

## **Ask the Experts: Drug Reimportation December 2, 2003**

---

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**LARRY LEVITT:** This is Larry Levitt from kaisernetwork.org. Welcome to Ask the Experts, our regular interactive web show that provides in-depth discussion of current health policy issues and allows you to interact directly with the nation's top policy experts. Today our topic is the reimportation of prescription drugs. It's not exactly a term that rolls off the tongue for most people but is without a doubt an issue that has captured popular sentiment like few others, tapping into public anxiety about the cost of drugs in particular and healthcare in general. We've seen busloads of seniors heading up to Canada to buy medications and a growing list of mayors and governors, from Springfield, Massachusetts, and Burlington, Vermont, to Illinois and Minnesota, taking steps to reimport drugs from Canada to reduce healthcare costs. On Capitol Hill legislation has passed the House that would pave the way for widespread reimportation from a number of industrialized countries, but it is stalled in the Senate. The recently passed Medicare reform legislation includes a reimportation provision and most everyone agrees that it would preserve the status quo because it requires the Secretary of HHS to certify that the program would pose no additional risk to health and safety. And the current Secretary has indicated he's not likely to do that. From a political perspective the reimportation movement has produced some strange bedfellows. Support in Congress has been bipartisan, bringing together some

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

very conservative and some very liberal members. But opposition has been equally bipartisan. And even within conservative and liberal think tanks views differ as to whether reimportation would be a good thing or a bad thing. We'll spend the next hour trying to sort some of this out and answer your questions. You can reach us in two ways. E-mail your questions to [ask@kaisernetwork.org](mailto:ask@kaisernetwork.org), or call us here at the Kaiser Family Foundation broadcast studio and ask your question on the air. You can phone toll-free at 1-888-kaiser-8 -- that's 1-888-524-7378 -- and we'll get to as many of you as we can over the next hour. To answer your questions we're joined by three experts who've been closely involved in recent debates on this issue. Jack Calfee is a scholar at the American Enterprise Institute, John Rother is Director of Policy and Strategy at AARP, and Tom McGinnis is Director of Pharmacy Affairs at the FDA. Tom, let's start with you. I'm sure we'll have plenty of time over the next hour to have sharp debates on this issue. But give us - let's start with some basic facts. Give us a sense of what current FDA policy is. The FDA's had an informal policy of compassionate use allowing individuals to reimport drugs from other countries. If you could just lay out what the basic law is today, or basic FDA policy regards to individual reimportation of drugs.

**TOM MCGINNIS:** Sure. Our compassionate use policy is from the 1950s when many drugs were approved in other countries

<sup>1</sup> [kaisernetwork.org](http://kaisernetwork.org) makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

before they were approved in the United States. So the FDA wanted to allow consumers, working with their physician to go to other countries to procure medications that might be beneficial to their condition -- this is generally after they tried everything available in the United States -- to bring those products back to treat their serious conditions such as cancer, and use those medications in the United States. That's mainly for things not available in the United States. Things that are available in the United States, products coming in have to be approved by FDA. Those that are not approved by FDA would be illegal to bring into the United States.

**LARRY LEVITT:** But I mean it's no surprise to anyone who reads the newspapers that people are importing drugs, reimporting drugs into the United States. Individuals over the Internet or going up to Canada. Is that something that's technically illegal but not something you're necessarily enforcing?

**TOM MCGINNIS:** Technically it is illegal, however, FDA only focuses its enforcement resources on commercial entities - those trying to make a profit from facilitating the importation of illegal medications.

**LARRY LEVITT:** Presumably people wouldn't be importing drugs if they weren't cheaper - or many drugs weren't cheaper in Canada and other countries than they are here. John Rother, AARP has done some studies on this, looked at the data. Can

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

you give us a sense of what, again, the basic facts are in terms of how prices of drugs here and compared to Canada and other industrialized countries?

**JOHN ROTHER:** Well, first let's start by saying that generic drugs are cheaper here and over-the-counter also. But we're talking about name brand drugs, the most expensive drugs. And there the differential in price between a drug purchased in Canada with U.S. dollars and one purchased here can be substantial. But other drugs not so much. We did a survey in March and we found that Celebrex, for example, a very heavily advertised drug, is about half price when purchased in Canada compared to the U.S. retail price. Other drugs there's not that much difference. Paxil, for example, \$74 U.S., 51 in Canada. So it's still a savings but not the dramatic savings that people might assume. So it varies by drug. And, you know, we urge people to always to look to generics and over-the-counters first in any event.

**LARRY LEVITT:** Jack Calfee from AEI - I hope it's fair to call you a conservative analyst.

**JACK CALFEE:** Free market.

**LARRY LEVITT:** Okay, free market analyst. There has not been a uniformity of opinion or view among free market or conservative analysts about reimportation. Some have argued that reimportation would simply allow the free market to function, allow prices in other countries and here to adjust.

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

You haven't taken that view. Give us a sense of why -

**JACK CALFEE:** You know -

**LARRY LEVITT:** - you don't think that's the right way to go.

**JACK CALFEE:** - where I part ways with some of the other free market people is not literally at the first stage. It's what happens down the road. I mean the people at CADO (misspelled?), very bright economists, you know. They want to have free importation and what they think will happen is that prices will equilibrate, which basically means the Canadian prices will go up rather than American prices go down. Well, one of the crucial issues is what happens when maybe 5% of U.S. consumers order their drugs from Canada? And when that happens not only does that put the pharmaceutical firms in a situation where the profits they would lose in the U.S. would exceed the entire profits they're getting from Canada, but the volume of drugs being ordered by Americans would really swamp the Canadian system. I mean it would involve almost a doubling of all the drugs going through Canada and you get immediate shortages, et cetera. And then the question is what would the pharmaceutical firms do? Would they be permitted to say to Canada, look, we'll ship you everything we shipped you last year, we'll give you an extra 15, 20%, but we're not going to send you two or three or five times as much. And when the manufacturers do that then something's going to give way. But

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

some of the supporters of reimportation want to have a law that prohibits the manufacturers from dictating how much they're going to ship to Canada. As far as I know there are no free market economists who would support a law like that.

**LARRY LEVITT:** In a sense that's what you're arguing, it wouldn't work? It wouldn't work because -

**JACK CALFEE:** I don't think it would work, no. Quite aside from the safety issue, and I think the safety issue could become quite a problem if you have lots and lots of drugs going through Canada.

