SCHOOL OF LAW
CASE WESTERN RESERVE UNIVERSITY

Canada-United States Law Journal

Volume 31 | Issue

Article 46

January 2005

Discussion following the Speeches of Ms. Rosenbaum and Ms. Orange

Discussion

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Recommended Citation

Discussion, *Discussion following the Speeches of Ms. Rosenbaum and Ms. Orange*, 31 Can.-U.S. L.J. 325 (2005)
Available at: https://scholarlycommons.law.case.edu/cuslj/vol31/iss/46

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DISCUSSION FOLLOWING THE SPEECHES OF MS. ROSENBAUM AND MS. ORANGE

MR. SCHAEFER: Well, thank you both for your presentations, and I think we will open the floor to questions.

Henry, do you have one?

DR. KING: Yeah. I see both sides of it. Sara Rosenbaum did a good job telling the U.S. story, and Jennifer the Canadian story. Is this something the two governments could mediate? In other words, you have got a lot of public interest here that is consumers' and it is patent rights. Is this something that is possible to work out from the standpoint of joint – some joint effort? In other words, I want to make sure that everybody gets the pills they want. On the other hand, I am concerned about the fact that these pills are developed here at great expense, and I want to make sure the pills keep continuing because I take a lot of pills. And so I am talking about myself. But, I wondered, is there any common denominator of interest that might be worked out here?

MS. ORANGE: I find the physician within the United States confusing, so who do you mediate with? The federal government and the White House have taken a – at varying times, a very harsh stance against Internet pharmacies, while you see at the state level and municipal level, they are welcoming Canadian Internet pharmacies. On state web sites, they have a link to Canadian Internet pharmacies that they have gone and inspected and approved.

So within the United States, I find it very, very confusing as to what you do if you are a representative of Canada, and politically speaking, who are you going to talk to? And the Health Minister recently met with the officials from the federal government. The Canadian Health Minister recently met with officials from the federal government, and all he could say was, "They didn't ask us to stop." I'm not sure – who we are going to cooperate with on this one?

MS. ROSENBAUM: This has to be one of the most peculiar issues ever. It just is. It is as if all of the national frustration with the high cost of medical care generally in the U.S. has focused like a laser beam on one particular issue that rose to the fore because of the politics of the Medicare legislation. Generally speaking, Americans pay more for health care than people everywhere. That, rather than pulling down our public health protections in the name of cut-rate pricing, should be our focus.

We have very good medical care if you can afford it, but we have far too many people who can afford nothing. Yet in this strange drug pricing battle, it is possible to see the political retribution that can flow from a single line in a piece of legislation that simply galls people. Ironically, the non-interference clause contained in the Medicare Modernization Act parallels virtually the

same clause that itself was part of the 1965 Act, and that somehow assuaged physicians that, despite the advent of national health reform, nothing would be altered for them. It took only a few years for Congress to begin its retreat from this pledge of course. Whether in fact Congress retreats from its commitment not to interfere with the price of prescription drugs remains to be seen. It will depend in part on how well the market solution works.

A far better avenue in my view would have been to take head-on the need to ensure aggressive pricing through the use of additional techniques for keeping the price of services low, such as a reference maximum price and profit – enhancing incentives to remain below such a price. But re-importation simply is a political fig leaf that ultimately could do more harm than good.

MR. SCHAEFER: Let's start down here in front and work our way back, right here in the front. And please identify yourself.

MR. JANSEN: Gordon Jansen. I am with the Government of Ontario. I have a double-barreled question, and both of you might be able to take a stab at it, but probably Jennifer would be in the better position.

First, both questions are about the allegation that you would risk shortages and higher prices. Has anybody done any asking of provincial health plans if they are buying – or not buying – arranging for supplies of more drugs to compensate for internet pharmaceutical sales across the border? And two, has anybody done any serious looking at whether the whole risk is a conspiracy by the drug companies because they don't like it?

MS. ORANGE: On the first question, I don't know if the provincial health plans have had to purchase higher numbers of drugs or whether – and we are talking about the formularies. I don't know. I don't know if there has been anyone who has been able to trace that, but if they had been, I think we might know about it, so somehow I doubt it. I don't think the shortage issues have really come to a head yet. What we are getting is anecdotally from pharmacies in Manitoba, "Oh, I couldn't find this," and it is just not clear that it is happening in high enough amounts to really be an issue, but the risk is there. We could see how the risk could be there. And so I have already forgotten the other question.

