope that the FDA would find a way to help us implement instead of going out of his way – Mr. McClellan goes out of his way to see if he can’t find a way to stop this stuff. It’s almost as if he represents the prescription drug industry rather than has some interest in American consumers. I regret he’s not here today, because I think he is creating a terrible record on behalf of the FDA. I don’t mean to – you’re here I know at his request, and your job is to represent what the FDA’s current views are according to Mr. McClellan. Let me – one final point. You know that the FDA even communicated with an insurance company in North Dakota to say, “We demand that you not cover prescription drugs even if you have a prescription drug piece in your insurance policy, we demand that you do not cover it if they get it from Canada.” That’s the sort of nonsense that’s going on with the FDA, and I regret it.

MR. JOHN TAYLOR: Sir, can I – in regards to the insurance company. I remember your exchange with Dr. McClellan

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SENATOR BYRON DORGAN: I was a little happier that day, wasn’t I?

MR. JOHN TAYLOR: No sir, you were not. We indeed are going to address that concern, and we are going to send you a letter by the end of the day. The letter is going to state that for insurance companies that are merely reimbursing, it is not a concern for us.

SENATOR BYRON DORGAN: That exchange took place, I think, probably eight months ago.

SENATOR JOHN MCCAIN: Senator Snowe?

SENATOR OLYMPIA SNOWE: Senator Wyden.

SENATOR JOHN MCCAIN: Senator Wyden.

SENATOR RON WYDEN: I want to thank my colleague and I’ll real brief. I just have one question for Mr. Taylor. Dr. McClellan has been quoted in the financial press several times in the last couple months, last 60 days, talking about how the agency is going to put a new focus on trying to make medicines more affordable, and the interviews essentially say, “Look, our obligation is safety and efficacy, but we also have a new focus on affordability.” I can not however, find any initiatives that actually translate into something specific that the agency is doing trying to make medicine more affordable, and I wanted to give you a chance on the record to tell us what the agency specifically is doing to make medicine more affordable.

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MR. JOHN TAYLOR: Sure, I will take a shot at that. As I stated in my oral testimony, one of our main focuses is to insure that there’s greater access to generic drugs both in terms of work with the Hill and work around, and I want to make sure that there is less legislation. In regards to the introduction of generics, more generics get on the market faster and so people have greater access to it. We want to do more outreach and education for the American public regarding the benefits of generics. One of the things that’s been discussed today is Tamoxifen. Well, a generic version of Tamoxifen was introduced in February of this year, and actually only costs $47 which is cheaper than any branded version either in Canada or the United States. We’re also taking steps as part of we have what is called a – it’s called the good manufacturing practice initiative. What it really is is an initiative to look at innovations in manufacturing to try to find a way to help industry reduce manufacturing costs without easing up on the regulatory oversight that we currently maintain over industry. We’re also trying to improve our education outreach in terms of making sure whether it be generic sponsors or sponsors of innovative products, that they have a better understanding of the agency’s expectations in regards to the approval process. Once again, to insure that there are fewer delays that again will be to more products being available to Americans. So, I think those are some of the
initiatives that form the basis of (UNINTELLIGIBLE).

SENATOR RON WYDEN: I’d like to hold the record open on this point, because again it seems to me what the agency has always said, is that they’re going to try to delay red tape and bureaucracy in terms of getting drugs out. I think that’s good, but that hasn’t translated into making medicine more affordable, and I can’t see anything other than these sort of outreach programs and I was — when I was director of the Gray Panthers, I was going to FDA outreach programs to tell people about medicine, and I don’t want to take Senator Snowe’s time, but I’d like to hold the record open and have you tell us exactly what these new initiatives are to make medicine more affordable than is being pursued at the agency, because I will tell you I can not find anything specific that really is different. Thank you, Mr. Chairman.

SENATOR JOHN MCCAIN: Senator Snowe?

SENATOR OLYMPIA SNOWE: Thank you, Mr. Chairman. Governor Awplenty, I want to commend you for your assertive and bold leadership. The people of Minnesota are being well served, and it’s just regrettable that we haven’t reached a point here in the Congress and with FDA to remove those hurdles and obstacles to give you a clear path towards doing what you need to do on behalf of the citizens of Minnesota, and Mr. Taylor I would like to ask you to speak to a question about why — what is preventing the FDA from seeking to do no harm when it comes
to helping consumers? Because the point is here is the safety certification under current law, and as was preventing from implementing because the Secretary of Health and Human Services has not implemented – hasn’t made the safety certification requirement under law. So, is it that you need a new law without those safety certification requirements? Are there things that you could do now to assist in this process like listing licensed websites and websites of pharmacies establishing a pedigree because it would get to the point that you raised earlier about some of the problems in tracking medications coming across the border? That obviously would help if we have FDA approved labs in Canada. We have not discerned any problems with those medications because they’ve been certified through the FDA approved standards. They have comparable safety requirements. So, what is the issue here? Is it because we don’t have the right law in place at this point to remove the safety certification which we had hoped that Senator Dorgan’s legislation? What is that would help you to do your job now?