**LARRY LEVITT:** Let's start, before we move to calls and e-mails -- which we have plenty of -- let's talk about the safety issue for a second. That - and something that's been a central part of the debate. I mean on the one side you have the issue that people probably could get lower prices, at least on a smaller scale, by reimporting drugs, but the administration has argued that they can't guarantee that safety. Tom, again, is there - are there -- and we've had a number of e-mails on this topic -- is there something, is there new authority the FDA could have? Is there something that could be done to provide greater guarantees of safety under a reimportation program?

**TOM MCGINNIS:** One of the things is the misnomer with the term reimportation that these things are nothing more than things made in the United States, shipped to Canada, and are

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

just coming back in. And that's not the case all the times. Manufacturers make things all around the world and they make them in different places for the Canadian market. We've had a recall of Serevent Diskus -- that's a few weeks ago -- where the Canadian product was made in the French facility that had the problem. The U.S. product was coming out of the Great Britain facility and it didn't have the problem. But any consumers who bought that product from a Canadian pharmacy didn't get notified that that, you know, with the Class I meaning it's serious recall of that product. And consumers might not have heard about it. FDA had to put out its own press release a couple days after Health Canada put out that press release. So a lot of these products are just not the same product that's made at the U.S. pharmacy. And it's hard to tell. It's hard for us to tell, especially with the limited resources that we have at the border right now looking at these products.

**LARRY LEVITT:** Do you think with extra resources you could at least get further to making a reimportation program work?

**TOM MCGINNIS:** Well, extra resources and extra authority, too, by the Congress is important. Many of these packages coming in the United States we see in baggies and paper bags and tissue paper. It would be nice just to be able to send those things back to where they came from. However,

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

the law doesn't allow us to do that. We have to issue a letter to the person who's trying to import that giving them adequate notice and time to come down and tell us why they think it might be illegal. Generally they don't show up because we still have to store those medications and then ship them back to the return address if there is one. If not they get destroyed at the end of that holding period. So that's very burdensome on the agency right now and we need to do better. We asked for a return to sender thing when we see something coming in as a baggie or in tissue paper, just immediately be able to send it back and Customs Service believes that's a doable situation.

**LARRY LEVITT:** John Rother, if I understand the AARP's position correctly, you've been supportive of expanded or permitted reimportation, at least from Canada, but also mechanisms to ensure safety. Is that a fair assessment?

**JOHN ROTHER:** Yeah, I think if we wanted to we could do a much better job by entering into bilateral agreements with Canada, with certain approved Canadian pharmacies. I don't think the safety problem is an insurmountable problem. I agree with Tom that the FDA does need resources and authority, but trying to inspect everything at the border is not how to solve this problem. I should say, by the way, that people who actually go to Canada to purchase drugs I think are acting in a very safe way. I think a more difficult situation is people who buy through the Internet where you're never really sure if

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

- well, you're not always sure if you're really purchasing drugs from an approved pharmacy or not.

**LARRY LEVITT:** Well, we have our first caller on the line from Vermont, which of course is one of the states where Burlington, a city that's actually been one of the most active in trying to reimport (inaudible) for their own workers. Caller, go ahead.

**MALE VOICE:** Good morning everybody. To protect against unsafe drugs coming across our borders, Congress would have to spend annually approximately 90 cents per American family -- that's about \$90 million annually -- to set up required testing and inspection facilities. If allowing free trade in pharmaceuticals only dropped prices at the pharmacy counter to all American families by a very conservative 10%, the average American family, if spread equally, would save approximately the equivalent of \$150 a year, which is 10% of the approximately 150 billion in U.S. sales. My question is this. Why is it so important for - it goes to - excuse me. My question goes to the who is being served here. And the question is why is it so important for Congress and the FDA to deny every family in the United States average - the equivalent of average annual savings of \$150 at the pharmacy counter in return for an investment of 90 cents per family for testing and inspection facilities to guard against unsafe drugs? By any other normal return on investment standards, such a huge return

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

would be a slam-dunk. And I have perhaps a follow-up question.

**LARRY LEVITT:** Let's start with your question and see if we can get to some others as well. Tom, again, let's start with you. I mean is that a - first of all is the figure of how much it might cost to preserve - guarantee safety, is that even in the right ballpark to you?

**TOM MCGINNIS:** We haven't done our study yet. The Congress called for us to do a plan over the next 12 months and we'll come up with some number as to what it might cost with the added resources that we would need to see if we can assure safety. So I don't know the number yet. Two years ago we had a number somewhere around \$100 million, which is close. It's in the ballpark to what we just heard. But I don't know what that number is right now.

**LARRY LEVITT:** And there are savings. I mean the Congressional Budget Office I think has estimated \$40 billion in savings over the next ten years with similar figures on price discounts. And I think John Rother laid out - and Jack Calfee, you - I assume you would have slightly different maths in -

**JACK CALFEE:** Well -

**LARRY LEVITT:** - terms of how you think this might play out?

**JACK CALFEE:** You've got to be careful when you're working with averages, as John pointed out. I mean if the

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

average drug - I mean if every drug cost 10% less in Canada I don't think we'd get a whole lot of shipping back to the U.S. because most people already have pretty good coverage, their co-pays are relatively small, et cetera. And there aren't that many people that have a big stake in it. I think what would happen is you'd have some people trying to bring in large quantities of drugs where the price difference is a lot more than 10%, the 30 or 40 or 50% that John was talking about. And then you've got to ask yourself, would that price differential persist? You know, and what I'm suggesting is, no, it wouldn't because Pfizer is not going to send ten times last year's supply of Celebrex to Canada only to lose all of their profits from the U.S. market.

**LARRY LEVITT:** And John Rother, I mean the - putting aside the precise calculations, you do - I would guess you would say that there is still some on balance savings to be had here.

**JOHN ROTHER:** Oh, there's - I believe there are savings to be had. Now in the longer run I think it's much harder to predict because we don't know what would happen to prices in Canada. We don't know what the manufacturers would do. But it is not just a matter of Canada and the U.S. We're really talking about a global market. I mean, after all, Canada can import drugs from elsewhere as well. So I think that the short-term situation is much easier to assess than the long-

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

term. And short-term, by which I mean from now until we get a Medicare drug benefit implemented, there's very substantial savings I think that are possible.