MR. JANSEN: Whether there is a whole shortage, whether it is a conspiracy.

MS. ORANGE: Oh, the safety issue.

MR. JANSEN: Well, that, too. One question at a time.

MS. ORANGE: I think certainly there are safety issues coming from the Canadian side, and Health Canada did inspections last summer of Internet pharmacies, and they did find a few problems, but they called them minor, and they said that they were solved, problems like shipping, medication that needs to be kept cold, needs to be kept refrigerated. There were minor infractions in that area.

I think the more concerning problem is pharmacies that – Internet pharmacies that set themselves up as being Canadian but aren't really. They are on the net. They advertise the medication is coming from Canada, but it is coming from a third country where the regulations may not be so strong. And there is some concern that medications, drugs from third countries, are coming through Canada. So they are being transshipped through Canada to the United States. Again, I don't think it is a high risk at the moment, but there has been some evidence that that has been happening, that there are these sorts of shadow pharmacies out there that aren't really Canadian.

MR. JANSEN: What about the shortage issue? The pharmaceutical company says, "We are not going to sell you so much because you will just ship it back into the U.S."

MS. ORANGE: The pharmaceutical companies have been smart in that they have really only acted against those pharmacies that sell to Internet pharmacies. They haven't limited sales to pharmacies generally. So the Canadian population has been able to get these drugs that they have been limiting.

MR. JANSEN: So it is a conspiracy.

MS. ORANGE: I really don't know.

MR. JANSEN: No, no, because you say that the pharmaceutical companies are restricting the sales of these drugs to these pharmacies. It is not as if there is a shortage of drugs, which is what you were saying as one of the risks. It is the pharmaceutical companies that are creating it.

MS. ORANGE: They are creating a shortage for Internet pharmacies, that's for sure.

MR. SCHAEFER: Do you know – just as a follow up – do you know $850 million in internet sales, what percentage of the total Canadian sales is that?

MS. ORANGE: I don't know, but it is not a great percentage. We are not talking about huge business here, really.

MR. SCHAEFER: Okay. Let's go all the way in the back middle there.

MR. BARRETT: Good afternoon. My name is Dick Barrett. I work for a pharmaceutical company, specifically Pfizer, Incorporated. However, I want to ask a question of Professor Rosenbaum, which is slightly off the subject of cross-border sales of pharmaceuticals but is, I think, very important and relates to what we talked about this morning with the two different health systems we have in the two countries.

We hear quite often in the United States about the large numbers of uninsured people, around 45 million I think is the last number I've heard. I believe the implication is, well, people don't have health insurance. Therefore, they are going wholly without medical care. I think some commentators have observed that's not necessarily the case, and that there are ways in which people get medical care, even if they are not insured. So I'd like to ask Pro-

fessor Rosenbaum, who are the uninsured in the United States, and what kind of care do they get, and how do they get it?

And I guess a second part of the question: Can you characterize the quality of care that is received by Medicaid patients who are indigent or low income, and compare that to the kind of care people get on a fully-insured basis, or receive it to the extent they do get care? How does that compare to the noninsured care?

MS. ROSENBAUM: Sure. Let me take the first question, which is, who are the uninsured in the United States, and what do they get in the way of care? Uninsured people in the United States are virtually all under the age of 65. Approximately 80% are members of working families. About 20% of them are children under the age of eighteen, and their incomes hover between abject poverty, meaning about one half the federal poverty level, and about 200%, twice the federal poverty level.

An uninsured family can look like a group of itinerant poultry workers on the Delmarva Peninsula, or a part-time salesperson at Macy's, or a full-time worker at Wal-Mart. The battle to address the low compensation levels in the U.S. that result in the absence of coverage recently reached an apex in the state of Maryland, where the legislature recently enacted a law known as the "Wal-Mart Bill," which would force large employers either to insure their workforce, or contribute funds to the state to underwrite affordable coverage.

What we know about uninsured Americans in particular is that few are so affluent that their lack of coverage can be considered a deliberate product of choice. That is simply a myth.

The studies on what it means to be uninsured in America could fill up this room from floor to ceiling. They go back in time all the way to the Committee on the Cost of Medical Care in the 1920s. Among the more recent studies, I commend the series published by the Institute of Medicine of the National Academy of Sciences, between about 1999 and 2004. This wonderful set of studies takes the uninsurance problem all the way from the point of a specific patient, all the way to its community-wide and national implications.