MR. JOHN TAYLOR: Well, Senator, I - for the agency, our overarching concern is that the legislative proposals that have been brought to us so far, we feel create loops in the FDA safety net and the state’s safety net and we have not in the light of the increasing number of products coming overseas, we just think that is problematic from a public health standpoint.

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As I noted earlier, it is also in stark contrast to the situation that we’re involved in Senate which is where we are actually taking steps to strengthen our ability to protect the food supply. So, our overarching concern is that so far the proposals that have been brought forth are proposals that actually undermine the system and I, right now, have people – I will acknowledge that my investigators are overwhelmed. I mean, you’ll hear that there are various estimates as to the number of packages that are coming overseas. In some cases, it’s as low as two millions, some cases five, ten or 20, but it doesn’t really matter the number because we are completely overwhelmed and even if in the legislation you set up a system that purports to introduce a product that is introduced in the course of certain provisions, at the end of the day, we are the ones – my people are the ones who are going to have to make sure that those products do no harm to the American consumer.

SENATOR SNOWE: We’ve heard so far that the FDA, to William Hubbard, Senior Associate Commissioner of the FDA in his testimony last June before the House Subcommittee, no evidence of any American died from taking legal drugs from another country. At the same time, according to data tracked by the National Institute for Health that 5,000 Americans die each year of food borne illnesses, food imported from other countries, that are monitored and inspected by the FDA. So, I’m confused. I think we got a problem, we want a solution. Now,
I’m not hearing any solutions from FDA. You’ve had plenty of opportunities to develop solutions. Okay, for example on the pedigree, that was mandated for prescriptions back in 1992 by Congress. That would take care of that problem, because you could easily monitor and track any medications coming across the border. Now, the FDA commissioner acknowledges there’s little risk in walking into a licensed Canadian pharmacy and filling prescriptions. So, what is the issue here that we need to solve immediately? We’re not talking about something down the road ten years. It’s already been ten years since the pedigree talking. What can we do right now, rather than threatening consumers? Why aren’t we trying to solve the problem?

**MR. JOHN TAYLOR:** The problem, Senator, you just read the commissioner’s statement as I described earlier. We think that the Canadian system obviously is a strong system that insures that its citizens get safe and effective products. However, the Canadian government does not assure that the products that are coming to the United States are safe and effective. So, there’s a gap between—

**SENIOR OLYMPIA SNOWE:** Doesn’t this law do it? I mean seriously.

**MR. JOHN TAYLOR:** We currently —

**SENIOR OLYMPIA SNOWE:** Go through a list of suggestions – a published list of licensed pharmacies and associated
MR. JOHN TAYLOR: No, to that - right now -

SENATOR OLYMPIA SNOWE: Would you do that right now to help Governor Awplenty in his job? I mean, could you do that? I mean what is difficult about doing that?

MR. JOHN TAYLOR: No -

SENATOR OLYMPIA SNOWE: Pharmacies, you couldn’t do that?

MR. JOHN TAYLOR: To the extent that we have taken action against pharmacies or against manufacturers, we do post that on our website so that the American consumers can know what products to stay away from and what websites to stay away from.

SENATOR OLYMPIA SNOWE: How about enforcing the requirement for all drug pedigree sales?

MR. JOHN TAYLOR: Right now, the pedigree requirement has been stayed Senator, and what we did is we sent a report to our House Appropriations Committee explaining the reason why it’s been stayed and asking further advice on that issue.

SENATOR OLYMPIA SNOWE: What about required counterfeit resistant packaging? How difficult is that? We do that with currency and numerous other instances. What is the difficulty there?

MR. JOHN TAYLOR: We currently, as part of our market initiative, we are looking at the different types of
counterfeit technologies that are available. I think, however, we need to be cautious about relying on any one technology. One of the things that we’ve discovered as part of this initiative is that they’re going to need to be used with multiple strategies to prevent counterfeiters from overriding the technology, but that is something that we are currently working.

SENATOR OLYMPIA SNOWE: I believe the 21st Century Americans had developed that technology.

MR. JOHN TAYLOR: Well, Senator just like the challenges of the Secret Service with the currency, over time there’s enough of an incentive for people trying to override the technologies no matter how good they are. So, there needs to be constant steps to develop newer and stronger technologies.

SENATOR OLYMPIA SNOWE: Many of the drugs sold, as I understand, in Canadian pharmacies were manufactured in the very same plant as those sold in US pharmacies. In fact, Doctor McClellan was quoted as saying with regard to the safety of prescription drugs in Canada, they keep drugs safer in Canada, and I think they do a very good job of that. So, again, getting back to the issue, what can we do that’s proactive? What I’m hearing from you, if we pass a different law with safety certification requirements, you still wouldn’t do the job. That’s what I’m concerned about. That’s what I’m hearing.