**LARRY LEVITT:** Well, that's a nice transition to another e-mail we've gotten, and I'll read part of it. In view of reports that U.S. Trade representatives are pressuring other countries to take a less proactive purchasing role and pay more for the prescription drugs sold in their country, how long would you expect Canada's drug prices to stay significantly below U.S. retail prices after U.S. based purchasing groups started to reimport drugs from Canada for groups of patients? And I think we've addressed that. How closely should consideration of drug reimportation be linked to questions about the appropriate method of control and amount to financing of drug R&D in the U.S. and other countries? I mean this has come up recently. The administration has started to say jawbone other countries to maybe ease up on their price controls, arguing that the U.S. is bearing is disproportionate - U.S. consumers are bearing a disproportional burden of paying for R&D. Jack Calfee, what's your reaction to -

**JACK CALFEE:** Whether you can make this part of the trade negotiations I think remains to be seen. There is a downside here. I mean I certainly sympathize with what people are arguing and I think Mark McClellan has been, you know, courageous in finding out some of these things. The problem is

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

that once you head down the path of linking these other factors into trade negotiations, there's a lot of other things that could also be linked, like - and some of those are things that the Europeans and the Australians and so on would like to see us, you know, get involved in. Maybe some labor rules, something like that, environmental restrictions, et cetera. So I don't know whether that's a promising route or not and I'd be very interested to see what comes out of it.

**LARRY LEVITT:** And John Rother, certainly I mean pharmaceutical - branded pharmaceutical - pharmaceutical companies argue that any downward pressure on prices will inevitably lead to reductions in R&D. Is that a -

**JOHN ROTHER:** Well, I think -

**LARRY LEVITT:** - accurate threat you think?

**JOHN ROTHER:** No, not at all. I think that first of all companies have to invest in R&D to survive. And that's a good thing. They may be forced to cut back on marketing expenses or - there are a lot of things in the pharmaceutical's budget that are a lot more expensive than R&D. So I think the claim that there's a one-to-one relationship is really overblown. I think, you know, we do want a vibrant research element in our drug industry, but that doesn't mean we should pay unjustifiably high prices. And other countries have looked at this as well. And I think, you know, there's an argument to be made that we're paying far too much, even given the need for

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

research and development.

**LARRY LEVITT:** And what do you think? We're focusing mostly on reimportation here, but can't ignore the fact that a major Medicare reform legislation recently passed. What's your view of what that might do to prices in the U.S. in the long-term?

**JOHN ROTHER:** Well, I certainly hope that it will substantially lower prices for those people who are most in need - Medicare beneficiaries likely to sign up. They will have the advantages of group purchasing power and we could do a lot more to help them make wise decisions - public education. Also we need to conduct more research head-to-head. We're finding out increasingly that the newer, more expensive drugs may not be all that much better than much less expensive alternatives. So there's a lot of ways in which we could save quite a bit of money for consumers.

**LARRY LEVITT:** Tom, again, let me bring you in before we go to our next caller. Since various proposals that do something like what John Rother suggests, that federal government or some other federal organization should be looking at these newer drugs, which are often much more expensive than the older drugs they replace, and looking at how much benefit do they really provide for that added cost. Is that - it's not something the FDA does now. Is it something that you think is an appropriate role for the FDA or some other entity?

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**TOM MCGINNIS:** Well, one of the things we're doing at FDA is approving generic drugs much quicker than we ever have before. We're putting a lot of resources into that program. So there's going to be generic drugs available for just about any disease state that a consumer goes to a doctor for. Those consumers that don't have adequate drug coverage need to inform their doctor of that, you know, I don't have prescription drug coverage. Is there a generic drug that you can prescribe for my condition? And to try that first. That's going to be cheaper than any other drug product in the world, as John mentioned. Even cheaper than Canada. And consumers need to engage with their doctor on those types of issues.

**LARRY LEVITT:** Do you think we should also be looking at newer branding drugs and factoring in cost, or at least providing people with information about sort of the cost benefit tradeoff with those new drugs versus the older drugs they replace?

**TOM MCGINNIS:** Well, as John mentioned, some of these older drugs will do the trick and they're much cheaper. Why not try that first? If it doesn't work then you have to go to some of these newer therapies (unintelligible).

**JOHN ROTHER:** I'd like to comment. I think the FDA is a regulatory agency and what we're talking about here may be more appropriate for a research group like the NIH or AHRQ - the Agency for Health Research and Quality. But nonetheless,

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

purchasers -- consumers and health plans -- need better information than we have now to get the best value out of the market. And that would drive prices down.

**LARRY LEVITT:** Let's move on to our next call from Colorado. Caller, go ahead.

**MALE VOICE:** Yes, why did this legislation leave out healthcare cost and payment and the right for Medicare to negotiate lower prices on prescription drugs?

**LARRY LEVITT:** Thanks for the call, and I assume you're referring to the recently passed Medicare reform legislation, and John maybe I'll start with you.

**MALE VOICE:** The last bill, H.R. 1.

**LARRY LEVITT:** Yes, thank you. John, I mean certainly there's been some criticism - there was some criticism on the floor of the Senate that legislation didn't go far enough to use Medicare's purchasing clout to keep drug costs down.

**JOHN ROTHER:** Right. But we are, you know, to be quite candid, in a Republican administration with Republican majorities in the House and the Senate, and it was their judgment that all purchasing of drugs should be through the private sector. Now, CBO estimated that using private pharmacy benefit managers, private sector entities, would actually save up to about 30% off existing prices. Well, we'll see. But they did not want the U.S. government setting prices for drugs in the way that other countries around the world do, so they

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

wrote it into the bill. And that's a kind of a philosophical approach to this issue. It doesn't mean that prices aren't going to come down but I think it's less certain. We'll have to wait and see.

**LARRY LEVITT:** And Jack Calfee, what -

**JACK CALFEE:** Yeah, let me put out a couple of things. We do have sort of an ongoing experiment because a lot of vaccines, especially trial vaccines, go through a system in which the government does negotiate prices exactly like people are talking about. And it has not worked very well at all. We've had serious shortages. It's taken the profit out of these things. We have the vaccines that are greatly underused, even the ones that would be extremely useful like the flu vaccines, and that's largely because the government negotiates and in effect sets the prices for these things. We even have vaccines where CDC has simply said we're not going to be buying any of these vaccines this year because the price that we have established through Congress is lower than the manufacturing cost and the supply is gone. It's an experiment that's given us very, very bad results. And the reason that most of the new drugs are coming from American manufacturers is precisely because we don't have price controls here and we do have price controls elsewhere. At least that's a major factor.