It goes without saying that in the United States of America, in particular, where health care is so very costly, one does not want to be uninsured. You might, if your health care emergency is sufficiently serious, and you are able to get to a hospital emergency department, receive screening and stabilization services under EMTALA (Emergency Medical Treatment and Active Labor Act). But a close look at the specific judicial application of EMTALA standards, as well as the regulatory limitations on the duty of hospitals, reveals how very constrained this protection appears to be. Indeed, 2003 regulations issued by the United States Department of Health and Human Services, make clear that the hospital's obligation is to stabilize you, and at admission.

There are about 1000 federally funded health centers scattered around the United States, serving about 12 million persons in 4000 service sites. Their

health care is excellent, but they are funded to deliver primary care only, and their numbers and capacity make them a modest investment at best. Thus, while 12 million people are served by health centers, there are another 36 million medically underserved Americans who go without care.

Uninsured people in this country get, at best, half the amount of medical care enjoyed by their insured counterparts. They get it later. They get it when they are sicker. They die sooner. They die from preventable causes. If I asked anybody in this room who is American, "Would you like to give up your insurance card right now and test out being without health insurance?" You would tell me "Hell, no."

Medicaid is the most important health insurance program for the poor, covering some 50 million persons. To give you a sense of just how far Medicaid reaches today – in the face of a collapsing voluntary employment-based insurance system and not affordable alternative source of care, the program covers more than a third of all births, 25% of all young children, and pays for half of all nursing home and long-term care.

One of the most important sources of charity care at this point is the voluntary programs offered by pharmaceutical companies such as Pfizer. I became familiar with these programs through my work with community health centers.

Despite Medicaid's reach, and its ability to ensure access to care of reasonable quality, the program carries a stigma in many communities and is under constant attack because of its size. Right now in Washington, where I am from, Washington DC, recently, I was told that there is no medical oncology in Washington for Medicaid beneficiaries with cancer. There is simply no oncology program that will regularly accept Medicaid patients. At the same time, despite Medicaid's efforts to fund adequate care, Congress appears bent on further reductions.

MR. SCHAEFER: Yes.

MR. SHANKER: I am Morris Shanker, a professor here at Case.

A lot of my American friends ask me – or they just ask "How come Canadians get their pharmaceuticals so much cheaper than we do for the very same pill, with the very same company?" Maybe we should ask this of the representative from the drug company – and, the hearsay we get back in return is, "Well, it is very costly to develop new pharmaceuticals. They must be recovered, these costs, and they can be recovered only in the one place you can have a free market to recover them. And Canada having a controlled market doesn't, therefore, contribute to that cost."

Any comments from either of our panel members?

MS. ORANGE: Well, Canada isn't the only developed western country that does have a controlled market or controls the prices. I think the European markets are – and you can correct me if I am wrong – are also controlled, and they are not cheap. So, I don't buy the argument that none of the

costs of R & D are being recouped in Canada or other countries with price controls. But I think it is more sort of a public policy, philosophical approach to healthcare, where you want to make sure that our drugs are not excessively priced. It has to be balanced with the ability for pharmaceutical companies to recoup a profit and have enough for R & D. Why are the prices so excessive in the United States? I'm not sure.

MS. ROSENBAUM: Well, the interesting thing, at least again I am not an expert in food and drug law, and I am not an expert – I am not an economist, and not an expert in drug pricing – but one of the things that struck me in the Secretary's report is that while the price of brand-name drugs may be higher, the generic market is in fact quite low.

MS. ORANGE: Those are patented drugs.

MS. ROSENBAUM: Right. Once a drug is off patent, obviously, things change of course. As I prepare to counsel my own parents about enrollment in a new Medicare Part D plan, I do know that many of the drugs they take are generic and relatively well priced.

MR. PHILLIPS: Jim Phillips. I am having – walking some of the highways and byways of this subject, I find it very interesting to hear you speak today.

I just offer you a couple of perspectives that you might want to think about. The Cleveland Clinic this morning, a fellow mentioned $500 million to bring a new drug to market, and less than 1% of the initial efforts are brought to market. So it is not $500 million. It is many hundreds of millions of dollars beyond that, so the development of drugs, I think you will find, predominantly are in the United States. And I remember back looking at things back in the '50s and '60s, when a certain country in Europe was using industrial espionage, formulas, and they were making genetic drugs with no control. The U.S. started to control genetic drugs about in the '60s. That's why there is a very tight control.