MR. JOHN TAYLOR: Let me try and answer the question,
obviously, once again, our overarching concern is that we realize that affordability is important, but we want citizens to have products that are safe, effective, and affordable. And, we understand that for these drugs that as part of our steps we look at generics in other ways to try to ensure that affordability, and as the head of my - as the office of regulatory affairs, it’s my job to ensure that to the extent that these products are coming across that they’re safe and effective. The decision really rests with the Congress in terms of how best to change the Act, because it’s Congress that decided that these safeguards need to be in place. We recognize that whatever that change will be, that if there’s a change in place that’s going to be used to facilitate the importation of drugs, we realize that change will be a fundamental change from the way that we’ve done these before, and what we need are steps that will help us despite that fundamental change to still provide the American citizens with the same requisites level of safety and effectiveness and that includes the need for the American citizens and my agency to go out and work together to inspect facilities, to make sure that there is the requisite level of controls that are in place now, that allow the system that we have in place to insure that people are not -

SENATOR OLYMPIA SNOWE: Because they have FDA approved facilities in Canada. We know this to be the case. And the
reason why the Secretary of Health and Human Services under existing laws not meeting the safety certification. So, is your agency charged with developing safety standards? Do you not do that? Could that be possible?

    MR. JOHN TAYLOR: Well, Senator, certainly everyday we try and take steps - try and build on the safety, but right now, we still are unable to say based on that certification - this is certification that’s made by Secretary Shalayla and Secretary Thompson - that that plan will insure that American citizens are getting products that are safe and effective. We just can not make that determination.

    SENATOR OLYMPIA SNOWE: That was several years ago. Now, we’re in 2003 going into 2004.

    MR. JOHN TAYLOR: That’s correct.

    SENATOR OLYMPIA SNOWE: And, that’s the point. I mean this is - this wouldn’t be difficult, Mr. Taylor, and I realize you’re not the commissioner, but this would not be difficult. I mean, we’re just complicating what could be a very simple situation. The counterfeiting that was referred to earlier was basically a domestic problem.

    MR. JOHN TAYLOR: That’s not exactly true. Some of the counterfeit cases that we handled this year including an appropriate case which involves cancer and AIDS medication, indeed was domestic in nature. It originated from the state of Florida. However, the Lipitor counterfeiting case - those
products were introduced from overseas.

SENATOR OLYMPIA SNOWE: But, if you had the pedigree in place that you would have been able to identify, would you not?

MR. JOHN TAYLOR: Senator Snowe, I can’t say – in light of this of scheme – in light of that particular counterfeit scheme, it’s not clear that the pedigree would’ve done anything to stop the spread of the product.

SENATOR JOHN MCCAIN: Senator Boxer?

SENATOR BARBARA BOXER: Thank you. I want to thank my colleagues for their questioning. Its just been very enlightening. I want to say to Mr. Taylor, I’ve been in Congress for 21 years, and I know a phony trade barrier when I see it, and that’s what’s going on here. You can tell from Senator Snowe’s questioning – not you personally – this administration and I might say the one before didn’t want to do this, period. And, it seems to me that you’re saying you’re overworked and understaffed, then tell us what you need in order to identify a couple of places where the good governor can go that you think would be safe. What would it take? I don’t think much. I think you’re reading a line that I’ve heard over the years, and the only people, I believe who we’re hurting are the senior citizens who can’t afford the medicine. It is a moral issue. Governor, I want to tell you something. I think you’re terrific. I want to tell you that everything in this bill that I know of, this Medicare bill, and I withhold
judgment because it hasn’t come out. I haven’t read every line of it, but everything that I’ve read so far – we have to read it before we vote on it, but everything I know about it says to me they’re doing everything they can to from getting cheaper drugs, period, end of quote. They took generic provision that was written by Schumar and some others, weakened it. They took the importation measures that have been worked on for so long by folks in the House and senate, including Senator Dorgan who really brought this to my attention, and what they have done that to is essentially emasculated it because you’ve got people like Mr. Taylor sitting over who don’t want to do anything even if it didn’t have a certification in it. So, it’s kind of a hopeless deal. They put a gag rule on Medicare in terms of their ability to negotiate drug prices. The only thing they haven’t done is stop you. They haven’t stopped you yet. So, my hope is you listen to what Senator McCain is offering you as a suggestion. Get the broadest support you can back home. Hold these open hearings. Get your Senators and your assembly people, whatever they’re called there, to go with you on this thing, and let’s have you be a model for the rest of us. I mean, I know they’re doing it in some other states, but I think you, it seems to me are going to go forward, and this is – these days of the Internet, you’ll be able to ID for the rest of the country, Internet sites for our senior citizens so they can get a 90 day supply of drugs. So, they won’t have to make

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these horrible choices that they’re making, awful choices
you’re making between living and eating and helping their kids
and the rest of this. This is really a life and death type of
deal. And, to have a trade barrier, artificial one put in place
that’s leading to people becoming impoverished – every penny
they get in social security increase is gone before they even
turn around. It’s just awful, and so I guess that’s all I
wanted to say, Mr. Chairman. I’d like to hear from you
Governor, one more time – I hope my Governor is listening
because I think that he should make a move on this situation.
We have folks going to Mexico day in and day out to get cheaper
drugs, you do to from Arizona, day in and day out. I just
don’t believe that you can’t in the FDA pick out four places in
Canada, pick out two places in Mexico, pick out one place in
Canada, pick out one place in Mexico, and say, “We have done
due diligence on this.” And help our governors because right
now, our people are hurting and its our job to make life easier
for people, not harder for people. The health and safety of our
people, that’s our number one responsibility, whether it’s
military protection, but this is our number one, and we need to
do it. So, Governor tell us one more time, have you given a
little thought to what Senator McCain said about making this
sort of a whole united Republican, Democrat, Independent, farm
raised or whatever you’ve got out there, kind of a move.