**LARRY LEVITT:** How would you respond, let's say, looking more broadly at how Medicare pays hospitals or doctors,

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

which -

**JACK CALFEE:** Well -

**LARRY LEVITT:** - largely is setting prices?

**JACK CALFEE:** That's right, and there's a big difference. With doctors and hospitals and so on they do set prices, and then when the prices tend to get too low you get a strong reaction. It's hard to find doctors, it's hard to find hospitals, et cetera. You can't get nurses and they have to adjust those prices. It's very different with drugs. As long as the price is above the manufacturing cost you're going to continue to get those drugs, when what we really need are new drugs. We need an Alzheimer's vaccine for example. And there's no way you can adjust the prices and say, oh, we're not getting new drugs fast enough and so we need to raise their prices a little bit, because no one knows how fast these drugs should come.

**LARRY LEVITT:** And the drug pipeline is a decade or more -

**JACK CALFEE:** That's right. That's right.

**LARRY LEVITT:** What's the - we've got another caller from Florida. Caller, please go ahead.

**FEMALE VOICE:** Yes, I am an advocate for seniors in Florida and I have a couple of questions. Number one when President Bush said that was good - what was good enough for our congressmen and our senators should be good enough for our

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

seniors, he wasn't really - when he said that he wasn't really talking about the same thing that our government - that our senators and our congressmen have. For instance on their prescription drugs they have no deductible. Our seniors do have a deductible. Now I - one of my questions is this. I would like to know why that the congressmen and the senators -- our elected officials -- why are they entitled to a better prescription drug program than the constituents that have put them in office? Now they've done some things that I have read. I have read that Pharma, which is a pharmaceutical research and manufacturer's association, they have poured more than half a billion dollars into efforts to advance their legislative agenda. There have been \$558 million that have been given to political contributions.

**LARRY LEVITT:** Ma'am, if I could just stop you there and maybe we can go back to your first question, which I think was a very good question, and thanks for the call. And, John Rother, maybe I'll start with you again. I think we're going to have a tough time staying solely on reimportation during this hour. There certainly was a lot of discussion about seniors deserve what federal employees or members of Congress get and the benefit that ended up in the bill was different. If you could maybe just describe for people what benefit ended up in the Medicare formal -

**JOHN ROTHER:** Sure.

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**LARRY LEVITT:** - legislation. How that does compare to what a typical working person might get.

**JOHN ROTHER:** Well, the benefit that was enacted is constrained very dramatically by the dollars available - the \$400 billion the President had made available for a drug benefit. That's not nearly enough to provide a typical benefit that people who are working have. So the caller definitely has a point. There is going to be a difference between what most members of Congress have and what Medicare will provide. However, the members of Congress have a choice of many different health plans and some of those have a deductible, some of them have different coverages, different formularies. And when the President was talking about making the same kind of choices available to Medicare beneficiaries I think what he meant was that people should have a choice and should, you know, find a plan that makes sense to them. Maybe for more generous coverage you pay more. But that's also true for members of Congress. So I think there are points on both sides. Senator Mark Dayton from Minnesota introduced an amendment that actually passed the Senate that would require senators that have the same drug benefit that was available for Medicare. That got dropped in the conference committee. So they did - there was a debate on this very point.

**LARRY LEVITT:** Have you got any sense - in order to provide a similar benefit to seniors what a typical working

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

person might get, any sense of what that might cost relative to the \$400 billion that was -

**JOHN ROTHER:** I don't have the exact figure with me but it would cost probably another 200, 250 billion over the 400 that's provided for today. So in the grand scheme of things perhaps not that expensive, but given our current budget clearly there was not political support to go beyond the 400 that is reflected in this benefit.

**LARRY LEVITT:** It's probably not the end of this discussion -

**JOHN ROTHER:** I don't think it's going to be the end of this discussion.

**LARRY LEVITT:** Jack, do you want to add something?

**JACK CALFEE:** You know, I don't understand how the difference could be that small. After all, this plan is paying for less than half of the drugs that people get. In many cases it's only paying for 15 or 20% of the drugs if they're buying 4 or 5,000. And I assume that the Congressional plans pay for much larger proportion of that. I think you have to bear in mind that if Mark Dayton legislation had become law - if there's a law that said the Medicare beneficiaries receive the same benefits as the Senate do, I don't think that Medicare beneficiaries would get what the Senate gets right now. I think the Senate would get whatever Medicare beneficiaries are going to get. And that could be very different. After all,

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

people in the Senate can afford to buy their own drugs whether they have a drug plan or not. And I think, you know, you've got to be careful sometimes what you wish for.

**LARRY LEVITT:** Well, we could clearly spend a whole another hour talking about Medicare issues in general and I will just say that people interested in finding out how much the enacted Medicare benefit would provide, we do have a drug calculator on our website at [www.kaisernet.org/drugcalculator](http://www.kaisernet.org/drugcalculator). And you can enter in your annual drug costs and see how much of your costs the benefit would provide. Let's move on to another e-mail and focus a little more on some of the regulatory issues and come back to Tom again. This is an e-mail from a reporter in Washington. I'd like to hear from the FDA official about the agency's focus and challenges in 2004. I'm particularly interested in any new focus or expected changes in enforcement in regulatory focus in 2004 in the areas of drug marketing and advertising and drug manufacturing practices. If we're going to broaden this discussion we might as well broaden it fully. Tom, what's your reaction to that?

**TOM MCGINNIS:** Well, again we worry about consumers getting fooled in buying medications. If they go to the Internet some of these sites look like they're legitimate U.S. pharmacies, however, when the medication comes they're coming from an offshore pharmacy or rogue pharmacy. There's a lot of these rogue pharmacies now offering controlled substances to

<sup>1</sup> [kaisernet.org](http://kaisernet.org) makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

consumers and medications without a prescription at all. That worries us. That'll be one of our focuses in 2004.

**LARRY LEVITT:** Great. We do have another call. This one from Hawaii. Caller, go ahead.

**MALE VOICE:** About six years ago the FDA changed its rules to allow advertising of prescription drugs direct-to-consumers and that's just about the time that the prices started to take off a big double-digit annual increase. The drug Celebrex was mentioned before and that's very heavily advertised in these ask your doctor promotions. And why is it that most countries don't permit direct advertising? And don't you think that there's some correlation between the advertising money spent and the very high -- two to three times higher -- prices of, say, Celebrex here versus in Canada?