So, Canada, you have to keep in mind, is a 30 million population country. So it is like a retail business. I buy 100 suits, and if I can sell 25 of them at full price, and I can sell the next 25 at 10% off, I can sell some pretty reasonably at the end. So I think there is a market balance there other than a control. Some of the markets are controlled higher. Canada isn't, but there are markets in the world that control drug prices higher for the very reason they have pharmaceutical industries in Europe that are developing drugs for large populations.

But the two things I wanted to tell you, we run a conference every May in Ottawa, and in Washington every September, and I will not mention names, but we had the head of Market Access to the United States, for the federal government, at our conference in May '03, and the fact was pharmaceutical business across border is going to stop. And that was the – this is from the federal government. It is going to take some time, but it is going to stop. But

you ought to get some government officials from Washington to talk about this to you because it is a little bit more along the line than you think.

And the last thing I would comment, I work very closely with customs, and it might be of interest in 2004, 15% of every drug that came into the United States had zero active ingredients in it. It was being sold – I am not talking about Canada. I am not talking about the source country, but 15% of the drugs sold as prescription drugs coming into the United States had zero active ingredients. They were placebos made to look like Lipitor, made to look like things.

I find what you had to say today extremely interesting, and I think – you have to make sure that both countries make sure this is legitimate, it is okay to be entrepreneurial, but I suggest when this started and some people thought it would stop because there was no doctor to sign the prescription, well, we found a way to do that.

I submit to you that as drug companies begin to not limit your supply, not take it away from you, but they don't want to sell you enough drugs for a population of 50 million people, when you only have 30 million. So there is a difference of limiting, and meeting your legitimate needs.

I would submit to you that there are some pharmacies that tend, if they can't get drugs, to buy them from another third country, even legitimate – even Canadian businesses. We have the third-world pharmacies that are pretty bad and that don't get any drugs from Canada.

So I would just point out that I think it is a very critical issue. It is an emotional one because – the point was made earlier – the states, politics is local, and if I can support my voters by saying, "I am going to find you a cheaper source" – but the reality is, look at the customs figures, and look at the true FDA analysis of what's coming in, and that's probably the story behind why this whole thing is probably going in a direction that you might find interesting when it is over, just to offer those backgrounds to you.

MR. SCHAEFER: Yes.

MR. JOHNSON: It seems to me that the cross-border trade issue is really a sort of classic arbitrage situation where you have a regulated price in one country, and an unregulated situation in another country, and it is only natural, of course, that people from the U.S. would try to buy the cheaper product in Canada. I don't think it is a particularly good situation for two reasons: Firstly, from the Canadian side, we regulate prices to control cost drivers in our healthcare system for the benefit of Canadians, and we aren't doing it for the benefit of the U.S. market, and it probably would lead – it certainly puts pressure on availability, if not leading to dramatic shortages. It certainly skews the situation for Canadians. And from the U.S. perspective, it seems to me that you have a big problem with the cost driver with drugs, something you shouldn't be solving by buying drugs from Canada. Firstly, it is not a good way to solve it.

Secondly, it is a drop in the bucket. I mean, you know, Jennifer said that the internet sales are a small fraction of what the Canada sales are. Well, they are even a smaller fraction of the U.S. sales It is not a way to solve your problem. You should be doing that in some other way.

Jennifer, you raised the point about the Import-Export Permits Act. I am wondering whether you could tie in an export ban with the requirement that there be a proper medical assessment. In other words, you would have to get an export permit, and the export permit would be issued conditional upon evidence of a proper medical assessment. That might be a way of dealing with the problem. I think it would be reasonably bulletproof.

MS. ORANGE: Right, because of the health and safety issues.

MS. ROSENBAUM: I wondered about the same thing.

MR. JOHNSON: Who could object to this?

MS. ORANGE: That's interesting.

MR. DELAY: Hello. I am Brendan Delay. I am an attorney. I have two questions: One is, is there a new industry starting to come up where there is a Canadian Internet pharmacy trade in what is called "herbal medicines," or supplements? These are in the category of – you wouldn't call them drugs, but they are not really regulated by the FDA, some of which are maybe controversial in the United States.

And the second thing is, is there a practice growing up in what's been called the world's "second oldest industry," and that is the smuggling of substances?