GOVERNOR TIM AWPLENTY: Senator, thank you, and thank

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you for the chance to add a few closing thoughts. First of all, I think this is the prescription drug equivalent of the Boston Tea Party. People are fed up. They’ve had it, and whether its this year in Congress or next year in another state, or this year in Minnesota, the rebellion is under way, and we hope you join us because the current structure can not be sustained. The generalized concerns that you hear from the FDA and others is this always gets fogged up. We’ve got fingers in the dike from all over the world. We’ve got all these problems. That’s not what I’m talking about. We’re talking about establishing a relationship with experienced, credentialed, accredited, established, reputable pharmacies in Canada and maybe a few other countries as a second step, and as applied to those institutions and as applied to the mail mechanisms we know already exist, this system does not have the problems that are being suggested by the FDA so, please don’t let the voices confuse the debate. Please narrow it to what we’re actually talking about, and I would hope that the FDA instead of finding a hundred reasons to say no, and a hundred reasons why this can’t work, will pull up along side and say, “We’ll help you.” I’ll even pay them for it. You don’t have to do it. I’ll find the money to get some people to come up and help us if they’ll do that. If they won’t, concerns about health safety and welfare are precisely what government is supposed to do. We can, in our own little Minnesota way, bring a Good Housekeeping
seal of approval to these entities on our website, and give people more assurance than they’re getting now on these roque sites that these are credible places. And, lastly, it probably is fair to say that if everybody in the whole country moved to this all at once, we would overwhelm the FDA, we would overwhelm the Canadian pharmaceutical industry and infrastructure and their regulatory authorities and so I have a suggestion for you. I hope we’ve demonstrated that this debate has crossed a threshold of credibility and it’s at last worth a try. So, as a compromise, could the Senate say we’re going to authorize a certain number of pilot projects, we’ll road test these theories or against. In a year and a half, we’ll evaluate it, or two years we’ll evaluate it. We’re not afraid of the results. I hope the industry and the FDA isn’t either, and then we can see. And, then lastly, to Senator McCain’s point and your point, I would be delighted to lead the charge in Minnesota to not only have us do this administratively and unilaterally, but to get a legislature on a bi-partisan, tri-partisan basis to endorse it and come along with us. As you do know, that once you put it into the broader political arena of the legislature, all the forces namely the industry comes down hard. So, we’ll have a fight on our hands. Its’ the kind of a fight I’m willing to fight. I mean, I’m happy to do it. I’ll add some extra security, Senator, and on we will go.

SENATOR JOHN MCCAIN: Well, there’s some of us who would

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love to come up and help you, and I mean that. I mean that very sincerely, many of as you mentioned this has passed a threshold which is the Secretary of Health and Human Services doesn’t testify on this issue, the pharmaceutical industry doesn’t show up. Mr. Taylor you do, and I want to thank you for that, and your reward, I’m sure will be in Heaven, but I do appreciate the fact that you have had the willingness to appear before this committee. Your suggestion, governor, we’ll try it. We’ll try it, but I’ve got to tell you, you may have the kind of power that’s on this prescription drug bill which is supposed to be saving not only individuals but the government money, and when they put in a provision that you can’t – the government is not allowed to negotiate in a fashion to keep those cost of drugs the lowest, and they’re able to get that as a provision in the bill, I’m sorry to tell you I’m not optimistic. It will not deter us from fighting for it, but if there’s ever ample evidence of incredible power of the pharmaceuticals and you’re going to see when they pass the bill even though it will have huge costs associated it, and 600 billion costs on a collapsing Medicare system which it can not stand more than six or seven more years. Thank your Senator or Congressman for voting for this bill and for prescription drugs paid for by guess who? The pharmaceutical association who have been able to prevent the costs of drugs from being lowered by allowing the government to do what the Department of Defense and the VA. I’m sorry to make

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you cynical about the way we try to do the Lord’s work in the
city of Satan governor, but I didn’t want to respond to.

GOVERNOR TIM AWPLENTY: Mr. Chair, I tell the people of
Minnesota that big change comes in one of three circumstances -
war, crisis, and particularly gifted leadership, and in
Minnesota we have a war, we have a crisis, and I don’t know
about the leadership, but the circumstances are such that
change will come, and now it’s just a matter of when and where
and how.

SENATOR JOHN MCCAIN: It is an issue of - I go to any
town hall meeting with seniors in my state, and I’ll tell you,
it’s a huge -

GOVERNOR TIM AWPLENTY: All the seniors from your state
are from my state.