**LARRY LEVITT:** Thanks for the call. Jack Calfee, I saw you shaking your head during the call.

**JACK CALFEE:** Actually there's no connection between the advertising and the prices. You've got to bear in mind what's been going up, you know, at double-digit rates, although I'm not sure that'll happen this year. It's not been the prices, it's been the total amount of money being spent on drugs. The prices have actually been pretty stable. A little bit faster than inflation but not very much, and that's without any kind of price controls for the most part. Spinnage has been going up but it's been going up for the drugs that are

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

advertised, it's also going up for the drugs that are not advertised. I think what's happened is that a lot of doctors and a lot of patients have just gotten really enthusiastic about a lot of the newer drugs, and that's why we're talking about reimportation. It isn't because people don't want to use the drugs. It's because they really do want to use them. It's not the advertising, it's basically the quality of the drugs.

**LARRY LEVITT:** Well, maybe to amend the question slightly, do you think advertising has had an effect on the increases in the use of drugs, in the number of prescriptions written?

**JACK CALFEE:** It's had some effect. Those effects are pretty small. There actually has been some research on this and you've got to remember that the amount of money being spent on advertising to consumers is roughly 2 or \$3 billion and that's out of a total drug bill of between 150 to \$200 billion. Really not very much in, you know, the circle of drugs being advertised it's still pretty restricted. It's a marginal impact. There's no reason to think that it's been a major factor in the growth of pharmaceutical expenditures.

**LARRY LEVITT:** John Rother?

**JOHN ROTHER:** If I could jump in on that, I really would beg to differ. I think that you don't have to talk to more than a handful of doctors to get the impression that advertising really is driving a lot of demand for drugs, and

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

not all of it medically appropriate. I mean to use the example of Celebrex, that's probably appropriate for a small number of people. Most of the people who are using that for arthritis could probably do just as well with a much cheaper drug, but because they only see the expensive drug on TV that's the one they tell the doctor they want and doctors feel under pressure to prescribe it. So I do think that it drives up total costs and it probably does skew the market in a way that steers consumers towards the most expensive alternatives, not the most cost-effective. That's why other countries don't permit it as a general rule, because they're paying for these drugs out of their tax revenues and they don't want to pay unnecessarily for very expensive alternatives when there are cheaper drugs available.

**LARRY LEVITT:** Tom McGinnis, what - the FDA has indicated some substantial changes in how they might be looking at advertising. Is that something we're likely to see?

**TOM MCGINNIS:** Well, what we've done is focus groups with both consumers and with physicians to try to get an idea what this advertising actually does to them. To address the question that John brought up, consumers coming in demanding this medication. What we found were interesting. We found that this advertising gets the consumer into the physician's office, which is an important aspect, as a public health service officer, the sooner you can see a disease the much

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

easier it is to treat. Again, as I mentioned before, there are alternative medications. If these consumers don't have drug coverage they need to tell the physician that and hopefully the physician will provide a generic medication to them. A lot of these pharmacy benefit managers now are putting in tiered co-pays. You take the generic medication it will cost you \$10. The formulary brand name will be \$20. Off formulary is going to be very high. Maybe as much as \$40 if you really want that particular medication that you saw on TV. Consumers will have to make that choice.

**LARRY LEVITT:** So the argument might be that the advertising brings consumers, brings patients into a doctor's office, might raise healthcare costs, the consumer might not actually get the same drug that they saw advertised. They might get some drug, again raising healthcare costs but also some benefits for the patient.

**TOM MCGINNIS:** It may actually lower healthcare costs because if you can treat a disease earlier on rather than let it go later where it's much more difficult to treat. The patient may wind up in the hospital, you know, spending a few days there. It may actually save healthcare dollars by catching it early on.

**LARRY LEVITT:** Well, we've got another call on the line. This one's from Arizona. Please go ahead.

**MALE VOICE:** Yes, my question is I am a retired federal

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

employee. What is this Medicare plan going to do to retired federal employees? Are they going to take us off of our insurance that already pays for our drugs or what?

**LARRY LEVITT:** Thanks for the call. And, John, sorry to direct all these questions to you, but maybe we can broaden it a little bit if that's okay with everyone, and talk about retiree coverage in general because it's one of the more controversial points of debate. I mean what's likely to happen to workers, federal workers or private sector workers who have retiree coverage now?

**JOHN ROTHER:** I think the answer is different. I think to respond directly to this question, I don't expect any change for federal workers. This is a voluntary legislation for people who choose to enroll. For people who are federal workers, assuming you have health insurance through the federal system, you have a better benefit where you are and there's no reason to change. For others, however, private employers have been dropping coverage for retirees for many years, and now only a small fraction even of large employers provide this coverage. So it's very important to have a Medicare benefit available to everyone else. We tried to design it in a way that would not encourage employers to drop further. There is \$86 billion in subsidies to employers in the bill expressly to keep that coverage intact. Whether an employer decides to keep it intact, though, is an employer's decision because this is

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

not mandatory. This is a voluntary program.

**LARRY LEVITT:** And what are their estimates from the Congressional Budget Office after that \$86 billion is on the table as to what might happen with retiree coverage?

**JOHN ROTHER:** Well, the Congressional Budget Office gave a fairly high estimate of about one in five retirees might lose coverage going forward. Other experts in the field, though, put the figure as much, much lower. So I think we really don't know the answer. It's clear that there's a long-term trend away from offering this coverage. This legislation is an attempt to kind of stop that in its tracks. But how successful it is we're not going to know for a while.

**LARRY LEVITT:** Well, we're traversing the country with our calls. We've got another caller from Kentucky on the line. Please go ahead.

**FEMALE VOICE:** Thank you very much. I'm just curious about the difference in policy with regard to negotiations in the Medicare bill. Government is not allowed to negotiate prices, whereas we know very well that HMOs do negotiate all kinds of prices with hospitals, with physicians, and also drugs. So why is there a difference to allow the private sector to have that privilege of negotiating prices of drugs and not have the traditional Medicare? Thanks you very much.

**LARRY LEVITT:** Thanks for the call. Jack Calfee, maybe we'll come to you. The - maybe I'll ask the question slightly

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

differently.

**JACK CALFEE:** Sure.

**LARRY LEVITT:** What's your prognosis, let's say? I mean this bill is - the Medicare reform legislation is based on private sector competition and private sector plans negotiating prices on behalf of patients. What's your sense of how well that's going to work?