MR. PHILLIPS: We had trouble hearing the questions.

MR. DELAY: Okay. The second question is: Is there an industry growing up to smuggle substances into the United States from Canada?

MS. ORANGE: I don't know for both questions. Unfortunately, I do know that Internet pharmacies do sell more than just patented prescription drugs, so you can get other substances from an Internet pharmacy. So herbal remedies might be one of them.

In terms of, like, big-time smuggling, I don't know. There have been Americans who have driven across the border and gone back with their own personal supply for decades, but I don't know if, in bulk, there is a lot of smuggling going on. That type of trade I think would be more likely to be caught by U.S. Customs or by Customs Canada. The personal-use drugs that are just really difficult to track, 2 million packages every year going across the border, small little packages, these are more difficult. So I don't know the answer to the question directly. If anyone else does, please feel free. That's a good question.

MR. SCHAEFER: Yes.

MR. GELFAND: Well, this is an interesting session, and like an earlier session today, this morning, it really comes down to a question of access, which Canada seems to be pretty good at, and advances in high tech, that the

United States seems to be pretty good at, but the two don't seem to be good at each other's things, and this really brings it to bear.

Now, it seems to me that Canada is really doing – you've got some great entrepreneurs in Canada that are really doing Americans a great service, and personally, if I needed drugs and wanted to get them from Canada, I would want to get them from Canada, rather than some other country. Maybe it is because I know Canada. It is close. I just feel more comfortable with getting it from Canadians than maybe some other country that I am not as familiar with.

But Jennifer, in your presentation, you at least implied that there are problems, and you know, I just don't see the problems. I see the problem is with the United States and limiting access, through economics, to all who need medication and all who need healthcare. So really, we are the ones with the dirty hands. If anybody approaches you and says – or your country, and that goes to all of you Canadians, that there is a problem with something that you're doing that you shouldn't be doing, you should be telling people in the United States who are complaining that it is their problem. They are the ones that are causing this problem by not enabling the larger pool through universal healthcare so we can access the drugs that we need at an affordable cost. Don't back down.

MS. ORANGE: No. No, I won't, and I agree. I think there is a problem in the United States, and I find it distressing that you don't have more universal healthcare here, but speaking personally as a resident of Canada, if these Internet pharmacies do lead to a shortage of a critical drugs that someone in my family needed, and it is because Americans are getting them when these drugs are supposed to go to Canadians, you Americans, you have your own drug supply, I find that disturbing.

And also, I find the conduct of physicians in Canada who are co-signing these prescriptions –I find it really upsetting. As a lawyer, I am in a self-regulated profession. Doctors in Canada are in self-regulated professions. We take our professional obligations seriously, and they are not even meeting their patients? They are not even providing an address and phone number for these patients to call if they have an adverse reaction. These doctors don't know what other medication these patients are on. Where is their professional pride? Where is the integrity in their profession? I find that really disturbing as a Canadian who is very proud of her healthcare system.

MR. GELFAND: I would go back to the doctor who signed the original prescription.

MS. ROSENBAUM: I would like to add one point: Which is that I think there is a great danger in this debate in confusing what is the fundamental, moral, unforgivable nature of the U.S. in failing to assure coverage for everybody, with some sort of meaningless, really a meaningless, political football, which this has become. I have spent a career representing people who

have no coverage. They have no more access to this system, and couldn't afford it if the prices were half the American prices. They can't afford the drugs, number one. So it does nothing to alleviate our problems, and we are so in this country, we are so inclined to look for the quick fix, the emergency treatment laws and cheaper drugs. These are no – community health centers, which I spent a life building, are no substitute for insurance coverage. So that's the first point.

And the second is the potential to compromise our own public health, and I think of all the things that I read in our report, the U.S. report, the most significant issue is the notion that you would have people so driven by the profitability of internet sales, physicians and the sellers, that they would begin to reach out to places where the drugs are not at all safe to get their supplies. And there is simply no way – the internet is so – it is a great boon, but it is also very dangerous. There is simply no way to stop an unscrupulous internet seller from supplementing supply with stuff from everywhere, and at that point, the entire American pharmaceutical supply is infected for what end? Not because my clients will have better insurance, will have better access, and not even because it will drive our prices down. And so it seems to be an utter *non sequitur,* like so much in U.S. health policy.

MR. SCHAEFER: We are going to have to cut off the questions there. Please join me in thanking both the speakers.

(Session concluded.)