MR. JOHN TAYLOR: Mr. Chairman, for fear of continuing
this. I just want to make a point that we obviously respect the
government’s goals and wishes, and we do look forward to
sitting down and talking to you, and not putting you in jail,
and hoping that we can at least express and articulate our
concerns. I mean we obviously want to make sure you know the
source of your products because we know that there at least in
the past there was some question about whether the
(Unintelligible) and just provide you other - we can even
provide you information what we see today, and that will help
you with your decision and allow us to engage in a give and

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take. So, as I said before (UNINTELLIGIBLE) to you before, but we’re happy to do so.

SENATOR JOHN MCCAIN: Thank you very much. Thank you.

Our last panel is Mr. Carmen Catizone; he’s the Executive Director of the National Association of Boards of Pharmacy, Mr. David Funderburk, who is legislative counsel, TREA senior citizens legal, Mr. Lewis Lupka, a senior citizen from Fargo, North Dakota, Mr. Donald MacArthur, Secretary General, European Association of Euro-Pharmaceutical companies. Welcome. Mr. Catizone – is that the proper pronunciation?

MR. CARMEN CATIZONE: Yes, sir.

SENATOR JOHN MCCAIN: Welcome, please proceed.

MR. CARMEN CATIZONE: Thank you. It’s an honor to appear before the committee today, and share our thoughts on this very important issue. I am the Executive Director of the National Association of the Boards of Pharmacy, which was founded in 1904 and consists of all the pharmacy regulatory and licensing jurisdictions in the United States, Guam, Puerto Rico, the Virgin Islands, eight providences of Canada, the Australian states, New Zealand and South Africa. Our association also maintains a list of pharmacies that operate on the Internet that are legal and safe in response to questions from Senator Dorgan and also the Governor of Minnesota. To purchase imported drugs from other countries, places access to affordable medications clearly in oppositions regarding the safeguards of
our drug approval process and state regulation. The philosophy among the present course, it will move the food and drug administrations approval process in dispensing of medications for chronic diseases from the US to the country, territory or backroom with the lowest prescription drug prices regardless of the standards or safeguards in place in those other countries or territories. NABP also understands that the pricing of pharmaceuticals in the US differs from Canada and other parts of the world. We believe that the US pharmaceutical industry must address this situation, and propose meaningful changes to the pricing policies in place in the US and the world. NABP has no affiliation with the pharmaceutical industry, nor do we receive any appreciable funding from the pharmaceutical industry. NABP acknowledges that appropriate safeguards exist within Canada’s several provincial regulatory systems to insure that the dispensing of medications in Canada to Canadian patients is safe. Important to note from information obtained directly from Canadian regulatory authorities that Health Canada prohibits the import of drugs for dispensing to Canadian patients, but it does not prohibit or regulate the distribution of drugs that are imported for export to US patients. This regulatory void and breach of the safety net for US patients is significant and unknown to the overwhelming majority of patients ordering drugs through Canadian pharmacies. Shockingly, Internet operations in Canada, are already

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providing US patients with drugs unapproved in Canada or the US. Several newspapers have documents interviews with Canadian Internet pharmacists who admit to freely purchasing and exporting to the US medications from Pakistan, Bulgaria, and Latin America that were not approved or regulated by Health Canada. The example given by Senator Dorgan of two licensed pharmacies and pharmacists interacting and exchanging medications would provide a safety net between the two countries, however, that system is not in place in all instances, and in fact the later situations is predominately in place for those Internet operations. NABP’s counterpart in Canada, the National Association of Pharmacy Regulatory Authorities, will be launching a program in Canada which is a verified Internet Pharmacy practice site program to accredit, identify and alert to Canadian patients which pharmacies are legal and safe to practice pharmacy and conduct business on the Internet. We are also working with NAPRA to discuss a regulatory framework for the interborder regulation of the practice of pharmacy in dispensing of medications to patients from the US and Canada. The framework will coordinate the regulatory efforts and resources of the Canadian providences and the US state boards of pharmacy, and look to the FDA for guidance and assistance. However, even if NABP and NAPRA successfully formulate the appropriate regulatory framework, neither NABP or NAPRA can make any representations for safety
when drugs are shipped to US patients and originate outside of the US and Canadian approval processes. In closing, NABP respectfully requests your support for careful and thoughtful approach to resolving this complex issue, and a rejection of the proposals fueled by populous rhetoric, that irresponsibly casts aside concerns about patient safety. And, we request further the committees’ assistance in preserving the sanctity of current laws and regulations so as to prevent any patient from being seriously injured by the illegal importation of medications from other countries. NABP believes that no patient should suffer or be harmed as a consequence of disregarding federal and state laws that insure the dispensing of safe and effective medications to US patients. Thank you.