**JACK CALFEE:** Well, it remains to be seen. I mean that's the principle all right, but there are a lot of escape hatches. I mean there can be situations in which a very large number of consumers might have available to them mainly only - maybe only one organization is offering drug insurance under this plan. In that case, you know, the backup provisions would look a whole lot like government negotiations. What I would emphasize is there's a big difference between competing pharmaceutical firms negotiating with competing buyers of their drugs, as opposed to negotiating with only one buyer, the 800-pound gorilla, the federal government. And when that happens then you get back into the situation we've had with child vaccines. You get very low prices, you get shortages, and you get a suppression of R&D.

**LARRY LEVITT:** Plenty of uncertainty, no question. Let's go to another e-mail and come back to reimportation. As we mentioned at the top of the show a number of state and local governments have started to use reimportation to reduce

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

healthcare costs for their workers and retirees. There's a question here. What action is FDA likely to take against Minnesota, Illinois, or similar plans that are intended to save money for state taxpayers by reducing the drug costs of state employees and retirees? Does that fall inside or outside of FDA enforcement policies? Tom McGinnis, I think that's a question to you.

**TOM MCGINNIS:** I know the Congress debated the issue whether there should be pilots like this in the Medicare legislation but they chose not to put it in there. So if any of these states - and they're just talking about these now. Most of the governors who we've talked to said they don't want to break the law, so I would expect that most of them would not move ahead with these type of plans. As John mentioned, or Jack, if a big state like that went to Canada it may cause shortages up there. Canada might have to step in -- the FDA counterpart in Canada -- to protect Canadians and make sure that they get the medications that they need.

**LARRY LEVITT:** And just to clarify, the FDA position is that these states or local governments are breaking, or would be breaking the law now if they were to seeking to reimport.

**TOM MCGINNIS:** That's right. Congress chose not to put those pilots into the Medicare legislation.

**LARRY LEVITT:** And could you also describe - there's been some discussion between the FDA and Heath Canada, which is

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

the regulatory counterpart in Canada, about some joint activities. Can you update folks on where those stand?

**TOM MCGINNIS:** Well, we want to share regulatory information. If we find a pharmacy that's doing something that we believe might be breaking either federal or provincial law in Canada, we wanted to set up a conduit to share that information with Health Canada, who agreed to work with the ten provinces aboard the pharmacy in Canada, to look into these type of issues to see if there is any provincial or federal law being broken there. And we'll do the same thing on this side.

**LARRY LEVITT:** And John Rother, you wanted to get in here?

**JOHN ROTHER:** Well, just on reimportation again, I think that this is not resolved and the Medicare bill chose not to deal with it. But that doesn't mean it's not going to be still a very big issue. And I'm going to predict that I think Congress will take action in 2004 on reimportation just because I think the public has basically made up their mind already. And we hope that when that happens we can do it with proper safety precautions, making sure it's still under the FDA's authority, and do it in a way that perhaps provides people with a bridge to a Medicare benefit that will lower prices for - at least for seniors.

**LARRY LEVITT:** Would you like to predict what Congress is likely to do?

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**JOHN ROTHER:** Well, we have our own recommendations. You know, I think working with Canada in a bilateral sense certainly makes a lot of sense. I think that making sure that there are safeguards in place on both sides of the border so when consumers order they know that they're - have the same confidence ordering from a Canadian pharmacy that they have of going to a U.S. pharmacy. I think the Internet's going to be the most difficult area because it's very hard to police that. But I'm reasonably confident that if we decide we want to do this, we could.

**LARRY LEVITT:** Okay. Well, we've got a caller on the line from New York. Please go ahead.

**MALE VOICE:** Yes, I work with senior citizens here in Albany and we've had hundreds of calls in the last few days after the story in the daily news about reimportation. They call here asking for our help on doing that. And, you know, the bill that's been passed has a huge doughnut hole and I'd like to find out if - I think Mr. Rother did say that the AARP will now use its new friends and considerable resources to get that bill passed. I'd also like to ask another question, though. Canada is only a short-term solution. I would like to know why our state and our Medicaid program and other programs can't buy our drugs at the federal United States price level through the VA or through some other federal mechanism. It seems ridiculous that a state could not purchase drugs at a

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

federal level. We have the 340B program for health clinics. That should be where we're moving, to expand access to cheaper prices in the United States. I'd like to get a comment on that.

**LARRY LEVITT:** Thanks for the call and let's maybe get some definitions on the table so everyone's on the same page. The doughnut I think the caller's referring to is the - within the new Medicare benefit which requires seniors and people with disabilities to pay all of their drug costs within this doughnut hole. They pay a deductible, they get some coverage, then they face this doughnut hole of no coverage until they qualify for catastrophic coverage. John, maybe come back to you. What do you think of the idea of allowing state Medicaid programs or individuals or cities and towns to be able to buy drugs at the federal supply schedule prices?

**JOHN ROTHER:** Well, I think that some of these federal supply prices were done on the basis of almost a compassionate policy that probably couldn't be sustained large-scale. But nonetheless there's no reason why we shouldn't have government being able to bargain directly with manufacturers when government's the purchaser. So we support that. On the doughnut hole it's a question of, you know, dollars, really. And that's certainly something that we're going to come back to because we know that the current benefit design in the Medicare benefit does not make sense to people. And we think that

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

ultimately that will have to be addressed. But we're going to - it's going to take resources to address it. So we are going to have to talk about how to pay for it, perhaps by canceling some tax breaks or other things that would free up those resources.

**LARRY LEVITT:** And AARP has said that this is - you supported this bill but said it wasn't perfect. Is the doughnut hole one of those areas where you think it's not perfect?

**JOHN ROTHER:** I think the two biggest weaknesses in the current bill are the - number one the doughnut hole, and number two the other issue we've been talking about is how to - can we put a greater price pressure to drive prices down on pharmaceuticals because there does seem to be quite a bit of room to do that.

**LARRY LEVITT:** Jack Calfee, let me bring you in again. I don't think we want to turn this into a full-scale debate on the recently passed Medicare legislation, but what do you think of the structure of this benefit with the doughnut hole? Do you think that's -

**JACK CALFEE:** Well -

**LARRY LEVITT:** - benefit something that -

**JACK CALFEE:** - my fear is that the doughnut hole -

**LARRY LEVITT:** - (crosstalk).

**JACK CALFEE:** My fear is that the doughnut hole will

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

gradually be filled in and that's going to make the entire program far more expensive than it is right now, far more expensive than projections, and I think it'll be more expensive than it needs to be. I think we have to bear in mind that there's some pretty good data out there showing that a very small proportion of the elderly actually face serious financial difficulty in buying their drugs. Very few of them actually deny themselves prescriptions because of financial reasons. Most people can afford to pay for their own drugs and I think that as a general rule - a general rule we're better off having people buy their own products rather than paying into a general fund and then getting the fund to pay for their products. If we go down that road then pretty soon you're going to have a great deal of trouble controlling your expenditures and then you're going to have the problems that you would expect to have. So I think that, you know, the Medicare drug benefit is going to do some good for some people. When it gets really, really filled in so that it becomes, instead of \$400 billion, 800 billion or a trillion or something like that, then I think we should look much more closely at a means testing version of the Medicare drug benefit.