**SENATOR JOHN MCCAIN:** Thank you. Mr. MacArthur, welcome. Thank you for joining us, and would you take the microphone.

**MR. DONALD MACARTHUR:** Mr. Chairman, Senators, the European Association of Euro Pharmaceutical Companies which represents around 70 parallel traders in medicines across 15 European countries is very grateful for the opportunity to contribute to this important debate. I think we can best do this by summarizing the experience gained over the past 25 years or more of parallel trading of medicines in Europe. Ours is an industry that last year alone moved 140 million packs of prescription drugs safely and efficiently across national borders within Europe. Given the opportunity, some of our...
members would undoubtedly like to bring the benefits of parallel trade to the US. Listening to some of our remarks made today and for those already in the US press, provokes a feeling of déjà vu, fears of unsafe, substandard, or counterfeit products flooding the market, and that any savings from parallel trade with any path to the middle man were made by truck manufacturers in Europe in the early 1980s. Both allegations are still made today. But, the mere fact that they’re repeated so often doesn’t make them true. They are not. Our biggest battle has been with misinformation. The facts clearly show that parallel trade is safe. There have been no adverse consequences to public health. Parallel trade is fairly regulated. All of our importing members hold manufacturing authorizations, all of our importing members hold wholesale authorizations. All of our members trade only in drugs which have European approval, in Europe to common standards. Every country accept one in the EU has abbreviated procedures for double checking parallel imports. The one country that doesn’t have procedures for allowing incoming parallel trade is France. So, it’s interesting that in at least one case France and the US have one thing in common. They don’t allow parallel imports. But, parallel trade can be strictly regulated with relatively light touch legislation. And, it allows only genuine products that have been approved for marketing elsewhere to common standards and produced by the same original manufacturers often

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in a very same plants. Parallel trade is totally free of counterfeits, pirated and substandard products through the 25 plus 30 years there’s been not one confirmed case of a counterfeit drug ever reaching a patient in Europe as a parallel import. Furthermore, on new occasion has a substantial product life (Unintelligible) parallel importers who were quietly maintained ever been needed. Parallel trade is the only form of price competition on the patented drugs. The part of the market that the generics can’t reach is present sufficient to moderate prices by manufacturers and to curtail subsequent price increases. Parallel trade brings significant savings to payers and patients. A recent independent study from one of the world’s leading academic centers for health economics, the University of York, shows that parallel trade in medicines directly save payers and patients the equivalent of almost 750 million dollars in 2002 at the current exchange rates in just five EU countries, UK, Germany, Netherlands, Denmark, and Sweden. Parallel trade fits in with the free market principle. If any one comes into the US to hear about drug prices being fixed. In Europe, they’re not. We have controls through the reimbursement system which I gather is the main method here. The minority of countries allow - have price fixing - the majority don’t. Some of the countries have total free markets over prescription drugs - UK and Germany are able to allow free pricing because they allow any incentive device to parallel

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imports. Parallel trade has absolutely new impact on the ability of the pharmaceutical industry to invest in R&D. We’re fully aware that the discussion in the US is focused on personal importation by the Internet and other means, and that Canada is seen as the main source opportunity. However, parallel trade unlike the Internet, can be affectively regulated. It’s capable of handling high volumes of all types of products, benefiting all patients rather than the favored few, and supports rather than destroys the local pharmacy and wholesaler infrastructure. While the policy of Canada products is not in doubt, the same is true of products from the EU. With the EU having the advantage of (UNINTELLIGIBLE), factory prices, the US drug market in 2002 was worth 196 billion dollars, while Canada was only eight billion dollars, 1/25th of this amount. So, achieve just ten percent penetration of the US retail drug market would require an impossible 262 percent of Canadian domestic sales. In contrast, next year, the EU will expand to 25 member states. The population of almost 500 million, and a drug market in excess of 100 billion dollars. But, even more important than adequate volume and attractive prices, Europe is where proven expertise in all aspects of parallel trade lies - in sourcing, quality assurance, regulatory, legal, labeling, transport and distribution. We believe that dialogue with the FDA should be started. We already in breaking a dialogue with the European medicine’s

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evaluation agency to see that we have a regular meeting with
them next week. The EMEA of course is in dialogue with the FDA,
let’s pool our expertise. We would welcome both members of the
US congress and the FDA to visit our plants to look them over
and check our procedures. In closing though, I believe that I
should say that Europe has a lot to learn from the US, and not
least from your Democratic processes and openness. Never once
in it’s existence has EAPC’s views ever been sought out by
European policy maker in a form like today. So, thank you for
that. Thank you.

SENATOR JOHN MCCAIN: Thank you for coming, Mr.
MacArthur. I think you contributed a great deal and given us
perhaps some avenues that we might pursue and we thank you.
And, from Fargo, North Dakota, Mr. Lupka, how cold is it in
Fargo today?

MR. LEWIS LUPKA: It’s like early spring. Global
warming.

SENATOR JOHN MCCAIN: We’re happy to see you here sir. I
think you have known Senator Dorgan in the past. So, there’s
several things you don’t want to reveal about him to the
committee.

SENATOR BYRON DORGAN: Mr. Chairman, if I might just say
again that I went to Canada on a trip and Mr. Lupka accompanied
me, and understands first hand the differences in pricing
between the US and Canada on the identical prescription drug.
SENIOR JOHN MCCAIN: Thank you. Mr. Lupka you’re welcome here and we appreciate the input of people like yourself who face these challenges on a day to day basis. Please proceed.