**LARRY LEVITT:** Would you broaden that principle to other services in Medicare? To hospital services, physicians -

**JACK CALFEE:** My own view?

**LARRY LEVITT:** Yes.

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**JACK CALFEE:** Oh, my own view is that as a general rule you're better off if you have services that are means tested. I mean we well know that Medicare, that although provides, you know, huge benefits to the population, there are a lot of things it does that are extremely inefficient. Things that you just wouldn't do in a normal world, and they do that because, you know, the person receiving the benefit bears no cost whatsoever in most cases. And when that happens you have - there's no mechanism for deciding what, you know, what benefits are really worth their cost and which ones aren't. (Off-mic).

**JOHN ROTHER:** Objection. I think that's an argument against insurance, and it certainly would be an argument against insurance for working people, for children, as well as for the elderly.

**JACK CALFEE:** (Off-mic).

**JOHN ROTHER:** Arguing the people should pay out of their own pocket rather than have coverage -

**TOM MCGINNIS:** Well, people are buying already out of their own pocket, too, and they can certainly do that. There's nothing -

**JOHN ROTHER:** Well, so do older people. I don't see the difference. But in any event I think that it's an overly broad argument. I do think that prescription drugs can save money, they can certainly save lives, and there's no reason to force people to pay 100% of that cost out of their own pocket

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

when we have to pay then for the consequences of that in the emergency room and the hospitals and the nursing homes.

**LARRY LEVITT:** Let's go back to the calls. We have a call on the line from Pennsylvania. Please go ahead.

**FEMALE VOICE:** Hi. I have about two questions that are related. The first one is in terms of the reimportation, a lot of people say that it's only a temporary solution to astronomical healthcare costs that we're going to be facing later on. Do you have any insights in terms of what are some of the alternatives to deal with that? And if the Medicare budget is going to be over \$400 billion are the pharmaceutical companies going to face price control to some extent in the future, how would they deal with that? And in terms of the second question I have is a lot of the U.S. consumers feel that they're unfairly treated relative to the rest of the world because they're subsidizing a lot of the prescription drug cards. And that that could be, you know, seen as a misperception and how could pharmaceutical companies actually use PR or other means to change that perception?

**LARRY LEVITT:** Thanks for the question. Let's take the last two at least. Jack Calfee, let's start with you. First of all, what do you think the future holds - knowing that Medicare reform legislation has passed with a prescription drug benefit, what does the future hold for, let's say, price controls or some other form of -

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

**JACK CALFEE:** You're asking me -

**LARRY LEVITT:** - cost control in -

**JACK CALFEE:** - to predict the future?

**LARRY LEVITT:** - Medicare and also this issue of, you know, are U.S. consumers subsidizing the rest of the world in terms of R&D? (Crosstalk).

**JACK CALFEE:** Okay, let's separate those. I think these. I think these are, well, these are questions that are easy. I think there is an extent to which American consumers are subsidizing R&D for the rest of the world. And I hope something you've done can resolve some of that. The extent of this subsidy is not real clear. I mean the most careful study of international drug pricing looked at 1999 data and found the differences between the U.S. and most European countries not as large as you might think. It's on the order of 25 to 35%. And a lot of that difference could actually be counted for by the simple fact that you normally charge higher prices in wealthier countries, and the U.S. right now is quite a bit wealthier than those countries. But we're moving in a direction to where we are subsidizing more and more of the R&D and I think that it's appropriate to put some pressure on those countries to try to resolve that to some extent. On the matter of price controls I think that's going to be the next really, really big debate in healthcare, generally in pharmaceutical specifically. Because whether or not, now that we have a Medicare drug benefit, which

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

here I agree completely with John, it's going to be expanded in the next few years. Whether or not, now that we have that, whether or not we're going to have some kind of more or less formal means for controlling drug prices, not just for the elderly but for the rest of the economy, too, I think that's going to be a major debate. I hope that price controls lose. I think there's a huge downside to that. I think there exists just absolutely no objective basis whatsoever for setting price controls and we can see that by looking at the other countries, too. But there's no doubt that that's going to be a big, big debate.

**LARRY LEVITT:** Tom McGinnis, let me ask you. As we talked about earlier, I mean there is this threat that pharmaceutical companies hold out there that if you do anything to control drug costs, hold prices down, R&D will suffer. Give a sense of where, if you can, where the drug pipeline sits now and how many drugs do you see getting approval compared to five years ago, ten years ago, and any major changes in that.

**TOM MCGINNIS:** Well, it's certainly slowed down a little bit from what it was. What the agency is doing was to try to streamline the approval process to lower some of the costs, the regulatory burden that these industries have to face in getting a product through the FDA onto the market. But if we can lower costs there a little bit, hopefully the industry will be able to pass those savings on to consumers. And like I

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

mentioned earlier, in approving more generic drugs much quicker we hope to offer consumers an alternative that will work.

**LARRY LEVITT:** Okay, another call on the line from New York again. Please go ahead.

**FEMALE VOICE:** Yes, hi. I'm interested to see what the panelists think about the - how we're going to get this drug reimportation issue going in Congress again. You had said earlier at the beginning of the broadcast that there had been some strange bedfellows on this issue, being both sides of the aisles. And I'm wondering how will this will get jump-started again? Is it going to be through local pressures through the citizenry or will it be through the governors and other municipalities who are pushing for cheaper drugs.

**LARRY LEVITT:** Okay, thanks for the question. John, let me come back to you. First give us a sense - AARP obviously has a strong grassroots membership. What are you hearing from members on reimportation?

**JOHN ROTHER:** Well, I think the perception in the public generally is that drugs are too costly, and particularly when you compare them to the prices in other countries. And there are a variety of ways to deal with that, but reimportation is something that people understand and is tangible - easily understood. It's going to be an issue in the campaigns next year and I think it will put a lot of pressure on the political system to be responsive. So I think all of

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

the things that the caller mentioned will be effective. But I do - my own view is that reimportation is a short-term answer. Ultimately we have to solve this problem for ourselves within our own borders. We can't just deputize another country to solve it for us. And I'm hopeful that Medicare drug benefit will be a beginning, but not the end, of an effort to - maybe not set prices -- I agree with Jack that that has some downsides -- but to be much more aggressive about really asking the value question. What are we really paying for? What are we really getting? And I think there is substantial savings to be had.

**LARRY LEVITT:** Jack Calfee, let me ask you - and you can pretty clear vet your view on reimportation. Where do you think - and there's no denying that there is sort of populous drive to support reimportation or some similar effort to control drug costs. Where do you think that pressure is coming from?

**JACK CALFEE:** I think the pressure comes mainly from the disparity between the U.S. and Canadian prices. I think that's almost the entire driving force in this. After all, you take away comparisons, you know, with other countries, how do they figure out whether their prices are too high or too low? Everyone thinks their price should be lower, but it's not at all clear what it ought to be. But there's something else I think that's worth mentioning, which John and Tom have both

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

mentioned along the way. And that is the growing roles of generics. I mean if you look back at the drug bill as recently as the year 2001, okay? By the year 2004 or 2005 between 25 and 30% of that entire drug bill is going to be on generic basis and no longer be on a branded basis. You have such big blockbuster drugs as Zocor, which is one of the leading statin and high cholesterol drugs, you know? It's going to be generic in 2005 or 2006. I mean as Tom mentioned, almost every major category we're getting generic drugs. And so what this debate is really about shouldn't be about the prices of the drugs that we have right now. Those prices are all going to be - I mean almost all will be going down in the next few years. It's really about the drugs we don't have yet that we really need, and that's where I think the debate ought to focus on.

**LARRY LEVITT:** And do you think the recent efforts to speed the entry of generic drugs into market has been a step in the right direction?

**JACK CALFEE:** I think on the whole - I mean on the whole I have no problems with what the FDA is doing. They're helping along a process. The thing that's really driving this is the mere fact that a lot of drugs were approved five, ten, fifteen years ago and they're reaching the end of their patent life right now.

**LARRY LEVITT:** And Tom McGinnis, do you think - as you described earlier, there have been these efforts to speed the

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

entry of generics. Is that - have we done everything we can or you think there's more that can be done?

**TOM MCGINNIS:** Well, there is more we can do. We can put more resources into our generic drug program, which we are going to do next year. The other thing we're looking at are moving things to the OTC market. We've been successful over the past few years, there are more things coming. Zocor was just mentioned. We just saw Great Britain looking at that now, looking to move that into the over-the-counter market. I'm sure the agency's going to be presented with data and information to look at it for the OTC market here in the United States, too.

**LARRY LEVITT:** Well, we've got a - speaking of Canada, we have a call from Toronto, which wasn't a U.S. state last time I checked. So maybe a slightly different perspective. Please go ahead.

**BRENT:** Yeah, hi. My name is Brent. I'm calling from Houston (misspelled?) Capital in Toronto and we're in the business of reimportation into the United States. And our business has been thriving. I'm encouraged to hear John Rother, you know, encourage the concept of reimportation. You know, we were quite disappointed to see pressures, obviously by the pharmaceutical industry, to curtail or certainly not to address it in the latest bill. But I wondered how John felt that this would be addressed. In other words, what do you see

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

as the future for reimportation on the short-term? We understand it's not a long-term solution, but the seniors that we talk to are members that are saving thousands of dollars a month are looking for some - well, as opposed to being coerced shall we say they are suggesting that they're doing something illegal to be encouraged that, you know, this is a safe solution and an alternative as Ron Blagojevich, the Governor of Illinois, and Barry Sanders have pointed out repeatedly.

**LARRY LEVITT:** Well, thanks for the call and it's a great question. And we're coming to the end of the hour so maybe we'll end here. John, you did predict that a bill will pass Congress. Maybe if I could push you a little bit on some specifics of what you think might happen. First, do you think this'll be a bipartisan effort or do you think it needs to be a bipartisan effort to happen?

**JOHN ROTHER:** This will be a bipartisan effort. There's already strong bipartisan support, both the House and the Senate, on this issue. It's more northern tier of the U.S. issue for understandable reasons. But I just want to say one thing, too. I think a lot of people have been critical of the FDA in all of this and I really think that's misplaced. The problem here is Congress has not changed the law. And if the Congress changes the law and provides appropriate authority, the appropriate resources, I'm confident the FDA could quite quickly set up a system that would assure safety and permit

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

people to realize some of these savings. But again that's not a longest-term solution. We're going to have to solve this for ourselves. But in the short-term as we continue to work on this problem in the U.S. it would mean the world to millions of people who are facing very high costs right now.

**LARRY LEVITT:** Tom McGinnis, I don't want to put you on the spot too much, but is there a reimportation bill that goes beyond the status quo that you think the FDA could live with and what might that look like?

**TOM MCGINNIS:** Well, first of all we need the authority that John mentioned and the resources that he mentioned. Without those I can't see us ever certifying that something would be safe coming in. Also we need to take a look at the market we're dealing with. If it's just Canada that's a lot different than the 26 other countries that some of the Congressmen have been talking about about reimportation. That type of matrix would be impossible to be able to handle. If it was narrowly focused we would need to look at it to develop a mechanisms to notify consumers, as I mentioned, when products coming from that market that we don't know anything about - data about, we can notify those consumers that there's been a Class I recall, get it back to wherever you bought it, and maybe to even try to put some recourse mechanisms in for better consumer protections. We need to look at all that and come up with some type of plan before, yeah, we could ever address that

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

issue.

**LARRY LEVITT:** And Jack Calfee, I'll give you the last word here. From what you said I'm not sure there's a reimportation bill that you would like to see, but -

**JACK CALFEE:** Well -

**LARRY LEVITT:** - maybe just broaden it a little bit.

**JACK CALFEE:** I just don't think the reimportation bill would do what people want it to do. It won't bring lower prices here. When this gentleman in Toronto, when he wants to supply the state of New York with Lipitor -- the state of New York is almost as big as Canada -- he's going to have to place a very, very large order for Lipitor and I think he's going to have trouble getting that order filled.

**LARRY LEVITT:** Well, thank you. This is Larry Levitt and this has been Ask the Expert from Kaiser Network. Thanks to our panelists and thanks to everyone who called in and e-mailed in questions. We got many more questions than we could possibly answer in an hour, probably ten hours. But thanks everyone for joining us.

[ END OF RECORDING ]

<sup>1</sup> kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.