MR. LEWIS LUPKA: Chairman McCain and members of the Commerce, Science and Transportation committee, thank you for holding this hearing today on the impact of prescription drug importation on consumers. My name is Lewis Lupka. I live in Fargo North Dakota. I’m here today representing the Alliance For Retired Americans, the Alliance is a national organization of over three million members. It works to create an America that protects the health and economical security of seniors, it strengthens family and builds thriving communities. It was launched in January 2001 by a national coalition of reunions and community based organizations dedicated to improving the quality of life for retirees and older Americans. I’m 77 years of age, and take at least three prescriptions at any given time. Between Myocalcium and Forsenex (Misspelled?) for osteoporosis, and Synthroid for my thyroid, I spend well over two thousand a year on my prescriptions. I purchase my drugs in Canada to help defray these costs. This is a trip that was organized by Senator Dorgan. I saw my doctor in Fargo who wrote out my prescriptions, brought them to a doctor in the city of Emerson, which is a little ways over the border. After I saw the Canadian doctor, I took the prescriptions to a Canadian
pharmacy located in a building, I brought $300 in cash I wished I had brought a lot more. I came back with about $800 worth of prescriptions, and I never got sick. I mean it was just like I’d been taking right along. I feel completely safe in taking medications from Canada. The Alliance For Retired Americans has made more than 20 trips to Canada from states stretching from coast to coast serving hundreds of riders. No one has ever reported getting sick or had an adverse affects from taking these medications. I’m a veteran of World War II. I was a paratrooper in the 82nd Airborne Division. As a former welder, then a professor, an ex shipyard worker, ex assembly line worker, and ex steel worker, as well as retired member of the NEA, National Education Association, I lived all over this country. I’ve seen many people and witnessed a lot in a lifetime. I worked in a Hoboken, New Jersey shipyard, with Bethlehem Steel, returning the Stockholm after it collided with the Andrea Doria. I worked for General Electric in Kentucky before becoming a professor at North Dakota State University. I’ve always been a human rights activist, and was a part of Martin Luther King’s Civil Right’s movement. I’m still working for human rights. Senators, I know right from wrong. The bill that is coming out of the conference committee is not good for retirees. It does nothing to contain the skyrocketing prices of prescription drugs. In fact, it forbids Medicare from using the purchasing power of 40 million beneficiaries to negotiate the

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best drug prices. The federal government currently bargains for
the best prices for the Department of Veteran Affairs, the
Department of Defense and the Indian Health Service Systems.
There is no logic on why economists would forbid Medicare from
doing the same. Seniors and all taxpayers are the losers.
This bill caters to the pharmaceutical industry by
unnecessarily preventing American citizens from getting their
drugs in Canada where they’re safe and affordable. I have yet
to see anyone get sick from taking a drug imported from Canada,
but I have seen many people suffering from high drug prices
that they can not afford. Drugs in Canada are just as safe as
American drugs. In fact, many of the drugs from Canada were
made in the USA. Members of the committee, I’m here today to
ask that you enact the drug benefit that allows drugs to be
imported from Canada without loopholes that permit the
Department of Health and Human Services to stop safe
reimportation. To do anything else would make million of
seniors worse off. Thank you for inviting me here.

SENIATOR JOHN MCCAIN: Mr. Lupka, thank you very much,
and finally Dr. Funderburk, thank you for joining us. Why don’t
you proceed?

DR. DAVID FUNDERBURK: Okay, Mr. Chairman, I want to
thank you for the opportunity to testify today on behalf of S-
17-81. I serve as legislative counsel for the TREA senior
citizens league known as TSCL. It’s the nationwide non-profit
educational organization with approximately 1.2 million members, which will be celebrating it’s 10\textsuperscript{th} anniversary in a few months. TSCL’s board of trustees is an all volunteer group of retired military and it’s vice chairman George A Smith. It sends out information news letters, stays in touch with its members via email, publishes informational booklets and has an information pack website \url{www.tscl.org}. TSCL has nearly 23,700 members and supporters in the state of Arizona and in your state of North Dakota, several thousand members, Mr. Chairman. On the House side, TSCL has been working diligently on behalf of HR-24-27 introduced by Congressman Gil Gutknecht and is happy today to announce it’s support for S-17-81, your bill the companion measure here in the Senate. And, TSCL annual survey in February 2003, fully 87 percent of membership responding voiced their support for drug importation. The current high cost of prescriptions if crippling our seniors. One of our members, Lillian F. told us – “I don’t get enough Social Security for my medications, and I had to quit taking a couple of them. I have Parkinson’s. I take medication for that. It’s very expensive. Now, my husband had a heart attack and he has to take a lot of medications, too. So, I might have to quit taking more of my medicine.” Lillian F. wrote that email to us in April of this year. Her husband passed away and she has had to cut back further on her medications. It is on behalf of individuals such as Lillian that we support more affordable
prescription drugs and we believe S-17-81 is a good place to start. TSCL is absolutely committed to this drug reimportation legislation. Prior to the vote in the House of HR-24-27, TSCL ran a half-page ad in the Washington Times urging members of Congress to support passage of the bill. We also sent out email alerts to thousands of our supporters urging them to contact their elected representatives, and we continue our efforts through similar grass roots activities. As has been mentioned by many of those speaking previously, a drug that a senior or any American can not afford and therefore can not take is not a safe drug. TSCL Chairman George Smith wanted me to tell you that seniors especially ask to be treated like responsible men and women, and seniors should have the right to assume the miniscule risk of using a drug obtained from Canada rather than suffer the risks of not having the prescription drug at all.

William Hubbard Associate Commissioner of the FDA was part of this saying “It’s not okay for an individual to bring in drugs.” Referring to these bus trips of these individuals going to Canada, but so much of this stuff is coming in and it’s so uncompassionate to go after patients. Well, should we then have compassion for Minnesotans who are able to make the trip or North Dakotans to Canada, but not for Mississippians and others who are not able to make this trip? I want to thank the distinguished chairman for holding a hearing on this critical legislation and on behalf of TSCL, and it’s members. I urge the
Senate to join the House and approve this important legislation, and in closing, let me say TSCL wants to work with you and the committee on this issue and other issues that reports to seniors in the future, and I thank you for the opportunity to testify here today on behalf of TSCL and it’s members and supporters. Thank you Mr. Chairman.

SENATOR BYRON DORGAN: Mr. Funderburk, thank you very much. Let me indicate on behalf of Senator McCain who had to leave for another engagement. We very much appreciate the testimony of this panel, and I regret that the hearing took some long while this morning. As a result of that, my colleagues had other hearings to go to, and other places to go and so, let me make a couple of comments if I might about your testimony. I’m not going to ask questions because we need to adjourn the hearing. Mr. Catizone, I happen to feel very strongly that it’s very important to keep our main street pharmacists in the middle of patient healthcare, especially with respect to how prescription drugs act or interact. We have so many senior citizens who take multiple prescription drugs - four, six, sometimes ten or 12 different prescription drugs everyday, and if there’s not a pharmacist somewhere watching all of these drugs to find out how they interact and they might say to the senior citizen “These two are dangerous if you take them together.” “These two if you take them together nullify each other so you’re wasting your money.” It’s important that
that be the case. There’s so many circumstances in which
there’s not a pharmacist involved and someone’s seeing four
different specialists and they’re ordering medicine from four
different directions. Our ultimate goal, my goal, is not to ask
Americans to go elsewhere to buy prescription drugs, it is to
force a repricing of prescription drugs in our country, but I
value the role of the pharmacist. I feel very strongly about
the viability and the need for main street pharmacists. Mr.
MacArthur, you described the issue of parallel trade in Europe,
and it is identical to that which in my judgement we should be
doing. We have taken a slightly different approach, but your
description of parallel trading describes to us that all of the
nonsense we are hearing about safety issues is just that –
nonsense. It is apparently by your testimony and I heard this
previously, it is easy for the countries in Europe to engage in
a regime in which you are able to certify the prescription
drugs in each other’s countries and also to monitor the drugs
that are moving country to country, and so all of these safety
issues here are just raised on behalf of those who don’t want
to do anything to interrupt the pricing strategy in the US. I
think you have raised, Senator McCain has said, some important
issues for us to consider with respect to parallel trading
itself, which is slightly different than that which we’ve been
proposing. Mr. Lupka, I’ve known you for some long while, and
as I indicated, on a snowy day in North Dakota, we rode in a
van to Emerson Canada, and a one room pharmacy, you discovered what all of us know, and that is five miles north of the US pharmacy you can buy exactly the same prescription drugs, FDA approved, in the same bottle, the same pill manufactured by the same company for dramatically lower price. And, it describes what’s wrong with this system and why we have these hearings. The US consumer’s paying the highest prices in the world for prescription drugs and it’s unfair.

MR. LEWIS LUPKA: Maybe I ought to make another run up to the Canada.

SENATOR BYRON DORGAN: Well, maybe you ought to do that, Mr. Lupka, and Dr. Funderburk, I appreciate your organization’s interest in this. I know that you make the case about not just those who live to take you to the border, but have access to these lower priced prescription drugs, you’re absolutely correct about that. Again, you’ve heard me say our ultimate goal is to force a repricing of prescription drugs in our country. There are no miracles from miracle drugs that people can’t afford, and let me finish by telling you one evening in a little town in Northern North Dakota at the end of a meeting, a woman close to 80 years of age came up to me when the meeting broke up and she grabbed me by the elbow and she said, “Mr. Senator, can you help me?” I said, “I’ll sure try, what’s wrong?” and, she began to describe me as her eyes welled with tears and her chin began to quiver she said, “I have heart
disease and diabetes, and my doctor says I have to take medicine to stay alive, and I can’t afford it. I don’t have any money. Can you help me?” And, she at near 80, a widow with very little income, understood the dilemma. She didn’t have the money, but she needed to take these prescription drugs to control her diabetes and her heart disease, and that’s why we have to do something about this, and we have to do it in a way that make sense for the consumers of this country. Let me make one final point - this is not a search for villains. Our pharmaceutical industry is big, strong, and healthy. I want our pharmaceutical industry to do well. I want them to discover new medicines. I want them to do research, but I also want from them fair pricing for the American consumers, and that is not the case today, and that’s why we are pushing for legislation. Let me thank this panel for being here. This hearing’s adjourned.

[END OF TAPE]